October 12, 2023

EPA-SAB-24-001

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

Subject: Transmittal of the Science Advisory Board report 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 EPA's request and deliberate on the charge questions. The full SAB discussed and approved the report with revisions in a public meeting held September 21-22, 2023. Oral and written public comments were considered throughout the advisory process. This final report conveys the consensus advice of the SAB.

With regard to the entire draft for a standardized framework, the SAB wishes to commend the EPA for the overall high level of work and for its responsiveness to a broad array of community concerns. The SAB found the framework's approach to be sound and the accompanying documentation generally accessible to stakeholders. The scenarios offered within the framework reflect current biosolids managements including common, beneficial uses in agriculture.

In reviewing framework components, the SAB identified some potential pitfalls and limitations, mostly associated with adapting existing tools, processes and models to biosolids risk assessment. While the SAB includes several recommendations within this report, we would like to highlight the following:

- PICS bias: An explicit and transparent evaluation step in the framework focused on the output from the PICS process is needed. This modification would allow decision-makers to rapidly determine the scientific necessity of having to evaluate chemicals for which there is known insignificant public health and/or ecological risk.
- Appropriate consideration of the biosolids and biosolids-soil matrix: The SAB is concerned that the approach may be insufficiently nuanced to account for the unique characteristics of the biosolids matrix and for the potential modifications to chemical availability/toxicity when applied to soil. Sources of data for baseline information may conflate concentrations in biosolids with those in industrial waste streams. Concentrations must also be considered in the context of those that occur naturally and/or can be sourced to other factors common to human environments. Further, the aspects of chemical fate and transport that may be markedly different from that expected in an aqueous matrix and their controlling factors are not well-represented in the selected models. Overall, the SAB recommends a more explicit consideration of the municipal biosolids-soil matrix to ensure scientifically defensible application of the framework.
- Compounded conservatism and high-end assumptions: The SAB is concerned that assumptions made within the framework align with those expected for a Maximally Exposed Individual rather than for Reasonable Maximum Exposure. For example, farm family exposures assume subsistence farming and patterns and durations of occupancy, farming activities, and consumptions of farm-sourced food and water, that are well outside the norm of present-day family farms. The SAB notes that the vast majority of biosolids applications are made to lands that are not used for producing foods directly consumed by humans but rather to lands used for producing animal feed, fiber and/or fuel. Further, for ubiquitous compounds, consideration is needed for how high-end assumptions compare to prevailing environmental concentrations and whether risk simulations reflect our current understanding of these contaminants. For these reasons, the SAB makes numerous recommendations intended to support a more reasonable estimate of exposures without curtailing the framework's ability to identify chemicals of risk to human and ecological receptors.
- Ecological risk assessment: The SAB finds that the farm pond and agricultural field are not appropriate ecosystems for the ecological risk assessment. For ecological receptors, the general practice of environmental risk assessment focuses on populations and communities greater than an individual (family farm) pond or field and on the attributes that are important to protect. The SAB recommends the EPA reconsider its problem formulation to be consistent with its own, previously published Guidelines for Ecological Risk Assessment.
- Software ease-of-use and longevity: The SAB encountered some challenges associated with installing the software and it is not agnostic with respect to operating systems. Further, the SAB noted the BST is superimposed on a Microsoft Access database using an outdated file type, Microsoft's commitment to supporting Access is uncertain, and combined these factors suggest the software may be difficult to maintain. The SAB recommends that for the BST and all other software development efforts, the EPA carefully consider the issues of stakeholder accessibility and software obsolescence to ensure tools are aligned with their inclusivity goals and incorporate state-of-the-art technologies.

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

Sincerely,

/s/

Alison C. Cullen, Sc.D.
Immediate Past Chair
EPA Science Advisory Board

/s/

Sylvie M. Brouder, Ph.D.
Chair
EPA Science Advisory Board Biosolids Panel

Enclosure

NOTICE

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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	Maximally Exposed Individual
MRA	Multimedia, Multipathway, Multireceptor
MT	Metric Ton
NACWA	National Association of Clean Water Agencies
OC	Organic Carbon
PCB	Polychlorinated biphenyl
PFAS	Per-and Polyfluoroalkyl Substances
PICS	Public Information Curation and Synthesis
RAIDAR	Risk Assessment IDentification and Ranking
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
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 a refined, probabilistic risk assessment (probabilistic risk assessment). The purpose of the framework is to support the EPA'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., EPA need) should be considered by the EPA 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. RESPONSE TO CHARGE QUESTIONS

2.1. Prioritization

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 (U.S. EPA, 2022) and in peer-reviewed literature available publicly. Prior to now, the EPA has had no framework for risk assessment of chemicals within the complex mixture of a biosolids. The Public Information Curation and Synthesis (PICS) was originally developed to support chemical prioritization under the Toxic Substances Control Act and underwent external peer review (U.S. EPA, 2023). PICS 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. The Information Availability Metric (IAM) utilizes information and data from relevant studies and databases such as the National Sewage Sludge Surveys and published literature. The Scientific Domain Matric (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 page 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 SAB supports the PICS process and sees it as a scientifically-defensible and technically sound approach for identifying and prioritizing chemicals found within biosolids that should undergo a screening-level risk assessment evaluation. Although we applaud the EPA'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? This is important because some parameters for either the IAM or SDM, are critical. For example, (1) dose response data on a given chemical is vital since without dose response data, no risk assessment can be undertaken; (2) if multiple routes of exposure to a given chemical are possible, which of the routes is the most important to consider; (3) if a chemical is highly soluble, contaminated groundwater ingestion would be important, whereas if it is highly volatile, inhalation could be more important; and (4) with respect to incidence, bioavailable concentrations are far more important than total concentrations, particularly for metals. Further the extent to which evaluations of the IAM and SDM data would be quantitative versus subjective was unclear as was the overall weight of the IAM relative to the SDM. We encourage the EPA 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 the vast majority of available published information on metals and trace organics? If not, we encourage the EPA to conduct one.

