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The use of oral bioaccessibility in assessment of risks to human health from contaminated land

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Abstract

Recent guidance allows for the possibility of using site specific tests to incorporate bioaccessibility tests in determining site specific assessment criteria with respect to human health. However unless care is taken such tests can be misused. Many tests have only been validated for a small number of determinands. The long-term representativeness of the test results has not been explored in any great detail. The results only apply to specific exposure pathways.

Key words: bioaccessibility, bioavailability, DQRA, site specific assessment criteria

BACKGROUND

The aim of this paper is to provide a discussion of the role of bioavailability and bioaccessibility in the assessment of the risk to human health from contaminated land in the context of UK policy.

The Soil Guideline Values (SGV) derived using the Contaminated Land Exposure Assessment (CLEA) model (DEFRA & Environment Agency 2002) are designed to be applicable throughout the wide range of ground conditions and contaminants forms that are encountered in the UK. The SGV and their scientific basis is described in a series of reports released since March 2002 (Table 1). Exposure may occur through direct contact of the contaminant with, for example, the skin, eyes or lungs or indirectly through, for example, absorption through the digestive system and transport in the blood (Environment Agency 2002). The UK SGVs reflect our current ability to model the exposure to (or dose from) and response of a target organ to contaminants in the soil. As such, the assumptions that underpin the derivation of the values are, rightly, cautious.

One of the fundamental assumptions behind most SGV is that 100% of the contaminant present in soil is in a form that is bioavailable and therefore contributes to uptake of the contaminant into the human system. This assumption is both precautionary and entirely sensible, since certain forms of contaminant are indeed almost totally bioavailable. This is reflected in the significance of soil contamination usually being assessed on the basis of intake (entry into the human body through the mouth, nose or skin) rather than uptake (entry of the contaminant into systemic fluids).

Parts of the UK have concentrations of naturally occurring potentially harmful elements that exceed the generic Soil Guideline Values. Part IIA of the Environmental Protection Act 1990 rightly makes no distinction between the risks from natural and man-made substances. Risk assessors are therefore presented with a dilemma when faced with concentrations of naturally occurring contaminants above the SGV. Relying on the assertion that the contamination is natural or even at background levels and therefore not posing an unacceptable risk should be considered to be unacceptable. Risk assessors either have to recommend remediation or develop site specific assessment criteria that better reflect site circumstances that can demonstrate that the natural contaminants do not pose an unacceptable risk to human health. CLR 9 warns that 'It is not justifiable to assume that the bioavailability of a contaminant at concentrations within the range found in natural soils

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Table 1. Contaminated land research reports published by DEFRA and Environment Agency in 2002 and 2003; available from www.defra.gov.uk

CLR	Title		
7	CLR 7	Assessment of Risks to Human Health from Land Contamination: an Overview of the Development of Soil Guideline Values and Related Research	
8	CLR 8	Priority Contaminants Report	
9	CLR 9	Contaminants in Soils: Collation of Toxicological Data and Intake Values for Humans	
10	CLR 10	Contaminated Land Exposure Assessment Model (CLEA): Technical Basis and Algorithms	
CLR 9 TOX 1–10 (Collation of toxicological data and intake values for humans)			
TOX 1 As	TOX 1	Collation of toxicological data and intake values for humans	Arsenic
TOX 2 BaP	TOX 2	Collation of toxicological data and intake values for humans	Benzo[a]pyrene
TOX 3 Cd	TOX 3	Collation of toxicological data and intake values for humans	Cadmium
TOX 4 Cr	TOX 4	Collation of toxicological data and intake values for humans	Chromium
TOX 5 Cyanide	TOX 5	Collation of toxicological data and intake values for humans	Inorganic cyanide
TOX 6 Pb	TOX 6	Collation of toxicological data and intake values for humans	Lead
TOX 7 Hg	TOX 7	Collation of toxicological data and intake values for humans	Mercury
TOX 8 Ni	TOX 8	Collation of toxicological data and intake values for humans	Nickel
TOX 9 Phenol	TOX 9	Collation of toxicological data and intake values for humans	Phenol
TOX 10 Se	TOX 10	Collation of toxicological data and intake values for humans	Selenium
TOX 11	TOX 11	Benzene	
TOX 12	TOX 12	Dioxins, furans and dioxin-like PCBs	
CLR 10 SGV 1–10 (derivation of the Soil Guideline Values)			
SGV 1 As	SGV 1	Soil Guideline Values for arsenic contamination	
SGV 2*	SGV 2	Soil Guideline Values for benzo[a]pyrene contamination	
SGV 3 Cd	SGV 3	Soil Guideline Values for cadmium contamination	
SGV 4 Cr	SGV 4	Soil Guideline Values for chromium contamination	
SGV 5 Hg	SGV 5	Soil Guideline Values for inorganic mercury contamination	
SGV 6*	SGV 6	Soil Guideline Values for inorganic cyanide contamination	
SGV 7 Ni	SGV 7	Soil Guideline Values for nickel contamination	
SGV 8*	SGV 8	Soil Guideline Values for phenol contamination	
SGV 9 Se	SGV 9	Soil Guideline Values for selenium contamination	
SGV 10 Pb	SGV 10	Soil Guideline Values for lead contamination	

