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MEMORANDUM | November 4, 2009

TO Richard Benware; U.S. EPA, Office of Resource Conservation and Recovery

FROM Christopher Lewis, Sarah Bolthrunis, and Mark Ewen; Industrial Economics, Incorporated

SUBJECT Peer review of "Risk Evaluation of Spent Foundry Sands in Soil-Related Applications"

The Office of Resource Conservation and Recovery (ORCR) of the U.S. Environmental Protection Agency (EPA), through the Resource Conservation Challenge (RCC), promotes the beneficial re-use of industrial and municipal by-products. In 2002, the U.S. Department of Agriculture's Agricultural Research Service (USDA-ARS) implemented the Foundry Sand Initiative to evaluate the re-use of spent foundry sands (SFS) in horticultural and agricultural applications. As part of this effort, EPA worked in collaboration with USDA-ARS and Ohio State University to investigate the potential risks associated with such activities. These entities then produced, through contract with RTI International, a draft report entitled "Risk Evaluation of Spent Foundry Sands in Soil-Related Applications" (Risk Assessment).

Subsequently, EPA retained Industrial Economics, Incorporated (IEc) to conduct an independent peer review of the Risk Assessment. This memorandum presents a description of the peer review process and summarizes the results of the peer review. Each of the peer reviews is included as an attachment to this memorandum. A copy of all materials sent to the peer reviewers is provided under separate cover.[1]

THE PEER REVIEW PROCESS

IEc conducted the review in accordance with the Peer Review Handbook, published by EPA (third edition, June 2006). Our management of the review consisted of the following general activities:

- Independently identified a list of 20 candidate expert peer reviewers, taking into consideration recommendations provided by EPA-ORCR related to targeted areas of expertise.
- Evaluated the expertise and appearance of potential conflict of interest or lack of impartiality of each of the 20 candidate expert peer reviewers.
- Determined the interest and availability of 16 of the 20 of candidate expert peer reviewers.

[1] We provide these review materials in a separate packet due to the volume of the Risk Assessment and supporting materials.

- Confirmed with each of the 16 candidate peer reviewers his or her area and level of expertise and any potential conflict of interest or lack of impartiality, or the appearance of any potential conflict of interest or lack of impartiality.
- Based on availability and interest, and excluding any candidates with any potential conflict of interest or lack of impartiality, or the appearance of any potential conflict of interest or lack of impartiality, created a short-list of eight candidate expert peer reviewers and a preferred panel of four peer reviewers.
- Finalized a team of four expert peer reviewers.
- Initiated the review.
- Coordinated with the peer reviewers to finalize their written reviews.

The review was conducted as a letter review. Each of the reviewers received a packet of review material consisting of the following documents:

- Cover Letter explaining the peer review process;
- Risk Assessment;
- Appendices to the Risk Assessment;
- Errata sheet for the Risk Assessment;
- Comments on the Risk Assessment made by the Michigan Department of Environmental Quality, the American Foundry Society, and U.S. EPA-Region 9;
- Article by Dayton et al. entitled "Characterization of physical and chemical properties of spent foundry sands pertinent to beneficial use in manufactured soils" (in review; Plant Soil); and
- Charge questions.

In seeking candidates to serve as expert peer reviewers, as well as in our selection of the final team of reviewers, we made an effort to include individuals with expertise in one or more of the areas outlined in Exhibit 1.

EXHIBIT 1 AREAS OF EXPERTISE SOUGHT IN POTENTIAL PEER REVIEWERS

AREA OF EXPERTISE	DESCRIPTION
Human Health Risk Assessment	Expertise in the methods and approaches to conducting human health exposure and risk assessments, including experience creating or reviewing exposure and risk assessment documents and familiarity with multimedia risk assessment
Soil / Plant Science	Expertise in the field of soil science, including metals transport in soils and metals uptake in plants
Groundwater Hydrology	Expertise in the methods and approaches used for modeling the fate and transport of contaminants in groundwater, as well as the effects of soil properties on groundwater movement

The final panel of expert reviewers included (with area of expertise in parentheses):

- Dr. Donna Vorhees, The Science Collaborative (Human Health Risk Assessment)
- Dr. Mary Fox, Johns Hopkins University (Human Health Risk Assessment)
- Dr. Ken Barbarick, Colorado State University (Soil Science)
- Dr. Charles Harvey, Massachusetts Institute of Technology (Groundwater Hydrology)

Each of the reviewers was allowed four weeks to complete his or her review. Upon receipt of the letter reviews, we reviewed each of them and clarified any inconsistencies and corrected any typographical errors with the assistance of the reviewer, and finalized the reviews. We outline the major findings and points of interest from the reviews, and provide short summaries of responses to individual charge questions below. We also include each of the final reviews provided by the peer reviewers as attachments.

MAJOR FINDINGS AND POINTS OF INTEREST

Each of the reviewers generally focused on those aspects of the Risk Assessment within the purview of his or her particular area of expertise. Taking the reviews together, the reviewers generally approved of the scientific methodologies applied in the analysis and the approach used for the Risk Assessment. The reviewers also highlighted the challenge of developing a national-scale risk assessment, and noted that given the challenges inherent in such a task, the authors successfully assembled a complex analysis. For example, Dr. Harvey noted: “The breadth of the study is impressive, and the assessment makes ingenious use of a variety of existing models and data sets” (p. 1). However, Dr. Vorhees reiterated a comment made by EPA Region 9, noting “this risk assessment might serve as a model for similar assessments of materials that might pose greater risk than SFS to ecological and human health…[and should be] held to a high standard with respect to methodology and documentation" (p. 1). As such, Dr. Vorhees and the remainder of the review panel also identified a variety of issues with the Risk Assessment and provided a number of suggestions for its improvement; in addition, none of the reviewers indicated that the Risk Assessment was ready to be finalized in its current draft form. Key issues identified by more than one reviewer include the following:

- **Technical Concerns.** Each of the reviewers raised a variety of technical issues. In general, the identified technical issues included, but are not limited to: the improper exclusion of pathways (Dr. Vorhees, Dr. Barbarick, and Dr. Fox); math errors in the probabilistic modeling (Dr. Fox); use of outdated data sources (Dr. Fox and Dr. Vorhees); inadequate characterization of uncertainty (Dr. Vorhees and Dr. Harvey); and the insufficient assessment of risk to general soil biota and wildlife (Dr. Barbarick and Dr. Fox). One reviewer, Dr. Fox, noted that "There are problems with implementation of the probabilistic modeling that compromise the conservatism of the home-produce ingestion pathway and ultimately the risk assessment findings and conclusions" (p. 1).

- **Organization.** Both of the human health risk assessment experts, Dr. Vorhees and Dr. Fox, noted that the organization of the Risk Assessment needed improvement. Specifically, Dr. Fox stated: "Parts of the report are poorly organized and lack clarity, particularly sections of Chs. 3 and 6 and the rationale and approach to the probabilistic modeling" (p. 1) and "the clarity [of the Risk Characterization section] is compromised by some organizational issues – there are some sections that appear out of place and some sections that don't seem well integrated into the discussion at all" (p. 6) Dr. Vorhees similarly notes that the selection of chemicals of concern is "spread out across Sections 3, 4, and 5, which makes it slightly difficult to follow" (p. 6). In addition, she identifies several other instances where discussion of certain topics is spread across numerous sections, and suggests later in her review that "the authors should clearly and succinctly document quantitatively how screening steps throughout the report ensure that SFS use will not be associated with cumulative risk levels of concern" (p. 9).

- **Transparency.** Three of the four reviewers identified areas where the Risk Assessment lacked transparency or would benefit from the inclusion of additional information or details about the analytical approach. For example, both Dr. Fox and Dr. Vorhees noted that, in addition to technical concerns they raised, the probabilistic risk assessment approach lacked sufficient documentation to allow for a full assessment of the validity of results. Dr. Fox also noted that she "would like to see a 'Data and Research' section where authors comment on the data quality, data gaps, and the feasibility/desirability of a validation study or other research needs" (p. 6). Dr. Harvey noted that hydrological models used in the analysis were not sufficiently explained to adequately evaluate results.

- **Tone.** Three reviewers noted that the Risk Assessment included language that strayed from that normally used in an objective evaluation of risk. Dr. Vorhees noted a tone of "advocacy" (p. 14) and Dr. Harvey identified a statement as a "value judgment" (p. 1), noting that one concluding statement in the Risk Assessment "combines both a quantification of the risks and an assessment of whether the risks are acceptable." Dr. Harvey went on to note: "I think the document would be easier to follow, and would remain just as valuable, if it simply stated the purpose of providing a good assessment of the risks, and then adhered to this narrower purpose" (p. 2). Dr. Barbarick highlighted a similar comment made by EPA Region 9, stating: "The USEPA Region 9 comments point out the mixing of Risk Assessment and Risk Management approaches. I agree that this needs clarification and the report should focus on Risk Assessment" (p. 2).
- **Justification of assumptions and statements.** Several of the reviewers indicated that some assumptions used and statements made in the Risk Assessment were not sufficiently supported by data or information. For example, Dr. Harvey noted that risk statements tied to comparisons of metal concentrations in SFS to background concentrations needed to be caveated, and Dr. Vorhees and Dr. Fox identified several circumstances where assumptions were inadequately supported. Dr. Fox, in her review, also highlights some statements for which citations are needed; for example: "Statement is made that composition of SFS may reduce bioavailabilty of lead but no reference is provided" (p. 6). Dr. Vorhees points out that the justification for eliminating the dermal contact pathway for exposure via groundwater and soils was not sufficient and that "The authors provide no justification for assuming that the fugitive dust pathway and ingestion pathway for soil should be separate" (p. 8).

RESPONSES TO CHARGE QUESTIONS

The majority of reviewers' responses consisted of answers to direct charge questions. Below we repeat individual charge questions, followed by a short summary of reviewer responses.

