



# SLOVENSKI STANDARD

## SIST EN ISO 7218:2007

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### Mikrobiologija živil in krmil - Splošna pravila za mikrobiološke preiskave (ISO 7218:2007)

Microbiology of food and animal feeding stuffs - General requirements and guidance for microbiological examinations (ISO 7218:2007)

Mikrobiologie von Lebensmitteln und Futtermitteln - Allgemeine Anforderungen und Anleitung für mikrobiologische Untersuchungen (ISO 7218:2007)

Microbiologie des aliments - Exigences générales et recommandations (ISO 7218:2007)

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Ta slovenski standard je istoveten z: **EN ISO 7218:2007**

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English Version

Microbiology of food and animal feeding stuffs - General  
requirements and guidance for microbiological examinations  
(ISO 7218:2007)

Microbiologie des aliments - Exigences générales et  
recommandations (ISO 7218:2007)

Mikrobiologie von Lebensmitteln und Futtermitteln -  
Allgemeine Anforderungen und Anleitung für  
mikrobiologische Untersuchungen (ISO 7218:2007)

This European Standard was approved by CEN on 19 April 2007.

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## Foreword

This document (EN ISO 7218:2007) has been prepared by Technical Committee ISO/TC 34 "Agricultural food products" in collaboration with Technical Committee CEN/TC 275 "Food analysis - Horizontal methods" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2008, and conflicting national standards shall be withdrawn at the latest by February 2008.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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**Microbiology of food and animal feeding  
stuffs — General requirements and  
guidance for microbiological  
examinations**

*Microbiologie des aliments — Exigences générales et  
recommandations*

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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.

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.

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 7218 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in collaboration with CEN Technical Committee CEN/TC 275, *Food analysis — Horizontal methods*.

iTeh STANDARD PREVIEW

This third edition cancels and replaces the second edition (ISO 7218:1996), which has been technically revised. It also incorporates the Amendment ISO 7218:1996/Amd.1:2001.

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## Introduction

When conducting microbiological examinations, it is especially important that

- only those microorganisms which are present in the samples are isolated and enumerated;
- the microorganisms do not contaminate the environment.

In order to achieve this, it is necessary to pay attention to personal hygiene and to use working techniques which ensure, as far as possible, exclusion of extraneous contamination.

Since, in this International Standard, it is possible to give only a few examples of the precautions to be taken during microbiological examinations, a thorough knowledge of the microbiological techniques and of the microorganisms involved is essential. It is important that the examinations are conducted as accurately as possible, including monitoring and recording aspects that may affect results and calculation of the number of microorganisms and the uncertainty of the results.

Ultimately, it is the responsibility of the head of the laboratory to judge whether the manipulations are safe and can be considered to be good laboratory practice.

A large number of manipulations can, for example, unintentionally lead to cross-contamination, and the analyst should always verify the accuracy of the results given by his or her technique.

In order to conduct the examinations correctly, it is necessary to take certain precautions when constructing and equipping the laboratory.

Certain precautions must be taken, not only for reasons of hygiene, but also to ensure good reproducibility of the results. It is not possible to specify all the precautions to be taken in all circumstances, but this International Standard at least provides the main measures to be taken when preparing, sterilizing, storing the media, and using the equipment.

If the guidance given in this International Standard is followed, this will also contribute towards maintaining the health and safety of personnel. Additional information on this subject is to be found in the literature listed in the Bibliography.

In order to distinguish the guidance in this International Standard, it has been printed in a different typeface (Times New Roman).

# Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations

## 1 Scope

This International Standard gives general requirements and guidance/options intended for three main uses:

- implementation of ISO/TC 34/SC 9 or ISO/TC 34/SC 5 standards for detection or enumeration of microorganisms, named hereafter “specific standards”;
- good laboratory practice for food microbiological laboratories (the purpose is not to detail them in this International Standard, manuals are available for that purpose);
- guidance for accreditation of food microbiological laboratories (this International Standard describes the technical requirements according to Annex B of ISO/IEC 17025:2005 for the accreditation of a microbiological laboratory by national organizations).

The requirements of this International Standard supersede the corresponding ones of existing specific standards.

Additional instructions in the field of molecular biology examinations are specified in ISO 22174.