* Unpublished

for a particular region of the UK is likely to be less than 100% without further investigation'.

This paper discusses only oral bioavailability and bioaccessibility. The bioavailability through dermal contact or through entry into the bloodstream via the lung fluid is not considered here. CLEA 2002, and by implication the Soil Guideline Values, assumes that, for example, 100% of the contaminant in inhaled dust is bioavailable. The Environment Agency (2002) suggests that CLEA assumes that 'all of a chemical in dust which is inhaled and which reaches the lung is available for absorption by the lung (i.e. is 100% bioaccessible)'. However, the CLEA2002 software (DEFRA and Environment Agency 2002) and CLR 10 do not make use of particle size distribution information to assess the contaminant concentration in the fraction of the soil that is inhalable and small enough to reach the alveoli. There is therefore, and entirely appropriately, a degree of over-conservatism in the inhalation pathway modelling that reflects current understanding that future developments in bioaccessibility testing may be able to help reduce.

ORAL BIOAVAILABILITY AND BIOACCESSIBIILTY

Bioavailability is defined by Kelley *et al*. (2002) as 'the extent to which a chemical can be absorbed by a living

organism'. The Environment Agency (2002) defines the term as 'the fraction of the chemical that can be absorbed by the body through the gastrointestinal system, the pulmonary system and the skin'.

In practice it is almost impossible to estimate or measure the bioavailable portion of a contaminant. Lead is one of the few contaminants for which there is sufficient information to assess the consequences of exposure through uptake rather than intake, and this is reflected in the health criteria value used to derive the UK Soil Guideline Value (CLR10 SGV 10).

The concept of bioaccessibility represents a half-way house that can be estimated under laboratory conditions. Bioaccessibility is the fraction of a chemical that is dissolved from a soil sample using in vitro ('test tube') test methods that simulate gastrointestinal conditions (Kelley *et al*. 2002). The Environment Agency (2002) describe this as 'the fraction of a substance that is available for absorption by an organism'. Bioaccessibility is used as a cautious estimator of relative bioavailability. The Bioavailability Research Group Europe (BARGE) was set up under the auspices of the CLARINET concerted action. BARGE uses an even simpler definition: 'the fraction of a substance that is released from the soil matrix in the human gastrointestinal tract and is available for absorption' (Schewald 2001).

HEALTH CRITERIA VALUES

According to CLR 9, health criteria values may take the form of a tolerable daily soil intake, an index dose or, currently exceptionally, a blood lead level. The basis of the health criteria varies and is set out for individual substances in a CLR 9 TOX report (Table 1). Some RHC are based on epidemiological studies, others are based on the results of laboratory animal studies and still others on the results of pharmacokinetic models. Most index doses are based on existing drinking water or air quality standards. The basis of some health criteria values may already implicitly incorporate an allowance for less than 100% bioavailability or less than 100% bioaccessibility.

RELATIVE BIOAVAILABILITY AND BIOACCESSIBILITY

Schewald (2001) asserts that 'it is widely believed that most contaminants are likely to be less bioaccessible (i.e. extractable in the human gut) than in the materials used in the past to derive tolerable daily intakes'.

In the context of human health risk assessment, Kelley *et al*. (2002) defined relative bioavailability as the ratio of the absorbed fraction from the exposure medium being considered (e.g. soil) to the absorbed fraction from the dosing medium used in the toxicity study on which the health criterion value has been based.

