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U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
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Submitted via www.regulations.gov

RE: Draft Sewage Sludge Risk Assessment for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS), Docket ID No. EPA-HQ-OW-2024-0504

Dear Mr. Tobias:

The undersigned national agricultural organizations appreciate the opportunity to submit these comments to the U.S. Environmental Protection Agency (EPA or Agency) in response to its proposed risk assessment entitled: “Draft Sewage Sludge Risk Assessment for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS).”

Our organizations represent the overwhelming majority of the farmers and ranchers in the United States raising row crops and livestock and state agriculture leaders. The livelihood of farmers and ranchers depends on healthy soil and groundwater. For that reason, we support EPA’s underlying goal of addressing widespread contamination of the environment caused by historic use of PFOA and PFOS. As passive receivers of PFAS chemicals, farmers and ranchers want to be fully aware of what is in the biosolids that they are accepting, as they want to ensure that any land application is not going to contribute to contamination of their land. We view a risk assessment as the first step towards setting up a system that will ultimately provide more information to landowners and allow farmers and ranchers to make more informed decisions. However, we have serious concerns regarding the methodology used to conduct this proposed risk assessment, which is based on extreme assumptions and estimates that must be scrutinized more carefully.

The purpose of the proposed risk assessment is to characterize the potential human health and environmental risks associated with land application, surface disposal, and incineration of biosolids that contain PFOA or PFOS. EPA assumed a source concentration of 1 ppb of PFOA or PFOS in biosolids as the basis for modeling contaminant release to other environmental media. The risk assessment focuses on estimating risks to a family living on or near affected sites and consuming products (e.g., food crops, animal products, drinking water) from the affected sites. The risk assessment does not model risks for the general public. EPA found that human health risk thresholds were exceeded for some of the exposure pathways in each scenario.

Our concerns are rooted not in the goals of the model, but rather in the assumptions used to inform the proposed model. While the proposed risk assessment is not a regulatory action per se, it may (and in some cases already has) lead to state and federal actions related to the land

application of biosolids, which is the management option used for over half of the biosolids produced in the United States.

We respectfully request that EPA consider the concerns outlined below and reexamine the information used to uphold this proposed risk assessment.

Biosolids in Agriculture

Biosolids are nutrient-rich organic materials that result from the treatment of sewage or wastewater sludge. These materials are typically derived from human waste and other organic substances that go through a process of treatment and stabilization. The treatment process reduces pathogens, contaminants, and odors, making biosolids safe for certain uses.

Once treated, biosolids are commonly used as a fertilizer or soil conditioner for agriculture, landscaping, or reclamation projects. They can help improve soil quality by adding organic matter and essential nutrients, such as nitrogen and phosphorus. However, biosolids must meet specific regulatory standards to ensure they are safe for human health and the environment. The use of biosolids by farmers is generally permitted and is regulated by strict guidelines to ensure safety for both the environment and human health. The EPA sets regulations for the use of biosolids under the 40 CFR Part 503 standards. These regulations ensure that biosolids meet specific treatment benchmarks to reduce pathogens and limit heavy metals and other contaminants. Once treated to meet these standards, biosolids can be applied to agricultural fields, but there are limits on the amount that can be applied based on the nutrient needs of the crops and the characteristics of the soil.

Farmers must follow guidelines related to:

1. Pathogen Reduction: Biosolids must undergo treatment processes (like anaerobic digestion or composting) to reduce harmful pathogens.
2. Heavy Metals: The biosolids must not exceed limits for heavy metals like lead, cadmium, and mercury, ensuring they do not pose risks to crops or human health.
3. Application Rates: The amount of biosolids applied to the land must be carefully managed to prevent nutrient overload, which could lead to water contamination or soil degradation.
4. Buffer Zones: There are regulations for buffer zones to prevent biosolids from coming into contact with water sources, residential areas, or places where food crops are grown.