IAM concerns:

- Are concentrations derived only from municipal biosolids and not industrially contaminated biosolids? This is a critical consideration since industrially contaminated biosolids have atypical levels of per- and polyfluoralkyl substances (PFAS). The SAB is concerned that the prioritization process may be initiated using data overly influenced by concentrations found only in industrial biosolids/waste-streams.

- Are total or bioavailable concentrations utilized? Only bioavailable concentrations should be used – total values do not provide useful information. For example, total metal concentrations are known to be greater than the bioavailable concentrations that are reflective of plant uptake (Smith et al., 2014).

- Are stated biosolid chemical concentrations current? For example, biosolid PFAS concentrations may be lower now versus twenty years ago, due to Perfluorooctane sulfonic acid and Perfluorooctanoic acid being phased out of production in the early 2000s.

- Is the biosolid matrix properly considered in modeling the fate and transport of chemicals? This is important since chemicals including metals, trace organics, and microbial pathogens are known to behave differently when contained within the biosolid matrix as opposed to being in aqueous solution. For example, there is a general consensus in the literature that metals are strongly bound to organic material due to complexation that limits their solubility and potential bioavailability in soil (Smith, 2009). An additional example is the leaching of viruses from biosolids. Chetochine et al (2006) showed that leaching from biosolids was significantly reduced by sorption within the biosolid matrix, which significantly reduced the potential for subsequent leaching through soil.

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 EPA recognize that, for some data, significant uncertainty may exist that is not captured within the SDM estimation process? For example, there is considerable variability among n-Octanol/Water Partition Coefficient (K_{ow}) values for many compounds of concern including polychlorinated biphenyl (PCB). This can result in significant differences in estimated human health or ecological risks (Linkov et al., 2005). 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. Finally, the SAB suggests that sorption be included in the SDM.

The following recommendations are noted:

Tier 1

- The EPA should examine the data and information found within the IAM and SDM to identify the maximum concentrations of chemicals of concern in biosolids that are allowable if the material is to be land applied. Biosolids with concentrations of chemicals higher than the maximum allowable level would not be eligible for land application until the industrial source of the chemicals of concern had been identified and removed from the municipal waste stream. This was the process that was implemented for metals, and the pre-treatment programs have been very successful in removing metals as an issue of concern for land application. A stringent monitoring and reporting program would be needed for implementation and compliance of this new program. A peer review panel of expert stakeholders could then review EPA's findings.[1]

Tier 2

- The SAB recommends that all data required for prioritization in the IAM and SDM should be prioritized using a quantitative approach, when possible, for critical aspects of chemical categories and their predominant exposure pathways, prior to the evaluation of the chemicals.
- The SAB recommends that EPA provide a clear and unambiguous description 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?

The 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. The SAB applauds the EPA's acknowledgement of biases within the PICS process including the potential for testing and publication bias and the statement that "a lack of available data does not indicate a lack of toxicity." However, given the expectation of data gaps and/or other limitations in the PICS approach's fit-for-purpose, the SAB also anticipates the potential for chemicals being spuriously identified as high risk or low risk. Given the Agency's limited financial resources, the SAB is cognizant of the need for efficiency in identifying those chemicals of greatest public health and environmental concern from among the over 700 already identified in land applied biosolids. To achieve greater efficiency, the SAB recommends implementation of a more formalized evaluation step for generating outputs from the PICS process. This evaluation step would consider important process nuances such as:

- Eliminating outcomes identified as artifacts due to their inherent and known biases inadvertently captured by the PICS process. These artifacts generate improbable weighting

[1] The SAB also acknowledges that a biosolid could have a chemical at concentrations that disallow land application without any comingling of sources; the EPA should also consider forwarding proposed solutions for this situation to expert stakeholders for peer review.

factors that are not germane to known biosolids exposure pathways and/or to the biosolids-soil matrix (examples previously described in 2.1.1).

- Modifying outcomes that identify human health and/or environmental risks associated with chemicals found in biosolids at concentrations that are well below the currently prevailing background levels (natural and anthropogenic) or substantially lower than levels of other, common exposure pathways. Potential examples include metals or metalloids with known occurrences of toxic geochemical background levels (Hettick et al., 2015; Kot, 2020), chemical concentrations that are on par with general dietary requirements, and/or chemicals at concentrations that are significantly lower than the intentional levels found in commercially available foodstuffs and/or other health, beauty, or personal care products. The SAB notes that currently prevailing background concentrations may attenuate over time as a result of measures that have been taken to address their anthropogenic release into the environment.

