International Standard

ISO 7218

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

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

Fourth edition
2024-06

Reference number
ISO 7218:2024(en)

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Published in Switzerland

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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 (see www.iso.org/directives).

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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 (ISO 7218:2007), which has been technically revised. It also incorporates the Amendment ISO 7218:2007/Amd 1:2013.

The main changes are as follows:

— the calculations section has been simplified and two further calculators have been added;

— the equipment section has been reorganized into groups with similar purposes and requirements;

— cross-references have been added to other general microbiology standards such as those for media, validation and verification, and uncertainty to reduce repetition;

— information on laboratory quality control and characterization of control microorganisms has been added.

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 in this document, 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 can 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 can differ and appropriate risk analysis should be considered to ensure good laboratory practices. Periodic evaluation and control of critical points not only maintains safe and hygienic practices but can also improve reliability of test results.

The purpose of this document is to help to ensure the validity of microbiology examinations in the food chain. 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.

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 (see References [43] to [47]).

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

In addition, the imperative mood is used to give instructions or where actions are required.

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

1 Scope

This document specifies general requirements and gives guidance on microbiological examinations.

It is applicable to:

— the implementation of specific horizontal or vertical International Standards developed by ISO/TC 34/SC 9 or ISO/TC 34/SC 5 for detection or enumeration of microorganisms, named hereafter "specific standards";

— good laboratory practices for microbiology laboratories testing samples from the food chain;

— guidance for microbiological laboratories testing samples from the food chain on the technical requirements for conforming to ISO/IEC 17025.

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

Additional instructions for examinations using the polymerase chain reaction (PCR) are specified in ISO 22174.

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

This document is applicable to microbiology of the food chain, from primary production stage to food and animal feed products, including the premises where the food or feed production and handling takes place. It 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.

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 terminology databases for use in standardization at the following addresses:

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

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

3.1
food chain
sequence of the stages in the production, processing, distribution, storage and handling of a *food* (3.2) and its ingredients, from primary production to consumption

Note 1 to entry: The food chain includes the environment of primary production, food and feed production, and handling.

Note 2 to entry: The food chain also includes the packaging materials intended to come into contact with food, *feed* (3.3) or raw materials.

[SOURCE: ISO 22000:2018, 3.20, modified — Notes to entry replaced.]

3.2
food
products intended for human consumption
substance (ingredient), whether processed, semi-processed or raw, which is intended for human consumption, and includes beverages and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances (ingredients) used only as drugs

[SOURCE: CAC/GL 81-2013, 6, modified — Admitted term added. “(ingredient)” added, “beverages” replaced “drink” and “chewing-gum” deleted in the definition.]

3.3
feed
products for feeding animals
single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to animals

Note 1 to entry: These products are intended for food-producing animals and non-food producing animals such as pets.

[SOURCE: ISO 22000:2018, 3.16, modified — Admitted term added. “food-producing” deleted in the definition. Note 1 to entry replaced.

3.4
food or feed production and handling
any operation in the processing (e.g. preparation, cooking, packaging), storage, transport, distribution and service of *food* (3.2) or *feed* (3.3)

[SOURCE: ISO/TS 22002-2:2013, 3.9, modified — “or feed production and” added in the term. “processing (e.g. preparation, cooking, packaging)” replaced “preparation, processing, cooking, packaging”, and “or feed” added in the definition.]

3.5
primary production stage
stage of the *food chain* (3.1) at which the production, rearing or growing of primary products, including harvesting, milking and farmed animal production before slaughter, takes place

Note 1 to entry: It also includes hunting, fishing and the harvesting of wild products.

3.6
horizontal method
method for microbiological examination that is broadly applicable to samples within the *food chain* (3.1), excluding any documented limitations

3.7
vertical method
sectorial method
method for microbiological examination that is specifically applicable to samples (e.g. from *primary production stage* (3.5)), a product or a group of products (e.g. milk and milk products, meat and meat products, fish and fishery products, *feed* (3.3))

3.8
specific standard
standardized reference method for the examination (e.g. detection, enumeration, confirmation or identification) of a specific microorganism or group of microorganisms

Note 1 to entry: A specific standard can describe a *horizontal method* (3.6) or a *vertical method* (3.7).

