EPA and Federal Regulation

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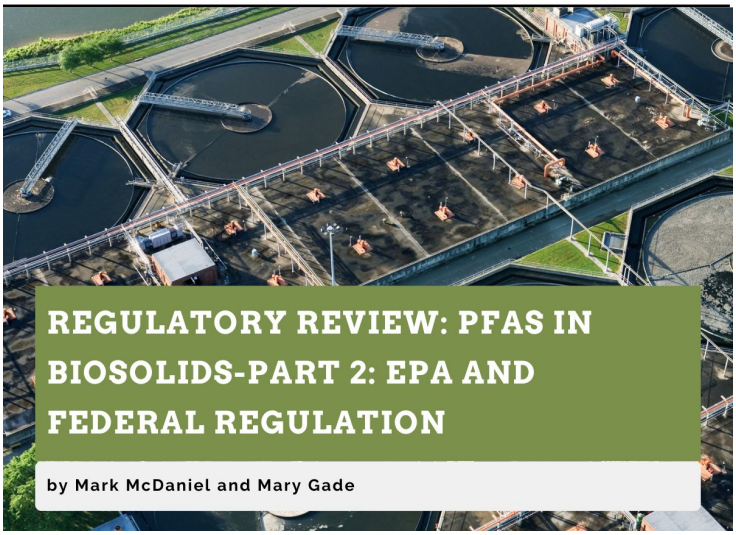

Regulatory Review: PFAS in Biosolids—Part 2: EPA and Federal Regulation
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Lead-In: This is the second of three articles exploring the implications of PFAS in biosolids—nutrient-rich organic materials derived from sewage treatment while highlighting the regulatory, legal, and management challenges associated with their presence.

Summary Bullets:
- Several federal statutes regulate biosolids, with primary authority under the CWA, but none directly address PFAS in biosolids.
- The EPA recently added two PFAS as hazardous substances under CERCLA.
- A newly released draft risk assessment for two PFAS in biosolids could lead to additional regulation of PFAS under the RCRA Part 503 regulation.

This is the second in a series of three articles exploring the implications of per- and polyfluoroalkyl substances (PFAS) in biosolids—nutrient-rich organic materials derived from sewage treatment while highlighting the regulatory, legal, and management challenges associated with their presence. This first article can be found here: PFAS in Biosolids—Part 1: How PFAS Biosolids Problems Evolved.

Related Federal Acts

Clean Water Act—Biosolids

The Clear Water Act (CWA) section 405(d) mandates the Environmental Protection Agency (EPA) to:

1. establish numeric limits and management practices to protect public health and the environment from the reasonably anticipated adverse effects of pollutants during the use and disposal of sewage sludge; and

2. review biosolid regulations every two years to identify any additional pollutants in the sewage sludge, setting regulations for those pollutants, if sufficient scientific evidence shows they may harm human health or the environment.

In the 30 years since EPA promulgated biosolid regulations in 40 CFR section 503, it has consistently promoted land application of sewage sludge (it dubbed “biosolids”) touting its benefits as a fertilizer and soil conditioner.

To protect human health and the environment, the rules currently provide specific limits and requirements for 10 heavy metals characterized as "pollutants" when in sewage sludge and explicitly exclude dioxins. No PFAS are included currently. 40 C.F.R 503.23
In *James Farmer et al. v. EPA,* plaintiff farmers from Texas and Maine contend that CWA section 405 mandates EPA to regulate PFAS in biosolids and EPA did not perform this nondiscretionary

duty.[1] EPA has identified additional pollutants in nine sewage sludge surveys conducted from 2004 through 2021 and three national sewage sludge surveys from 1988 to 2006 and must promulgate regulations if there is sufficient scientific evidence that these pollutants harm human health or the environment.

The plaintiffs argue that EPA failed to regulate toxic PFAS in biosolids, noting that in 35 years of regulation, EPA has identified 350 pollutants in biosolids, including 29 PFAS. This includes 10 PFAS that the plaintiffs assert already have sufficient scientific evidence to justify regulation.[2] EPA has pushed back, countering that the litigation should be dismissed, noting that its only duty is to conduct the biennial reviews, which it has done.[3]

A ruling could accelerate the trajectory for PFAS biosolids regulation and force EPA to add PFAS to the list of pollutants in 40 CFR 503.