Other process nuances that could be relevant in chemical prioritization include the explicit parsing out of the chemical hazard to humans versus the ecological risks (see charge questions 2.2.1 for further discussion and recommendations).

Furthermore, the SAB encourages the EPA to provide additional clarity on how it intends to mitigate the potential elimination of those chemicals from the prioritization process for which published scientific literature may be sparse. The SAB fully recognizes that many high-risk, biosolids-associated chemicals may fall into this category, and a method to ensure their appropriate evaluation is needed. Moreover, chemicals that are known to have high toxicity and/or high exposure may be eliminated from the final list of those identified for risk evaluation if their scores were disadvantaged by the unweighted summing process employed by the SDM. While the draft framework explicitly states that the EPA "will begin by evaluating a set of chemicals from both the highest ranked chemicals by PICS for screening and a set of chemicals that were amongst the lower ranked chemicals," the SAB found that the scientific justification for this plan was vague and, therefore, wholly inadequate given the number of potential missteps that could ultimately undermine the credibility of reported outcomes. An additional, well-described, and transparent review and evaluation step would enhance the scientific credibility of the PICS process by reducing its inherent uncertainty. Ultimately, the decision framework may benefit from a geographic and state regulation component. For example, if a contaminate is only identified in a specific state and that state has regulations permitting applications resulting in concentrations higher than that identified by EPA as the level of concern, then the subsequent Risk Screening toward a Reasonable Maximum Exposure could be modified accordingly.

The SAB applauds the EPA's intention to improve future chemical prioritizations using the PICS process by identifying and implementing more conservative exposure parameters. The SAB supports establishment of a weighted (versus a summed) approach to rank chemicals within the SDM process. Establishing a scientifically defensible and transparent framework for developing and assigning weighting factors to specific chemical characteristics would advance this chemical ranking process objective.

The following recommendations are noted:

<u>Tier 1</u>

- The SAB recommends that the EPA develop an explicit and transparent evaluation step in the framework focused on the output from the PICS process. This modification would allow decision-makers to rapidly determine the scientific necessity of having to evaluate chemicals for which there is known insignificant public health and/or ecological risk. This step creates an immediate and necessary off-ramp for spuriously identified chemicals and potentially strengthens the focus for understudied, yet potentially high-risk chemicals. Inclusion of this step also permits consideration of state-specific regulations and parameters important for efficient screening toward Reasonable Maximum Exposure.

- The SAB recommends that the EPA develop weighting factors for specific chemical characteristics to be employed in the PICS process. Specifically, assigning chemical weighting factors that consider the biosolids-soil matrix conditions would result in a more efficient prioritization process.

Tier 2

- The SAB has no specific recommendations for this tier.

Tier 3

- The SAB has no specific recommendations for this tier.

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 found available, modifiable models to predict the exposure pathways, that could integrate 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 of potential concern, a more refined assessment will be conducted using a probabilistic modeling framework.

The SAB appreciates the clarity provided in the EPA's framework document (U.S. EPA, 2023) on the individual pathway model selection process. In general, the models selected are reasonable for a '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 for selecting models 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 (Arnot Research & Consulting, n.d.)[2] as a potential tool.

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 (Constanza et al., 2019; Brusseau and Guo, 2023). For the ionizability issue, the User Guide notes the limitation of ionizable compounds with a focus on organic compounds and indicates the need to conduct 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 (Sigmund et al., 2022). 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, failure to consider the role of soil pH will lead to over-predicting Al transport and adverse impacts on crops, etc.

Artificial drainage enhancements of agricultural fields are not accounted for in any models despite their prevalence, especially in the US Midwest (USDA, 2019). Subsurface, tile drainage involves 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 versus the dilution-attenuation factor (DAF).

The EPA clarified during the peer review public meetings that biotransformation is considered in the BST transport modeling within the top 2-m of soil; this point may need clarification in the User Guide. However, as pointed out in the User Guide, the risk evaluation does not include the transformation products (U.S. EPA, 2023a). 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.

EPA also noted a need to consider the IAM/human health concern bias (i.e., chemicals for which there is already a greater volume of available information and therefore a higher IAM tend to have a higher health and/or environmental impact concern (U.S. EPA, 2023)) specifically for chemicals found in biosolids and the potential that data availability, or lack thereof, may bias the deterministic/screening level analysis. It is not clear how this bias will be addressed in the process to ensure that a chemical is not inappropriately listed.

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

[2] 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.

(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 reevaluating "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.
- Likewise, many chemicals at concentrations found in biosolids could only be a risk concern to ecological receptors (e.g., aquatic communities) and not human health, which includes pharmaceuticals and other chemicals intentionally integrated into food and consumer products. Therefore, the SAB recommends reviewing concentrations acceptable to humans on this basis.
- For chemicals deemed a potential concern through the deterministic screening level assessment using the BST, the SAB recommends that EPA consider literature and/or a measurement approach to evaluate the chemical bioavailability specifically in relation to the biosolids matrix before deciding if the chemical needs to move forward to the refined risk assessment.

Tier 2

- 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.

Tier 3

- 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 regarding ecological community effects.
- EPA should ensure clarity for what is and is not stated in the User Guide concerning biotransformation, hydrolysis, and sorption are considered in the model. This would benefit the public who directly requested the information during the peer review process.

