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September 14, 2023

Dr. Shaunta Hill-Hammond
Designated Federal Officer
U.S. Environmental Protection Agency

RE: NACWA considerations for the chartered Science Advisory Board in reviewing EPA's draft Standardized Framework for Sewage Sludge Chemical Risk Assessment

Dear Dr. Hill-Hammond:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to provide comments to the full chartered Science Advisory Board as it reviews EPA's draft *Standardized Framework for Sewage Sludge Chemical Risk Assessment* and the recent recommendations and analysis completed by the ad hoc biosolids Science Advisory Board (SAB).

NACWA represents the interests of over 350 publicly owned wastewater utilities of all sizes across the country. Our members are anchor institutions in their communities that everyday provide the essential service of treating billions of gallons of our nation's wastewater and managing the millions of tons of biosolids generated as a byproduct of the wastewater treatment process in a manner that ensures the continued protection of public health and the environment.

NACWA applauds the work of the SAB in reviewing EPA's proposed approach to assessing the risk of chemicals in biosolids. The SAB experts selected to serve on the panel gave considerable attention to detail throughout the process, astutely debated the scientific merits of the charge questions before them, and ended the review process with a final report that NACWA believes speaks to both the strengths and practical shortcomings of the proposed biosolids framework. NACWA supports the recommendations put forward in the SAB's draft report dated August 30, 2023.

In particular, NACWA supports the SAB's identification of several "potential pitfalls and limitations" in EPA's proposed approach with a specific focus on the overall need for the Agency to truly consider the unique characteristics of biosolids and the biosolids-soil matrix and individual chemical fate and transport, rather than simply looking at chemical concentrations. NACWA also supports the SAB's

concerns over compound conservatism and how the farm family narrative put forth by EPA is not a realistic exposure framework for considering modern day biosolids land application. NACWA also supports the SAB's rejection that the farm pond and agricultural field are not appropriate metrics when considering ecological risk and that EPA should use its own Guidelines for Ecological Risk Assessment.

NACWA has participated in all three SAB public meetings to date and submitted comments for the SAB to consider throughout the process. Those comments from the SAB's May 5, 2023, and July 5, 2023 meetings are attached to this letter. NACWA would appreciate if the full charted Science Advisory Board consider these comments as it reviews the draft *Standardized Framework for Sewage Sludge Chemical Risk Assessment*, and we encourage the chartered SAB to have EPA to address the concerns raised in the SAB report before it begins screening chemicals in biosolids and assessing potential risks of those chemicals. If there are any comments or concerns, please contact me via email at eremmel@nacwa.org or by phone at 202/533-1839.

Sincerely,

Emily Remmel
Senior Director of Regulatory Affairs

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March 22, 2023

Dr. Shaunta Hill-Hammond
Designated Federal Officer
U.S. Environmental Protection Agency

RE: NACWA Considerations for the Science Advisory Board Biosolids Panel meeting on April 5, 2023.

Dear Dr. Hill-Hammond:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to provide written feedback on the U.S. Environmental Protection Agency's (EPA) *Approach to Biosolids Chemical Risk Assessment and Biosolids Tool* review before the Scientific Advisory Board (SAB).

NACWA represents the interests of over 350 publicly owned wastewater utilities of all sizes across the country. Our members are anchor institutions in their communities that everyday provide the essential service of treating billions of gallons of our nation's wastewater and managing the millions of tons of biosolids generated as a byproduct of the wastewater treatment process in a manner that ensures the continued protection of public health and the environment.

We offer the following comments for the SAB:

The overall Charge for the Biosolids Panel includes SAB comment on the risk assessment framework. However, the three Charge Questions before the Panel assume the framework is appropriate in and of itself and focus on reviewing three specific elements within the framework. The overall Charge neglects to consider whether the framework itself is a sound approach.