1) *Please comment on the transparency of the risk assessment.*

   Three reviewers (Drs. Barbarick, Fox, and Vorhees) responded that the risk assessment was, for the most part, clear and transparent. Drs. Fox, Harvey, and Vorhees also provided suggestions on how to improve upon the Risk Assessment's transparency. For example, Dr. Vorhees specifically proposed inclusion of a graphical overview of the assessment to improve transparency. One common suggestion (Drs. Fox and Harvey) was to provide a more thorough explanation of the soil/ingestion pathway. Other suggestions included improving the clarity of the Risk Assessment's intent and purpose (Dr. Harvey), and making the organization of the report more succinct (Dr. Vorhees).

2) *Please discuss the adequacy of the risk assessment execution.*

   Three of the reviewers (Drs. Barbarick, Fox, and Vorhees) responded that the execution of the Risk Assessment is adequate. These reviewers agreed that the models used are appropriate. Dr. Harvey (not in agreement) questioned the validity of the groundwater model (and proposed that a simpler model would be sufficient) and proposed changing the distance assumption for the inhalation exposure model to make it more likely to overestimate rather than underestimate risk. In addition, Dr. Fox noted that "data limitations and issues with implementation of the probabilistic modeling…compromise the author's claims of conservatism and the assessment conclusions" (p. 2).

3) *Please comment on whether the selection of U.S. foundries was representative of the industry and if the characterization of these foundry sands was adequate.*

   There was not consensus among reviewers on whether the sample of foundries or the characterization of foundry sands is adequate. Dr. Barbarick affirmed that the selection of foundries is adequate and that foundry sands are well-characterized, while Dr. Vorhees agreed that it "appears" (p. 5) to be a representative, but presented multiple questions for consideration, particularly related to SFS characterization. Dr. Fox noted that more detailed information was necessary to affirm that the selection of U.S. foundries is representative of the industry (e.g., overall size of the industry, proportion of the industry represented by the 43 samples, geographic representativeness) but affirmed that the characterization of SFS is adequate. Dr. Harvey questioned the adequacy of the sample size. Suggested revisions (Drs. Fox and Vorhees) included clarifying citations for the foundry sands research and expanding the explanation of the data sources.

4) *Please comment on the methodology used for choosing constituents to evaluate.*

   Generally, the reviewers agreed that the methodology used for choosing constituents to evaluate is adequate. However, two reviewers (Drs. Harvey and Vorhees) pointed out shortcomings in the methodology: (1) mercury and selenium are missing from the model; (2) an expert should review possible organic contaminants; and, (3) it is unclear why cumulative risk levels are not considered.

5) *Please comment on the conceptual models, particularly the plausibility of the sources, pathways, and receptors included.*

   Three reviewers (Drs. Fox, Harvey, and Vorhees) generally agreed that the conceptual models used in the Risk Assessment capture the appropriate sources, pathways, and receptors; but they also identified problems in some of the conceptual models used. Dr. Barbarick and Dr. Fox commented that the review omits the consideration of potential leaching of components from the storage pile. Dr. Barbarick provided two suggestions for pursuing this pathway further: including a series of batch leaching studies and utilizing breakthrough curves. Dr. Fox questioned ruling out contact and ingestion of air deposited particles as a potential exposure pathway for wildlife. Finally, Dr. Vorhees expressed concern about the exclusion of dermal contact with soil and groundwater pathways.

6) *Please discuss the appropriateness of the Manufactured Soil conceptual model, as protective of the other conceptual models.*

All reviewers agreed that the manufactured soil model is protective of the other conceptual models. Dr. Vorhees suggested including a discussion of current and future controls on SFS use, as well as addressing questions such as the amount of SFS produced and whether a home gardener could also be exposed through food purchased at the super market or from community agriculture, if SFS use in agricultural soils were to become widespread.

7) *Please discuss whether the screening steps reported in Chapter 4 were appropriately conservative in their application to support the conclusions.*

Three of the reviewers (Drs. Barbarick, Fox, and Vorhees) agreed that the screening steps are conservative, though Dr. Vorhees voiced concern about cumulative risk levels. Dr. Harvey pointed out that the distance from the nearest source used in the inhalation screening is likely not conservative (i.e., is less likely to overestimate risk than choosing a closer distance) and pointed out a number of potential shortcomings in the groundwater model, noting that using a simpler model might be preferred to using default values in a sophisticated model. He also noted that the data and information regarding the groundwater model was insufficient to characterize the level of its conservatism.

8) *Please comment on the appropriateness of the various probabilistic modeling steps employed to develop national-scale screening values.*

Though three of the reviewers (Drs. Barbarick, Fox, and Vorhees) conveyed that the probabilistic modeling steps are reasonably appropriate, the reviewers provided numerous suggestions for improvement of this section. Specifically, reviewers noted: (1) some data applied in the Risk Assessment is dated and should utilize newer data on produce consumption and body weight in particular; (2) statistical methods and assumptions should be revisited, and presentation of results and methodology may be improved with revisions; and (3) since this assessment is designed for states to utilize, results and methods should be presented in a way that makes them easily understood and replicable.

9) *Within the context of a screening risk assessment, please comment on the level of conservatism inherent in the Home Gardener scenario, with special attention to the assumption of independence of the ingestion pathways. Please also comment on the rationale for modeling the 50%tile and 90%tile general population consumption rates, each with a 50% homegrown fraction.*

Dr. Barbarick stated that the Home Gardener scenario is “very conservative” (p. 2) and that the general population and independence of ingestion pathways are appropriate assumptions. The other three reviewers presented various qualms. Two reviewers (Drs. Fox and Vorhees) agreed that the model is conservative, but not a "significant overestimation" (p. 4 and p. 13, respectively) as the review states. Two reviewers (Drs. Harvey and Vorhees) found the assumption of independent consumption pathways to be unsubstantiated. Drs. Fox, Harvey, and Vorhees pointed out that the assumptions made throughout the model, including the assumption of consumption levels and some statistical assumptions for the probabilistic model, were too simplified, unclear, or unsubstantiated. These three reviewers also generally found the documentation of referenced data/assumptions to be inadequate.

10) *Please comment on how soil background, phytotoxicity, and impacts on soil biota were considered in the assessment.*

Dr. Barbarick found the soil background, phytotoxicity, and the impacts on soil biota adequate, but suggested further study methodologies to expand on the analysis. Of the three other reviewers, none provided substantial feedback on the adequacy of the soil background, phytotoxicity, or the impacts on soil biota. Dr. Fox declined to respond, noting that the question is out of her area of expertise; Dr. Harvey commented only that the research used is "broad and representative" (p. 7); and Dr. Vorhees made some suggestions to improve clarity and the applicability of the analysis to individual states.

11) *Please comment on the clarity of the Risk Characterization section, with special attention to the discussion of uncertainties.*

All four reviewers found the Risk Characterization and discussion of uncertainties reasonably clear. Suggestions for improvement included improving organization to assist with clarity (Dr. Vorhees and Dr. Fox), discussion of data quality and data gaps (e.g., organic contaminants; Dr. Harvey), and broadening the discussion of uncertainties (Dr. Vorhees and Dr. Harvey).

12) *Please comment on whether the assessment supports the report's conclusions.*

Three of the reviewers (Drs. Barbarick, Harvey, and Vorhees) stated that the assessment supports the report's conclusions. Dr. Fox, however, stated that she does not believe that the conclusion is sufficiently supported given shortcomings in the probabilistic modeling. Drs. Fox, Harvey, and Vorhees each noted that issues raised in their respective reviews needed to be addressed in order to fully endorse the conclusion.

LIST OF ATTACHMENTS

Following is a list of attachments to this memorandum.

- Review by Dr. Donna Vorhees
- Review by Dr. Mary Fox
- Review by Dr. Ken Barbarick
- Review by Dr. Charles Harvey

THE SCIENCE COLLABORATIVE
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September 14, 2009

Christopher Lewis, Sc.D.
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Re: Review of Risk Assessment of Spent Foundry Sands in Soil-Related Applications (Peer Review Draft, May 2009)

Dear Dr. Lewis:

Thank you for the opportunity to assist you in reviewing the May 2009 peer review draft *Risk Assessment of Spent Foundry Sands in Soil-Related Applications* (the "risk assessment"), authored by RTI, International, and developed jointly by the U.S. Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA), and Ohio State University. This letter provides my responses to questions in the Charge to Peer Reviewers.

Scope of Review

My comments largely relate to the human health risk assessment as this is my primary area of expertise. Some of my comments have already been raised in the public commentary received by EPA.

I reviewed the following documents:

- Charge questions
- Draft Risk Assessment
- Appendices to the draft Risk Assessment
- Errata sheet
- Comments on the draft Risk Assessment by the Michigan Department of Environmental Quality, the American Foundry Society, and EPA Region 9
- Dayton, E.A., S.D. Whitacre, R.S. Dungan, and N.T. Basta. In review. Characterization of physical and chemical properties of spent foundry sands pertinent to beneficial use in manufactured soils. *Plant Soil.*

Summary of Review

This report benefits from recent research targeting spent foundry sands (SFS) characterization that supports the evaluation of exposure. SFS appears to contain chemical concentrations that are similar to what is found in undisturbed soils under natural conditions. In addition the authors explore whether other factors besides concentration might result in more exposure to chemicals in SFS relative to natural soil and conclude that there is limited potential for such increased exposure. Therefore, it is understandable to propose use of SFS for manufactured soil and other beneficial uses. The authors present a labor-intensive, national-scale risk assessment to determine risk associated with likely uses of SFS. Like all risk assessments, this one is inherently uncertain. The authors understand this reality and carefully explain many sources of uncertainty both qualitatively and quantitatively in the form of a probabilistic risk assessment for exposure pathways believed to be associated with the highest levels of exposure. But as has been noted by EPA Region 9 in its comments, this risk assessment might serve as a model for similar assessments of materials that might pose greater risk than SFS to ecological and human health. Therefore, the assessment should be viewed in this light and held to a high standard with respect to methodology and documentation. In general, my comments focus on opportunities to improve what is generally a sound and useful risk characterization of the beneficial use of SFS.

