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EPA-SAB-xx-xxx

The Honorable Michael Regan
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Transmittal of the Science Advisory Board titled "SAB Review of EPA's Standardized Framework for Sewage Sludge Chemical Risk Assessment (External Peer Review Draft)".

Dear Administrator Regan,

Please find enclosed the final report from the Scientific Advisory Board (SAB). The EPA's Office of Water requested that the SAB review the Agency's draft Standardized Framework for Sewage Sludge Chemical Risk Assessment. In response to the EPA's request, the SAB assembled the SAB Biosolids Panel with subject matter experts to conduct the review.

The SAB Biosolids Panel held three meetings on April 5, 2023, May 2-3, 2023, and July 5, 2023, to discuss the Agency's request and deliberate on the Agency's charge questions. Oral and written public comments were considered throughout the advisory process. This report conveys the consensus advice of the SAB.

While the SAB includes several recommendations within this report, we would like to highlight the following. [pending determination].

As the EPA finalizes its draft assessment, the SAB encourages the Agency to address the panel's concerns raised in the enclosed report and consider their advice and recommendations. The SAB appreciates this opportunity to review the draft assessment and looks forward to the EPA's response to these recommendations.

Sincerely,

Chair

Chair

EPA Science Advisory Board EPA Biosolids Panel

Enclosure:

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board, a public advisory committee providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. Reports of the EPA Science Advisory Board are posted on the EPA website at https://sab.epa.gov.

The SAB is a chartered federal advisory committee, operating under the Federal Advisory Committee Act (FACA; 5 U.S.C., App. 2). The committee provides advice to the Administrator of the U.S. Environmental Protection Agency on the scientific and technical underpinnings of the EPA's decisions. The findings and recommendations of the Committee do not represent the views of the Agency, and this document does not represent information approved or disseminated by EPA.

Biosolids Panel Roster

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Science Advisory Board Roster

Pending inclusion

SAB Review of EPA's "Standardized Framework for Sewage Sludge Chemical Risk Assessment (External Peer Review Draft)"

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ACRONYMS AND ABBREVIATIONS

3MRA	Multimedia, Multi-Pathway, Multi-Receptor Exposure and Risk Assessment
Al	Aluminum
B[a]P	Benzo[a]pyrene
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BER	bioactivity to exposure ratios
BST	Biosolids Tool
CFR	Code of Federal Regulations
DAF	Dilution Attenuation Factor
DOC	Department of Commerce
DOE	Department of Energy
EPACMPT	EPA's Composite Model for Leachate Migration
EPI Suite	Estimation Program Interface Suite
ExpoFIRST	EPA's Exposure Factors Interactive Resource for Scenarios Tool
HER	hazard to exposure ratio
IAM	Information Availability Metric
K_{oc}	OC-normalized sorption coefficient
K_{ow}	n-Octanol/Water Partition Coefficient
MEI	Maximum Exposed Individual
MEI	Maximally Exposed Individual
MRA	Multimedia, Multipathway, Multireceptor
MT	Metric Ton
OC	Organic Carbon
PFAS	Per-and Polyfluoroalkyl Substances
PICS	Public Information Curation and Synthesis
RAIDAR	Risk Assessment IDentification and Ranking
RME	Reasonable Maximum Exposure
RME	Reasonable Maximum Exposure
SAB	Science Advisory Board
SDM	Scientific Domain Matric
TER	Toxicological Concern to Exposure Ratios
TNSSS	Targeted National Sewage Sludge Survey
U.S. EPA	U.S. Environmental Protection Agency
USDA	U.S. Department of Agriculture
VOC	Volatile Organic Compounds
VVWM	Variable Volume Water Model
WBAN	Weather Bureau Army Navy
WW	Wet Weight

1. INTRODUCTION

The Environmental Protection Agency (EPA) Office of Water requested that the Science Advisory Board (SAB) conduct a peer review of its draft "Standardized Framework for Sewage Sludge Chemical Risk Assessment". The framework includes a prioritization process, deterministic screening-level risk assessment, and refined risk assessment. The purpose of the framework is to support the Agency's efforts to assess human health and ecological risk from pollutants found in biosolids. Specifically, EPA's goal is to identify pollutants, pathways, and receptors of greatest interest to inform decisions on whether to perform a more refined biosolids risk assessment.

In response to the EPA's request, the SAB convened a panel of subject matter experts to conduct the review. The Science Advisory Board Biosolids Panel convened three public meetings to conduct a peer review of the EPA's assessment framework. Meetings were held on April 5, 2023, May 2-3, 2023, and July 5, 2023. Oral and written public comments were considered throughout the advisory process.

Charge questions were specified by the Office of Water. Recommendations are prioritized to indicate relative importance during EPA's revisions. Priorities are defined as follows:

- Tier 1: Key Revisions – Actions that are necessary to improve the critical scientific concepts, issues, and/or narrative within the assessment/document/model/guidelines.

- Tier 2: Suggestions – Actions that are encouraged to strengthen the scientific concepts, issues, and/or narrative within the assessment/document/model/guidelines, but other factors (e.g., Agency need) should be considered by the Agency before undertaking these revisions.

- Tier 3: Future Considerations – Useful and informative scientific exploration that may inform future evaluations of key science issues and/or the development of future assessments/documents/models/guidelines. These recommendations are likely outside the immediate scope and/or needs of the current review.

All materials and comments related to this report are available at: https://sab.epa.gov/ords/sab/f?p=114:18:9587163122946:::RP,18:P18_ID:2610

2. TO CHARGE QUESTIONS

2.1. <u>Prioritization</u>

2.1.1. Application of the PICS process:

Does the SAB find that the application of the PICS process to the chemicals found in biosolids is sufficient to identify the chemicals that should move to a deterministic screening-level risk assessment?

Over 700 chemicals have been identified in sewage sludge during three national sewage sludge surveys covering the years 1988, 2001, and 2006 and in peer-reviewed literature available publicly. The Public Information Curation and Synthesis (PICS) approach integrates publicly available information on these chemicals to establish occurrence, fate, and transport in the environment, human health and ecological effects, and other relevant information for these chemicals found in biosolids. Synthesis of this information is used to understand the overall degree of potential concern related to human health and the environment. The PICS process utilizes two matrices to identify whether or not each chemical that has been identified in biosolids is a high- or low-priority candidate for further study and analysis:

- Information Availability Metric (IAM)
  The IAM utilizes information and data from relevant studies and databases such as the National Sewage Sludge Surveys and published literature.
- 2. Scientific Domain Matric (SDM)
  The SDM groups the information into seven scientific domains affecting human or environmental health (Table 1).

Chemicals with large amounts of information and a high potential risk of adverse health effects are identified as strong candidates for further risk assessment.

Table 1. Scientific Domain Matric Groups (see p. 13, U.S.EPA, 2023)

Human hazard to exposure ratio
Ecological hazard
Carcinogenicity
Genotoxicity
Susceptible populations
Persistence and bioaccumulation
Skin sensitization and skin/eye irritation

Overall, the Science Advisory Board (SAB) supports using the PICS process and views it as a scientifically-defensible and technically sound approach for identifying and prioritizing these chemicals found within biosolids that should undergo a screening-level risk assessment evaluation. Although the SAB applauds the Agency's basic approach, the following concerns and questions have been identified.

Overall concerns:

- Has the information needed for prioritization in both the IAM and SDM itself been evaluated and prioritized?

- What is the overall weight of the IAM relative to the SDM? The Agency is encouraged to provide a clear and unambiguous description of the process by which IAM values will be utilized relative to SDM values in supporting its chemical prioritization decisions.

- Has a full-scale, exhaustive literature search of peer-reviewed, and non-peer-reviewed reports been conducted to glean all available published information on metals and trace organics?

IAM Concerns

- Are concentrations derived only from municipal biosolids, not industrially contaminated? This is a critical point since industrially contaminated biosolids with abnormally high PFAS concentrations should not be land applied.

- Are total or bioavailable concentrations utilized? Only bioavailable concentrations should be used – total values do not provide useful information.

- Are stated biosolid chemical concentrations current? For example, biosolid PFAS concentrations are much lower now than twenty years ago.

- Have current values been reduced from those stated in prior reports due to a chemical being phased out of production?

- Is the biosolid matrix considered? This is important since chemicals including both metals and trace organics are known to behave differently when contained within the biosolid matrix as opposed to aqueous solution.

SDM Concerns

- Of the seven scientific domains identified as affecting human or environmental health, only the human hazard to exposure ratio (HER) and the ecological hazard domain are quantitative. The other five scientific domain matrices are qualitative in nature and can only be evaluated subjectively, which represents a potential weakness in the chemical prioritization process. Specifically, will the Agency recognize that, for some data, significant uncertainty may exist that is not captured within the SDM estimation process? For example, inherent data quality differences associated with HERs, bioactivity to exposure ratios (BER), and threshold of toxicological concern to exposure ratios (TER) should be fully described and explained within the SDM estimation process.