NACWA recommends that an additional charge be added, a step zero, which considers the appropriateness of the framework itself in light of existing significant data gaps and gaps that may emerge during the risk assessment process. This is particularly important when the framework is applied to contaminants of emerging concern, such as per- and polyfluoroalkyl substances (PFAS) and

microplastics. This is critical as 43% of the country's biosolids are land-applied to provide a number of benefits, including nutrients and soil amendments.[1]

The risk assessment framework should be viewed in the context of alternative impacts, including environmental justice and sustainability concerns regarding impacts of regulations on biosolids disposal. This requires the unique perspectives of stakeholders other than scientists and should include agronomists, sanitary engineers, farmers, and diverse non-governmental organizations (NGOs). Stakeholders that are concerned about environmental and sustainability impacts, including the impacts associated with the increased use of commercial fertilizer, need to be included in the evaluation of acceptable risk.

EPA proposes advancing contaminants of "high information, and high concern" through the risk assessment process. The "high concern" is based on seven scientific domains, including: susceptible populations, persistence and bioaccumulation, and skin sensitization and skin/eye irritation. Each of these domains require evaluating the potential risk considering the unique nature of biosolids disposal.

NACWA specifically seeks review from the SAB panel on its Charge for the following:

- The PICS process is too broad and needs to be refined for biosolids. As an example, skin sensitization and skin/eye irritation (7th domain) makes sense for the Toxic Substances Control Act (TSCA) but direct dermal contact is not an exposure route that is evaluated for biosolids.

- We encourage the human hazard-to-exposure ratio (1st domain) to use exposure values specific to biosolids. Making PICS biosolid-specific from the get-go will streamline the prioritization of chemicals if the list is filtered/reduced accordingly.

- The framework needs to include uncertainty analysis, especially when using second-tier toxicity criteria. The Panel should evaluate how to improve the information availability metric, which will encourage development of meaningful data gaps assessments.

- The Panel should consider the importance of background levels of contaminants in the framework. For example, the maximum contaminant levels (MCLs) for two PFAS (PFOA and PFOS) in drinking water are more stringent than background levels in surface waters, including ocean spray. If the regulatory limits of a contaminant resulting from the risk assessment process exceed background levels in soils, then there is no benefit to regulating biosolids using that limit.

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[1] 2021 Biosolids Annual Program Report data – see https://www.epa.gov/system/files/styles/large/private/images/2021-07/biosolids-use-disposal-potws-2019.png?itok=FbNe4iKp .

NACWA appreciates the opportunity to provide the above considerations. If there are any questions or concerns, please do not hesitate to contact me at eremmel@nacwa.org or 202/533-1839.

Sincerely,

Emily Remmel
Director, Regulatory Affairs

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June 28, 2023

Dr. Shaunta Hill-Hammond
Designated Federal Officer (DFO)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC

Submitted via electronic mail to: hill-hammond.shaunta@epa.gov

Re: NACWA Considerations for the Science Advisory Board Biosolids Panel's Review of the Standardized Framework for Sewage Sludge Chemical Risk Assessment and Biosolids Screening Tool

Dear Dr. Hill-Hammond:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to provide written feedback on the U.S. Environmental Protection Agency's (EPA) *Approach to Biosolids Chemical Risk Assessment and Biosolids Screening Tool* review before the Science Advisory Board (SAB) Biosolids Panel.

NACWA represents the interests of over 350 publicly owned wastewater utilities of all sizes across the country. Our members are anchor institutions in their communities that everyday provide the essential service of treating billions of gallons of our nation's wastewater and managing the millions of tons of biosolids generated as a byproduct of the wastewater treatment process in a manner that ensures the continued protection of public health and the environment.