CWA Biosolids Liability and Litigation

The CWA biosolids rules in 40 CFR section 503 are notable for the breadth of their applicability and being "self-implementing" so compliance is mandated even without a permit.

They cover "any person or treatment works that prepares sewage sludge, applies sewage sludge to land, fires sewage sludge in an incinerator, and the owners and operators of disposal sites."[4] The rule's applicability closely mirrors the reach of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) with its expansive list of potentially responsible parties (PRPs) with one important exception: CERCLA liability applies retroactively to PRPs while the biosolids rule is forward facing.

The broad scope of the biosolids rule creates significant future consequences for federal and state enforcement, citizen suits, and third-party liability under the civil and criminal enforcement authorities in section 309 of the CWA with 40 CFR 503.3 expressly providing "direct enforceability" of the regulation's requirements against any person applying sewage sludge. This could create the opportunity for citizen suit litigation against a wide variety of defendants, as various plaintiffs allege biosolids contain PFAS after EPA lists any PFAS as a pollutant under the CWA biosolids rule.

Even without specific PFAS biosolids federal regulation, plaintiffs recently relied on the citizen suit provisions of the CWA and the Resource Conservation and Recovery Act (RCRA) to file a complaint against Calhoun, Georgia, for land application of biosolids and the owner of the property on which it was applied. In *Coosa River Basin Initiative v. City of Calhoun, Georgia* (Civil Action No. 4:24-cv-00068-WMR 2024),[5] the Southern Environmental Law Center alleged that the city's biosolids application on farm fields has threatened northwest Georgia's water supply with PFAS contamination, which requires a CWA National Pollution Discharge Elimination System (NPDES) permit since the land receiving the biosolids is hydrologically connected to U.S. navigable waters. Plaintiffs further contend the City of Calhoun violated its actual NPDES permit by not appropriately meeting its requirements for the management of toxic pollutants. Citing RCRA, the plaintiffs also alleged that the land application of biosolids with PFAS is an improper handling of hazardous waste that creates an imminent and substantial

endangerment to human health or the environment despite PFAS not now, nor currently proposed to be regulated as a RCRA hazardous waste.

This case settled after the city agreed to address PFAS in past and future biosolids land application, including stopping land application until the biosolids PFAS meet the stringent federal Safe Drinking Water maximum contaminant levels (MCLs). Additionally, Calhoun must test private wells within a specified radius and provide municipal drinking water or point-of-entry treatment systems if the levels exceed 75 percent of the MCLs. The city will survey upstream industrial dischargers over PFAS use and discharges into its system and ultimately require that these industries meet Best Management Practices as specified in EPA guidance, which is discussed more below. The city appointed a third-party compliance monitor over the next three years. As often occurs in citizen suits, the city must pay its opponent's attorney fees.

While there is no reported court ruling, one can expect similar litigation against municipalities and wastewater treatment plants (WWTPs) given publicity. There are clearly costly consequences that parties, including upstream dischargers, may face, even in the absence of any past or current federal regulatory limits on PFAS in biosolids. If federal limits on PFAS in biosolids are eventually imposed, the potential obligations to treat PFAS will increase.

Clean Air Act

The Clean Air Act (CAA) regulates air emissions from all sources, including commercial and municipal solid waste incinerators that burn biosolids.[6] Unfortunately, as EPA has noted, "The effectiveness of incineration to destroy PFAS compounds and the tendency for formation of fluorinated or mixed halogenated organic byproducts is not well understood."[7] Technical questions abound regarding appropriate temperatures, residence time and the formation of smaller PFAS products, or products of incomplete combustion (PICs).

This has been a particularly difficult problem for the U.S. military[8] given mandates in the 2020 and 2022 National Defense Authorization Acts (NDAA) first, requiring the phasing out by 2024 of the use of aqueous film-forming foam (AFFF) used in fighting high-intensity fires caused by flammable liquids and second, banning incineration of PFAS-laden items, including AFFF, until EPA issues guidance on the destruction and disposal of PFAS. EPA's most recent guidance concludes that "further research is required to gain a better understanding of what might be possible in practice."[9] In the meantime, the military continues to use AFFF under waivers through October 1, 2026, and for shipboard fires[10] in the absence of PFAS-free firefighting products that work as effectively.[11]