The following recommendations are noted:

<u>Tier 1</u>

- The Agency should convene a panel of expert stakeholders including academics, utility personnel, State Biosolid Coordinators, and regulators to examine the data and information found within the IAM and SDM and identify chemicals of concern in biosolids and their allowable concentrations. Biosolids with levels beneath these thresholds would be defined as municipal. Biosolids with levels above these concentrations would be considered industrially contaminated. A stringent monitoring and reporting program would be needed for implementation and compliance.

Tier 2

- The SAB recommends that all types of information required for prioritization in the IAM and SDM should itself be prioritized following evaluation.
- The Board also recommends that the Agency should provide a clear and unambiguous description of the process of how the IAM and SDM data will be utilized in the prioritization process.

Tier 3

- The SAB recommends that a full-scale literature search for information on all 700 chemicals identified in biosolids be conducted and utilized in both the IAM and SDM.

2.1.2. Implementation consideration:

Are there additional steps EPA should consider for implementation during the prioritization process?

EPA should consider offering a well-defined explanation of how the SDM and IAM standards will be applied in prioritizing screening-level risk assessment for chemicals with known/potential human and ecological health risks. Additionally, EPA should examine the appropriateness and scientific relevance of the PICS process in the prioritization of the list of chemicals for screening-level risk assessment moving forward.

The following recommendations are noted:

Tier 1

[pending determination]

Tier 2

[pending determination]

Tier 3

[pending determination]

2.2. Deterministic Screening-level Risk Assessment

2.2.1. Selection process:

Does the SAB find the selection process for models within the BST to be appropriate for the exposure pathways for a screening-level risk assessment? If not, indicate why and provide recommendations for alternative model selection criteria.

EPA has developed a deterministic Biosolids Tool (BST) to evaluate if chemicals found in biosolids need a more refined risk assessment. To develop the BST, EPA had to find models to predict the exposure pathways – models needed to be available, be modifiable, and work well with other models in the BST. The four major transport mechanisms of interest are (1) air transport (dispersion and deposition of vapor phase and dust); (2) runoff and erosion to surface water; (3) leaching to groundwater; and (4) plant uptake. For chemicals that are deemed potential concern, a more refined assessment will be conducted using a probabilistic Modeling Framework.

The SAB appreciates the clarity provided in the white paper "A Standardized Framework for Sewage Sludge Chemical Risk Assessment White Paper" on the individual pathway model selection process. In general, the models selected are reasonable for 'screening' -level risk assessment given the prevailing conceptual model, and the exposure pathways that need to be considered are appropriate. Some shortcomings were noted as summarized below. While there are many other models available that could have been evaluated, the process is largely fit-for-purpose.

The models evaluated for use in the BST are largely single-media models for which the outputs are knitted together. EPA may want to consider exploring some of the many multimedia fate models that can estimate concentrations in particular media at a broader scale. Moreover, the scale at which risks to human receptors and ecological receptors are typically evaluated are often not the same. It is common practice for human health risk assessment to focus on evaluating (and protecting) individuals while ecological risk assessment often focuses on communities and populations. Given the latter, a larger-scale conceptual model for agricultural land application of biosolids may be more appropriate. If EPA were to evaluate potential ecological exposures and risks at a larger scale, the SAB suggests the Risk Assessment IDentification and Ranking (RAIDAR) model as a potential tool (Arnot Research & Consulting, n.d.)[1].

Aspects of the models that were lacking included algorithms that address 1) pH-impacted availability and transport that are relevant for ionizable organic chemicals and speciation of inorganic compounds, which greatly impacts bioavailability-related parameters; and 2) air-water interfacial sorption, which is known to substantially retard PFAS transport in the vadose zone. For the ionizability issue, the User Guide notes the limitation of ionizable compounds with a focus on organic compounds and indicates the need to run separate runs with updated parameters specific to the conditions of interest. However, this alone may not suffice when attempting to apply an organic carbon (OC)-normalized sorption coefficient (K_{oc}) concept when OC is not the driver, e.g., organic cation sorption, transport, and bioavailability can be controlled by the soil cation exchange capacity rather than OC. In most cases, assuming OC as the driver when it is not will overpredict transport and bio-uptake. In the case of some metals such as aluminum (Al), failure to consider the role of soil pH will lead to over-predicting Al transport and adverse impacts on crops, etc.

Artificial drainage enhancements are not accounted for in any models. Subsurface, tile drainage includes placement of a perforated tile approximately 1-m below the soil surface to improve field drainage, thus reducing runoff, but allowing for direct transport from immediately below the rooting zone to streams. Therefore, the role of runoff in these cases will be overpredicted, thus impacting exposure estimates of more highly retained compounds of interest, but possibly underestimating the impact to streams of more mobile/soluble chemicals. For addressing tile-drain networks, it could be plausible to use the Multimedia, Multi-Pathway, Multi-Receptor Exposure and Risk Assessment (3MRA) to 1 meter (vs 2 m) and then direct discharge to stream coupled with the Variable Volume Water Model (VVWM) versus the dilution-attenuation factor (DAF).

[1] American Chemistry Council has provided funding to support Arnot Research and Consulting to further develop the RAIDAR model and other models through the ACC Long-Range Research Initiative.

The Agency clarified during the peer review public meetings, that biotransformation is considered in the BST transport modeling within the top 2-m of soil. However, as pointed out in the User Guide, the risk evaluation does not include the transformation products. The latter must be dealt with in individual model simulations with the addition of a new chemical, which is reasonable given the complexities of trying to simultaneously address the variety of degradation products that may occur on the way to mineralization.

It is also noted that there seems to be a need to consider the IAM/human health concern bias (i.e., chemicals with a higher IAM tend to have a higher health/environmental impact concern) specifically for chemicals found in biosolids and the potential that data availability, or lack thereof, may bias the deterministic/screening level analysis.

The following recommendations are noted:

<u>Tier 1</u>

- The SAB strongly recommends that the evaluation of the BST include corroboration, sensitivity analysis, and uncertainty analysis for a given chemical run consistent with EPA guidance (U.S. EPA, 2009). While EPA did conduct a Validation and Sensitivity Analyses of the model inputs (Appendix E of the Biosolids Tool (BST) User's Guide, (U.S. EPA, 2023a)), there is no step proposed to do a reality check for a chemical-specific output. Prior to the time-intensive probabilistic modeling, the SAB recommends that EPA conduct additional confirmatory evaluation of chemicals for which the BST estimates excess risk, such as evaluating "background" levels, reviewing literature regarding key variables such as bioaccumulation or bioconcentration factors and/or data regarding the presence of the chemical in various exposure media/foodstuffs or ecological receptors. This would serve as a good "reality" cross-check of model results. Also, this may aid in addressing concerns regarding how significantly the IAM influences the results of the deterministic/screening level analysis. It was noted that the chemicals with a higher IAM tend to have a higher health/environmental impact concern specifically for chemicals found in biosolids.

<u>Tier 2</u>

- The SAB notes some limitations to the current BST. Addressing the Tier 1 recommendation may very well also address these concerns.
- The role of pH on chemical fate is not explicitly considered in the current models, which is acknowledged indirectly in noting the limitations for ionizable compounds. However, the SAB notes this may not be sufficient and urges EPA to consider how this may be best addressed.
- While the role of air-water interfacial sorption may not impact most of the chemicals on the list to be evaluated, PFAS transport to groundwater is known to be greatly impacted by this process in the vadose zone. Given the significance of PFAS in the current regulatory framework, the SAB urges EPA to consider how to address this transport process.

<u>Tier 3</u>

- EPA may want to consider exploring some of the many multimedia fate models that are able to estimate concentrations in particular media at a broader scale, particularly in regard to ecological community effects.

2.2.2. BST receptors:

Are the receptors contained in the BST appropriate for a screening-level risk assessment for 1) human health and 2) aquatic and terrestrial wildlife? If not, please indicate why and provide recommendations for alternatives.

The use of the subsistence farm family for the crop and pasture scenarios generally represents an upper bound/high-end setting, receptor, and exposure scenario. Conceptually, the SAB consensus is that this is sensible for a screening step, assuming the purpose of this step is to simply "screen in" or "screen out" constituents and pathways to be carried forward in a more robust, probabilistic (to the extent feasible), refined risk assessment. However, as described in more detail below, it may be useful to consider modifications to the use of such a large number of exposure pathways/routes and upper bound exposure assumptions for some of the key variables such that a "compounding conservatism" with respect to the exposure setting the and intensity of exposures does not result in a "maximally exposed individual" (MEI) versus a reasonable maximum exposure (RME). It is current practice and recommended per EPA guidance for risk assessment (1989), that an RME receptor should be used, combining both average and upper-bound values for various exposure parameters, to simulate an upper-bound exposure that could "reasonably be expected to occur." Because of the intertwined nature of the receptor scenarios selected, and the exposure pathways and assumptions, some of the comments presented below overlap with and are reiterated in the responses to charge questions 2.2.3. and 2.2.5.