Major issues requiring attention are:

1. The risk assessment should incorporate exposure information from EPA's Final Child-Specific Exposure Factors Handbook (September 2008). This guidance document provides more recent reviews of exposure data and recommendations for point estimate and distributions of some risk model inputs than those provided in EPA's 1997 Exposure Factors Handbook.

2. The probabilistic risk assessment (PRA) complies with much of what EPA recommends in its PRA guidance (EPA 2001), but some additional documentation and potentially additional analysis is warranted. I refer to EPA recommendations in my responses to charge questions.

3. The risk assessment should provide a brief, succinct explanation of why, despite multiple screening steps, cumulative risks associated with SFS use are below pre-established levels of concern.

Responses to Charge Questions

1. Please comment on the transparency of the risk assessment.

The document is generally clear and well-organized although it would benefit from more succinct text in some places. For example, the statement that SFS is assumed to comprise 50% of manufactured soil appears 11 times in Sections 1 through 5 alone.

Provide graphical overview of the assessment. A single graphic that shows steps in COC selection, the deterministic screening analysis, the probabilistic analysis, and the relationship between the deterministic and probabilistic analyses would help improve clarity of the document. Figure 3-4 is a start but is missing important information about how COCs were selected in a manner that ensures cumulative risks (i.e., risk across exposure pathways and chemicals that together might cause an adverse health outcome) associated with use of SFS do not exceed levels of concern. This understanding is important for states to determine whether use of SFS will meet their risk management goals.

Compliance with EPA Condition #1 for probabilistic risk assessment (PRA). EPA (2001) requires that:

> *The purpose and scope of the assessment should be clearly articulated in a "problem formulation" section that includes a full discussion of any highly exposed or highly susceptible subpopulations evaluated (e.g., children, the elderly). The questions the assessment attempts to answer are to be discussed and the assessment endpoints are to be well defined.*

The assessment includes a "problem formulation" section, which discusses the purpose and scope of the assessment and defines the primary question and assessment endpoints to be addressed: "determine whether the proposed unencapsulated uses of SFS have the potential to cause adverse health or ecological effects (for this assessment, we used the following risk management criteria: 10-5 risk for cancer effects and an HQ of 1 for noncancer and ecological effects)."

The problem formulation does not include discussion of highly exposed or highly susceptible populations, but this discussion appears later in Sections 5.3.2 in the context of the PRA (i.e., home gardeners more exposed than the general population) and 6.3.5 (i.e., discussion of the potential for plants to take up concentrations of cadmium and selenium that pose a concern for human health).

Highly exposed populations. The document would benefit from a clear discussion of the population targeted for evaluation – not just identifying the scenario (e.g., home gardener) - but the degree of exposure. The authors explain that the analysis is intended to be protective of the 90^{th} percentile exposure level, but does not clearly define this criterion until Section 5.1.

Susceptible subpopulations. The problem formulation appropriately discusses the importance of evaluating children separately from adults, given their potentially higher intake to body weight ratios. The screening analysis does not explicitly evaluate childhood exposures, but the probabilistic exposure assessment includes four age groups for individuals younger than 20 to account for variation in exposure over this time interval. These groups do not include the 0-1 year old life stage, and the authors assume that this exclusion overestimates risk. How is risk overestimated if the intent is to evaluate risk to an individual who is more than 1 year old? If the intent is to evaluate someone from birth, then why not do so? At a minimum, discuss the significance of ignoring this age group should be discussed (i.e., explain that there is no exposure from birth to about six months when babies typically do not eat solid food and review what is known about body-weight normalized ingestion rates for babies 6 months to one year old). More important, the risk assessment makes no reference to EPA's most recent guidance for evaluating childhood exposures (Child-Specific Exposure Factor's Handbook, September 2008, Final). All analyses should be re-visited and updated as appropriate after considering the relevant data, analyses, and recommendations in this guidance document.

Except for lead and its associated CDC benchmark blood concentration, chemicals of concern selected in the assessment do not have toxicity values that are specific to susceptible subpopulations (e.g., PAH age-dependent adjustment factors). However, the authors should discuss the potential for increased susceptibility among certain subpopulations in general, how they checked for this potential in evaluating risk from use of SFS in manufactured soil and other applications, and the results of their evaluation.

2. Please discuss the adequacy of the risk assessment execution.

Overall, the execution of the risk assessment is adequate and excels in some respects. My responses to all charge questions highlight opportunities to improve the document.

This charge question relates to EPA's condition #2 for PRA:

> *The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results) are to be documented and easily located in the report. This documentation is to include a discussion of the degree to which the data used are representative of the population under study. Also, this documentation is to include the names of the models and software used to generate the analysis. Sufficient information is to be provided to allow the results of the analysis to be independently reproduced.*

The assessment includes documentation of models, data and assumptions used to perform all analyses, except as otherwise specified in responses to charge questions. Ideally, the final version of this risk assessment will include either (1) the Dayton et al. paper with SFS data, which is referred to as "under review," or (2) reference to the version of this paper that is accepted for publication in a peer-reviewed journal. How well the data represent SFS is a separate question that is addressed in response to charge question #3. The assessment briefly describes EPA models such that all work could be independently reproduced. Some additional discussion of the 3MRA model would be helpful for the reader to understand the modeling in greater detail. However, it is possible for a reader to consult EPA guidance regarding the model as well as the software itself.

3. **Please comment on whether the selection of U.S. foundries was representative of the industry and if the characterization of these foundry sands was adequate.**

The selection of U.S. foundries appears to be representative of the industry. The characterization of foundry sands appears to have included chemicals that might reasonably occur in SFS and have the potential for causing adverse health outcomes. However, additional documentation is needed to ensure the representativeness of the foundry sampling effort, which is the basis of all risk analyses.

Sections 1.1 and 1.2 refer to a multiyear research project conducted to characterize inorganic and organic constituents in SFS and to assess the potential mobility and uptake of these constituents by environmental receptors. The authors say that the results of this research are in the public domain, but do not list any citations. Including them all in one place early in the document would briefly convey the scope of the multiyear study.

In the first paragraph of Section 2.4, the authors explain that "the foundry industry routinely analyzes their sands for metals and/or organics," but these data were not considered in the assessment because of "inconsistencies between foundries in the sampling and testing protocols." They also refer to a database compiled by Dr. Tikalsky at the Pennsylvania State University but did not use these data either because "method detection limits varied for similar constituents, and as a result, comparisons could not easily be made between the data." None of the reasons for excluding these data suggests data quality problems, just inconsistencies in how data were collected. Consequently, it is not apparent why the data were completely dismissed. For example, despite differences in sampling and analytical methods, do the data suggest that much higher or lower concentrations of any chemicals were found in the other data sets? Might there be additional COCs? Or are the data sets generally consistent with the USDA data, after taking into account the inconsistencies?

The authors should describe past and ongoing use of SFS in more detail. They refer to these uses: "Approximately 25% of the 10 million tons of SFS produced annually are beneficially used outside of the foundry, but only 3.9% of SFS is used in soil-related applications (AFS Survey, 2008)…" The authors explain in Section 2.4 that they conducted a peer-reviewed literature search regarding metals and organics in SFS. In Section 2.5, they refer to a literature search for field studies of SFS leaching. But they found no field studies related to past or ongoing uses of SFS in amended soil. Beyond the scientific literature, have there been reports by other credible sources of any problems that have arisen from past or ongoing use of SFS in amended soils?

The USDA study appears to have collected a reasonably representative sample of SFS material over multiple years. However, not until Section 6.8.2 (point 1) do the authors clearly describe how the initial set of foundries was selected for sampling. This description aside, industry representatives rather than USDA scientists collected samples in years 2 and 3, and only a subset of facilities with data for the first year provided data in subsequent years. Might there have been any selection bias such that facilities with higher chemical concentrations in SFS elected not to report these results or did not provide samples at all? Also, is there any reason to think that foundry operations might be modified in the future in a way that influences SFS properties? I suspect that the authors considered these questions, but it would be helpful to document this information to provide assurance that this assessment provides an upper bound on potential risks under current and future conditions.

The authors assume that manufactured soil is 50% SFS and explain that a higher percentage would not be feasible because it would be cost-prohibitive for a home gardener (i.e., see note 5 on page ES-6, which indicates that blends "are more likely to include 5-10% SFS" for this reason), and the manufactured soil would not have the characteristics needed to grow plants (See Dayton et al. manuscript, in review). Still, over time, manufactured soil could be used repeatedly in a single location, so it makes sense to consider the potential for a higher percentage contribution of SFS. The assumption that SFS comprises 50% of manufactured soil is not certain but does seem to provide an upper bound given soil requirements for growing plants.

4. Please comment on the methodology used for choosing constituents to evaluate.

I assume that this question relates to selection of chemicals of concern and not chemicals that should be measured in SFS. In general, the method seems reasonable, but is spread out across Sections 3, 4, and 5, which makes it slightly difficult to follow. On pages 1-2 and 1-3, the authors indicate that "This report is intended to provide states with a sound scientific basis with which to evaluate the potential risks to human health and the environment associated with the beneficial use of SFS in soil-related applications." This goal could be achieved more easily by succinctly explaining the various screening steps that are described in Sections 3, 4, and 5 that resulted in elimination of chemicals from the list of COCs and, in some cases, elimination of entire exposure pathways. Specifically, demonstrate briefly but quantitatively why SFS use is not associated with cumulative risk levels of concern despite:

1. screening out chemicals that were never detected (this step should not be problematic because the authors checked for and addressed detection limits that exceeded screening levels),
2. screening out chemicals that do not have health benchmarks,
3. assuming independence among some exposure pathways (exception is the evaluation of cumulative ingestion exposure to soil and homegrown food),
4. applying the target hazard index of 1 to single chemicals associated with each exposure pathway despite the fact that each exposure pathway involves exposure to chemical mixtures,
5. eliminating some exposure pathways from quantitative evaluation (e.g., dermal contact with soil and groundwater and inhalation of fugitive dust [although predicted soil screening concentrations for the dust pathway are sufficiently high relative to SFS concentrations that this pathway should not contribute negligibly to cumulative risks]),
6. use of 95th percentile concentrations instead of maximum detected concentrations to screen for chemicals of concern (it is common practice in EPA's Superfund program to use the maximum detected concentration for this purpose, but practices might vary among different federal and state programs), and

7. assuming that the groundwater ingestion pathway did not require further evaluation because estimated exposures for five modeled constituents were below EPA's maximum contaminant levels (MCLs) [While this assumption may be practical, MCLs are not all necessarily risk-based].