We offer the following comments for the SAB:

The Biosolids Risk Assessment Framework Needs to Consider the Practical Implications of Implementation

The objective of the draft document *A Standardized Framework for Sewage Sludge Chemical Risk Assessment* (hereinafter referred as "Document") is to "allow EPA to prioritize and efficiently evaluate chemicals for their potential to cause harm" based on their concentrations in biosolids. While the framework presents a straight-forward tiered process, the actual steps require further refinement to ensure that the chemical prioritization and evaluation are appropriate for biosolids, labor and time-effective, and protective of

human and ecological health without being excessively conservative. General comments for each step of the framework are presented below.

As the first step, EPA's Public Information Curation and Synthesis (PICS) approach can effectively process information for multitudes of chemicals and assign them scores for prioritization. The PICS approach was designed under the Toxic Substances Control Act (TSCA) to prioritize chemicals for the general use, pulling in an expansive hazards list to cover all conceivable exposure scenarios.

The PICS approach, as presented in the framework, needs further modifications to prioritize chemicals for detailed biosolids risk assessments rather than relying on general chemical risk assessments.

Of the seven scientific domain metrics (SDM) in the Document, only one SDM considers the actual human exposure potential to a chemical from biosolids, while the remaining SDMs characterize chemical hazards. The PICS approach, in selecting the SDMs, should also be consistent with the receptors and exposure pathways outlined in biosolids risk assessment. For example, the Skin Sensitization & Skin/Eye Irritation SDM highlights acute exposure hazards, but the biosolids screening tool (BST) does not currently consider acute or dermal exposure pathways. The inclusion of that metric is not useful and the SDMs should be evaluated for their value and applicability in a biosolids risk assessment. The benefit of the PICS approach is that the SDMs are modular with adjustable weighting and can be readily adapted for a biosolids risk assessment. Specific technical suggestions and comments regarding the PICS approach are presented under the heading sections below.

After the PICS approach, there should be an intermediate step before the screening risk assessment that evaluates whether the prioritized chemicals are appropriate for a human health and/or ecological risk assessment (ERA).

The framework needs an off-ramp for chemicals where a risk assessment would be unwarranted or provide meaningless results. The off-ramp is particularly relevant for chemicals (e.g., pharmaceuticals) that are intentionally ingested in food and consumer products. Pharmaceuticals, for example, have undergone rigorous toxicological testing for human consumption. If pharmaceuticals are found in biosolids at lower concentrations than in intentionally ingested consumer products, a human health risk assessment would not be warranted. In such cases, only an ERA would be valuable. A risk assessment off-ramp is also necessary for chemicals that are present in biosolids at or below background soil concentrations.

Some chemicals (*e.g.,* per- and polyfluoroalkyl substances (PFAS) and microplastics) are globally pervasive in environmental media. The proposed intermediate step should consider what the risk assessment results would mean for globally pervasive chemicals that continue to be prevalent in commercial products, if their concentrations in biosolids are similar to background levels in soil. The risk assessment framework is meant to identify and characterize potential for harm and can only efficiently do so if there are opportunities to

dismiss chemicals from the screening risk assessment based on rational considerations, like comparing chemical biosolid concentrations to intentionally ingested levels for pharmaceuticals and background soil levels for globally pervasive chemicals. The proposed intermediate step serves to distinguish chemicals that are worth evaluating.
As the second step, a screening risk assessment (using the BST) rudimentarily evaluates the prioritized chemicals for human health and ecological risks from high-end exposures. The conceptual models are comprehensive and center on the most sensitive receptor, a farm family.

While NACWA acknowledges that the screening risk assessments are purposefully conservative, we express concerns that the layers of conservatism within the BST will result in "compounded conservatism" and produce excessively conservative and improbable cancer risks and noncancer hazards.

The National Academy of Sciences (NAS), in reviewing the historical Part 503 risk assessments, recommended the use of a reasonable maximum exposure (RME) receptor rather than a highly exposed individual (HEI) receptor (NAS 2002). The final RME exposure should be an upper-bound estimate with a reasonable expectation of occurrence.