The two land application scenarios, i.e., the "crop" and "pasture" scenarios, involve the greatest number of pathways and assumptions, and represent a very common, beneficial use for biosolids and hence are the focus of many of the SAB comments here and below in the related Charge Questions 2.2.3. and 2.2.5. The SAB finds the receptors, pathways, and settings for the other two scenarios included in the BST (reclamation and sewage sludge landfills) are generally appropriate and representative with one exception noted (below). In addition, the ecological receptors used in the BST are reasonable and appropriate, representing typical indicator species for various trophic levels and habitats. One panelist expressed concern that it may be more appropriate to look at ecological receptors on a population and/or community level versus selecting and evaluating effects to individuals as further articulated in charge question 2.2.5. However, the approach taken for receptor selection for the ecological screening does not appear inconsistent with the EPA guidelines for ecological risk assessment.

According to information available from the U.S. Department of Agriculture (USDA) (e.g., Census of Agriculture, 2017 (USDA, 2019)) and similar sources such as the American Farm Bureau Federation ((American Farm Bureau Foundation, 2021), it appears that (roughly) less than 2% of the U.S. population is comprised of farm and ranch families. Of that, only about 3% are used to grow crops for human consumption, with the overwhelming majority used to raise livestock for meat and/or dairy or to grow feedstock for animals or for ethanol production. Also of note, less than 1% of all agricultural land uses biosolids (U.S. EPA, 2003) and almost none is used for human consumption crops. For those farms growing crops, only a portion of them is used for subsistence agriculture, which is more prevalent on smaller, "family" type farms. It is reasonable that, due to the inferred rural nature of farmland areas, the farm family may rely on a private water supply well for potable water use including ingestion, showering, etc. The setting used in the tool, however, also assumes that the "farm pond" surface water body receives runoff of the biosolids into pond water and sediment (which may be reduced/mitigated by biosolid land application and soil conservation requirements in some areas) and then uptake into fin fish/shellfish upon which the farm family is assumed to rely for all of their fish intake[2]. The combination of all of these factors for this population may lead to a characterization of potential risks above and beyond an RME, which is the intent of the EPA deterministic risk assessment process.

Also, we note that the farm family (adult and child) may not represent a reasonable maximum exposure to chemicals in biosolids with respect to fish consumption if a regional watershed was evaluated. As discussed later in sections 2.2.3 and 2.2.5, EPA should consider providing additional information regarding the potential for regional watershed exposures to the freshwater recreational angler and/or the Native American freshwater subsistence fishing receptors.

There was substantial discussion by the SAB regarding the typically low probability of the same individuals in a "farm family" not only doing all land management practices (i.e. application/tilling of biosolids and associated planting/harvesting) with the associated inhalation and incidental ingestion exposures, but incurring additional exposures from soil via field runoff, from relying on their total annual consumption of crops and fish exclusively from the farm property, and from drinking and showering in impacted water from a private well. It appears that it may be a completely different set of individuals who provide and apply biosolids versus those who work in croplands or pastures and rely on that for an income stream versus those who may reside on essentially subsistence farms. Some of these workers may also have Occupational Safety and Health Administration regulations that apply. The SAB recommends that EPA consider occupational exposures to chemicals in biosolids for dedicated workers (e.g. contract applicators) who may be responsible for their application or, if appropriate explain other safeguards already in place.

The same concern regarding bundling of multiple pathways applies to the farm family for the pasture scenario, except that the consumption of all meat and milk is derived from the farm instead of the crops. Both of these land application scenarios and receptors are assumed to engage in all of these activities, behaviors, and uses at or on the same farm Property year after year, for a period of 61 years (13 years as a child and 48 as an adult). The vast majority of exposure parameters used for these subsistence scenarios were "upper bound," typically at or above the 90th percentile of the distributions described in the Exposure Factors Handbook. These specific parameters are discussed in more detail in Charge Question 2.2.3, below. Therefore, to ensure that the receptor scenarios remain protective but plausible, the SAB panel recommends that the EPA consider re-evaluating the current combination of conservative receptors/exposure scenarios/routes in the context of both the typical workflows, activities, and methods for the applicators of biosolids as well as the farmers who own/reside on both croplands and pastures. The logic for the selected receptor scenarios/pathways/routes could be described more robustly and be used to support the Conceptual Site Model. The basis for this recommendation is the potential for compounding conservatism beyond the RME and recent data from the USDA and other sources regarding US farm demographics and the use of biosolids.

Concerning the sewage sludge disposal scenario, it seems as if the receptor scenario/pathways evaluated (inhalation of air, use of groundwater for private potable well, and inhalation of shower air) are more consistent with a "Local Child/Adult Resident" who may be living in proximity to the sewage sludge landfill, versus the current nomenclature of "Child/Adult Farmer." This receptor name change

[2] This seems to be somewhat in conflict with the fishing scenario described on page 39 of the Framework which indicates that the farm pond is assumed to be used for "recreational fishing".

suggestion would likely also be perceived as more generically representative of residents who may live proximate to such sludge disposal landfills.

Another approach to help maintain an RME (versus an "MEI") assessment and output for the screening tool would be to consider using the midpoint of the EPA target risk range (i.e., 1×10^{-5}) versus 1×10^{-6}. This could help counter the potential for an overestimation bias through the use of these settings and scenarios. For comparison, the EPA has used 1×10^{-6} as a "point of departure" for calculation of risk-based cleanup levels at Comprehensive Environmental Response, Compensation, and Liability Act Sites and has permitted the use of alternative target risk limits in certain settings or to take potential population impacts into account. For example, in the original development of 40 CFR part 503, EPA used a risk target of 1×10^{-4}, largely because the aggregate risk assessment found little risk from biosolids even in the absence of regulation (U.S. EPA, 1993).

Lastly, the SAB recommends that EPA incorporate a model evaluation step of the BST consistent with EPA guidance (U.S. EPA, 2009). EPA conducted some sensitivity and uncertainty analyses, and additional analyses are recommended in the following sections. However, EPA should also conduct *model corroboration* for "evaluating the degree to which [the BST] corresponds to reality." For example, in cases where the model exposure results indicate the potential for significant risk for an analyte based on the screening scenarios, and assessment of consistency with existing observational data needs to be done. Additional factors that may warrant consideration may include typical "background" levels of the analyte, and a review of literature documenting levels of the analyte in environmental media, ecological receptors and/or food items, etc.

The following recommendations are noted:

<u>Tier 1</u>

- The SAB recommends that the current receptor/exposure pathways/routes for the Land Applications Scenarios be reviewed and modified as appropriate to confirm consistency with an RME evaluation and additional information be provided to support the Conceptual Site Model in the Framework document.

- The SAB recommends that the evaluation of the BST include corroboration, sensitivity analysis, and uncertainty analysis consistent with EPA guidance (U.S. EPA, 2009). The SAB recommends that EPA conduct additional confirmatory evaluation of chemicals for which the BST estimates excess risk, such as evaluating "background" levels, reviewing literature regarding key variables such as bioaccumulation or bioconcentration factors and/or data regarding the presence of the chemical in various exposure media/foodstuffs or ecological receptors. This could be a good "reality" cross-check of model results.

<u>Tier 2</u>

- The type of receptor and exposure setting evaluated for the sewage sludge disposal scenario is more consistent with a "child/adult local resident" versus a "child/adult farmer." The pathways evaluated are limited to airborne exposures and potable water use exposures, including ingestion of tap water and inhalation of shower air. Accordingly, the SAB recommends revising the nomenclature for this receptor.

- The SAB recommends that EPA consider occupational exposures to chemicals in biosolids for dedicated workers who may be responsible for their application.

Tier 3

- The SAB has no specific recommendations for this tier.

2.2.3. Screening parameters:

Several screening parameters are set to health-protective, high-end values (e.g., concentration of chemical in biosolids, drinking water ingestion rates), but others are set near the central tendency for that parameter (e.g., bioaccumulation factor). Does the SAB agree that these metrics generate reasonable high-end exposure estimates appropriate for screening for 1) human health and 2) aquatic and terrestrial wildlife? If not, please indicate why and provide recommendations for alternatives.

The SAB finds that the compounded conservatism resulting from the selection of the screening level parameters may not result in "reasonable" high-end exposure estimates for humans. Moreover, the approach for selecting whether a central tendency or high-end value is used appears arbitrary. A consistent approach for selecting central tendency or high-end values should be articulated and applied. In addition, what constitutes "high-end" should also be clearly articulated and consistently applied.

The SAB recommends that EPA conduct a sensitivity analysis of human exposure factors and other parameters (such as BAFs and BCFs) used in the BST so that it is understood how variability in the parameters may affect results from simulations, as well as which parameters exert the greatest influence on the model results so that these parameters can be considered carefully.

The SAB finds that the farm pond and agricultural field are not appropriate ecosystems for the ecological risk assessment. The SAB recommends that EPA reconsider its problem formulation for the ecological risk assessment of land applied biosolids consistent with the Guidelines for Ecological Risk Assessment (U.S. EPA, 1998). For the ecosystem of concern or other ecological entities, it is necessary to identify attributes that are important to protect. For ecological receptors, the general practice of environmental risk assessment focuses on populations and communities. Therefore, a reasonable high-end exposure estimate should not be overly conservative. That is, the environmental exposure level should estimate conditions that might occur at a reasonable high-end across ecosystems of concern such that they are ecologically relevant for the appropriate ecological endpoint.

