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Mikrobiologija v prehranski verigi - Splošne zahteve in smernice za mikrobiološke preiskave (ISO/DIS 7218:2022)

Microbiology of the food chain - General requirements and guidance for microbiological examinations (ISO/DIS 7218:2022)

Mikrobiologie der Lebensmittelkette – Allgemeine Anforderungen und Leitlinien für mikrobiologische Untersuchungen (ISO/DIS 7218:2022)

Microbiologie de la chaîne alimentaire - Exigences générales et lignes directrices pour les examens microbiologiques (ISO/DIS 7218:2022)

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Microbiology of the food chain — General requirements and guidance for microbiological examinations

Microbiologie de la chaîne alimentaire — Exigences générales et lignes directrices pour les examens microbiologiques

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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 34, *Food products*, Subcommittee SC 9, *Microbiology*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 463, *Microbiology of the food chain,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition of ISO 7218:2007, which has been technically revised and updated. It also incorporates the amendment ISO 7218:2007/Amd.1:2013.

The main changes compared with the previous edition are as follows:

- simplifying the calculations section and addition of two further calculators;
- reorganising the equipment section into groups with similar purposes and requirements;
- cross-referencing other general microbiology standards such as those for media, validation and verification and uncertainty to reduce repetition;
- addition of sections on laboratory quality control and characterisation of control microorganisms.

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 conducting microbiological examinations, it is especially important that:

- only those microorganisms present in the samples are detected and/or enumerated;
- these microorganisms do not contaminate the environment.

To achieve this, good laboratory practices are essential, including personal hygiene and aseptic working techniques which exclude extraneous contamination as far as possible.

Only limited information on the precautions to be taken during microbiological examinations is given here, so a thorough knowledge of the microbiological techniques and microorganisms involved is essential. It is important that examinations are conducted safely, correctly and as carefully as possible, including monitoring and recording aspects that may affect results, calculating numbers of microorganisms and assessing the uncertainty of test results.

The most common risks and their control in the microbiological laboratory are given in this document. However, work processes in each laboratory may differ and appropriate risk analysis should be considered to ensure good laboratory practices Periodic evaluation and control of critical points will not only maintain safe and hygienic practices but may also improve reliability of test results.

This document includes the main measures necessary for conducting the wide range of microbiological examinations. Additional information is available from the literature listed in the Bibliography.

In this document, the text is presented following ISO conventions to ensure ISO standards convey:

- criteria to be fulfilled, i.e. "requirements", using "shall";
- actions to be performed, i.e. "instructions", using the imperative mood;
- advice and guidance, i.e. "recommendations", using "should";
- permission, using "may";
- possibility/capability, using “can”;
- information, generally in the present tense and marked “NOTE”, is for guidance in understanding or clarifying the associated sentence.

Microbiology of the food chain — General requirements and guidance for microbiological examinations

1 Scope

This document gives general requirements and guidance 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 practices for food microbiology laboratories;
- guidance for food microbiological laboratories on the technical requirements for accreditation to ISO/IEC 17025.

The requirements of this document supersede corresponding ones in existing specific standards.

Additional instructions for molecular biology examinations are specified in ISO 22174.

This document covers examination for bacteria, yeasts and moulds and can be used, if supplemented with specific guidance, for parasites and viruses. It is not applicable to examinations for toxins or other metabolites (e.g. amines) from microorganisms.

This document applies to microbiology of the food chain, including food, animal feed, the food production environment and primary production environment. This document is also applicable to the microbiological examination of water where water is used in food production or is regarded as a food in national legislation.

The purpose of this document is to help to ensure the validity of food microbiology examinations. In particular to ensure that general techniques for conducting examinations are the same in all laboratories, to achieve consistent results in different laboratories, and to contribute to safety of laboratory personnel by preventing risks of infection.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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

strain
the progeny or subculture of a single isolated colony in pure culture that displays the phenotypic characteristics or possesses the molecular attributes/properties as identified with being associated within the classification of the species of that microorganism

3.2
target strain
strain, defined according to the scope of the method

[SOURCE: ISO 16140-1:2016, MOD]

Or

target organism
microorganism which is the designated analyte for a microbiological examination

[SOURCE: ISO 22117:2019, MOD]

3.3
laboratory strain
microorganism that is defined to at least the genus and species level, and characterised biochemically, and/or serologically and/or with molecular testing, and preferably originating from the food chain