Though biosolids can be a valuable resource for improving soil health and providing nutrients for crops, farmers must follow these regulations closely to ensure they are applied safely and sustainably. Additionally, there may be local or state-specific rules governing the use of biosolids.

EPA has long supported and encouraged the application of biosolids to agricultural land. For decades, farmers have beneficially used biosolids instead of the material being disposed of in a landfill. Currently, 31% of our nation's biosolids are land applied for agricultural purposes. However, concern has grown within the agricultural community regarding the use of biosolids because, more recently, we have learned that the use of biosolids is one of the methods by which

PFAS chemicals are contaminating farm fields. It is worth noting—again—that farmers are passive receivers, and in these instances where land contamination has occurred, farmers have unknowingly accepted biosolids with high levels of PFAS.

Our organizations appreciate EPA's acknowledgement that there will be variability due to site-specific factors (e.g., geology, hydrology, and climate) along with disparity in agricultural practices and that "[n]ot all farms or disposal sites where sewage sludge containing PFOA or PFOS have been used or disposed of are expected to pose a risk to human health." The presence and concentration of PFAS varies throughout communities across the country. Cities and towns that are located near manufacturing facilities that produce or use PFAS chemicals will likely have higher concentrations. Additionally, areas located near Department of Defense installations may have higher levels due to the use of PFAS heavy Aqueous Film-Forming Foam. However, other communities that are not located near these facilities may only have background levels of PFAS. More recently, the use of biosolids on agricultural land has received considerable negative publicity in the media, so it must be stated that not all biosolid material is harmful.

Proposed PFAS Risk Assessment

Through its proposed risk assessment, EPA has proposed to set the threshold for biosolid land application at 1ppb. In order to reach this threshold, EPA used hypothetical scenarios and assumptions to reach its outcome. EPA concluded that there are excess risks from drinking water, as well as consuming fish, beef, eggs or milk on farms where biosolids with PFAS levels that exceed 1ppb have been land applied for 40 years.

Our organizations would like to highlight our serious concerns over the highly conservative model – with an assumed starting point of 1 ppb – that was used to determine the potential risks on a national-scale.

- 1) There are many variables to consider and, therefore, many steps that need to be modeled or estimated to reach a conclusion on human intake risks. EPA first must have an estimate of soil concentrations and then obtain a full understanding of the transfer factors, such as plant bioaccumulation and animal biotransfer factors. They must also have an estimate of what the PFAS concentrations are in crops, as well as meat, milk and homegrown produce, before being able to calculate an intake level. For instance, one concern that immediately stands out is how the Agency addresses uptake levels across different crops. Different crops uptake PFAS chemicals at different rates, however, EPA relied on an average bioaccumulation. We question why the Agency took this approach when uptake levels vary across crop types. Furthermore, the uptake factors used by EPA to calculate bioaccumulation into plant and animal tissues are based on controlled studies that may overestimate field conditions where biosolids are a source of contamination. Studies of biosolids-amended soils generally find less uptake under field conditions than when the same biosolids-amended soils are moved to a pot and plants are cultivated in a greenhouse. This has a tremendous impact on risk estimates.