Resource Conservation and Recovery Act

RCRA regulates biosolids, but no PFAS yet, placed in municipal solid waste landfill units at 40 CFR Part 258. On February 8, 2024, the EPA proposed regulating nine PFAS compounds, their salts, and their structural isomers as "hazardous constituents" under the RCRA Appendix VIII list in 40 CFR Part 261. The chemicals include both PFOA and PFOS, as well as GenX chemicals. EPA will only list chemicals if scientific studies show toxic, carcinogenic, mutagenic or

teratogenic effects on humans or wildlife. Designation as a “Hazardous Constituent” would activate RCRA’s corrective action requirements at treatment, storage and disposal facilities with solid waste management units. More importantly, such a designation is often the first step in listing these nine PFAS as a RCRA “Hazardous Waste,” making them automatically CERCLA “Hazardous Substances” with all the attendant legal consequences.

CERCLA: New PFAS Hazardous Substance Designations

Recent regulatory action by EPA under CERCLA could further complicate this evolving arena. In an April 19, 2024, Final Rulemaking, EPA finally designated PFOA and PFOS as “Hazardous Substances” under CERCLA.[12] If upheld, this designation has potentially significant implications for a large cast of possible plaintiffs and defendants related in varying ways to biosolids, including reopening closed Superfund sites containing these listed PFAS.

In response to an ongoing industry challenge, the Trump administration has sought a 60-day stay of litigation on this rulemaking, to make its own assessment of the rule that may lead to modifications or its withdrawal.

Under this new rule, releases of PFOA and PFOS of one pound or more per 24-hour period must be reported to the National Response Center (NRC). Existing Superfund sites, both open and closed (including brownfields), and future Superfund sites, may need to sample and monitor for PFOA and PFOS and potentially re-open or expand remediation to address their findings. EPA publishes and updates Regional Screening Levels (RSLs) for PFAS that it uses to determine if a response or remediation is needed. While these screening levels are not regulatory and not cleanup- or health-based standards, plaintiffs concerned about PFAS contamination in biosolids will likely rely on them in litigation as an arguable basis for a threat the two PFAS pose to human health and the environment.

CERCLA Liability and PFAS in Biosolids

CERCLA casts a wide net for PRPs in cleanup of sites listed on the National Priority List. There are four classes of PRPs: 1. Current facility owners and operators; 2. Past facility owners and operators; 3. Generators and parties arranging for disposal and transport of the hazardous substances; and 4. Transporters to the site. Unlike the CWA, CERCLA specifically makes PRPs potentially liable as past owners on a site where the newly designated hazardous substances, PFOA and PFAS, are found.

In addition to retroactivity, Superfund's strict, joint, and several liability provisions are notoriously broad. For land applications of biosolids, this means that if PFOA or PFOS are found in any of the millions of acres of agricultural land where biosolids were spread, the current and past landowner and generators of the biosolids and parties that arranged for disposal and transporters that selected the site are all potentially liable. This is strict liability with no evidence of negligence, and deep pockets pay for those empty chairs (i.e., indigent or bankrupt parties).

Accordingly, any PRP could be subject to litigation brought by EPA, states, municipalities, Tribal nations, and other third parties. Plaintiffs will surely invoke the Polluter Pays principle, seeking

recourse from parties in the supply chain, including PFAS chemical manufacturers and upstream PFAS industrial sources contributing effluent to WWTPs, characterizing them as "generators" under CERCLA. Wholesale and big box retail vendors of containerized or bagged biosolids, or materials mixed with biosolids, could likely also be in litigation crosshairs, as will be golf courses, cemeteries, public parks, and other public areas where PFAS biosolids were applied. Similarly, litigation against property owners of mining, forest land, and construction sites where biosolids served reclamation purposes are likely, as are cases against final surface disposal and temporary storage sites for various tort claims from personal injury to property damage. Lastly, we can expect state and federal natural resource damage claims.

CERCLA and PFAS Enforcement Discretion

The applicability and liability provisions of Superfund and the potential for third-party claims for cleanup of Superfund sites or recovery of costs incurred by other PRPS have caused widespread concern across so-called "passive receivers" of PFAS-contaminated biosolids, including many in the waste, wastewater, and agriculture sectors.

EPA has attempted to directly address this issue. Two days after the final rulemaking, the Office of Enforcement and Compliance Assurance issued a memorandum with a new CERCLA enforcement discretion policy for PFAS. EPA states that its focus will be on "major parties who significantly contributed to the release of PFAS into the environment" including parties that manufactured or used PFAS in the manufacturing process, other industrial parties, and federal facilities.

