PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY
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February 22, 2024

Michael Regan
Administrator
U.S. Environmental Protection Agency
Mail Code 1101A
1200 Pennsylvania Ave., NW
Washington D.C. 20460

Re: Notice of Intent to File Suit Regarding Alleged Violation of the Clean Water Act (CWA)

Dear Administrator Regan:

Public Employees for Environmental Responsibility (PEER) and James Farmer, Robin Alessi, Tony Coleman, Karen Coleman, and Patsy Schultz are hereby providing notice of their intent to sue you and the U.S. Environmental Protection Agency (collectively, EPA) in accordance with the citizen suit provision of the Clean Water Act (CWA), 33 U.S.C. § 1365, for failing to perform non-discretionary acts or duties under the CWA. Specifically, the EPA has unlawfully failed to identify at least 18 per- and polyfluoroalkyl substances (PFAS) in biosolids and has failed to promulgate regulations for at least 12 PFAS in biosolids as required under 33 U.S.C. § 1345(d)(2)(C).

Sewage sludge, or biosolids, are the treated solids that are separated from sewage waste. Biosolids, and the pollutants in them, enter the environment when biosolids are: (1) applied as fertilizer to agricultural lands, home gardens, pastures, and other lands; (2) landfilled; or (3) incinerated.

EPA's failure to adequately implement the law allows toxic pollutants into our environment, causing widespread and significant harm to human health and the environment. Overwhelming scientific evidence demonstrates that biosolids contain several types of PFAS, substances that pose health and environmental threats because of their persistence, mobility, accumulation in people and the biosphere, and serious toxicity, which then enter our water and food supply. PFAS in biosolids leach into the soil or ground water, are then taken up by plants, which are subsequently consumed by humans and wildlife. This chemical contamination of farms and communities exposes workers, consumers, and livestock across the United States to toxic PFAS.

Congress enacted the CWA to prevent such harms. This statute requires EPA, by July 31, 1987, and biennially thereafter, to: (1) identify toxic pollutants in biosolids; and (2) promulgate regulations, based on available information, for identified pollutants if sufficient scientific evidence shows they may harm human health or the environment. EPA has failed to fulfill both portions of this mandate regarding PFAS chemicals. First, scientific studies show that there are additional PFAS in biosolids which EPA did not identify in the agency's most recently published Biosolids Biennial Report No. 9. Second, additional scientific studies show that sufficient

scientific information is available to promulgate regulations for at least 12 PFAS previously identified in biosolids. As a result of these two failures, harmful and toxic pollutants continue to be spread on farms, pastures, home gardens, yards, and even on wildlands (as soil amendments in forests) where these chemicals then contaminate our nation's food and water supply.

I. EPA Failed to Comply with its Nondiscretionary Duties to Identify and Promulgate Regulations for PFAS in Biosolids

The Clean Water Act was enacted to "restore and maintain the chemical, physical, and biological integrity of the nation's waters." Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, § 2, 86 Stat. 816, codified as amended at 33 U.S.C. §§ 1251–1387 (2013) (the "Clean Water Act"). To achieve this goal, the CWA requires EPA to develop a comprehensive program for the identification of toxic pollutants in biosolids and the promulgation of regulations for those pollutants. 33 U.S.C. § 1345.

