

United States
Environmental
Protection Agency

OSWER 9200.1-113



Recommendations for Default Value for Relative Bioavailability of Arsenic in Soil

December 2012

The Risk Assessment Guidance for Superfund (RAGS) Part A (U.S. EPA, 1989), Framework for Metals Risk Assessment (U.S. EPA, 2007a), and Guidance for Evaluating the Bioavailability of Metals in Soils for Use in Human Health Risk Assessment (U.S. EPA, 2007b) discuss using site-specific bioavailability data to make adjustments to exposure estimates in site-specific risk assessments when the medium of exposure in the exposure assessment differs from the medium of exposure associated with the toxicity value (cancer slope factor, reference dose value, etc.). In the absence of reliable site-specific data, the default assumption is that the bioavailability of the contaminant in the exposure medium at the site (e.g., soil, water, etc.) is the same as the bioavailability in the exposure medium used to derive the toxicity value. For arsenic, the toxicity values in EPA's Integrated Risk Information System (IRIS) are based upon exposure to arsenic in water (U.S. EPA, 2012). The current default assumption for assessing risk from arsenic in soil is that the bioavailability of arsenic in soil is the same as the bioavailability of arsenic in water (relative bioavailability [RBA] soil/water = 100%). However, recent bioavailability studies conducted in animal models show that bioavailability of arsenic in soil is typically less than that of highly water soluble forms of arsenic (e.g., sodium arsenate dissolved in water). This suggests that bioavailability of arsenic in soil will typically be less than that of arsenic dissolved in drinking water (i.e., $RBA < 100\%$). At sites where this applies, the default assumption of $RBA = 100\%$ will result in an overestimation of risk.

In an effort to provide a more accurate default RBA value for arsenic in soil, the TRW Bioavailability Committee compiled all available estimates of soil arsenic RBA (U.S. EPA, 2011). The resulting database included 103 RBA estimates: 64 estimates obtained from swine bioassays, 24 estimates obtained from monkey bioassays, and 15 estimates obtained from mouse bioassays. Analyses of these data showed that while soil RBA exhibited substantial variability, all of the RBA estimates were less than 1. The RBA estimates considered in the above analysis are derived from an opportunistic sample of soils and do not represent a statistical sample of soils in any geographic region or source of arsenic contamination. This limits the use of these data for making statistical inference about arsenic RBA in U.S. soils in general. Most of these samples were collected to support remedial investigation and risk assessments of specific sites. Although the data set includes samples from sites impacted by various sources of arsenic contamination (mining and/or smelter operations, pesticide application, and manufacturing/electrical waste, and

volcanic soils with naturally occurring high arsenic levels), the absence of a statistical sampling design limits any inferential value of the data set. For example, sample statistics such as the mean and standard deviation, even for specific categories of arsenic contamination, mineralogy, or soil characteristics, cannot be reliably assumed to represent these categories in general. Nevertheless, the data set has unique value to describe the distribution of arsenic RBA values that have been encountered in soils from various sites of regulatory interest. The empirical distribution of RBA values in this data set suggests that values for arsenic RBA exceeding 60% are relatively uncommon (i.e., <5% of the RBA estimates exceed 60%). Based on this data set, it is reasonable to expect that future RBA estimates exceeding 60% would also be uncommon, if samples were to be drawn from a collection of similar types of sites and soils. This prediction could be further evaluated with additional data collection efforts.

Based on the above considerations, the TRW Bioavailability Committee recommends a default value for RBA of arsenic in soil based on an upper percentile from the data set of arsenic RBAs reported in U.S. EPA (2011). An RBA value of 60% was selected as the default value and is supported by the analysis of soil arsenic RBA estimates which showed that less than 5% of the RBA estimates exceeded 60%. Selection of a default RBA value that is expected to be in the upper percentile range reduces the likelihood that sites are screened out from further evaluation when, in fact, they may present a significant health risk.

Agency guidance (U.S. EPA, 2007b) recommends that even in cases where sufficient data exist to support default medium-specific absorption factors for a chemical, site-specific data collection may also be important. Important factors that can affect the bioavailability of arsenic in soil can be expected to vary from site to site, or within a given site. These include the chemical forms of the arsenic, as well as the physical and chemical characteristics arsenic-bearing soil particles. Default values for arsenic RBA may not reflect all of these factors (e.g., chemistry, particle size, matrix effects) at any given site. Therefore, site-specific assessments of bioavailability should still be performed where such assessments are deemed feasible and valuable for improving the characterization of risk at the site. Default RBA values generally should not be used when site-specific assessments are performed. In general, the Agency (U.S. EPA, 2007b) recommends that efforts be made to collect data that support site-specific estimates,

rather than relying on the default value recommended in this memorandum which may not accurately represent arsenic RBA at any specific site. Use of the national default in place of site-specific estimates may underestimate or overestimate risk. Where development of site-specific RBA estimates is not feasible (e.g., screening-level assessments), the default value of 60% can be used, recognizing that the default value is an estimate that is not likely to be exceeded at most sites and is preferable to the assumption of an RBA equal to 100%.

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