- 2) The Agency makes several concerning assumptions about exposure. In order to showcase their thinking, the Agency created hypothetical scenarios where they are forced to make a series of assumptions. At every turn, the Agency chose to adopt the most conservative assumption. For instance, the Agency assumes that farm families are consuming all of their diet directly from the land where biosolid land application is occurring, without any other sources of food. Needless to say, that is an extraordinary assumption regarding ingestion that must be more thoroughly examined. In EPA's Frequently Asked Questions (FAQ) document, they admit that "the modeling in the risk assessment includes certain assumptions that are not representative of all farms" and acknowledges the many site-specific factors that vary across farm operations. Factors such as application duration, application rates, duration of individual exposure, concentrations of PFOA and PFOS in biosolids and the median consumption rates of impacted products for households who farm. They admit that "every farm is unique and the amount of PFOA and PFOS that moves from biosolids into food products will vary considerably based on a wide range of factors, including type of food, geography and climate, soil types and the uses of agricultural land." Pulling all of the assumptions together is troubling and deserving of extra scrutiny.
- 3) EPA makes an unsubstantiated leap when they discuss livestock's exposure to PFAS. The food chain modeling assumes that all the forage, silage and water consumed by beef cattle, dairy cows and chickens are contaminated with PFAS. We believe that this overestimates the PFAS accumulation in livestock because it is unlikely that livestock will exclusively graze in contaminated pastures, and it is very likely that livestock will consume grain and feed that is produced off the farm.
- 4) EPA believes that the hypothetical farm family is experiencing long-term exposure to PFAS because the models assume a 40-year period of constant land application of biosolids. However, this assumption is unlikely to reflect the majority of farm scenarios across the United States. Farmers are constantly making changes to their operations and adapting to a multitude of variables. The assumption that a farmer has consistently applied biosolids for 40 years straight is misguided, and it is not based on data that provides a realistic estimate of average application rates.
- 5) The proposed risk assessment does not consider use of common best management practices (BMPs) for biosolids land application that farmers are likely to incorporate into farming practices. The use of BMPs would likely alter the results of the proposed risk assessment. Some BMPs will restrict how and where biosolids can be applied and the Agency assumes that BMPs have not been incorporated into the hypothetical farmer's operation. Farmers across the country regularly use BMPs to improve the environment.
- 6) EPA adopted a linear risk scale and relied on models where risks scale linearly with the amount of PFOA and PFOS that are added to the site, assuming all factors are held constant. According to EPA's FAQ document, this means if the concentration of PFOA and PFOS were doubled compared to the value of 1ppb in the risk assessment, and assuming there are no other changes, the estimated risks at the farm in question would also double. Once again, the Agency admits uncertainty over this approach by stating

“though these types of ‘back of the envelope’ scaling of the risk assessment results may be helpful in providing some context for potential risks at different biosolids land application sites, the draft risk assessment is not meant to predict true risks at any specific site.”

- 7) EPA failed to:
 - a. Evaluate potential exposure and risk to general public.
 - b. Account for the many exposure pathways of PFAS chemicals and incorporate those sources into their evaluation.
 - c. Quantify exposure from biosolids incineration or exposure through home or community gardens.
 - d. Consider cumulative effects of PFOA and PFOS.
 - e. Account for exposure to other PFAS chemicals outside of PFOA and PFOS.
 - f. Consider loading of background levels of PFOA and PFOS in soils.
- 8) Finally, the Agency’s most spectacular assertion is that the draft risk calculations are not conservative estimates. Our organizations represent the farm and ranch families that were highlighted in the hypothetical situation. And, drawing on our member families’ experiences, we believe that the many layers of assumptions made to support this assessment lead to a nonsensical conclusion. We challenge the Agency to reevaluate this work and create a model that is more in line with real-world conditions.

EPA’s FAQ Document

As noted above, EPA developed an FAQ document regarding the proposed risk assessment. The FAQ is problematic for a number of reasons and should be reevaluated and revised as noted herein. Overall, it is most concerning that the EPA is providing recommendations to farmers and ranchers through this official document, even though this is a proposed risk assessment that has not completed regulatory review. In several sections of the FAQ, the Agency encourages farmers to adopt different practices. We believe that the Agency exceeded their authority, and it is inappropriate for them to be dictating farming practices at this stage of the regulatory process.

De Facto Ban of PFAS

In addition to the concerns outlined above, the agricultural community is fearful that this risk assessment will serve as the underpinning for an overly restrictive regulation on biosolid application. In our opinion, setting a regulatory threshold of 1ppb will effectively serve as a de facto ban on biosolids.