The CWA mandated that by August 31, 1987, the Administrator was to promulgate regulations concerning toxic pollutants in sewage sludge (biosolids). 33 U.S.C. 1345(d)(2)(A). Thereafter, EPA is required to biennially review toxic pollutants in biosolids to: (1) identify additional pollutants; and (2) promulgate regulations for those pollutants. 33 U.S.C. § 1345(d)(2)C). Toxic pollutants in sewage sludge are to be identified and regulated when they "on the basis of available information on their toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations which may adversely affect public health or the environment." 33 U.S.C. § 1345(d)(2)(A)(i). The statutory obligation to identify those pollutants not yet subject to regulation requires the EPA to identify all such pollutants and creates a mandatory duty to promulgate regulations for such pollutants when sufficient information is available. *See Nat'l Res. Def. Council v. EPA,* 437 F. Supp. 2d 1137, 1160 (C.D. Cal. 2006) (holding a similar biennial review scheme under the CWA creates a mandatory duty both to identify pollutants and promulgate regulations); *see also Nat'l Res. Def. Council v. Reilly*, 1991 U.S. Dist. LEXIS 5334, *21-*26 (D.D.C. 1991) (holding that EPA's statutory duty to promulgate biennial plans for effluent guidelines under the CWA is not met by a plan that identifies less than all industries currently known to be in need of regulation). Therefore, EPA has a statutory duty under the CWA to identify additional pollutants in biosolids and promulgate regulations for those identified pollutants if sufficient scientific evidence shows they may harm human health or the environment.

To assist the agency in meeting its statutory obligation to identify pollutants in biosolids under the CWA, EPA publishes a Biosolids Biennial Review. During the biennial review process, EPA collects and reviews publicly available information for: (1) toxic pollutants in biosolids that were newly identified; and (2) toxic pollutants in biosolids that were previously identified in EPA national sewage sludge surveys and previous biennial reviews. PFAS in biosolids have been identified by EPA as subject to these CWA requirements.[1] Information on these pollutants is

[1] PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, EPA, https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf ("Biosolids, or sewage sludge, from wastewater treatment facilities can sometimes contain PFAS. When spread on agricultural fields, the PFAS can

then collected on the occurrence and concentration, effects on human health and ecological receptors, and fate and transport in the environment.

One way for EPA to collect this data is to conduct literature searches, or an overview of the previously published works on a topic. For chemical pollutants, EPA uses health-related keywords[2] to search for peer-reviewed scientific papers in either the U.S. or Canada that provide evidence of unregulated chemical pollutants in biosolids.

Biennial reports do not automatically result in adding regulated pollutants in biosolids; instead, to meet its statutory obligations, the agency must regulate pollutants in biosolids based on findings that they have reasonably anticipated adverse effects on human health and the environment. 40 C.F.R. Part 503 establishes general requirements, pollutant limits, management practices, operational standards, and requirements for the frequency for monitoring, recordkeeping, and reporting when biosolids are: (1) land applied as fertilizer; (2) placed on a surface disposal site for final disposal; or (3) incinerated.[3] 40 C.F.R. Part 503.

However, EPA failed its mandatory statutory duty to: (1) properly identify additional pollutants in biosolids, as the agency's recently published Biosolids Biennial Report No. 9 fails to identify additional PFAS; and (2) promulgate regulations under 40 C.F.R. Part 503 for PFAS where there is sufficient scientific information showing adverse effects to human health and the environment.

A. EPA Failed Its Statutory Duty to Identify Additional PFAS in Biosolids

EPA has already recognized the need for, and undertaken an effort to curate, a complete list of chemicals found in biosolids based on previous sewage sludge surveys and biennial reports where the agency determined that more than 250 chemicals were not previously reported as detected. However, EPA's recently published Biosolids Biennial Report No. 9 (the Biennial

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contaminate crops and livestock. The CWA authorizes EPA to set pollutant limits and monitoring and reporting requirements for contaminants in biosolids if sufficient scientific evidence shows that there is potential harm to human health or the environment.").

[2] According to EPA's Biennial Review No. 9: To be identified as a candidate, a paper had to have at least one biosolids-related keyword, one chemical keyword, one land application keyword, one health-related keyword, and one geographic keyword. Asterisks at the end of search terms broaden the search by returning results of that term with any relevant ending. The search keywords are based on the following search strings:

• Biosolids-related keywords: sewage sludge OR biosolids OR treated sewage OR sludge treatment OR sewage treatment

AND

• Land application-related keywords: land application OR farm OR agriculture OR soil

AND

• Chemical-related keywords: pollutant* OR toxic* OR chemical OR constituent OR contaminant* OR metal* OR dioxin* OR inorganic* OR organic* OR flame retardant* OR pharmaceutical* OR steroid* OR hormone* OR antibiotic* OR personal care product*

AND

• Health-related keywords: occurrence OR concentration OR effect* OR propert* OR fate OR transport OR health

AND

• Geographical keywords: United States OR Canada OR USA OR U.S.A. OR U.S. OR US.

