Utility FAQs and Suggested Talking Points Related to EPA's Draft Risk Assessment of PFAS in Biosolids

The U.S. Environmental Protection Agency (EPA) released a <u>pre-publication version</u> of its Draft Risk Assessment for PFOA and PFOS in Biosolids on January 14, 2025, which was <u>published in the Federal Register</u> with a 60 day comment period on January 15, 2025. Information from EPA on the draft assessment can be found <u>here</u>.

Clean water utilities and other entities that help manage municipal biosolids may get questions about the risk assessment from the media, utility customers, agriculture partners, and other stakeholders. This document provides some potential Frequently Asked Questions (FAQs) and suggested talking points that utilities and others could use in response. It is not intended to be an exhaustive list of potential questions/FAQs or talking points. Nothing in this document should be considered legal advice.

Why Did EPA Complete the Draft Risk Assessment?

EPA committed to doing the risk assessment as part of its broader, Agency-wide <u>PFAS</u> <u>Strategic Roadmap</u>, which was published in 2021. EPA indicated at the time that completion and publication of a risk assessment for PFOA and PFOS would help determine any potential harm from these chemicals in biosolids and whether regulation of these chemicals in biosolids is necessary. Section 405 of the Clean Water Act requires that EPA collect data on potential pollutants in biosolids and conduct risk assessments, as deemed necessary, to determine if additional regulations are required.

It is important to note that while EPA has released this risk assessment in draft form, it has not proposed any changes to its current biosolids regulations as a result. EPA has also not proposed any regulation of PFOA or PFOS in biosolids. If EPA finalizes this draft risk assessment and determines that additional regulations are needed, those regulations would then be developed at a later date.

What Did the Draft Risk Assessment Find?

The Draft Risk Assessment found that the presence of PFOA and PFOS in biosolids, even at relatively low concentrations, may adversely impact human health for a very narrow and specific segment of the population – a hypothetical farm family – that EPA considers most likely to be exposed from the land application or surface disposal of biosolids or through direct consumption of products grown or raised on land where biosolids were used as fertilizer. However, as outlined further below, EPA used conservative, hypothetical assumptions in its model.

Importantly, the Draft Risk Assessment did not identify any risk from PFOA and PFOS in biosolids to the general public.¹ The draft risk assessment also did not find any direct impact or risk from PFOA and PFOS in biosolids to the general food supply.²

It is critical to note that the risk levels identified in the Draft Risk Assessment cannot and should not be used as placeholder regulatory standards for PFOA and PFOS while EPA determines whether to move forward with development of regulations. As outlined further below, the Draft Risk Assessment is not a regulation, establishes no standards and does not create any regulatory obligations.

How Was the Draft Risk Assessment Developed?

EPA developed the draft risk levels for PFOA and PFOS using conservative, hypothetical assumptions that do not reflect the typical household. EPA used what it calls a "farm family" as its baseline to measure human health exposure to PFOA and PFOS from biosolids via a variety of different exposure pathways involving ingestion.

However, the "farm family" that EPA used does not actually exist. Instead, to ensure that any risk-based decisions made are protective of any individuals exposed to biosolids containing PFOA or PFOS, EPA used a hypothetical farm family to simulate a high end of exposure to PFOA and PFOS from biosolids. The assessment assumes that the family, including adults and children, lives on a farm that uses municipal biosolids as its fertilizer. The assessment further assumes that, for ten years, all of the family's food was grown and produced on the farm and that they only drink water from a well on the farm. The assessment also assumes the family's children ingest dirt from the farm that applied biosolids. Within each of these assumptions about the family's way of life, EPA has further built in layers of conservative assumptions regarding exposure from each potential pathway.

These assumptions are extremely conservative and do not reflect real world conditions. In fact, the Agency's own Science Advisory Board (SAB) took issue with the conservative nature of EPA's approach when it reviewed the framework for the risk assessment, noting that the assumptions used by EPA are "well outside the norm of present-day family farms." The SAB also noted that "the vast majority of biosolids applications are made to lands that are not used for producing food directly consumed by humans but rather to lands used for producing animal feed, fiber and/or fuel."³

Does the Draft Risk Assessment Have Any Regulatory Impact?

No. EPA characterized the draft risk assessment as a scientific study. As such, the concentrations of PFOA and PFOS in biosolids used in the risk assessment modeling

¹ <u>https://www.epa.gov/system/files/documents/2025-01/fact-sheet-draft-sewage-sludge-risk-assessment-pfoa-pfos.pdf</u>

² <u>https://www.epa.gov/newsreleases/epa-releases-draft-risk-assessment-advance-scientific-understanding-pfoa-and-pfos</u>

³ SAB Review of EPA's Standardized Framework for Sewage Sludge Chemical Risk Assessment (Oct. 12, 2023)

should not be interpreted as regulatory standards. The Draft Risk Assessment does not change any of the existing EPA Part 503 biosolids regulations, nor does it require utilities to do anything different from a regulatory standpoint or to manage their biosolids any differently. It does not create any specific standards for PFOA and PFOS in biosolids. Even if/when the Draft Risk Assessment is finalized, after EPA addresses any comments received on the draft, it will have no regulatory impact. See below on what happens next for more details.

