Use of Non-Cancer Age-Adjusted Factors and Chronic vs. Sub-chronic Reference Doses in Deriving Screening Levels vs. Remediation Standards

Presented to:

NJDEP Remediation Standards Committee

November 12, 2014

Overview of the Issues

- **What's the Difference ?**
  - Screening Levels vs. Remedial Goals/Standards
  - Chronic vs. Sub-chronic Non-Cancer Toxicity Factors/RfDs
- **History of Using Age-Adjusted Factors and Chronic vs. Sub-Chronic Reference Doses**
- **Potential Ramifications**
- **Recommendations**

Screening Level vs. Remedial Goal ???

Screening Level

- Preliminary Remediation Goals (once called PRGs – now RSLs) are the *initial* cleanup goals to provide conservative risk reduction targets and identify where remediation is needed.
- SSLs *are not national cleanup standards*, they do not trigger actions or define "unacceptable" levels of contaminants. "Screening" refers to identifying areas and contaminants that do not require attention. Where contamination is at a level below SSLs, no further action is warranted under CERCLA. Where it is equal/exceeds SSLs, further investigation, *not necessarily cleanup*, is warranted.
- *Screening Levels are refined into Remedial Goals* during CERCLA RI/FS process based on NCP criteria for choosing a remedy; compliance with ARARs (we are really talking here about setting the ARARs - promulgated soil standards), baseline risk and uncertainty, cost, technical feasibility, community acceptance, schedule.

Screening Level vs. Remedial Goal ???

Remedial Goal

- CERCLA required development of methods and criteria for determining the *appropriate extent of removal, remedy and other measures (e.g.*, institutional controls)
- EPA developed a process to develop remedial action objectives/remedial goals that are protective of human health and environment based on environmental standards **or** risk calculations.
- Final Remediation Goals are media-specific cleanup goals specific to a remedial action. *Remediation is considered complete and no further action is necessary once Remediation Goals are attained*.
- Documented in Record of Decision (ROD) or in SRP, the RAO.

SLs are usually less conservative… with rare exception:

Clarification of the Role of ARARs in Establishing PRGs (this was largely related to issues with radioactive standards)

In the rare circumstances where, based on available information, application of an ARAR would not be protective of human health or the environment, EPA should establish PRGs at levels that are more protective than required by the ARAR even absent multiple pathways or contaminants. As noted above, in deciding whether a PRG should be established at a level more protective than required by an ARAR, consideration should be given to the level of risk associated with application of the ARAR; the soundness of the technical basis for the ARAR; and other factors relating to the ARAR or to its application at an individual site.

Chronic vs. Sub-Chronic RfD ???

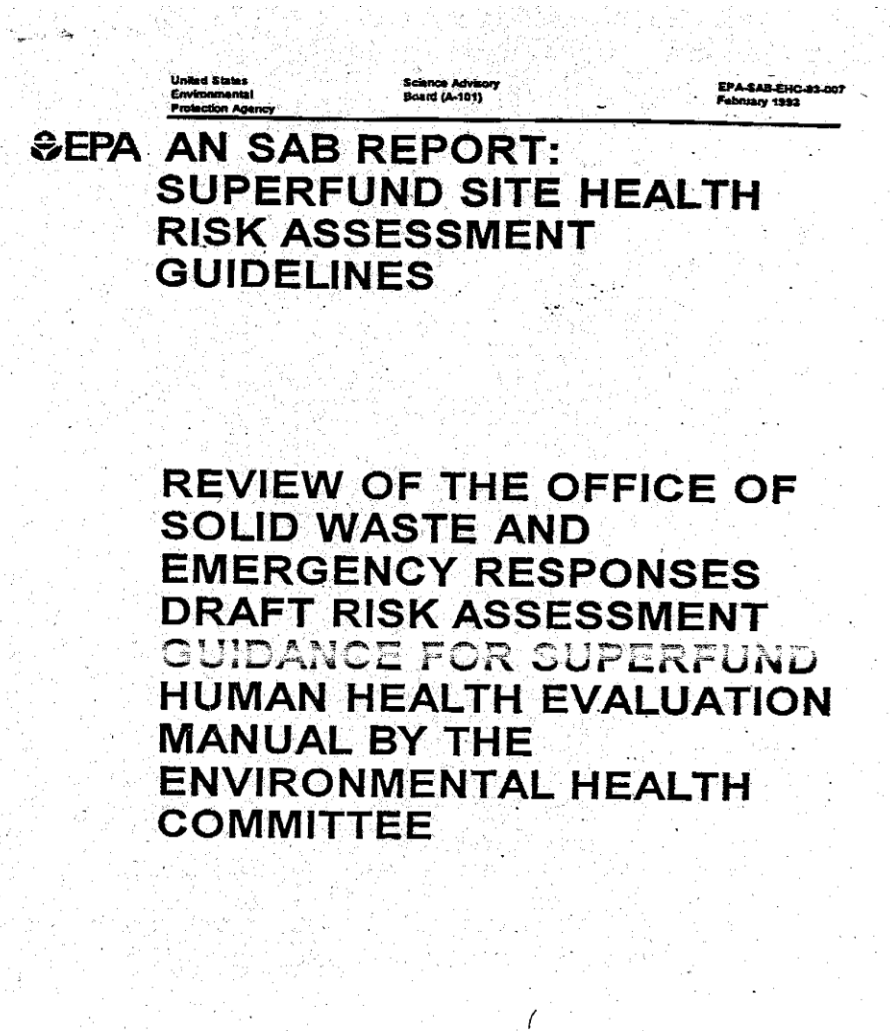
- Sub-Chronic RfD: An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure levels for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a portion of a lifetime (as a Superfund program guideline, two weeks to seven years).
- Chronic RfD: An estimate of daily exposure levels…including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime. Chronic RfDs are specifically developed to be protective for long-term exposure to a compound (seven years to lifetime).
- Comes down to considering exposure over 7 or 70 years in calculating risk

USEPA Risk Assessment Guidance for Superfund, Part A (1996)

History of Using Age-Adjusted Factors and Chronic vs. Sub-Chronic Reference Doses to Derive Remedial Standards

How DID we get here?

