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RE: NACWA Comments on the U.S. Environmental Protection Agency's (EPA) Draft Sewage Sludge Risk Assessment for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) (Docket ID No. EPA-HQ-OW-2024-0504)

Dear David:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA) Draft Sewage Sludge Risk Assessment for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) (90 FR 3859). NACWA represents the interests of 360 publicly owned wastewater and stormwater agencies of all sizes across the country. Each day, these public clean water agencies provide the essential service of protecting public health and the environment by managing and treating billions of gallons of our nation's wastewater and stormwater, as well as the millions of tons of biosolids generated as a byproduct of the wastewater treatment process. Responsible management of these biosolids is an important element of our members' commitment as public health and environmental stewards. Guidance from EPA can provide important clarity and assurances for our members and the public regarding best practices and public health protection.

NACWA has consistently raised concerns with the revised framework EPA is using as the basis for its Draft Risk Assessment for PFOA and PFOS. Our members participated in all three of the Science Advisory Board's public meetings and provided comments throughout the process. We have raised concern that this framework will produce excessively conservative and improbable risks. This will have considerable impacts to public clean water utilities that manage municipal biosolids.

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We are also appreciative of EPA hosting a three-part listening session with the wastewater and agricultural sectors among other stakeholders to better understand the on-the-ground realities of land applying municipal biosolids and hear how farmers across the United States depend on and use this necessary product. Our members echo the concerns raised by the agricultural community that this draft risk assessment is flawed in the sense it does not represent actual agronomical practices, nor does it represent how individual farm families live today.

Unfortunately, the draft risk assessment ignores the complete PFAS risk picture – that humans are exposed to these chemicals at far greater concentrations and frequency in everyday consumer products than they would be from municipal biosolids. It is well understood that PFAS chemicals have circulated in society for decades and are ubiquitously present in the environment. The Agency has often stated that understanding the potential risks of PFAS in commercial products to human health are "outside the scope" for the draft biosolids risk assessment. However, NACWA reiterates that the Agency must look holistically at the relative risks posed by these chemicals and the fact that humans are exposed to PFAS in consumer products as well as in household dust, air, and rainfall. Further, understanding background levels of PFAS in our environment, particularly in soils, is something EPA must consider, because any regulatory standard derived from this risk assessment that falls below background levels will be impractical.

While the Draft Risk Assessment is not a regulatory action per se, it will 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. If the risk assessment is finalized and indicates there are risks above acceptable thresholds associated with biosolids reuse or disposal, EPA could propose regulations that would set numeric limits under the Clean Water Act's Section 405 (40 CFR Part 503) to manage PFOA and/or PFOS in biosolids. Additionally, in the interim, states may also decide to erroneously and improperly use the draft risk assessment itself, before any Part 503 standards have been promulgated, as the basis to regulate land application of biosolids. State legislative bills have already surfaced using or citing EPA's 1 ppb draft risk assessment threshold in a proposed statutory framework that would ban land application if biosolids concentrations exceed this level, which is not how the draft risk assessment should be used.

NACWA appreciates EPA's acknowledgement in the preamble that there will be variability due to site-specific factors (e.g., geology, hydrology, and climate) along with disparity in agricultural practices and the concentration of PFOA and PFOS in municipal biosolids. 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." However, even with these considerations noted in the Draft's preamble, EPA inappropriately used single, conservative values for critical factors in a deterministic risk assessment. A probabilistic risk assessment should have been used instead, so that the uncertainty of each model factor

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could be characterized and the effects of the uncertainty could be considered in the calculation of human health risks.

Given the potential implications of the risk assessment and the lack of national data on occurrence, NACWA urges EPA to significantly revise the Draft Risk assessment before finalizing it.

NACWA's comments on the Draft Risk Assessment will first discuss the general issues with the overly conservative approach taken by EPA and the how the Agency presented the risk assessment, followed by an explanation of the specific data and modeling gaps that EPA must address to develop a more realistic evaluation of the risk of PFOA and PFOS in biosolids.

EPA's Risk Assessment Approach and Presentation of Results

The purpose of the Draft Risk Assessment is to characterize the potential human health and environmental risks associated with land application, surface disposal, and incineration of biosolids¹ 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.