It is possible that the risk assessment, if finalized, could result in future changes to federal biosolids regulations. EPA has indicated that such action, if taken, is likely at least three or four years away due to the significant amount of additional work and study that must be done to craft an actual regulation based on a risk level value.

EPA has also stated that this is the first time in the history of the federal biosolids program that it has released a risk assessment of a new constituent without also releasing a proposed new regulation to address the constituent as part of the Part 503 regulations.

I've Seen the Value of 1 ppb Used in the Draft Risk Assessment. Will That be the New Standard for PFOS and PFOA in Biosolids?

No. As outlined above, the Draft Risk Assessment does not create any new regulatory standards. EPA used a value of 1 part per billion (ppb) of PFOS and PFOA in its model to develop the Draft Risk Assessment, but it does not mean that will be the standard moving forward. If EPA chooses to move forward with establishing a regulatory standard for PFOA and PFOS, significantly more scientific research and data collection will need to be done to determine what the appropriate standard should be.

Should I Change My Biosolids Management Practice or Other Utility Operations Based on the Draft Risk Assessment?

This is an individual decision that each utility should make on its own based on consultation with appropriate technical and legal experts. However, there is nothing in the draft risk assessment that requires utilities to make any changes to their current management practices.

To the extent that the Draft Risk Assessment causes utilities to get questions from customers, agricultural partners, or other stakeholders about PFAS, it may be beneficial to begin monitoring biosolids for PFAS levels if utilities are not already doing so. Many utilities that are already monitoring for PFAS are finding extremely low to trace levels in their biosolids, and having this information may help allay any concerns. Some utilities have opted to publicly release the results from their monitoring to their customers to be transparent on the issue of PFAS in biosolids.

Alternatively, if monitoring does indicate higher levels of PFAS, a utility may decide to investigate whether the source of the chemicals is domestic, industrial, or both. Industrial

sources of PFAS may be reduced through a utility's pretreatment program, but utilities have no authority to regulate domestic sources.

Does the Draft Risk Assessment Examine the Risk of PFOA and PFOS from Alternative Fertilizers or Exposure Pathways for Comparative Purposes?

No. Despite requests from NACWA and other clean water sector advocates, EPA declined to include risk information associated with exposure to PFOA and PFOS from other fertilizers, such as synthetic fertilizers and manure, which might be used as alternatives by the farm family. EPA also declined to assess other exposure pathways, such as consumption of food wrapped in fast food wrappers or other food containers coated in PFAS chemicals. Additionally, the assessment does not examine relative risk between ingestion of PFOA and PFOS versus other exposure pathways present in people's everyday lives, such as dermal exposure via products such as makeup, cosmetic products and contact lenses – just to name a few.

The lack of comparative risk information between biosolids and these other substances and exposure pathways means that the risk assessment does not provide any way to determine the relative risk associated with PFAS exposure from biosolids versus these other substances and pathways. Without this additional context, the results from the Draft Risk Assessment could easily be misconstrued to imply that the risk from biosolids is greater than these other pathways, when biosolids could present a significantly lower risk.

What Happens Next with the Draft Risk Assessment?

The risk assessment has been released in draft form and will undergo a 60-day public comment period, with comments due on March 17, 2025. NACWA and other clean water associations will provide detailed comments on the draft, outlining our concerns and shortcomings in its findings. Other utilities and stakeholders with concerns about the risk assessment should also consider submitting comments.

Once the public comment period has closed, EPA will review the comments and decide whether to move forward with finalizing the assessment as-is, finalizing it with changes, or not finalizing it at all. If EPA decides to move forward with a final version of the risk assessment, it likely would not be released until late 2025.

However, with the transition between the outgoing Biden Administration and the incoming Trump Administration, the new administration has the power to withdraw the risk assessment entirely because it has only been issued in draft form. That would allow the new administration to review the basis of the assessment and decide if it wants to continue working to finalize the risk assessment, potentially make changes to it, or to not proceed. It is not known at this time how the new Trump EPA team plans to proceed on this issue.

How Will State Regulators React to the Draft Risk Assessment?

Nothing in the draft assessment requires state regulators to take any regulatory action on biosolids. That being said, no one knows for certain how state regulators may react to the draft risk assessment, so utilities should track what their state may do. Some states may opt to not wait until EPA determines whether Part 503 biosolids regulations are in fact needed for PFAS and move ahead with their own state regulations. Some states already have state regulations in place around biosolids and PFAS – especially involving land application – while many others do not.

