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Subject: Peer Review Comments on SP1010 – Development of Category 4 Screening Levels for Assessment of Land Affected by Contamination – Final Project Report

Dear Mr. Middleton:

I have reviewed the June 7, 2013 draft report, *Development of Category 4 Screening Levels for Assessment of Land Affected by Contamination – Final Project Report,* and I am very happy to provide the comments below. The discussion of the approach to the evaluation was very thoughtful and very well documented; and the qualitative and quantitative evaluation of the uncertainties associated with soil screening levels and the sensitivity analyses is the most thorough and detailed evaluation I have ever seen.

The Final Project Report includes an explanation that Defra is concerned with the "effectiveness and efficiency" of its approach to managing human health risks associated with contaminated land. In addition, the Report notes that Defra is trying to develop soil screening concentrations that would serve as "relevant technical tools" to aid in the identification and management of contaminated land. The discussion presented in the Final Project Report mentions that the charge to the project team from the Statutory Guidance is to address the concern that current screening levels are "over cautious," as well as the need for levels that are "more pragmatic." Nonetheless, the desire to have screening levels that are also "strongly precautionary" is expressed.

The challenge posed by the Statutory Guidance would appear to be one that can be addressed by using established risk assessment methods to derive soil screening levels that are higher (i.e., "more pragmatic") than those derived using methods and assumptions that provide the basis for current Soil Guideline Values, and yet are not so high that they would not be "strongly precautionary." This assumption underlies the methodology described in Section 5 of the Final Project Report. The discussion of the Statutory Guidance and the thinking behind the incorporation of background exposure presented on pages 76 and 77 of the Final Project Report suggests that a more fundamental conflict needs to be resolved, however, and it is not clear that standard regulatory risk assessment approaches can resolve the conflict. The intentionally conservative methodology used to develop exposure standards and soil clean up levels based on hypothetical exposures and health risks is not well-suited to developing exposure levels or soil levels that pose "small" levels of actual incremental exposure or "small" levels of actual incremental health risk.

My comments are based on the assumption that properties with soil concentrations above the Category 4 Screening Levels might be subjected to additional sampling and site-specific risk assessment effort, with attendant cost and time requirements. Based on my experience with the practical use of soil screening levels, however, I have also made the assumption that some properties with concentrations above screening levels may be subject to risk management measures (e.g., use restrictions) or remediation without performing more refined site investigation or risk assessment. I recognize that exceeding the Category 4 Screening Levels would not necessarily trigger site management or remediation.

Like all other soil screening values developed by government or other organizations around the world, derivation of Soil Guidance Values (SGVs), and the provisional Category 4 Screening Levels (C4SLs), include an accumulation of many conservative elements. Conservative methods are used in combination with uncertainty factors in the derivation of the toxicity factors on which soil screening levels are based. Similarly, conservative assumptions are used in the quantification of chemical exposure and dose corresponding to specific concentrations of chemicals in soil. In addition, adjustments to account for site-specific consideration, such as bioavailability, are often not explicitly included in the derivation of soil screening levels. Consequently, soil screening values are designed to be conservative estimates of the concentration corresponding to acceptably small health risk levels (e.g., Hazard Index of 1.0 or lifetime incremental cancer risk of 10 in a million).

Although there are variations between agencies around the world in the details of how this risk-based approach is used to calculate soil screening levels, the fundamental approach is well established and generally accepted. By design, the approach of applying conservative risk assessment approaches to the "back calculation" of soil screening levels will produce soil concentrations that are well below levels at which any adverse health effects would be expected. Such low levels are certainly "strongly precautionary" and one can have a high degree of

confidence that soil with concentrations of chemicals below concentrations calculated using these methods does not pose a significant human health risk.

Because soil screening levels calculated using standard risk assessment approaches are so conservative, exposures to soil with chemicals above such screening levels do not necessarily pose a health risk. While this point is well recognized among risk assessors and other professionals associated with the management of contaminated land, other people can understandably be worried that chemical concentrations above screening levels are not safe. Unfortunately, there is no fixed ratio between a screening level calculated using conservative risk assessment procedures and the level at which one might expect to see an adverse health effect. This point was well illustrated in the many sensitivity analyses and in the critical evaluations provided in the Final Project Report and Appendices for the six example chemicals.