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 and the 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 (U.S. EPA, 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 SAB panelist expressed concern that it appeared EPA was seeking to protect organisms in individual family farm ponds and suggested that it may be more appropriate to look instead at ecological receptors on a population and/or community level at a greater scale (e.g., watershed scale, regional scale (U.S. EPA 1998 and 2003). This issue is further addressed in charge question 2.2.5. However, the approach taken for the specific 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) (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% grow crops for human consumption, while the remaining families raise livestock for meat and/or dairy or to grow feedstock for animals or ethanol production. Also of note, less than 1% of all agricultural land receives biosolids (U.S. EPA, 2003) and almost none of that land 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 BST, however, assumes that the surface water body "farm pond" 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 assumes uptake into fish/shellfish upon which the farm family is assumed to rely for all of their fish intake[3]. The combination of all 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.

[3] 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".

There was substantial discussion by the SAB regarding the expected low probability of the same individuals in a "family farm" simultaneously experiencing all possible exposure pathways. The BST has the same receptors 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 also incurring additional exposures from soil via field runoff, from relying on their total annual consumption of meat, dairy, crops and fish exclusively from the farm property, and from drinking and showering in impacted water from a private well. The farmer exposure scenario recommended by EPA (U.S. EPA, 2005) has several differences from the scenario used in the BST, some of which could support a protective but more realistic evaluation of exposures and risks from application of biosolids. Specifically, the default exposure pathways listed in this 2005 document do not include the ingestion of fish for the farmer exposure scenario. Furthermore, the consumption rates used for relevant ingestion pathways (such as ingestion of homegrown beef and milk or ingestion of homegrown produce) do not assume 100% is derived from the farm, but rather, only a portion of the farmer's diet. A related discussion point concerned the need to differentiate among 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 two separate and distinct risk assessments: one for the farm family and, if deemed necessary, one for dedicated workers (e.g., contract applicators) who may have occupational exposures to chemicals in biosolids.

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 (U.S. EPA, 2011). 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 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 abutter 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 suggestion would likely also be perceived as more generically representative of residents who may live proximate to such sludge disposal landfills.

Another approach which may 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 Standards for the Use or Disposal of Sewage Sludge (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). While EPA conducted some sensitivity and uncertainty analyses, a *model corroboration* for "evaluating the degree to which [the BST] corresponds to reality", should also be conducted. For example, in cases where the model exposure results indicate the potential for significant risk for an analyte based on the screening scenarios, an assessment of consistency with existing observational data should be done. As noted previously in response to charge questions 2.1.2 and 2.2.1, 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:

Tier 1

- 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 an 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.

Tier 2

- The abutter 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 for this abutting receptor are appropriately 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 result in exposure estimates that are greater than the RME. Moreover, the approach for selecting whether a central tendency or high-end value is used appears arbitrary. While the overall approach may be linked to how the EPA's Office of Water intends to interpret "…any reasonably anticipated adverse effects…" (U.S. EPA, 2023), the rationale is not transparent. 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 Bioaccumulation factors (BAFs) and Bioconcentration factors (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. As such, using high-end values for parameters in exposure modeling will result in overly conservative estimates. 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. <u>Adult Farmer</u>: 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 finfish and shellfish (raw weight) by consumers (based on U.S. EPA, 2014, Table E-7). However, the 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. Also, the generalization of higher BCFs (or BAFs) for trophic levels 3 and 4 fish may not apply to all contaminants. For example, the BCFs for PFAS (which are not lipophilic, but rather accumulate in fish through binding to proteins) may be higher in some lower trophic level fish than in higher trophic levels (Munoz et al., 2022).

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 communities with environmental justice concerns. 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) compare to those chemicals detected in the Targeted National Sewage Sludge Survey (TNSSS).

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 U.S. population (U.S. EPA, 2011, Table 16-108), the 90^{th} percentile rate for "living in the same home" is 26 years, the 95^{th} is 33 years, the 99^{th} is 47 years and the 99.9^{th} 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 farm child, consumption of milk and beef associated with the default biosolids concentration of 2.19 ppm B[a]P resulted in risk estimates of 1.1×10^{-3} and 5.1×10^{-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 both inhalation rate and dermal exposure factors among the human exposure factors included in the BST (see page 36, U.S. EPA, 2023).

The following recommendations are noted:

Tier 1

- The SAB recommends central tendency parameters should be applied when evaluating the example *subsistence farm family* including concentration of chemicals in biosolids, drinking water ingestion rates and tenure on a farm.
- 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 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 use 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 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 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 using the adult farmer fish consumption exposure scenario for fish consumption of trophic levels 3 and 4 fish at a central tendency consumption rate (e.g., 50^{th} percentile consumption rate).
- 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 for 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 TNSSS 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 representative locations selected by EPA 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 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 1×10^{-7} for the dry climate (Boulder) versus 1×10^{-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:

Tier 1

- 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.
- 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 the different soil types impact results.

Tier 2

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

Tier 3

- 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 Standardized Framework for Sewage Sludge Chemical Risk Assessment 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 Figure 5, U.S. EPA, 2023).

