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

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

December 5, 2003

OSWER Directive 9285.7-53

MEMORANDUM

SUBJECT: Human Health Toxicity Values in Superfund Risk Assessments

FROM: Michael B. Cook, Director /s/
Office of Superfund Remediation and Technology Innovation

TO: Superfund National Policy Managers, Regions 1 - 10

Purpose

This memorandum revises the hierarchy of human health toxicity values generally recommended for use in risk assessments, originally presented in Risk Assessment Guidance for Superfund Volume I, Part A, Human Health Evaluation Manual (RAGS) (OSWER 9285.7-02B, EPA/540/1-89/009, December 1989). (http://www.epa.gov/superfund/programs/risk/ragsa/index.htm)

It updates the hierarchy of human health toxicity values and provides guidance for the sources of toxicity information that should generally be used in performing human health risk assessments at Comprehensive Environmental Response Compensation and Liability Act (CERCLA or "Superfund") sites. It does not address the situation where new toxicity information is brought to the attention of the U.S. Environmental Protection Agency (EPA). It also does not provide guidance or address toxicity or reference values for ecological risk.

This memorandum presents current Office of Solid Waste and Emergency Response (OSWER) technical and policy recommendations regarding human health toxicity values in risk assessments. EPA and state personnel may use and accept other technically sound approaches, either on their own initiative, or at the suggestion of potentially responsible parties, or other interested parties. Therefore, interested parties are free to raise questions and objections about the substance of this memorandum and the appropriateness of the application of this document to a particular situation. EPA will, and States should, consider whether the recommendations or interpretations in this memorandum are appropriate in that situation. This memorandum does not impose any requirements or obligations on EPA, States, or other federal agencies, or the regulated community. The sources of authority and requirements in this matter are the relevant

statutes and regulations (e.g., CERCLA, Resource Conservation and Recovery Act). EPA welcomes public comments on this memorandum at any time and may consider such comments in future revisions of this memorandum.

Background

Superfund risk assessments are performed for a number of reasons, including to evaluate whether action is warranted under CERCLA, to establish protective cleanup levels, and to determine the residual risk posed by response actions. Generally, toxicity assessment is an integral part of risk assessment. Volume I, Part A of RAGS provides guidance on how to conduct the human health portion of the risk assessment. Chapter 7.4.1 presents a hierarchy of human health toxicity values for use in risk assessments at Superfund sites. The hierarchy presented in RAGS Part A is being updated to reflect that additional sources of peer reviewed values have become available since 1989. In addition, the EPA Health Effects Assessment Summary Tables (HEAST) document, which was identified as the second tier of data, has not been updated since 1997. As a result, HEAST may not provide the most current source of information on some contaminants.

This revised hierarchy recognizes that EPA should use the best science available on which to base risk assessments. In general, if health assessment information is available in the Integrated Risk Information System ["IRIS," http://www.epa.gov/iris/] for the contaminant under evaluation, risk assessors normally need not search further for additional sources of information. Since EPA's development and use of peer review in toxicity assessments, IRIS assessments have undergone external peer review in accordance with Agency peer review guidance at the time of the assessment. IRIS health assessments contain Agency consensus toxicity values. If such information is not available in IRIS, risk assessors should consider other sources of available data based on the hierarchy presented in this memorandum.

EPA recognizes that there may be other sources of toxicological information. As noted in the December 1993 memorandum entitled "Use of IRIS Values in Superfund Risk Assessment" (OSWER Directive 9285.7-16, December 21, 1993):

> "...IRIS is not the only source of toxicology information, and in some cases more recent, credible and relevant data may come to the Agency's attention. In particular, toxicological information other than that in IRIS may be brought to the Agency by outside parties. Such information should be considered along with the data in IRIS in selecting toxicological values; ultimately, the Agency should evaluate risk based upon its best scientific judgement and consider all credible and relevant information available to it."

This memorandum is intended to help regional risk assessors identify appropriate sources of toxicological information as a means of streamlining decisions. It does not specifically address the situation where additional scientific information is brought to the attention of EPA. In those cases, EPA risk assessors and decision makers should consider the information as appropriate on a case by case basis.