Michigan has been a national leader on a science-based strategy to identify PFAS sources and has focused removal efforts at the most efficient and effective points in water and waste streams. Working through the Michigan PFAS Action Response Team, samples from virtually every municipal water supply and many private wells have been tested for PFAS chemicals. The state worked diligently to build out laboratory and sampling capacities in order to implement sampling and filtering requirements. Drinking water and wastewater utilities now operate under state-derived MCL limits and effluent discharge limits.

To achieve effluent and biosolids limits, wastewater utilities work with businesses to install industrial pre-treatment to prevent PFAS chemicals from reaching the wastewater facility in the first place and are not allowed to land apply biosolids with high concentrations of PFOA or PFOS. The state worked with wastewater utilities to set limits on PFAS concentrations, notification of sampling results to landowners receiving biosolids, as well as limits on concentrations of PFOS and PFOA for land application.

- Industrially impacted: PFOS or PFOA at or above 100 ppb, cannot be land applied, requires development of source reduction plan
- Elevated: PFOS or PFOA between 20 – 100 ppb, require application rate of no more than 1.5 dry tons/acre, requires development of source reduction plan
- Not impacted: PFOS or PFOA below 20 ppb, no additional action needed

In a report updated in 2022, wastewater utilities producing biosolids reported sampling results showing that 84% of them produced biosolids below 20 ppb, 12% of them produced biosolids above 20 but below 50 ppb, 4% produced biosolids above 50 and below 150 ppb (the state's initial biosolids concentration limit for land application), and 1% produced biosolids above 150 ppb. In total, wastewater facilities sampled in this study had average concentration of PFOS of 14 ppb, and a median concentration of 8ppb.¹ This is a dramatic improvement from results collected by a smaller study in 2018, which collected samples from 42 wastewater facilities and found average concentrations of PFOS of 195ppb, but it does not meet the 1ppb standard.

These improvements came on the heels of years of hard work, cooperation, and tens of millions of dollars spent annually on developing and implementing a strategy to reduce the risk of PFAS exposure to humans and the environment. Crucially however, this work has not brought Michigan's average PFOS concentration in biosolids to 1 ppb as has been identified by EPA's Risk Assessment, and there is no documented methodology or strategy outlined by any agency on how to achieve 1ppb of PFOS or PFOA in biosolids. This presents a significant challenge even to a state like Michigan that has been actively working to reduce PFAS in the environment for nearly a decade, and a nearly impossible lift for states that have not yet begun a similar process.

There are other consequences of a de facto biosolids ban that must be considered by the Agency. As you know, in 2022, Maine outlawed the use of biosolids and there are many lessons to be learned from their experience. The state's decision has raised several challenges for farmers, local governments, and waste management systems in the state. The ban creates a need for alternative ways to dispose of the material—with landfilling and incineration as the only disposal options. This has already increased Maine's landfill capacity demands and created additional environmental concerns due to the long-term decomposition of organic material. Landfills also generate methane, a potent greenhouse gas, which is problematic for the state's environmental goals. Additionally, waste may need to be incinerated or transported out of state for processing,

¹ 2022. Michigan Department of Environment, Great Lakes, and Energy. *Land Application of Biosolids Containing PFAS: Interim Strategy Updated April 2022*. Retrieved from: <https://www.michigan.gov/egle/-/media/Project/Websites/egle/Documents/Programs/WRD/Biosolids/PFAS-Biosolids-Interim-Strategy-2022.pdf?rev=1794807fc34243f999fa178c07b378c0&hash=F631B051FEF3EC15D09B9CEA625CAB78>.

which are both energy-intensive and expensive options. It is imperative that we learn from the actions that Maine has taken and proactively create solutions to these inevitable challenges.

It is also worth noting that farmers may also face challenges in obtaining alternative sources of fertilizer. This could lead to a significant strain on the traditional fertilizer market, leading to higher input costs for farmers. Agriculture input costs have never been higher, and farmers are struggling to absorb those costs to keep their operations afloat. These additional costs will only deepen the challenges associated with a struggling farm economy, which has only been exacerbated by new trade policies and market volatility. These unintended outcomes must be considered when crafting a regulatory standard.