Defra appears to be seeking resolution of this conflict by posing the challenge of requesting movement in the soil screening values from values that may considered "over cautious" toward levels that are "more pragmatic." While the agency recognizes the problem, it doesn't appear to provide direct guidance on how to resolve it. As noted above, the discussion of background levels on pages 76 and 77 of the Final Project Report illuminates the fundamental conflict the project team was asked to address, and the discussion provides insight into a route toward resolution.

As noted in the Final Project Report, Paragraph 4.21 of the Statutory Guidance describes several criteria to be used in identifying land to be placed in Category 4 for Human Health. One of these criteria addressed the issue of background exposure:

> **(d) Land where estimated levels of exposure to contaminants in soil are likely to form only a small proportion of what a receptor might be exposed to anyway through other sources of environmental exposure (e.g., in relation to average estimated national levels of exposure to substances commonly found in the environment to which receptors are likely to be exposed in the normal course of their lives).**

Although "small" is not defined in the Statutory Guidance, the Final Project Report includes a discussion of this point on page 76 noting that, "presumably the rationale for this policy is that there is unlikely to be an appreciable benefit to human health from managing risks from soil contamination if the major source of exposure of a particular contaminant is from non-soil sources such as food, water, or air." The point is further discussed on page 77 where a view is offered on the point of what might be considered a "small" incremental exposure. The text includes the suggestion that, "a value of 10 to 25% may not be unreasonable for the purposes of setting a C4SL." While the discussion of this point also includes the note that the 10 to 25% increment was not unanimously agreed to, the concept of a threshold incremental exposure above background being necessary to trigger the initiation of risk management measures is

noteworthy. As discussed on page 76, the suggestion that the intent of the Statutory Guidance is that the cost and effort of managing risks from chemicals in soil should bring about an "appreciable benefit to human health." This notion appears to be reflected in the reference to "over cautious" screening levels, which presumably refers to screening levels well below those at which one might expect a benefit to human health from remediation or other forms of management.

Although the discussion of incremental risk above background was specifically addressing incremental exposure to individual chemicals from all sources, the management principle is logically applicable to the incremental health risk posed by a single chemical or the incremental health risk posed by all of the chemicals at a contaminated site. With that management principle in mind, it is worth noting that exposure to a carcinogen at a level estimated as corresponding to a lifetime incremental cancer risk of one in a hundred thousand (i.e., 10 in a million) would represent an increase of the average lifetime incremental cancer risk for people living in the United Kingdom from 330,000 per million to 330,010 in a million (www.cancerresearchuk.org/cancer-info/cancerstats/incidence/risk), an increase of about 0.003%. When talking about the soil concentration of a chemical calculated as corresponding to an incremental cancer risk of one in a hundred thousand, it should be noted that the estimated risk associated with a given soil concentration is a very conservative estimate because it includes conservative assumptions about the human exposure associated with a given concentration and because the derivation of the dose-response factor includes conservative assumptions. Thus, managing exposure to a chemical in soil with an estimated lifetime incremental cancer risk of 10 in a million will actually achieve a much smaller reduction in health risk for people who are exposed to soil from a site.

The fact that a nominal, hypothetical cancer risk of ten in a million is a small fraction of a person's actual probability of being diagnosed with cancer at some point over their lifetime is well recognized among risk assessors. The uncertainties and conservative assumptions incorporated into the calculation of soil concentrations corresponding to a nominal level of risk are discussed in great detail in the Final Project Report. These characteristics of the fundamental approach of regulatory risk assessment, which has been used to derive the provisional Category 4 Screening Levels, assure that screening levels derived using these methods will be "strongly precautionary." Use of this fundamental approach to derive screening levels also virtually guarantees that the screening levels will be such that no appreciable benefit to human health would be derived from managing chemical concentrations at or even somewhat above screening levels derived using these methods. Accordingly, such levels could still be considered "over cautious" and at odds with the management principle of not managing sites where no health benefit would be realized from the cost and effort of additional site investigation or risk assessment even remediation or other risk management effort, should someone elect to manage or remediate a site in response to exceeding the Category 4 Screening Level.

The fundamental methodological conflict lies in the fact that hypothetical risks estimated using conservative regulatory risk assessment approaches are not directly comparable with actuarial risks used to estimate incidence of health effects (e.g., cancer incidence). Because the methods are fundamentally different, it is a virtual certainty that a soil screening level calculated using conservative regulatory risk assessment approaches will be "over cautious" if the standard for that criterion is that the screening level only pose a "small" increase above actual background exposure or above actual health incidence.

