TECHNICAL SPECIFICATION

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Soil quality — Assessment of human exposure from ingestion of soil and soil material — Guidance on the application and selection of physiologically based extraction methods for the estimation of the human bioaccessibility/bioavailability of metals in soil

Qualité du sol — Évaluation de l'exposition humaine par ingestion de sol et de matériaux du sol — Lignes directrices pour l'application et la sélection de méthodes d'extraction fondées sur le point de vue physiologique pour l'estimation de la bioaccessibilité/biodisponibilité pour l'être humain de métaux dans le sol

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

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An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 17924 was prepared by Technical Committee ISO/TC 190, *Soil quality*, Subcommittee SC 7, *Soil and site assessment*.

Introduction

When assessing soils contaminated with, for example, metals, soil ingestion, especially by children, is often considered to be the most important exposure pathway. Currently, this assessment is often carried out on the basis of the total content of the metals in question in the soil. However, several studies suggest that the availability of the metals in the gastrointestinal tract is dependent on the form of the metals present and the site-specific soil chemistry. Test methods based on *in vivo* tests with, for example, juvenile swine or mini-pigs are time consuming and expensive, and not very compatible with the decision processes connected with the assessment and clean-up of contaminated sites. At present, test methods are being developed and validated, which involve *in vitro* laboratory tests aimed at simulating *in vivo* results. This will reduce the cost and practicalities related to the use of such testing on contaminated land.

Due to the large expenditure necessary for both private landowners and public funds set aside for the remediation of contaminated land, International Standards on the assessment of contaminated soil, especially with regard to human health, are in great demand. International Standards in this complex field will support a common scientific basis for the exchange of data, development of knowledge and sound evaluation. Furthermore, International Standards will facilitate international recommendations and regulations. The aim of this Technical Specification is to describe the elements of such an *in vitro* test system, and give advice on the appropriate combination and use of these elements in the specific situation.

In human health-risk assessment, "bioavailability" is specifically used in reference to absorption into systemic circulation, consistent with the toxicological use of the term. This encompasses bioaccessibility, which again is a combined measure of the processes determining the interaction between the metal associated with the soil and the liquid in the human digestion system. Bioavailability furthermore includes the absorption of the contaminant through a physiological membrane and the metabolism in the liver. The bioavailable fraction is thus the fraction left after release into the human digestive liquid, transport across the intestinal epithelium and metabolism in the liver. A further description of these processes is given in Clause 4.

When considering bioavailability as the fraction of the chemical that is absorbed into systemic circulation, two operational definitions are important, *absolute* and *relative* bioavailability. Absolute bioavailability is the fraction of the applied dose that is absorbed and reaches the systemic circulation (and can never be greater than 100 %). Relative bioavailability represents a comparison of absorption under two different sets of conditions, for example, from a soil sample vs. food or another matrix used in a toxicity study, and can be greater than or less than 1. This factor can be used in exposure assessments for exposure by direct ingestion of soil, for instance, if the absolute bioavailability of the metal in the specific soil is suspected to differ significantly from the absolute bioavailability implicit in the toxicity value/quality criteria used.

Soil quality — Assessment of human exposure from ingestion of soil and soil material — Guidance on the application and selection of physiologically based extraction methods for the estimation of the human bioaccessibility/bioavailability of metals in soil

1 Scope

This Technical Specification deals with the assessment of human exposure from ingestion of soil and soil material.

This Technical Specification gives guidelines to be used when choosing a physiologically based test procedure for the estimation of the human bioaccessibility/bioavailability of metals from contaminated soil in connection with the evaluation of the exposure related to human oral uptake. Suggestions are made for the use of as many generic-method elements as possible, but it is important that the choice of method be based on the needs of the specific investigation. Methods that are validated for specific metals and/or contexts are highlighted.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11074, *Soil quality — Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11074 and the following apply.

3.1
absorption
process by which a body takes in substance and makes it a part of itself

3.2
bioaccessible fraction
fraction of a substance in soil or soil material that is liberated in (human) gastrointestinal juices and is thus available for absorption

3.3
bioavailable fraction
fraction of a substance present in ingested soil or soil material that reaches the systemic circulation (bloodstream)

3.4
contaminant
substance or agent present in the soil as a result of human activity

NOTE 1 There is no assumption in this definition that harm results from the presence of the contaminant.

NOTE 2 Adapted from ISO 11074:2005.

