SLOVENSKI STANDARD
SIST EN ISO 7218:2007/A1:2013

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Mikrobiologija živil in krme - Splošne zahteve in navodila za mikrobiološke preiskave - Dopolnilo A1 (ISO 7218:2007/Amd 1:2013)

Microbiology of food and animal feeding stuffs - General requirements and guidance for microbiological examinations - Amendment 1 (ISO 7218:2007/Amd 1:2013)

Mikrobiologie von Lebensmitteln und Futtermitteln - Allgemeine Anforderungen und Leitlinien für mikrobiologische Untersuchungen - Änderung 1 (ISO 7218:2007/Amd 1:2013)

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Microbiologie des aliments - Exigences générales et recommandations - Amendement 1 (ISO 7218:2007/Amd 1:2013)

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NORME EUROPÉENNE

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Microbiology of food and animal feeding stuffs - General requirements and guidance for microbiological examinations - Amendment 1 (ISO 7218:2007/Amd 1:2013)

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This amendment A1 modifies the European Standard EN ISO 7218:2007; it was approved by CEN on 15 June 2013.

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Ref. No. EN ISO 7218:2007/A1:2013: E

SIST EN ISO 7218:2007/A1:2013

Contents

Page

Foreword **3**

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 7218:2007/A1:2013
https://standards.iteh.ai/catalog/standards/sist/099b8b41-ba1c-43cb-a48e-a4617caedcf4/sist-en-iso-7218-2007-a1-2013

SIST EN ISO 7218:2007/A1:2013

Foreword

This document (EN ISO 7218:2007/A1:2013) has been prepared by Technical Committee ISO/TC 34 "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of an identical text or by endorsement, at the latest by February 2014, and conflicting national standards shall be withdrawn at the latest by February 2014

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Endorsement notice

The text of ISO 7218:2007/Amd 1:2013 has been approved by CEN as EN ISO 7218:2007/A1:2013 without any modification.

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INTERNATIONAL STANDARD

ISO 7218

Third edition
2007-08-15

AMENDMENT 1
2013-08-01

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

AMENDMENT 1

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Microbiologie des aliments — Exigences générales et recommandations

AMENDEMENT 1

SIST EN ISO 7218:2007/A1:2013
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Foreword

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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, www.iso.org/directives.

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The committee responsible for this document is ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*.

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SIST EN ISO 7218:2007/A1:2013

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

AMENDMENT 1

Page 1, Clause 2

Delete ISO 8261. This has been superseded by ISO 6887-5 [already included in "ISO 6887 (all parts)"].

Delete the entries numbered "ISO 835 (all parts)", "ISO 8655-1", "ISO/TS 11133 (all parts)", and "ISO 16140" and insert the following.

ISO 835, *Laboratory glassware — Graduated pipettes*

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ISO 8655 (all parts), *Piston-operated volumetric apparatus*

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ISO 11133, *Microbiology of food, animal feed and water — Preparation, production, storage and performance testing of culture media*

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ISO 16140-2, *Microbiology of food and animal feed — Method validation — Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*

Pages 6 to 30, Clauses 5 and 6

Delete the existing text and insert the following.

5 Apparatus and equipment

5.1 General

In accordance with good laboratory practice, all apparatus and equipment should be kept clean and in good working condition. Before use, equipment should be verified as fit for the intended purpose and its performance monitored during use, where appropriate.

Where necessary, equipment and monitoring devices should be calibrated to traceable national standards, and recalibration and any necessary intermediate checks performed, and procedures and results documented.

Equipment should be regularly checked and maintained to ensure safety and fitness for use. Equipment should be monitored according to the working conditions and the accuracy demanded for the results.

The frequency of calibration and verification checks of each item of equipment is, in most cases, not specified in this International Standard, since it shall be determined by each laboratory, depending on the type of equipment and on the laboratory's level of activity, and in accordance with the manufacturer's instructions. In a limited number of cases, a frequency has been specified since it was considered to be essential.

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Apparatus and equipment shall be constructed and installed to facilitate operation and to allow for ease of maintenance, cleaning, decontamination and calibration.

Any measurement uncertainties given in this clause relate to the apparatus and equipment concerned and not to the whole method of analysis.

Throughout this clause, requirements for accuracy of measuring equipment are given. These are based on the practical tolerance required to demonstrate suitable control of equipment in routine use. The accuracy stated is related to the metrological uncertainty of the device (see ISO/IEC Guide 99).