[3] Currently, 40 C.F.R. Part 503 sets pollutant limits for arsenic, cadmium, copper, lead, mercury, molybdenum, nickel, selenium, and zinc in biosolids that are land applied or placed in a reclamation site. 40 C.F.R. 503.13. Part 503 also sets pollutant limits and pollutant limits for arsenic, cadmium, chromium, lead, mercury, and nickel in biosolids that are incinerated. 40 C.F.R. 503.43.

Report)[4] continues to be inadequate to meet the agency's obligations under the CWA as the agency failed to identify additional PFAS in biosolids. Several peer-reviewed scientific studies indicate at least 18 PFAS that are present in biosolids were not listed in the Biennial Report, even though each may affect public health and the environment based on their toxicity, persistence, concentration, mobility, or potential for exposure.

These PFAS are:

1. FBSA;
2. PFHpS;
3. EtFOSE;
4. MeFOSE;
5. 6:2FTOH;
6. 7:2FTOH;
7. 8:2FTOH;
8. 9:2FTOH;
9. 10:2FTOH;
10. 11:2FTOH;
11. 12:2FTOH;
12. 13:2FTOH;
13. 14:2FTOH;
14. 8:2/10:2 diPAP;
15. 10:2 diPAP;
16. 10:2/12:2 diPAP;
17. 7:3 FTCA; and
18. HFPODA (GenX).

From 2005 to 2021, various scientific studies conducted by EPA and others found concentrations of each of the above listed PFAS in biosolids across the United States and Canada. Each of these studies were available to EPA during the time the biennial report was created and published in 2022. The following is a list of some such studies:

- In 2017, scientists detected FBSA in biosolid amended soil in three separate locations: (1) Tillsonburg, Ontario, Canada; (2) Delhi, Ontario, Canada; and (3) Cambridge, Ontario, Canada. (Chu, 2017).
- PFHpS was found in biosolids, industrially impacted soil, and biosolid amended soil in various parts the midwestern United States. (Sepulvado, 2011; Blaine, 2013; Blaine, 2014).
- In 2021, EtFOSE was found in biosolids. (Thoma, 2022).
- In 2010, scientists found concentrations of 6:2FTOH, 7:2FTOH, 8:2FTOH , 9:2FTOH, 10:2FTOH, 11:2FTOH, 12:2FTOH, 13:2FTOH, 14:2FTOH in biosolids in Decatur, Alabama. (Yoo, 2010).
- In 2014, scientists found concentrations of 8:2/10:2 diPAP, 10:2 diPAP, and 10:2/12:2 diPAP in biosolids in Canada. (Lee, 2014).
- In 2021, scientists found concentrations of ErFOSE, MeFOSE, 5:3 FTCA, and 7:3 FTCA in biosolids. (Thomas, 2021).

[4] https://www.epa.gov/system/files/documents/2022-12/2020-2021-biennial-report.pdf

- In 2021, researchers revealed the presence of GenX (HFPO-DA) in biosolids (Lee, 2021).

The biennial review requirement imposes on EPA a duty to continue collecting the technical data necessary to identify additional pollutants, such as PFAS, in biosolids, to list them for potential regulatory action under the CWA. 33 U.S.C. § 1345(d)(2)(C). The continuing obligation to prepare biennial plans provides a way for both Congress and the public to monitor the safety of biosolids as advancements in pollutant detection technology may allow EPA to uncover PFAS in biosolids not previously known.