Excessive Conservatism in Risk Assessment

EPA noted in the Draft Risk Assessment that the assumptions used "may not be conservative estimates," as this refined risk assessment focuses on using central tendency estimates of risk assessment parameters wherever possible. Despite this attempt towards reasonable estimates, there are multiple layers of conservatism built into the models, data, and assumptions used in the risk assessment. The risk assessment mischaracterizes affected population risk and hazards as it incorporates significant excess conservatism, rather than a more reasonable basis aligned with EPA's general approach to the risk assessment process within and across programs.

¹ The terms "biosolids" and "sewage sludge" are often used interchangeably by the public; however, the EPA defines the term "biosolids" to mean sewage sludge that has been treated to meet the requirements in the EPA's regulation, "Standards for the Use or Disposal of Sewage Sludge," promulgated under 40 CFR part 503, and intended to be applied to land as a soil conditioner or fertilizer. These comments will refer to "sewage sludge" as "biosolids" in general terms.

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EPA's standard reasonable maximum exposure (RME) condition represents a mix of upper-bound and mean values and is not intended to represent "worst-case" conditions. However, the layers of conservatism in the models, methods, data, and assumptions relied on in the Draft Risk Assessment resulted in "compounded conservatism," producing excessively conservative and improbable cancer risks and noncancer hazards. NACWA finds this particularly concerning if these individual exposure pathways are taken out of context and added together to represent an aggregate risk for an individual population (*e.g.*, a family living on a farm and subsisting solely food and drinking water from the farm).

This hypothetical "farm family" that EPA used as the centerpiece of its Draft Risk Assessment is not a typical control group and generally is not a viable lens through which to make health risk assessments. The draft assessment assumes that the family, including adults and children, lives on a farm that uses municipal biosolids as its fertilizer. The assessment further assumes that, for ten years, all of the family's food comes only from food grown and produced on the farm and that they only drink water from a well on the farm. The assessment also assumes the family's children consume soil from the farm that has been exposed to biosolids. Within each of these assumptions about the family's way of life, EPA has further built in layers of conservative assumptions regarding exposure from each potential pathway.

These assumptions are extremely conservative and do not reflect real-world conditions. In fact, EPA's own Science Advisory Board (SAB) took issue with the conservative nature of this approach when it reviewed the framework for the risk assessment, noting that the assumptions used by EPA are "well outside the norm of present-day family farms." The SAB also noted that "the vast majority of biosolids applications are made to lands that are not used for producing food directly consumed by humans but rather to lands used for producing animal feed, fiber and/or fuel."²

In addition to the unrealistic farm family used in the risk assessment, other overly conservative factors contribute to the "compounded conservatism" of the assessment. For example, the assumed 40-year biosolids application period used in the models overpredicts concentrations of PFOA and PFOS in receiving media. The risk assessment also fails to account for other mitigating exposure phenomena, such as a cooking loss factor. These and other specific factors will be explained further below. Overall, projected risks from individual pathways are overestimated as the risk assessment focuses on "worst-case scenarios." The calculated risk in the Draft Risk Assessment represents a hazard with an extremely low

² See U.S. EPA, Science Advisory Board, EPA-SAB-001, "SAB Review of EPA's Standardized Framework for Sewage Sludge Chemical Risk Assessment (External Peer Review Draft)" (2023) available at: https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/advisoryactivitydetail?p18_id=2610&clear=18&session=1">https://sab.epa.gov/ords/sab/advisoryactivitydetail?p

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probability of occurrence, rather than a realistic risk to any real person in the U.S., even families that live on farms.

Absence of Comparative Risks

The draft assessment suffers from a significant flaw in that, despite requests from NACWA and other clean water sector advocates, EPA declined to include risk information associated with exposure to PFOA and PFOS from other fertilizers, such as synthetic fertilizers and manure, which might be used as alternatives by the farm family. EPA also declined to assess other exposure pathways, such as consumption of food wrapped in fast food wrappers or other food containers coated in PFAS chemicals. Additionally, the assessment does not examine relative risk between ingestion of PFOA and PFOS versus other exposure pathways present in people's everyday lives, such as dermal exposure via products such as makeup, cosmetic products, and contact lenses—just to name a few.