Several specific examples where overly conservative assumptions may lead to unreasonably high screening level exposure estimates are discussed below.

1. **Subsistence Farming Family:** A subsistence farming family is an extremely small subset of the general U.S. population and even the U.S. farming population. The SAB recommends central tendency parameters (e.g., concentration of chemicals in biosolids, drinking water ingestion rates) be used for the exposure scenarios associated with a subsistence farm family.

2. **Fish Consumption:**
   a. Adult Farmer: The consumption rate for the adult farmer is listed in the BST as 22 g WW/day which is the 90th percentile consumption at the 95% confidence interval for

fresh and estuarine fin and shellfish (raw weight) by consumers (based on Table E-7 from the 2014 Fish Consumption Report, U.S. EPA 2014). However, the BST Users' Guide (Appendix A, Attachment A.1.6) states that the equations used to calculate the concentration in fish filet considers trophic levels 3 and 4 only (which have higher bioconcentration factors relative to lower trophic levels). The combined 90th percentile for fish consumption of trophic levels 3 and 4 fish is 13.7 g/day (see U.S. EPA, 2014 Tables 17 and 18). Furthermore, the use of 90th percentile consumption rates at the 95% confidence interval for a scenario where a small farm pond is used for "recreational" purposes is overly conservative.

b. Recreational Freshwater Anglers and Native American Fishers: The "family farm" scenario may not represent a reasonable high-end exposure estimate for fish consumption. EPA may want to consider a high fish consumption scenario separate from the family farm model such as a recreational freshwater angler or a Native American subsistence freshwater fisher, especially in relation to Executive Orders 13985 (86 FR 7009) and 14008 (86 FR 7619) regarding equity for underserved communities and environmental justice. The 2014 Fish Consumption Report (U.S. EPA, 2014) does not appear to include recreational freshwater anglers or Native American fishers among its subpopulations for usual fish consumption rates. However, the EPA Exposure Factors Handbook (U.S. EPA, 2011) has summaries of relevant studies for Freshwater Recreational Fish Intake (Table 10-5) and Native American Fish Intake (Table 10-6). Additionally, EPA may want to consider how its target analytes for fish advisories (U.S. EPA 2000) compares to those chemicals detected in the Targeted National Sewage Sludge Survey.

3. **Residential mobility:** Regarding residential mobility (and associated tenure for living in the same home), the BST assumes a total duration for a child and adult farmer is 61 years (13 years for children and 48 years for adults). Focusing on adult tenure, the Exposure Factors Handbook (U.S. EPA, 2011) indicates that the tenth percentile for mobility for farmers is 48 years. The 25th percentile for adult farmer mobility is much lower, or 26.7 years, which is close to the 10th percentile mobility for the more general "owners" population (32 years). The median length of home ownership is roughly 15 years. When looking at residential occupancy periods for the population as a whole (U.S. EPA 2011, Table 16-108), the 90th percentile for living in the same home is 26 years, the 95th is 33 years, the 99th is 47 years and the 99.9th is 59 years (this is for total combined, regardless of age). It may be useful to consider these residential tenure durations as they relate to the assumptions in the BST.

4. **Air pathway:** It appears that a 24-hour per day exposure duration (350 days per year) is assumed for the (outdoor) dust and/or vapor inhalation pathway. Since no traditional volatile organic compounds (VOCs) were included among the BST example chemicals, it is difficult to evaluate the appropriateness of these parameters. One would expect that the off-gassing of VOCs that may be present in biosolids would persist for only a few days following application. Concerning fugitive dust/particulate exposures, although they are likely elevated during the application of biosolids and tilling, that same level of airborne particulate would not persist throughout the exposure period. Once the biosolids are applied, the potential for airborne emission of VOCs decreases over time. In addition, moisture and crop growth would further reduce the potential emission of VOCs and their inhalation.

5. **Beef and milk consumption**: The results from BST using defaults for the pasture scenario for Benzo[a]pyrene (B[a]P) indicated an unusually high level of risk. For a child farmer, consumption of milk and beef associated with the default biosolids concentration of 2.19 ppm B[a]P resulted in risk estimates of 1.1 X 10^{-3} and 5.1 X 10^{-4}, respectively, for the cancer endpoint and a non-cancer hazard index of 27 and 83, respectively. A soil concentration of 2.19 ppm B[a]P is generally consistent with an anthropogenic background in soils in the United States, such as those reported in a large study of both "natural" and "fill" soils in Massachusetts (MassDEP, 2002). These estimated risks seem very high and potentially could imply that background levels of select chemicals are posing an unacceptable risk to certain populations or, potentially, general consumers even without biosolids application. These elevated risks appear to be largely associated with the BAFs used for estimating exposure concentrations in beef and milk. The SAB recommends that EPA conduct a more in-depth evaluation of the assumptions and equations used to evaluate these two pathways, in particular, the approach used to estimate or calculate BAFs. The EPA Office of Water has issued recent documents regarding the development of "National" BAFs and BCFs (U.S. EPA, 2016), and there is also a plethora of literature regarding field measurements of BCFs and BAFs for many of the chemicals that have been identified in biosolids. Accordingly, it is recommended that a clearer explanation of the approach used to develop the BAFs and BCFs integrated into the BST equations be provided and that an emphasis be placed on using the most up-to-date literature and/or recommended methods to derive these values.

6. **Human exposure factors**: EPA should consider including inhalation rate and dermal exposure factors among the human exposure factors included in the BST (see p. 36 U.S. EPA, 2023).

The following recommendations are noted:

<u>Tier 1</u>

- The SAB recommends central tendency parameters should be applied when evaluating the example *subsistence farm family*.
- The SAB recommends EPA review the data regarding fish consumption rates for an adult farmer to confirm the correct values are used corresponding with trophic level 3 and 4 fish consumption.
- The SAB recommends EPA use central tendency values for human receptor tenure on the subject subsistence farm receiving biosolids.
- The SAB recommends that EPA provide clarification on the approach used to develop BAFs and BCFs used in the BST equations and that empirical measurements and/or the most up-to-date approaches for estimation/modeling are used for these parameters.
- For common, ubiquitous contaminants (e.g., benzo(a)pyrene), the SAB recommends EPA consider how high-end assumptions compare to background concentrations and whether risk results from such a simulation reflect our current understanding of those contaminants.
- The SAB recommends EPA consider including inhalation rate and dermal exposure factors among the human exposure factors included in the BST.
- The SAB finds that the farm pond and agricultural field are not appropriate ecosystems for the ecological risk assessment. The SAB recommends that EPA reconsider its problem formulation for the ecological risk assessment of land-applied biosolids consistent with the Guidelines for Ecological Risk Assessment (U.S. EPA, 1998).

- The SAB recommends that site-specific, high-end values *not* be used in the ecological exposure assessment. The SAB recommends screening parameters for ecological exposure and risk assessment to represent values that are more consistent across a broader geographic range than the family farm though they could be at the high-end of the distribution for that broad geographic area.
- The SAB recommends EPA review all of the parameters used to configure the BST and cite in detail the source of the information. For example:
  - In the BST, under "Configure Model," in the "Inputs" tab and "Human Exposure" subtab, adult body weight is listed as 79 kg and EPA's 2011 Exposure Factors Handbook is cited. However, Table 8-1 lists the Recommended Values for Body Weight for Adults as 80.0 kg. If the BST is using data from a different source, that source should be cited.
  - In the BST, under "Configure Model," in the "Inputs" tab and "Chemicals" subtab, Reference body weight (bird) [Ref_BW_Bird] is listed as 191 kg (clearly an error).

Tier 2

- The SAB recommends EPA consider substituting the adult farmer fish consumption exposure scenario with a recreational freshwater angler or a Native American fishers' scenario.
- The SAB recommends EPA evaluate the appropriateness of the 24-hour per day exposure duration (350 days per year) for the (outdoor) dust and/or vapor inhalation pathway.

Tier 3

- The SAB recommends EPA study the appropriateness of a high fish consumption scenario separate from the family farm model such as a recreational freshwater angler or a Native American subsistence freshwater fisher.
- The SAB recommends that EPA study the alignment between the list of chemicals detected in the Targeted National Sewage Sludge Survey and the list of target analytes for fish advisories (U.S. EPA, 2000).

2.2.4. Geographic exposure:

EPA proposes to evaluate three locations that have different meteorological characteristics (wet, median, dry). Are these three geographic exposure scenarios appropriate for this screening-level risk assessments? If not, please provide recommendations for an alternative set of locations and a rationale for selecting the locations.