Therefore, EPA has not met its obligations of identifying additional toxic pollutants under the CWA.

B. EPA Failed Its Statutory Duty to Promulgate Regulations for PFAS in Biosolids Where Sufficient Scientific Information Exists

There is overwhelming scientific evidence that PFAS previously identified by EPA in biennial reviews may adversely affect human health or the environment such that EPA is statutorily mandated to promulgate pollutant limitations for PFAS in biosolids under 40 C.F.R. Part 503. At least 12 previously identified PFAS in biosolids have sufficient scientific information, including concentration data, human health toxicity data, ecological toxicity data, and environmental fate and transportation data, which shows that these PFAS may adversely affect public health and the environment.

These PFAS are:

1. PFBA;
2. PFBS;
3. PFHxA;
4. PFHxS;
5. PFHpA;
6. PFOA;
7. PFOS;
8. PFNA;
9. PFDA;
10. PFUnDA;
11. PFDoDA; and
12. HFPODA (GenX)

For the above listed PFAS, EPA has found concentration data and ecological toxicity data but has stated that the agency is missing data on human health toxicity and environmental fate and transportation data. Specifically, for PFHxS, PFOA, and PFOS, EPA stated that it is only missing environmental fate and transportation data, while EPA stated that it was only missing human health and toxicity data for PFHxA.

However, from 2005 to 2021, various studies, conducted by EPA and others, have shown both human health toxicity data and environmental fate and transport data for each above listed PFAS. Each of these studies were available to EPA during the time when EPA conducted the Biennial Report. Despite this, EPA failed to review any of these studies during the agency's literature review and, as a result, failed to promulgate any regulations for any of these PFAS under 40 C.F.R. Part 503.

Studies Demonstrate Each Listed PFAS has Data on Human Health Toxicity Sufficient for EPA to Promulgate Regulations Under 40 C.F.R. Part 503

Several studies provide human health and toxicity data for PFBA, PFBS, PFHxA, PFHpA, PFNA, PFDA, PFUnDA, and PFDoDA, demonstrating that EPA has sufficient available scientific information to promulgate regulations for these pollutants in biosolids under 40 C.F.R. Part 503.

First, scientific evidence demonstrates PFBS has been associated with asthma (Rappazzo 2017, Sunderland 2018), the disruption of thyroid hormone balances (Lee and Choi 2017, Ren et al. 2016), the disruption of reproductive hormone concentrations (Zhou 2016), immunosuppression (Sunderland 2018), higher LDL cholesterol (Zeng et al. 2015, Seo et al. 2018), and impaired lung function in children (Qin et al. 2017).

PFHxA has been associated with abnormal levels of thyroid hormones (Ren et al. 2016), impaired lung function in children (Qin et al. 2017), impaired liver function (Nian et al. 2019), higher low-density lipoprotein (LDL) cholesterol (Zeng et al. 2015), allergies (Okada 2014), and the disruption of reproductive hormone concentrations (Zhou 2016).

PFHpA has been associated with heightened reproductive hormone concentrations (Zhou 2016), impaired lung function in children (Qin et al. 2017), allergies (Okada 2014), the failure of renal transport systems to control the excretion of uric acid (Seo et al. 2018).

PFNA has been associated with higher LDL cholesterol in overweight men and women (Jain and Ducatman 2018, Zeng et al. 2015), immunosuppression (Sunderland 2018), asthma (Sunderland 2018), impaired lung function in children (Fu et al. 2014, Zeng et al. 2015), impaired liver function (Nian et al. 2019), allergies (Okada 2014), the disruption of reproductive hormone concentrations (Zhou 2016, Seo et al. 2018), and the failure of renal transport systems to control the excretion of uric acid (Seo et al. 2018).