3.5
dermal contact
contact with (touching) the skin

3.6
exposure
dose of a chemical that reaches the human body

3.7
exposure pathway
route a substance takes from its source to a receptor

3.8
ingestion
act of taking substances (e.g. soil and soil material) into the body by mouth

3.9
in vitro bioaccessibility test
designation for bioaccessibility test carried out outside a living organism

3.10
no observed adverse-effect level
NOAEL
dose at which no adverse effect on a receptor can be observed

3.11
pica
eating habit where usually strange and unpalatable materials are consumed, e.g. soil material, stones

NOTE The term “pica” stems from the Latin name Pica pica for the raven bird magpie which randomly picks up any kind of material for nest construction.

3.12
provisionally tolerable weekly intake
PTWI
designation of the provisional weekly tolerable amount of a substance which can be taken in by a human body in its lifetime through the food chain without affecting human health

3.13
receptor
potentially exposed person or part of ecosystem

[ISO 11074:2005]

3.14
relative absorption fraction
RAF
ratio between the amount of a contaminant reaching systemic circulation when ingested with, for example, soil and the same amount obtained when ingested in the toxicity experiment underlying the criteria

3.15
species
different forms of a substance always arising with each other in a reaction equilibrium

3.16
tolerable daily intake value
TDI
designation of the tolerable daily amount of a substance which can be taken in by a human body in its lifetime through the food chain without affecting human health

4 Bioaccessibility/bioavailability as a concept in assessment of soils and sites with respect to human exposure

The characterisation of bioaccessibility/bioavailability is usually performed as a part of a risk and/or exposure assessment.

A risk assessment comprises the following elements:

— a hazard identification;

— a dose-response assessment;

— an exposure assessment;

— and, based on the above, a risk characterisation.

An exposure assessment is the process wherein the intensity, frequency, and duration of human exposure of a contaminant are estimated, and it comprises the following:

— source identification and characterisation;

— identification of exposure routes;

— identification of relevant receptors/target groups;

— and, based on this, the actual exposure assessment.

For the assessment of possible effects on human health, an analysis of the exposure routes is a prerequisite. Where receptors are not directly exposed to a contaminant, exposure assessment needs to consider the various ways by which indirect exposure might occur and the significance of them.

Human exposure from soil contamination may occur through different media.

Directly from the soil, the following exposure routes exist.

— Soil ingestion, both dietary and through adherence to hands and unwashed vegetables, etc.

— Dermal contact.

— Ingestion of house dust that predominantly consists of soil material.

Airborne exposure comprises the following:

— inhalation and ingestion of fugitive dust;

— inhalation of elevated outdoor concentrations;

— inhalation of vapours that have intruded into buildings.

Exposure through the food chain comprises the following:

— consumption of plants including crops, plants, wild plants and fungi;

— consumption of animals and animal products, including wild animals;

— consumption of contaminated water.

Within this Technical Specification, direct uptake of soil via ingestion and/or ingestion of fugitive dust is considered. Oral ingestion is one of the most important exposure routes for humans to soil contaminants.

Quality criteria for soil (the maximum concentration limits for soil) are usually calculated on the basis of a tolerable daily intake value (TDI) or a provisionally tolerable weekly intake (PTWI), that can be derived from the no observed adverse-effect level (NOAEL) found in human data or experimental animal data. For genotoxic carcinogens for which no lower threshold for increased risk for cancer risk is assumed, the TDI value is set at a level that corresponds to a tolerable low (negligible) cancer risk level.

For determining the TDI, data on oral toxicity are primarily considered. Often these data pertain to animal experiments where the substance is administrated to the animals mixed in the feed or in drinking water (the vehicle or transporter of the contaminant). The amount of contaminant needed to produce adverse health effects in the animal is then recorded. As an alternative, epidemiological studies relating observed human health effects to recorded exposures have been used. Most toxicological studies report the total ingested amount and only seldom indicate exact values for the bioavailability of the substances administered.

When extrapolating from such experimental conditions to other conditions, for example, the intake of contaminated soil, this approach assumes that the uptake efficiency is equal for all scenarios, i. e. that the absolute bioavailability of the contaminant is constant. The absolute, oral bioavailability can be defined as the fraction of an orally ingested contaminant that reaches systemic circulation, i. e. enters the bloodstream. The absolute oral bioavailability of a contaminant may range from close to 0 to almost 1 (i. e. 100 %) depending upon the physiochemical form of the contaminant. In this context, the use of the concept of absolute, oral bioavailability rests upon the assumption that adverse health effects are systemic and thus triggered by the contaminants reaching the bloodstream, i. e. the internal exposure, as opposed to the external exposure measured directly as the intake of contaminated medium multiplied by the concentration of the contaminant in the medium, see Figure 1.