The three locations selected are Charleston, South Carolina (Wet), Chicago, Illinois (Average), and Boulder, Colorado (Dry). The average annual precipitation for each location is 48, 37, and 21 inches respectively. These different meteorological characteristics only impact atmospheric transport and leaching to groundwater. Subsurface properties for each site were modeled probabilistically based on their hydrogeological properties as follow: Charleston (coastal beaches), Chicago (limestone), and Boulder (bedded sedimentary rocks). Based on the sensitivity analysis conducted for each site, climate was a relatively an insensitive parameter. The results were impacted most by chemical and pathway selections rather than the climatic conditions. For example, the Boulder site had significantly greater DAF values or a reduction in chemical concentration at the well site when compared to the Chicago and Charleston sites. For the crop and pasture scenarios, the air pathway was the most sensitive. However, the reclamation scenario appeared the most impacted by climate with 4-Chloroaniline yielding results of 1 x 10^{-7} for the dry climate (Boulder) versus 1 x 10^{-3} for the average climate (Chicago) condition.

The SAB initially discussed the possibility of replacing Chicago with Kansas City, Missouri to represent the average condition. However, subsequent research has found Kansas City to have only marginally less rainfall than Chicago. The SAB instead recommends replacing Chicago with Omaha, Nebraska. Omaha has an annual average precipitation volume of roughly 30 inches, which is the national average for the Continental United States. Omaha has similar hydrogeological properties (Miller, 1964) as Chicago (Bretz, 1955) with limestone being the dominant parent soil material. Both features support recommending this change. There had been discussion of selecting an alternative site to represent the dry condition at a location where irrigation is the norm. However, the SAB concluded that this could be dealt with better and in greater detail in the refined risk assessment. The SAB also agrees with the EPA recommendation to utilize 41 climatic regions in the probabilistic refined risk assessment.

With respect to the overall impacts of precipitation on runoff and erosion, it was very difficult to parse out how such information was utilized in the model. Moreover, a description of chemical transport in the vadose zone is lacking. Since the intent is to make this model transparent and user-friendly, it is recommended that more explicit information be provided on how climate and soil type are utilized in the model formulations. It is not clear if runoff and erosion were considered in the BST or the probabilistic comparison of the three locations. This appears to be critical information based on rainfall and rainfall intensity. Short-duration/intense storms would likely cause more runoff but how these parameters are considered is not clear.

The following recommendations are noted:

<u>Tier 1</u>

- The SAB recommends that EPA replace Chicago with Omaha as the average meteorological location in the BST assessment as Omaha is much closer to the national average for annual precipitation than Chicago.

<u>Tier 2</u>

- The SAB recommends that EPA provide a clear explanation of how the different meteorological locations are evaluated in the BST. This should include impacts from rainfall frequency, duration, and intensity as well as how soil types impact results.

<u>Tier 3</u>

- The SAB does not offer a recommendation in this tier.

2.2.5. Exposure pathways:

EPA has developed four scenarios for the screening-level risk assessment, including specific pathways. Are the pathways for exposure simulated in the BST appropriate for a national screening-level risk assessment? If not, provide recommendations on pathways of exposure EPA should consider for the screening-level risk assessment.

The four scenarios for the screening-level risk assessment of land-applied biosolids available in the BST described in Section 6.4 of the White Paper are:

1. Agricultural land application – crop
2. Agricultural land application – pasture
3. Land reclamation
4. Disposal in a surface impoundment or lagoon

The four scenarios for the screening-level risk assessment of land-applied biosolids are appropriate for assessing human exposures as they represent potential high emissions to the environment and exposures to individual human receptors. However, the SAB finds that the current approach may not be sufficient as a national screening-level human health risk assessment. Several specific examples of enhancements to the existing human exposure scenarios or additional scenarios to complement the BST are discussed below.

1. **Dermal Exposure:** For those pathways where there is human contact with contaminated media (soil, groundwater, surface water), dermal exposures should be evaluated. It appears those pathways might include Pathways 3, 12 & 15 of the conceptual model of human exposure (see p. 20, Fig. 5, U.S.EPA, 2023).

   Many of the chemicals regulated under Part 503 are metals that could present a dermal exposure opportunity. Based on recent research, such metals can transfer to other surfaces such as general and/or personal protection equipment, and then present a dermal exposure opportunity even if there is no direct skin contact with the biosolids.

   Additionally, many of the chemical classes related to biosolids (anions, metals, polycyclic aromatic hydrocarbons, semi-volatiles, flame retardants, pharmaceuticals, steroids, hormones, and PFAS; p. 24, White Paper) have quantitative dermal transfer data in the published literature.

2. **Fish Consumption**: As noted above (Charge Question 2.2.3), the "family farm" scenario may not represent a reasonable high-end exposure estimate for fish consumption. EPA may want to consider a high fish consumption scenario separate from the family farm model such as a recreational freshwater angler or a Native American subsistence freshwater fisher, especially in relation to Executive Orders 13985 (86 FR 7009) and 14008 (86 FR 7619) regarding equity for underserved communities and environmental justice. The 2014 Fish Consumption Report (U.S. EPA, 2014) does not appear to include recreational freshwater anglers or Native American fishers among its subpopulations for usual fish consumption rates. However, the EPA Exposure Factors Handbook (EFH; U.S. EPA, 2011) has summaries of relevant studies for Freshwater Recreational Fish Intake (Table 10-5) and Native American Fish Intake (Table 10-6). Additionally, EPA may want to consider how its target analytes for fish advisories (U.S. EPA, 2000) compares to those chemicals detected in the Targeted National Sewage Sludge Survey.

3. **Family Farm**: The BST conceptual model assumes a 2.5-acre farm pond is immediately adjacent to the field where the farm family fish and where all aquatic ecological exposures occur (BST User's Guide, Appendix A, p A-1). The Guide states that the farm pond would not in most cases be considered a "water of the United States" under the Clean Water Act (see 40 CFR 230.3(t)(5)(ii), which specifically states that "Artificial lakes or ponds created by excavating and/or diking dry land and used exclusively for such purposes as stock watering, irrigation, settling basins, or rice growing" are not "waters of the United States."). Therefore, no buffer is modeled for the farm pond. Notwithstanding this policy position, the SAB finds this assumption

to be overly conservative and recommends that a 10-meter buffer be included between the farm pond and agricultural field receiving biosolids.

The four scenarios and associated ecological exposure pathways simulated in the BST *are not* appropriate for a national screening-level ecological risk assessment. The SAB finds that the farm pond and agricultural field are not appropriate ecosystems for the ecological risk assessment. The SAB recommends that EPA reconsider its problem formulation for the ecological risk assessment of land applied biosolids consistent with the Guidelines for Ecological Risk Assessment (U.S. EPA, 1998). For the ecosystem of concern or other ecological entities, it is necessary to identify attributes that are important to protect. For ecological receptors, the general practice of environmental risk assessment focuses on populations and communities. Therefore, a reasonable high-end exposure estimate should not be overly conservative. That is, the environmental exposure level should estimate conditions that might occur at a reasonable high-end across ecosystems of concern such that they are ecologically relevant for the appropriate ecological endpoint. Land application and surface disposal are appropriate uses of biosolids that should be evaluated but not at the scale of an individual family farm.
The BST is designed as a series of single media models the output of which are knitted together. The SAB notes that multimedia fate models estimate chemical concentrations in several environmental media simultaneously and at a broad scale. The SAB recommends that a larger-scale conceptual model for agricultural land application of biosolids be utilized. The SAB recommends EPA evaluate the PROduction-To-EXposure framework as a potential tool for evaluating the multimedia fate of chemicals found in biosolids that are land-applied (Li et al., 2021).

The following recommendations are noted:

<u>Tier 1</u>

- The SAB recommends that EPA enhance the existing human exposure scenarios by including dermal exposure screening where appropriate.
- The SAB finds that the farm pond and agricultural field are not appropriate ecosystems for the ecological risk assessment.
    - The SAB recommends that EPA reconsider its problem formulation for the ecological risk assessment of land-applied biosolids consistent with the Guidelines for Ecological Risk Assessment (U.S. EPA, 1998).
    - The SAB recommends that EPA revise the scenarios and pathways for the screening-level ecological risk assessment such that they reflect an appropriate scale at which population or community-level effects may be observed.

<u>Tier 2</u>

- The SAB recommends that EPA update the family farm scenario to include a 10-meter buffer between the farm pond and the agricultural field receiving biosolids.

<u>Tier 3</u>

- The SAB recommends that EPA explore the use of multimedia fate models for the screening-level ecological risk assessment.
- The SAB recommends EPA study the appropriateness of a high fish consumption scenario separate from the family farm model such as a recreational freshwater angler or a Native American subsistence freshwater fisher.
- The SAB recommends that EPA study the alignment between the list of chemicals detected in the Targeted National Sewage Sludge Survey and the list of target analytes for fish advisories (U.S. EPA, 2000).

2.2.6. User guide:

Does the User Guide describe how to use the BST for screening at an appropriate level of detail? If not, what additional information does the SAB recommend EPA add to the User Guide?

When evaluating written documents for clarity, accuracy, and usefulness it is important to keep the context in mind. While the user's manual alludes to the model being perhaps solely used by EPA it does not explicitly state who the intended target audience is or who the intended users will be. It would be helpful for EPA to articulate more clearly who the intended audience is.

The SAB raised several questions regarding the use of sets or ranges of percentages for some inputs and the absence of evaluation pathways (dermal). Questions about the mechanisms of the model are likely to be somewhat universal. It is recommended that EPA consider brief explanations as to why the inputs are limited the way they are or why certain numbers were chosen over others.

