External Stakeholders
Remediation Standards 7:26D

Review of Draft Standards

12 August 2014

Draft Standards Review Questions

- **What are the concerns and issues with the equations used to calculate the preliminary values for the various pathways?**
- **What are the concerns and issues with the toxicity values used to calculate the preliminary values for the various pathways?**
- **What are the concerns and issues with the chemical and physical parameters used to calculate the preliminary values for the various pathways?**
- **What are the concerns and issues with any of the 17 provided documents?**
- **What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?**

What are the concerns and issues with the equations used to calculate the preliminary values for the various pathways?

- Develop cancer and noncancer based soil standards which account for cumulative exposure across each route.

- The residential noncancer SRS, should use an age-adjusted calculation that accounts for combined exposure during childhood years and adult years.

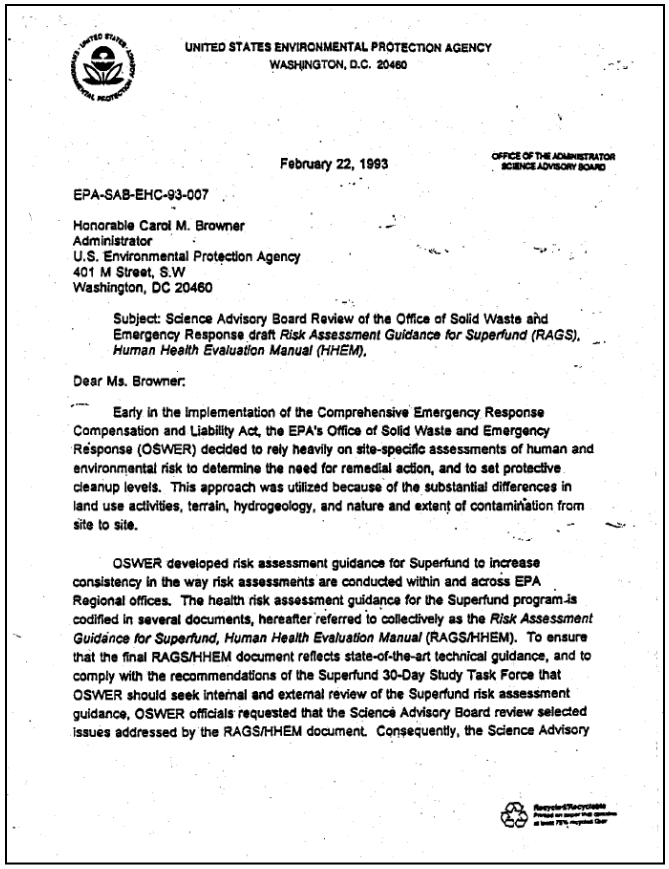
What are the concerns and issues with the equations used to calculate the preliminary values for the various pathways?

- Develop cancer and noncancer based soil standards which account for cumulative exposure across each route

$$RBC = \frac{1}{\frac{1}{RBC_{ing}} + \frac{1}{RBC_{derm}} + \frac{1}{RBC_{inh-part}} + \frac{1}{RBC_{inh-vap}}}$$

What are the concerns and issues with the equations used to calculate the preliminary values for the various pathways?

- The residential noncancer SRS, should use an age-adjusted calculation that accounts for combined exposure during childhood years and adult years.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 22, 1993

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-EHC-93-007

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W
Washington, DC 20460

Subject: Science Advisory Board Review of the Office of Solid Waste and Emergency Response draft *Risk Assessment Guidance for Superfund (RAGS), Human Health Evaluation Manual (HHEM),*

Dear Ms. Browner:

Early in the implementation of the Comprehensive Emergency Response Compensation and Liability Act, the EPA's Office of Solid Waste and Emergency Response (OSWER) decided to rely heavily on site-specific assessments of human and environmental risk to determine the need for remedial action, and to set protective cleanup levels. This approach was utilized because of the substantial differences in land use activities, terrain, hydrogeology, and nature and extent of contamination from site to site.