The farm family, as presented in the BST screening risk assessment, represents a conglomeration of worst-case scenario exposures for an adult farmer and a child. The fate and transport model for the agricultural land application scenario outputs a time series of annual average concentrations over 150 years, centering the farm family's exposure duration around the year of maximum annual exposure concentrations. The model assumes minimal surface water dilution as the farm field is assumed to exist immediately adjacent to a farm pond and 10-meters (legal buffer) from an index reservoir. Additionally, the model assumes zero groundwater dilution for chemicals leaching down the soil column. The farm adult and child are assumed to exclusively drink contaminated water (*e.g.,* undiluted leachate) and exclusively consume homegrown contaminated produce and animal products (*e.g.,* crops, beef, milk, and fish) for 350 days per year. The resulting cancer risks and noncancer hazards, especially in aggregate, are unreasonable and extreme high-end estimates.

In conducting the screening risk assessment, NACWA encourages EPA to evaluate the pathway-specific results rather than relying on the aggregate results for identifying chemicals to move onto the refined risk assessment.

The screening risk assessment should be re-examined and modified to ensure parameters are reflective of a RME receptor. For chemicals that exceed acceptable risks in the screening risk assessment, there should be an opportunity to evaluate and fine-tune some parameters to determine if the chemical truly needs to undergo a refined risk assessment. Specific technical suggestions and comments regarding the screening risk assessment are presented under its own heading section below.

Finally, the refined risk assessment uses probabilistic modeling to evaluate risks using distributions of parameter inputs. For a national assessment, the Monte Carlo modeling

framework produces a distribution of risk estimates for each chemical, management scenario, receptor, and pathway. The selection of site locations (for agricultural land application and surface disposal) determines the development of input data. The Document states that EPA will use the 95th% of the risk distributions to evaluate if a level of concern has been exceeded, but it does not elaborate on what that risk exceedance *means*.

NACWA believes there needs to be more clarity on how geographic differences play a role in the framework and how those results can be interpreted and applied to those regions.

This point is particularly relevant for ERA, where different geographic areas support different ecosystems and habitats. For example, the diet of ecological receptors can greatly vary depending on geographical location. Specific technical suggestions and comments regarding the refined risk assessment are presented below.

Specific Comments on Prioritization

NACWA recommends the SDMs should be more specific to a biosolids risk assessment.

- Skin Sensitization & Skin/Eye Irritation
    - As mentioned previously, this metric highlights acute exposure hazards, which are not currently assessed in the BST. Acute exposure hazards are typically relevant for occupational exposures and mitigated through exposure control methods, like the use of personal protective equipment (PPE). Historical EPA biosolids risk assessments have determined that the farm family is the most sensitive receptor. This SDM should only be considered if EPA decides to include an occupational receptor (e.g., biosolids land applicator) with dermal exposure in the biosolids risk assessment.

- Human Health-to-Exposure Ratio (HER)
    - The exposure estimate is currently based on EPA ExpoCast for general population exposures. EPA plans to revise the HER to be more biosolids-specific, but it is unclear how EPA will calculate such a biosolids exposure estimate. We would appreciate more details on this process once EPA advances on this topic.

    - The HER SDM estimation process should distinguish quality concerns for ratios derived from lower tier toxicity criteria. In the absence of an *in-vivo* toxicity criteria, lower tier toxicity criteria are used to calculate a bioactivity-to-exposure ratio (BER) or threshold of toxicological concern (TTC)-to-exposure ratio (TER), which then comprise the numerical value for the HER SDM. The data quality differences between an *in-vivo* toxicity criteria-based HER and the lower tier BER and TER are significant. To avoid conflating the data quality of the HER, BER, and TER, the HER SDM estimation process should incorporate and convey uncertainties regarding BER and TER-based values.

- Proposed Ecological Hazard-to-Exposure Ratio
    - Like the biosolids-specific HER, we would appreciate more details on the process of estimating the biosolids-exposure metric, selecting the ecological point of departure (POD), and distinguishing uncertainties between ratios derived from lower tier toxicity criteria.