PFDA has been found to disrupt reproductive hormone concentrations (Zhou 2016), has been associated with autoimmune diseases (Sunderland 2018), impaired lung function in children (Qin et al. 2017), higher LDL cholesterol (Fu et al. 2014, Zeng et al. 2015, Seo et al. 2018), the disruption of reproductive hormone concentrations (Zhou 2016), and allergies (Okada 2014).

PFUnDA has been associated with asthma (Sunderland 2018), autoimmune diseases (Sunderland 2018), allergies (Okada 2014), higher LDL cholesterol (Seo et al. 2018).

PFDoDA has been associated with asthma (Sunderland 2018), autoimmune diseases (Sunderland 2018), impaired liver function (Nian et al. 2019), higher LDL cholesterol (Zeng et al. 2015, Seo et al. 2018), allergies (Okada 2014, Goudarzi et al. 2016).

GenX results in gene expression changes despite lower levels of internal accumulation, and this suggests a mechanism of placental dysfunction in human trophoblasts in vitro; GenX altered the

expression of several genes encoding proteins involved in proliferation, syncytialization, and transport (Bangma et al, 2020).

EPA failed to take into consideration these additional scientific studies which show human health and toxicity data for the PFAS listed above, all of which support the need to regulate PFAS in biosolids under 40 C.F.R. Part 503.

Studies Demonstrate Each Listed PFAS has Data on Environmental Fate and Transport Sufficient for EPA to Promulgate Regulations Under 40 C.F.R. Part 503

In addition to scientific studies providing human health and toxicity data for the above listed PFAS, other scientific studies provide environmental fate and transport data for the above listed PFAS indicating that EPA has sufficient scientific information to promulgate regulations under 40 C.F.R. Part 503.

PFAS are known to leach from biosolids to soil and water. Specifically, PFAS in soils leach during rain, floods, or even irrigation, as such events promote dissolution and migration (Sepulvado et al. 2011; Ahrens and Bundshuh 2014; Sharifan et al. 2021). This process can result in PFAS transport from surface soils to groundwater and surface water because PFAS releases often involve surface applications (Gellrich, Stahl, and Knepper 2012; Anderson, Adamson, and Stroo 2019; Galloway et al. 2020). PFAS can then be taken up by plants and ingested by humans and wildlife. (Benskin et al. 2012; Yan et al. 2015; Lang et al. 2017). There are a significant number of studies which review the fate and transport data for PFAS.

Most notably, in 2020, scientists developed an equation for predicting PFAS uptake and concentrations in plants from biosolids and calculated the potential exposure to humans and animals consuming harvested vegetation. (Lasee et al. 2020). They determined that EPA's current daily reference doses of PFOA and PFOS (i.e., 20 ng/kg body weight for PFOA and 30 ng/kg body weight for PFOS)[5] could be met by consuming vegetables grown in biosolid amended soils.

Additionally, in 2020, an assessment of fate and transport models for groundwater leaching, surface water runoff, and plant uptake conducted by Arcadis U.S. and the National Council for Air and Stream Improvement identified five models to determine the amount of PFAS: (1) leaching from land applied residuals, (2) concentrations in surface runoff from land applied residuals, and (3) absorbed by plants from land applied residuals. (Arcadis U.S. 2020). Arcadis U.S. found that these existing models may be adequate to develop conservative estimates of PFAS concentrations in surface water runoff and accumulation of PFAS in different soil, plant species and tissues. This demonstrates that there is available information on fate and transportation data for the listed PFAS.