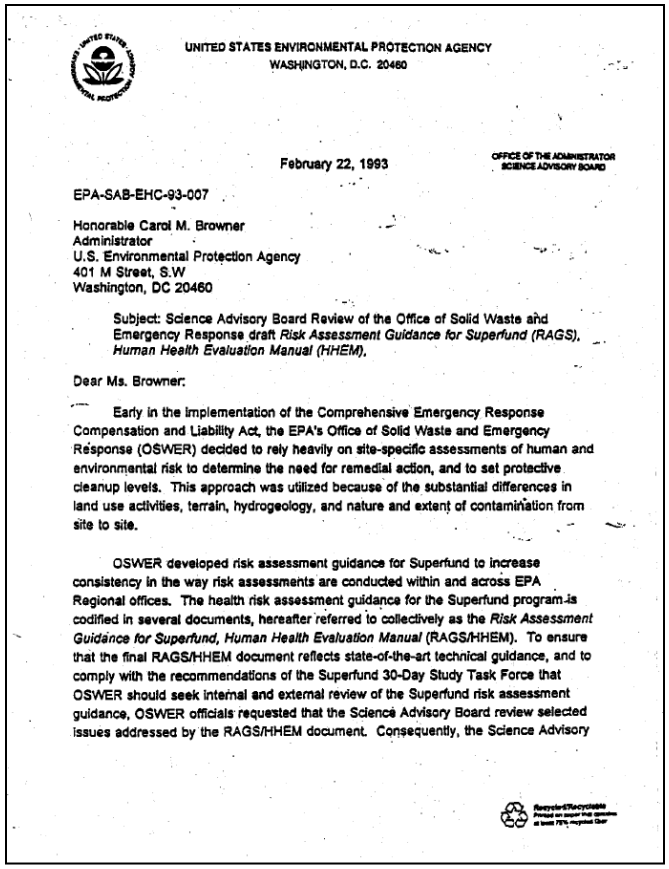
OSWER developed risk assessment guidance for Superfund to increase consistency in the way risk assessments are conducted within and across EPA Regional offices. The health risk assessment guidance for the Superfund program is codified in several documents, hereafter referred to collectively as the *Risk Assessment Guidance for Superfund, Human Health Evaluation Manual* (RAGS/HHEM). To ensure that the final RAGS/HHEM document reflects state-of-the-art technical guidance, and to comply with the recommendations of the Superfund 30-Day Study Task Force that OSWER should seek internal and external review of the Superfund risk assessment guidance, OSWER officials requested that the Science Advisory Board review selected issues addressed by the RAGS/HHEM document. Consequently, the Science Advisory

<u>Section 3.3 (RfDs in Goal Setting)</u>

OSWER initially considered two approaches for using RfDs in setting risk-based remediation goals in soil: 1) comparison of a 6-year, childhood exposure to contaminants in soil with a <u>sub-chronic</u> RfD; and, 2) comparison of a 30 year, time-weighted average exposure to contaminants in soil (including exposures to both children and adults) with a <u>chronic</u> RfD. Now, a third approach has been proposed: comparison of **a 6-year, childhood exposure with a chronic RfD**.

What are the concerns and issues with the equations used to calculate the preliminary values for the various pathways?

- The residential noncancer SRS, should use an age-adjusted calculation that accounts for combined exposure during childhood years and adult years.



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<u>Section 3.3 (RfDs in Goal Setting) [cont.]</u>

The second approach proposed by the OSWER probably **is the more reasonable**.

That is, to compare a 30-year TWA exposure with a chronic RfD. It is likely to be **adequately conservative**.

Comparison of a 6-year old's exposure with a chronic RfD may be **<u>overly</u> conservative**.

What are the concerns and issues with the equations used to calculate the preliminary values for the various pathways?