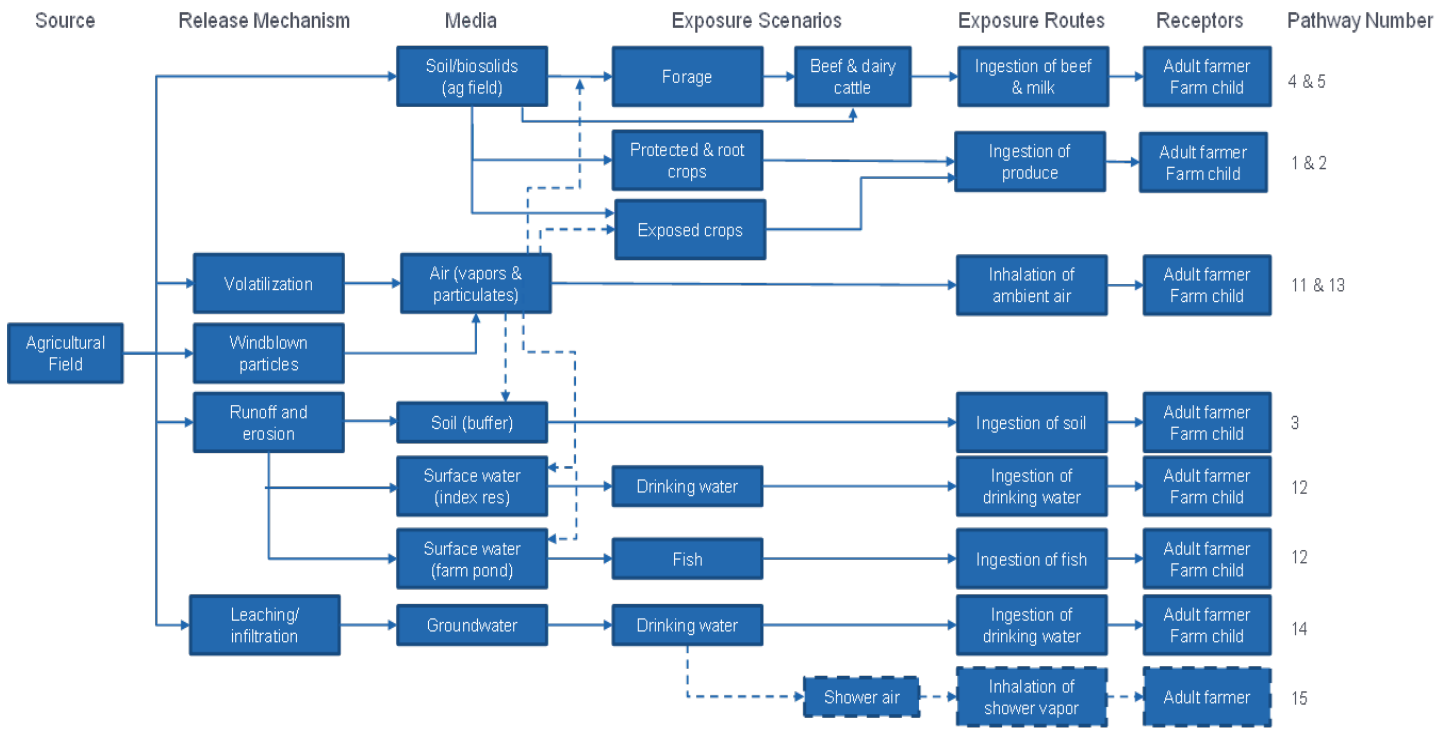

Figure 5. Conceptual model for the agricultural land application scenario and land reclamation scenario for human exposures. Dashed arrows and box outlines indicate a pathway or route that has been added since 1993 (when risk assessments that supported the Part 503 rule were completed) (U.S. EPA, 2023).

Many of the chemicals regulated under 40 CFR part 503 are metals that could present a dermal exposure opportunity through direct transfer to the skin. Studies have measured the potential for the dermal transfer from a source directly to the skin for arsenic (Hemond and Solo-Gabriele, 2004; Barraj et al., 2007; Gorman et al., 2011), iron (Avissar et al., 2004), zinc (Hughson and Cherrie, 2005), beryllium (Day et al., 2007), nickel (Lidén et al., 2008; Hughson et al., 2010; Gorman et al., 2011), cobalt (Klasson et al., 2017; Kettelarij et al., 2018 and 2018a), chromium (Lidén et al., 2008; Day et al., 2009; Julander et al., 2010; Gorman et al., 2011), lead (Enander et al., 2004; Sahmel et al., 2021, 2022) and cadmium (Gorman et al., 2011). Based on recent research, such metals or other substances may also be able to transfer to other surfaces such as general and/or personal protective equipment, and then present a dermal exposure opportunity even if there is no direct skin contact with the biosolids (Sahmel et al., 2021; Christopher et al., 2007).

Additionally, a number of the other chemical classes related to biosolids (anions, metals, polycyclic aromatic hydrocarbons, semi-volatiles, flame retardants, pharmaceuticals; see page 24, U.S. EPA, 2023) have quantitative dermal transfer data in the published literature (Vaananen et al., 2005; Api et al., 2007; Fransman et al., 2007; Henriks-Eckerman et al., 2007; Boeniger et al., 2008; Stapleton et al., 2008; Watkins et al., 2011; Keller et al., 2014; Fent et al., 2017).