This comment is related to the graphic suggested in response to charge question #1. More attention needs to be paid to the concept of cumulative risk, referencing relevant EPA guidance (e.g., EPA 2000, 2003, 2007).

5. Please comment on the conceptual models, particularly the plausibility of the sources, pathways, and receptors included.

The conceptual models are plausible and appear to include relevant sources, pathways, and receptors. However, the authors should document the sources of information (e.g., stockpile management practices) used to construct conceptual models. Why do the authors assume that engineering controls will prevent runoff but not fugitive dust? Also, engineering controls are not likely to be used for home gardens as appears to be assumed in Figure 3-3. Where are direct links between SFS-containing materials (e.g., manufactured soil on a garden/field") and receptors (e.g., home gardener) that ingest or come into dermal contact with it [Note: This direct contact pathway is shown correctly later in Figure 5-3]? Finally, the conceptual models are somewhat confusing, e.g., the legend suggests that dashed lines are used only for the surface water runoff pathway, but dashed lines are used for other pathways.

The screening assessment is based almost entirely on the conceptual model for manufactured soil use on a home garden because this use is assumed to be associated with the highest degree of exposure. The exception is the use of a soil blending operation to represent an upper bound exposure estimate for the inhalation of fugitive dust pathway. Home gardeners are assumed to be exposed via the following exposure pathways:

(1) inhalation of SFS emitted from soil blending operations
(2) ingestion of groundwater contaminated by the leaching of SFS constituents
(3) incidental ingestion of manufactured soil
(4) ingestion of fruits and vegetables grown in the manufactured soil

Except for the concern expressed below about exclusion of the dermal contact with soil and groundwater pathways, these exposure pathways are appropriate. There is also the potential for home-produced poultry, dairy, and beef. Did the authors consider this possibility (e.g., links to several newspaper articles regarding the increase prevalence of backyard chickens can be found at: http://www.backyardchickens.com/LC-links.html), assuming that there is any reason to use manufactured soil for grazing areas?

On Page 3-6, the authors explain that "Dermal contact for the groundwater and soil pathways was excluded because available data indicate that the contribution of dermal exposure to soils to overall risk is typically small" based on results of a risk assessment conducted 14-15 years ago that reportedly involves only exposure to soil. This is not sufficient justification for excluding the soil dermal and groundwater dermal exposure pathways from further analysis. Did the cited risk analyses include the same exposure pathways and quantitative assumptions, i.e., are they directly relevant to the current assessment? I doubt that the large differences between dermal exposure and other pathways cited in Note #2 on this page apply to a COC such as arsenic in the context of this assessment. Such short cuts might be technically justifiable in some instances, but the goal of this assessment is to provide states with the risk information they need to reach decisions. The best way to do this is to quantify risk from all exposure pathways or to quantitatively demonstrate within the document (not by reference to an older risk assessment with no explanation of its relevance) that the pathway does not warrant further analysis.

The authors assumed independence of groundwater, soil, and fugitive dust exposure pathways for the following reasons: "Each of the three pathways listed above was evaluated through a screening model to see if any pathway (or alternatively, any constituents) could be eliminated from further analysis. It is important to note that these pathways are likely to operate individually on a human receptor, not cumulatively. First, inhalation of materials will generally cause different health impacts than ingestion of those materials. Therefore, the inhalation pathway should be evaluated separately from the ingestion pathways. Second, exposures via groundwater ingestion occur on a significantly different time-scale from ingestion of produce and soil. Thus, the groundwater pathway can also be evaluated separately. Given the individual nature of these pathways, they were each evaluated in turn." The authors provide no justification for assuming that the fugitive dust pathway and ingestion pathway for soil should be separate. Would one really expect different health effects for the COCs in this assessment? What about the fraction of fugitive dust that is ultimately ingested rather than inhaled (i.e., that fraction that enters the airway and is cleared via the mucociliary escalator before entering the gastrointestinal tract)? I will leave it to those who are expert in groundwater modeling to comment on the timescales, but it seems that exposures to SFS in groundwater and soil could occur at the same time and place if SFS-containing materials are used in the same place over time.

6. Please discuss the appropriateness of the Manufactured Soil conceptual model, as protective of the other conceptual models.

The authors focus on SFS use in manufactured soil applied to gardens because this application is expected to result in the highest exposure. Therefore, if exposure to manufactured soil is not associated with significant risk, then other applications also will not be problematic. If the description of possible uses for SFS-containing materials is accurate, then the conceptual model for manufactured soil use appears to be protective of other SFS uses. However, it would be useful to include a section that describes current controls and possible future controls on SFS use, if any, to support this assumption. How much SFS is produced annually? How much might end up in manufactured soil and what fraction of agricultural land used for food production might ultimately have SFS-containing manufactured soil placed on it? The answers to these questions are relevant to the assumption that the home garden pathway represents an upper bound of possible exposure. Could a home gardener also be exposed from what they buy in the supermarket and/or the local community supported agriculture farm?

7. **Please discuss whether the screening steps reported in Chapter 4 were appropriately conservative in their application to support the conclusions.**

I assume that "appropriately conservative" means that cumulative noncancer hazard indices do not exceed 1 and cumulative cancer risks do not exceed 1E-5 for any receptors. In all likelihood, the screening steps were appropriately conservative but, as explained in response to charge questions #1 and #6, the authors should clearly and succinctly document quantitatively how screening steps throughout the report ensure that SFS use will not be associated with cumulative risk levels of concern.

8. **Please comment on the appropriateness of the various probabilistic modeling steps employed to develop national-scale screening values.**

The PRA modeling steps are generally appropriate to develop national-scale screening values. However, more work is needed to comply with EPA recommendations for PRA documentation and EPA's most recent recommendations for evaluating children's exposure. In addition, the authors should consider adding a section that explains how states might modify the analyses to incorporate state-specific information, thus reducing the uncertainty in applying results of a "national-scale" model to specific locations.

Compliance with EPA conditions for PRA. In earlier responses to charge questions, I commented on whether the report satisfied 2 of EPA's 8 conditions for PRA. EPA condition #3 recommends that:

> *The results of sensitivity analyses are to be presented and discussed in the report. Probabilistic techniques should be applied to the compounds, pathways, and factors of importance to the assessment, as determined by sensitivity analyses or other basic requirements of the assessment.*

The assessment incorporates appropriate sensitivity analyses and describes them clearly.

EPA condition #4 recommends that:

> *The presence or absence of moderate to strong correlations or dependencies between the input variables is to be discussed and accounted for in the analysis, along with the effects these have on the output distribution.*

The assessment incorporates discussion of correlations; see response to charge question #9 for additional discussion regarding correlations.

EPA condition #5 recommends that:

> *Information for each input and output distribution is to be provided in the report. This includes tabular and graphical*

representations of the distributions (e.g., probability density function and cumulative distribution function plots) that indicate the location of any point estimates of interest (e.g., mean, median, 95th percentile). The selection of distributions is to be explained and justified. For both the input and output distributions, variability and uncertainty are to be differentiated where possible.

The assessment includes clear descriptions of distributions used in the PRA. However, the authors made no attempt to differentiate variability and uncertainty. This level of effort is not necessarily warranted if conservative risk-based screening results are well below cumulative risk levels of concern. Some distributions were truncated. Truncation steps are not likely to strongly influence results of the analysis, and truncating at zero for inputs that cannot be negative is certainly reasonable as long as one accounts for the effect on parameters of the truncated distribution. Other truncation steps are not so easily defined. For example, is a reasonable maximum value for a homegrown produce ingestion rate really estimated by doubling the sum of the mean and 3*standard deviation? If not, what is the next best value? It seems far less complicated to leave distributions as they are with very low probabilities assigned to extreme values. The authors could always use sensitivity analyses to examine the influence of extreme values.

A puzzling aspect of the PRA is the fact that only some inputs are defined with distributions. Why quantify variability and/or uncertainty for only some model inputs when data are available to develop distributions for others? The following sections describe information that is available for inputs that either were treated as point estimates in the PRA or were defined with distributions that could be improved.

Toxicity Values. EPA's PRA guidance:

> *"does not propose probabilistic approaches for dose-response in human health assessment and, further, discourages undertaking such activities on a site-by-site basis" (EPA 2001).*

I assume that this is why EPA chose not to quantify uncertainty in toxicity values. But EPA should at least discuss uncertainty associated with chemical toxicity values in the risk assessment to facilitate interpretation of risk results.

Body weight. The authors use body weight data from EPA's 1997 Exposure Factors Handbook. Body weight data representative of the U.S. population have been collected more recently as part of the CDC's NHANES study. EPA developed distributions for children through age 21 using NHANES data from 1999-2006 (See Chapter 8 in EPA's 2008 Child-Specific Exposure Factors Handbook). Additional NHANES data could be obtained to evaluate adults.

Soil Ingestion. The authors define soil ingestion with point estimates, but distributional information is provided in EPA's 1997 Exposure Factors Handbook as well as the 2008 Child-Specific Exposure Factors Handbook.

Cooking and Preparation Loss. Cooking and preparation loss data from USDA (Table 1 in USDA [1975] Food yields summarized by different stages of preparation. Agriculture Handbook No. 102. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC) could have been used to define distributions for this variable. This publication is the source for the mean net cooking loss, mean net post-cooking loss, and mean paring and preparation loss (for fruits) values reported in Tables 13-6 and 13-7 in EPA's 1997 Exposure Factors Handbook.

