



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

OSWER No. 9285.7-82

JAN 28 2009

MEMORANDUM

SUBJECT: Supplemental Guidance for Inhalation Risk Assessment, or Part F of Volume I of Risk Assessment Guidance for Superfund, Human Health Evaluation Manual

FROM: James E. Woolford, Director
Office of Superfund Remediation and Technology Innovation

TO: Superfund National Policy Managers, Regions 1-10
Regional Toxics Integration Coordinators (RTICs), Regions 1-10

Purpose

This memorandum transmits the *Supplemental Guidance for Inhalation Risk Assessment* or Part F of Volume I of Risk Assessment Guidance for Superfund, Human Health Evaluation Manual (RAGS Part F) to U.S. Environmental Protection Agency (EPA) regional offices for use in risk assessments on Superfund sites. The memorandum describes intended uses of this guidance and clarifies how additional information and data, relevant to the use of this guidance, will be made available by the EPA.

Background

This guidance is the sixth annex of the Risk Assessment Guidance for Superfund (RAGS), Volume I, which address human health risk at Superfund sites. Parts A, B, C, D and E of Volume I addressed other aspects of human health risk. RAGS Part F was developed by a workgroup composed of toxicologists and risk assessors in the EPA Superfund Program and other hazardous waste programs in EPA regional offices, with significant involvement from the Office of Research and Development (ORD), the Office of Air Quality Planning and Standards (OAQPS), the Office of Children's Health Protection and Environmental Education (OCHPEE), and the Office of Solid Waste and Emergency Response (OSWER). This guidance received internal EPA review in July 2007 and external peer review and state risk assessor review in April-May 2008.

Since many comments were received on drafts of RAGS Part F on the following issue, the workgroup feels that it is important to reiterate the following point. RAGS Part F provides some information on how inhalation toxicity values (reference concentrations or "RfCs" for non-cancer and inhalation unit risks or "IURs" for cancer) are developed or derived by EPA using the EPA Office of Research and Development's *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (EPA/600/B-90/006F, October 1994). However, it is not intended that RAGS Part F be used as guidance for deriving or adjusting inhalation toxicity values. The primary purpose of RAGS F is to discuss the appropriate use of RfCs and IURs in generating inhalation risk estimates using a concentration-based approach. The background that RAGS Part F provides on the derivation of inhalation toxicity values is for informational purposes only, to help RAGS Part F users understand the linkage between exposure scenarios and toxicity values and the importance of selecting toxicity values that most closely match each exposure scenario addressed in a risk assessment.

Implementation

Some of the statutory provisions described in this memorandum or in the guidance released by this memorandum contain legally binding requirements. However, neither this memorandum nor the guidance substitute for those provisions or regulations. Nor is this memorandum or guidance document a regulation itself. Thus, it cannot impose additional legally-binding requirements upon EPA, states, Tribes, other Federal agencies, or the regulated community. In some instances relating to a particular situation or circumstance this might not be the most relevant guidance to follow. Any decisions regarding the selection of a particular remedial or other response action on a CERCLA (Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended) site will be made based on the statute and regulations, and EPA decision-makers retain the discretion to adopt approaches on a case-by-case basis that may differ from this guidance where appropriate. In the future, EPA may modify this guidance.

The EPA Office of Superfund Remediation and Technology Innovation and the RAGS Part F workgroup recommend that RAGS Part F be used when assessing human inhalation risk at Superfund sites instead of those portions of RAGS Part A released in 1989.

Future Developments

The EPA Superfund program and this workgroup will continue to track current developments of the science of human inhalation risk assessment. If ORD modifies its methods for deriving inhalation toxicity values, including any modifications to address children's susceptibilities, RAGS Part F will be modified or updated to remain consistent with the most current ORD methodology. The EPA Superfund program may post such developments on its risk assessment website where RAGS Part F will be posted (http://www.epa.gov/oswer/riskassessment/superfund_hh_exposure.htm).

Future users of RAGS Part F are advised to periodically visit this website to ensure that they have current information relating to this inhalation risk guidance, and to contact a member of the RAGS Part F workgroup with any implementation questions.

If you have questions about the information presented in this memorandum, please contact Dave Crawford at (703) 603-8891, or by e-mail at crawford.dave@epa.gov, or Michael Sivak at (212) 637-4310 and Sivak.Michael@epa.gov.

Attachment

cc: Barry Breen, OSWER
Renee Wynn, OSWER
OSRTI Managers
Brigid Lowery, CPA
Debbie Dietrich, OEM
Matt Hale, OSW
David Lloyd, OBLR
John Reeder, FFRRO
Marcia Mulkey, OSRE
David Kling, FFEO
John Michaud, OGC
Cliff Rothenstein, OUST
Wendy Lubbe, Superfund Lead Region Coordinator, US EPA Region 7
NARPM Co-Chairs