It should be noted that the transfer and adherence to the skin of both soils generally and pesticides have also been measured (Holmes et al., 1999; Lu et al., 2000; Shoaf et al., 2005; Choate et al., 2006; Yamamoto et al., 2006; Aprea et al., 2009; Gorman et al., 2011). We also note that studies quantifying these values have different methodologies (e.g., mechanistic studies of soil ingestion e.g., by quantifying finger to mouth frequency, size of finger in mouth *etc.* versus by measuring soil tracers in diapers on toddlers) and the different methodologies can yield different results.

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 (2021) and 14008 (2021) regarding equity for underserved communities and communities with environmental justice concerns 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) compare to those chemicals detected in the TNSSS.

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 (see page A-1, U.S. EPA 2023a). 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 and U.S. EPA, 2003a). 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 at a scale greater than an individual (family farm) pond. 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 (e.g., watershed scale, regional scale, national scale). 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 that 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.
- 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 2</u>

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

<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 TNSSS 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 inserting 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 draft framework and while not inconsistent, they could be confusing for the reader. Additionally, there are missing figure references in section 6.1 of the framework (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 panelist experienced installation issues with a folder path shorter than 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. For example, the user could be instructed to install the BST in their download folder to ensure they are not downloading to 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 there seems to be no difference from the relevant model attributes 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 for clarification 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

- The SAB recommends that EPA provide clarifications for the inclusion or exclusion of pathways and why specific concentrations values are set. EPA should also consider including brief explanations as to why some of the parameters were set the way they were. This would help make the guide more user-friendly.

- The SAB recommends that EPA clarify the software limitations (i.e., Apple is not supported).

Tier 2

- The SAB recommends that additional clarifying language be used in the User's Guide document as described in the comments above. Specifically, the guide would be improved with the inclusion of an acronyms list and definitions. For example, the term sludge and biosolids seem to be used interchangeably. In reality, both require different land application procedures and are not the same media type. Land application of sludge is a process requiring a permit that is currently covered under regulation.

Tier 3

- The SAB recommends that EPA continue to provide public access to the BST and that the revisions to the software and user guide be user-friendly.

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 insufficient 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 TNSSS (U.S. EPA, 2009a and 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 EPA mentions 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 (U.S. EPA, 2023). The SAB recommends that the U.S. EPA develop biosolid rate distributions from the agronomic rates from different geographical regions. 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). Although EPA states that there are distributions for the crop and pasture scenarios (U.S. EPA, 2023), 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. EPA states that the meteorological data for probabilistic simulations represent 41 climate regions (U.S. EPA, 2023), but no specific reference was provided for the source of these data. The 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 (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 and 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.

The EPA should provide sources for the hazard values used in the probabilistic risk assessment model and clearly state that the hazard values are either chronic (NOEC, LOEC, NOAEL, LOAEL) or acute (LD50, EC50, LC50) values. In addition, more discussion is needed on how allometric scaling is combined with available test data to estimate terrestrial/avian hazard values. Moreover, a better explanation is needed for how the Pesticide Ecotoxicity Database was used for assessing the hazard of similar compounds. Perhaps a better source for determining ecological benchmarks is the Risk Assessment Information System Ecological Benchmark Tool.

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 the 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.

The deterministic screening and probabilistic modeling largely rely on the same models, as noted in Table 3 of EPA's Framework (U.S. EPA, 2023). 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 address background levels of common substances/contaminants be considered.

The SAB finds that there is a need for defining the difference between the RME, which is the goal of the assessment process per EPA, versus an MEI, particularly for the refined risk assessments, and the SAB recommends that the EPA clarify the goal of the assessment process and employ models that address the appropriate endpoint.

At the refined risk assessment stage, the SAB recommends that EPA 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 observations and comments regarding the refined assessment step for specific pathways and parameters used or recommended for use in the BST:

1. The SAB finds that EPA should consider improving the descriptions of the transport models being used to represent the leaching of contaminants through the till zone and the unsaturated zone to the groundwater table. It is not clear if the current approach takes the pore water concentration in the till zone and uses the DAF method to estimate the groundwater concentration or if there is an additional modeling step that estimates the transport down to two meters in the unsaturated zone. Also, it is not clear if biodegradation is taken into account in the unsaturated zone (the guidance document for the DAF determination states that biodegradation was not considered). The SAB recommends that biodegradation and sorption should be considered in any refined risk assessments. The SAB agrees with the written comments submitted by National Association of Clean Water Agencies (NACWA) (2023) that the screening risk assessment assumptions in the BST associated with DAF are too conservative for the refined risk assessment step, and in certain instances will also be unrealistic for the screening risk assessment step. 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. It is not clear that the current refined risk assessment method simulates chemical transport in the unsaturated zone. The SAB recommends that EPA consider compound biotransformation and sorption of ionizable compounds in ionization, particularly at the refined risk assessment step.

   The SAB also finds that EPA should clarify how attenuation is being addressed in the BST, again, particularly at the refined risk assessment stop. The screening model currently uses the EPA's Composite Model for Leachate Mitigation model to define the DAFs, while the refined risk assessment step uses the Hydrus model. The SAB recommends that EPA consider using the Hydrus tool for both the screening and refined assessments and eliminate the use of the DAF. The SAB also recommends that EPA investigate how soil and groundwater transport is modeled in the European Union System for the Evaluation of Substances model (ECHA, 2019) and incorporate aspects of this approach as appropriate.