Based on the discussion in the Final Project Report, it would appear that the Statutory Guidance is anticipating the derivation of a set of soil screening levels that do not leave unmanaged properties that could pose a health risk and yet do not cause unwarranted effort to further investigate or evaluate a property or do cause unwarranted fear and the attendant, serious practical problems, such as interference with the sale and financing of private property or the unnecessary quarantine of public property. It is also clear that the Statutory Guidance is also anticipating the development of soil screening levels that are "strongly precautionary." As noted above, the standard approaches to regulatory risk assessment do no lend themselves to defining levels above which actual risk reduction might be realized by appropriate management or to defining levels that only pose a "small" increase above background. Rather, standard risk assessment approaches are designed to produce exposure limits and screening concentrations that are "strongly precautionary."

One approach to the challenge of balancing the desire to be "strongly precautionary" without being "over cautious" is to develop two screening levels. One screening level would be designed to estimate soil concentrations above which some appreciable benefit to human health would be derived by applying risk management measures. Another, lower screening level would be designed to produce levels below which there is essentially no health risk posed. This concept is essentially that of the risk management range which is described in U.S. EPA Superfund Guidance and is defined for carcinogens as corresponding to a lifetime incremental cancer risk of 1 to 100 in a million. Acceptable risk ranges for non-carcinogenic chemicals are less often addressed explicitly, although some jurisdictions have formally or informally adopted a Hazard Index of 1 to 3 as a risk management range for non-carcinogenic health risks. The risk management range leaves discretion to regulatory authorities to consider, among other factors, the degree to which the conservative assumptions incorporated into the derivation of the screening levels deviate from site-specific conditions.

The use of a risk management range to guide site management decisions is appealing because it can better reflect the conceptual difference between a level that would trigger risk management and a level that would be a conservative cleanup goal. It also provides the site manager with more discretion to accommodate site-specific considerations. As was well illustrated in the Final Project Report (and Appendices), however, there is considerable and largely unquantified uncertainty embedded in the calculation of any soil screening level, and the level of uncertainty is highly variable between chemicals and exposure routes. This uncertainty is difficult to

characterize (quantitatively and qualitatively) for each chemical/exposure route combination for a site manager and is not likely to be effectively incorporated into site management decisions. Use of a risk management range can create a perception problem for sites at which estimated risks are below the level that triggers risk management, but have concentrations above the levels that would be required for remediation. Such a site might appear to be "contaminated" and the use of a risk management range leaves room for disagreement. Thus, while a risk management range has a certain appeal and can be explained logically, it has practical drawbacks that appear to have discouraged its effective use in favor of "bright line" approaches.

The "bright line" approach to addressing the dilemma is to derive a single screening value that essentially splits the difference between the higher and lower screening levels. This approach does not resolve the conceptual difference between a level that triggers remediation and a conservative remediation goal. If offers the simplicity, for administration purposes, of presenting a simple "bright line" for making decisions. It does not directly point to the uncertainties in the derivation of screening levels. Use of a single bright line, in fact, tends to mask the uncertainties.

Both approaches have their advantages and disadvantages, and it is my observation that virtually all authorities that use screening levels to support site management decision making tend to derive them and use them in the "bright line" fashion described above, even if underlying regulation and policy is based on the use of a risk management range. The proposed methodology for derivation of the Category 4 Screening Levels is based on the derivation of a single value that is simultaneously "strongly precautionary" and not "over cautious" or at least, "more pragmatic." Because the proposed methodology is based on the fundamental approach to risk assessment described above that is designed to produce intentionally conservative results, it can be expected to produce results that are "strongly precautionary." To the extent that the provisional Category 4 Screening Levels are higher than their corresponding Soil Guideline Values, they could be viewed as being "more pragmatic." That is to say they would be less likely to trigger additional site investigation or evaluation (or possibly remediation or other management measures) that produce no "appreciable benefit to human health." As discussed above, the difference between the level that poses a *de minimis* hypothetical cancer risk and a small actual risk is very difficult to quantify, but probably differs by roughly two orders of magnitude. The corresponding range for non-carcinogens is also difficult to quantify but is probably much smaller. If the intention of the Statutory Guidance was, however, to not trigger the expenditure of resources for further evaluation (or management) of risks that pose a "small" increment above background, the method proposed for developing Category 4 Screening Level appears to produce screening levels that are much closer to the "over cautious" level than they are to the levels at which "appreciable benefit to human health" would be realized by further site investigation (or site management).

