Oral Bioavailability of Nonpolar Organic Chemicals in Soil for Use in Human Health Risk Assessment

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Background/Objectives. Risk-based soil cleanup goals derived from human health risk assessment (HHRA) for contaminated soil are not typically adjusted to account for reduced bioavailability of chemicals in soil. Considering only the concentration in soil tends to lead to overly restrictive remedial requirements and higher remediation costs without commensurate increases in health protection. The use of appropriately derived bioavailability adjustments in the HHRAs could reduce uncertainties associated with intake estimates and contribute to more meaningful and realistic risk results for use in risk management decisions (e.g., establishing cleanup goals). This literature-based study focused on the characterization and HHRA application of oral bioavailability of two groups of nonpolar organic chemicals commonly associated with the greatest risk and reduced bioavailability in weathered soils, i.e., polycyclic aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs).

Approach/Activities. Based on a comprehensive literature review, this study characterized the oral bioavailability of PAHs and PCBs in soil in relation to human toxicology (soil-eating children), and evaluated the feasibility of developing regulatory guidelines for *in vitro* tests (laboratory tests) of bioavailability of these chemicals as a part of HHRAs. This study also summarized various differences in the regulatory approaches to evaluating and using bioavailability in risk assessment among countries (i.e., the US, UK, The Netherlands, France, Canada, and Australia), including acceptable test methods and reporting requirements.

Results/Lessons Learned. Unlike metals for which adjustments reflecting reduced bioavailability in soil are much more common with standardized methods and regulatory guidance available from several countries, the review of this study revealed very limited application of bioavailability adjustments for organic chemicals in HHRAs. Based on a critical review of an extensive body of *in vivo* and *in vitro* studies, the Colon Extended Physiologically-Based Extraction Test (CE-PBET) was recommended as the *in vitro* method to evaluate oral PAH bioavailability in soil due to its simplicity, cost effectiveness, and potential for standardization. Several aspects in study design were recommended to ensure the *in vitro* test consistent with a good practice established by the Bioaccessibility Research Group in Europe (BARGE). A single standard *in vitro* method for PCB bioaccessibility measurement cannot be recommended due to data limitations, especially using *in vitro* approaches, but approaches being used for PAHs may provide a useful template and similar aspects in study design to PAHs should be considered for an *in vitro* approach for PCBs. Several aspects of additional research and development (especially for PCBs) were also identified in order to fill data gaps and support broader application of bioavailability adjustments in HHRAs. Finally, since assessing PAHs and PCBs *in vivo* is not straightforward, validation of *in vitro* methods by comparison with *in vivo* data may not be feasible.