If a state should decide to move forward with state biosolids regulations based solely on the draft risk assessment, there are several reasons why such action is inappropriate at this time that clean water utility advocates can make in response. Among them are that 1) EPA has not yet determined whether the findings of the risk assessment warrant changes to federal biosolids regulations, so it would be inappropriate for states to do so, 2) the assessment does not provide any meaningful comparative risk of PFOA and PFOS from biosolids as compared to other exposure pathways, thus additional regulation of biosolids will not necessarily result in meaningful health protections without further study, and 3) the risk assessment findings have only been released in draft form, and it would be inappropriate to take any regulatory action based on them until EPA decides if and how to finalize the risk assessment findings.

I'm Getting Questions From my Customers and the Media About the Risk Assessment. What Should I Say?

This should be decided on a utility-by-utility basis based on unique factors and considerations. But some potential talking points are below, which draw from many of the above FAQs:

- We at XXX utility recognize and share the public's concern about PFAS and are committed to pursuing smart and practical solutions to addressing PFAS issues while ensuring our customers are not unfairly burdened with paying for the costs to address PFAS. Our utility and the households we serve have neither produced nor profited from PFAS and ultimately should not be forced to pay the costs of addressing PFAS.
- EPA's draft risk assessment is an important data point in the ongoing research into the impacts of PFAS chemicals on biosolids, but it is not definitive. More study and research must be done, and we support those efforts.
- EPA has not suggested any proposed changes at this time to the existing federal regulations governing biosolids management, including land application, as a result of the draft risk assessment.
- The risk assessment has only been released in draft form and it is subject to public review and comment, including challenges to its scientific and technical bases. It is possible that EPA may refine the risk assessment findings based on feedback or

decide not to finalize it at all. No complete conclusions about the risk assessment or its findings can be made unless/until it is finalized.

- EPA developed the draft risk assessment using conservative assumptions and conditions that do not exist in the real world or reflect the communities we serve. Even EPA's own Science Advisory Board criticized the Agency for its overly conservative approach.
- EPA did not consider the relative risk from other ways that people can be exposed to PFAS, meaning this assessment provides no way to determine how the risk from PFAS in biosolids compares to risk from other sources. These other potential exposure pathways include eating food wrapped in packaging or packed in containers containing PFAS, applying makeup or cosmetic products containing PFAS to your skin, or wearing clothing treated with these chemicals.
- We want to work with EPA and others to address PFAS and ensure it stays out of our environment – we are committed to that goal. But we need to do it in a way that ensures the risk of PFAS exposure from all sources is considered – not just certain sources – and that any eventual regulations are targeted in the most effective way to remove PFAS from the environment at their original source. We also want to protect our customers by ensuring that the cost for addressing PFAS is paid by the companies that made the chemicals and profited from them in the first place – not by our local community and customers.

I'm Getting Questions From My Agriculture Partners. What Should I Say?

This should be considered on a utility-by-utility basis based on unique factors and considerations and the nature of the relationship with agriculture partners. But some potential talking points are as follows, which draw from many of the above FAQs:

- We at XXX utility strongly value our farmers and agriculture partners who use our biosolids for land application. We have had a long and productive mutually beneficial relationship and are committed to maintaining that. We want to ensure you are comfortable with the biosolids we are providing and address any concerns you may have about PFAS.
- EPA's draft risk assessment is an important data point in the ongoing research into the impacts of PFAS chemicals on biosolids, but it is not definitive. More study and research must be done, and we support those efforts.
- EPA has not suggested any proposed changes to the existing federal regulations governing biosolids management, including land application, as a result of the draft risk assessment.

- The biosolids we provide continue to meet all applicable federal regulations.
- EPA developed the draft risk assessment using conservative assumptions and conditions that do not exist in the real world. Even EPA's own Science Advisory Board criticized the Agency for its overly conservative approach, noting that the conditions it used as a baseline for the assessment were "well outside the norm" of those that the average farm family faces. This resulted in overly conservative findings that do not reflect real world conditions in terms of potential impacts on farmers or their land.
- The risk assessment has only been released in draft form and it is subject to public review and comment, including challenges to its scientific and technical basis. It is possible that EPA may refine the risk assessment finding based on feedback or decide not to finalize it at all. No conclusions about the risk assessment can fully be drawn until it is finalized.
- [if applicable] In the absence of federal regulations, our utility has been proactively monitoring our biosolids for PFAS levels. This work has found [fill in information about the findings of your monitoring program].
- We are committed to ensuring that the biosolids we provide you are safe for you, your family, your farm and your livelihood. We are happy to discuss any concerns you may have and how we are working to limit the presence of PFAS in our biosolids.