The absolute bioavailability can be measured as the ratio between amounts in the blood of animals or man after intravenous injection (100 % bioavailability) and after oral ingestion (uptake of bioavailable fraction).

A more feasible approach is to measure the relative bioavailability or relative absorption fraction (RAF), which is the ratio between the amount of a contaminant reaching systemic circulation when ingested with, for example, soil and the same amount obtained when ingested in the toxicity experiment underlying the criteria.

It should be noted that, although most relative bioavailabilities are less than 1 and would result in increased acceptable levels, RAF values above 1 could be found that would result in a demand for a decreased acceptable level.

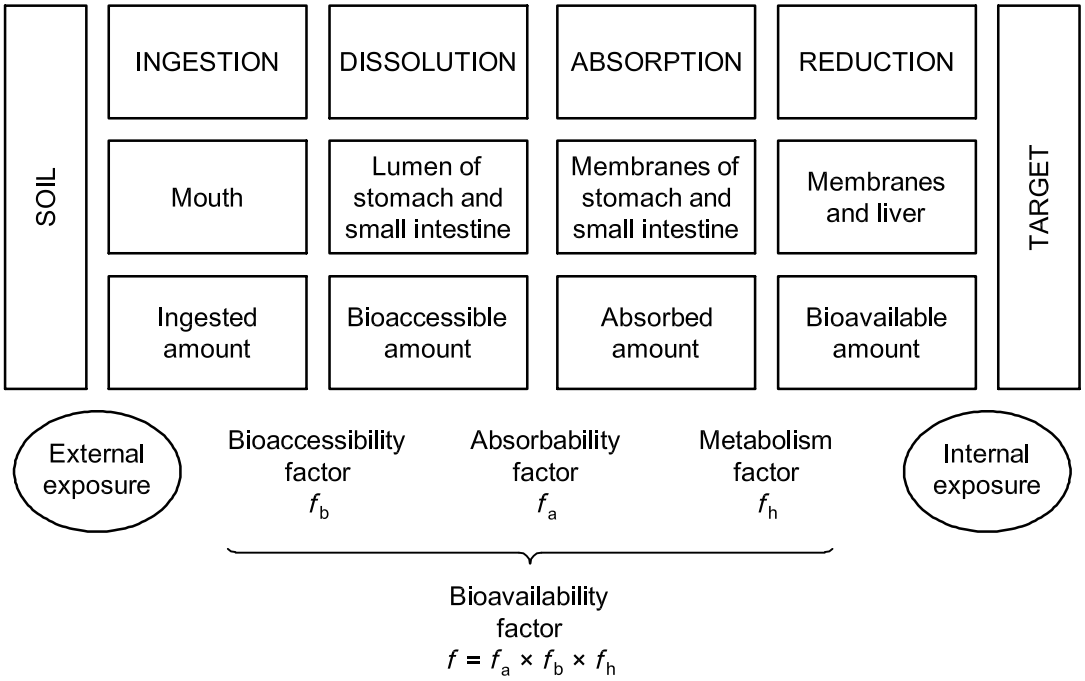

Figure 1 — Schematic presentation of oral uptake processes

5 Description of the mechanisms of human contaminant uptake

A series of compartments are involved in human bioavailability of ingested soil contaminants, as described in Clause 4.

The overall pathway leads the food and soil with contaminants from the mechanical grinding in the mouth, through a series of chemical and microbiological processes, to partial dissolution through the entire gastrointestinal tract (bioaccessibility processes). The dissolved components are transported through the membranes of the gastrointestinal epithelium (absorption) and into the bloodstream. During transport through the membranes, degradation can occur (metabolism). The blood passes through the liver before entering the systemic circulation, allowing for degradation or removal of unwanted compounds in the liver (metabolism, first-pass effect). Most of the dissolution processes are completed before the material leaves the small intestine, and it is generally accepted that most of the uptake takes place in the small intestine. To which extent uptake takes place in the stomach depends on the compound. The environment in the compartments differs and accordingly impacts the bioaccessibility process differently, see Table 1.

The pH in the stomach may vary from close to 1 under fasted conditions to as high as 5 after feeding. Residence time (1/2 time for emptying) in the stomach varies similarly from 8 min to 15 min to 30 min to 3 h for fasted and average fed conditions, respectively. Furthermore, bile release varies as well, with high releases under fed conditions. Finally, the pH in the stomach can be lower for small children than for adults.