Aside from models available to EPA, there exist numerous publicly available scientific studies which specifically review environmental fate and transport data for the above listed PFAS:

First, PFBS was found to: have a plant uptake in the shoot twice as high as in the root (Krippner et al 2014); remain in the soil to be taken up by plants for years, (Milinovic et al. 2015); be taken

[5] On June 21, 2022, EPA updated its health advisories for PFOA and PFOS to 0.004 parts per trillion (ppt) for PFOA, 0.02 ppt for PFOS, 10 ppt for GenX chemicals, and 2,000 ppt for PFBS. *Lifetime Drinking Water Health Advisories for Four Perfluoroalkyl Substances*, 87 Fed. Reg. 36848. EPA's previous lifetime health advisory was 70 parts per trillion for both PFOA and PFOS.

up by soil, leachate, earthworms, and plants (Zhu, 2019); and elevate water concentration where biosolids were distributed (Linstrom et al. 2011)

PFHpA was found to have a high plant uptake in the shoot (Krippner et al 2014), was taken up by soil, leachate, earthworms, and plants (Bräunig, 2019, Zhu, 2019), and was found to compete for sorbtion spots in soil, which results in a greater spreading of PFAS through soil, plants, and water. (Gellrich, Stahl, and Knepper 2012).

PFOA and PFOS were found to remain in the soil to be taken up by plants for years (Milinovic et al. 2015), was taken up by soil, leachate, earthworms, and plants (Bräunig, 2019, Zhu, 2019), was found to be more likely to interact with soil instead of wash out of it (Li et al. 2018), and was found to elevate water concentration where biosolids were distributed (Linstrom et al. 2011)

PFNA was found to be more likely to interact with soil instead of wash out of it (Li et al. 2018), found to elevate water concentration where biosolids were distributed (Linstrom et al. 2011), and was found to compete for sorbtion spots in soil, which will results in greater spreading of PFAS with lower attractions to soil (Gellrich, Stahl, and Knepper 2012).

PFDA; was taken up by soil, leachate, earthworms, and plants (Bräunig, 2019, Zhu, 2019), was found to be more likely to interact with soil instead of wash out of it (Li et al. 2018), and found to elevate water concentration where biosolids were distributed (Linstrom et al. 2011)

PFHxS, PFDoDA and PFUnDA were found to be taken up by soil, leachate, earthworms, and plants (Bräunig, 2019, Zhu, 2019), and were found to compete for sorbtion spots in soil, which will result in greater spreading of PFAS with lower attractions to soil (Gellrich, Stahl, and Knepper 2012).

GenX has considerable migration potential in soil and the vadose zone, and therefore has significant potential for impacting groundwater (Yan, et al 2020); GenX has also been found in vegetation within 3 km of a factory, with a declining gradient farther away from the factory (Brandsma 2019).

EPA's failure to promulgate limits for PFAS in biosolids where there is sufficient scientific information demonstrating a need to do so is contrary to the language and intent of the CWA. EPA's requirement to biennially review the list of identified pollutants "for the purpose of . . . promulgating regulations for such pollutants" demonstrates Congressional intent for EPA to continually reassess the current scientific knowledge and update the regulations accordingly. 33 U.S.C. § 1345(d)(2)(C)). EPA's continued failure to carry out the agency's mandatory duty results in a failure to meet the requirement to promulgate regulations for pollutants, like PFAS, in biosolids. Since Congress enacted the biennial review requirements for pollutants in biosolids under the CWA, EPA has only promulgated nine sewage sludge regulations for land application for the more than 700 pollutants identified. 40 C.F.R. Part 503. In other words, EPA has deemed it acceptable for biosolids containing PFAS and other known toxic chemicals to be applied directly to soil as fertilizer, where these man-made contaminants then build up in the environment, exacerbating the PFAS contamination crisis. This is not protective of human health or the environment.

In short, EPA has failed in its statutory duty to promulgate regulations for PFAS in biosolids which may adversely affect human health or the environment based on available scientific information.

II. Exposure to PFAS in Biosolids Adversely Affects Human Health and the Environment

Spreading PFAS-contaminated biosolids on farmlands, in gardens, and on lawns threatens public health**,** and is contaminating drinking water, crops, and livestock with PFAS.

