

**SCIENTIFIC PEER REVIEW OF THE  
EPA REGION 2/CENAN FRAMEWORK FOR EVALUATING DREDGED MATERIAL  
FOR PROPOSED PLACEMENT AT THE HARS**

Introduction: Goals of the peer review

The August 29, 1997 Final Rule, *Simultaneous De-designation and Termination of the Mud Dump Site and Designation of the Historic Area Remediation Site*, specifies that the historic area remediation site (HARS) will be remediated with uncontaminated dredged material (i.e., dredged material that meets current Category I standards and will not cause significant undesirable effects including through bioaccumulation; hereinafter referred to as “Remediation Material”). The rule further specifies that the HARS will be managed so as to reduce impacts within the Priority Remediation Area (PRA) to acceptable levels in accordance with 40 CFR 228.11. Placement of dredged material within the PRA is restricted to Remediation Material. This material will not cause significant undesirable effects, including through bioaccumulation or unacceptable toxicity in accordance with 40 CFR 227.6.

Evaluation of proposed dredged material regarding unacceptable toxicity is clearly defined in the Green Book as statistical criteria which require no interpretation. Evaluation regarding significant undesirable effects including through bioaccumulation requires assessment of chemical analyses of tissue from 28-day bioaccumulation tests. There are no specific regulatory criteria for this evaluation; however there are existing regional guideline values that have been developed and used, by the U.S. Environmental Protection Agency (EPA) Region 2 and the U.S. Army Corps of Engineers New York District, to evaluate the constituents in accordance with 227.6.

This peer review charge is to assess whether the testing evaluation process is adequate to properly determine whether a tested sediment is suitable for Remediation Material as defined. Your review should focus on the framework for evaluation of bioaccumulation data and guideline values used; it should not deal with on toxicity/mortality testing. Please bear in mind that the testing evaluation applies to risks pertaining to ocean placement of the sediment, and not to risks pertaining to other alternatives such as leaving the sediment in place.

This charge is in the form of questions on critical aspects of the evaluation framework. General references are cited in each charge question to aid in finding the issue in question. Note that these are general guiding referrals and should not be considered the only review item for those specific issues. Please answers the assigned questions as directly as possible, given the provided materials and your own expertise. If you are unable to answer a particular question on the basis of the provided materials, please inform us of information needed to answer the question. Also, keep in mind that there are additional environmental data resources and test data pertaining to the New York Bight available in EPA Region 2, if they are needed.

## Framework

1. Is the EPA Region2/CENAN Framework for evaluating bioaccumulation results scientifically appropriate for determining the suitability of dredged material as Remediation Material? If not, describe deficiencies. (*Please see Region2/CENAN joint evaluation memorandum, Figure 1*)
2. Which of the risk-based values derived constitute “true” conservative estimates of risk levels (i.e., exceeding the value should be interpreted as sufficient cause to conclude that significant undesirable effects may result through bioaccumulation)? Which of the risk-based values derived constitute conservative screening values (i.e., test tissue concentrations below the value can confidently be interpreted to pose no risk of significant undesirable effects and exceeding should be further evaluated before the probability of significant undesirable effects can be assessed)? How can the “true” risk levels be calculated for those compounds which you believe only to have screening values? How should test concentrations be compared to risk-based levels to determine whether they are exceeded.
3. In conducting the integrated effects evaluation using the types of data provided by the applicant, which of the eight factors for LPC compliance listed in the Green Book are appropriate and relevant? How can a quantitative/strategic framework be established to evaluate tissue data for those factors? Considering that comparison to regional Matrix values and site-specific risk values represent case-specific evaluations, is it necessary to conduct the integrated effects evaluation of the bioaccumulation results? (*Please see Reference No. 61, page 6-6*)

## Benchmark and Risk Evaluation Values

4. Regional Matrix Values
  - A. Are the Matrix values suitable for determining the suitability for placement at the HARS as Remediation Material?
  - B. Regional Matrix values were developed in 1981 by compiling available field data for mercury, cadmium, PCBs, and total DDTs. Were these values derived appropriately for their intended use? Based on current data sets and scientific literature, are these 1981 values suitable for predicting the significant undesirable effect due to bioaccumulation? (*Please see Reference No. 57*) If not, identify more current references, data sets, and/or actual chemical specific values that would be more appropriate.
5. Regional Dioxin Values

