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U.S. Environmental Protection Agency
Office of Water
1200 Pennsylvania Ave., NW
Washington, DC 20460

Submitted via: Federal eRulemaking Portal: https://www.regulations.gov/

RE: Docket EPA-HQ-OW-2024-0504 Draft Sewage Sludge Risk Assessment for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS)

To Whom It May Concern:

Public Employees for Environmental Responsibility, together with the Maine Organic Farmers and Gardeners Association; the Potomac Riverkeeper Network; Johnson County, Texas; and Texas ranchers James Farmer, Robin Alessi, Tony Coleman, and Karen Coleman offer the following comments on the U.S. Environmental Protection Agency's (EPA's) Draft Sewage Sludge Risk Assessment for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS).

The draft risk assessment reflects the agency's latest scientific understanding of the potential risks to human health and the environment posed by the presence of PFOA and PFOS that is land applied as a soil conditioner or fertilizer (on agricultural, forested, and other lands), surface disposed (e.g., placed in a sewage sludge-only landfill called a monofill), or incinerated. When finalized, the risk assessment will provide information on risk from use or disposal of sewage sludge and will inform the EPA's potential future regulatory actions under the Clean Water Act.

In the draft assessment, EPA came to a reasonable conclusion that land-applied sewage sludge (i.e., biosolids) containing 1 part per billion (ppb) of PFOA or PFOS exceeds the Agency's acceptable human health risk thresholds. However, there are flaws in EPA's model assumptions and approaches that warrant correction. Specifically, the draft risk assessment:

- Contains demonstrably false statements;
- Fails to reflect actual farming practices;
- Ignores mixture effects of being exposed to multiple PFAS simultaneously;
- Fails to consider precursors to PFOA and PFOS; and,
- Fails to consider all exposure routes of PFAS.

Addressing these flaws in the final risk assessment will give the agency, consumers, and the public a better understanding of sewage sludge's true risks and allow for better regulations and practices to avoid these risks.

We urge EPA to address these risks and finalize this Draft Risk Assessment as soon as possible.

Our specific comments are set forth below.

Background. Sewage sludge, also referred to as "biosolids," is the solid waste filtered from wastewater treatment plants. It includes chemicals discharged in industrial wastewater as well as everything sent down the drains of homes and businesses, from human excrement flushed down toilets, to materials exiting via utility sinks, laundry machines, and dishwashers. Under federal law, wastewater treatment facilities are allowed to sell sewage sludge as fertilizer but must first treat it to remove pathogens and a small number of toxic contaminants EPA identified in the 1990s.

PFOA and PFOS are part of a class of chemicals called per-and polyfluoroalkyl substances (PFAS). These toxic human-made chemicals are associated with a wide range of risks to human and animal health such as cancer, hormone disruption, liver and kidney damage, birth defects, developmental and reproductive harm, changes in serum lipid levels, increased cholesterol and risk of obesity, and immune system toxicity.[1]

PFAS are so highly persistent, bio-accumulative, and bio-magnifying that they have earned the nickname "forever chemicals."[2] They are present in a wide range of consumer products, including shampoo, makeup, clothes, non-stick cookware, plastic containers, pesticides, and food packaging, as well as in industrial products. PFAS gets into the bodies of living organisms via three exposure pathways: ingestion through food or drink, inhalation, and dermal absorption.

Some PFAS are so dangerous to humans that in April of 2024, EPA released a National Primary Drinking Water Regulation (NPDWR) for several PFAS, including maximum contaminant levels (MCLs) and maximum contaminant level goals (MCGLs).[3] Specifically, EPA set the MCLs for PFOS and PFOA at 4 parts per trillion (ppt), and the MCLGs for these two compounds at zero. This is significant because, by setting the MCGLs for PFOS and PFOA at zero, EPA concluded that there is no safe consumption level for these two PFAS.

Because PFAS are ubiquitous in consumer products, they are also present in municipal and industrial wastewater, and biosolids. When these biosolids are land-applied on farm fields, the

[1] U.S. Dept. of Health and Human Services, Agency for Toxic Substances and Disease Registry, Toxicological Profile for Perfluoroalkyls, (May 2021), available at https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf (last visited April 7, 2025)
[2] https://www.washingtonpost.com/opinions/these-toxic-chemicals-are-everywhere-and-they-wont-ever-go-away/2018/01/02/82e7e48a-e4ee-11e7-a65d-1ac0fd7f097e_story.html
[3] https://www.federalregister.gov/documents/2024/04/26/2024-07773/pfas-national-primary-drinking-water-regulation

PFAS contaminates the soil,[4] groundwater,[5] and vegetation,[6] and an then bio-magnify in milk,[7] eggs,[8] and meat of farm animals.[9] Because remediation of PFAS in soils is difficult, if not impossible,[10] spreading PFAS-laden biosolids on our farms and ranches will contaminate our food supply, our agricultural soil, and our water.

