



SLOVENSKI STANDARD
SIST ENV ISO 11133-1:2002
01-september-2002

A] fcV]c`c[]Uÿ]j]`]b`_fa Y!'BUj cX]UnUdf]dfUj c`]b`]nXYUj c`[c^ÿ U!'%'rXY'.
Gd`cýbUbu] cX]Uc`nU] cUj`Ub`f`_U_cj cgh`df]dfUj Y[c^ÿ Uj`UVcfUrcf]f` fIGC#HF
%%%' !%&\$\$\$L

Microbiology of food and animal feeding stuffs - Guidelines on preparation and production of culture media - Part 1: General guidelines on quality assurance for the preparation of culture media in the laboratory (ISO/TS 11133-1:2000)

iTeh STANDARD PREVIEW

Mikrobiologie von Lebensmitteln und Futtermitteln - Anleitungen für die Zubereitung und Herstellung von Nährmedien - Teil 1: Allgemeine Anleitungen für die Qualitätssicherung bei der Zubereitung von Nährmedien im Laboratorium (ISO/TR 11133-1:2000)

[SIST ENV ISO 11133-1:2002](https://standards.iteh.ai/catalog/standards/sist/a8b953c3-a7e0-4fce-8e62-11d395000000/iso-11133-1-2000)

<https://standards.iteh.ai/catalog/standards/sist/a8b953c3-a7e0-4fce-8e62-11d395000000/iso-11133-1-2000>

Microbiologie des aliments - Guide pour la préparation et la production des milieux de culture - Partie 1: Guide général pour l'assurance de la qualité pour la préparation des milieux de culture en laboratoire (ISO/TR 11133-1:2000)

Ta slovenski standard je istoveten z: ENV ISO 11133-1:2000

ICS:

01.040.07	Matematika. Naravoslovne vede (Slovarji)	Mathematics. Natural sciences (Vocabularies)
07.100.30	Mikrobiologija živil	Food microbiology

SIST ENV ISO 11133-1:2002 en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST ENV ISO 11133-1:2002](#)

<https://standards.iteh.ai/catalog/standards/sist/a8b953c3-a7e0-4fce-8e62-95606047c5bf/sist-env-iso-11133-1-2002>

EUROPEAN PRESTANDARD
PRÉNORME EUROPÉENNE
EUROPÄISCHE VORNORM

ENV ISO 11133-1

June 2000

ICS 01.040.07; 07.100.30

English version

Microbiology of food and animal feeding stuffs - Guidelines on preparation and production of culture media - Part 1: General guidelines on quality assurance for the preparation of culture media in the laboratory (ISO/TR 11133-1:2000)

Microbiologie des aliments - Guide pour la préparation et la production des milieux de culture - Partie 1: Guide général pour l'assurance de la qualité pour la préparation des milieux de culture en laboratoire (ISO/TR 11133-1:2000)

Mikrobiologie von Lebensmitteln und Futtermitteln - Anleitungen für die Zubereitung und Herstellung von Nährmedien - Teil 1: Allgemeine Anleitungen für die Qualitätssicherung bei der Zubereitung von Nährmedien im Laboratorium (ISO/TR 11133-1:2000)

This European Prestandard (ENV) was approved by CEN on 1 August 1999 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Contents

Foreword	3
1 Scope	3
2 Normative references	4
3 Terminology	4
3.1 General.....	4
3.2 Terminology of quality assurance.....	4
3.3 Terminology of culture media.....	5
3.4 Terminology for test organisms.....	7
4 Practices for quality control of culture media	8
4.1 Documentation.....	8
4.2 Storage.....	8
4.3 Laboratory preparation of media.....	9
4.4 Preparation for use.....	11
4.5 Disposal of media.....	12
5 Quality control of finished product	12
5.1 Physical quality control.....	12
5.2 Microbiological quality control.....	12
Annex A (informative) Designation of the components of the culture media in standards on microbiological analysis of food and animal feeding stuffs products	14
Annex B (informative) Guidance on preservation and maintenance of control strains	15
Annex C (informative) Quality assurance of culture media – troubles-shooting	16
Bibliography	17

Foreword

The text of ENV ISO 11133-1:2000 has been prepared by Technical Committee CEN/TC 275 "Food analysis - Horizontal methods", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 34 "Agricultural food products".

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 December 2000, and conflicting national standards shall be withdrawn at the latest by December 2000.

This draft European standard "Microbiology of food and animal feeding stuffs – Guidelines on preparation and production of culture media" consists of two parts :

- *Part 1 : General guidelines on quality assurance for the preparation of culture media in the laboratory*
- *Part 2 : Practical guidelines on performance testing of culture media in the laboratory*

Annexes designated as "informative" are given for information only. In this standard Annexes A, B and C are informative.