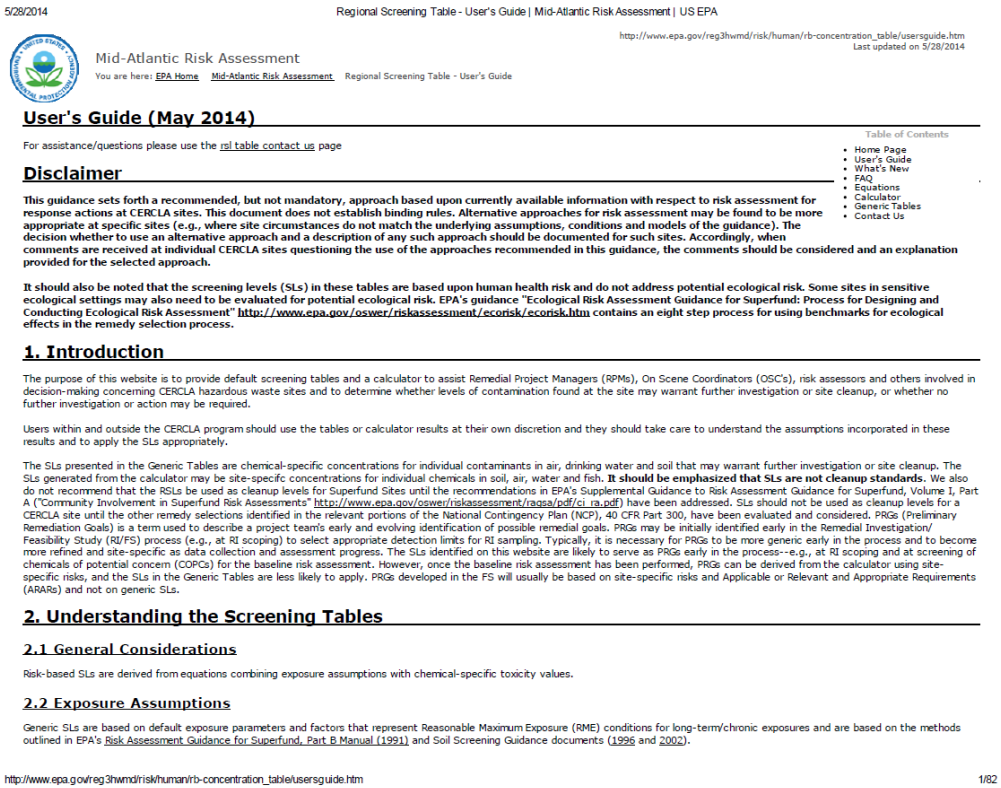
- The residential noncancer SRS, should use an age-adjusted calculation that accounts for combined exposure during childhood years and adult years.

Section 2.2 (Direct Ingestion)

In their analysis of the issue, the SAB indicates that, for most chemicals, the approach of combining the higher 6-year exposure for children with chronic toxicity criteria **is overly protective** (U.S. EPA, 1993e).
Thus, **for the purposes of screening**, OERR opted to base the generic SSLs for noncarcinogenic contaminants on the more conservative "childhood only" exposure.

What are the concerns and issues with the equations used to calculate the preliminary values for the various pathways?

- The residential noncancer SRS, should use an age-adjusted calculation that accounts for combined exposure during childhood years and adult years.



5/28/2014 Regional Screening Table - User's Guide | Mid-Atlantic Risk Assessment | US EPA

http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/usersguide.htm
Last updated on 5/28/2014

Mid-Atlantic Risk Assessment

You are here: EPA Home Mid-Atlantic Risk Assessment Regional Screening Table - User's Guide

User's Guide (May 2014)

For assistance/questions please use the rsl table contact us page

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Disclaimer

This guidance sets forth a recommended, but not mandatory, approach based upon currently available information with respect to risk assessment for response actions at CERCLA sites. This document does not establish binding rules. Alternative approaches for risk assessment may be found to be more appropriate at specific sites (e.g., where site circumstances do not match the underlying assumptions, conditions and models of the guidance). The decision whether to use an alternative approach and a description of any such approach should be documented for such sites. Accordingly, when comments are received at individual CERCLA sites questioning the use of the approaches recommended in this guidance, the comments should be considered and an explanation provided for the selected approach.

