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BSI Standards Publication

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

bsi.

National foreword

This British Standard is the UK implementation of ISO 17924:2018. It supersedes DD ISO/TS 17924:2007, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EH/4, Soil quality.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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30 June 2022	Implementation of ISO corrected text 30 September 2021: see ISO foreword for details

BS ISO 17924:2018

INTERNATIONAL STANDARD

ISO 17924

First edition
2018-10-15

Corrected version
2021-09

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

Qualité du sol — Évaluation de l'exposition humaine par ingestion de sol et de matériaux du sol — Mode opératoire pour l'estimation de la bioaccessibilité/biodisponibilité pour l'homme de métaux dans le sol

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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.

This corrected version of ISO 17924:2018 incorporates the following corrections:

— in 8.3.12, the CAS number for magnesium chloride hexahydrate has been corrected to CAS-Nr 7786-30-3;

— in 8.4.1, third paragraph, the sentence "The solutions are made according to detailed instructions given on the day before the extractions." has been deleted to avoid duplication of information given in the second paragraph;

— in 8.4.4, Table 9, $NaHCO_3$, has been added with the following quantities: 5,607 g (Volume/mass made up to 500 ml), 11 214 mg/l (Final concentration);

— in 8.4.5, Table 12, the mass of NaCl has been corrected to 5,230 g;

— in 8.4.5, Table 12, the mass of $NaHCO_3$ has been corrected to 5,796 g;

— in 8.6.17, the text "the pH should be pH = 6,3 ± 0,5." has been deleted, as the BARGE method does not stipulate a tolerance for the final pH.

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.

INTERNATIONAL STANDARD **ISO 17924:2018**

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