History of Using Age-Adjusted Factors and Chronic vs. Sub-chronic Reference Doses (SAB, 1993)



United States Environmental Protection Agency | Science Advisory Board (A-101) | EPA-SAB-EHC-93-007 February 1993

EPA

AN SAB REPORT:
SUPERFUND SITE HEALTH RISK ASSESSMENT GUIDELINES

REVIEW OF THE OFFICE OF SOLID WASTE AND EMERGENCY RESPONSES DRAFT RISK ASSESSMENT GUIDANCE FOR SUPERFUND HUMAN HEALTH EVALUATION MANUAL BY THE ENVIRONMENTAL HEALTH COMMITTEE

History of Choosing Exposure and RfDs

USEPA Considered - and Science Advisory Board Commented on Three Methods *to Derive Remedial Goals*

- Comparison of 6-year childhood exposure to soil with subchronic RfD
- Comparison of a 30-year time weighted average exposure to soil (including exposures to child and adult) with chronic RfD
- Comparison of 6-year childhood exposure with a chronic RfD

History of Choosing Exposures and RfDs - SAB Comments

The second approach proposed by the OSWER probably is the more reasonable. That is, to compare a 30-year time-weighted average (TWA) exposure with a chronic RfD. It is likely to be adequately conservative. Comparison of a six-year old's exposure with a chronic RfD (a third approach) may be overly conservative. It also assumes the six-year old is the more vulnerable. The second approach accounts for variable susceptibility with age in a more conservative manner than does method three. Actually, all three methods could be considered, and the one giving the most conservative (in the absence of specific information) or the most reasonable estimate (in the presence of such information) used. It would be helpful to see a group of diverse examples for all three approaches. Perhaps the most relevant exposure scenario could then be selected (i.e., childhood vs. lifetime). Clearly, the model selected must be one that accommodates the most intense future land utilization, e.g., housing, lest repeat remediation become necessary.

History of Choosing Exposures and RfDs

- **And the SAB verdict (of sorts):**

Three approaches for using RfDs to develop risk-based remediation goals for contaminated soil were presented. The most supportable of these uses a 30-year time-weighted average with a chronic RfD; differences between the three approaches are not dramatic however, and OSWER should study all three approaches to verify its ultimate choice (or range of choices).

Potential Ramifications

Comparison of six-year old's exposure with a chronic RfD (Method 3) uses value meant to be protective over a lifetime (70 years) and may be overly conservative.

Comparing a 30-year time-weighted average (TWA) exposure with a chronic RfD (Method 2) is thought to be more reasonable. This approach actually accounts for variable susceptibility with age in a more conservative manner than does Method 3.

USEPA's Science Advisory Board

Potential Ramifications

As noted earlier, the SSLs *are derived for screening purposes only, they are not meant to be cleanup standards.*

Yet the current proposal is to use Method 3 (6-year exposure duration combined with chronic toxicity values) used in deriving SSLs to set Soil Remediation Standards, with no option to develop ARS using Method 2.

Recommendations

> The most reasonable and supportable approach appears to [be] using a 30-year time-weighted average with a chronic RfD…

USEPA Science Advisory Board Recommendation

Details – for further discussion?

Calculation of SSLs for direct ingestion of soil is based on RAGS Part B, using an age-adjusted soil ingestion factor for children 1-6 years old vs. others 7-31; child's risk-based SSL is lower than for adults only.

For non-carcinogens, the definition of an RfD (chronic vs. sub-chronic) has caused debate whether sub-chronic exposure should be compared to the chronic RfD.

For most chemicals, SAB has said combining the 6-year child exposure with chronic RfD is overly protective, except when the chronic RfD is based on child-specific toxicity (e.g., nitrates) or when the dose/response curve is steep (i.e., NOAEL vs. LOAEL is small). For screening only, the generic SSLs for non-carcinogens use the "child only" exposure equation.

The issue of whether to maintain this more conservative approach in the baseline risk assessment and in establishing remediation goals will depend on how the toxicology of the chemical relates to the issues raised by the SAB.

Soil Screening Level Technical Background Document

Recommendations

- Maintain the current approach in deriving the default noncancer residential SRS (i.e., 6 year exposure period with chronic toxicity values) adopted from USEPA's *Soil Screening Guidance and* using "child only" exposure.
- Allow, as an option, subject to DEP review (as are all ARS proposals) development of ARS for residential direct contact with soil that use age-adjusted calculation to account for exposure over childhood and adult 30 year exposure timeframe, using chronic toxicity values.
- This would be consistent with methods EPA uses to develop both screening levels and remediation standards.
- Promote further discussion of exceptions and how to advance science moving forward.

Discussion/Questions?

Thank you!