TOIDU JA LOOMASÖÖTADE MIKROBIOLOOGIA

Üldnõuded ja juhised mikrobioloogilisteks uuringuteks

Microbiology of food and animal feeding stuffs

General requirements and guidance for microbiological examinations

(ISO 7218:2007 + Amd 1:2013)





EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 7218:2008 +A1:2013 sisaldab Euroopa standardi EN ISO 7218:2007+EN ISO 7218:2007/A1:2013 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7218:2008 +A1:2013 consists of the English text of the European standard EN ISO 7218:2007+EN ISO 7218:2007/A1:2013.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.08.2007.	Date of Availability of the European standard is 15.08.2007.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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ICS 07.100.30

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 7218

August 2007

ICS 07.100.30

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 recommendations (ISO 7218:2007)

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

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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of an identical text or by endorsement, at the latest by February 2008, and conflicting national standards shall be withdrawn at the latest by February 2008.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.

Endorsement notice

The text of ISO 7218:2007 has been approved by CEN as a EN ISO 7218:2007 without any modification.



Contents

Page

Forewo	ord	V	
Introductionvi			
1	Scope	1	
2	Normative references	1	
3 3.1	Premises	2	
3.2 3.3	Safety considerationsLaboratory design		
3.4 3.5	Laboratory areas Layout and fittings of the premises		
3.6	Cleaning and disinfection		
4 4.1	StaffGeneral		
4.2 4.3	Competence Verification of on-going staff competence		
4.4	Hygiene		
5	Apparatus and equipment		
6 6.1	Preparation of glassware and other laboratory materials Preparation	. 28	
6.2	Sterilization/decontamination	. 28	
6.3 6.4	Disposable equipment and materials		
6.5	Management of sterile glassware and materials	. 29	
6.6 6.7	Use of decontamination and disinfection		
6.8	Washing		
7	Preparation and sterilization of culture media		
8	Laboratory samples		
8.1 8.2	Sampling Transport		
8.3	Receipt	. 31	
8.4 8.5	Storage Test portion		
9	Examination	_	
9.1 9.2	Hygienic precautions during analysis Preparation of initial suspension and dilutions		
10	Enumeration		
10.1	General		
10.2 10.3	Enumeration using a solid medium Calculation and expression of results obtained with solid media		
10.4	Enumeration of yeasts and moulds	. 43	
10.5	Enumeration using a liquid medium		
11 11.1	Detection method (qualitative method)		
11.2	Principle	. 50	
11.3	Measurement of uncertainty	. 50	

EVS-EN ISO 7218:2008+A1:2013

12	Confirmatory methods	50
12.1	General	50
12.2	Preparation of a pure culture	50
12.3	Gram's stain (modified Hucker technique)	50
12.4	Use of biochemical galleries for identification	52
12.5	Use of nucleic probes for identification	
12.6	Serological methods	
13	Test report	53
_		
14	Validation of microbiological methods	
14.1	Validation of reference methods	
14.2	Validation of alternative methods	
14.3	Validation of in-house methods	54
15	Quality assurance of results/quality control of performance	54
15.1	Internal quality control	
15.2	Reference strains	
15.3	External quality assessment (proficiency testing)	55
Annex	x A (informative) Properties of some disinfectants	56
	·	
Annex	x B (normative) Determination of most probable number (MPN)	5/
Riblio	graphy	64



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.