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

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

OSWER 9285.7-80

JUL 3 2007

MEMORANDUM

SUBJECT: Guidance for Evaluating the Oral Bioavailability of Metals in Soils for Use in Human Health Risk Assessment

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 guidance to the Regions on evaluating the oral bioavailability of metals in soil for use in human health risk assessment at contaminated sites. This guidance specifically addresses three issues: 1) a recommended process for deciding when to collect site-specific information on the oral bioavailability of metals in soils for use in human health risk assessments; 2) a recommended process for documenting the data collection, analysis, and implementation of a validated method that would support site-specific estimates of oral bioavailability; and 3) general criteria that EPA normally will use to evaluate whether a specific bioavailability method has been validated for regulatory risk assessment purposes. This guidance is focused on media-specific relative bioavailability and does not address adjustments to default absolute bioavailability values. Also, this guidance applies only to human health risk assessment and is not necessarily applicable to ecological receptors. Finally, the guidance document provides information on methodologies for directly assessing bioavailability and does not pertain to indirect methods for predicting bioavailability (*e.g.*, speciation).

This guidance addresses sites where human health risks from ingestion of chemical contaminants in soil or soil-like media are evaluated under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) process or under the Resource

Conservation and Recovery Act (RCRA) Corrective Action process. This document supplements the guidance in RAGS, Part A, regarding adjustments to absorption (U.S. EPA, 1989). In addition, this document provides guidance on how to consider bioavailability in metals risk assessments, which is one of the many key guiding principles outlined in the Framework for Metals Risk Assessment (U.S. EPA, 2007).

This final guidance document reflects incorporation of comments from offices within the Office of Solid Waste and Emergency Response, the Regions, and the Office of General Counsel. This document also reflects incorporation of comments received from independent external peer reviewers.

Background

Site-specific human health risk assessments often play a key role in decision-making processes at contaminated sites. Risk assessments generally are used to determine whether a contaminated site poses a current or future threat to human health that warrants remedial action. The term *bioavailability* (as used in this memorandum) refers to the fraction of an ingested dose that crosses the gut and becomes available for distribution to internal target tissues and organs, from which it may exert a toxic response. Bioavailability can be a critical factor in determining the potential uptake of contaminants by receptors and an important consideration in determining potential threats to human health that may be posed by contaminated sites.

The "Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation (Part A)" (RAGS) (U.S. EPA, 1989) supports the consideration of bioavailability in the determination of site-specific human health and environmental risks. This guidance has been used to support bioavailability adjustments across different routes of exposure at contaminated sites. However, the use of bioavailability information in site-specific risk assessment has not been widespread to date (in part due to limited data, uncertain methodologies, and lack of method validation). The primary impediment to the broad use of bioavailability data in risk assessment and decision-making is the absence of rapid and inexpensive tools that can generate reliable bioavailability estimates in the receptors of concern.

Over the past several years, considerable effort has been directed at developing validated laboratory methods for determining bioavailability of soil-borne lead, arsenic, and other metals, including the development of rapid screening tools (*e.g.*, *in vitro* bioaccessibility tests). The availability of new methods has reinforced the need for additional guidance on evaluating bioavailability data and incorporating this information into site-specific risk assessments. Beginning in mid-2002, the Office of Solid Waste and Emergency Response initiated an intra-agency work group to respond to the need for additional guidance. A bioavailability workshop was held in April 2003 that brought together a diverse group of experts from academia, industry, and government to discuss and provide input to EPA on bioavailability issues. The information shared at the workshop was used in developing the guidance attached to this memorandum. The workgroup's efforts are reflected in the attached guidance which is intended to help facilitate national consistency in the use of bioavailability information in human health risk assessments.

Implementation

The Office of Superfund Remediation and Technology Innovation (OSRTI) recognizes that conducting a bioavailability assessment is complex and crosses several scientific disciplines (geochemistry, toxicology, etc.). Using this guidance often will require considerable scientific judgment and expertise. As a result, EPA believes it is important to provide technical support to those engaged in human health risk assessment at contaminated sites and has established a "Bioavailability Committee" which will operate under EPA's Technical Review Workgroup for Metals and Asbestos (TRW). This committee will be composed of EPA staff with expertise in bioavailability assessment and its application to site-specific risk assessments.

The Bioavailability Committee of the TRW will act as the primary point of contact, information archive, and repository of outreach materials for alternate bioavailability methods. It will meet on an as-needed basis to review site-specific applications, provide assistance to the Regions, and issue additional guidance, as necessary. Moreover, the Committee will review new methods for assessing bioavailability of inorganic soil contaminants (new method validation). In addition, the Bioavailability Committee will compile and evaluate information on applications of bioavailability assessments in EPA site-specific risk assessments, with the objective of promoting consistent application of the framework described in this guidance across the EPA Regions. Additional information, technical assistance, and future bioavailability guidance will be provided on the following website: http://www.epa.gov/superfund/bioavailability.

For further information, please contact Aaron Yeow in OSRTI at 703-603-9149 or Michael Beringer in Region 7 at 913-551-7351.

References

U.S. EPA. 1989. Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A). EPA/540/1-89/002.

U.S. EPA. 2007. Framework for Metals Risk Assessment. EPA 120/R-07/001.

Attachment

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