Clarity is important to any user's manual and the SAB noted inconsistencies with the term "biosolids". Different definitions were presented in sections 3 and 4 of the Whitepaper and while they were not entirely inconsistent, it could be confusing for the reader. Additionally, there are missing figure references in section 6.1 of the white paper page 17.

The User Guide should be amended to include additional guidance on the installation process. The guide currently states "The Tool will be installed in [**your_folder**]\BST. *Please note that the length of this install folder path cannot exceed 48 characters; if it does, the Tool will generate all zero results when run*". At least one member shared that issues were experienced even with a folder path shorter 48 characters. The SAB recommends adding specific suggestions for naming the file pathway during installation, e.g., C:\Users**username**\BST with the 'username 'being something simple, e.g., initials, etc. The EPA could also consider adding a note for security issues, where the user could be instructed to install the BST in their download folder to ensure they are not working from a network drive.

Currently, the User Guide provides details on chemical limitations on Pages 44-45. The SAB recommends placing this information upfront in the User Guide when first mentioned since the details are limited. Several questions are noted for specific compounds.

1. It is not clear why the model would not work for dioxin-like and PCB compounds since seems no different from things that apply to PAHs, etc. in regard to a biota-sediment accumulation factor, especially for the PAHs with more than 4 aromatic rings as well as for highly brominated organics.

2. For ionizable compounds, the guide just says, "EPA encourages you to update these estimated parameter values with reported data from peer-reviewed literature when available to reduce uncertainties." However, the biggest parameter affecting ionizable behavior is pH, which also affects some of the inorganic compounds, e.g., aluminum as one obvious example but this applies to other metals of potential concern as well. Further, whether a compound is acidic or basic also affects the sorption mechanism and the significant soil properties, e.g., cation exchange capacity in the case of basic compounds like chloroaniline that forms organic cations in environmentally relevant conditions, which then affects all the bioaccumulation-related parameters.

3. Mercury compounds were noted early on as also not appropriately addressed by the BST, but no additional details are provided on pages 44-45 clarifying the limitation.

To aid the usability, the SAB recommends adding a Table of Contents to the front of each appendix and defining all acronyms included in the appendices. Finally, there are a few places where additional text could be added to clarify the text instead of referring the user to the appendices (e.g., the guide is not clear that tilling referred to the 'depth of waste incorporation', etc.).

The following recommendations are noted:

Tier 1
[pending determination]

Tier 2
[pending determination]

Tier 3
[pending determination]

2.3. Refined Risk Assessment

2.3.1. Data sources:

The whitepaper describes data sources EPA intends to search to support conducting a refined risk assessment (section 7.1). Are there any additional existing data sources on exposure that can be used as model inputs for Monte Carlo simulations? This could include data related to distributions describing biosolids land application rate, timing, number of applications per year, and operating life of the farm. Please provide references for these data sources.

While the SAB doesn't have any specific new data sources, several recommendations are provided for input parameters used in the refined assessment probabilistic model simulations.

The main difference between the screening BST and the refined risk assessment probabilistic tool is that BST is a single-parameter assessment tool while the refined assessment tool uses a distribution for several of the input parameters in a Monte Carlo model simulation. The input parameters identified by the EPA that require input distributions are biosolids chemical concentrations, biosolids application rate, operating life of biosolids application, location of the family farm (meteorological, hydrological), farm size, nearby water bodies, drinking well placement, human consumption (crops, animals, and drinking water), body weight of individuals, and exposure duration of the contaminants. The EPA uses a variety of data sources for these input parameters that have previously undergone extensive review.

When there are not sufficient data available to develop input parameter distribution values for the probabilistic model, the EPA uses single values based on the best available data. Input parameters that currently have single input values include chemical-specific parameters (e.g., physical-chemical properties, degradation rates, human toxicity, and ecological benchmarks) and ecological exposure factors (i.e., diet fractions, consumption rates, body weights, and exposure durations). These input parameters currently do not have distribution information for the probabilistic model and selected input values are used that represent a reasonable conservative value.

For biosolids chemical concentrations, the EPA uses distributions from the Targeted National Sewage Sludge Survey (TNSSS) (U.S. EPA, 2009a, 2009b) and for chemicals not in the TNSSS the data are obtained from the literature to estimate distribution concentrations. While the SAB agrees with this approach, the SAB recommends that a literature review be conducted for the highest priority chemicals to supplement the TNSSS database since that data is now approximately 15 years old, and chemical use may have changed.

For the biosolids application rate, a single value of 10 metric tons (MT) dry weight/ha applied once per year for 40 years (crop and pasture) and a single value of 40 MT dry weight/ha applied one time (reclamation) is used. While it is mentioned in the U.S. EPA External Peer Review Document (March 2023) that a distribution may be developed and applied for the crop and pasture scenarios, it appears there is currently no distribution available for the land application rate. The SAB recommends that the U.S. EPA develop distributions for the land application rate of biosolids. Such information could be requested from State Agencies or regional EPA offices.

The operating life of biosolids application to the family farm is assumed to occur once a year for 40 years (crop and pasture). While the EPA External Peer Review Document (March 2023) states that there are distributions for the crop and pasture scenarios, there was no reference to the source of these distributions. The SAB recommends that the EPA provide more detail on which input parameters have distribution values and the source of the distributions.

For locations of the family farms, meteorological and hydrologic data are needed. Meteorological data is used in the air model and hydrologic data is used for assessing the fate and transport of chemicals in the soil, groundwater, and surface water body due to runoff. The EPA External Peer Review Document (March 2023) states that the meteorological data for probabilistic simulations represent 41 climate regions, but no specific reference was provided for the source of these data. The Biosolids Tool User's Guide (Appendix B, page B-5) (U.S. EPA, 2023a) provides input parameters for air temperature, meteorological WBAN (Weather Bureau Army Navy) station number, site latitude (degrees), mean annual wind speed, and water body temperature, which was obtained from Samson (U.S. DOC and U.S. DOE, 1993). The User's Guide also states that the meteorological inputs were obtained from U.S. EPA (2015). Since the User's Guide is for the BST, it is not clear which input parameters have distributions for use in the probabilistic model. The SAB recommends that the EPA provide more detail on which input parameters have distributions and the source of the distributions.

The agricultural field sizes were obtained from the 2012 Census of Agriculture (USDA, 2014). An 80-acre farm corresponds to the national median farm size. Probabilistic simulations are sampled from this dataset for farms up to 180 acres. The SAB agrees with this approach for assessing field sizes.

The size of nearby water bodies remains constant for all probabilistic model scenarios; thus, no distributions are currently applied. The standard farm pond size is assumed to be 1 hectare in area and 2 meters deep (U.S. EPA, 2019a) and the index reservoir is represented by Shipman City Lake in

Shipman, Indiana (area of 13 acres and depth of 9 ft, and watershed area of 427 acres). The SAB recommends that the EPA develop a distribution for nearby water bodies for the probabilistic refined assessment simulations.

Drinking water exposure is assessed either via the index reservoir or from the groundwater near the family farm. Placement of the drinking water well could significantly impact the exposure concentration. The EPA Framework document (U.S. EPA, 2023) states that the farm well may be located further downgradient and at varying depths in the refined assessment. However, there was no reference to the distributions used in the probabilistic refined assessment. The SAB recommends that the EPA provide more detail on the distribution of well placements and the source of the distributions.

The input parameters related to human exposure factors (consumption rates, body weight, and exposure duration) are also considered for use in the refined probabilistic simulations. The distributions for these input parameters were obtained from the Exposure Factors Handbook (U. S. EPA, 2011; U. S. EPA, 2017). The SAB agrees that these distributions are appropriate for use in the probabilistic refined risk assessment, although distributions for factors such as inhalation rates and dermal exposures (i.e., the dermal surface area of contact, duration of dermal contact, dermal absorption rate in mass per square surface area of skin over time, etc.) may need to be added at the refined assessment stage.

There are empirically derived and estimated BCF and BAF values available for some pathways and chemicals. In particular, the SAB recommends that the EPA develop BAF input parameter distributions for the ingestion of beef and dairy.

In summary, while the SAB does not specifically provide any recommendations on additional data sources for conducting a probabilistic risk assessment, the SAB recommends that the EPA conduct additional data searches for determining appropriate distributions for several of the input parameters used in the probabilistic risk assessment model. In addition, the SAB recommends that a sensitivity analysis be performed to determine the most influential factors for conducting the data searches.

The following recommendations are noted:

Tier 1

- The SAB recommends that the EPA conduct additional data searches for determining appropriate distributions for several of the input parameters used in the probabilistic risk assessment model. These distributions should include biosolids concentrations for the highest priority chemicals, biosolids land application rates, nearby bodies of water, and BAF values for the ingestion of beef and dairy.

Tier 2

- The SAB recommends that the EPA provide more detail on which input parameters have distributions and the source of the distributions.

Tier 3

- To guide prioritization of searches for additional data, the SAB recommends that a sensitivity analysis be performed to determine the most influential factors.