EPA says it will look at "equitable factors "and does not intend to pursue those that satisfy them. It specifically identifies community water systems and publicly owned treatment works, municipal separate storm sewer systems, publicly owned/operated municipal solid waste landfills, publicly owned airports and local fire departments, and farms where biosolids are applied to the land.

Given the risk of third-party litigation against these parties, EPA proposes its settlement authority to provide contribution protection from third-party claims. Since these settlements will be time-consuming and difficult to negotiate against the large PRP set, EPA intends to require "major PRPs" to waive their rights in any settlement with EPA to sue parties that meet the equitable factors. It remains to be seen whether PRPs find comfort in EPA's approach.

American Farm Bureau Federation President Zippy Duvall worries that "farmers could be unfairly targeted even though they do not create or use any PFAS in their operations but may have passively received the chemicals. We acknowledge that we do not want farmers and ranchers to be penalized for a situation they did not create."[13]

While EPA has chosen for now to address potential liability for PFAS contamination in biosolids through an enforcement discretion guidance document, others contend that the statute itself provides a protection against liability. CERCLA section 101(22) exempts "the normal application of fertilizer" from the definition of "release."[14] Organizations like the Environmental Working Group contend that land application of biosolids as a fertilizer, as EPA has long encouraged, would bring biosolids, even contaminated with PFAS, squarely within this exemption.[15] But, to

date, EPA has chosen not to recognize this exemption as applicable perhaps to avoid letting other upstream contributors "off the hook."

In the meantime, there is ongoing discussion in Congress about providing clear safeguards against CERCLA liability in biosolids for passive receivers from the PFAS designation as hazardous substances. It will be important to keep an eye on this activity to see what, if anything, is enacted and to whom it covers since this could substantially change the legal landscape.

For now, it means increased scrutiny for any land application, incineration, storage or disposal of biosolids and probably a tsunami of future litigation stemming from PFAS contamination of biosolids. A biosolids PFAS Federal Multi-District Litigation (MDL) scenario similar to the current MDLs: PFAS cases for AFFF used in firefighting with over 10,000 cases pending, and over $10 billion in settlements for contamination to public water systems.[16]

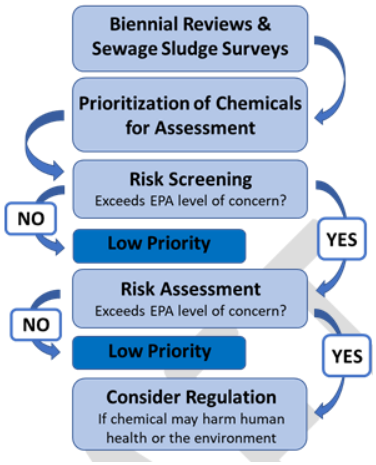
What's Next?

A newly released draft risk assessment for two PFAS in biosolids could eventually lead to additional regulation of PFAS under the RCRA Part 503 regulation. On January 14, 2025, EPA released its long-anticipated draft risk assessment for PFOA and PFOS in biosolids that are land-applied as fertilizer or soil conditional, surfaced disposed of, or incinerated.[17] It is taking comments on the draft's findings and methodology until April 16, 2025, in accord with a 30-day extension to the original comment period by the new Trump administration.[18] If the recent interest in EPA's PFAS rulemakings is any indicator, EPA will be flooded with comments (it received 120,000 for the proposed designation of PFOA and PFOS as CERCLA "Hazardous Substances").

EPA used a newly created risk assessment framework (see figure) to more efficiently identify, assess, and manage pollutants in biosolids that may pose a threat to human health and the environment.