It should also be noted that the screening levels (SLs) in these tables are based upon human health risk and do not address potential ecological risk. Some sites in sensitive ecological settings may also need to be evaluated for potential ecological risk. EPA's guidance "Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessment" http://www.epa.gov/oswer/riskassessment/ecorisk/ecorisk.htm contains an eight step process for using benchmarks for ecological effects in the remedy selection process.

1. Introduction

The purpose of this website is to provide default screening tables and a calculator to assist Remedial Project Managers (RPMs), On Scene Coordinators (OSC's), risk assessors and others involved in decision-making concerning CERCLA hazardous waste sites and to determine whether levels of contamination found at the site may warrant further investigation or site cleanup, or whether no further investigation or action may be required.

Users within and outside the CERCLA program should use the tables or calculator results at their own discretion and they should take care to understand the assumptions incorporated in these results and to apply the SLs appropriately.

The SLs presented in the Generic Tables are chemical-specific concentrations for individual contaminants in air, drinking water and soil that may warrant further investigation or site cleanup. The SLs generated from the calculator may be site-specifc concentrations for individual chemicals in soil, air, water and fish. **It should be emphasized that SLs are not cleanup standards.** We also do not recommend that the RSLs be used as cleanup levels for Superfund Sites until the recommendations in EPA's Supplemental Guidance to Risk Assessment Guidance for Superfund, Volume I, Part A ("Community Involvement in Superfund Risk Assessments" http://www.epa.gov/oswer/riskassessment/ragsa/pdf/ci_ra.pdf) have been addressed. SLs should not be used as cleanup levels for a CERCLA site until the other remedy selections identified in the relevant portions of the National Contingency Plan (NCP), 40 CFR Part 300, have been evaluated and considered. PRGs (Preliminary Remediation Goals) is a term used to describe a project team's early and evolving identification of possible remedial goals. PRGs may be initially identified early in the Remedial Investigation/ Feasibility Study (RI/FS) process (e.g., at RI scoping) to select appropriate detection limits for RI sampling. Typically, it is necessary for PRGs to be more generic early in the process and to become more refined and site-specific as data collection and assessment progress. The SLs identified on this website are likely to serve as PRGs early in the process--e.g., at RI scoping and at screening of chemicals of potential concern (COPCs) for the baseline risk assessment. However, once the baseline risk assessment has been performed, PRGs can be derived from the calculator using site-specific risks, and the SLs in the Generic Tables are less likely to apply. PRGs developed in the FS will usually be based on site-specific risks and Applicable or Relevant and Appropriate Requirements (ARARs) and not on generic SLs.

2. Understanding the Screening Tables

2.1 General Considerations

Risk-based SLs are derived from equations combining exposure assumptions with chemical-specific toxicity values.

2.2 Exposure Assumptions

Generic SLs are based on default exposure parameters and factors that represent Reasonable Maximum Exposure (RME) conditions for long-term/chronic exposures and are based on the methods outlined in EPA's Risk Assessment Guidance for Superfund, Part B Manual (1991) and Soil Screening Guidance documents (1996 and 2002).

http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/usersguide.htm 1/82

USEPA RSL User's Guide

"It should be emphasized that [screening levels] are not cleanup standards."

"The SLs identified on this website are likely to serve as PRGs early in the process--e.g., at RI scoping and at screening of chemicals of potential concern (COPCs) for the baseline risk assessment."

What are the concerns and issues with the toxicity values used to calculate the preliminary values for the various pathways?

