Charge Questions for SAB

EPA's Draft Standardized Framework for Biosolids (Sewage Sludge) Chemical Risk Assessment

Introduction

Assessing human health and ecological risk from pollutants found in biosolids (i.e., treated sewage sludge) is the top priority for EPA's Biosolids Program. EPA's goal is to identify pollutants, pathways, and receptors of greatest interest to inform decisions on whether to perform more refined biosolids risk assessment. EPA is committed to updating the risk assessment process by developing a risk assessment framework for surface disposed sewage sludge (i.e., sewage sludge landfill) and land-applied biosolids (crop, pasture, and land reclamation). The framework includes a prioritization process, deterministic screening-level risk assessment, and refined risk assessment.

EPA is consulting its Science Advisory Board (SAB) for feedback on this framework to assess risk more efficiently for the chemical pollutants found in biosolids. EPA is proposing a three-step process:

- **STEP 1.** Prioritize the risk assessment of chemical pollutants found in biosolids using the EPA's Public Information Curation and Synthesis (PICS) process.
- **STEP 2.** Conduct deterministic screening-level risk assessments using the Biosolids Tool (BST).
- **STEP 3.** Conduct refined risk assessments for chemicals that pose the greatest risk.

The use of a prioritization method and screening-level model will help the Agency focus limited resources on chemicals that pose the greatest potential risk to human health and the environment. The screening process may also identify areas of research needed to address data gaps and uncertainties. The model and associated user guide are included as part of this SAB review. More complex, resource-intensive risk assessments are intended for chemicals that fail the screening-level assessment.

Overall charge: EPA is seeking SAB comment on the overall risk assessment framework, including the prioritization process and the choice of models and usability of the BST by risk assessors. EPA intends to use the risk assessment framework as the foundation for EPA's human health and ecological risk assessment for chemicals found in biosolids.

Charge Questions

1. **Prioritization**

Hundreds of chemicals have been detected in sewage sludge over the past several decades, and EPA needs a process to efficiently prioritize chemicals that require a refined risk assessment. To accomplish this goal, EPA is using PICS approach to support chemical risk assessment prioritization for biosolids. The PICS approach, originally developed to support chemical prioritization under the Toxic Substances Control Act (TSCA), integrates publicly available hazard, exposure, persistence, and bioaccumulation information for chemical substances. The PICS approach synthesizes information from traditional methods and new approach methods (NAMs) to understand the overall degree of potential concern related to human health and the environment. This PICS approach also provides information on the relative coverage of potentially relevant human health and ecological toxicity and exposure information.

a. 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?

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

2. Deterministic Screening-level Risk Assessment:

EPA has developed a deterministic Biosolids Tool (BST) to evaluate if chemicals found in biosolids need a more refined risk assessment. By using health-protective, high-end exposure scenarios, the BST allows EPA to determine whether a chemical in biosolids poses risks of concern to human health and the environment and which pathways are of greatest concern. BST exposure scenarios are modeled for four biosolids management practices: three land application practices (crop, pasture, and land reclamation) and one surface disposal practice (sewage-sludge landfill). The human exposure pathways in the crop land application scenario are consistent with the conceptual model EPA has used in previous assessments that have been reviewed by the National Academy of Sciences (NAS, 2002). The land application scenario is the most complex and focuses on a farm family that lives and works near a field with land-applied biosolids, grows their own food, and eats fish from a farm pond. The conceptual model includes ingestion of contaminated drinking water, soil, crops, milk and meat, and inhalation from the chemical volatilizing from the farm field and during showering. These pathways are consistent with those recommended by NAS in 2002. Ecological receptors including aquatic and terrestrial species are evaluated based on their dietary exposure and direct exposure to contaminated surface water or soil. The other scenarios in the BST allow simulation of human and environmental risk from biosolids applied to pasture, reclaimed lands and disposed in landfills. The pathways and receptors for these scenarios are a subset of those modeled for land application, as described in the whitepaper and user's manual for the BST. If a chemical fails the risk screen using the BST, then EPA prioritizes the chemical for a refined risk assessment to provide a more complete understanding of the risks, and if necessary, risk management. On the other hand, if a chemical passes the risk screen (e.g., low risk) the EPA would consider the chemical to be a lower priority for a refined risk assessment. Screening may also be helpful to identify important data gaps or areas for additional refinement (e.g., exposure/toxicity assumptions and inputs). The BST is designed for use by experienced risk assessors and should provide consistency and transparency for EPA's screening-level risk assessments.

a. 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.

b. 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.

c. 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.

d. 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.

e. 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.

f. 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?

3. Refined Risk Assessment:

Chemicals that are determined to pose a potential risk to human health or the environment using the BST at the screening -level risk assessment stage will be prioritized for a refined risk assessment. The refined assessment could utilize a Monte Carlo simulation if sufficient information is available (e.g., nationally representative concentrations in sewage sludge). This step of risk assessment could also entail deeper evaluation of inputs used in risk assessment, inclusion of analog data to fill data gaps, and/or further consideration of pathways or receptors that pose the greatest potential risk (as identified by the BST). The refined risk assessment may also apply additional managment scenarios and/or pathways, if necessary.

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