Responses to External Peer Review Comments: Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals

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United States Environmental Protection Agency
Office of Solid Waste and Emergency Response
Office of Resource Conservation and Recovery

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Abbreviations

CCR	Coal Combustion Residual
COPC	Constituent of Potential Concern
EPA	Environmental Protection Agency
HEI	Highly Exposed Individual
LEAF	Leaching Environmental Assessment Framework
OIG	Office of Inspector General
ORCR	Office of Resource Conservation and Recovery
OSWER	Office of Solid Waste and Emergency Response
RSL	Regional Screening Level
WOE	Weight of Evidence

1 Introduction

1.1 Background

The US Environmental Protection Agency ("EPA" or "the Agency") Office of Solid Waste and Emergency Response (OSWER) developed a document titled, *Methodology for Evaluating Beneficial Uses of Coal Combustion Residuals* ("the methodology document"), to detail an evaluation methodology developed to determine whether releases from encapsulated products containing coal combustion residuals (CCR) are comparable to or lower than those from analogous non-CCR products, or are at or below relevant regulatory and health-based benchmarks for human and ecological receptors, during use by the consumer (US EPA, 2013). In March 2012, the Agency contracted with Versar, Incorporated ("Versar") to conduct an independent external letter peer review of the draft methodology document. As part of this review process, a copy of the draft methodology document, as well as four specific charge questions were provided to the peer reviewers for comment. Versar compiled the comments received from the peer reviewers and, in April 2012, completed a report for EPA titled, *Peer Review Summary Report: Independent External Peer Review of the Preliminary Draft Report, Methodology for Evaluation Encapsulated Beneficial Uses of Coal Combustion Residuals* (US EPA, 2012). The report generated by Versar enumerates the individual peer review comments received and summarizes them by charge question.

1.2 Objectives and Organization

The purpose of this document ("the response document") is to provide a summary discussion of the substantive peer review comments received, the corresponding responses to these comments, and any changes to the methodology made in response. This response document does not address individual editorial comments received on topics, such as formatting, grammar, and typographical errors. All editorial comments were considered and addressed as appropriate while updating the methodology document.

This document is organized into five main sections. The first four sections pertain to comments provided for each of the charge questions. The final section pertains to additional comments that were provided independent of a specific charge question. Each section consists of the peer review comments received for a given charge question, grouped by topic, followed by the corresponding responses to those comments.

2 Charge Question #1

"Is the evaluation methodology proposed in this report sufficiently written in a manner that is clear, robust, transparent, and flexible for the intended purpose?**"**

The following subsections present the peer review comments provided for the first charge question and the corresponding responses. Comments are organized based on their relevancy to topics of the clarity, robustness, transparency, and flexibility of the methodology. Comments provided for this charge question on additional topics are presented at the end of this section.

2.1 Comments on Clarity

2.1.1 Peer Review Comment:

Two reviewers commented that the methodology is sufficiently clear.

Reviewer #1: **"***In general, yes.***"**

Reviewer #3: **"***The methodology is clear, transparent and flexible and is appropriate for the intended purpose.***"**

Response:

No changes made in response to these comments.

2.1.2 Peer Review Comment:

One reviewer asked for clarification on the identity of the party responsible for implementing each step of the evaluation.

Reviewer #4: **"***In the "Purpose," who is in charge or manages each step of the evaluation methodology? Is this all handled by EPA? Which Agencies? Or by local or state governments or agencies?***"**

"*In "Step 5 - Risk Assessment," paragraph 3, please specify who judges, and how the determination is made, to whether the "existing data gaps and uncertainties are too great to reach a final conclusion, and then additional data and evaluation may be needed.***"**

"*Is the Office of Resource Conservation and Recovery the only EPA Agency involved with implementing this methodology? What is the role of OSWER?***"**

Response:

OSWER agrees this point could be made clearer. In response, text has been added to clarify that OSWER and others outside of EPA, such as states; industry; or the public, may choose to use the methodology. In addition, the document makes clear that of this methodology is voluntary, not regulatory. There are no legally binding requirements for any party to use the methodology.

2.1.3 Peer Review Comment:

One reviewer noted that it is unclear whether Step 5 (Risk Assessment) involves a comparison of the CCR and analogous products.

Reviewer #4: **"***It is unclear whether a comparison of health-based risks (noncancer and carcinogenic) are taken into account in the final step.***"**

Response:

Only Step 2 (Comparison of Available Data) involves a direct comparison of the CCR beneficial use product to an analogous product. Subsequent steps only involve an evaluation of the CCR beneficial use product. The text of each step throughout the document now clarifies this point.

2.1.4 Peer Review Comment:

One reviewer asked how chemical mixtures are addressed in the methodology.

Reviewer #4: **"***Also, please clearly state whether mixtures or specific chemicals are taken into account in the comparative risk assessment.***"**

Response:

No changes were made to the document based on this comment. Consideration of chemical mixtures is possible within the framework of the methodology. If consideration of different chemical mixtures will be incorporated into an evaluation, then the party conducting the evaluation may refer to existing EPA guidance on this topic.

2.1.5 Peer Review Comment:

One reviewer asked for clarification on the meaning and application of the term "surrogate."

Reviewer #4: **"***In Section 2.2, Comparison of Available Data, the discussion of surrogate COPC needs to be more clearly presented (i.e., in the third paragraph of Section 2.2). It is unclear whether the surrogate is a product or chemical, or a chemical mixture in the product containing encapsulated CCR. How is the surrogate selected? What are some criteria for establishing an appropriate surrogate?***"**

"*In "Step 4 - Screening assessment, it is confusing to use "surrogate for exposure" in paragraph 3 and also "surrogate in place of releases" in Section 2.2, paragraph 3. A consistent use of the word "surrogate" is needed.***"**

Response:

OSWER agrees that this should be clarified. In response, the text in Step 2 (Comparison of Available Data) has been updated to elaborate on the criteria for an appropriate surrogate. In addition, a specific example was provided to illustrate OSWER's intent.