2.3.2. Transport models:

Are there alternative transport models that EPA should consider for the refined biosolids risk assessment? Please explain the basis for your recommendations and provide references.

As noted in U.S. EPA (2023, Table 3), the deterministic screening and probabilistic modeling largely rely on the same models. In the probabilistic modeling, probabilistic distributions of certain parameters are used. Below, the SAB suggests additional consideration be given to other models.

For the refined assessments, the SAB recommends that a model or models which consider background levels of common substances/contaminants be considered.

The SAB suggests that there is a need for defining the difference between the RME, which appears to be the goal of the assessment process per EPA, vs. an MEI, particularly for the refined risk assessments, and the SAB recommends that the Agency employ models that address the appropriate endpoint.

At the refined risk assessment stage, the SAB recommends that EPA should consider models that can differentiate between the total concentration and bioavailable concentration of substances in biosolids (i.e., the biosolids matrix).

The SAB has the following recommendations for the refined assessment step regarding specific pathways and parameters used or recommended for use in the BST:

1. The SAB recommends that EPA better describe the transport models being used to represent the leaching of contaminates through the till zone and the unsaturated zone to the groundwater table. The current approach takes the pore water concentration in the till zone and uses the DAF method to estimate the groundwater concentration. Depending on the soil type, chemical composition, and amount of rainfall (or irrigation), it is suggested that a better representation of the transport from the till zone to the groundwater could be simulated. The current method does not simulate chemical transport in the unsaturated zone. The screening model with DAF currently uses the EPA's Composite Model for Leachate Mitigation (EPACMTP) and the refined risk assessment uses the Hydrus model. The SAB recommends that EPA could consider using the Hydrus tool for both the screening and refined assessments. The SAB also recommends that EPA should investigate how soil and groundwater transport is modeled in the European Union risk assessment model.

2. The SAB recommends that evaluation of the air-water interface should be included for groundwater using tools such as Hydrus or Predictive Integrated Stratigraphic Modeling.

3. The EPA DAF model assumes that sorption of a contaminant occurs only by sorption to soil solids, which is appropriate for some contaminants such as metals, chlorinated solvents, and fossil fuel hydrocarbons. However, while the sorption model assumes that a contaminant is a neutral (no charge) species and sorption is determined by a Koc, many compounds are charged under agricultural soil pH conditions. The SAB recommends that EPA consider developing a model for compounds that ionize. This could be done using the Dow approach where the pH and pKa are used.

Additionally, the SAB finds that for PFAS, an assumption of sorption to soil solids is not appropriate (Brusseau and Guo, 2023). It has been reported that many PFAS analytes function as surfactants that sorb significantly at air/soil pore-water interfaces, particularly longer chain PFAS analytes (Costanza et al., 2019; Silva et al., 2021). Since the EPA DAF soil screening model for PFAS does not consider the air-water interface sorption, the SAB recommends that EPA consider the Brusseau and Guo (2023) analysis, which recently revised the EPA model. In addition, Guo et al. (2020) published a model for the retention of PFAS in the vadose zone. Specifically, this model evaluates surfactant-induced flow and solid-phase air/water interfacial adsorption and its effects on PFAS leaching potential. A simplified version of this model was recently published (Guo et al., 2022), and the SAB recommends that EPA also consider this model for use in BST.

4. The SAB recommends that it could be important for certain substances for the Agency to consider adding a dermal pathway model in the refined assessment step and that the Agency should also consider updating the human exposure pathways and routes considered in order to make the BST more internally consistent. For example, it seems inconsistent that inhalation exposure is considered during showering but not dermal exposure to the water. Additionally, it seems inconsistent to assume that a high percentage of fish consumption could occur directly from a farm pond, but that there would be no dermal exposure to the water in this pond or the solids around the pond. The EPA's 3MRA model, which is listed in the BST White Paper, does not directly address dermal exposures, and so the SAB recommends that other models should be added/considered at the refined risk assessment step. Several other EPA documents include recommendations and guidance for performing dermal exposure and risk assessments, including the Agency's 2019 Guidelines for Human Exposure Assessment (U.S. EPA, 2019), the 2007 document entitled Dermal Exposure Assessment: A Summary of EPA Approaches (U.S. EPA, 2007), and the 2004 document on dermal exposure assessment that is part of the Risk Assessment Guidance for Superfund Volume I, entitled Human Health Evaluation Manual: Part E, Supplemental Guidance for Dermal Risk Assessment (U.S. EPA, 2004). The EPA's ExpoFIRST, Exposure Factors Handbook, and EPI Suite™ tools may also be useful resource (U.S. EPA, 2011; U.S. EPA, 2012; U.S. EPA, 2016a).

5. If plant uptake is based on soil concentration in the screening-level model, the SAB recommends that a more advanced pathway model should be considered at the refined risk assessment step.

6. The SAB recommends that EPA clarify how saturated hydraulic conductivity and silt content are used in the model. It is not clear when soil biodegradation is used and when it is not used. According to the BST documentation, biodegradation was not used in the DAF assessment.

The following recommendations are noted:

Tier 1:

- The SAB recommends that at the refined risk assessment stage, EPA should consider models that can differentiate between the total concentration and bioavailable concentration of substances in biosolids (i.e., the biosolids matrix). Further, the SAB recommends that EPA should revisit the current approaches in BST for modeling of contaminant leaching through the till zone to groundwater, the current models used for sorption pathways, and the internal consistency of the human exposure pathways.

Tier 2:

- The SAB recommends that EPA define and consider background levels for common substances/contaminants evaluated in the BST model.

Tier 3:

- The SAB recommends that EPA consider updating its existing models or develop a new model that incorporates dermal exposures for human health risk assessment and allows for the assessment of multiple media, pathways, and receptors. The SAB also recommends that EPA consider developing a new sorption model for compounds that ionize.

2.3.3. Additional scenarios:

Are there additional scenarios for biosolids management that the EPA should consider for refined assessments? Please explain the basis for your recommendations.

The SAB applauds the Agency for identifying the most important biosolids management scenarios to evaluate in both the screening-level and refined risk assessments. These scenarios include 1) agricultural land application on cropland, 2) agricultural land application on pastureland, 3) reclamation of disturbed/marginal land, and 4) surface disposal in a liquid biosolids-only lagoon. While the SAB Panel acknowledges that these scenarios represent biosolids management practices with significant potential human and ecological health risks, some members have expressed concern over the Agency's decision to ignore the potential human health risks specifically associated with the biosolids land applier activities.

Upon reflection of the Agency's focus on conducting high-end chemical risk screening and the specific field activities with which a "typical" biosolids land applier would be engaged, the SAB agrees with the Agency's decision that the "farm family" scenario represents a significant greater human health risk from chemical exposure than the biosolids land applier scenario. The SAB further acknowledges that the physical distance established between the biosolids product and the biosolids land applier significantly reduces the potential human health risks associated with this scenario. For example, if liquid biosolids (< 10% solids) were land applied, they would have been initially transferred from the generation point (i.e., water reclamation facility) to an enclosed tanker truck using a pressurized conveyance system (e.g., flexible hoses or pipes). Once filled, the tanker truck would be driven across the agricultural field where the liquid product would be surface applied or subsurface injected. In either case, the biosolids land applier would remain in the truck cab during the land application event minimizing chemical exposure.

Similarly, if a dewatered or dried biosolids product (> 10% solids) were land applied, the biosolids product would have been transferred from its generation point to a staging area using a solids conveyance system (e.g., dump truck, front-end loader, or similar equipment). From the staging area, the biosolids material would be mechanically transferred to a land application vehicle (e.g., dry manure spreader or similar land application equipment) that would be pulled across the agricultural field by a tractor or equivalent farm vehicle. Since the biosolids land applier would remain in the truck, front-end loader, and/or tractor cab through the entire duration of the biosolids land application event, potential chemical exposure would be relatively minor compared to the farm family that would experience daily exposure to the biosolids product.

Before specifically addressing the question of additional biosolids recycling and/or disposal scenarios suitable for the refined risk assessment, the SAB strongly encourages the Agency to consider the number of cross-cutting scientific issues that may significantly affect the interpretation of the refined risk assessment results.

An important cross-cutting scientific issue that has been ignored in the Agency's refined risk assessment model formulation is the fate and transport of ionizable compounds and how they are influenced by different soil types (including various clay soils) and soil pH. Basis for Recommendation: The refined risk assessment model relationships established between n-Octanol/Water Partition Coefficient (K_{ow}) and bio-uptake factors were developed for hydrophobic organic chemicals. These relationships are inappropriate for ionizable compounds, which often do not exhibit hydrophobic behavior. Various mathematical relationships exist to predict Koc and the soil adsorption coefficient from K_{ow} values, but these relationships also assume that hydrophobicity is the dominant mechanism. Ionizable compounds do not follow the traditional hydrophobic organic compound paradigm because they exist in an ionic form under typical field pH conditions. The SAB strongly encourages the Agency to explicitly address the fate and transport of ionizable compounds within the refined risk assessment model formulation.