Homegrown Produce Consumption Rates. A particular strength of this assessment is its reliance on recent research regarding plant uptake of metals for soil amended with SFS. Unfortunately, this research is ultimately combined with consumption rate data for home-produced food that is nearly 20 years old. EPA (1997) cautions those who use these data that they may be outdated, but the authors of this assessment are silent on this topic. Unfortunately, I am not aware of more recent, systematically collected consumption rate data for home-produced food that are representative of the U.S. population. However, I have attached a recent National Gardening Association (NGA 2009) white paper that suggests that home gardening is on the rise. I am not familiar with the NGA survey beyond this report and cannot attest to its accuracy. Plus it looks forward rather than backward in time and does not provide consumption rate data needed to quantify exposure. However, findings from the report mirror a trend that I've observed anecdotally in the northeast and suggest that the uncertainty associated with 20-year old consumption rate data warrants at least some discussion in the assessment. The authors refer to the consumption rates as "conservative" based on comparison to a 1993 USDA risk assessment, but this comparison is irrelevant. In addition, the authors argue that

> "In the probabilistic modeling conducted for this assessment, the total consumption rate of home-grown fruits and vegetables for the adult at the 90th percentile risk level was approximately 500 g (WW) d-1 for an average adult. In addition, it is not possible to harvest most garden crops for more than a short period when the crop is ripe, which considerably limits potential exposure to garden foods. Given the size of the garden required to support such a diet, the costs of delivering SFS would likely reduce the actual exposure to manufactured soil containing SFS by several orders of magnitude due to the limited garden area. Thus, the results of the home gardener risk screening modeling should be considered as a significant overestimation of the actual risks associated with SFS use."

The NGA white paper reports that the average size of a home garden is 600 square feet and that a well-tended garden produces ½ pound of produce per square foot, or about 300 pounds per year. This equates to about 380 g/d for a 1-person household or about 90 g/d for a 4-person household. Again, these quantities are based on mean garden size, not upper percentile garden sizes, and they do not include consumption of produce grown on other agricultural land where SFS might be used. I imagine authors from the USDA would have additional and perhaps better sources of data to estimate this quantity, and I strongly recommend that this discussion be included. Consumption should also be described in terms that people understand. For example, the 90th percentile consumption rate of 500 g/day corresponds to 2 or 3 garden tomatoes per day. [Note:

the garden size assumed in the assessment is 111-180 acres, while the NGA (2009) reports that 6% of home gardens are greater than 2,000 square feet without specifying a maximum value. Nevertheless, as the authors note, their assumption of garden size greatly overestimates the size of home gardens.]

Future assessments of SFS or other materials proposed for beneficial use should extend beyond research regarding environmental mobility and uptake and include studies to improve our understanding of important human exposure variables, such as consumption rates of homegrown produce.

EPA condition #6 recommends that:

> *EPA Condition #6: The numerical stability of the central tendency and the higher end (i.e., tail) of the output distributions are to be presented and discussed.*

I could not find discussion of numerical stability of PRA model outputs. Does the 3MRA model provide any quality assurance output to check for such stability? If so, provide a summary in this assessment.

EPA condition #7 recommends that:

> *EPA Condition #7: Calculations of exposures and risks using deterministic (e.g., point estimate) methods are to be reported if possible. Providing these values will allow comparisons between the probabilistic analysis and past or screening level risk assessments. Further, deterministic estimates may be used to answer scenario specific questions and to facilitate risk communication. When comparisons are made, it is important to explain the similarities and differences in the underlying data, assumptions, and models.*

The assessment appropriately includes deterministic methods. The extensive use of screening in lieu of "forward" risk calculations might make risk communication a challenge.

EPA condition #8 recommends that:

> *EPA Condition #8: Since fixed exposure assumptions (e.g., exposure duration, body weight) are sometimes embedded in the toxicity metrics (e.g., Reference Doses, Reference Concentrations, Cancer risk factors), the exposure estimates from the probabilistic output distribution are to be aligned with the toxicity metric.*

The exposure durations and averaging times are aligned. The PRA allows for variability in body weight, and some toxicity values might incorporate a body weight assumption of 70 kg. If so, I doubt that this inconsistency would have much influence on risk estimates.

Application of National-Scale Screening Values and PRA to Individual Regions/States. The assessment accounts for variability in chemical mobility in the environment and in soil background concentrations across the U.S. This accounting of regional variability is essential for a national-scale analysis. To provide states with as much flexibility as possible in applying findings in a manner that ensures compliance with their own risk management goals, the authors could include a section explaining how states could substitute their own data (e.g., soil characteristics and chemical concentrations) into the PRA model and other screening models.

9. Within the context of a screening risk assessment, please comment on the level of conservatism inherent in the Home Gardener scenario, with special attention to the assumption of independence of the ingestion pathways. Please also comment on the rationale for modeling the 50%tile and 90%tile general population consumption rates, each with a 50% homegrown fraction.

The authors conclude that "the results of the home gardener risk screening modeling should be considered as a significant overestimation of the actual risks associated with SFS use." This conclusion might be true but is not substantiated adequately in the assessment as discussed in response to charge question #8.

Assumption that the Consumption Rate for Homegrown Produce is ½ the General Population Consumption Rates. This assumption is too simplistic. EPA (1997) provides some seasonally corrected consumption rates. Even where such adjusted data are not available, one can estimate adjustment factors that can be used to estimate seasonally adjusted consumption rates (See Section 6.5.6.2 in Volume 5 of EPA's 2005 Baseline Human health Risk Assessment for the GE/Housatonic Rest of River Site.)

Independence of Ingestion Pathways. "Sub-pathways include the incidental ingestion of soil, as well as the ingestion of exposed fruits (e.g., strawberries), protected fruits (e.g., oranges), exposed vegetables (e.g., lettuce), protected vegetables (e.g., corn), and root vegetables (e.g., carrots)" (page ES-4). On page 6-31, the authors argue that "it would be unlikely that a person would consume a high-end amount of root vegetables *and* leafy greens *and* apples that were all grown from the same garden." This statement might be true, but the authors do not provide any data that substantiates this assumption. Instead, they refer generally to consumption rates being high.

10. Please comment on how soil background, phytoxicity, and impacts on soil biota were considered in the assessment.

The comparison of SFS concentrations to USGS background concentrations in Figures 6-1 through 6-4 is useful, although I suggest that axes on paired plots should be consistent to facilitate the comparison. Treatment of nondetect results should be specified on these plots and any other data manipulation that might influence the comparisons. In addition, some states have defined soil background concentration data sets that could be presented in this assessment along with the SFS data, USGS data, and other data briefly discussed in Section 6.8.2, item #2 (e.g., see "Background Levels of Polycyclic Aromatic Hydrocarbons and Metals in Soil" at http://www.mass.gov/dep/service/compliance/riskasmt.htm).

11. Please comment on the clarity of the Risk Characterization section, with special attention to the discussion of uncertainties.

The assessment provides a clear discussion of how risk-based screening levels were developed, including a discussion of uncertainties that influence interpretation of results. I also understand the utility of screening levels as opposed to "forward" risk calculations in this context where states and others might want to compare chemical concentrations associated with individual samples of SFS or SFS-containing materials to "acceptable" concentrations. However, as noted in response to other charge questions, this section could more succinctly address the general question of whether the assessment, in its entirety, ensures that cumulative risks are below levels of concern.

12. Please comment on whether the assessment supports the report's conclusions.

Yes, the assessment supports the overarching conclusion that beneficial use of SFS can occur without significant risk to human health. However, the issues raised in response to other charge questions require attention.

Other issues

There is a tone of advocacy at several points in this document that are not typically found in risk assessments, nor are they helpful as they stray from the topic at hand. For example: "Given their inherent properties and low cost, SFSs present a significant opportunity for the manufacture of soil and soil-less media" (Page 3-4). From a technical perspective, it appears that the work was performed in a scientifically objective manner, but such statements do not instill confidence that the risk evaluation was conducted objectively in the minds of those who are unfamiliar with the details of the technical evaluation. I suggest that the authors consider deleting them.

Please do not hesitate to contact me if you have questions about this review.

Sincerely,

Donna J. Vorhees

References

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EPA (U.S. Environmental Protection Agency). **1997b**. *Exposure Factors Handbook, Volume II, Food Ingestion Factors.* EPA/600/P-95/002Fa. Office of Research and Development, Washington, DC. August.

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EPA (U.S. Environmental Protection Agency). **2000**. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures, Risk Assessment Forum, US Environmental Protection Agency, EPA/630/R-00/002, August 2000.

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EPA (U.S. Environmental Protection Agency). **2008**. Child-Specific Exposure Factors Handbook (External Review Draft). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-06/096F.

Risk Assessment of Spent Foundry Sands in Soil-Related Applications
Peer Review Comments by Mary Fox

SUMMARY

Overall approach of screening steps leading to a more refined analysis of selected constituents is sound. Parts of the report are poorly organized and lack clarity particularly sections of Chs 3 and 6 and the rationale and approach to the probabilistic modeling. There are problems with implementation of the probabilistic modeling that compromise the conservatism of the home produce ingestion pathway and ultimately the risk assessment findings and conclusions.

* Data inputs for ingestion scenarios (particularly home gardener) must be double checked for accuracy and revised to reflect source data in some cases.

* Probabilistic analysis of soil and produce ingestion scenarios must be revised and repeated before concluding that use of manufactured soils will be protective of human and ecological receptors.

RESPONSE TO QUESTIONS

1) Please comment on the transparency of the risk assessment.

For the assessment overall:

For the most part, the deterministic screening modeling was straightforward and clearly presented.

The rationale and approach to the probabilistic modeling of the soil/produce ingestion pathway (Section 5.3) is not clear. Why were unitized exposure estimates preferable to health risk estimates? More background on development and uses of unitized exposure estimates is needed. Why was 1 mg/kg chosen as the assumed concentration?

Further comments on transparency of the probabilistic modeling:

Software used and specifications of the probabilistic modeling including number of iterations and type of sampling (Monte Carlo or Latin Hypercube) should be provided in the main text or as an appendix. This information is needed for transparency. A complete evaluation of the probabilistic modeling cannot be conducted without this information.