The lack of comparative risk information between biosolids and these other substances and exposure pathways means that the draft risk assessment does not provide any way to determine the relative risk associated with PFAS exposure from biosolids versus these other substances and pathways. Without this additional context, the results from the Draft Risk Assessment could easily be misconstrued to imply that the risk from biosolids is greater than these other pathways, when biosolids could present a significantly lower risk. While EPA's responsibility to evaluate risk only extends to biosolids, the Agency must be cognizant of how the risk assessment will be interpreted by the public, the media, and lawmakers without the context of the risks from other PFAS exposures.

Role of Pretreatment Programs

Notably for the clean water utility community, the *Federal Register* notice for the Draft Risk Assessment contains language overstating the ability of utility pretreatment programs to reduce sources of PFAS:

"Regardless of the management practice to use or dispose of sewage sludge, exposure and risk reduction is possible through pretreatment at industrial facilities discharging to a WWTP [wastewater treatment plant]. By monitoring sewage sludge for PFOA and PFOS, WWTPs can identify likely discharges of PFOA and PFOS from industrial contributors, require pretreatment, and achieve significant reductions in PFOA and PFOS concentrations in their sewage sludge. In some state programs, WWTPs with industrial sources have achieved a 98 percent reduction in PFOS sewage sludge concentrations through industrial pretreatment initiatives. The EPA recommends that states, Tribes, and WWTPs monitor sewage sludge for PFAS contamination, identify likely industrial discharges of PFAS, and implement industrial pretreatment requirements, where appropriate. Doing so will help reduce downstream PFAS contamination and lower the concentration of PFOA and PFOS in sewage sludge."

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This statement ignores the fact that EPA has not yet developed pretreatment standards for any industrial category, and although its recent *Effluent Limitations Guidelines Plan 16* outlines planned rulemakings for some industrial categories, it will still be many years before utilities have federal pretreatment standards for industrial categories that may be discharging PFAS to the sewer system.

Additionally, while some utilities have significantly reduced PFAS contributions from industrial sources through pretreatment, utilities without easily controllable industrial PFAS sources will not be able to achieve the same results. Studies from states such as California have shown that domestic discharges of PFAS can constitute the majority of the PFAS received at a publicly owned treatment works (POTW). Utilities have no authority to regulate discharges from domestic sources. While pretreatment programs will have an important role in limiting industrial sources of PFAS, and thus can have impactful reductions like EPA notes in industrially-impacted utility service areas, domestic discharges will still be a problem until PFAS are removed from the multitude of household products that contain these chemicals. Even then, PFAS will likely continue to be released from households to the POTW for many years while durable goods such as cookware and textiles produced with PFAS remain in use.

NACWA asks that EPA acknowledge the limitations of utility pretreatment programs in controlling the presence of PFAS in biosolids and not support the erroneous notion that pretreatment programs can eliminate most PFAS discharges to POTWs. NACWA also asks that EPA take responsibility for developing federal pretreatment standards for PFAS, rather than relying on local utilities and states to determine the appropriate treatment levels and attempt to enforce them while the science related to PFAS continues to develop.

Data and Modeling Gaps

While the Draft Risk Assessment presents a standardized process grounded in EPA's risk assessment methods, the implementation of the process for biosolids resulted in unrealistic risk values due to the data and assumptions used in the modeling, including limitations in the conceptual site model, extreme conservatism in modeling of PFOA and PFOS concentrations in receiving environmental media, and unreasonable exposure and chemical toxicity values. The following sections provide additional details on the factors that led to an overly conservative risk assessment and recommendations for revisions to the risk assessment.