2.1.6 Peer Review Comment:

One reviewer requested clarification on the identity of the regulatory organizations with which the party conducting the evaluation should engage.

Reviewer #4: **"***In Section 2, Methodology, the second paragraph states that "…is encouraged to engage with the appropriate regulatory organizations to ensure that all assumptions, models, and calculations used are valid and appropriate." It appears that further clarification needs to be provided as to who the (initial) contact agencies should be so that "the party conducting the evaluation" will know who or what agency to contact.***"**

Response:

OSWER agrees that this point should be clarified. In response, the text in the Section 2 has been updated to provide additional details on the type of regulatory organizations relevant to beneficial use evaluations.

2.2 Comments on Robustness

2.2.1 Peer Review Comment:

Two reviewers commented that the methodology is sufficiently robust.

Reviewer #1: **"***In general, yes.***"**

Reviewer #2: **"***The evaluation method proposed is robust and transparent and based on proven methods EPA has; however, it is not totally clear to a reader. Some aspects can be made clearer. Please see the general comments above.***"**

Response:

No changes made in response to these comments.

2.2.2 Peer Review Comment:

One reviewer commented that the methodology is generally robust, but leaves the determination of whether an evaluation is adequate to the individual reviewing the document.

Reviewer #3: **"***The robustness of the methodology remains a question in my mind. In one sense, the methodology is robust in that a very general set of principles for how one would approach evaluating a beneficial use of CCRs. In fact, it is general enough that it would extend far beyond beneficial uses of CCRs. In a second sense, the robustness is questionable because its general framework nature leaves the assessment of a potential decision made with this approach largely up to the individual reviewing the evaluation. For example, lack of data on both CCR-containing product and non-CCR-containing product could lead to high uncertainty of exposures for both materials resulting in an inability to say that they are different. The methodology and flow chart do not indicate whether or when collection of additional data is warranted.***"***

Response:

The methodology is intended to be flexible to account for variability in and quality of the information that is available. The general framework of the methodology requires the party conducting the evaluation, whether EPA or some other party, to exercise their best professional judgment when making decisions on topics, such as the adequacy of available data. Any data relied upon or uncertainties associated with the evaluation should be fully documented, explained, and disclosed in the text of the evaluation. No changes were made to the document in response to this comment.

2.3 Comments on Transparency

2.3.1 Peer Review Comment:

Three reviewers commented that the methodology is sufficiently transparent.

Reviewer #1: **"***In general, yes.***"**

Reviewer #2: **"***The evaluation method proposed is robust and transparent and based on proven methods EPA has.***"**

Reviewer #3: **"***The methodology is clear, transparent, and flexible and is appropriate for the intended purpose.***"**

Response:

No changes made in response to these comments.

2.3.2 Peer Review Comment:

One reviewer suggested including a timeline describing the groups involved in the development of the methodology and the timeframe for its development.

Reviewer #4: **"***In Section 1.2 - Purpose, consider presenting a flowchart or diagram summarizing the history (timeline) of the development of a methodology for evaluating the beneficial use of encapsulated CCRs. This diagram could include the EPA agencies, and other government agencies and programs that have been associated with the development of guidelines and methodology for evaluating the encapsulated (and unencapsulated) use of CCRs. This would provide a useful summary of how this methodology evolved and how stakeholders interact.***"**

"*If a figure such as that suggested above in Section 1.2 would be included, then the agencies and regulatory organizations involved with the evaluation for encapsulated use of CCRs would be easily identified.***"**

Response:

OSWER has not made changes to the document to summarize the history (timeline) of the development of the methodology. OSWER believes that such a discussion is not essential to the purpose of the document, and therefore believes its inclusion is not necessary. However, the text of the methodology document has been revised to make clear that the methodology was developed by OSWER for use by the Agency. The methodology responds to a recommendation from a report issued by the EPA Office of Inspector General (OIG) in March 2011 (US EPA, 2011a).

2.4 Comments on Flexibility

2.4.1 Peer Review Comment:

Two reviewers commented that the methodology is sufficiently flexible.

Reviewer #1: **"***In general, yes.***"**

Reviewer #3: **"***The methodology is clear, transparent, and flexible and is appropriate for the intended purpose.***"**

Response:

No changes made in response to these comments.

2.5 Additional Comments

2.5.1 Peer Review Comment:

One reviewer stated that the methodology should consider natural background levels of COPCs to determine if additional significant risk is added to natural background.

Reviewer #1: **"***I do have concerns re: Step 5-Risk Assessment. Specially, maximum allowable concentrations of COPC that are below natural environmental media background such as arsenic. The methodology should be flexible by consideration of natural background levels of these COPC to determine if additional significant risk is added to natural background from the encapsulated CCR.***"**

Response:

OSWER agrees that, in some cases, naturally occurring background concentrations of COPCs are potentially relevant benchmarks for consideration in Step 4 (Screening Assessment) and Step 5 (Risk Assessment). Other parties using this methodology should consult with the appropriate regulatory organizations to ensure that their evaluation is consistent with any relevant State requirements. No changes were made to the document in response to this comment.

2.5.2 Peer Review Comment:

One reviewer requested discussion of dermal contact as a potential exposure route in Step 3 (Exposure Review), as well as further discussion on the exposure models for human and ecological receptors referenced in the hypothetical conceptual exposure model (Figure 2-1).