- A. Currently, the presence of 2,3,7,8-TCDD at a detectable concentration (i.e., greater than or equal to one part per trillion (pptr)) in tissues of organisms exposed to dredged material precludes its classification as Category I (hence Remediation Material); presence of the remaining dioxin/furan congeners, at concentrations of TEQs equal to or greater than 4.5 pptr, results in a similar conclusion. When 28-day tissue concentrations exceed these values, is there sufficient cause to conclude that placement of the material is not suitable as HARS Remediation Material? If not, what levels indicate sufficient cause for this conclusion? (*Please see Reference No. 89*)
- B. Are dioxin values suitable for predicting the significant undesirable effects due to bioaccumulation? If not, should these values be based on a risk analysis paradigm in which the size of the human population subgroup potentially exposed through intentional behavior is compared to the size of the general population in the region? Since the primary route of exposure is through consumption of fish and shellfish, should the variability in potential exposure due to differences in fishing behavior (e.g., target species, seasonal preferences) be incorporated in the risk paradigm? How would a benchmark protective of human health compare to benchmarks determined using an ecological risk analysis paradigm for resident fish and piscivorous wildlife?
6. FDA Action Levels (*Please see Reference No.61, Sec. 6.3*)
- A. Are FDA Action Levels useful as upper limit human health benchmarks?
- B. Would the evaluation be improved by omitting comparison of tissue results to FDA Action Levels?
7. Human Health Risk, Cancer and Noncancer
- A. Are the risk values suitable for determining the suitability for placement at the HARS as Remediation Material? If there are better alternatives for human risk, specifically what are they?
- B. Benthic tissue levels for cancer protection were derived using assumptions focused on attaining a cancer protection at the  $10^{-4}$  risk level. Is this risk appropriate for a determination of ocean placement of Remediation Material? (*Please see Region2/CENAN joint evaluation memorandum, Appendix for Table 1, Page A-4, A-5*)
- C. Benthic tissue levels for noncancer protection were derived using Reference Dose (RfD) of several organic and inorganic contaminants for the protection of human health. Are these values appropriately and consistently derived? Is the whole body/fillet

conversion factor of 1.35 an appropriate factor for all of the contaminants considered if human exposure is assumed to be primarily via consumption of the fillet portion of the fish? (Please see Region2/CENAN joint evaluation memorandum, Appendix for Table 1, Attachments B and C) If not, what factors would be appropriate? For the lead noncancer value, since there is no RFD for lead the value was derived differently than the other metals. Was the value derived appropriately? (Please see Reference No. 88)

- D. Are the risk values suitable for predicting the significant undesirable effects due to bioaccumulation? Since the primary route of exposure is through consumption of fish and shellfish, should the variability in potential exposure due to differences in fishing behavior (e.g., target species, seasonal preferences) be incorporated in the risk paradigm?

8. Ecological Risk

- A. Ecological effects benchmarks include the Water Quality Criteria Tissue Level (WQCTL), Critical Body Residue (CBR) associated with narcotic responses, and certain mutagenic/teratogenic effects. Is it valid to use the CBR effect end point for evaluating significant undesirable effect? Are there other ecological end points that should be used to measure ecological risk that are protective of marine benthic and fish life via trophic transfer, particularly for PAHs? If so, identify. With regard to a narcotic effect for chlorinated organic compounds, should an additive approach be considered to include the contribution of chlorinated hydrocarbons against this narcotic (CBR) endpoint.
- B. Is the Region 2 WQCTL approach (i.e., multiplying the Water Quality Criterial Chronic Value by the Bioconcentration factor) appropriate for determining ecological effects levels of the contaminants for which they were developed? Specifically, are the appropriate BCFs used (for fish, bivalves, etc)? (Please see Region2/CENAN joint evaluation memorandum, Appendix for Table 1, Page A-1)
- C. BCFs reported for fish were used in the calculations of WQCTLs for organics; is this derived level appropriate for setting benthic tissue ecological effects levels? If the fish tissue levels are used, should adjustments be made to the derived levels to reflect the higher lipid contents of the benthic organisms used in the testing program?
- D. Are the WQCTLs calculated for metals using bivalve BCFs appropriate for setting levels for polychaetes or vice versa?