Joint probability approach for determining the combination of site conditions evaluated in the probabilistic modeling is not well described in Chapter 5 or

Chapter 3. How is the joint probability approach implemented within the modeling framework?

I could not locate the data on fraction of home grown produce grown in manufactured soil (home gardener scenario). This information is key to evaluating the conservatism of this scenario.

Some data inputs do not correspond to the source data referenced (see response to question 9 below)

2) Please discuss the adequacy of the risk assessment execution.

I believe the assessment was conducted as the authors report. The overall approach is reasonable. The formulae appear correct and models (SCREEN3, IWEM, 3MRA, ISCST3) used are appropriate. However, as detailed in answers to subsequent questions there are data limitations and issues with implementation of the probabilistic modeling that compromise the authors claims of conservatism and the assessment conclusions.

3) Please comment on whether the selection of U.S. foundries was representative of the industry and if the characterization of these foundry sands was adequate.

Information provided in the risk assessment is not adequate to evaluate whether selection of SFS for analysis was representative of the industry. What is the size of the industry? The 43 samples available represent what percent of the industry? Also, the sands analyzed were from foundries in the east, south and mid-west. No samples were taken from western states. If geographic representativeness is not relevant to developing a national assessment a justification should be provided.

I believe the SFS samples used were adequately characterized. It was helpful to have the SPLP leachate data to supplement the TCLP.

4) Please comment on the methodology used for choosing constituents to evaluate.

The general methodology outlined for choosing constituents consisted of three types of information:

- Information on completed exposure pathways (see response to #5-6 below regarding gaps in exposure pathways captured by the conceptual models)
- Availability of sampling data above the limit of detection
- Availability of human or ecological health benchmarks

This is an acceptable methodology for selecting SFS constituents to evaluate in each stage of the assessment.

5) Please comment on the conceptual models, particularly the plausibility of the sources, pathways, and receptors included.

With the following exception, the conceptual models capture the relevant sources, pathways and receptors: Figure 3.1 should include roadway construction or construction operations (i.e., moving SFS from storage to road building area) as a source with dispersion in air and deposition to soil as pathways.

I am not sure that the assumptions regarding engineering controls on the storage pile for the roadway subbase model are reasonable. Therefore, particulate emissions and runoff should be considered for evaluation. However, the nature of roadway construction is likely temporary or intermittent which would reduce concern about this source and related pathways. The temporary nature of construction activities is discussed in Ch 6 but it should be included in Ch 3 along with the descriptions of the conceptual models.

Regarding Figure 3-2 the blending site model – There is a footnote to the figure explaining that deposition of particles and subsequent contact and ingestion were not quantified because it was assumed that related exposures would be insignificant compared to the manufactured soil (home garden) model. I agree with this for the human receptor but the justification may not hold for wildlife.

6) Please discuss the appropriateness of the Manufactured Soil conceptual model, as protective of the other conceptual models.

I agree that the Manufactured Soil conceptual model can be considered protective of the other conceptual models for human receptors. See above comment about the blending site model and exposures to wildlife from deposition of particles leading to ingestion.

7) Please discuss whether the screening steps reported in Chapter 4 were appropriately conservative in their application to support the conclusions.

The air and groundwater screening steps were clearly designed to be conservative, e.g., 95^{th}%ile sampling data were used for modeling and comparisons. Selection of constituents to evaluate in drinking water scenario is conservative. Contaminants were retained because LOD for leachate testing falls above the screening reference levels.

The screening of soil and produce ingestion pathways was trickier because it involved the “dilution” of SFS concentrations due to mixing with other soil components in the manufactured soil and consideration of multiple sub-pathways. To address the issue of multiple sub-pathways of exposure the authors divided the SSL health screening benchmarks by 10 to derive an adjusted SSL that allows for multiple pathways of exposure. This is an appropriate and conservative approach.

8) Please comment on the appropriateness of the various probabilistic modeling steps employed to develop national-scale screening values.

I believe the authors took reasonable steps to develop models to represent the range of site conditions in the continental US. This included using regional meteorological data, modeling multiple soil types and climate conditions and defining SFS use feasibility zones. Regarding the produce consumption modeling the assessment uses consumption rate data from national surveys conducted in the late 1980's – this information is dated but remains in use.

Concerns: Numerous subsurface parameters for groundwater modeling were set to model default values. This is outside my area of expertise but I wonder how these defaults influence the "national representativeness" of the groundwater ingestion pathway.

9) Within the context of a screening risk assessment, please comment on the level of conservatism inherent in the Home Gardener scenario, with special attention to the assumption of independence of the ingestion pathways. Please also comment on the rationale for modeling the 50%tile and 90%tile general population consumption rates, each with a 50% homegrown fraction.

The home gardener scenario as described is probably conservative but not necessarily a "significant overestimation (page 6-31)". Independence of ingestion pathways is an appropriate assumption. Gardeners will grow produce that they like and will consume it in season as well as preserve it in various ways to be eaten in winter. Further, the probabilistic model inputs include no intake (minimums of 0 grams). The authors do make a good point that a home gardener may not grow all five of the produce types but likely grow 4 of the 5 types. **Another key consideration in evaluating the home gardener scenario is the fraction of produce assumed to be home grown. I could not locate that number so my evaluation of the conservatism of this scenario is incomplete**.

The stated reason for modeling the general population was concern that the home gardener scenario was overly conservative. I do not share that view. However, it is useful to have a range of estimates to represent other populations with moderate intakes.

Other comments related to probabilistic modeling inputs for Home Gardener:

More care should be taken in defining minimum and maximum values on distributions used in the probabilistic modeling. For example, for the body weight distributions the mins and maxs found in Appendix I (Table I-2) do not reflect the Exposure Factors Handbook data referenced (see comparisons below). It is especially important to choose conservative (and reasonable) maximums for probabilistic modeling particularly for body weight and averaging time which appear in the denominator of exposure/dose equations. **Generally speaking, when defining body weight and averaging time for a conservative scenario**

lower values should be chosen. For greater transparency and reproducibility, inputs should reflect the source data.

Table 1a Comparing Data in Table I-2 with EFH Data – Body Weight Minimums

Units = kg	Min Table I-2	Min EFH Table 7-4 (5th%ile)	Min EFH Table 7-5 (5th%ile)
Adult	15	50.8	46.2
		Min EFH Table 7-6 (5th%ile)	Min EFH Table 7-7 (5th%ile)
Child 1	4	9.6 – 16	8.8 - 15.3
Child 2	6	18.6 - 26.8	17 - 29.8
Child 3	13	30.7 - 55.9	32.2 - 48.5

Table 1b Comparing Data in Table I-2 with EFH Data – Body Weight Maximums

Units = kg	Max Table I-2	Max EFH Table 7-4 (95th%ile)	Max EFH Table 7-5 (95th%ile)
Adult	300	106.3	117.5
		Max EFH Table 7-6 (95th%ile)	Max EFH Table 7-7 (95th%ile)
Child 1	50	14.4 – 25.4	13.4 – 26.6
Child 2	200	30.1 – 61.0	29.6 – 60
Child 3	300	67.5 – 92.1	64.3 – 78.1

Note: EFH tables 7-2 and 7-3 are also referenced but these contain data on means and not the tails of the distributions.

Exposure duration – Table I-2 lists the maximum value set for exposure duration at 100 years – longer than the 70 year lifetime assumption reportedly used for cancer risk comparisons and longer than data in the table referenced (maximum value in EFH Table 15-168 is 57 years).

Table I-3 Child 3 exposed fruit – I believe there is a typo or calculation error. On page I-3 it reads that the maximum was set at twice the 99th%ile. By my calculation that should be 5.9*2=**11.8 g** and not 18 g.

10) Please comment on how soil background, phytoxicity, and impacts on soil biota were considered in the assessment.

Question 10 is outside my area of expertise.

11) Please comment on the clarity of the Risk Characterization section, with special attention to the discussion of uncertainties.

I think chapter six contains most of the relevant information to characterize the assessment and put the results in context. However, the clarity is compromised by some organizational issues - there are some sections that appear out of place and some sections that don't seem well integrated into the discussion at all.

Section 6.2 Key risk assessment questions: The fourth question (nutritional health and essentiality) doesn't seem to be directly addressed in the chapter.

Section 6.3.5 is not well-integrated into Chapter 6. How does this discussion of highly exposed populations relate to uncertainty or the assessment overall? Does it relate to how ecological risks were evaluated?

The information in Section 6.4 seems more appropriate as part of the preceding section on Overarching Concepts.

Substance specific sections (6.5 through 6.7) are good summaries of the assessment information. I would substitute "Summary" or "Integrated Summary" for "Weight of evidence" - "weight of evidence" is risk assessment jargon that can mean different things to different readers.

The authors present section 6.8 Uncertainty Characterization as a high-level overview for risk managers/ policy makers and therefore do not re-hash assumptions and uncertainties in detail. The information presented is useful, however, as a technical reader I was looking for more. I would like to see a "Data and Research" section where the authors comment on data quality, data gaps, and the feasibility/desirability of a validation study or other research needs.

12) Please comment on whether the assessment supports the report's conclusions.

I cannot endorse the risk assessment findings and conclusions as presented in the peer-review draft. The probabilistic modeling analysis needs to be revised considering these comments and repeated.

OTHER COMMENTS

Executive Summary

Pg ES7: Statement is made that composition of SFS may reduce bioavailability of lead but no reference is provided.

Fox

Chapter 2

Pg 2-24: Discussion of TCLP and SPLP. Usefulness of data "unresolved" potentially not representative of complex soil mixture settings. Is this an important uncertainty to include in uncertainty discussion? Is there any further information about this uncertainty? E.g., are the data expected to over- or underestimate contaminant concentrations from leaching in more complex settings?

Chapter 3 Problem formulation

Pg 3-1 to 3-2: Section 3.1.1, 3.1.2 are repetitive of chapter 2 – not needed in this chapter

Pg 3-6: Section 3.1.5 Assumptions on indirect exposure pathways from temporary storage and use of SFS – reference needed to support the claim about biomagnification

Pg 3-7: Section 3.2 Benchmarks and criteria can also be re-located to appropriate sections of the analysis.