Reviewer #4: **"***Is there an exposure model that takes into account HEI and separately the ecological receptor? Figure 2-1 seems to indicate that there is. If there is not, then it would be useful to suggest or recommend exposure models that characterize the exposure pathways and resulting exposure concentrations for each of the receptors.***"**

"*It is unclear whether human dermal exposures are accounted for in this evaluation model framework. (screening levels for dermal exposures are lacking, however, e.g., the ATSDR does not have MRLs for hazardous substances for the dermal exposure route).***"**

Response:

OSWER agrees that dermal contact with COPCs is a potentially relevant exposure route for consideration in Step 3 (Exposure Review). The main text of Step 3 already references dermal contact as one potential exposure route. Additional text was added to the hypothetical example at the end of Step 3 to provide an accompanying narrative to the conceptual exposure model (Figure 2-1). This narrative explains why certain exposure pathways were identified as incomplete in the hypothetical example. No changes were made in response to the request for additional information on exposure models for human or ecological receptors because Step 4 (Screening Assessment) already discusses models that may be used to characterize COPC concentrations at the point of exposure.

3 Charge Question #2

Please comment on the applicability of this methodology to the range of potential encapsulated beneficial uses of CCRs.

The following subsections present the peer review comments provided for the second charge question and the corresponding responses. Comments are organized based on their relevancy to the topic of the applicability of the methodology to the range of potential encapsulated beneficial uses of CCRs. Comments provided for this charge question on additional topics are presented at the end of this section.

3.1 Comments on Applicability

3.1.1 Peer Review Comment:

Two reviewers commented that the methodology is applicable for a range of potential encapsulated beneficial uses of CCRs.

Reviewer #1: **"***The methodology is robust and covers most of the critical exposure scenarios for encapsulated CCR such as wallboard, concrete, roofing materials and bricks.***"**

Reviewer #2: **"***Because of the uncertainty what encapsulated beneficial uses cover, it is difficult to answer. But considering some of these uses individually as listed under the general comments above, it appears to be applicable. However, the pathways and critical aspects are different for different uses.***"**

Reviewer #3: **"***The methodology is entirely applicable. In fact, it seems just as appropriate for non-encapsulated uses and uses of other types of byproducts in addition to CCRs. Its general nature makes it quite widely applicable.***"**

Response:

No changes made in response to these comments.

3.2 Additional Comments

3.2.1 Peer Review Comment:

One reviewer asked whether Step 2 (Comparison of Available Data) addresses environmental releases or receptor exposures.

Reviewer #4: **"***Also, in Section 2.2, Comparison of Available Data, it is important to distinguish b/w whether emissions to the environment or human exposure*

*concentrations are being assessed with respect to screening levels and health-based thresholds. For ecological endpoints and possibly direct exposure pathways to humans, the former may be sufficient, but for human receptors the comparison should ideally be made on an exposure basis, using fate and transport modeling to characterize direct and indirect exposure routes.***"**

Response:

OSWER agrees that this point should be clarified. In response, Step 2 (Comparison of Available Data) was clarified to emphasize that only COPC releases, or an appropriate surrogate, from a CCR product are compared to those from an analogous non-CCR product. In addition, Step 3 (Exposure Review) was clarified so that receptor exposures are first discussed in this step of the methodology. Step 4 (Screening Assessment) was clarified so that fate and transport modeling is first discussed in this step of the methodology.

3.2.2 Peer Review Comment:

One reviewer requested clarification on the meaning and application of the term "weight of evidence."

Reviewer #4: **"***It is unclear how a WOE approach will be incorporated into this methodology. In the introductory paragraph to Section 2 - Methodology, it is stated that "this methodology is intended to be broad and flexible to allow a weight of evidence approach to the evaluation of beneficial use of CCRs." The WOE approach is not brought up again until Section 2.4 - Screening Assessment (page 2-7). But, how will the WOE approach aid in making decisions with respect to conflicting data in Step 2? I also suggest that in Section 2.1, Step 1- Literature Review, the first paragraph could end with whether and how the WOE approach fits in with this stage of the evaluation. Please consider incorporating the findings from the four references under my response to Charge Question 4, which may help with defining the role and use of the WOE approach in this methodology.***"**

Response:

As evidenced by the references supplied by the reviewer (Burton at al., 2010; Linkov et al., 2009; Mumtaz and Durkin, 1992; and Weed 2005), the term "weight of evidence" has been applied in multiple ways to the field of risk assessment. The term may be taken to mean different things in different contexts. Therefore, in order to avoid confusion, "weight of evidence" was removed from the document in favor of the more general term "lines of evidence."

4 Charge Question #3

Are there any additional steps or considerations that should be included in the methodology for encapsulated uses of CCRs?

The following subsections present the peer review comments received for the third charge question and the corresponding responses. Comments are organized based on their relevancy to topics of additional steps and additional considerations recommended for inclusion in the methodology. Comments provided for this charge question on additional topics provided are presented at the end of this section.

4.1 Comments on Additional Steps

None of the peer reviewers called for the inclusion of additional steps to or removal of existing steps from the methodology.

4.2 Comments on Additional Considerations

4.2.1 Peer Review Comment:

One reviewer requested discussion of dust ingestion as a potential exposure route in Step 3 (Exposure Review)

Reviewer #1: **"***The dust ingestion pathway must be considered. This pathway is mentioned on page 2-5 but is absent in Figure 2-1.***"**

Response:

OSWER agrees that ingestion of COPCs in dust is a potentially relevant exposure pathway for consideration in Step 3 (Exposure Review). The main text of Step 3 already generally references ingestion as one potential exposure route. Additional text was added to the hypothetical example at the end of Step 3 to provide an accompanying narrative to the conceptual exposure model (Figure 2-1). This narrative explains why certain exposure pathways were identified as incomplete in the hypothetical example.

4.2.2 Peer Review Comment:

One reviewer requested additional guidance on how to deal with sensitive ecological receptors.

Reviewer #4: **"***The draft states that both human and ecological receptors will be considered for the exposure modeling. What are some of the analogous HEIs considered for ecological receptors? As pointed out in "Step 3 - Exposure Review," identifying the appropriate receptor is key and although a comprehensive*

description of human receptor types is provided, relatively little discussion of ecological receptor types is provided (beyond phylogenic class). It is suggested that additional references be provided for additional information on characterizing ecological receptor, e.g., providing a link to tools that the EPA has developed to screen for ecological risks, e.g.