What is the Risk to Our Nation's Food Supply?

Our organizations understand that this is a proposed risk assessment and currently not regulatory in nature. However, this assessment will likely serve as the basis of future Agency action regulating the use of biosolids. And, as outlined above, setting a regulatory standard of 1ppb will effectively eliminate agricultural use of biosolids. It is not clear what wastewater utilities will do with the 31% of biosolids that are traditionally applied to agricultural land. It is further unclear whether we have the landfill capacity to store this amount of biosolids. Ultimately, we must evaluate the many tradeoffs involved, particularly where EPA has not demonstrated that setting a regulatory standard of 1ppb actually will make our food safer.

The Food and Drug Administration (FDA) is responsible for ensuring the safety of the U.S. food supply, which includes monitoring for potential contaminants like PFAS. The FDA began testing PFAS in food in 2019 as part of its broader effort to understand the extent of PFAS contamination in the food supply. Since then, the FDA released the results of its total diet study focused on PFAS, which tested a range of foods consumed in the US diet, including vegetables, dairy, fish, and packaged foods. The results showed that most food items did not test positively for PFAS and most products that did test positively, did so at trace levels—often due to the food packaging materials that contain these chemicals. The only outliers were some fish and shellfish items that were raised in areas with known environmental contamination (China). For instance, in 2019, the FDA evaluated 91 samples with only 2 samples reaching a detectable level of PFAS. Additionally, in 2021, the FDA studied 94 samples with only one fish sample reaching detectable levels. Thus far, FDA has had a very low frequency of detection with extremely low concentrations. FDA continues to be proactive in testing food products and maintains that our country has the safest, most abundant food supply in the world.

Additionally, it is worth noting the relationship between PFAS exposure and various health effects is still a subject of ongoing scientific debate and research, and EPA has acknowledged that it is challenging to prove causation between PFAS exposure and adverse health outcomes. The health endpoints associated with PFAS exposure are a significant area of concern and research, but some of the potential health effects remain controversial due to inconsistent study results, the complexity of human exposure, and the difficulty in establishing causation. The question of whether PFAS definitively leads to negative health outcomes is complex, and while there is evidence linking PFAS to various health problems, establishing causality for potential health outcomes is an ongoing area of scientific research.

While these questions still remain, it is undeniable that we have seen dramatic decreases in the levels of PFOA and PFOS in the environment and human exposure, largely due to the discontinuation of their use in many products, coupled with regulatory actions and the voluntary phase-out efforts by manufacturers. Specifically, since 2002, production and use of PFOS and PFOA in the U.S. have declined substantially. As a result, from 1999-2000 to 2018-2019, blood PFOS levels have declined by more than 85% and blood PFOA levels have declined more than 70%. While there are many chemical compounds that make up the PFAS family, the discontinuation of the most prevalently used chemicals has gone a long way towards improving the situation.

The farming and ranching community strongly encourages EPA to reevaluate the proposed risk assessment and the methodology used to uphold the 1ppb threshold. Our organizations stand ready to assist the Agency in developing a risk assessment that relies on accurate and relevant estimates and assumptions. As farmers and ranchers, the goal of our collective membership is to produce the safest, most abundant food supply that our country—and the world—can confidently rely upon. The agricultural community supports the development of a regulatory limit of PFAS in biosolids because our members want to ensure that they are not contributing to any contamination of our environment or adverse health risks. But it is critically important that we first study the real-world risks of this issue more carefully.

Thank you for considering our concerns. Should you have any questions please do not hesitate to contact Courtney Briggs at CourtneyB@fb.org.

Sincerely,

American Farm Bureau Federation
American Soybean Association
National Association of State Departments of Agriculture
National Cattlemen's Beef Association
National Corn Growers Association
National Milk Producers Federation
National Pork Producers Council
National Turkey Federation
United Egg Producers
U.S. Poultry & Egg Association