Beyond the proper modeling of ionizable compounds, the SAB recommends that EPA modify its refined risk assessment model formulation to effectively account for the irreversible chemical sorption and desorption that occurs within the biosolids-soil matrix. Since many organic compounds become irreversibly bound to either soil organic matter or biosolids-derived organic matter making them effectively unavailable to human and/or ecological receptors, the refined risk assessment model should capture these important chemical fate mechanisms when evaluating potential human health and ecological risk.

The remaining discussion summarizes additional land application and surface disposal scenarios that EPA may consider in future, more refined risk assessments.

Land Application (Beneficial Use)

1. Owing to the recent ban of all biosolids land application in the State of Maine, the Agency is strongly encouraged to conduct a refined risk assessment focused on land reclamation using large one-time application rates (i.e., > 100 dry tons/acre). While, in many states, land reclamation rates are limited to five (5) times the nitrogen-based agronomic rate, there are no federally mandated numerical limits on the amount of biosolids that may be land applied under the land reclamation scenario. There are several mining operations where successful revegetation of the sites has required one-time biosolids land application rates in excess of 100 dry tons/acre (Pepper et al., 2013).

   Land reclamation requiring the use of large amounts of biosolids has the potential to result in the accumulation of known and/or suspected hazardous chemicals, such as PFAS, in soil, plant, and animal tissue. Given current public health concerns and regulatory focus on PFAS chemicals affecting the human food supply, the SAB recommends that EPA conduct a refined risk assessment on the following specific human health exposure scenario: PFAS in biosolids → biosolids land application → PFAS uptake by animal feed crop → PFAS affected animal feed crop/PFAS affected soil consumed by dairy cattle → PFAS accumulation in milk and/or other agricultural products → human ingestion. The results of a refined risk assessment of land reclamation employing large one-time application rates will generate important technical guidance to those states where land reclamation remains an important biosolids management option. Basis of Recommendation: To reduce potential public exposure to PFAS compounds contained in commercial beef and dairy products, the State of Maine has established numerical concentration limits on specific PFAS compounds contained in land applied biosolids. Other states are considering enacting similar regulatory restrictions. Moreover, to further reduce the potential of human ingestion of PFAS-impacted food supplies, public health advisories have been promulgated by a number of states to restrict game fish and waterfowl consumption.

2. Within the BST, land reclamation is limited to the restoration of mining sites. While restoration of mining sites is required as part of the site's closure plan under federal law, there are a number of other potential land reclamation scenarios where biosolids could be utilized to restore highly disturbed and/or marginal land. Biosolids land application has been employed to restore vegetation on wildfire-damaged land, sand dunes, construction sites, and over-grazed rangelands.

Each of these scenarios has a unique set of requirements and potential human health and ecological chemical exposure pathways. For example, on over-grazed rangelands, ranchers are typically interested in maximizing the animal density on their property. The land application of large amounts of biosolids on over-grazed rangelands allows ranching operations to increase the animal stocking rate (# of acres/animal unit) and significantly increase financial profit. However, the potential exposure of grazing animals to biosolids-associated chemicals increases with the large application rates, which could potentially compromise food (dairy and meat) quality resulting in greater human health risks.

3. Within the current federal biosolids regulations (Title 40 CFR Part 503), biosolids may be legally land-applied on certain permitted sites at annual rates that are significantly greater than the nitrogen-based agronomic rate. While these dedicated beneficial use sites cannot be utilized to grow food for human or animal consumption, they may be employed to grow biomass for energy production (e.g., biofuels). The Agency should consider the potential human health and ecological chemical exposure risks that may be associated with these highly-regulated agricultural operations.

4. The Agency should consider how land application of dried (or pelletized) biosolids could negatively affect the quality of farm-generated fugitive dusts (i.e., PM10). Historically, large municipalities (e.g., City of New York, City of Boston, etc.) dry and pelletize their biosolids prior to transport and eventual land application in western states (e.g., Arizona, Texas, etc.). The plowing (or tilling) of these biosolids within relatively arid soils generates large amounts of fugitive dusts containing biosolids-associated chemicals. The respiration of these particles by farm workers has the potential to significantly increase human health risks.

5. The potential contribution of domestic septage land application on human health and ecological chemical exposure within the model farm scenario should be considered given its inclusion within the current biosolids federal regulation (Title 40 CFR Part 503 Subpart B). Approximately twenty

percent (20%) of US households utilize on-site septic systems. The residual solids removed from septic tanks (i.e., domestic septage) are legally categorized as biosolids and maybe land applied as a crop fertilizer and/or soil amendment. While domestic septage applied to non-public contact sites (i.e., private farms) does not have numerical chemical limits, domestic septage applied to public contact sites (i.e., parks, cemeteries, home gardens, etc.) must meet the same chemical numerical limits as land applied biosolids.

6. With growing interest in the land application of new biosolids products, such as biochar, understanding the public health and ecological hazards associated with these materials is vital. Biochar production consists of pyrolytic processing of biosolids. The pyrolytic process significantly reduces biosolids volume, eliminates all pathogens and generates a final product that enhances the cation exchange capacity and water holding capacity of soils.

However, because pyrolysis involves high temperature processing, the biological, chemical, and physical characteristics of biochar are significantly different from the raw biosolids product. While the pyrolysis process removes essentially all of the volatile and semi-volatile chemicals from biosolids, it also results in the concentration of many non-volatile chemical species. Because of the growing interest in biochar production and its use in agricultural operations, the Agency should consider how the final list of chemicals undergoing a refined risk assessment will be impacted if biosolids were to undergo pyrolytic treatment prior to land application.

Surface Disposal

The BST screening-level risk assessment only evaluates the surface disposal of thickened biosolids (solids content > 10%) in a liquid biosolids-only lagoon. While liquid biosolids-only lagoons are technically and financially feasible when located short distances from the water reclamation facility, in most cases, biosolids surface disposal sites are located in remote areas at considerable distances from the biosolids generation site. Given the increasing costs associated with biosolids transport, biosolids generation facilities normally reduce the moisture content of their biosolids through physical dewatering and/or drying operations.

While the SAB acknowledges that the final moisture content of surface disposed biosolids will have a minimal impact on chemical transport, the selection of surface disposal systems that permit the installation of liners will significantly affect the potential leaching of chemicals to groundwater. For example, narrow surface disposal trenches (≤ 10 feet wide) can accept liquid or dewatered biosolids but are constructed without liners. Other types of biosolids surface disposal systems such as area-filled mounds and wide surface disposal trenches (> 10 feet wide) must receive dewatered biosolids and are typically constructed with liners. The Agency is encouraged to compare the potential human health and/or ecological risks associated with these alternative biosolids surface disposal systems with the results obtained from examining the liquid biosolids-only lagoon system (constructed with or without a liner) during the refined risk assessment effort.

The following recommendations are noted:

Tier 1

- The SAB recommends that EPA conduct proper modeling of the fate and transport of ionizable compounds with consideration of how their fate and transport are influenced by different soil types (including various clay soils) and soil pH
- The SAB recommends that EPA incorporate the irreversible adsorption behavior of organic contaminants within the soil organic matter and/or biosolids-derived organic matter complex
- The SAB recommends that EPA model land reclamation scenarios that reflect the use of extremely large one-time biosolids application rates (i.e., > 100 dry tons/acre) (Pepper et al., 2013)

<u>Tier 2</u>

- The SAB recommends that EPA include a refined risk assessment on the following specific human health exposure scenario: PFAS in biosolids → biosolids land application → PFAS uptake by animal feed crop → PFAS affected animal feed crop/PFAS affected soil consumed by dairy cattle → PFAS accumulation in milk and/or other agricultural products → human ingestion.
- The SAB recommends that EPA consider the potential human health and ecological chemical exposure risks that are associated with beneficial use sites.
- The SAB recommends that EPA compare the potential human health and/or ecological risks associated with the disposal of sewage sludge in liquid-only lagoons to that associated with the disposal of dewatered biosolids cake in area-filled mounds as well as narrow and/or wide-area trenches (with and without liners).

<u>Tier 3</u>

- The SAB recommends that EPA consider the following to inform future evaluations/revisions of the BST.
    - Land reclamation is limited to the restoration of mining sites within the BST. There are several other potential land reclamation scenarios where biosolids could be utilized including being employed to restore vegetation on wildfire-damaged land, sand dunes, construction sites, and over-grazed rangelands.
    - Land-applied dried (or pelletized) biosolids could negatively affect the quantity and quality of farm-generated fugitive dusts (i.e., PM10). The respiration of these particles by farm workers (or farm family) has the potential to significantly increase human health risks.
    - With the growing interest in biochar use in agricultural operations, how will the final list of chemicals undergoing a refined risk assessment be impacted if biosolids were to be applied as a biochar product?
    - The potential contribution of domestic septage land application on human health and ecological chemical exposure within the model farm scenario should be considered. While domestic septage applied to non-public contact sites (i.e., private farms or ranches) does not have numerical chemical limits, domestic septage applied to public contact sites (i.e., parks, cemeteries, home gardens, etc.) must meet the same chemical numerical limits as land-applied biosolids.

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