*http://www.epa.gov/oswer/riskassessment/tooleco.htm***"**

"*Also, please consider providing an (example or recommended) Ecological screening level tool.***"**

Response:

OSWER agrees that the document could benefit from further discussion of sensitive ecological receptors. In response, additional discussion of sensitive ecological receptors has been added, where relevant, throughout the document. In Step 3 (Exposure Review), additional text was added to note that an evaluation should capture, at a minimum, the ecological receptors determined to be most sensitive to the COPCs, and that these receptors may differ based on the specific COPCs and exposure routes evaluated. In Step 4 (Screening Assessment), a link to some potentially relevant ecological screening benchmarks was added.

4.2.3 Peer Review Comment:

One reviewer commented that the methodology should consider the persistence of COPCs.

Reviewer #4: **"***A key hazard screening criteria is the chemical persistence in the air, soil, or water media. But, persistence is not mentioned anywhere in the document. This might be a useful fate parameter to use to make comparisons between the COPC associated with the encapsulated CCR beneficial use product, and the COPC from the analogous product made of virgin material. The US EPA's EPI Suite screening level tool may be useful to include in the assessment in order to characterize the overall persistence in environmental media.*

*(http://www.epa.gov/oppt/exposure/pubs/episuite.htm).***"**

Response:

OSWER agrees that COPC persistence in environmental media may be a potential consideration in the evaluation. In response, the text in Step 3 (Exposure Review) has been updated to clarify that chemical persistence may be an reasonable consideration when developing the conceptual exposure model. Additionally, OSWER added an example of a general resource that may aid in characterizing the persistence of COPCs in the environment. EPI Suite is another potentially relevant example.

4.2.4 Peer Review Comment:

One reviewer requested additional background discussion of fate and transport models.

Reviewer #4: **"***"Step 4 - Screening assessment," paragraph 4, presents the first mention of "fate and exposure modeling." I think some background on fate and exposure modeling is needed, beyond a reference to the "Protecting Air" and "Assessing Risk" chapters of the Guide for Industrial Waste Management (US EPA, 2003). Perhaps a summary of some commonly used and agency-approved fate and transport and exposure models in the Appendix. See, for example, the following EPA screening-level models:*

EMSOFT for chemical volatilization from soil to air (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=2862)

*MMSOILS for modeling the chemical transport across multi-media environments, and the direct and indirect human exposure pathways (http://www.epa.gov/ceampubl/mmedia/mmsoils/).***"**

Response:

OSWER disagrees. The methodology is not intended to be an overview of general risk assessment topics, such as fate and transport modeling. If fate and transport modeling is warranted, then the party conducting the evaluation may refer to existing EPA guidance on this topic. An additional reference to the "An Overview of Exposure Assessment Models Used by the US Environmental Protection Agency" chapter of *Modeling of Pollutants in Complex Environmental Systems, Volume II* (Williams et al., 2010) was added to Step 4 (Screening Assessment). This reference, along with the other reference already cited in Step 4, provides a good overview of several specific fate and transport models.

4.3 Additional Comments

4.3.1 Peer Review Comment:

One reviewer asked who the party is that is responsible for conducting the evaluation.

Reviewer #4: **"***In addition, in the Hypothetical Application of Step 1, what party makes the conclusion that there are "no significant data gaps or other concerns." Is this based on expert judgment and/or EPA determination or by implementing a WOE approach?***"**

Response:

As noted in **Section 2.1.2** of this document, the judgment is made by the party conducting the evaluation.

4.3.2 Peer Review Comment:

One reviewer asked if the statistical analysis referred to in Step 2 (Comparison of Available Data) is a t-test.

Reviewer #4: **"***In Section 2.2, Paragraph 4; Please clarify what is meant by "if data are available, this may be accomplished using statistical analysis or another appropriate comparison method"? What type of statistical analysis is referred to? Is this a t-test to compare the means of the distributions of the emission rates from the encapsulated CCR beneficial use product with the analogous product? Also, in the hypothetical Application of Step 2, what does the "statistical test conducted" indicate, e.g., is that also a t-test? Clarification and specific guidance would be useful in terms of recommended (or required) statistical tests.***"***

Response:

OSWER agrees that the example of a t-test suggested by the reviewer is one potentially applicable statistical analysis test; however, it is not the only test that may or necessarily should be used. In response, however, OSWER added an example of statistical software in Step 2 (Comparison of Available Data) that may be used to help select and conduct statistical analyses.

4.3.3 Peer Review Comment:

One reviewer asked if the regional screening levels (RSLs) are "officially" recommended for use in evaluations.

Reviewer #4: **"***Based on the material in "Step 4 - Screening Assessment": Is the RSL officially recommended for use in the evaluation? Please specify in the evaluation report.***"**

Response:

The examples provided at various points in the methodology represent only some of the available resources that may be relevant for a given evaluation. Screening benchmarks may already be defined by state or federal legislation, regulations, or existing risk management policy. In addition, screening benchmarks may also be calculated by the party conducting the evaluation. In all cases, it is important to understand and disclose all of the assumptions behind each set of screening benchmarks to ensure that they are appropriately conservative. No changes were made to the text in response to this comment.

4.3.4 Peer Review Comment:

One reviewer asked whether Step 2 (Comparison of Available Data) addresses environmental releases or receptor exposures.

Reviewer #4: **"***In Section 2.2, Comparison of Available Data, it is unclear whether dermal exposures are considered, e.g., through direct handling of the end product? Depending on the type of encapsulated CCR beneficial use product, there may be a potential for dermal contact and human exposure.***"**

Response:

As noted in **Section 3.2.1** of this document, Step 2 (Comparison of Available Data) only addresses releases from CCR products with a comparison to those from an analogous non-CCR product.