For temperature control equipment, check the stability and homogeneity of the temperature before initial use and after any repair or modification which might have an effect on the temperature control.

5.2 Protective cabinets

5.2.1 Description

A protective cabinet is a work station with horizontal or vertical laminar airflow to remove dust and other particles, such as microbes, from the air.

The maximum tolerable number of particles per cubic metre with a size greater than or equal to 0,5 µm represents the dust-spreading class of a safety cabinet. For cabinets used in food microbiology, the number of particles shall not exceed 4 000 per cubic metre.

Cabinets for use in food microbiology laboratories are of four types.

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a) Class I biosafety cabinets are open-fronted exhaust-protective cabinets that are intended to protect the operator and the environment but will not protect the product from extraneous contamination. Potentially infected aerosols will be contained within the cabinet and trapped by impaction on the filter. The filtered air is normally discharged to the atmosphere; if this is not done, the air shall pass through two high-efficiency particulate air (HEPA) filters mounted in series. They are not recommended for work with risk category 3 pathogens because of the difficulties in maintaining and ensuring appropriate operator protection.

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b) Class II biosafety cabinets protect the product, the operator and the environment. They recirculate some filtered air, exhaust some to the atmosphere and take in replacement air through the working aperture, thereby providing operator protection. They are suitable for work with risk category 2 and 3 pathogens.

c) Horizontal laminar outflow cabinets protect the work from contamination, but blow any aerosols generated into the operator’s face. Therefore they are not suitable for handling inoculated cultures or preparation of tissue culture.

d) Vertical laminar airflow cabinets protect the product by the use of vertical laminar flow of HEPA-filtered air. They also protect the operator by the use of internally recirculated air. They are particularly suitable for providing an aseptic environment for handling sterile products and for protecting the operator when handling powders.

Use protective cabinets for all work involving the handling of pathogens and contaminated powders, if required by national regulations.

The use of a gas burner or wire incinerator is not recommended in protective cabinets. If it is necessary, the gas burner should have a small flame so that the airflow is not disturbed. The use of disposable equipment (loops, pipettes, etc.) is a suitable alternative.

5.2.2 Use

Use protective cabinets that are appropriate for the intended application and environmental conditions in the laboratory.

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Cabinets should be kept as free of equipment as possible.

Where practicable, place everything needed inside the cabinet before starting work to minimize the number of arm movements into and out of the working aperture. Position equipment and materials so as to minimize disturbance to the airflow at the working aperture.

Operators should be adequately trained in the correct use of cabinets to ensure their safety and the integrity of the product or culture.

5.2.3 Cleaning and disinfection

Clean and disinfect the working area after use with appropriate and non-corrosive disinfectant in accordance with the manufacturer's instructions. Regularly examine wire grids protecting prefilters, if they exist, and wipe clean with a disinfectant-soaked cloth.

For laminar flow cabinets, the filter face should be vacuum cleaned regularly, taking care not to damage the filter medium.

Safety cabinets should be fumigated before filter changing or servicing.

After cleaning of the cabinets, ultraviolet (UV) lamps may be used for disinfection. UV lamps should be regularly cleaned and replaced in accordance with the manufacturer's instructions. If they are used, they should be cleaned regularly to remove any dust and dirt that may block the germicidal effectiveness of the light. Ultraviolet light intensity should be checked when the cabinet is recertified to ensure that light emission is according to the manufacturer's instructions.

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See Reference [17].

5.2.4 Maintenance and inspection

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The efficiency of a protective cabinet shall be checked by a qualified or certified person on receipt and thereafter at regular intervals as recommended by the manufacturer, as well as after any repair or modification. The efficiency should be checked after relocation.

Periodic verification of freedom from any microbial contamination should be carried out by a check of the working surface and walls of the cabinet.

A periodic verification of the number of airborne microorganisms present should be carried out during operation of the filters using the usual equipment. For example, expose several open Petri dishes containing a non-selective agar culture medium (e.g. Plate Count Agar) in each cabinet for 30 min. Other methods may be used.

5.3 Balances and gravimetric diluters

5.3.1 Use and measurement uncertainty

Balances are mainly used for weighing the test portion of the sample to be examined and the components of the culture media and reagents. In addition, they may be used for carrying out measurements of dilution fluid volumes by mass.

