PUBLIC COMMENT SUMMARIES AND RESPONSES
SW-846 UPDATE VI, PHASE 1
"METHOD 1340 FOR IN VITRO BIOACCESSIBILITY ASSAY FOR LEAD IN SOILS"

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Prepared by:

TechLaw, Inc.
14500 Avion Parkway
Suite 300
Chantilly, VA 20151

Prepared For:

U.S. Environmental Protection Agency
Methods Team, Office of Resource Conservation and Recovery (ORCR)

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EPA Work Assignment Managers:
S. Yang and C. Langlois-Miller

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Introduction

On March 31, 2017, the U.S. EPA published a notice to announce the availability of, and to request comment on, SW-846 Update VI, Phase 1 - Method 1340 for In Vitro Bioaccessibility Assay for Lead in Soils. EPA welcomed the public to submit comments on this new analytical method. The comment period closed on May 1, 2017. The Agency has received public comments on this method, and after consideration, is placing this new method in the SW-846 methods compendium. EPA is issuing this update as guidance.

A total of eight comments were received. Seven of those comments were unrelated to Method 1340 (or any technical discussion about it) and were regarding statements supporting EPA's overall mission and/or expressing concern for other environmental issues. One four-part technical comment was received that pertained to Method 1340. This document provides draft summaries and responses to the public comments submitted to date regarding Method 1340 in Update VI, Phase I. Complete copies of the comments can be found in docket EPA-HQ-OLEM-2017-0122 on regulations.gov.

Method 1340

Comment #1

This commenter (#1) had a four-part inquiry:

1a. Comment:
The commenter indicated that EPA Method 1340 should be performance-based and any deviations/modifications made to the method seem reasonable as long these method deviations are tested and documented. As long as deviations from the method as written are noted and reliable results are demonstrated by acceptable recoveries from standard reference materials (SRMs) that represent typical field conditions with lead-contaminated soil, then modifications should be allowed.

1a. Response:
Most SW-846 methods, including Method 1340, are intended to be performance-based and may be modified by the laboratory as long as the modification is documented to have equivalent performance for the matrix and analyte, and the modification meets the project's previously-determined data quality objectives (DQOs). However, some extraction methods, in particular, require that certain conditions be followed more exactly in order to get reproducible results. Laboratories are encouraged to generate their own project specific DQOs and control charts for recovery criteria. However, any changes to the extraction and filtration criteria in this method may alter the results and are not recommended. If such alterations to the method are made, documentation of the revised method's equivalent performance must be maintained.

1b. Comment:
Commenter is unsure if Method 1340 has been tested to demonstrate that drying and sieving does not affect the relative bioavailability of lead from different sites.

1b. Response:
The method was developed with dried and sieved materials to increase homogeneity in the sample aliquot used for extraction. The method development studies found that dried and sieved materials produced far more precise and accurate results. It is important to note that exposure to soil-bound lead through ingestion is expected to occur primarily through soil particles less than 150 µm in size, and therefore that is the size fraction that the method was developed to test. The method has been tested on soils sieved to several different sizes (<38, 38 – 75, 75 – 150, and 150 – 250 µm) and no differences in bioavailability were observed between the size fractions. Studies have observed differences in the bioavailability of larger size fractions compared to particle sizes less than 250 µm, but the bioavailability of lead in larger size fractions is considered unimportant for incidental soil ingestion exposure. It should be noted that the SRMs available for this method are sieved to a particle size between 74 and 250 µm. It should also be noted that lead is not a volatile analyte and is not subject to loss from drying at ambient temperatures. Therefore, lead loss from drying should be minimal for any material that would be present in and bioavailable to a person.

1c. Comment:
Commenter asked if the procedure was designed to be representative for the dry particle size that would stick to a child's hands, what would be the effect of wet soils?

1c. Response:
The method calls for samples to be dried and sieved to reduce the variability associated with sample moisture content and particle size. Generally, the smaller the particle size the greater the adsorption potential. A sieve size of 150 µm was chosen to match the recent update to the input parameters for the Integrated Exposure Uptake Biokinetic Model for lead exposure. There is much variability in the size fraction that sticks to human skin, but recent work analyzing the scientific literature on this topic indicates that the <150 µm size fraction captures 80-95% of the mass adhered to hands in all but two studies. The EPA memorandum "Recommendations for Sieving Soil and Dust Samples at Lead Sites for Assessment of Incidental Ingestion" (US EPA, 2016, OLEM Directive 9200.1-128) generally recommends the use of 150 µm, but allows for the use of 250 µm when the exposure is expected to be wet soils, sediments, or wetland soils.

1d. Comment:
Commenter recommended that EPA Method 1340 should specify the number of samples and distribution of data across a given site in order to provide a better representative data set.

1d. Response:
It is not the intention of the method to require predetermined batch sizes or to place limitations or requirements on site sampling. The number of samples required is dependent on the area to be sampled, the distribution of the data, and how that data will be used. The practical limit on sample throughput is the ninety-minute total time allowed for the process batch (found in Sec. 11.12). Each laboratory/data user will have to determine batch size by the number of samples they can process in the required interval. The number of samples required at a given site should be determined during the site-specific DQO process which considers the data distribution, source material, transport mechanism, subsequent disturbances, and other factors described by a site-specific Conceptual Site Model, and should be addressed in relevant project planning documents.