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Markundersökningar – Bedömning av humanexponering för jord och jordmaterial genom intag – Metod för uppskattning av human biotillgänglighet av metaller i jord (ISO 17924:2018, IDT)

Soil quality – Assessment of human exposure from ingestion of soil and soil material – Procedure for the estimation of the human bioaccessibility/bioavailability of metals in soil (ISO 17924:2018, IDT)

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The International Standard ISO 17924:2018 has the status of a Swedish Standard. This document contains the official English version of ISO 17924:2018.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Karaktärisering av avfall, mark och slam, SIS/TK 535.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 190, *Soil quality*, Subcommittee SC 7, *Impact assessment*.

This first edition of ISO 17924 cancels and replaces ISO/TS 17924:2007, which has been technically revised. The changes compared to the previous edition are as follows:

— 7.1 "General", 7.2 "Choosing an appropriate test", 7.3 "Description of applicable test methods" and 7.4 "Recommendations" have been deleted. 7.5 "Use and interpretation of *in vitro* tests for risk assessment" has been retained and renumbered to Clause 7;

— Clause 8 "Description of test method" has been added;

— Clause 9 (formerly Clause 8) "Data handling, quality control and presentation of results" has been completely revised;

— Annex A "Human bioaccessibility testing" has been replaced by Annex A "Sample preparation procedure";

— the figures have been revised;

— the complete document has been editorially revised;

— the Scope has been adapted.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

When assessing soils contaminated with, for example, potentially harmful elements (e.g. arsenic), soil ingestion (especially by children) is often considered to be the most important exposure pathway. This assessment is often carried out on the basis of total content of the potentially harmful elements in question in the soil. However, several studies suggest that the availability of the potentially harmful elements (e.g. arsenic) in gastrointestinal tract is dependent on the form of the potentially harmful elements 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. Test methods have thus been 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. The aim of this document is to describe the elements of such an *in vitro* test system and give advice as to the appropriate combination and use of these elements in the specific situation. The method is based on the Bioaccessibility Research Group of Europe, Unified Bioaccessibility Method (BARGE UBM), which has been developed and agreed upon by the BARGE group.

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. 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 percent). 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 — Procedure for the estimation of the human bioaccessibility/bioavailability of metals in soil

1 Scope

This document deals with the assessment of human exposure from ingestion of soil and soil materials. It specifies a physiologically based test procedure for the estimation of the human bioaccessibility of metals from contaminated soil in connection with the evaluation of the exposure related to human oral uptake.

The method is a sequential extraction using synthetic gastrointestinal fluids and can be used to estimate oral bioaccessibility. Soils or other geological materials, in sieved form, are extracted in an environment that simulates the basic physicochemical conditions of the human gastrointestinal tract.

This document describes a method to simulate the release of metals from soil and soil materials after passage through three compartments of the human gastrointestinal tract (mouth, stomach and small intestine). It produces extracts that are representative of the concentration of potentially harmful elements in the human gastrointestinal tract for subsequent chemical characterization.

NOTE 1 Bioaccessibility can be used to approximate oral bioavailability.

NOTE 2 The test has been validated for arsenic, cadmium and lead in an interlaboratory trial. The method has been *in vivo* validated to assess the oral bioavailability of arsenic, cadmium and lead.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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

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

3.3
bioavailability
fraction of a substance present in ingested soil that reaches the systemic circulation (blood stream)

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

Note 1 to entry: There is no assumption in this definition that harm results from the presence of the contaminant.

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, such as soil and soil material, into the body by mouth

3.9
***in vitro* bioaccessibility test**
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 material such as soil material and stones are consumed

Note 1 to entry: The term pica stems from the Latin name *pica pica* for the raven bird magpie which picks up randomly any kind of material for nest construction.

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

3.13
receptor
<human> potentially exposed person

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
daily tolerable amount of a substance which can be taken in by a human body during a lifetime through the food chain without effecting human health

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

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

Risk assessment comprises the following elements:

— hazard identification;

— dose-response assessment;

— exposure assessment;

— and based on the above: risk characterization.

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

— source identification and characterization;

— 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 can 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 food chain comprises the following:

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

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

— consumption of contaminated water.

Within this document, 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 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. These data often 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 seldom indicate exact values for the bioavailability of the substances administered.

