ITRC PROJECT PROPOSAL FORM
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BIOAVAILABILITY ADJUSTMENTS FOR CONTAMINATED SOIL

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PROPOSAL DATE: May 2, 2014

Proposal Contacts

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Proposal Topical Area

CHAR: Characterization

Bioavailability of Contaminants in Soil

Proposal Summary

Problem Statement: Researchers have known for over 20 years that contaminants in soil may not pose as much risk as contaminants administered directly to organisms during toxicity and carcinogenicity testing. Contaminants may be tightly bound to soil particles, or sequestered within particles, greatly reducing the potential for uptake by people (and other receptors) that are exposed to the soil. In fact, numerous studies have shown that the relative bioavailability (RBA, defined as the bioavailability from the environmental media of concern relative to the availability in the toxicity test that form the basis of regulatory toxicity criteria) may be much lower than 100%, and this fact is reflected in the recommended default RBA factors of less than 100% for both arsenic and lead in soils.

However, bioavailability adjustments to cleanup criteria for contaminated soils are rarely used in site-specific risk assessments, even though they are explicitly allowed by regulatory guidance. The reasons for the limited use of site-specific adjustments include a continuing lack of understanding of the issue, as well as the expense of testing bioavailability on live animals (*in vivo* tests) and the uncertainty involved in less costly chemical assays (*in vitro* tests). These issues remain, although there has been considerable progress in the last decade, particularly in generating high-quality supporting data, in validating less costly *in vivo* methods, and in refining and validating the *in vitro* tools for estimating bioavailability. In several cases (notably lead and arsenic, and to a lesser extent for the carcinogenic PAHs and other organic chemicals), relatively low-cost *in vitro* tests have been developed that correlate well with approved *in vivo* test results designed to evaluate bioavailability to humans, and the results

indicate that site-specific factors can significantly affect the bioavailability of chemicals from soil.

The situation is complicated by the fact that there are several *in vivo* and *in vitro* test protocols, each having their own strengths and limitations, and different tests may be best suited to different site conditions and exposure pathways. State regulators are understandably confused and hesitant to allow bioavailability adjustments given the evolving state of the science and the lack of clear national guidance on the use of *in vitro* methods for chemicals other than lead. Even for lead in soils, specific guidance on data needs and application to risk assessment are not generally available. Credible guidance is critically needed on the proper test methods for different situations, and the issues that regulators should be aware of when bioavailability tests are proposed or the results are evaluated. Such guidance would allow the use of site-specific adjustments when appropriate, and standardize the methods and interpretations of site-specific bioavailability tests.

Technical, Knowledge, and Regulatory Barriers Addressed: This team will bring together the leaders in soil bioavailability testing for both inorganic and organic contaminants to develop much-needed regulatory and technical guidance. The objectives will be to develop consensus guidance on the proper uses of site-specific bioavailability testing, the pros and cons of different *in vivo* and *in vitro* methods, the methods most appropriate for different situations, and the current state of the science. The resulting guidance document will include case studies of bioavailability testing at different types of sites, and a decision tree to assist regulators and practitioners considering site-specific bioavailability adjustments. In some cases, the guidance will likely indicate that little is to be gained from bioavailability testing, whereas in other cases it is likely that bioavailability adjustments will lead to significant cost savings while still ensuring protection of human health.

The team members will work in a coordinated fashion on selected inorganic and organic contaminants. The team will develop state of the science reviews, and compile case studies of the use of bioavailability for specific sites or wastes. It is anticipated that the team will focus primarily on lead and arsenic (though other metals will also be addressed, including mercury, nickel, cadmium, and zinc), and will develop reasonably prescriptive guidance for establishing site-specific RBA values that can be used in human health risk assessment. The team will also address the potential for using bioavailability adjustments for organic contaminants, particularly the human health risks from carcinogenic PAHs and dioxins/furans. Recent research on the bioavailability of munitions constituents may also be summarized.

Work funded by USEPA, SERDP/ESTCP, NIEHS, and industry groups will be critically reviewed and will form the technical basis for the resulting guidance. Much of this work has not been reviewed in a comprehensive manner since the NRC Bioavailability report (2003), although there has been considerable progress in the meantime. Specific SERDP/ESTCP projects expected to be key resources (available at www.serdp-estcp.org/Program-Areas/Environmental-Restoration/Risk-Assessment) include recent work on arsenic (ER-1742), PAHs (ER-1743), and the effects of soil properties on bioavailability (ER-200517). The team will also include the results from a study of *in vitro* testing for arsenic that is being completed by the California DTSC, with funding from EPA's Brownfields program. Potential case study sites identified so far include sites in Hawaii, Oregon, and California.

The importance of bioavailability was pointed out by the recent Risk Assessment team, which briefly discussed the issue (draft Section 6.1.3). The team's draft final report indicates that bioavailability adjustments can be used, but offers no specific guidance on the topic.

Approach: The team will begin work with the team leaders attending a 2014 Kick-Off meeting. The team leaders will hold monthly conference calls with team members and the first meeting of the entire team will be at the 2015 spring meeting. The team will evaluate the status of the technology, with an overview of bioavailability in soils and a review of the available literature, focusing on advances in the last decade. Individual *in vivo* and *in vitro* tests will be described, with discussions of their advantages and limitations, and the current state of acceptance and validation. The team will prepare separate sections on the specific contaminants of interest.