Around 74% of land applied biosolids are used on farmlands for agricultural purposes;[6] introducing hazardous and toxic PFAS from biosolids into the soil and water used to grow food and feed crops consumed by people and animals. Research has shown that the PFAS in biosolids are slowly released from the biosolids into the nearby soil and water, where they are then absorbed by plants.[7] The physicochemical, environmental, and toxicological properties of PFAS mean that PFAS either have high persistence or can (partially) transform into highly persistent end products that are still PFAS, may accumulate in the environment, and cause known and unknown human and environmental health hazards.[8] This high persistence indicates the potential for long-lasting human exposure to a chemical that is difficult to control and remedy.

This pollution poses a significant threat to public health and the environment. Based on the chemical properties of PFAS, these substances are likely to migrate out of biosolids into the soil and water and persist in the environment, leading to human exposure.[9] PFAS are associated with a wide range of human health risks such as cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune

[6] *See* EPA Unable to Assess the Impact of Hundreds of Unregulated Pollutants in Land-Applied Biosolids on Human Health and the Environment, OIG, 6-7, https://www.epa.gov/sites/default/files/2018-11/documents/_epaoig_20181115-19-p-0002.pdf (Nov. 15, 2018) (citing *A National Biosolids Regulation, Quality, End Use & Disposal Survey*, North East Biosolids and Residuals Association (NEBRA), 1, https://static1.squarespace.com/static/54806478e4b0dc44e1698e88/t/5488541fe4b03c0a9b8ee09b/1418220575693/NtlBiosolidsReport-20July07.pdf (July 20, 2007)).

[7] While the uptake or accumulation of PFAS varies with soil properties, plant type, and individual PFAS chemical properties, the general trend is that soil and plants accumulate PFAS. Stahl et al. 2009; Lechner and Knapp 2011; Felizeter et al. 2012; Blaine et al. 2013; Stahl et al. 2013; Wen et al. 2013, 2014, 2016; Blaine et al. 2014a, 2014b; Felizeter et al. 2014; Krippner et al. 2014, 2015; Bizkarguenaga et al. 2016; Gottschall et al. 2017; Gobelius et al. 2017; Navarro et al. 2017; Gredelj et al. 2019; Lasee et al. 2019;

[8] Carol F. Kwiatkowski et. al., *Scientific Basis for Managing PFAS as a Chemical Class*, ACS PUBLICATIONS, (June 30, 2020) https://pubs.acs.org/doi/10.1021/acs.estlett.0c00255.

[9] EPA recognizes the large body of scientific evidence which reveals that, "when spread on agricultural fields, the PFAS can contaminate crops and livestock." *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024*, EPA, https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

system toxicity.[10] While EPA has recognized the need to address PFAS in biosolids,[11] the agency has largely failed to regulate PFAS identified in biosolids for which there is sufficient scientific information to show that they may adversely harm human health and the environment.

A 2021 Sierra Club and Ecology Center report on PFAS in biosolids describes how farmers and gardeners unwittingly introduce PFAS into the food and water supply when using fertilizer made from biosolids. *See Sludge in the Garden, Toxic PFAS in Home Fertilizer Made from Sewage Sludge* available at https://www.sierraclub.org/sites/default/files/PFA-Garden-Sludge-Report.pdf. The testing of nine biosolid products found PFAS chemicals in each product. *Id.* Of the 33 PFAS compounds analyzed, 24 were detected in at least one product, with each product containing 14 to 20 detectable PFAS compounds with total concentrations ranging from 38 to 233 parts per billion. *Id.* Sierra Club and the Ecology Center found that because the treatment process of biosolids does not remove PFAS, and the application of biosolids resulted in a transfer of PFAS to soil, land application of biosolids introduces PFAS into the food and water supply. *Id.* This demonstrates that EPA's failure to adequately identify PFAS in biosolids and regulate them is likely exposing humans and the environment to toxic chemicals which may cause adverse health effects.