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

iTeh STANDARD PREVIEW (standards.iteh.ai)

Introduction

[SIST ENV ISO 11133-1:2002](https://standards.iteh.ai/catalog/standards/sist/a8b953c3-a7e0-4fce-8e62-95606047c5bf/sist-env-iso-11133-1-2002)

<https://standards.iteh.ai/catalog/standards/sist/a8b953c3-a7e0-4fce-8e62-95606047c5bf/sist-env-iso-11133-1-2002>

In the microbiology laboratory many tests and procedures depend upon culture media being consistent and providing reproducible results. Culture media are used in all traditional cultural techniques and also for many alternative techniques. Many formulae of dehydrated culture media are commercially available and many more, designed for specific growth purposes, are described in the literature. Additionally, in laboratories carrying out the microbiological examination of food, the main objectives are to maintain, resuscitate, grow, detect and / or enumerate a wide variety of microorganisms. The requirements for media are specific to both the sample and the organisms to be detected. Culture media meeting established or minimal performance criteria are therefore a prerequisite for any reliable microbiological work. Sufficient testing should be carried out to demonstrate i) the acceptability of each batch of medium ii) that the medium is 'fit for purpose' and iii) that the medium can produce consistent results.

These three criteria are an essential part of internal quality control procedures and, with appropriate documentation, will permit effective monitoring of culture media and contribute to the production of both accurate and precise data.

1 Scope

This European prestandard provides the general terminology related to quality assurance of the preparation of culture media and specifies the **minimum** requirements to be used for the microbiological analysis of products intended for human consumption or animal feeding.

These requirements are applicable to three categories of culture media used in laboratories that prepare and/or use culture media for performing microbiological analyses :

- commercially manufactured ready-to-use media ;
- media prepared from commercially available dehydrated formulations (either complete e.g. plate count agar or basal media to which supplements are added e.g. Baird-Parker agar) ;
- media prepared from its individual components.

2 Normative references

This European Prestandard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1659:1996, *In vitro diagnostic systems – Culture media for microbiology – Terms and definitions.*

EN 12322:1999, *In vitro medical devices – Culture media for microbiology – Performance criteria for culture media.*

ISO 8402:1995, *Quality - Vocabulary.*

3 Terminology

3.1 General

This clause gives the general definitions related to quality assurance and provides different types of terminology related to culture media and to control cultures. Standards cited between brackets indicate that the text given is identical to that cited.

3.2 Terminology of quality assurance

3.2.1 quality assurance

all the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfil the requirements for quality

[ISO 8402]

iTeh STANDARD PREVIEW
 (standards.iteh.ai)
<https://standards.iteh.ai/catalog/standards/sist/a8b953c3-a7e0-4fce-8e62-95606047c5bf/sist-env-iso-11133-1-2002>

3.2.2 quality control

operational techniques and activities that are used to fulfil the requirements for quality

[ISO 8402]

3.2.3 internal quality control

a continuous control programme of the laboratory's work prepared by or for them, and based on control analysis together with follow-up and, if necessary, corrective actions

3.2.4 batch of culture media ; lot of culture media

fully traceable unit of a medium referring to a defined amount of bulk, semi-finished product or end product, which is consistent in type and quality and which has passed the requirements of production (in-process control) and quality assurance testing, and which has been produced within one defined production period, having been assigned the same lot number

[EN 12322]

3.2.5 performance of culture media

the response of a culture medium to challenge by test organisms under defined conditions

3.3 Terminology of culture media

3.3.1 Culture medium

formulation of substances, in liquid, semi-solid or in solid form, which contain natural and/or synthetic constituents intended to support the multiplication, or to preserve the viability, of microorganisms

NOTE When used in connection with compound words, this term is often shortened into "medium" (e.g. enrichment medium).

[EN 1659]

3.3.2 Culture media classified by composition

3.3.2.1

chemically defined culture medium

culture medium consisting only of chemically defined constituents (i.e. of known molecular structure and degree of purity)

[EN 1659]

3.3.2.2

chemically incomplete culture medium

culture medium consisting entirely or partly of natural materials, processed or otherwise, the chemical composition of which is not completely defined

NOTE For the various chemically undefined components used in culture media, ISO/TC 34/SC 9 has specified harmonised designations - see Annex A.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

3.3.3 Culture media classified by consistency

SIST ENV ISO 11133-1:2002

<https://standards.iteh.ai/catalog/standards/sist/a8b953c3-a7e0-4fce-8e62-95606047c5bf/sist-env-iso-11133-1-2002>

3.3.3.1

liquid culture medium

culture medium consisting of an aqueous solution of one or more constituents (e.g. peptone water, nutrient broth)

NOTE 1 In some cases, solid particles are added to the liquid culture medium.

