

GENERAL COMMENTS

In general, the draft workplan for the baseline risk assessment conforms to EPA guidance for risk assessments. However, you should be aware that the region is now in the process of developing a "generic" workplan for risk assessments. Once completed, EPA will forward this information to you. This workplan will, in general, conform to plans now in existence and those under development in other regional offices. Included in the workplan will be a set of regionally specific exposure parameters to be used in the exposure assessment portion of the baseline risk assessment. Deviation from these exposure parameters will require adequate documentation, and the approval of EPA.

SPECIFIC COMMENTS

Page 4-6: Paragraph 3: Objectives

Objective 2 includes fate and transport analysis within environmental media. It is also essential that the baseline risk assessment address cross-media fate and transport. For instance, such analysis must include contamination of ground water from soil sources, contamination of air from soils or water, etc.

Page 4-7: Paragraph 1: Documents to be used

In addition to the documents listed in Table 4-1, EPA will be using documents included on the attached list for development and review of the baseline risk assessment.

Page 4-9: Paragraph 1: Contaminants to be considered

The following criteria must be used in identifying chemicals to be addressed in the baseline risk assessment:

- a.) Those chemicals positively detected in at least one CLP sample (RAS or SAS) in a given medium, including chemicals with qualifiers attached indicating known identities, but unknown concentrations.
- b.) Chemicals detected at levels elevated above background.
- c.) Chemicals which have been tentatively identified and may be associated with the site based on historical information, or have been confirmed by SAS.
- d.) Transformation products of site associated chemicals.

It is unclear what is meant in the draft workplan by "risk based detection limits". Analytical detection limits based upon

the best available technology must be used.

Chemicals must not be eliminated based upon environmental fate predictions until the exposure assessment phase of the baseline risk assessment is completed.

Page 4-10: Bullet 2: Exposure scenarios

Scenario selection should proceed regardless of the ability to quantify exposure. This may require exposure to be addressed qualitatively under circumstances where quantitative evaluation is not possible.

Page 4-10: Paragraph 2: Factors examined in pathway identification

In addition to the factors listed, detailed local meteorological data must be considered.

It may be advantageous to consider receptor characteristics rather than "exposure scenarios" for the purpose of the baseline risk assessment. Each of the scenarios listed include several of the same receptor subpopulations. To avoid a duplication of effort, it may be more efficient to directly assess exposure and potential toxicity to subpopulations.

Page 4-11: Paragraph 1: Cancer risk

It is not clear what is meant by the statement "Doses or the dose might result in an excess cancer risk for noncarcinogenic health". Please explain.

Page 4-11: Paragraph 2: Critical toxicity values

Reference values for systemic or carcinogenic risk derived from SPHEM or PHRED will not be acceptable for use in the baseline risk assessments. Both of the above sources are now obsolete and have been replaced.

Page 4-12: Paragraph 2: Types of toxicity values

It will be unnecessary to generate toxicity values for subchronic exposure. Chronic exposure will provide a more conservative assessment and will drive the rationale for any cleanup activity which may be indicated.

The preferred terminology for acceptable intake for chronic exposure (AIC) is now "risk reference dose" (RFD). To avoid confusion, this terminology should be used throughout the baseline risk assessment and the AIC terminology should be discontinued.

Page 4-12: Paragraph 3: Risk characterization

The reasonable maximum estimate of exposure (RME), based upon the 95% upper confidence limit of the exposure data, must be used throughout the baseline risk assessment process. Details must be provided regarding the rationale and methodology for development of subchronic exposure estimates.

Page 4-12: Paragraph 2: Aquatic toxicity

Where applicable, assessment of sediment toxicity must be included in the environmental portion of the risk assessment.

RISK ASSESSMENT IN SUPERFUND

The following are selected program guidances and other key documents useful in the conduct of Superfund risk assessments (current as of July 1989). Unless otherwise noted, further information on these materials can be obtained by calling the Toxics Integration Branch in the Office of Emergency and Remedial Response at 202-475-9486.

"Superfund Public Health Evaluation Manual (SPHEM)" -- Office of Emergency and Remedial Response, (October 1986) EPA/540/1-86/060. The current program risk assessment guidance manual. Explains how to conduct a baseline site risk assessment, set preliminary remediation goals, and evaluate risks of remedial alternatives. Currently under revision; revised interim final expected by summer 1989.*

"EPA's Integrated Risk Information System (IRIS)" -- Office of Research and Development, (continuously updated). Agency's primary source of chemical-specific toxicity and risk assessment information. Includes narrative discussion of toxicity database quality and explains derivation of Reference Doses, cancer potency factors, other key dose response parameters. IRIS presents information that updates data originally presented in Exhibits A-4 and A-6 of the SPHEM (see above). Further information: IRIS Users Support, 513-569-7254.

"Health Effects Assessment Summary Tables (HEAST)" -- Office of Research and Development/Office of Emergency and Remedial Response, (updated quarterly). Since the IRIS chemical universe (while growing) is currently incomplete, the HEAST has been produced to serve as a "pointer" system to identify current literature and toxicity information on important non-IRIS chemicals. While HEAST data in some cases may not be "Agency-verified", the information is considered valuable for Superfund risk assessment purposes. Available from Superfund Docket, 202-382-3046.

"Exposure Factors Handbook" -- Office of Research and Development, (March 1989) EPA/600/8-89/043. Provides statistical data on the various factors used in assessing exposure; recommends specific default values to be used when site-specific data are not available for certain exposure scenarios. Further information: Exposure Methods Branch, 202-382-5988.

"OSWER Directive on Soil Ingestion Rates" -- Office of Solid Waste and Emergency Response, (January 1989) OSWER Directive #9850.4. Recommends soil ingestion rates for use in risk assessment when site-specific information is not available. Available from Darlene Williams, 202-475-9810.

"Superfund Exposure Assessment Manual (SEAM)" -- Office of Emergency and Remedial Response, (April 1988) EPA/540/1-88/001. Provides a framework for the assessment of exposure to contaminants at or migrating from hazardous waste sites. Discusses modeling and monitoring.*

"Risk Assessment Guidance for Superfund -- Environmental Evaluation Manual, Interim Final (RAGS-EEM)" -- Office of Emergency and Remedial Response, (March 1989) EPA/540/1-89/001A. Provides program guidance to help remedial project managers and on-scene coordinators manage ecological assessment at Superfund sites.

"Superfund Risk Assessment Information Directory (RAID)" -- Office of Emergency and Remedial Response, (November 1986) EPA/540/1-86/061. Describes sources of information useful in conducting risk assessments. Currently under revision.*

*Available from Center for Environmental Research Information, 513-569-7562.

EPA 540/12-89/002 Risk Assessment Guidance for Superfund Human Health Evaluation manual