- Susceptible Populations (e.g., children)
    - While we acknowledge the need to identify susceptible populations in risk assessments, we question the applicability of the Susceptible Populations SDM in the biosolids risk assessment framework. This SDM characterizes potential for exposure to children based on EPA Consumer Product Database (CPDat) and EPA Chemical Data Reporting (CDR) (USEPA 2018). The potential for a chemical to be present in children's products is relevant for general chemical risk assessments under TSCA, but not in the context of biosolids. The BST already evaluates a child receptor as part of the farm family from extremely conservative assumptions about environmental exposures (air, water, food, soil). By identifying the prevalence of a chemical in children's products, this SDM does not add any value to the biosolids risk assessment framework.

- Weighting of SDMs
    - We appreciate that SDMs can be modified and encourage EPA to weight the SDMs for a biosolids-specific risk assessment rather than a general chemical risk assessment. We encourage that the SDMs with an exposure estimate (e.g., HER and ecological hazard-to-exposure ratio) be weighted higher because they aim to characterize hazards from biosolids exposures. As discussed previously, we believe that the Susceptible Populations SDM and Skin Sensitization & Skin/Eye Irritation SDM are not relevant and should be removed or weighted significantly lower.

<u>NACWA recommends the Information Availability Metric (IAM) be made more clear and more streamlined to assist with the biosolids risk assessment.</u>

- We commend EPA in characterizing knowledge gaps via the IAM. However, it is unclear how EPA will use the IAM in the PICS approach. For a chemical with a high SDM score, what IAM values would signify that there is sufficient information to prioritize/screen the chemical? For chemicals with low IAM scores, what methods (if any) will EPA pursue to fill in the knowledge gaps? We encourage EPA to clarify how it will use the IAM in prioritizing chemicals.

- The IAM data categories should be refined for consistency with the other components of the biosolids risk assessment. For example, if the BST does not consider acute or dermal exposure pathways, data category #8 (skin sensitization or eye corrosivity)

should be eliminated. Additionally, it is unclear what data category #9 (exposure) means.

- We encourage EPA to refine the modifying criteria such that IAM is more specific to hazards from biosolids exposure. For example, the PICS approach currently utilizes the modifying criteria for "Is this a chemical intermediate AND a short environmental half-life (hours)?" to avoid penalizing a chemical for lack of aquatic toxicity data. Chemical intermediates with short environmental half-lives are not expected to exist in processed biosolids at substantive concentrations or cause significant exposures to the evaluated farm family. Adjustments to the modifying criteria could prioritize certain data gaps (i.e., environmental persistence) that are more specific to biosolids and prove more useful in the risk assessment process.

Specific Comments on the Screening Risk Assessment

NACWA recommends there should be an acknowledgement of the uncertainties regarding the chemical concentrations inputted in the BST for the screening risk assessment.

- Chemical concentrations in the screening risk assessment are based on the 95th percentile of the Targeted National Sewage Sludge Survey (TNSSS), which was last conducted more than 17 years ago and are likely no longer representative.

- According to the Document, "If the chemical is only reported in the biennial review, then the literature will be evaluated to determine if a high-end estimate for concentration can be developed." The literature generally includes State or other governmental monitoring studies. We encourage EPA to provide more information about the literature and data criteria needed to derive high-end estimates for chemicals only reported in the biennial review.

- In estimating chemical concentrations, we encourage EPA to evaluate the biosolids survey data regarding relative contributions from municipal versus industrial waste sources. Identifying summary statistics for chemical concentrations for biosolids from predominantly municipal versus industrial sources sets up the framework for a pragmatic risk management approach.

- If the screening risk assessment identifies a chemical as a potential concern, EPA should test the chemical bioavailability from the biosolids matrix to determine if moving on to the probabilistic refined risk assessment is necessary.