4.3.5 Peer Review Comment:

One reviewer asked how a more realistic exposure scenario is generated in Step 5 (Risk Assessment).

Reviewer #4: **"***The second sentence of "Hypothetical Application of Step 5," i.e. "The fifth step begins by reevaluating the conservative assumptions used in the previous screening step to generate a more realistic exposure scenario." Seems to be referring to conducting a sensitivity analysis on the output of the fate and exposure model by varying the assumptions/inputs. Are there any guidelines by which a "more realistic exposure scenario" is generated? Seems that a probabilistic or Monte Carlo assessment of risk is needed, and central tendencies need to be evaluated as well as the 75th or 95th [percentile – language added] (for a HEI) and then presented for each scenario, i.e., based on which model input(s) were adjusted.***"***

Response:

OSWER agrees that this point should be clarified. In response, the text in Step 5 (Risk Assessment) has been updated to clarify that more realistic exposure assumptions are generated by incorporating environmental data, fate and transport assumptions, and/or exposure assumptions that are more representative of real world conditions than those used in the previous Step 4 (Screening Assessment). The methodology is flexible and allows consideration of different methods of incorporating these data and assumptions into the evaluation and different ways to present the results. Other parties using this methodology should consult with the appropriate regulatory organizations to ensure that their evaluation is consistent with any relevant State requirements.

4.3.6 Peer Review Comment:

One reviewer requested clarification on whether the term "potential adverse effects" referred to cancer and non-cancer endpoints for humans.

Reviewer #4: **"***In "Step 4- Screening assessment," in the first sentence of the second paragraph, what does "potential adverse effect" refer to specifically? I assume that it is a health-based endpoint for the human receptor, so a carcinogenic or non-carcinogenic effect (this should be explicitly stated somewhere in the document though).***"**

Response:

The term "potential adverse effect" is a broad term used to address toxicological endpoints in both human and ecological receptors. The text in Step 4 (Screening Assessment) has been updated to clarify this.

4.3.7 Peer Review Comment:

One reviewer requested clarification on the meaning of the term "inherent variability."

Reviewer 4: **"***In Section 2.2 - Comparison of Available Data, Paragraph 4, Additional clarification on the material presented here is needed. How is inherent variability defined? Three references are suggested and listed under my response to Charge Question 4, in order to characterize and assess the true uncertainty and variability in the evaluation.***"**

Response:

OSWER agrees that additional clarity is needed. Consequently, the text in Step 2 (Comparison of Available Data) has been updated to remove the term "inherent variability" and, instead, the methodology document elaborates on some of the variables that an evaluation may need to account for during a comparison of CCR beneficial use products and analogous products.

4.3.8 Peer Review Comment:

Two reviewers requested clarification on the meaning and application of the terms "sufficient," "quality," and "adequately addressed."

Reviewer #3: **"***I would like to see data sufficiency be incorporated more clearly. I don't know that this is easily done at this general level, but it should be addressed clearly in the methodology. The first step of the methodology briefly mentions that additional data may be collected, but this is a different issue than the sufficiency of existing (or even newly collected) data.***"**

Reviewer #4: **"***In Section 2.1, Step 1- Literature Review, it is recommended that additional guidance be provided in terms of determining the "sufficient application and quality to demonstrate the potential beneficial use is comparable to the*

*analogous non-CCR product." What are some [sic] the criteria for defining "sufficient" and "quality"? Also, along these lines, what is the definition of "sufficient" in paragraph 5? Or the definition of "adequately addressed" in Paragraph 6? Is this based on expert judgment or review by the ORCR? Please specify in the report.***"**

Response:

OSWER agrees that the meaning and application of these terms could be made clearer. In response, a reference has been added to Step 1 (Literature Review and Data Collection) detailing the general assessment factors used by EPA to determine if the quality of the data that is submitted to or gathered by the Agency is sufficient. The term "adequately addressed" has been replaced by the phrase, "sufficient applicability and quality to demonstrate that releases from the CCR beneficial use under evaluation are comparable to or lower than those from an analogous product, or are at or below relevant regulatory and health-based benchmarks."

5 Charge Question #4

Are you aware of any additional references or other resources that could improve the methodology?

The following subsections present the peer review comments received for the fourth charge question and the corresponding responses.

5.1 Response on Additional References and Resources

5.1.1 Peer Review Comment:

Two reviewers provided additional references and resources for consideration in the methodology.

Reviewer #1: **"***Scheckel, K.G., R.L. Chaney, N.T. Basta and J.A. Ryan. 2009. Advances in Assessing Bioavailability of metal(loid)s in Contaminated Soils. Adv. Agron. 107:10-52***"**

Reviewer #2: **"***No.***"**

Reviewer #3: **"***There are loads of references and resources that are available about the performance of encapsulated CCRs, about leaching methods and evaluation frameworks, that would be appropriate to reference. However, the methodology as presented in not reliant on such sources and inclusion would complicate what is a Spartan approach to presentation of a very general methodology.***"**

Reviewer #4: **"***Hertwich, EG, TE McKone, and WS Pease (1999). Parameter uncertainty and variability in evaluate fate and exposure models. Risk Analysis 19(6): 1193-1204.*

Hertwich, EG, TE McKone , and WS Pease (2000). A systematic uncertainty analysis of an evaluate fate and exposure model. Risk Analysis 20(4): 439-454.

Paté-Cornell, ME (1996). Uncertainties in risk analysis: Six levels of treatment, Reliability Engineering and System Safety 54(2–3): 95-111.

Mumtaz, MM and PR Durkin (1992). A weight-of-evidence approach for assessing interactions in chemical mixtures. Toxicology and Industrial Health 8(6); 377-406.