Toxicity Values

The PFOA and PFOS toxicity values used in the risk assessment – reference doses (RfD) and cancer slope factors (CSF) – are based on values promulgated in EPA's Final Human Health Toxicity Assessments for PFOA and PFOS (2024). In the final toxicity assessment, the RfD for PFOA was revised from 2×10^{-5} to 3×10^{-8} milligram per kilogram per day (mg/kg/day), based primarily on vaccine response in children. Similarly, the RfD for PFOS was revised from 2×10^{-5} to 1×10^{-7} mg/kg/day, based primarily on decreased birthweight and increased serum

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cholesterol in adults. These changes to the toxicity values significantly and directly change the risk calculated in the Draft Risk Assessment. Decreasing the RfD for PFOA by three orders of magnitude increases the risk by three orders of magnitude, and decreasing the RfD for PFOS by two orders of magnitude increases the cancer risk by two orders of magnitude.

These changes to the toxicity values were based on overly conservative assumptions – the endpoints observed in the most sensitive populations and immunotoxicity in children that likely do not reflect the same population in the United States. Burgoon et al. (2023) concluded from an international collaborative examination that the available epidemiologic information could not form a reliable basis for a PFOA safe-dose assessment in the absence of human mechanistic data at serum concentrations in the general population. Thus, the Draft Risk Assessment is based on excessively conservative toxicity values that overestimate risk from PFAS exposure in biosolids. EPA must reevaluate the complete body of the evolving toxicological evidence to determine a more realistic RfD and CSF for PFOA and PFOS.

Modeling Concentrations of Environmental Contaminants

The Draft Risk Assessment uses EPA's Multimedia, Multipathway and Multireceptor Risk Assessment (3MRA) modeling system to estimate concentrations of PFOA and PFOS released from biosolids to the environment. The models provide the ability to conduct a screening-level risk-based assessment of potential human and ecological health risks resulting from long term (chronic) exposure to chemicals released from land-based waste management units.³ While these models have been used extensively for modeling agricultural scenarios, the risk assessment has amended input parameters to adjust for PFAS-specific physical-chemical properties that affect fate and transport. The risk assessment attempts to balance model development with the incorporation of central tendency parameter values, avoiding extreme conservatism; however, the risk assessment still allows for conservative assumptions that result in inappropriate, "compounded conservatism" in the final risk estimates. These assumptions are as follows:

Concentration of PFOA and PFOS in Biosolids

The fate and transport modeling begins with a source concentration of PFOA or PFOS of 1 ppb in land applied biosolids. The risk assessment suggests that this represents the lower end of detected concentrations in various studies, but it likely overestimates the risk basis in

³ This includes a Land Application Unit, which models the amendment of biosolids into the top layer of soil. The results from this model support an analysis to simulate dissociation of PFAS from biosolids and model vertical movement of contaminants through the vadose zone to groundwater using EPA's Composite Model for Leachate Migration with Transformation Products (EPACMTP). The model also assesses horizontal movement of contaminants entrained in suspended soil particles in runoff and erosion from a field to a buffer area and discharge to surface water using Variable Volume Waterbody Model (VVWM). Secondary modeling is used to generate representative concentrations of PFOA and PFOS in drinking water and fish tissues for risk evaluation.

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light of current conditions suggesting the likelihood of lower actual concentrations in municipal biosolids. The Agency's reasoning relies on dated findings from the last National Sewage Sludge Survey (NSSS, 2001) and Targeted National Sewage Sludge Survey (TNSSS, 2009). Other studies cited by EPA reflect more recently detected concentrations of PFOA and PFOS in site-specific and targeted studies in states like Florida and Michigan (both exhibiting high soil porosity and sandy geologic conditions), which may overestimate leaching potential and fail to represent nationwide average conditions.

While the more recent studies already recognize a declining trend in overall concentrations following the phase out of PFOA and PFOS manufacturing in the U.S.—which also underscores the importance of source control—as well as differences in pre- and post-treatment concentrations, the risk assessment fails to consider what these declining concentrations might mean for model parameterization. EPA should apply a bounding adjustment factor to account for this documented decline in concentrations as well as identify a source value that more specifically reflects the lower end of a range derived from very recent studies only. Moreover, this range should be generalized to account for the heterogeneity in the physical, meteorological, and chemical characteristics for a nationwide assessment since a NSSS has not been conducted since 2001. One option for EPA is the development of a range of acceptable values, accounting for physical differences in geographical locations and hydrogeological conditions at more than the three places considered in the current risk assessment.