EPA's proposed prioritization and risk assessment framework for chemicals in sewage sludge and biosolids (Draft).[19]

EPA's draft risk assessment is notable in that it does not address risk to the general public. Instead, it's more narrow focus is on people living on or near impacted farms or those who rely on products from these farms or those proximate to surface disposal sites. EPA finds, based on its modeling, that there may be human health risks exceeding EPA's acceptable thresholds for some scenarios when land-applying sludge contains 1 ppb of PFOA or PFOS. EPA also finds that there may be human health risks associated with drinking contaminated groundwater from a source near a surface disposal site when sewage sludge containing 1 ppb of PFOA or 4 to 5 ppb of PFOS is disposed in an unlined or clay-lined surface disposal unit. For sewage sludge incinerators, EPA notes it cannot provide quantitative risk estimates due to data gaps relative to the efficacy of incineration destroying PFAS. See EPA Fact Sheet "Draft Sewage Sludge Risk Assessment for PFOA and PFOS," January 2025.[20]



After taking comments, EPA will issue a final risk assessment and determine whether risk reduction actions, including regulation, are appropriate to protect human health and the environment from PFOA and PFOS in biosolids. If so, proposed rulemaking under CWA section 405(d) establishing actual numerical pollutant and volume limits for PFOS and PFOA in biosolids is the most likely outcome. This process will trigger inevitable litigation.

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[1] CWA section 405(d)(2)(C).
[2] *James Farmer et al. v. EPA,* Civil No. 1:24-cv-01654 (U.S.D.C. D.C 2024).
[3] Jacob Wallace, *EPA says it has no obligation to regulate PFAS in biosolid fertilizers, Agriculture Dive* (Sept. 18, 2024), https://www.agriculturedive.com/news/epa-pfas-biosolids-lawsuit-fertilizer-farm-texas/727256/.
[4] 40 CFR 503.1(b)(1).
[5] *Coosa River Basin Initiative v. City of Calhoun, Georgia* (Civil Action No. 4:24-cv-00068-WMR 2024).
[6] 42 U.S.C. 7429.
[7] USEPA Technical Brief, *Per- and Polyfluoroalkyl Substances (PFAS): Incineration to Manage PFAS Waste Streams* (Feb. 2020).
[8]Maureen Dooley, *The Problem with PFAS Waste Incineration*, Envtl. Sci. & Eng'g Mag. (Oct. 6, 2022), https://esemag.com/hazmat-remediation/problem-with-pfas-waste-incineration/.
[9] EPA "Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances (2024), https://www.epa.gov/pfas/interim-guidance-destruction-and-disposal-pfas-and-materials-containing-pfas.
[10] GAO, *Firefighting Foam: DOD is Working to Address Challenges to Transitioning to PFAS-Free Alternatives,* FAO-24-107322 (July 8, 2024).
[11] DOD*, DOD PFAS Task Force Website, FAQ, When will DoD stop using Aqueous Film Forming Foam (AFFF)*? (2024), https://www.acq.osd.mil/eie/eer/ecc/pfas/faqs.html#twenty.
[12] EPA, *Proposed Rule—Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances* (Sept. 6, 2022), https://www.federalregister.gov/documents/2022/09/06/2022-18657/designation-of-perfluorooctanoic-acid-pfoa-and-perfluorooctanesulfonic-acid-pfos-as-cercla-hazardous.

[13] American Farm Bureau Federation, *"Forever Chemical" Rule Creates Uncertainty for Farmers,* News Release (April 19, 2024), https://www.fb.org/news-release/forever-chemical-rule-creates-uncertainty-for-farmers.
[14] 42 U.S.C. section 9601 (22)(D).
[15] Environmental Working Group, *CERCLA Tools to Limit Utility Liability,* Memo (May 22, 2023), https://static.ewg.org/upload/pdf/EWG_CERCLA_water_utility_memo_.pdf.
[16] U.S. District Court of South Carolina, Aqueous Film-Forming Foams (AFFF) Products Liability Litigation MDL No. 2873 (2024), https://www.scd.uscourts.gov/mdl-2873/index.asp.
[17] EPA, *Draft Sewage Sludge Risk Assessment for PFOA and PFOS* (Jan. 2025), https://www.epa.gov/system/files/documents/2025-01/fact-sheet-draft-sewage-sludge-risk-assessment-pfoa-pfos.pdf.
[18] 90 FR 10078 Notice of Extension of Comment Period for FR-12451-01-OW (FR 90 FR 3859), Feb. 21, 2025.
[19] EPA, *SAB review of EPA's Standardized Framework for Sewage Sludge Chemical Risk Assessment* (External Peer Review Draft)EPA Document No. 822D23001 (2023).
[20] EPA, *Draft Sewage Sludge Risk Assessment for PFOA and PFOS* (Jan. 2025), https://www.epa.gov/system/files/documents/2025-01/fact-sheet-draft-sewage-sludge-risk-assessment-pfoa-pfos.pdf.