3.4
reference strain
microorganism obtained directly from an official culture collection or reference laboratory and defined to at least the genus and species level, catalogued and described according to its characteristics and preferably originating from food, food production areas, primary production stages, animals or water as applicable

[SOURCE: ISO 22117:2019]

3.5
natural background microorganisms
microorganisms which are naturally present or can be introduced which compete with or mimic the target microorganism

[SOURCE: ISO 20976-1]

3.6
matrix
all the components of a sample

[SOURCE: ISO 16140-1]

3.7
biological resource centres
BRCs
service providers and repositories of the living cells, genomes of organisms and information relating to heredity and the functions of biological systems

Note 1 to entry: BRCs contain collections of culturable organisms (e.g. microorganisms), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as

well as databases containing molecular, physiological and structural information relevant to these collections and related informatics (OECD:2007, MOD).

3.8
microbial (sub)type
a group of closely related microorganisms (within a species) distinguished by their shared specific characteristics as determined by, for example, serological testing (serotype) or molecular testing (genotype)

[SOURCE: ISO 16140-6:2019]

3.9
challenge test
study of the growth or inactivation of microorganism(s) artificially inoculated in a food

[SOURCE: ISO 20976-1]

3.10
measurement accuracy
accuracy of measurement
accuracy
closeness of agreement between a measured quantity value and a true quantity value of a measurand
[SOURCE: ISO Guide 99]

3.11
resolution
smallest change in a quantity being measured that causes a perceptible change in the corresponding indication

[SOURCE: ISO Guide 99]

3.12
measurement uncertainty
uncertainty of measurement
uncertainty
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: ISO Guide 99]

3.13
contamination
undesirable presence of microorganisms in the environment, on surfaces (including human skin) or in (or on) laboratory samples

3.14
cross-contamination
unintentional transfer of microorganisms from one area or article to another

NOTE 1 to entry: This can include, but is not limited to, transfer of microorganisms from:
the laboratory environment to laboratory samples;
laboratory personnel to laboratory samples;

one laboratory sample to other laboratory samples;
the laboratory area to adjacent production areas.

4 Premises

4.1 General

This clause gives general requirements, including the principles of design and organization, for the layout of a microbiological laboratory testing samples from the food chain.

NOTE Further specifications for molecular biology laboratories are given in ISO 22174.

4.2 Biosafety considerations

The laboratory design shall comply with biosafety requirements which will depend on the type of microorganism and potential for causing human illness.

The current four Biosafety Levels and laboratory design requirements for each are fully described in the WHO Laboratory Biosafety Manual [42] or the OIE Terrestrial Manual [40].

WARNING — Refer also to regional or national regulations which may differ in definitions of Biosafety Levels or risks from microorganisms.

4.3 Laboratory design

The guidelines for laboratory layout described below cover examinations for the detection and enumeration of microorganisms belonging to Biosafety Levels 1 and 2, as only these are routinely handled in food microbiology laboratories. Further details can be found in the WHO Laboratory Biosafety Manual [42].

National and regional legislation may require different and/or additional safety measures.

4.4 Laboratory areas

4.4.1 General

The laboratory comprises separate areas associated with samples and testing (see 4.4.2) and other general areas (see 4.4.3).

4.4.2 Areas associated with samples and testing

It is good practice to allocate separate rooms or clearly designated areas, with dedicated equipment where necessary, for the following activities. The areas can be interconnected provided hygiene recommendations (see 5.4) are met and, if space is limited, activities can be separated by time:

— receipt and storage of laboratory samples before and after testing;

— preparation of laboratory samples and test portions (separate powders and those likely or known to contain high numbers of microorganisms to reduce the risk of cross-contamination, and also commercially sterile foodstuffs to prevent contamination by other samples);

- examination of test portions from the initial suspension, including all dilution, plating, incubation and counting steps of enumeration tests and detection tests up to isolation of presumptive pathogens;
- manipulation of presumptive pathogens, including those from proficiency schemes or laboratory spiked samples deliberately contaminated with pathogens;
- handling and storage of reference cultures and other laboratory strains;
- preparation and testing of samples by molecular methods (see ISO 22174 for full details);
- preparation and sterilization of culture media, reagents and necessary equipment;
- storage of culture media and reagents;
- decontamination and disposal of biohazard waste;
- cleaning of glassware and other equipment;
- storage of hazardous chemicals, preferably in specially designated cabinets, cupboards, rooms or buildings.

4.4.3 General areas

Separate areas are set aside for the following:

- entrances, corridors, stairways, lifts;
- cloakrooms, toilets and staff rooms;

- administration (e.g. secretarial, offices, document archives);
- storage of general laboratory supplies.