Rate of Land Application of Biosolids

The models assume a 40-year period of constant land application of biosolids. This is consistent with a prior EPA biosolids risk assessment, focused on PCB and dioxin content (EPA 2003). However, this assumption is unlikely to reflect the majority of farm scenarios across the United States, especially with industrial and regulatory changes in agricultural practices, advancements in wastewater treatment technology, and differing physical conditions of agricultural sites. Even though the current biosolids regulations allow for yearly or multiple applications per year (depending on crop nitrogen needs), the 40-year period is not based on data that provide a realistic estimate of average application rates nationwide. Additional empirical data are needed to define a more realistic land application duration.

Mass Conservation Assumption

The models assume mass conservation, while estimating losses from leaching and particle emissions. Biodegradation and volatilization are not considered as pathways of mass losses due to the surfactant properties and environmental persistence of PFAS compounds. However, in the risk assessment, the models do not account for any losses from onsite agricultural management practices such as runoff management through retention ponds and constructed wetlands or other erosion control (the erosion control factor is set to 1, assuming no control, as per defaults in the 3MRA). The models also assume that there is no suspended solids loss in effluent from surface disposal units, such that the mass of PFAS is conserved within site boundaries.

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Additionally, the science around environmental degradation of PFAS is emerging and conditions influencing the breakdown and recombination of PFOA and PFOS in environmental media should be accounted for in the assessment. The models underestimate mass losses of PFOA and PFOS and hence overestimate environmental media concentrations. PFAS system mass loss considerations should be incorporated to provide a more realistic evaluation of risks specific to PFOA and PFOS and their behavior in environmental media.

Limitations of Groundwater Source Model

The groundwater source model, EPACMTP, can only be run assuming linear, instantaneous, and kinetic effects of solid-phase adsorption, and assuming homogeneous aquifer conditions within the bounds of the mass conservation assumption. The model cannot account for the behavior of PFOA and PFOS at the air-water interface or potential for non-equilibrium solid-phase sorption. The primary flow equation used by EPACMTP is Darcy's Law, which may not be able to accurately characterize the flow of PFOA and PFOS in multi-phase systems like those involving the air-water interface and in sites with extensive soil property heterogeneity. PFOA and PFOS are known to have significant retention at the air-water interface and in soil (Anderson et al, 2019), affecting leaching into groundwater.

For the purposes of the risk assessment, given data limitations affecting the ability to use alternative and comprehensive models, the EPACMTP was found to be a sufficient simulator. However, since groundwater pathway simulations rely on equilibrium sorption, it is possible that groundwater concentrations have been overestimated by simplifying the groundwater flow and transport modeling. Evaluating other groundwater models available for use and their ability to incorporate PFAS-specific properties is critical as this risk assessment is revised for finalization.

Model Time Period

The Draft Risk Assessment states that peak concentrations in soils, runoff, and leachate are expected to occur around the time application ceases (i.e., at 40 years). However, the source modules of the models are allowed to run for 150 to 10,000 years (maximum defaults possible within the Land Application Unit modules and EPACTMP, which is the groundwater source model) to identify peak concentrations in receiving media. These peak concentrations of leachate flux and infiltration rates are used as constant modeling inputs instead of time-averaged maximum detected concentrations. The risk assessment does not provide statistical analyses to compare peak concentrations at different model run periods to justify the use of the chosen periods.

The risk assessment also assumes that shorter frequency fluctuations (e.g., rainfall/infiltration) are insignificant in assuming long-term risk. Thus, the long model run periods may overestimate environmental concentrations and hence, risk – especially considering an already active phase out of the contaminants under consideration and a 10 - year exposure duration. Since the science around fate and transport of PFOA and PFOS over

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long durations is emerging, a more detailed analysis should be used in choosing peak concentrations to ensure that the models do not overestimate current and future environmental concentrations.