- E. Are the uncertainty factors applied while deriving ecological effects levels for PAH contaminants appropriate? Does this adequately address the uncertainty around the derived values? Can uncertainty be accounted for using these order of magnitude adjustments? Should they be applied elsewhere to the other risk-based values?
- F. Are the risk values suitable for predicting the significant undesirable effects due to bioaccumulation; are there better alternatives for ecological nonspecific risk?
- G. If you believe that these values are over- or under- conservative, what do you believe to be an appropriate way to improve them.)

### Calculations

- 9. Should total PCBs continue to be estimated by doubling the total of 22 congeners or should it be quantified directly using another measure of quantification? What method is most appropriate for sediments in the NY/NJ Harbor area? (*Please see Reference No. 60, Table 4-4B*)
- 10. Currently, 28-day tissue concentrations of certain organic contaminants are adjusted by some multiplier to estimate the concentrations of those compounds had the exposure been of sufficient duration to allow attainment of steady state levels. (*Please see Reference Nos.5 and 46*) Are these adjustments appropriate? Should steady state corrections be applied to any other of the listed contaminants? Are there other compounds for which we test that are not expected to approach steady state within the 28-day period?
- 11. Is the calculation and use of BaP toxicity equivalence an appropriate way to estimate the potential carcinogenicity of PAHs? (*Please see Region2/CENAN joint evaluation memorandum, Appendix for Table 1, Section C.*)
- 12. Similar to PCBs, only a subset of those PAHS present in New York Harbor are measured for testing evaluation. How should the remainder be considered?
- 13. Is the assumption of a trophic transfer coefficient of one appropriate for use in evaluating the potential for human health and ecological impacts associated with metals in Remediation Material? Are the trophic transfer factors calculated for organic compounds correct? (*Please see Region2/CENAN joint evaluation memorandum, Appendix for Table 1, Attachment C.*)
- 14. Is the assumption of a fish consumption rate of 6.5 g/day appropriate for use in evaluating the potential for human health impacts associated with metals in Remediation Material? (*Please*

*see Region2/CENAN joint evaluation memorandum, Appendix for Table 1, Page A-5)*  
Would it be appropriate that the evaluation focus on a higher consumption population?

### General

15. Is it plausible to replace any other risk assessment assumptions with assumptions specific to the HARS site? *(Please see Region2/CENAN joint evaluation memorandum, Appendix for Table 1, Attachment C and Reference Nos. 88)* Is it appropriate to consider the HARS intended use to be factored into an evaluation of effects at the community or population level?
16. Is use of the Squibb et al. (1991) report appropriate for identifying the contaminants of concern? Are there contaminants which should be added to or deleted from the list of contaminants for which we presently test? *Please see Reference No. 51)*
17. Should risks from synergistic effects, from exposure to multiple contaminants, be evaluated using results from tissue analyses? If so, how? If not, why not?
18. Is test tissue concentration exceeding reference tissue concentration by less than 10X a meaningful evaluative criterion? *(Please see page 9 of the Region2/CENAN joint evaluation memorandum)?*
19. Are the studies from which background tissue concentrations were calculated weighted appropriately? If not, what method is recommended? Is the use of the mean the most appropriate measurement of central tendency? If not, what measure should be used? *(Please see Reference No. 98)* Are the assumption, presented on page 14 pertaining to comparisons of bioaccumulation in test tissue to tissue concentrations in organisms from the vicinity of the remediation site, valid for evaluating undesirable effects?
20. Can baseline tissue concentrations, from appropriate benthic organisms resident to the HARS, be used as standards to determine suitability for Remediation Material as defined above?