The technical/regulatory guidance document will have a summary of the technical background discussion, with appendices detailing the different methods available. The heart of the document will be a decision tree, designed to help regulators determine whether or not to evaluate bioavailability at a given site, to select the appropriate tests, and to use the results in risk-based decision making. Specifically, the guidance document will address the following issues that typically face state regulators faced with making site-specific decisions regarding soil bioavailability:

1. When should bioavailability be considered?
2. What tests are best suited for use given the site-specific conditions (soil types, contaminant forms, exposure scenarios) and objectives?
3. What data are needed to make site-specific decisions?
4. Summaries of case studies where bioavailability has been used.
5. Summaries of available tests: advantages, limitations, costs, and precautions.
6. Guidance on sampling (e.g., when is incremental sampling appropriate).
7. Recommended uses of data in site-specific decisions.

It is anticipated that the guidance will be more detailed and prescriptive for some of the contaminants (notably lead and arsenic), and less so for others (PAHs), depending on the state of the science and the consensus regarding validation of specific test protocols. Finally, the team will prepare an internet training course to summarize the documents and foster the appropriate uses of soil bioavailability testing.

Schedule: The project will require three years total. The first year will be dedicated to gathering information, preparing technical overviews of specific methods, developing the document outline, and evaluating case studies. The majority of the guidance document will be prepared during the second year, and the document will be finalized in the third year, along with the development of the training webinar.

Proposed Personnel

The desired types of personnel for this team include:

1. State Regulators: Senior staff with backgrounds in toxicology, risk assessment, and/or soil science who can serve as resources in their own states. States expressing interest in participation include California (Claudio Sorrentino and Valerie Mitchell), Texas (Kip Haney), Hawaii (John Peard), Oregon (Bryn Thoms), and Utah (Scott Everett). Team members also have worked with personnel from other states on establishing site-specific bioavailability

adjustments for metals in soil, and have had promising initial discussions regarding participation with individuals from some of these states, as well as potential case studies.

2. EPA Experts: EPA has a Technical Review Workgroup of experts in this area, and has funded relevant research that should be incorporated into the document. The TRW has expressed tentative interest in participating.

3. Federal Agencies: The DoD TriServices Risk Assessment Workgroup has agreed to participate. Members of this group have worked on and funded several relevant studies and worked at numerous sites where bioavailability is an important issue. At a minimum, DOD participation will include a representative of the Army (Richard Anderson) and Navy (Amy Hawkins) will participate. The team will also include a representative of the Strategic Environmental Research and Development Program (SERDP), which has funded recent projects on soil bioavailability. Representatives from DOE and the National Institute of Environmental Health Sciences (NIEHS) will also be contacted.

4. Academics: Several of the leading academic researchers in this area have agreed to participate, providing expertise and technical reviews to ensure accuracy. To date these include Dr. Stephen Roberts (Univ. Florida), Dr. Nicholas Basta (Ohio State Univ.), and Dr. Stan Casteel (Univ. of Missouri).

5. Consultants and Practitioners: The proposal team includes leaders in this area, with practical experience in both in the research and demonstration of bioavailability methods, and in modifying site-specific risk assessments to incorporate bioavailability. Practitioners agreeing to participate so far include representatives of Integral Consulting (Michael Ruby), Chicago Bridge and Iron (Paul Hatzinger), Exponent (Charles Menzie), and Environ (Yvette Lowney). Additional practitioners with relevant experience and expertise would be helpful to identify and summarize relevant case studies, and to transfer the resulting knowledge and guidance to future sites.

6. Public Stakeholders: A stakeholder representative will be included to increase the confidence that bioavailability adjustments are credible, and to ensure the document clearly addresses potential public concerns.

Summary of Deliverables

Technical/Regulatory Guidance: The team will prepare a formal ITRC technical regulatory document. This effort will start with an assessment of the existing documents and protocols, including a thorough literature review for the purpose of understanding and summarizing the current state of the science and any major remaining uncertainties. The team will collect case studies that demonstrate the uses and limitations of bioavailability adjustments. The technical overview will focus on the progress made since the NRC 2003 report on Bioavailability in Soils and Sediments. The document will describe and evaluate different proposed bioavailability test methods, and discuss the lessons learned from case studies where site-specific bioavailability adjustments have been proposed and/or adopted. The document will be designed to develop step-by-step practical guidance to assist regulators faced with making site-specific decisions on the uses of bioavailability.

Upon completion of the draft technical and regulatory document, the team will go through the formal ITRC review process. The final technical regulatory document should lead to a greater knowledge base for regulators faced with determining if bioavailability testing is worth pursuing, how to conduct such testing, and what issues to consider when evaluating

bioavailability testing results. A web-based document is planned, to improve the usefulness of a document covering several topics, and to allow updating in the future.

Training: Concurrent with the development of the draft technical regulatory document, the team will begin development of Internet training. One webinar is anticipated, focusing primarily on the guidance for setting site-specific bioavailability adjustments for inorganic contaminants, particularly arsenic and lead.

Targeted Users

The primary targeted users of this document and training will be state personnel of regulatory programs that are tasked with characterizing and remediating state, Superfund, RCRA, and other sites that have contaminated soils. The team also expects that consultants will use the document to design and evaluate bioavailability adjustments, as well as public stakeholders and responsible parties who will have to evaluate the technical basis for such adjustments.