NACWA encourages adjustments to the fate and transport models for more realistic results:

- For the screening risk assessment, the soil-to-groundwater dilution attenuation factor (DAF) (*e.g.*, 1 for land application unit [LAU]) assumes that unfiltered and unaltered soil leachate directly enters groundwater. The BST Appendices state that a "more

specific DAF can be used to adjust the risk results before deciding if the chemical should be carried forward to a more detailed probabilistic assessment." We appreciate that EPA acknowledges the conservatism of the DAF and will assess DAF variability to evaluate the need for a refined risk assessment. This adjustment of the screening risk assessment needs to be more clearly stated in the Document.

- Hydrolysis and biodegradation are set to zero in the screening risk assessment for the LAU (page A-8 of BST Appendices). Zero degradation is an extremely conservative assumption, particularly for a scenario where biosolids are applied outside and exposed to environmental elements. We encourage EPA to apply a screening risk assessment adjustment, like for the DAF above, that will assess degradation variability before deciding if the chemical should be carried forth for a refined risk assessment.

- Emerging contaminants could have unique fate and transport modeling considerations that are not currently included in the BST (*e.g.*, air-water interface for PFAS). This data gap needs to be assessed in the IAM, in whether the BST models need to be modified to predict fate and transport more accurately for these chemicals.

- As mentioned previously, the fate and transport models focus on maximum exposure concentrations, with cancer risk exposure duration centered around the year of maximum exposure and noncancer hazard based on the maximum annual exposure. To avoid characterizing risks for a HEI rather than a RME receptor, we encourage EPA to set the model with a focal point on central tendency exposures.

- While we understand that the conceptual model is designed to be conservative, some of the assumptions appear unrealistic. The farm pond is assumed to exist immediately adjacent to the field and receives surface runoff. In estimating surface runoff that enters the farm pond, EPA should consider that nutrient loading from the field could kill the fish in the pond. As such, the conceptual model should include a buffer between the field and the farm pond. Additionally, it seems improbable that most farm families would live within a 10-meter buffer between a farm field and an index reservoir for the land application scenario or immediately adjacent to a landfill for the landfill scenario. EPA should consider evaluating the appropriate buffer distance based on existing geographic data rather than worst-case scenarios.

<u>For the human health risk assessment, NACWA urges EPA to consider central tendency parameters for the farm family.</u>

- EPA selected the exposure duration for the adult farmer (48 years) from the 10th% residential mobility for farm households, based on US housing survey data from the 1980s (USEPA 2011, Table 16-113). In 1987, only a small percentage (1.9%) of total households lived on farms (USEPA 2011, Table 16-112). As noted in the SAB Draft Report (June 14, 2023), the percentage of farm households who partake in subsistence farming is a much smaller percentage. Smaller still, would be the

percentage of subsistence farming households that have the conditions set out in the conceptual site model, proximate to the farm pond and index reservoir. Given the conservatism already built-in the model, we encourage EPA to use more central tendency exposure duration values, such as the 25th% residential mobility from farms (27 years) to avoid characterizing risks for a HEI rather than RME receptor. The exposure duration of 27 years would be closer to the 5th% mobility for all households (23 years) and 10th% mobility for rural households (22 years).

For the ERA, NACWA recommends EPA provide more details.

- Overall, EPA should consider following an ERA approach consistent with the *Guidelines for Ecological Risk Assessment* (USEPA 1998) and *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (USEPA 1997). These guidance documents from EPA are well-known, utilized, and accepted by regulators. The ERA process within the framework lacks clarity in many areas pertinent to conducting an ERA, such as problem formulation, receptor selection, selection of appropriate endpoints, and selection of appropriate toxicity criteria. Details such as endpoint selection is critical to the ERA process, and EPA should also clarify which endpoints are appropriate for use in this framework. Typically, ERAs are conducted to protect populations or communities of ecological receptors, and not individual organisms. The selected endpoints should be based on reproduction, growth, and/or survival to protect the population and community level. The risk assessment framework currently references the Multimedia, Multi-pathway, Multi-receptor Exposure and Risk Assessment (3MRA) guidance; however, this document is not referenced or utilized following the EPA's 1997 or 1998 ERA frameworks.