Problem formulation chapter should reflect the framework shown in Figure 3-4. Rather than describe exposure pathways – this is the place to describe the screening modeling approach. Section 3.3.4 jumps the gun and includes results of screening analyses, listing constituents modeled as a result of screening

Chapter 4

Pg 4-1: Section 4.1. More justification is needed to support separate (not cumulative) evaluation of pathways. Inhalation and ingestion – what are the critical health effects underlying health benchmarks for each constituent of concern for each route of exposure. Ingestion: What is known about leaching to groundwater? How long does it take? Quantify/describe the difference in time-scale. Inhalation and ingestion in combination would also seem plausible for residents near a soil blending plant.

Pg 4-3: Split table 4-1 into sections for cancer and non-cancer benchmarks – add the health effect of concern for non-cancer benchmarks

Pg 4-11: Section 4-4. Some SFS constituents do not have tox benchmarks (so they are not included in the assessment) – is this discussed as possible source of underestimation of risk in limitations or uncertainty section?

Pg 4-16: Table 4-9 Adjustment to the SSL should be presented. Why is SSL for lead shaded in gray?

Page 4-17: First paragraph, sentence 4: Check spelling for 'arsenic'

Fox

Chapter 5

Page 5-5, section 5.3
Probabilistic modeling of soil/produce ingestion pathway
Need more explanation for risk assessment approach to soil/produce ingestion pathway. Why not directly estimate risks using the available SFS data? Is it possible to make some experimental manufactured soils to develop data for this part of the risk assessment?

Methodology for developing unitized exposure estimates needs to be explained more thoroughly including a specific example and references to other US EPA uses of unitized exposure or risk estimates. Why is this approach necessary or preferred? How does the assumed concentration of 1 ppm relate to actual manufactured soils or what would be expected?

Page 5-15, Section 5.3.6.2 Exposure model inputs
Authors should consult Child-Specific EFH to ensure they are using the currently accepted values for child intakes, etc. (In many cases the data in the 1997 and more recent Child-Specific EFH may be the same.)

Responses to Charge Questions for the Peer Review of:

"Risk Assessment of Spent Foundry Sands in Soil-Related Applications"

Comments by:
K.A. Barbarick
University Distinguished Teaching Scholar and Professor of Soil Science
Colorado State University

1) The document does a thorough job of providing and interpreting information without hidden assumptions or preconceived notions. The risk assessment is "transparent".

2) The study used different screening levels developed at Oak Ridge National Laboratory. The risk assessment execution is solid. The screening levels from Oak Ridge National Laboratory are commonly used and are the best information available. They are sufficiently protective for the risk assessment used in this study.

3) The selection of the foundries and the characterizations of the foundry sands are adequate. The study used a good distribution of geographical and process-types.

4) The report presents a very thorough scrutiny of soil fertility, nonessential elements, and potentially toxic compounds.

5) The researchers appropriately eliminated olivine sands for testing since they most likely would not be used in a soil mix that grows vegetables or fruits. An oversight or weakness of the conceptual model is not considering leaching of the components studied from the "storage pile". This process may not pose a risk; however, it should be discussed including documentation that is available. A series of column "batch" leaching studies could be utilized to determine the extent to which any constituents are transported. Breakthrough curves could help estimate how many pore volumes of water would need to move through simulated piles to move significant quantities of each component. These data then could be included in the pathway modeling.

6) The "Manufactured Soil" conceptual model is a highly conservative approach that will be protective of the other conceptual models. A 20-cm deep soil mix with 50% spent foundry sand is highly unlikely. The material and incorporation of a 50% mix to this depth would be expensive.

7) Yes, the screening steps were appropriately conservative. Model equations are based on documented modeling research. The elimination of the TCLP test for "Ingestion of Groundwater" pathway is appropriate. The study also provides good justification for which metals were retained to determine risk of exposure. One suggestion is to include the soil contributions to $Conc_{MS}$. No doubt the contribution would be small in most cases; however, including this information provides a more thorough analysis.

8) The "Home Gardener" scenario is the best choice for modeling since it would pose the greatest risk to an individual. The comment in #7 regarding $Conc_{MS}$ should be considered.

9) The “Home Gardener” scenario is very conservative; it almost represents a worst-case scenario. The assumptions for the general population consumption and independence of the ingestion pathways are appropriate.

10) The soil background and phytotoxicity are adequate. The impacts on general soil biota needs more detailed study. For example, earthworms are mentioned as a group in terms of potential risks. Earthworms are a very diverse group of organisms who will more than likely respond differently to the potential risks associated with spent foundry sand additions to soil. This study probably did not have the resources to look at specific groups of biota, however. Shifts in microbial communities should be studied to determine if the “Home Garden” scenario encourages changes between major microbial groupings such as bacteria and fungi and if particular individual species of organisms are favored or harmed by the additions of the spent foundry sand. Good references for this approach are:

Ritchie, Schutter, Dick, and Myrold.2000. Applied and Environmental Microbiology 66:1668-1675.

Schutter, Sandeno, and Dick. 2001. Seasonal, soil type, and alternative management influences on microbial communities of vegetable cropping systems. Biology and Fertility of Soils 34:397-410.

11) The “Risk Characterization” section is very clear. The weight of evidence approach for (a) risk screening modeling and (b) uncertainties associated with state-of-the-science research provided the best assessment.

12) The assessment does support the report’s conclusions that spent foundry sands can safely be used as an up to 50% manufactured or garden soil mix.

Summary

The American Foundry Society’s request for an Abstract (I would recommend 1 page or less) and their suggested final statement at the bottom of page 2 of their response are reasonable requests. I also support their recommendation to call the material “recycled foundry sand”. This change puts a more positive spin on the nature of the material and how it could be re-used. The American Foundry Society’s Comments point out some technical inaccuracies concerning the foundry processes and materials that should be corrected.

The report submitted by the Michigan Department of Environmental Quality studied the data for possible impacts and concluded that the material possibly could be used with restrictions. I believe the report actually adequately addressed most of the issues raised by the Michigan Department of Environmental Quality; however, a point-by-point response would be needed to assuage their concerns.

The USEPA Region 9 comments point out the mixing of Risk Assessment and Risk Management approaches. I agree that this needs clarification and the report should focus on Risk Assessment.

I think the report did do a comprehensive risk assessment of the use of spent (recycled) foundry sands. I support their conclusions that their “Home Garden” scenario is protective of human health. I recommend that they include leaching of constituents for the storage pile as a part of the modeling process and that they pursue microbial-community studies to better characterize the impact on soil biota. I do not believe that this report has answered all necessary questions (i.e., the impact on specific soil biota). Several more studies would be needed to also quell the concerns expressed by the Michigan Department of Environmental Quality. I would characterize the report as an excellent start and foundation but it is not a complete vetting of the potential impacts.

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Peer review of:
Risk Assessment of Spent Foundry Sands in Soil-Related Applications
Prepared for:
Industrial Economics
2076 Mass. Ave, Cambridge, MA 02140
August 31, 2008

This risk assessment synthesizes a remarkably wide range of data and models of environmental processes. The breadth of the study is impressive, and the assessment makes ingenious use of a variety of existing models and data sets. As an academic researcher, it is easy to suggest that some data sets are insufficient to fully characterize the range of conditions across the US, and that we do not yet understand some physical and biogeochemical processes well enough to construct accurate models. However, many of these complaints would be counterproductive – the point of this assessment must be to construct the best estimates of risks given available data and existing models. Therefore, I will focus this review primarily on basic conceptual issues and on aspects of the evaluation that can be improved with available methods and data. I have chosen to first construct a list of broad comments, and to note how these comments relate to the charge questions. I then provide a few specific questions, and finally to come back to the charge questions with specific responses.

Broad Comments

A. Clarity of the Purpose of the Assessment
(Relates to charge questions 1 and 12)

The study arrives at a strong conclusion (ES-8): "*…no evidence was found that the specified uses of non-olivine SFS produced by iron, steel, and aluminum foundries evaluated in this report could pose significant risks to human health or the environment when used in manufactured soils, soil-less media, or road base.*" This statement (and other statements) is more than objective descriptions of the risks of using SFS, it is a value judgment about whether the risks of the anticipated uses of SFS are acceptable. As such, the conclusion combines both a quantification of the risks and an assessment of whether these risks are acceptable. The document would be easier to follow if clearly separated these two steps. However, I was not convinced that the study fully considered the second step, the judgment that risks are acceptable. For example, would the risks be acceptable under all types of SFS use? Is the choice of the 90-percentile risk appropriate, or should risks in the top decile, that are potentially much higher, also be considered? Do the risks need to be weighed against the benefits?

I think the document would be easier to follow, and would remain just as valuable, if it simply stated the purpose of providing a good assessment of the risks, and then adhered to this narrower purpose.

The study also uses a “weight-of-evidence approach”, and claims (p. 1-4) that it is “useful to consider exactly what this means” but does not appear to present a definition that clearly distinguishes this approach from simply conducting a good study. As best I can tell, the “weight-of-evidence” approach means a comprehensive study that brings together all useful lines of evidence. But, I am left wondering if there might be something more to this phrase.

Finally, in several places the report emphasizes that background concentrations of metals in SFS do not appear to be much higher than in natural soils, and therefore use of SFS poses no danger. This may be true, but this statement should be tempered with several caveats. First, SFS could contain artificial organic contaminants left after heating the binding agents. Second, the metals could be in a less recalcitrant state than in natural soils.

B. Adequacy of Screening Calculation for Inhalation of SFS (Section 4.2)
(Relates to charge questions 2 and 7)

The calculated risks from inhalation were based on a minimum distance of 500 m between the nearest residence and the source. This choice of value for the downwind distance does not appear to be conservative, especially relative to other selected parameter values. The choice is based on a single areal photograph of a blending facility. It is reasonable to suspect that, if more sites were considered, some would have closer distances to the nearest residence. For a conservative screening calculation, the assessment should use a minimum distance closer to 100 m. For the groundwater model, the choice of a 1 m distance from a garden to a drinking water well appears to have been an attempt to be conservative (however, see comment above). The same philosophy was not used for the choice of the distance between blending site and the nearest house. A distance of 100m seems like a reasonable, conservative choice.