Lawsuit against EPA. On June 4, 2024, the signatories of this comment sued EPA under the citizen suit provision of the Clean Water Act, 33 U.S.C. § 1365(a)(2), for failing to perform its non-discretionary duty to identify and regulate certain toxic PFAS, including PFOA and PFOS, in sewage sludge as required by 33 U.S.C. § 1345(d).[11] Available data show that PFOS and PFOA - along with numerous other PFAS - are present in biosolids in concentrations that may pose a risk to human health and the environment, and thus the Clean Water Act requires EPA to regulate them. While EPA's risk assessment is not a statutorily-required step in the regulation process, in the case of PFOS and PFOA the agency has already devoted a large amount of time and effort to its assessment. We urge the agency, therefore, to promptly (1) address the deficiencies of the draft risk assessment as described herein, (2) finalize the risk assessment, and (3) comply with the statutory mandate to regulate PFOA and PFOS in sewage sludge.

EPA's Draft Risk Assessment. EPA's Draft Risk Assessment (hereinafter "DRA") focuses on PFOA and PFOS because:

> PFOA and PFOS bioaccumulate in humans, plants, fish, and livestock and are persistent in the environment. Finally, these chemicals are highly toxic to human beings; the EPA has classified both chemicals as likely to be carcinogenic to humans, and the available human epidemiological and animal toxicological evidence indicates that they adversely impact developmental, cardiac, hepatic, and immune systems depending on exposure conditions (citations omitted).[12]

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[4] Gwynn R. Johnson, PFAS in soil and groundwater following historical land application of biosolids, Water Research, Volume 211, 2022, https://www.sciencedirect.com/science/article/abs/pii/S004313542101229X?via%3Dihub

[5] Jeff A.K. Silva, Jennifer L. Guelfo, Jiří Šimůnek, John E. McCray, Simulated leaching of PFAS from land-applied municipal biosolids at agricultural sites, Journal of Contaminant Hydrology, Volume 251, 2022, https://www.sciencedirect.com/science/article/abs/pii/S0169772222001371

[6] Steven Lasee, Seenivasan Subbiah, Sanjit Deb, Adcharee Karnjanapiboonwong, Paxton Payton, Todd A. Anderson, The Effects of Soil Organic Carbon Content on Plant Uptake of Soil Perfluoro Alkyl Acids (PFAAs) and the Potential Regulatory Implications, *Environmental Toxicology and Chemistry*, Volume 40, Issue 3, 1 March 2021, Pages 832–845, https://doi.org/10.1002/etc.4786

[7] Hill, N.I., Becanova, J. & Lohmann, R. A sensitive method for the detection of legacy and emerging per- and polyfluorinated alkyl substances (PFAS) in dairy milk. *Anal Bioanal Chem* **414**, 1235–1243 (2022). https://doi.org/10.1007/s00216-021-03575-2

[8] https://pfascentral.org/news/maine-forever-chemicals-problem-has-now-spread-to-chicken-eggs

[9] https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1870&context=pelr

[10] Yifei Wang, Umar Munir, Qingguo Huang, Occurrence of per- and polyfluoroalkyl substances (PFAS) in soil: Sources, fate, and remediation, Soil & Environmental Health, Volume 1, Issue 1, 2023, https://www.sciencedirect.com/science/article/pii/S2949919423000043

[11] https://peer.org/wp-content/uploads/2024/06/6_6_24_Complaint_Farmer-v-EPA_24-1654_as-filed.pdf (Note that the lawsuit was subsequently amended to add additional plaintiffs)

[12] DRA, p. iv

The DRA's ultimate conclusion is that single application of sewage sludge containing 1 part per billion (ppb) of PFOS or 1 ppb of PFOA on land, results in significant human health risks. Specifically, EPA found that "draft risk estimates exceed the agency's acceptable human health risk thresholds for some pasture farm, food crop farm, and reclamation scenarios...."[13]

While we believe that EPA's conclusion is not unfounded, it did make several incorrect assumptions and limitations in its analysis that should result in an even lower limit. Those assumptions and limitations are detailed below.

1) **Domestic manufacturing of PFOA has *not* been phased out.** EPA states that, "[a]lthough domestic manufacturing of PFOA and PFOS have been phased out and their uses restricted, multiple activities still result in PFOA, PFOS, and their precursors being released to WWTPs."[14] This statement is demonstrably false. As EPA well knows, over 200 million plastic containers are fluorinated each year, and this fluorination process results in the production of PFOA and numerous other long and short chain PFAS.[15] Unless and until EPA halts this fluorination process, PFOA will continue to be manufactured in the United States, contaminating our land, water, soil, air, and food.

2) **The draft risk assessment irrationally assumes that there is only a single application of biosolids on each farm in its risk assessment.** While it is possible that some farms may only apply biosolids once, many farms have repeated applications of biosolids over the years. Therefore, this assumption does not reflect actual practice. EPA should include repeated applications in its final risk assessment.

3) **The draft risk assessment ignores mixture effects and PFAS other than PFOA and PFOS.** EPA's final risk assessment should examine both other individual PFAS typically found in biosolids, and the impacts of being exposed to multiple PFAS simultaneously. Indeed, EPA concedes:

> PFOA and PFOS have been shown to be dose additive and are nearly always found in mixtures in biosolids, and it follows that the environmental media impacted by use or disposal of biosolids also contains mixtures of PFOA and PFOS. The presence of mixtures and multiple pathways for exposure would result in higher risks of adverse health effects at a population scale than are reflected in the pathway-specific results.[16]

If EPA does not address the mixture and additive effects of all of individual PFAS found in biosolids, or otherwise account for that uncertainty, the risk assessment will not be protective of human health.