3.9
general standard
supporting document describing general guidance and requirements necessary for application of *specific standards* (3.8)

3.10
strain
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

3.11
target strain
strain (3.10), defined according to the scope of the method

[SOURCE: ISO 16140-1:2016, 2.74, modified — "method" replaced "reference method that is expected to be detected or enumerated by the alternative method".]

3.12
target organism
microorganism that is the designated analyte for a microbiological examination

[SOURCE: ISO 22117:2019, 3.1, modified — "microbiological examination" replaced "proficiency testing sample".]

3.13
laboratory strain
microorganism that is defined to at least the genus and species level, and characterized biochemically, and/or serologically and/or with molecular testing, and preferably originating from the *food chain* (3.1)

3.14
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* (3.2), food production areas, *primary production stages* (3.5), animals or water, as applicable

[SOURCE: ISO 22117:2019, 3.4]

3.15
natural background microorganism
microorganism that is naturally present or can be introduced to compete with or mimic the target microorganism

[SOURCE: ISO 22117:2019, 3.2, modified — "natural background microorganism" replaced "background flora" as the term. "included in a proficiency testing sample" deleted in the definition.]

3.16
matrix
all the components of the sample

[SOURCE: ISO 16140-1:2016, 2.38, modified — "(product)" deleted in the term.]

3.17
biological resource centre
BRC
service provider or repository 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

[SOURCE: OECD, 2007[44]]

3.18
microbial (sub)type
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, 3.5]

3.19
challenge testing
study of the growth or inactivation of microorganism(s) artificially inoculated in *food* (3.2)

[SOURCE: ISO 20976-1:2019, 3.5]

3.20
accuracy
accuracy of measurement
measurement accuracy
closeness of agreement between a measured quantity value and a true quantity value of a measurand

[SOURCE: ISO/IEC Guide 99:2007, 2.13, modified — "accuracy" replaced "measurement accuracy" as the preferred term. Notes to entry deleted.]

3.21
resolution
smallest change in a quantity being measured that causes a perceptible change in the corresponding indication

[SOURCE: ISO/IEC Guide 99:2007, 4.14, modified — Notes to entry deleted.]

3.22
uncertainty
uncertainty of measurement
measurement uncertainty
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: ISO/IEC Guide 99:2007, 2.26, modified — "uncertainty" replaced "measurement uncertainty" as the preferred term. Notes to entry deleted.]

3.23
calibration
set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard

3.24
verification
provision of objective evidence that a given item fulfils specified requirements

[SOURCE: ISO/IEC Guide 99:2007, 2.44, modified — Examples and notes to entry deleted.]

3.25
contamination
undesirable presence of microorganisms in the environment, on surfaces (including human skin) or in (or on) laboratory samples

3.26
cross-contamination
unintentional transfer of microorganisms or their constituents, such as DNA, or metabolites from one area or article to another

Note 1 to entry: This can include, but is not limited to, transfer from:

— the laboratory environment to laboratory samples;

— laboratory personnel to laboratory samples;

— one laboratory sample to other laboratory samples;

— one laboratory area to another;

— the laboratory area to adjacent production areas.

3.27
process control
internal quality control (IQC) system that is used to confirm acceptable conditions of the entire process have been achieved

Note 1 to entry: This includes the use of a target organism that is tested in accordance with the method from start to finish with each batch of samples, as well as positive, negative and blank samples that are used to confirm the acceptability of media/reagents and consumable supplies, and of the incubation environment (temperature/equipment), and to confirm the competence of personnel.

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 Guidelines referring to PCR in this document apply equally to other nucleic acid amplification methods. Further specifications for laboratories using PCR are given in ISO 22174.

4.2 Biosafety considerations

The laboratory design shall comply with the relevant biosafety requirements for 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[47] or the OIE Terrestrial Manual[45].

NOTE Regional or national regulations can differ in definitions of biosafety levels or risks from microorganisms.

4.3 Laboratory design

The guidelines for laboratory layout described in this clause 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[47].

NOTE National and regional legislation can 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:

— 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 testing 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 PCR nucleic acid amplification 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.

The areas can be interconnected provided hygiene recommendations (see 5.4) are met and, if space is limited, activities can be separated by time.

4.4.3 General areas

Separate areas are set aside for the following:

— entrances, corridors, stairways and 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).