UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
LAND AND EMERGENCY
MANAGEMENT

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MEMORANDUM

SUBJECT: Release of 2020 Guidance for Sample Collection for In Vitro Bioaccessibility Assay for Arsenic and Lead in Soil and Applications of Relative Bioavailability Data in Human Health Risk Assessment

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TO: Superfund National Program Managers, Regions 1-10

The purpose of this memorandum is to transmit the Technical Review Workgroup (TRW) Bioavailability Committee's "Guidance for Sample Collection for In Vitro Bioaccessibility Assay for Arsenic and Lead in Soil and Applications of Relative Bioavailability Data in Human Health Risk Assessment". This is an update to the 2015 Guidance for Sample Collection for In Vitro Bioaccessibility Assay for Lead (Pb) in Soil. The update is intended to help EPA risk assessors, remedial project managers, and on-scene coordinators develop and use bioavailability data at their sites. It incorporates sample planning and data analysis recommendations from EPA's Guidance on Systematic Planning Using the Data Quality Objectives Process (US EPA, 2006[1]) that are pertinent to sampling for In Vitro Bioaccessibility (IVBA) and Relative Bioavailability (RBA). It also clarifies the application of IVBA and RBA data to human health risk assessment, the development of risk-based goals at CERCLA remedial and removal sites, and includes arsenic which was recently added to the In Vitro Bioaccessibility Assay (US EPA, 2017[2]).

Since the 2015 publication of the Guidance for Sample Collection for In Vitro Bioaccessibility Assay for Lead (Pb) in Soil, the TRW Bioavailability Committee and the Bioavailability Hotline have provided technical support on the use of EPA's In Vitro Bioaccessibility Assay (SW 846 EPA Method 1340) at contaminated sites across the country. Many of the questions followed two common themes: 1) data quality and statistical analyses, or 2) the application of the data to the CERCLA risk assessment process. As part of the update, the Bioavailability Committee revised the appendix to provide a more user-friendly tool for calculating the number of both IVBA and

[1] US Environmental Protection Agency, 2006. Guidance on Systematic Planning Using the Data Quality Objectives Process. QA/G-4. EPA/240/B-06/001.
[2] US Environmental Protection Agency. 2017. Standard Operating Procedure for an In Vitro Bioaccessibility Assay for Lead and Arsenic in Soil. OLEM 9200.2-164.

soil concentration samples needed. In addition to the updated guidance, the committee has created a Frequently Asked Questions (FAQ), fact sheets on lead and arsenic RBA, and several case studies of the use of IVBA data at CERCLA remedial and removal sites. The FAQ draws directly on the updated guidance and provides an easily accessible summary of the most common questions regarding IVBA sampling and application. Likewise, the case studies provide concrete examples of the approaches described in the updated guidance and used by the regions.

This updated guidance will facilitate consistent collection and application of bioavailability data at these cleanups. The RBA of lead in soil varies substantially between contaminated sites due to differences in the source, transport, and weathering of the lead. The use of EPA SW-846 Method 1340 to calculate the site-specific RBA is therefore a significant improvement in accuracy of lead human health risk assessments. This method is also generally more cost-effective and efficient than available in vivo methods for assessing RBA and reduces our dependence on animal testing.

The goal of this update is to clarify how existing EPA guidance applies to sampling, analysis, and use of IVBA data. It does not create any new policy, neither does it alter nor supersede existing policy. Rather, it applies existing guidance to sampling for IVBA and to using that data in risk assessment.

If you have any questions regarding this document, please contact the Matt Lambert (lambert.matthew@epa.gov, 703-603-7174) or the Bioavailability Hotline (bahelp@epa.gov, 1-866-282-8622).

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