The levels found by Sierra Club and Ecology Center are particularly concerning in light of EPA's June 21, 2022, updated health advisories. *Lifetime Drinking Water Health Advisories for Four Perfluoroalkyl Substances*, 87 Fed. Reg. 36848. The new health advisories for PFOA and PFOS are 0.004 parts per trillion (ppt) for PFOA, 0.02 ppt for PFOS, 10 ppt for GenX chemicals, and 2,000 ppt for PFBS. *Id.* EPA's previous lifetime health advisory was 70 parts per trillion for both PFOA and PFOS in 2016. *Fact Sheet PFOA & PFOS Drinking Water*

Health Advisories, EPA, (Nov. 2016), available at https://www.epa.gov/sites/default/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf. As the levels found by the Sierra Club were in parts per billion, and EPA now is advising to not consume levels in the parts per quadrillion and trillion, any amount of PFAS added to the environment is potentially harmful to human health and the environment. In March of 2023, EPA proposed a National Primary Drinking Water Regulation (NPDWR) for six PFAS: PFOA, PFOS, GenX, PFNA, PFBS, and PFHxS, available at https://www.federalregister.gov/documents/2023/03/29/2023-05471/pfas-national-primary-drinking-water-regulation-rulemaking. Specifically, EPA proposes to limit the amount of PFOA and PFOS at 4 parts per trillion (ppt) each and proposed a Hazard Index of 1.0 for the other four PFAS. EPA stated that in regard to PFOA and PFOS, "there is no dose below which either

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[10] Elsie M. Sunderland et. al., A Review of the Pathways of Human Exposure to Poly- and Perfluoroalkyl Substances (PFASs) and Present Understanding of Health Effects, 29 JOURNAL OF EXPOSURE SCIENCE AND ENVIRONMENTAL EPIDEMIOLOGY, no. 2, (2018), https://pubmed.ncbi.nlm.nih.gov/30470793/; AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, Toxicological Profile for Perfluoroalkyls, (May 2021) https://www.atsdr.cdc.gov/ToxProfiles/tp200.pdf; Pelch KE, Reade A, Kwiatkowski CF, Wolffe T, Merced-Nieves FM, Cavalier H, Schultz K, Rose K, Varshavsky J. 2021. PFAS-Tox Database available at https://pfastoxdatabase.org DOI: 10.17605/OSF.IO/F9UPX.

[11] EPA is expected to finalize its risk assessment for PFOA and PFOS in biosolids in 2024. This is only two out of at least 11 PFAS which have sufficient scientific information showing there is a potential harm to human health or the environment. *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024*, EPA, https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

chemical is considered safe," and as such, set the Maximum Contaminant Level Goal (MCLG) at zero.

Farms in Michigan, Texas, and Maine have been forced to stop selling meat and dairy products due to PFAS contamination from biosolids. It is likely that many farms that have used biosolids as fertilizer, and those farms adjacent to other lands where biosolids have been land applied, are highly contaminated. The continued use of PFAS-laden biosolids is therefore impacting our food supply.

EPA must protect against adverse health effects to human health and the environment from biosolids. The CWA was enacted to address concerns about pollutants entering our environment which may adversely affect human health. By failing to identify and declining to adopt regulations for PFAS in biosolids, specifically including those listed here, EPA has violated its nondiscretionary duty to establish criteria for the purpose of protecting human health and the environment.

III. Conclusion

PFAS contaminated biosolids raise serious health and environmental concerns because of their persistence, mobility, accumulation in people and the biosphere, and serious toxicity. The wide application of biosolids, extensive distribution in commerce, and frequent contact with both workers and consumers results in the potential for widespread exposure and significant harm. To comply with its statutory duties, EPA must: (1) adequately identify PFAS in biosolids; and (2) promulgate regulations for PFAS in biosolids for which it has sufficient scientific information, specifically including those listed here.

If EPA fails to take immediate steps to address its non-compliance with the CWA within sixty days, we will file suit in federal district court seeking declaratory relief, injunctive relief, and litigation costs as appropriate.

Sincerely,

Tim Whitehouse
Executive Director