This International Standard covers examination for bacteria, yeasts and moulds and can be used if supplemented with specific guidance for prions, parasites and viruses. It does not cover the examination for toxins or other metabolites (e.g. amines) from microorganisms.

This International Standard applies to the microbiology of food, animal feeding stuffs, the food production environment and the primary production environment.

The purpose of this International Standard is to help to ensure the validity of food microbiology examinations, to assist in ensuring that the general techniques used for conducting these examinations are the same in all laboratories, to help achieve homogeneous results in different laboratories, and to contribute towards the safety of the laboratory personnel by preventing risks of infection.

## 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 835 (all parts), *Laboratory glassware — Graduated pipettes*

ISO 6887 (all parts), *Microbiology of food and animal feeding stuffs — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination*

ISO 8199, *Water quality — General guidance on the enumeration of micro-organisms by culture*

ISO 8261, *Milk and milk products — General guidance for the preparation of test samples, initial suspensions and decimal dilutions for microbiological examination*

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ISO 8655-1, *Piston-operated volumetric apparatus — Part 1: Terminology, general requirements and user recommendations*

ISO/TS 11133 (all parts), *Microbiology of food and animal feeding stuffs — Guidelines on preparation and production of culture media*

ISO 16140, *Microbiology of food and animal feeding stuffs — Protocol for the validation of alternative methods*

ISO/TS 19036, *Microbiology of food and animal feeding stuffs — Guidelines for the estimation of measurement uncertainty for quantitative determinations*

ISO 22174, *Microbiology of food and animal feeding stuffs — Polymerase chain reaction (PCR) for the detection of food-borne pathogens — General requirements and definitions*

### 3 Premises

#### 3.1 General

This clause gives general requirements, e.g. the principles of design and organization, for the layout of a microbiological laboratory.

Examination of primary production stage samples (especially for sample reception and sample preparation) shall be separated from examination of other samples to reduce the risks of cross-contamination.

#### 3.2 Safety considerations

The laboratory design shall comply with safety requirements which will depend on the type of microorganism. To this end, microorganisms are classified in four risk categories:

- **Risk category 1** (no or very low risk to the individual and to the community).

A microorganism that is unlikely to cause human or animal disease.

- **Risk category 2** (moderate risk to the individual, low risk to the community).

A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community or the environment. Laboratory exposures may cause serious human infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

- **Risk category 3** (high risk to the individual, low risk to the community).

A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.

- **Risk category 4** (high risk to the individual and to the community).

A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

**WARNING — Refer to national regulations which will define, in particular, the risk category of the microorganisms encountered within the boundaries of the country concerned.**

#### 3.3 Laboratory design

The guidelines for laboratory layout described below cover examinations for the detection of microorganisms belonging to risk category 1, 2 and 3 for food microbiology.

It should be noted that additional safety measures may be necessary depending on local legislation.

### 3.4 Laboratory areas

#### 3.4.1 General

The laboratory comprises areas associated with samples and testing (see 3.4.2) and general areas (see 3.4.3). These shall be separated.

#### 3.4.2 Areas associated with samples and testing

It is considered good practice to have separate locations, or clearly designated areas, for the following:

- receipt and storage of samples;
- preparation of samples, particularly in the case of raw materials (e.g. powdered products containing a high number of microorganisms);
- examination of samples (from the initial suspension), including incubation of microorganisms;
- manipulation of presumptive pathogens;
- storage of reference and other strains;
- preparation and sterilization of culture media and equipment;
- storage of culture media and reagents;
- examination of foodstuffs for sterility; [SIST EN ISO 7218:2007](https://standards.iteh.ai/catalog/standards/sist/368d5e7f-b3c8-4101-b551-d0b60e44413a/sist-en-iso-7218-2007)
- decontamination; <https://standards.iteh.ai/catalog/standards/sist/368d5e7f-b3c8-4101-b551-d0b60e44413a/sist-en-iso-7218-2007>
- cleaning of glassware and other equipment;
- storage of hazardous chemicals, preferably kept in specially designated cabinets, cupboards, rooms or buildings.

#### 3.4.3 General areas

Separate areas should be considered for the following:

- entrances, corridors, stairways, lifts;
- administrative areas (e.g. secretarial, offices, documentation rooms, etc.);
- cloakrooms and toilets;
- archive rooms;
- stores;
- rest rooms.