The topic not addressed in the Final Product Report is the degree to which the provisional Category 4 Screening Levels are "more pragmatic." What fraction of sites that would be

unnecessarily investigated and evaluated further or managed/remediated under the current screening levels would be relieved of unproductive effort were the provisional Category 4 Screening Levels to be applied? For reasons noted above, the screening levels calculated using the proposed methods for calculating Category 4 Screening Levels can certainly be viewed as "strongly precautionary." If they also provide sufficient relief from the practical problems associated with the use of "over cautious" screening levels, they may strike the balance Defra appears to be seeking in the Statutory Guidance directing the development of the Category 4 Screening Levels.

If, on the other hand, the screening levels coming from the proposed methodology still cause a significant number of properties to be unnecessarily evaluated in greater detail or unnecessarily managed or remediated, it would appear that the balance envisioned by Defra has not been realized by the methodology proposed in the Final Project Report. While there appears to be a wide distance between the provisional Category 4 Screening Levels and levels that would represent even a "small" increment above background, the discussion in the Final Project Report suggests that it may be difficult to achieve consensus to move to higher, "more pragmatic" screening levels at the expense of being "strongly precautionary."

Based on the very thorough review and evaluation of the several conservative assumptions built into the toxicity factors and used in the exposure assumptions, it does appear that application of fixed factors to existing Soil Guideline Values could be considered and could produce screening levels that would still be "strongly precautionary." Applying factors of 10 to screening levels based on cancer risk and 3 to soil screening values based on noncancer effects, for example, would not be without precedent. Because they would be higher than current screening levels, they would also be "more pragmatic." As with the provisional Category 4 Screening Levels, however, it is not clear that application of such factors would produce screening levels that avoid unnecessary site investigation or site management measures. While there would be value in the undertaking the whole procedure outlined in Section 5 of the Final Project Report, the process would take substantial time and resources to complete. The entire review process called for in Section 5 could be undertaken over time. If interim screening values are needed more quickly than can be achieved by undertaking the process outlined in Section 5, application of a fixed factor to the current Soil Guideline Values could be considered. The evaluations completed by the project team suggest that application of a fixed factor to current Soil Guideline Values would provide screening values that would meet the test of being "strongly precautionary. Such an approach would only address chemicals and exposure scenarios for which Soil Guidelines have been developed. One important drawback to the approach of applying fixed factors in this manner is that one can raise the allowable exposure to a level at which a health effect other than the one on which the original screening level was based. For example, raising the screening level based on a cancer risk by a factor or 10, for example, could result in a screening level that poses a risk of a noncancer health effect. If application of fixed factors are employed a toxicologist should review the documentation for the current screening

level to make sure that the revised screening level does not pose a risk of a different health effect. This issue was noted in the discussion of deriving exposure limits corresponding to a Low Level of Toxicological Concern in the Final Project Report. While there is less likely to a problem posed by applying a fixed factor to a screening level than just to the toxicity factor, it would be a valid consideration in such an adjustment to a soil screening value as well.

In summary, I think it must be recognized that the challenge of balancing the competing goals of being "strongly precautionary" while avoiding being "over cautious" is substantial. Because such a balance requires technical and policy considerations, identification of the optimal balance point is highly subjective and it is safe to say that it would be impossible to develop screening levels that would have unanimous support. It is important to acknowledge this point when reviewing the recommendations in the Final Project Report.

The project team accepted a substantial challenge and provided a very well thought out and well documented approach, and they clearly identified the scientific uncertainties, as well as the fact that policy considerations are important in the derivation of any soil screening levels. Because the approach proposed by the project team is based on conservative human health risk assessment methods and acceptable risk policies, the provisional screening values produced by the proposed process are virtually certain to be "strongly precautionary." Even the higher end of the range of provisional screening levels proposed for individual chemicals can be supported as being "strongly precautionary." Comparison of provisional Category 4 Screening Levels for residential settings to corresponding residential Soil Guideline Values suggests that the methodology recommended by the project team also provides movement toward the goal of being "more pragmatic." Until the resulting screening levels are compared to levels measured in soil at properties subject to being categorized, however, one cannon know if the new levels are sufficiently "more pragmatic." Would the provisional Category 4 Screening Levels prevent the unwarranted concerns and non-productive site investigation/evaluation effort or even unnecessary risk management/remediation measures that would be initiated by "over cautious" screening levels?

I am very pleased and honored to have been invited to provide this peer review. I hope the comments are helpful, and I would be happy to answer any follow up questions you may have for me.

Sincerely,

Robert Scofield, D.Env.
Director of the Center for Exposure
Assessment and Dose Reconstruction