Weed, D (2005). Weight of Evidence: A Review of Concept and Methods. Risk Analysis 25(6): 1545- 1557. http://onlinelibrary.wiley.com/doi/10.1111/j.1539-6924.2005.00699.x/full

Burton, GA, PM Chapman, EP Smith. (2010). Weight-of-Evidence Approaches for Assessing Ecosystem Impairment. Human and Ecological Risk Assessment: An International Journal 8 (7): 1657-1673.
http://www.tandfonline.com/doi/abs/10.1080/20028091057547

Linkov, I, D Loney, S Cormier, and T Bridges (2009). Weight-of-evidence evaluation in environmental assessment: Review of qualitative and quantitative approaches. Science of the Total Environment 407(19): 5199-5205.

*US EPA (2011). Exposure Factors Handbook 2011 Edition (Final). US Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F.***"**

Response:

OSWER reviewed the literature sources provided by the reviewers and generally found them to be outside of the scope of this document. The methodology document was developed to discuss topics specific to the evaluation of encapsulated CCR beneficial use products. Consideration of broader risk assessment topics is considered outside the scope of the methodology document. The literature sources Burton at al. (2010), Linkov et al. (2009), Mumtaz and Durkin (1992), and Weed (2005) were all found to be relevant to the use of the term "weight of evidence." Based on a review of these sources, it was determined that use of the term "weight of evidence" is more confusing than helpful to the reader and the term was removed from the document and replaced with the phrase "lines of evidence." Therefore, while considered, these literature sources were not directly incorporated or cited in the document. The literature source, *2011 Exposure Factors Handbook* (US EPA, 2011b) was found to be both relevant and helpful to the discussion of calculation of screening benchmarks and was cited in the document.

6 Additional Comments

The following subsections present the additional peer review comments that were not provided in response to a specific charge question and the corresponding responses.

6.1 Comments Provided Independent of a Charge Question

6.1.1 Peer Review Comment:

All four reviewers provided positive feedback on the methodology. One reviewer indicated that the methodology is comprehensive and scientifically sound. Two reviewers indicated that the methodology is clear, flexible, and consists of logical and straightforward steps. Another reviewer stated that the methodology follows a traditional risk assessment paradigm.

Reviewer #1: **"***The methodology described in the preliminary draft is comprehensive and offers a scientifically sound quantitative evaluation of environmental human and ecological risk associated with select beneficial use[s] of encapsulated CCR.***"**

Reviewer #2: **"***The methodology presented is intended to provide an evaluation approach for beneficial use of CCRs for encapsulated uses. The introduction rightfully states the EPA's policy of supporting beneficial use of CCRs, balanced with its mission of protecting human health and the environment. The purpose given on page 1-1 makes reference to the EPA's C^2P^2 program and describes the motivation for developing the methodology. The seven damage cases that were not made accessible by the C^2P^2 Website, I believe, did not involve any "encapsulated beneficial use." Therefore, this phase of the methodology is probably not rooted in a real demonstrated damage, thus it should not be unnecessarily cumbersome and extensive but needs to be in place to bring everything, including new encapsulated uses, to the EPA's accepted and standard practice.* **"**

"*Overall, the methodology provides an approach with flexibility to evaluate the beneficial uses. I believe there is a deliberate effort not to invent the wheel again by taking advantage of historical information through the literature survey and employing the methodology with proper exits as shown on the flowchart, avoiding unnecessary extra unneeded steps.***"**

Reviewer #3: **"***The "Methodology for Evaluating Encapsulated Beneficial Uses of Coal Combustion Residuals" presents a hierarchical method that can be used for assessing potential risks associated with CCR beneficial use, specific only to encapsulated forms. The methodology consists of very logical steps that one*

would fully expect to use to conduct such an evaluation, in particular a comparative analysis with the analogous product not containing CCRs. In general terms, this amount[s] to:

- *Find out if it's already been done (by searching literature);*
- *If not, use available data to make your own comparison;*
- *If some concerns are raised from the second step, evaluate potential exposure;*
- *If potential exposures are greater in the CCR product, conduct screening-level assessment; and*
- *Screening level exceedances are carried through to a risk assessment.*

*Included in each step of the methodology are examples to clarify the text of the document. The document is clearly written and presented. There is essentially no chance of misunderstanding from the reading of this document. The methodology presented is very general, but also logical and straightforward. There is scant room for inaccurate information given the general nature of the methodology presented.***"**

Reviewer #4: **"***The preliminary draft Methodology encompasses a traditional risk assessment paradigm, with the main objective to compare end-use or consumer risks between potential COPC and the analogous product. Overall, this document has most of the elements of a traditional risk assessment, i.e., hazard identification, exposure assessment, and risk evaluation. Dose response is not explicitly considered though but taken into account in the health-based screening levels.***"**

"*Once the issues addressing the clarity of the document are addressed, I believe that the methodology will satisfactorily address the OIG's comments to "define and implement risk evaluation practices to determine the safety of the CCR beneficial uses EPA promotes.***"**

Response:

No changes made in response to these comments.

6.1.2 Peer Review Comment:

Two reviewers requested clarification on the scope of the methodology. One reviewer asked if the methodology was intended to conduct a general or specific evaluation of CCRs and beneficial uses. The other reviewer asked if the methodology applies to CCRs from sources other than electric utilities.