- It would be beneficial for EPA to clarify what is involved with a threshold of toxicological concern approach and when it would be enacted. This approach is mentioned on page 31 (second paragraph under Section 6.5 Ecological Hazards) of the Document. The text states, "There may be situations where it would be appropriate for EPA to use a threshold of toxicological concern (TTC) approach to screen a pathway. The TTC approach involves determining a reasonable worst case hazard values for a receptor. It may be appropriate for EPA to employ a TTC approach to decide if further data collection or collaboration for data creation is merited." However, there are no subsequent details on what this TTC approach involves, and what is the result of the approach. There does not appear to be any information (such as a guidance document or information webpage) available from the EPA online. Additionally, this does not appear to be discussed within the BST User Guide. It is also not clear what a "worst case hazard value" represents.

- EPA should provide a definition of "hazard values" or use terminology consistent with other EPA ERA guidance documents (such as USEPA 1997, 1998). Section 6.5 of the Document provides a brief discussion of an approach for evaluating ecological hazard

and discusses the use of hazard values. However, it is not clear if a hazard value is meant to represent a concentration-based benchmark and/or a dose-based toxicity reference value.

- EPA should clarify sources of hazard values, or clarify if the intended user of this framework should be developing hazard values. Section 6.5 (fourth paragraph) of the Document discusses using "allometric scaling combined with available test data to estimate terrestrial/avian hazard values."

    - EPA should consider including additional sources to identify Ecological Toxicity Values. Sources of ecological toxicity values are provided in Appendix D of the BST User Guide. The first source listed is the Pesticide Ecotoxicity Database (PED), and the text notes "Because the chemicals included in PED are limited to pesticides, some of the data pulled from PED may be used in the BST for other similar chemicals (e.g., potassium permanganate data may be used as a surrogate for manganese data)." The Risk Assessment Information System (RAIS) Ecological Benchmark Tool for Chemicals provides a comprehensive source of toxicity criteria for many chemicals. A search in RAIS reveals numerous benchmarks available for manganese for soil, sediment, and surface water. It would be more appropriate to use a benchmark developed for specific chemicals rather than assuming and using a surrogate from a limited pesticide only database.

    - EPA should also note if selection of ecological criteria is based on no-effect dose or low-effect dose (i.e., no observed adverse effect level [NOAEL], lowest observed adverse effect level [LOAEL], median effective concentration [EC50], median lethal concentration [LC50], etc.). This information should be provided in the main framework document, rather than in the appendices of the BST User Guide.

- The BST User Guide should not recommend fish-based bioaccumulation factors (BAFs) for plants and invertebrates. The BST User Guide should be updated to allow for the use of biota-sediment accumulation factors (BSAFs).

    - The BST User Guide states, "BAFs for aquatic plants and benthic filter feeders are lacking for many chemicals; when this is the case, if a BAF for T3 fish is available, that is used, otherwise a default value of 1 is used." It is inappropriate to apply a BAF for fish to plants or benthics, as these are different receptor groups with different physiology, and a BAF specific for a fish is not representative as a BAF for a plant or invertebrate.

- The tool also states, "The concentrations in benthic filter feeders are calculated by applying a BAF to the sediment concentration. The BST does not include the capability to use a biota-sediment accumulation factor (BSAF)." BSAFs are appropriate for sediment-dwelling invertebrates. BAFs are typically calculated using a water concentration and a tissue concentration, and BSAFs are calculated using a sediment concentration and a tissue concentration. Therefore, the model should be updated to use BSAFs for sediment-dwelling invertebrates, as this represents a more accurate model for exposure.