Relative bioaccessibility may be defined as the ratio of the extractable fraction from the exposure medium being considered (e.g. soil) to the extractable fraction from the dosing medium used in the toxicity study on which the health criterion value has been based.

This means that before a site-specific assessment criterion can be developed by applying a bioaccessibility correction to the oral exposure pathways, the risk assessor should demonstrate the relative bioaccessibility with respect to the basis of the health criterion value.

EXPOSURE ASSESSMENT TOOLS

UK legislation for assessing the risks from land contamination does not prescribe which exposure assessment or risk estimation tool should be used. Three tools have a completely UK provenance: CLEA (DEFRA and Environment Agency 2002; SNIFFER Method (Land Quality Management 2002 in prep.); GasSIM (Golder Associates and Land Quality Management 2002).

The CLEA model has been used to derive SGV and is based on comparing estimated intake with relevant health criteria. CLR 7 states that the 'CLEA model estimates contaminant intake from soil as a function of the contaminant concentration and the potential exposure of adults and children living, working and playing on contaminated land. It derives Soil Guideline Values by comparing the calculated intake with the TDI (*sic*) or Index Dose'. The model, its key assumptions, and the underpinning conceptual models for each land-use are described in detail in CLR10.

CLR 9 defines Intake Dose as 'the amount of a chemical entering or contacting the human body at the point of entry (that is, mouth, nose or skin) by ingestion, inhalation, or skin contact'. CLR 9 recognises that 'Actual intake will be a function of the chemical characteristics and the nature of the target population and their behaviour patterns'. Intake dose is expressed in terms of mass of substance per kg body weight over a period of time ($mg_{contaminant}\ kg^{-1}{}_{bodyweight}\ day^{-1}$).

Uptake dose is the amount of a contaminant that reaches the circulating blood having been absorbed by the body through the skin, the gastrointestinal system and the pulmonary system, expressed in terms of mass

of substance per unit volume of blood (for example, $mg_{contaminant}\ L^{-1}_{blood}$). Uptake is commonly related to the intake by the bioavailability of the contaminant.

CLR 9 warns that uptake is not relevant for contaminants that produce their principal adverse effects before transfer to the systemic circulation, and points out that, for the purpose of deriving Soil Guideline Values, contaminant intakes are generally used as a basis for health criteria for the protection of human health.

BIOACCESSIBILITY TESTS

Two laboratories in the UK offer the physiologically based extraction test and the Simplified Bioavailability Extraction Test (SBET) (Ruby *et al*. 1996; 1999). These mimic, via a sequential extraction process, the leaching of a solid matrix in the entire gastrointestinal tract and only the stomach respectively, and thereby provide an estimate of the oral bioaccessibility of a particular element.

In combination with the considerations provided above, the results of the PBET or SBET may be applied to modify the estimate of uptake through oral exposure and thereby derive site specific assessment criteria that better reflect the soil-contaminant properties. However, the use of these tests has to be explicitly justified on a site by site basis for individual materials and contaminants. In particular, the translation of the results of the PBET or SBET into a relative bioaccessibility requires consideration of the experimental basis underpinning the relevant health criterion, and confirmation that the SGV is not already taking into account bioavailability.

FUTURE DIRECTIONS

The discussion in this paper has been limited to discussion of oral bioaccessibility of metals. Other pathways, such as inhalation, and other contaminants, such as organic substances, suffer from overcautious risk estimates.

Development of tests to mimic the processes of other pathways, such as inhalation and bioaccessibility via the lungs, would help ensure that the resources expended on managing risks from contaminated soil are in proportion to the seriousness of those risks rather than the overly cautious approach taken to find a way around current scientific uncertainties.

CONCLUSIONS

Incorporation of bioavailability is permitted within the guidance published by DEFRA and the Environment Agency (Table 1). In practice the results of bioaccessibility tests can be applied to modify the estimated uptake through oral exposure. Our recent experience in peer reviewing third party risk assessment reports has shown that such results have been misapplied in risk estimation (Nathanail 2002).

Cautious estimates of relative bioavailability, often based on bioaccessibility test results, have a role to play in the estimation of oral exposure during the development of site-specific assessment criteria. However, this use of conservatively estimated relative bioavailability should be justified on a site by site and substance by substance basis.

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