Reviewer #2: **"***It is not clear whether the methodology is intended in a generic sense for a given beneficial use, e.g. cement replacement in concrete and a class of CCR,*

*e.g. fly ash or specifically for each fly ash produced by a power plant and for each percentage replacing the analogous material.***"**

"*Is this literature search to be conducted for every individual CCR produced by a plant during a period when various factors kept constant and for a specific beneficial use application or for a class of CCR, say fly ash or a more specified fly ash defined in terms of e.g., source of coal, combustion process, etc.? The question is about how often this search needs to be done.***"**

Reviewer #4: ***"****I recommend that the origin of the coal combustion residues be specified in the document (e.g., in Section 1.1, Background). For instance, is this method applicable to CCRs originating from plant effluents and flue gases from electrical utilities and independent power plants, or are there other sources of CCRs?***"**

Response:

OSWER agrees with the comments provided. In response, the text of the methodology was updated in Section 2 to note that the methodology is intended to be flexible to allow evaluation of the range of possible encapsulated beneficial uses for any CCR. The party using the methodology should exercise professional judgement in scoping an evaluation. The scope of the evaluation will determine the type of data required.

6.1.3 Peer Review Comment:

One reviewer asked who the party is that is responsible for conducting the evaluation.

Reviewer #2: ***"****Who is the intended party conducting this evaluation?***"**

Response:

As noted in **Section 2.1.2** of this document, OSWER and others outside of EPA, such as states; industry; or the public, may choose to use the methodology.

6.1.4 Peer Review Comment:

One reviewer requested clarification on the identity of the party responsible for making a final beneficial use determination at the end of the methodology.

Reviewer #2: ***"****Furthermore, who makes the final determination that the use is acceptable at the end of the methodology?***"**

Response:

OSWER agrees that this point could be clarified in the methodology. In response, the text in Section 2 has been updated to note that the party conducting the evaluation is also encouraged to engage with the appropriate regulatory organizations to ensure that application of the methodology is consistent with any relevant State beneficial use requirements. Use of this

methodology is voluntary, not regulatory, and is not a replacement for existing regulatory requirements for beneficial use determinations.

6.1.5 Peer Review Comment:

One reviewer asked if the absence of damage cases in the existing literature found during Step 1 (Literature Review and Data Collection) is a basis to determine that releases from a CCR product are comparable to those from an analogous product.

Reviewer #2: **"***If Step 1, Literature Survey demonstrates that no case to be found where the specific beneficial use resulted in damage to human health or the environment, would this be a basis to determine that the use of CCR is comparable to analogous product?***"**

Response:

The absence of a proven or potential damage case in the existing literature does not prove that one cannot occur. Therefore, this line of evidence alone would not be considered sufficient to demonstrate that releases from the CCR beneficial use product are comparable to or lower than those from an analogous product. No changes were made to the text in response to this comment.

6.1.6 Peer Review Comment:

One reviewer requested clarification on whether Step 4 (Screening Assessment) and Step 5 (Risk Assessment) involve a comparison of the CCR to an analogous product.

Reviewer #3: **"***It's not clear in this paragraph that the approach described is comparative in nature. One of the very positive elements of the entire methodology is the clarity of this aspect: that the CCR-containing product is being compared with the non-CCR product. As this paragraph starts out, it is not clear this is the case ("…evaluation of risks associated with COPC exposures carried forward from previous steps."And "the purpose of this step is to determine whether the beneficial use product may result in unacceptable risk to human or ecological receptors." This is a very different tone compared to the rest of the document which clearly focuses on the comparison between products. Indeed, later in this section (3rd paragraph), it says, "If the identified risks and associated uncertainties are found to be comparable." While it's not very clear (it could be inferred that the risks and uncertainties are comparable) I believe it to mean the risks and uncertainties of the two products are comparable). This section should be edited to make the intent more clear throughout and focus on the comparative risk***"**

Response:

As noted in **Section 2.1.3** of this document, Step 2 (Comparison of Available Data) is the only step that involves a comparison of the CCR products to analogous non-CCR products made with virgin materials. The text of each step throughout the document now clarifies this point.

6.1.7 Peer Review Comment:

One reviewer requested that the methodology clarify that a CCR may not always replace a raw material in a beneficial use product, such as fly ash used for soil for stabilization.

Reviewer #2: **"***There seems to be an implication of substituting CCR for an analogous material such as fly ash for cement in concrete production. However, certain uses do not result in substitution but addition, such as adding fly ash to soil for stabilization.***"**

Response:

No changes were made to the document in response to this comment. OSWER agrees with the reviewer that there may be instances where a CCR is not used to replace a virgin raw material. However, the specific example provided by the reviewer of fly ash used for soil stabilization is considered an unencapsulated use and is not addressed in this methodology. OSWER believes the text in Step 2 (Comparison of Available Data) already clearly addresses how the party conducting the evaluation may handle instances where one or more COPCs from the CCR beneficial use product do not have a counterpart in an analogous product.

6.1.8 Peer Review Comment:

One reviewer asked how chemical mixtures are addressed in the methodology.

Reviewer #4: **"***It is also unclear how mixtures are treated in this method? Certainly, the presence or absence of other chemicals within the encapsulated CCR matrix can influence the fate and exposure of a given COPC. But whether "constituents" includes mixtures or specific chemicals should be made explicit in the method documentation.***"**

Response:

As noted in **Section 2.1.4** of this document, if consideration of different chemical mixtures will be incorporated into an evaluation, then the party conducting the evaluation may refer to existing EPA guidance on this topic. The term "constituent," as used in this methodology, refers to an individual chemical. This usage is consistent with the language in the Resource Conservation and Recovery Act (40 CFR 261) and in previous evaluations of CCRs (US EPA, 2010). No changes were made to the document in response to this comment.

6.1.9 Peer Review Comment:

One reviewer requested clarification on the meaning of the term "analogous material."

Reviewer #2: **"***Meaning of "comparable to analogous material" can be clarified to cover both cases [the presence and absence of analogous product for comparison - clarification added]. It is also not clear what "analogous material" is. Is it the component being substituted, e.g. cement or is it final product, e.g. concrete without CCR? This should be clarified.***"**

Response:

No changes were made to the document in response to this comment. There is no instance of the term "analogous material" in the document. Instead, the term "analogous product" is used and defined in the introduction to the methodology. OSWER believes that Step 2 (Comparison of Available Data) already addresses the considerations involved in comparing the CCR beneficial use product to an analogous product.