Buffer Zone Assumption

The buffer zone between the field/surface disposal unit to an index water reservoir is assumed to be 10-meters wide, with a drinking water well located in the buffer zone, equidistantly placed at five meters from the edge of the disposal unit and reservoir. This is also assumed to be the point centered around the highest concentration in the groundwater plume below the water table. This 10-meter assumption is not based on any observed or surveyed data, but in fact is based on the minimum buffer required by 40 CFR Part 503 of biosolids regulations between land application of sewage sludge and water bodies. This may overestimate concentrations, as this assumed site configuration likely does not represent standard land and water stewardship-based farming practices which account for factors such as erosion and distance of land applied biosolids from a drinking water source. For instance, the buffer may be much wider, or the drinking water wells may be deeper or located cross- or upgradient from the groundwater plume affected by biosolids.

Current agricultural management practices and guidance from EPA and other state agencies indicate that farmers are likely to be actively using runoff management methods and appropriate handling and application of manure to avoid washing away of fertilizer (USEPA, 1995; USEPA 2007b; University of Florida IFAS, n.d.). Moreover, this may be an irrelevant pathway for many farming communities using municipal or community-level water sources that are unimpacted by PFAS contamination from biosolids.

Assumptions in Exposure Assessment

While the conceptual model is designed to be conservative, some of the exposure assumptions do not appropriately represent realistic exposure scenarios. The farm family scenarios represent a conglomeration of worst-case scenario exposures for an adult farmer and a child. The adult and child receptors are assumed to exclusively drink contaminated water and exclusively consume contaminated homegrown produce and animal products (e.g., crops, beef, milk, and fish) for 350 days per year. There is no consideration of consuming a fraction of the farm family's diet procured from outside sources such as grocery stores, where food products are sourced from multiple sources. The resulting cancer risks and noncancer hazards, especially in the aggregate condition, are unreasonable and represent extreme, high-end estimates that are inappropriate for rule making. These conditions are described below:

Best Management Practices

The 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 (USEPA, 1995; USEPA 2007b; University of Florida IFAS, n.d.). Application of BMPs are

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expected to greatly reduce the likelihood of risks found in the risk assessment. Examples include:

- A farm pond is assumed to exist immediately adjacent to the biosolids-applied field and receives surface runoff. Some BMPs restrict the application of biosolids within 300 feet of a water supply well, sinkhole, lake, pond, water supply reservoir or water supply intake in a stream. Furthermore, in estimating surface runoff that enters the farm pond, EPA should consider that nutrient loading from the field could adversely affect fish in a pond. It is recommended that the conceptual model include a buffer between the field and the farm pond, which will lead to a more reasonable estimation of surface water concentrations of PFOA and PFOS in the pond.
- A farm family is assumed to live adjacent to the land used for grazing cows, raising chickens, or growing feed for these animals. Adults and children on the farm could have exposure through meat, dairy, or egg products they produce. However, there are BMPs restricting the application of biosolids to land within 30 days of harvest or grazing by cattle. Also, some states have requirements concerning grazing restriction of lactating dairy cattle.

Exposure Parameters

Some of the exposure parameters provided in the Draft Risk Assessment could not be verified based on the information provided, e.g., selected adult consumption rates in Table 17. As noted in the Draft Risk Assessment, there are no consumer-only intake rates of home-caught fish, home-produced beef, and home-produced fruits for young children (aged 1 to 5) in EPA's Exposure Factor Handbook (EFH). EPA therefore used intake rates for older children (aged 6 to 11 or 12 to 19). Using intake values from older children and applying them to younger children will result in overestimation of risks to younger children.

PFAS Loss in Cooking

The risk assessment assumes no PFAS loss in preparing and cooking fruits, vegetables, meats, eggs, and milk. This is based on the European Food Safety Authority's conclusion regarding insufficient data from supporting studies. However, it is overly conservative to assume that there is no loss during food preparation and cooking. Based on methods and literature outlined in Chapter 13 of EPA's Exposure Factors Handbook, applying appropriate cooking loss factors could result in a 49% to 68% reduction in intake rates of contaminants from food (USEPA, 2011). These factors can be amended to reflect the uptake, intake, and accumulation mechanisms of PFOA and PFOS, depending on the food group (i.e., meats, fish, fruits, or vegetables) using relevant literature. Subsequently, the cancer risks and noncancer hazards associated with consumption of fish, fruits, vegetables, meats, eggs, and milk will also be reduced. More relevant to PFAS directly, a peer-reviewed scientific article reported an average of 29% reduction of PFAS concentration after cooking seafood and fish (Vendl et al, 2022).