4.5 Layout and fittings of the premises

4.5.1 Objectives

The primary objective is to ensure that the environment in which microbiological examinations are carried out is safe and does not adversely affect the validity of test results.

Arrange the premises to avoid risk of cross-contamination, for example:

- construct the laboratory according to the pattern and flow of work (the “no way back” principle);
- carry out procedures in a sequential manner using appropriate precautions to ensure test and sample integrity (e.g. use of sealed containers);
- separate activities by space or time (see 4.4.2)..

Avoid conditions such as extremes of temperature outside the accepted range (18 ˚C – 27 ˚C), draughts, dust, humidity, steam, noise, vibration, etc., all of which can affect the validity of microbiological test results.

Locate air flows into and out of the laboratory to minimise the risk of contaminating samples under test or any adjacent food processing facilities.

Sufficient space should be available so work areas can be kept clean and tidy. The space required should be proportional to the number of samples and tests handled, the number of staff and the overall internal organization of the laboratory. Always follow any requirements specified in national or regional regulations.

4.5.2 Fittings

The test premises should be constructed and equipped as follows to reduce the risk of contamination by dust and therefore by microorganisms:

— The walls, ceilings and floors should be smooth, easy to clean and resistant to detergents and disinfectants used in laboratories;

— Floors should be slip-resistant;

— Overhead pipes should not cross the premises unless they are sealed or enclosed. Any other overhead structures should be covered or readily accessible for regular cleaning;

— Windows and doors should be closed when testing to minimize draughts and potential airborne contamination; they should be designed to avoid formation of dust traps and to facilitate cleaning;

— The ambient temperature (18 °C to 27 °C) and air quality (microorganism content, dust spreading rate, etc.) should be compatible with testing. Air-conditioning systems should supply filtered air and be regularly cleaned and serviced or maintained;

— Adequate measures, such as special workstations, should be taken to minimise exposure to and cross-contamination from dust when handling dehydrated culture media and dusty or powdered samples;

— When tests are to be conducted in a low-contamination atmosphere, the room should be equipped with a clean laminar airflow and/or safety cabinet;

— If necessary, the laboratory environment should be protected from the harmful effects of solar radiation by use of shutters or suitably treated window glass. Internally installed blinds are not suitable as they may be difficult to clean and could become a source of dust.

4.5.3 Other arrangements for laboratory premises

Consider also general arrangements such as the following:

— availability of water supply, of suitable quality for the intended use;

— availability of electricity;

— availability of gas (piped or bottled);

— sufficient lighting for tasks undertaken in each area of the laboratory;

- laboratory bench tops and furniture manufactured in smooth, impermeable material that is easily cleaned and disinfected;
- laboratory furniture that is movable or designed to allow access for cleaning floors and equipment;
- no furniture, documents or other items than those strictly necessary for testing activities to be kept in the testing areas;
- separate storage for test records and other necessary documents away from samples and test materials;
- provision of hand wash facilities (or special solutions or gels containing alcohol) in each testing room, preferably near the door. Provide designated hand wash facilities, preferably with hands free operation, at the entrance/exit to pathogen testing areas;
- provision for hanging used laboratory gowns when exiting laboratory areas;
- availability of an autoclave for destruction of contaminated waste materials and culture media, unless an appropriate system for removal and incineration is in place (see 6.2.2);
- provision of safety systems for fire and electrical emergencies;
- provision of safety showers and eyewash facilities, where necessary;
- provision of first aid facilities.

4.6 Cleaning and disinfection

Consider methods, frequency and controls for cleaning and disinfection according to risk and check the following points:

- The floors, walls, ceilings, laboratory bench tops, furniture and junctions between these should be regularly maintained and repaired to avoid cracks which may harbour contamination.
- Carry out regular cleaning and disinfection to keep the premises in a condition suitable for conducting tests. Contaminated or potentially contaminated surfaces should be decontaminated using a disinfectant known to be bactericidal and fungicidal (see Annex A).
- Use dedicated cleaning equipment for all microbiology laboratories, with separate equipment for high-risk areas such as pathogen laboratories.

NOTE Rooms and equipment can be decontaminated by fumigation with formaldehyde vapour, if permitted in national regulations.

- Maintain the ventilation systems and filters and change the filters when necessary.
- Monitor the microbiological contamination level of laboratory work surfaces, staff contact surfaces and the air regularly (at a frequency depending on previous monitoring results and risk to validity of test results).