When extrapolating from such experimental conditions to other conditions, e.g. to 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 blood stream. 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 blood stream, i.e. the internal exposure as opposed to the external exposure measured directly as intake of a 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).

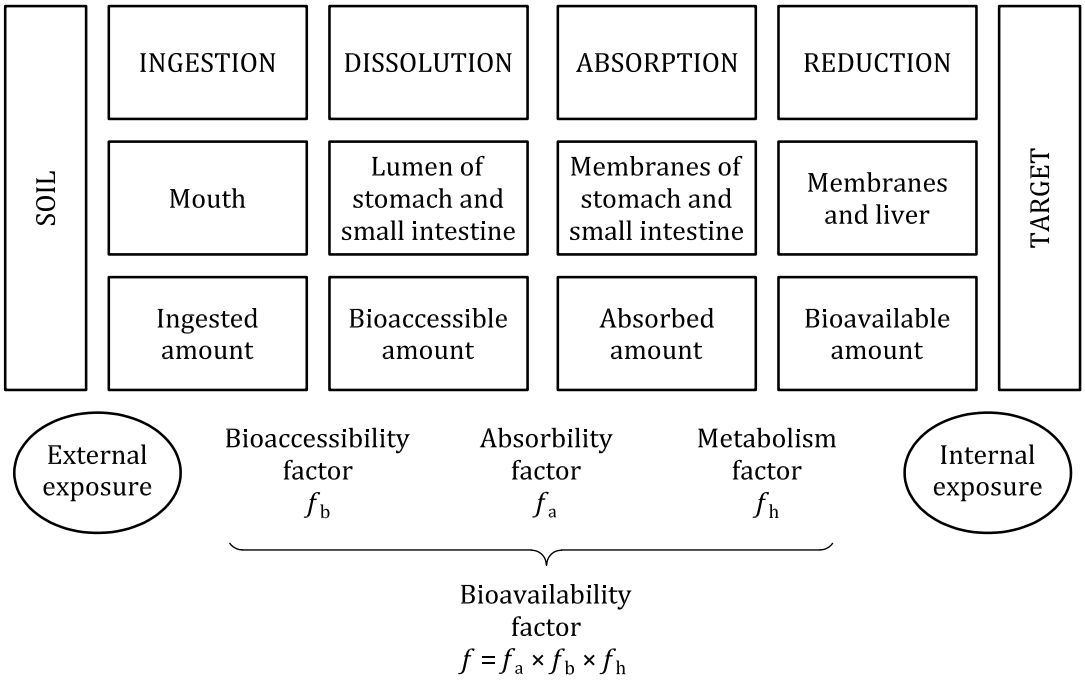

Figure 1 — Schematic presentation of oral uptake processes

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 criterion.

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

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 blood stream. During transport through the membranes, degradation can occur (metabolism). The blood passes 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.

Table 1 — Functions and conditions in the compartments involved in bioaccessibility processes

Compartment	Primary digestion functions	Main added "reagents"	pH	Residence time	Contaminant dissolution function
Mouth	Grinding Cleavage of starch	Moisture Amylase	6,5	Seconds to minutes	Grinding enhances subsequent dissolution
Gullet	Transport	None	6,5	Seconds	None
Stomach	Cleavage of proteins and fats	Hydrochloric acid Proteases Lipases	1 - 5	8 min to 3 h	Acid dissolves labile mineral oxides, sulphides and carbonates to release metals.
Small intestine	Cleavage of oligosaccharides, proteins, fats and other constituents Solubilization of fats	Bicarbonate Bile Proteases Lipases Oligosaccharases Phosphatases	4 - 7,5	2 h to 10 h	Organic matter is dissolved and bound contaminants released Cationic metals are solubilised by complexation with bile acids Some metals are precipitated by the high pH or by phosphate

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 and 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.

The gastrointestinal tract constitutes a complex ecosystem with aerobic and anaerobic microorganisms. The density of microorganisms is less in the human stomach and in the upper part of the small intestine but increases towards and in the large intestine. Anaerobic microorganisms dominate in human faeces, whereas aerobic bacteria are found in high densities in the large intestine. Sulfate reducing bacteria have been detected in the human large intestine while high concentrations of oxygen have