1) Use of chronic toxicity values rather than subchronic toxicity values in deriving the residential (child only) soil remediation standards represents an overly conservative approach.
2) NJDEP's approach in applying a 10-fold adjustment to the noncancer calculation for Class C carcinogens is not consistent with generally accepted approaches for developing soil remediation standards or indoor air screening levels.
3) USEPA's IRIS notes that ethylbenzene is a Class D chemical. Ethylbenzene should not be assessed as a carcinogen.

What are the concerns and issues with the toxicity values used to calculate the preliminary values for the various pathways?

- USEPA's IRIS notes that ethyl benzene is a Class D chemical. Ethylbenzene should not be assessed as a carcinogen.
  - USEPA's IRIS notes that ethylbenzene is a Class D chemical
  - USEPA uses CalEPA cancer toxicity values for Regional Screening Levels
  - International Agency for Research on Cancer (IARC)

    "[t]here is inadequate evidence in humans for the carcinogenicity of ethyl benzene"

  - Recognizing that NJDEP's Tier 1 source for toxicity information is IRIS (with the exception of NJ DWQI)
  - IRIS is currently in the process of updating the hazard assessment for ethylbenzene.

What are the concerns and issues with the chemical and physical parameters used to calculate the preliminary values for the various pathways?

- In 2008, NJDEP's approach for selecting physical/chemical values was significantly more robust and technically defensible than what is currently being proposed. The USEPA's SSL Guidance document (USEPA 1996) values and its recommended hierarchy of sources should continue to be NJDEP's first choice in deriving soil remediation standards.

What are the concerns and issues with any of the 17 provided documents?

No specific comments.

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

1) Polycyclic Aromatic Hydrocarbons (PAHs): It appears that the residential draft standards for several PAHs (for example, benzo(k)fluoranthene, benzo(b)fluoranthene, benzo(a)anthracene, benzo(a)pyrene) are lower than the current standards derived in 2008, while the non-residential draft standards are higher than the current standards. What are the driving reasons for this shift? Is this due to the ADAF adjustment now incorporated into the residential standards calculation, due to a change in the physical chemical values used in their derivation (e.g., K_{oc}), or some other reason?

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

Contaminant	CAS No.	Soil PQL (mg/kg)	Direct Contact Soil Remediation Standards							
			Residential (mg/kg)				Non-Residential (mg/kg)			
			Draft Proposed Ingestion- Dermal	Draft Proposed Inhalation	Draft Proposed Standard	Current Standard	Draft Proposed Ingestion- Dermal	Draft Proposed Inhalation	Draft Proposed Standard	Current Standard
Acenaphthene	83-32-9	0.2	3,500	NA	3,500	3,400	51,000	NA	51,000	37,000
Anthracene	120-12-7	0.2	17,000	NA	17,000	17,000	250,000	NA	250,000	30,000
Benzo(a)anthracene (1,2-Benzanthracene)	56-55-3	0.2	0.15	15,000	0.20	0.6	3.2	200,000	3.2	2
Benzo(a)pyrene	50-32-8	0.2	0.015	1,500	0.20	0.2	0.32	20,000	0.32	0.2
Benzo(b)fluoranthene (3,4-Benzofluoranthene)	205-99-2	0.2	0.15	15,000	0.20	0.6	3.2	200,000	3.2	2
Benzo(k)fluoranthene	207-08-9	0.2	1.5	15,000	1.5	6	32	200,000	32	23
Chrysene	218-01-9	0.2	15	150,000	15	62	320	NA	320	230
Dibenz(a,h)anthracene	53-70-3	0.2	0.015	1,400	0.20	0.2	0.32	19,000	0.32	0.2
Indeno(1,2,3-cd)pyrene	193-39-5	0.2	0.15	15,000	0.20	0.6	3.2	200,000	3.2	2
Naphthalene	91-20-3	0.2	2,400	5.7	5.7	6	35,000	27	27	17
Pyrene	129-00-0	0.2	1,700	NA	1,700	1,700	25,000	NA	25,000	18,000

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

2) The draft residential standards for PAHs indicate that two compounds (dibenz(a,h)anthracene, benzo(a)pyrene) will remain at PQLs, while three additional compounds (benzo(a)anthracene, benzo(b)fluoranthene, indeno(1,2,3-cd)pyrene) have draft standards that would be reduced to PQLs. It would seem that these PQLs are below background concentrations in many areas. While background can be accounted for in remediation, these standards make the task of identifying clean fill, beneficial use of recycled concrete and dredged materials difficult. We would encourage NJDEP to consider the use of background levels in place of PQLs. We realize that the Brownfields Act refers to "natural background" or compounds/elements that are not anthropogenic in nature.