Decreasing the assumed distance to the closest residence may push the 95th-percentile for manganese over the screening concentration. At 500 m, the calculated value of 501 mg/kg is only a factor of two less than the screening concentration (Table 4.4). Such an outcome would complicate the overall assessment. However, it could be very useful for devising future regulations for building blending facilities.

Issues related to manganese poisoning from inhalation have been considered in studies on the dangers of mining dust.

<u>C. Probabilistic Modeling of Groundwater Ingestion Pathway (section 5.2)</u>
(Relates to charge questions 2 and 7)

The groundwater modeling resulted in a result of "zero" for all estimated 90th percentile exposures (Table 5.1). First, "zero" for a chemical concentration appears a little peculiar – "zero" really means that the modeled results are at or below some minimum value that the model can accurately produce.

The more important question about these findings is: why are the values so low? Why does the simulated leachate not reach the well, or why is it so greatly diluted? Some simple calculations are useful for approaching these questions. First, it is useful to consider how long it will take the leachate to reach the well. If we only consider the time to flow through the saturated zone to the well, then the model parameters imply that it will take about a year for a conservative solute to reach the well from the far upstream side of the plot. (In all model runs, the plot was 1 acre (~40m x ~40m), the gradient was 0.0057, and the hydraulic conductivity was 1890 m/yr. So, assuming a porosity of 0.25, T = (40x0.25)/(1890x0.0057) = ~1 year). Thus, the modeled time for one of the solutes (e.g. arsenic) to reach the well will be longer, and perhaps much longer, than a year because the model includes the transport time through the unsaturated zone, and solutes are subject to sorption as parameterized by retardation factors. But, what time duration was modeled? The description states that the "land application unit was operated for 1 year", but for how long was the leachate input simulated, and for what time period was groundwater transport simulated?

Furthermore, what was the screened interval of the well? If concentrations at the bottom of the well were considered, then they would be "zero" because the bottom of the well is on a stream line that extends upgradient to a recharge source beyond the plot. <u>For groundwater concentrations below some depth in the aquifer, putting the well very close to garden plot is, in fact, not conservative</u> –contaminants from the SFS will pass above the depth of the well because the well is so close to the garden plot. (For a stream line to extend from the plot to the bottom of the well, recharge would have to be greater than 2.5 m. For a porosity of 0.25 again, and approximating stream lines as parallel, the recharge rate that will reach the bottom of the 10m aquifer in one year is, 10x0.25 = 2.5m. None of the realizations should have such a large recharge rate, and hence solute should not reach the bottom of the well in any of the realizations.) If only top levels of the aquifer are considered, then concentrations will rise more quickly after creation of the garden plot because leachate will reach the well quickly near the top of the aquifer. The "protective" approach would be to use the maximum concentration with depth.

In summary, there simply isn't enough explanation of the model to understand whether the "zero" concentrations are a robust finding, or whether they result from a peculiarity of the model setup. This report does not make a convincing case that the groundwater modeling has been carefully considered. For example, hydraulic conductivity is the largest source of uncertainty in most groundwater models, yet in this probabilistic assessment that parameter is set to a constant value. In fact, it appears that this assessment would be better served by employing a simpler approach -- that a sophisticated groundwater model may be unnecessary. Simple approximations of pore-water velocities and retardation factors would produce equally valid outcomes, and such an approach would be more transparent.

D. Presentation of Risk Results
(Relates to charge questions 1, 8 and 12)

Rather than present only 90th-percentile hazard estimates (e.g. table 5.8), the assessment would benefit by presenting the entire histogram. Using histograms instead of point estimates has a number of advantages: (1) It would remind the reader that the estimates are the result of a Monte-Carlo simulation and give the reader a visual representation of the spread of the resultant distribution. (2) In the current presentation, there is no indication of the skewness of the distribution – above the 90% cutoff, just how large are the values? As a hypothetical example, if the distribution is very skewed then more than half of the health risks could lie above the 90% cutoff, and hence the approach taken in this assessment would miss the real danger. (3) Using the 90% cutoff is arbitrary. The full histogram offers the possibility of estimating other point measures.

Detailed Comments

Page ES-2, paragraph 6. Are the heavily contaminated sands used for brass or olivine sands ever mixed with other sands? In other words, is the distinction between the contaminated SFS left out of this assessment and the safer SFS retained for the assessment always clear? Would foundries ever shift from one kind of sand to another and in the process mix the sands?

Page ES-3, paragraph 2. The assessment should document the claim that inhalation and ingestion cause different health impacts – I was not aware that this is true across the range of contaminants considered here. Furthermore, the effects of ingestion on different time scales could be cumulative. For example, I am unaware of any research that indicates arsenic ingestion over different timescales is not cumulative. I suspect that rapid exposure from produce followed later by exposure from groundwater could be cumulative.

Page 1-1, paragraph 2. Why do heat and abrasion render sands unsuitable? To develop a conception of SFS, it would be useful to better understand how it has been altered in the foundry from natural sands so that it is no longer useful.

Page 1-4, paragraph 3. What does the spatial scale of the risk assessment mean? The size of the garden plots? The extent to which SFS is applied over a geographic area?

Page 1-4, paragraph 5. Needs editing – "… *the characteristics of individual metals, such as the soil-plant barrier,...*"

Page 2-4, paragraph 3. *Core butts were removed by sieving*. Will these butts be removed before the use of SFS, and if not, could they be a source of contamination in SFS neglected by this assessment?

Page 2-5, paragraph 3. **"***The method detection limit for this data set was calculated by multiplying the standard deviation of the baseline noise by the t-value at the 99% confidence interval.*" This statement needs explanation, and description of the implications.

Page 3-7, paragraph 1. The statement that SFS will not be used for agronomic purposes is not convincing. It may be true that economics will always limit the use of SFS by farms, but I see no concrete evidence to support this contention. How expensive is SFS, and how much is it worth to improve soils for a farm? If SFS were used for a farm, then clearly a larger plot or garden area would need to be considered for the groundwater and home gardener models.

Page 3-13, paragraph 1. Needs editing **–** "*It was also clear that certain scenarios were more significant in some scenarios than in others."*

Page 5-4, last bullet point. Why were the concentrations of antimony, beryllium, cadmium, and lead modeled at half their detection limits? The detection limit would be the appropriate "protective" value.

Charge Questions

1) Please comment on the transparency of the risk assessment.

See A and D above. Also, as a more specific comment, the report should better illustrate the Soil/Produce Ingestion Pathway model (section 5.3). This model is an important part of the overall assessment, and is bewilderingly complex. A simple way to bring some clarity to the model presentation is to illustrate a mass balance for the model. The flow chart of mass fluxes for the conceptual model is intricate, and as presented it is impossible for the reader to determine the magnitude of the different fluxes. A mass balance for the model would illustrate how much mass of a particular contaminant is applied, and then how much of this contaminant is transported through the different pathways. This would give the reader some notion of the importance of the different pathways. Also, constructing a mass balance is absolutely key to validating a model – the mass fluxes must sum to the mass loss. Thus, presentation of the mass balance would also provide some confidence in the workings of the model. This balance continues to hold when mean values across all realizations are used, and showing the average values may be the best way to illustrate the mass balance, although augmenting the averages with their standard deviations would improve the illustration.

2) Please discuss the adequacy of the risk assessment execution.

See B and C above.

3) Please comment on whether the selection of U.S. foundries was representative of the industry and if the characterization of these foundry sands was adequate.

I have no experience with variability among foundries. However, 43 samples appears to be a small sample size. More samples would benefit the assessment given the differences among natural sands, the metals cast, and the different binders.

4) Please comment on the methodology used for choosing constituents to evaluate.

The list of metals contains the most likely contaminants except for the neglect of mercury and selenium in the screening model. I do not have the background to comment on potential organic contaminants. However, it is clearly very important to carefully consider all possible organic contaminants, and I hope that one of the other reviewers can bring this expertise to the review.

5) Please comment on the conceptual models, particularly the plausibility of the sources, pathways, and receptors included.

The major sources, pathways and receptors are included.

6) Please discuss the appropriateness of the Manufactured Soil conceptual model, as protective of the other conceptual models.

Yes, it appears "protective."

7) Please discuss whether the screening steps reported in Chapter 4 were appropriately conservative in their application to support the conclusions.

See B and C above.

8) Please comment on the appropriateness of the various probabilistic modeling steps employed to develop national-scale screening values.

See D above.

9) Within the context of a screening risk assessment, please comment on the level of conservatism inherent in the Home Gardener scenario, with special attention to the assumption of independence of the ingestion pathways. Please also comment on the rationale for modeling the 50%tile and 90%tile general population consumption rates, each with a 50% homegrown fraction.

The assessment should document the claim of independence of ingestion pathways. I am not aware (across the range of contaminants) that inhalation and ingestion cause different health impacts (e.g. lead?). Furthermore, the effects of ingestion on different time scales could be cumulative, so groundwater and produce may not be independent pathways. For example, I am unaware of any research that indicates arsenic ingestion over different timescales is not cumulative.

10) Please comment on how soil background, phytotoxicity, and impacts on soil biota were considered in the assessment.

The assessment describes a broad and representative sampling of the research literature.

11) Please comment on the clarity of the Risk Characterization section, with special attention to the discussion of uncertainties.

I found the writing and organization in this section reasonably clear. The discussion of uncertainties should be broadened to include important uncertainties that are very difficult to assess from the available data. The section should discuss uncertainty associated with using 43 SFS samples to represent all SFS that would be provided by large-scale projects. The report section should also highlight the possibility of organic contaminants not considered in the assessment.

12) Please comment on whether the assessment supports the report's conclusions.

See A and D above. The report makes a strong argument that SFS use is safe. However, the report would ultimately be more compelling, and certainly more useful, if it focused on providing the best description of the distribution of risks.