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[13] DRA, p. v
[14] DRA, pp. iii-iv
[15] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/orders-significant-new-use-certain
[16] DRA at 24

4) **The draft risk assessment fails to consider PFAS precursors (PFAS that degrade to PFOA and PFOS).** EPA concedes that, "the occurrence data of PFAS in biosolids indicate precursors significantly contribute to the overall PFOA and PFOS loading to soils and disposal facilities," and suggests that, "[f]uture assessments could be expanded to include other chemicals including environmental precursors to PFOA and PFOS, or other PFAS. [17] We agree. Indeed, failure to include these precursor chemicals will underestimate the risk to human health.

5) **The draft risk assessment fails to consider all exposure routes of PFAS.** As stated above, humans are exposed to PFAS from ingestion, inhalation, and dermal absorption. Despite this, the DRA model assumes that:

> …an adult living on a farm consumes, on average, 1 egg per day from the impacted property for ten years, which represents the median egg consumption rate for households who farm…The model further assumes that when the adult lives on the impacted farm, they have no sources of PFOA or PFOS exposure other than eggs and that for the remainder of the adult's life, they have no exposure to PFOA or PFOS through any pathway.[18]

These are patently erroneous assumptions. In reality, it is clear that:

- EPA cannot rationally assume that PFOA or PFOS from biosolids would affect *only chicken eggs* and nothing else on the farm that family members would ingest, such as animal products, plants, or drinking water. The reality is that during the years that a person lives on a farm, that person is exposed to *many more* PFAS, and to additional PFOA and PFOS, from, for example, other farm products they consume, from their well water, from soils (which can result in both dermal and inhalation exposures), and from consumer products.

- The assumption that an adult living on a farm does so for only ten years flies in the face of the realities of farming.

- The assumption that after the (arbitrary) 10-year period of living on an impacted farm, the adult will have no source of PFOA or PFOS exposure for the remainder of their life through any pathway is a virtual impossibility.

EPA concedes that that "draft risk calculations are not conservative estimates," and "exposure to other PFAS would be greater than those presented in this draft risk assessment."[19] While we understand the difficulty of calculating risk given these variables, it is imperative that EPA address these issues in its Final Risk Assessment.

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[17] DRA at 9
[18] DRA at vii
[19] DRA at vi - vii

Conclusion. The facts are clear: PFAS in biosolids threatens the health and livelihoods of farmers across the country and contaminates drinking water and our nation's food supply. This DRA, while an important first step, does not go far enough. While the conclusions in the DRA warn about risks from just 1 ppb of either PFOA or PFOS in biosolids, EPA admits:

> This assessment includes several assumptions that could result in an underestimate of risk at specific sites. Perhaps most significantly, this assessment assumes that the starting concentration of PFOA and PFOS in biosolids is only 1 ppb. The available biosolids monitoring data from the U.S. suggest that nearly all biosolids have higher concentrations than this threshold… Furthermore, the modeling indicates that PFOA and PFOS incorporated into soils from biosolids can be persistent sources of contamination to groundwater, surface water, and human or animal food over time…[20]

Nearly all people in the United States have PFAS in their blood.[21] Every day, we learn of new health effects from exposure to PFAS.[22] Every day PFAS-laden biosolids are land-applied to farms, we risk additional contamination to our food and our water. EPA's reckless disregard for human health from land application of biosolids must be addressed. As such, we call on EPA to:

- Define PFAS comprehensively;
- Regulate PFAS as a large family, rather than on a chemical-by-chemical basis;
- Regulate PFAS from cradle to grave, meaning from the moment they are produced until their disposal;
- Ban all non-essential PFAS (where essentiality is defined as use that is necessary for health and safety, *and* is critical for the functioning of society, *and* there are no available technically and economically feasible alternatives); and
- Work on finding substitutions for any remaining essential uses.

Finally, we would be remiss if we failed to mention recent Congressional attempts to prohibit actions to protect people from PFAS in biosolids.[23] While this is a rapidly evolving situation, it is inappropriate for a rider of this type to be attached to an appropriations bill. The DRA, while flawed, must be finalized, and regulations promulgated which protect our water, food, farmland, and health.

Thank you for considering these comments.

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[20] DRA at 113.

[21] https://www.atsdr.cdc.gov/pfas/data-research/facts-stats/index.html

[22] See, e.g., Roy, V. C., Bala, R., & Mehta, S. (2025). Poly- and per-fluoroalkyl substances toxicity on skeletal and cognitive well-being: a comprehensive review. *Journal of Environmental Science and Health, Part C*, *43*(2), 159–183. https://doi.org/10.1080/26896583.2025.2460884

[23] See Section 507 in https://appropriations.house.gov/sites/evo-subsites/republicans-appropriations.house.gov/files/evo-media-document/fy26-interior%2C-environment%2C-and-related-agencies-bill-text.pdf