NOTE 2 Liquid media in tubes, flasks or bottles are commonly called "broth".

[EN 1659]

3.3.3.2

solid culture medium and semi-solid culture medium

liquid culture medium containing solidifying materials (e.g. agar-agar, gelatine, etc.,) in different concentrations

NOTE 1 Due to the world-wide use of culture media solidified with agar-agar, the shortened term "agar" is often used synonymously for solid culture media and therefore in connection with nouns, e.g. "Plate count agar".

NOTE 2 Solid culture media poured into Petri dishes are commonly called "plates". Solid culture media poured into tubes that are kept in slanted positions while the media are solidifying are often called "slants".

[EN 1659]

3.3.4 Culture media classified by intent of use

3.3.4.1

transport medium

culture medium designed to preserve and maintain the viability of microorganisms for the time period between sample collection and laboratory processing of the sample

NOTE Transport media usually contain substances that do not permit multiplication of microorganisms but ensure their preservation (e.g. Stuart's or Amies' Transport medium).

[EN 1659]

3.3.4.2

preservation medium

culture medium designed to preserve and maintain the viability of microorganisms over an extended period, to protect them against the adverse influences which may occur during long-term storage and to allow recovery after this period (e.g. Dorset egg medium)

[EN 1659]

3.3.4.3

resuscitation medium

culture medium enabling stressed and damaged microorganisms to repair and recover their capacity for normal growth without necessarily promoting their multiplication

[EN 1659]

3.3.4.4

enrichment medium

predominantly liquid culture medium which, due to its composition, provides particularly favourable conditions for multiplication of microorganisms

[EN 1659]

iTeh STANDARD PREVIEW (standards.iteh.ai)

3.3.4.4.1

selective enrichment medium

enrichment medium which supports the multiplication of specific microorganisms whilst partially or totally inhibiting the growth of other microorganisms (e.g. Rappaport-Vassiliadis medium)

<https://standards.iteh.ai/catalog/standards/sist/a8b953c3-a7e0-4fce-8e62-95606047c5bf/sist-env-iso-11133-1-2002>

3.3.4.4.2

non-selective enrichment medium

enrichment medium which supports the growth of most microorganisms (e.g. nutrient broth)

3.3.4.5

isolation medium

solid or semi-solid culture medium which supports the growth of microorganisms

3.3.4.5.1

selective isolation medium

isolation medium which supports growth of specific microorganisms, while inhibiting other microorganisms (e.g. PALCAM agar, MacConkey agar)

[EN 1659]

3.3.4.5.2

non-selective isolation medium

isolation medium which is not devised to selectively inhibit microorganisms (e.g. nutrient agar)

[EN 1659]

3.3.4.6

differential medium

culture medium which permits the testing of one or more physiological/biochemical characteristics of the microorganisms for their identification (e.g. Urea medium, Kligler agar)

NOTE Differential media which can be used as isolation media are referred to as isolation/differential media (e.g. xylose lysine desoxycholate (XLD) agar).

[EN 1659]

3.3.4.7

identification medium

culture medium designed to produce a specific identification reaction which does not require any further confirmatory test

NOTE Identification media which can be used as isolation media are referred to as isolation/identification media.

[EN 1659]

3.3.4.8

media having multiple uses

certain culture media may be assigned to several categories, e.g. Blood agar is a resuscitation medium according to 3.3.4.3. an isolation medium according to 3.3.4.5 and a differential medium according to 3.3.4.6 used for detection of haemolysis

3.3.5 Culture media classified according to preparation method

3.3.5.1

ready-to-use medium

culture medium which is supplied in containers in ready-to-use form (e.g. Petri dishes or tubes or other containers)

3.3.5.2

culture medium prepared from commercially dehydrated formulations

culture medium in dry form which is not ready for immediate use (e.g. powders, granules, lyophilised products). Rehydration will make one of two kinds of medium

- a complete ready-to-use medium ;
- an incomplete medium to which labile components are added at the time of use

3.3.5.3 Culture medium prepared from individual components **in the laboratory**

3.4 Terminology for test organisms

3.4.1 General

These are microorganisms generally used for quality control and performance testing of culture media. They are defined according to their source as follows.

3.4.2

reference strain

microorganism defined to at least the genus and species level, catalogued and described according to its characteristics and preferably stating its origin

[EN 12322]

3.4.3

reference stocks

a set of separate identical cultures obtained in the laboratory by a single sub-culture from the reference strain either in the laboratory or from a supplier

[EN 12322]

3.4.4

working culture

a primary sub-culture from a reference stock (3.4.3)