   The SAB recommends that evaluation of the air-water interface - be included for unsaturated zones and groundwater modeling using tools such as Hydrus or Predictive Integrated

Stratigraphic Modeling. This recommendation is also consistent with NACWA's written comments (2023).

2. The EPA DAF model assumes that sorption of a contaminant occurs only in a neutral (no charge) species state and sorption is determined by a K_{oc}. 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 when appropriate.

   Additionally, the SAB finds that for PFAS, an assumption of sorption to soil solids may not be appropriate for modeling purposes (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.

3. The SAB finds that for certain substances, it could be important for the EPA to consider adding a dermal pathway model in the refined assessment step and that the EPA 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 Framework, 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 EPA'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 resources (U.S. EPA, 2011; U.S. EPA, 2012; U.S. EPA, 2016a).

4. Currently, use of field or lab BCFs and BAFs are recommended by EPA as part of the framework for selecting methods to derive National BAFs (U.S. EPA, Development of National Bioaccumulation Factors: Supplemental Information for EPA's 2015 Human Health Criteria Update, Jan. 2016). If plant uptake is based primarily on soil concentration and the K_{ow} in the screening-level model, the SAB recommends that a more advanced pathway model(s) be considered at the refined risk assessment step.

5. 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. As previously noted, the SAB recommends that the EPA consider using a fate and transport model for saturated and unsaturated zones in the BST at both the screening and the refined risk assessment steps.

The following recommendations are noted:

Tier 1:

- The SAB recommends that at the refined risk assessment stage, EPA consider models that can differentiate between the total chemical concentration and bioavailable concentration in biosolids (i.e., the biosolids matrix).
- The SAB recommends that EPA revisit the current approaches in BST for modeling of contaminant leaching through the till zone to groundwater and the current models used for sorption pathways that include ionization, attenuation, and fate and transport models in the saturated and unsaturated zones.
- The SAB recommends that EPA define and consider background levels for common substances/contaminants evaluated in the BST model.
- The SAB recommends that EPA examine the internal consistency of the human exposure pathways and routes used in the BST and the refined assessment. Currently, the SAB finds that evaluation of inhalation exposure potential but not dermal exposure potential in scenarios such as showering is not an appropriate application of risk assessment principles, particularly at the refined risk assessment step.

Tier 2:

- The SAB recommends that EPA consider compound biotransformation and sorption of ionizable compounds in the refined risk assessment step.

Tier 3:

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

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 EPA 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 EPA's decision to ignore the potential human health risks specifically associated with the biosolids land applier activities.

Given EPA's decision to focus on conducting high-end chemical risk screening and considering the field activities with which a "typical" biosolids land applier would be engaged, the SAB agrees with the EPA's conclusion that the "farm family" represents a significantly greater chemical exposure risk scenario than the potential risk confronting a biosolids land applier. 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, conveyor belt or similar equipment). From the staging area, the biosolids material would be mechanically transferred to a land application vehicle (e.g., spreader truck, tractor-pulled manure spreader or similar land application vehicle) that would slowly drive across the agricultural field. 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 and prolonged 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 EPA to consider a number of cross-cutting scientific issues that could potentially affect the interpretation of the refined risk assessment results.

An important cross-cutting scientific issue that has been ignored in the EPA's refined risk assessment model formulation is the fate and transport of ionizable compounds. Specifically, the model should consider how the mobility and bioavailability of these compounds is influenced by various soil types as well as soil pH. The refined risk assessment model relationships established between 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 K_{oc} and the soil adsorption coefficient from K_{ow} values, but these relationships also assume that hydrophobicity dominates the chemical fate and transport behavior. Ionizable compounds do not follow the traditional hydrophobic organic compound paradigm because they exist in an ionic form under typical field pH conditions. To enhance the robustness of the refined risk assessment, the SAB strongly encourages the EPA to explicitly account for the effects of soil type and pH on the behavior of ionizable compounds associated with land applied biosolids.

Beyond the effective modeling of potentially ionizable compounds, the SAB recommends that EPA modify its refined risk assessment model formulation to account for the irreversible chemical sorption that typically occurs within the biosolids-soil matrix. Within this unique physico-chemical matrix many organic compounds become unavailable to human and/or ecological receptors through irreversible adsorption. Utilizing the total chemical concentration found in biosolids within the refined assessment model may result in significantly overestimating the true human health and/or ecological risks. The SAB encourages EPA to account for irreversible chemical adsorption as well as other relevant mechanisms that attenuate chemical risk exposure within the refined assessment. 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) Scenarios:
In terms of a general approach to identifying additional scenarios beneficial to the Reasonable Maximum Exposure and the Risk Screening step, the SAB recommends utilizing the data reporting required in part 503 for appliers of sewage sludge (Process Design Manual Land Application of Sewage Sludge and Domestic Septage 15.6.3 EPA/625/R-95/001). Agronomically surface applied nutrients tend to stratify toward the soil surface impacting crop access to them. The most reasonable scenario for the agricultural land application crop scenario is that biosolids would either be injected or at a minimum eventually incorporated. Data from the data reporting may provide valuable insight into developing these scenarios. Additional scenario parameters that should be considered resulting in a more reasonable exposure screening include setbacks, application methods, food crops vs. commodity crops, soil pH, timing of applications, and number of subsequent applications. The SAB also recommends the following four, high-rate land application scenarios be considered for future refined assessments:

1. Given the absence of federal limits on the amount of biosolids that may be land applied under the land reclamation scenario, evaluation of beneficial use of biosolids under large, yet realistic land application rates, would allow the EPA to gauge the potential impact of this practice on ecological and human health chemical exposure. Mining site restoration, which has successfully employed biosolids land application rates in excess of 100 dry tons per acre, would represent an ideal worst-case scenario in which to evaluate ecological receptor exposure to biosolids contaminants as well as establish any potential correlation between emerging pollutant levels found in land applied biosolids and those reported in human foodstuffs (Pepper et al., 2013).

   To reduce human health and ecological exposure to current and emerging contaminants in biosolids, the establishment of chemical concentration limits are necessary, particularly in cases where large amounts of biosolids are land applied to reclaim disturbed and/or marginal lands used for animal grazing. The results of a refined risk assessment of land reclamation employing large one-time application rates will generate important technical guidance to those states and jurisdictions where land reclamation remains an important biosolids management option.

2. Within the currently available scenarios for refined assessments, the land reclamation scenario is limited to the restoration of mining sites. While restoration of mining sites is required as part of the federally mandated site closure plan, 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 (McFarland et al., 2009).

   Each of these land reclamation 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. Land application of large amounts of biosolids on over-grazed rangelands allows ranching operations to increase the animal stocking rate (animal units/acre) resulting in greater financial profits. However, the potential exposure of grazing animals to current and emerging biosolids pollutants increases with larger application rates. The economic benefits of an increased animal stocking rate must be considered and balanced against the potential adverse effects that increased soil pollutant loading have on grazing animal health and human food quality.

3. Within the current federal biosolids regulations (40 CFR Part 503), biosolids may be legally land-applied on certain permitted sites at annual rates that are significantly greater than the nutrient-

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 SAB encourages the EPA to consider the potential human health and ecological chemical exposure risks that may be associated with these highly-regulated agricultural operations.

4. The potential contribution of domestic septage land application on human health and ecological chemical exposure within the model farm scenario should be considered in the refined risk assessments given its inclusion within the current biosolids federal regulation (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) can be land applied as a crop fertilizer and/or soil amendment. While domestic septage applied to non-public contact sites (i.e., private farms, ranches) do not have to meet specific numerical pollutant limits, domestic septage applied to public contact sites (i.e., parks, cemeteries, home gardens, etc.) must meet the same numerical pollutant limits as land applied sewage sludge.

Surface Disposal Scenarios:
Only the surface disposal of thickened biosolids (solids content ≤ 10%) in a liquid biosolids-only lagoon is evaluated under the refined assessment framework. 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 biosolid's moisture content 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 limit 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. However, other types of biosolids surface disposal systems such as area-filled mounds and wide surface disposal trenches (> 10 feet wide) are typically constructed with liners. The SAB encourages the EPA to provide a scientifically-defensible explanation for its decision to include only the liquid biosolids-only lagoon scenario in the refined assessment. Unless they are demonstrated to pose an insignificant public health and ecological risk, explicit consideration of the full range of available biosolids surface disposal options are warranted within the refined assessment.

The following recommendations are noted:
<u>Tier 1</u>

- The SAB recommends that EPA conduct effective modeling of the fate and transport of ionizable compounds with specific consideration of how various soil types and pH may affect their behavior.
- The SAB recommends that EPA incorporate the irreversible adsorption behavior of organic contaminants within the biosolids-soil matrix.
- The SAB recommends that EPA model land reclamation scenarios that reflect the use of large one-time biosolids application rates (i.e., > 100 dry tons/acre) and its potential impact on public health and ecological risks (Pepper et al., 2013).

Tier 2

- The SAB recommends that EPA consider the potential human health and ecological chemical exposure risks that are associated with dedicated biosolids beneficial use sites.
- The SAB recommends that EPA compare the potential human health and ecological risks associated with the disposal of sewage sludge in liquid-only lagoons to that associated with the disposal of liquid biosolids in unlined narrow trenches as well as disposal of dewatered biosolids cake in area-filled mounds, narrow and wide-area trenches (with and without liners).

Tier 3

- The SAB recommends that EPA consider the following to inform future evaluations/revisions of the refined assessment.
  - Land reclamation is currently limited within the refined assessment to the restoration of mining sites. 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 (McFarland et al., 2009).
  - 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 pollutant limits, domestic septage applied to public contact sites (i.e., parks, cemeteries, home gardens, etc.) must meet the same numerical pollutant limits as land-applied sewage sludge.

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APPENDIX A

The following comments are noted for the EPA review documents.

Biosolids Tool (BST) User's Guide (U.S. EPA 2023a):

1. The User Guide states that scientists and staff at Research Triangle Institute (RTI), who developed this tool and associated User's Guide. (EPA Contract NO. 68HERC20D0019 Task Order: PR-OW- 20-00582. However, EPA Contract NO. 68HERC20D0019 was awarded to the Great Lakes Environmental Center, not RTI.

   EPA should clarify the developer of the BST or the contract number; which ever is applicable.