Revised Recommended Human Health Toxicity Value Hierarchy

This memorandum revises the recommended hierarchy of toxicological sources of information which Regional risk assessors and managers should initially consider for site-specific risk assessments. The revised recommended toxicity value hierarchy is as follows:

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Tier 1- EPA's IRIS

Tier 2- EPA's Provisional Peer Reviewed Toxicity Values (PPRTVs) – The Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center (STSC) develops PPRTVs on a chemical specific basis when requested by EPA's Superfund program.

Tier 3- Other Toxicity Values – Tier 3 includes additional EPA and non-EPA sources of toxicity information. Priority should be given to those sources of information that are the most current, the basis for which is transparent and publicly available, and which have been peer reviewed.

IRIS remains in the first tier of the recommended hierarchy as the generally preferred source of human health toxicity values. IRIS generally contains reference doses (RfDs), reference concentrations (RfCs), cancer slope factors, drinking water unit risk values, and inhalation unit risk values that have gone through a peer review and EPA consensus review process. IRIS normally represents the official Agency scientific position regarding the toxicity of the chemicals based on the data available at the time of the review.

The second tier is EPA's PPRTVs. Generally, PPRTVs are derived for one of two reasons. First, the STSC is conducting a batch wise review of the toxicity values in HEAST (now a Tier 3 source). As such reviews are completed, those toxicity values will be removed from HEAST, and any new toxicity value developed in such a review will be a PPRTV and placed in the PPRTV database. Second, Regional Superfund Offices may request a PPRTV for contaminants lacking a relevant IRIS value. The STSC uses the same methodologies to derive PPRTVs for both.

The third tier includes other sources of information. Priority should be given to sources that provide toxicity information based on similar methods and procedures as those used for Tier I and Tier II, contain values which are peer reviewed, are available to the public, and are transparent about the methods and processes used to develop the values. Consultation with the STSC or headquarters program office is recommended regarding the use of the Tier 3 values for Superfund response decisions when the contaminant appears to be a risk driver for the site. In general, draft toxicity assessments are not appropriate for use until they have been through peer review, the peer review comments have been addressed in a revised draft, and the revised draft is publicly available.

Additional sources may be identified for Tier 3. Toxicity values that fall within the third tier in the hierarchy include, but need not be limited to, the following sources.

- The California Environmental Protection Agency (Cal EPA) toxicity values are peer reviewed and address both cancer and non-cancer effects. Cal EPA toxicity values are available on the Cal EPA internet website at http://www.oehha.ca.gov/risk/chemicalDB//index.asp.

- The Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels (MRLs) are estimates of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure. The ATSDR MRLs are peer reviewed and are available at http://www.atsdr.cdc.gov/mrls.html on the ATSDR website.

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- HEAST toxicity values are Tier 3 values. As noted above, the STSC is conducting a batch wise review of HEAST toxicity values. The toxicity values remaining in HEAST are considered Tier 3 values. The radionuclides HEAST toxicity values are available at http://www.epa.gov/radiation/heast/. The HEAST values on chemical contaminants are not currently available on an EPA internet site. They may be obtained by contacting a Superfund risk assessor.

Neither IRIS nor the PPRTV database contains radionuclide slope factors. Because EPA's Office of Radiation and Indoor Air (ORIA) obtains peer review on the radionuclide slope factors contained in Table 4 of HEAST (which are available on EPA/ORIA's internet website at http://www.epa.gov/radiation/heast/download.htm), routine consultation with STSC is generally not necessary on these values even when they may be a risk driver on a Superfund site. These radionuclide slope factors have been adopted by EPA in its Preliminary Remediation Goals for Radionuclide Calculator and are available on EPA's internet website at: http://epa-prgs.ornl.gov/radionuclides/ and the Soil Screening Guidance for Radionuclide documents, which are available at: http://www.epa.gov/superfund/resources/radiation/radssg.

Implementation

This memorandum provides a revised recommended hierarchy of human health toxicity values for Superfund sites and represents a revision of Chapter 7 of RAGS, Volume I, Part A. Superfund risk assessors should look to this hierarchy when evaluating risk for CERCLA response actions. Additional sources of toxicity values, which are not specifically referenced in this recommended hierarchy, can be considered.

Additional Information

Questions regarding this guidance or its use and implementation on a particular site should be directed to an EPA Regional Superfund risk assessor or toxicologist. Questions of a more general nature relating to this guidance should be directed to Mr. Dave Crawford of my staff at (703) 603- 8891, Crawford.Dave@epa.gov.

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