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

3) The standard for di-n-octyl phthalate is substantially less than the current standard. What is (are) the driving reason(s) for this shift? Is it due to a change in the physical chemical values used in its derivation (e.g., K_{oc}) [see comment above] or a change in the toxicity values used?

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

Contaminant	CAS No.	Soil PQL (mg/kg)	Direct Contact Soil Remediation Standards							
			Residential (mg/kg)				Non-Residential (mg/kg)			
			Draft Proposed Ingestion- Dermal	Draft Proposed Inhalation	Draft Proposed Standard	Current Standard	Draft Proposed Ingestion- Dermal	Draft Proposed Inhalation	Draft Proposed Standard	Current Standard
Di-n-octyl phthalate	117-84-0	0.2	620	NA	620	2,400	9,200	NA	9,200	27,000

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

4) NJDEP should consider using a different exposure time (ET) in the derivation of residential soil remediation standards for the inhalation route of exposure which currently assumes that residential outdoor inhalation exposure occurs 24 hours/day. NJDEP should consider developing a conservative but more reasonable exposure time consistent with reasonable maximum exposure assumptions regarding time spent outdoors by residents at a specific property. We are currently investigating the scientific basis for alternatives for the 24hr exposure scenario.

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

5) The draft residential standard for manganese is 1,900 mg/kg; currently the standard is 11,000 mg/kg. The draft non-residential standard is 31,000 mg/kg; the current standard is 5,900 mg/kg. What is (are) the reasons(s) for this shift?

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

6) The migration to groundwater draft standard for benzene is higher than the current impact to groundwater screening level (IGW). This appears to be due to the use of a different K_{oc} than used in 2008. NJDEP should use the approach used in 2008 for selecting physical/chemical values since it was significantly more robust and technically defensible than what is currently being proposing.

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

Contaminant	CAS No.	Soil PQL (mg/kg)	Migration to Groundwater			
			Draft Proposed Default Soil Standard (mg/kg)	Current Screening Criterion (mg/kg)	Draft Proposed Default Leachate Standard (ug/L)	Current Leachate Criterion (ug/L)
Benzene	71-43-2	0.005	0.0094	0.005	20	4

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

7) The migration to groundwater draft standards for several phthalates are substantially lower than the current IGW (butyl-benzyl phthalate (230 mg/kg to 29 mg/kg), bis-2-ethylhexyl phthalate (1200 mg/kg to 14 mg/kg). What is (are) the driving reason(s) for these shifts? Is it due to a change in the physical chemical values used in their derivation (e.g., K_{oc}) [see above comment]? If so, NJDEP should use the approach used in 2008 for selecting physical/chemical values since it was significantly more robust and technically defensible than what is currently being proposed.

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

8) In general, draft migration to groundwater standards have not been set for PAHs. We assume that this is due to low solubility of these compounds in water. The exception appears to be benzo(a)anthracene, which does have a draft standard. Is there a reason why this compound appears to be an exception?

What are the issues and concerns with any preliminary value for a specific contaminant, pathway, or exposure scenario?

9) The direct contact draft standards for 1,1,1-trichloroethane are substantially higher than the current direct contact standards (160,000 mg/kg vs 290 mg/kg), presumably due to recent toxicity data. However, the draft migration to groundwater standard is lower than the current IGW (0.2 mg/kg vs. 0.3 mg/kg). Is this due to the current groundwater quality standard?