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Livestock Exposure to PFAS

In evaluating PFAS exposures for livestock and related products that are ultimately consumed by human receptors in the pasture farm scenario, the food chain modeling assumes that all the forage, silage and water consumed by beef cattle, dairy cows and chickens are contaminated by setting the fractions of forage, silage, and water contaminated to one. This likely overestimates PFAS accumulation in livestock and related products, especially in a scenario where livestock do not graze exclusively in affected pastures and/or consume grain and feed procured externally.

Plant Uptake Factors

PFOA and PFOS plant uptake factors were not parameterized using data from field-based studies of land-applied biosolids due to lack of sufficient data. This might lead to an overestimation of biosolids-based bioavailability of PFOA and PFOS in plants, and hence accumulated concentrations ingested by human receptors from farm crops. Existing research demonstrates that field studies produce uptake values that are lower than greenhouse-based studies. It is important to identify, commission, and evaluate studies that are most representative of realistic plant uptake factors for PFOA and PFOS.

In addition, identifying the plants with comparatively higher potential for uptake of PFOA and PFOS can lead to developing more reasonable guidelines on which plants are more amenable to biosolids applications. For instance, EPA should consider conducting studies to compare uptake factors from below ground and above ground vegetables, and those that produce leafy vegetables versus seeded fruits.

Conclusion

As a result of the extreme conservatism in deriving the risk and hazard values for individual exposure pathways, the Draft Risk Assessment mischaracterizes risk and hazards from impacted biosolids and leaves the results open to misinterpretation based on unrealistic assessment results. NACWA has shared these concerns with the Agency since the beginning when the risk assessment framework was under review with the Science Advisory Board. Now, the numerous modeling parameters, exposure assumptions, and toxicity values used in the risk assessment predictably resulted in EPA's draft risk assessment overestimating risk. This "compounded conservatism" has suggested risk exceedances can be found at a low modeling value of 1 ppb.

Given the risk exceedances observed in individual pathways and scenarios in the Draft Risk Assessment, EPA, the state regulatory agencies and legislatures, and/or local municipal districts may develop regulations – ahead of any promulgated numeric limits or standards – that will adversely impact wastewater treatment plants across the United States. Importantly, EPA's draft risk assessment is only one step in a longer process and should not be used as the only basis to develop regulations. EPA has not collected any data on the widespread occurrence of PFOA or PFOS in municipal biosolids and has not completed a

NSSS in over two decades. EPA made determinations after conducting two previous risk assessments for dioxins and PCBs that their occurrence data in biosolids did not warrant the Agency moving forward with Part 503 numeric limits. EPA must gather the necessary occurrence data on PFOA and PFOS in municipal biosolids before it or other state or local regulatory agencies determine that based on the risk assessment alone, municipal biosolids should be regulated for PFOA and PFOS. While the risk assessment is only one step in the process, it is also a critical one that the Agency must get right before moving forward.

Further, clean water utilities and agricultural users face a significant challenge ahead: for utilities, compliance with regulations might involve extensive amendments to existing treatment technologies and processes, and larger volumes of sewage sludge undergoing incineration or landfilling; for agriculture, the industry may lean more heavily on alternative sources of fertilizers.

Further, clean water utilities face a significant challenge ahead: compliance with these regulations might involve extensive amendments to existing treatment technologies and processes, larger volumes of sewage sludge undergoing incineration or landfilling, and potential mandates leading the agriculture industry to identify alternative sources of fertilizers.

The risks observed in the draft risk assessment need to be contextualized with these challenges, especially since the findings from the risk assessment are likely to be highly conservative and overestimated in light of the assumptions, exposure parameters, toxicity values and methods discussed herein. Any regulatory actions taken based on the risk assessment should consider technological feasibility, wider policy implications, and economic viability.

Thank you for your consideration of these comments. Please contact me by phone at 202-533-1839 or by email at *eremmel@nacwa.org* if you have any questions.

Sincerely,

Emily Remmel

Guily M

Senior Director, Regulatory Affairs

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