- If BAFs or BSAFs are not available in the model, then additional resources could be used to identify appropriate BAFs. For example, consider sources such as the Biota-Sediment Accumulation Factor Database provided by the United States Army Corps of Engineers (2023).

- The dietary composition for exposure modeling should be revised:

  - The BST User Guide notes that, "The default dietary composition provided in the BST was drawn from 3MRA… based on species-specific data on foraging and feeding behavior, and reflects a year-round adult diet in a waterbody margin habitat." We recommend using dietary information from EPA's Wildlife Exposure Factors Handbook (USEPA 1993), as this is a well-known and accepted source for exposure parameters use for ERAs for Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Resource Conservation and Recovery Act (RCRA) projects.

  - The BST User Guide discusses the approach used to determine the dietary composition (as in, what percent of insects, fruit, vegetation, etc. that each receptor consumes for its diet). This approach takes an average of minimum and maximum compositions, which results in a sum of more than 100 percent.

    This approach is confusing, and it may skew the diet composition rather than accounting for variability. The User Guide provides an example for an American Robin diet, with 50.5% soil invertebrates and 49.5% fruits. However, when looking at EPA's Wildlife Exposure Factors Handbook (1993), these are the following ranges of diet for the American Robin: 7% fruit and 93% invertebrates (based on a study from the eastern United States); 8% fruit and 92% invertebrates (based on a study from the central United States); 17% fruit and 83% invertebrates (based on a study from the western United States). This example also shows how geographic regions can play a role in assessing risk, as noted in an earlier comment.

- NACWA suggests the following comment on Food Chain Concentrations in Attachment A1 of the BST User Guide Appendix A:

- Equation A1-22 (concentration in whole fish) notes that the concentration in the water column uses a dissolved fraction or organics and total fraction for inorganics. We recommend using a dissolved fraction for inorganics as well, as the total concentration is not fully bioavailable for fish and receptors to uptake; only the dissolved fraction is bioavailable. Using the total fraction overestimates risk.

Specific Comments on Refined Risk Assessment

NACWA recommends the refined risk assessment include more details and parameter adjustments.

- Compared to the screening risk assessment, which had the BST User Guide and Appendices to provide more details, the refined risk assessment process is vague. We encourage EPA to provide more information in an appendix, especially regarding summary statistics, sources, and rationale for the distribution data.

- Information is particularly sparse for the refined ERA. Table 4 of the Document does not include any input parameters for the refined ERA, such as whether ecological based benchmarks and/or toxicity reference values (and sources of these) should be used to calculate the hazard quotient (HQ). Additionally, Section 7.2.5 of the Document states that the level of concern for ecological species is identified when a HQ is above one. It would be beneficial for EPA to also define what exactly the "level of concern" means, and what this means for management of the chemicals that exceed this.

- EPA assumed 100% fraction contaminated for the LAU in the screening risk assessment, such that the farm family obtained 100% of their water, produce, and animal products from the contaminated farm. The Document does not mention if the fraction contaminated would be different in the probabilistic refined risk assessment (i.e., a distribution) rather than the 100% assumed in the screening risk assessment. For the refined risk assessment, we encourage EPA to consider lower values for the fraction contaminated, especially in regard to seasonal effects on fish and crop production for regions with icy winters.

- The physical dimensions of the waterbodies (index reservoir and farm pond) remain unchanged between the screening risk assessment and the refined risk assessment. The index reservoir is based on Shipman City Lake in Indiana. If the purpose of probabilistic refined risk assessment is to estimate risk for a national screening, the waterbody dimensions should also reflect a distribution.

Conclusion

NACWA appreciates the opportunity to provide the above considerations ahead of the July 5, 2023 SAB meeting and hopes they are considered as EPA reviews the recommendations ultimately made by the SAB. If there are any questions or concerns with these comments and considerations, please do not hesitate to contact me at eremmel@nacwa.org or 202/533-1839.

Sincerely,

Emily Remmel
Director, Regulatory Affairs
NACWA

References

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