6.1.10 Peer Review Comment:

Three reviewers requested that examples of encapsulated beneficial uses be included in the text. One reviewer provided some potential examples. Another reviewer also requested further discussion of the specific COPCs and complete exposure pathways associated with these examples.

Reviewer #1: **"***The draft can be improved by listing expected major beneficial uses of encapsulated CCRs and specific COPC/exposure pathways of concern associated with that use.***"**

Reviewer #2: **"***It is not clear what "encapsulated" covers based merely on the definition. Perhaps examples, including but not limited to, can be provided to clarify.***"**

"*The definition of "encapsulated" is not clear enough. I think some examples in an "including, but not limited to, type of list" would be helpful. For instance, the Ireland EPA lists the following for "bound" applications, meaning encapsulated applications (use of the word "bound" in the US context is not appropriate):*

- *Type I addition in concrete, e.g. as filler or lightweight filler aggregate.*
- *Type II addition in concrete, e.g. cementitious component in concrete.*
- *Cement manufacture, e.g. added as a raw material into kiln feed or added to Portland cement.*
- *Ceramic tiles and brick-making.*
- *Paints, plastics, rubber and similar.*

- *Lightweight filler in bitumen-bound materials, e.g. foamed bitumen or asphalt.*
- *Hydraulically bound mixtures in pavement construction, e.g. capping, subbase and road base, and ground stabilization.*

*This list clearly indicates that soil stabilization is included in "encapsulated." Perhaps, addition of the word "hydraulically bound" is a useful one (as mixtures that set and harden by hydraulic reactions); as it would clearly allow beneficial use of self-cementing fly ash in stabilization of soil and road base materials. I was not sure if soil stabilization was considered in "encapsulated" use reading the definition given in the methodology. There are some other uses that may or may not be interpreted to be within the given definition. For instance, embankment in which fly ash is hydraulically bound to some analogous material or itself hydraulically bound like self-cementing fly ash as opposed to non-reactive fly ash.***"***

Reviewer #4: **"***It would also be worthwhile to provide a few examples of materials or products where the beneficial use of an encapsulated CCR can be used to replace an analogous product. For example, can encapsulated CCRs be used to manufacture underground storage containers? That would make the soil leaching route the most critical human and ecological exposure pathway.***"**

Response:

OSWER agrees that some specific examples of encapsulated beneficial use products may be useful to the reader. In response, an illustrative list of encapsulated beneficial uses was added to the introductory text. However, some of the specific examples provided by the reviewers, such as soil stabilization and embankment fill, are considered unencapsulated, rather than encapsulated, beneficial uses. Unencapsulated beneficial uses are not addressed by this methodology. Identification of the COPCs and complete exposure pathways associated with the examples in the list would require implementation of the methodology and is outside the scope of this the methodology document.

6.1.11 Peer Review Comment:

One reviewer requested additional guidance on how to deal with sensitive ecological receptors.

Reviewer #4: **"***While HEI is considered as the human receptor, it is recommended that there be additional guidance provided on how to deal with sensitive ecological receptors.***"**

Response:

As noted in **Section 4.2.2** of this document, additional discussion has been added to Step 3 (Exposure Review) and Step 4 (Screening Assessment) to address sensitive ecological receptors.

6.1.12 Peer Review Comment:

One reviewer asked if a comparison of COPC concentrations at the point of exposure to maximum contaminant levels (MCLs) is sufficient to reach a conclusion.

Reviewer #2: **"***In this hypothetical example, if concentration of a COPC at the point of exposure were determined to be below the maximum contaminant level (MCL) for the COPC, would it not be the point to stop? Because MCLs are already based on a risk assessment exercise.***"**

Response:

No changes were made to the text in response to this comment. MCLs are potentially relevant regulatory benchmarks for consideration in Step 4 (Screening Assessment) and Step 5 (Risk Assessment) of the methodology. Other parties using the methodology are encouraged to consult with the appropriate regulatory organizations to ensure reliance on MCLs as the only benchmark in an evaluation is consistent with relevant State beneficial use requirements.

6.1.13 Peer Review Comment:

One reviewer commented that data collection efforts may generate ambiguous results, as most available leachate data are single pH and Leaching Environmental Assessment Framework (LEAF) methods are not yet in wide use.

Reviewer #2: **"***Identification of COPC is achievable in the literature survey irrespective of the laboratory leaching method employed and through field leachate data. However, there is not unanimity regarding what method to be used to determine COPC release concentration. So the literature survey may result in ambiguous results regarding concentration as single pH is used mostly and the LEAF method is not used widely yet as it is still under development. This issue needs to be addressed.***"**

Response:

OSWER agrees this point could be made clearer. In response, Step 1 (Literature Review and Data Collection) has been updated to clarify that when previously collected data are not sufficient to characterize the CCR beneficial use product, additional data may need to be collected by the party conducting the evaluation. Characterization methods should be chosen based on their capacity to generate data applicable to the environmental conditions relevant to

the beneficial use under evaluation. In addition, the discussion of the LEAF methods has been updated to note the current status of the methods and where they may be found online.

6.1.14 Peer Review Comment:

One reviewer stated that the methodology should consider that inclusion of CCRs in a beneficial use product may mobilize COPCs from the remaining raw materials

Reviewer #2: **"***There is some ambiguity here. For instance, mixing fly ash may change pH and cause releases from the remaining raw materials. Perhaps can be simplified as stated in the last sentence of the paragraph: "compare releases from the products as a whole.***"**

Response:

OSWER agrees that inclusion of CCRs may alter the mobilization of constituents from the other raw materials used in the product as a result of changes in pH, porosity, or other factors. In response, the methodology has been updated to note that the impact of CCRs on other raw materials in the product should also be considered when conducting the evaluation.

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