Gravimetric diluters are electronic instruments consisting of a balance and programmable liquid dispenser and are used during the preparation of initial sample suspensions; they function by adding diluent to a subsample at a set ratio. The subsample is then weighed to the tolerance specified in the application, and the diluter set to dispense sufficient diluent for the ratio required (e.g. 9 to 1 for decimal dilutions). See ISO 6887-1.

A food microbiology laboratory shall be equipped with balances of the required range and measurement uncertainty for the different products to be weighed.

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Unless otherwise stated, the resolution of the balance should achieve a tolerance of 1 % but shall be sufficient to achieve a maximum tolerance of 5 % of the mass.

EXAMPLE To weigh 10 g, the balance should be capable of being read to 0,1 g.

To weigh 1 g, the balance should be capable of being read to 0,01 g.

Place the equipment on a stable horizontal surface, adjusted as necessary to ensure that it is level and protected from vibration and draughts.

5.3.2 Cleaning and disinfection

Equipment should be cleaned and disinfected after use or following spillage during weighing with an appropriate and non-corrosive disinfectant.

5.3.3 Performance verification and calibration

5.3.3.1 Calibration

Calibration shall be checked across the entire range by a qualified person at a frequency dependent on use.

5.3.3.2 Verification

The performance of the balance system shall be regularly verified during use and after cleaning with check weights in the range of use by a qualified person.

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NOTE Check weights may also be verified immediately after calibration of the balance.

5.4 Homogenizers, blenders and mixers

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5.4.1 Description

This equipment is used to prepare the initial suspension from the test sample.

The following apparatus may be used:

— a peristaltic blender with sterile bags, possibly with a device for adjusting speed and time; or

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— a rotary homogenizer (blender), the notional speed of which is between 8 000 r/min and 45 000 r/min inclusive, with sterilizable bowls equipped with covers; or

— a vibrational mixer with sterile bags; or

NOTE The Pulsifier® is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

— another homogenizing system with equivalent efficiency.

In certain cases, manual mixing may be carried out using sterile glass beads having an appropriate diameter (approximately 6 mm; see ISO 6887-2 to ISO 6887-5).

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5.4.2 Use

The usual operating time of a peristaltic homogenizer is 1 min to 3 min (see ISO 6887-2 to 6887-5 for specific foods).

Do not use this type of apparatus for certain foodstuffs, such as:

— products which risk puncturing the bag (presence of sharp, hard or dry particles);

— products which are difficult to homogenize because of their texture (e.g. salami-type sausage).

The rotary homogenizer shall operate for a duration such that the total number of revolutions is between 15 000 r/min and 20 000 r/min inclusive. Even with the slowest homogenizer, this time shall not exceed 2,5 min.

The vibrational mixer may be used for most foodstuffs, including hard or dry products. The usual operating time is 0,5 min to 1 min. If microorganisms are likely to be encountered deep inside cohesive structures, the sample should be cut into small pieces prior to processing.

Glass beads can be used for the preparation, by shaking, of the initial suspensions of certain viscous or thick products, in particular certain dairy products (see specific standards).

5.4.3 Cleaning and disinfection

Clean and disinfect peristaltic homogenizers and vibrational mixers regularly and after any bag spillage or leakage.

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For rotary homogenizers, clean and sterilize the glass or metal bowl after each use.

5.4.4 Maintenance

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Inspect and maintain equipment in accordance with the manufacturer's instructions.

5.5 pH meter

5.5.1 Description

A pH meter is used to measure the potential difference, at a determined temperature, between a measuring electrode and a reference one, both electrodes being introduced into the product. It shall be capable of being read to the nearest 0,01 pH unit, enabling measurements to be made with a tolerance of ±0,1 pH unit. The pH meter shall be equipped with either manual or automatic temperature compensation.

NOTE The measuring electrode and the reference electrode are usually grouped together in a combined electrode system.

5.5.2 Use

A pH meter is used to measure the pH value of culture media and reagents to check if adjustment is needed during preparation and as a quality check after sterilization.

It may also be used to measure the pH value of samples and sample suspensions. The use of a pH meter is discussed in the standard specific to the product to be analysed, in which the conditions for the determination of the pH value and for adjustment of the pH value are specified.

Adjust the pH meter as indicated in the manufacturer's manual to measure the pH value at a standardized temperature, e.g. 25 °C. Read the pH value after stabilization has been reached. Record the value to two decimal places.

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