
**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**

*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*



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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed every three years with a view to deciding whether it can be transformed into an International Standard.

Attention is drawn to the possibility that some of the elements of this Technical Specification may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 11133-1 was prepared by the European Committee for Standardization (CEN) in collaboration with ISO Technical Committee TC 34, *Agricultural food products*, Subcommittee SC 9, *Microbiology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this part of ISO/TS 11133, read "...this European Prestandard..." to mean "...this Technical Specification...".

ISO/TS 11133 consists of the following parts, under the general title *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*
- *Part 2: Practical implementation of the general guidelines on quality assurance of culture media in the laboratory*
- *Part 3: Performance testing*

Annexes A, B and C of this part of ISO/TS 11133 are for information only.

Contents	Page
Foreword	v
Introduction	v
1 Scope	1
2 Normative references	1
3 Terminology	1
3.1 General.....	1
3.2 Terminology of quality assurance	1
3.3 Terminology of culture media.....	2
3.4 Terminology for test organisms.....	5
4 Practices for quality control of culture media	5
4.1 Documentation	5
4.2 Storage.....	6
4.3 Laboratory preparation of media	7
4.4 Preparation for use.....	9
4.5 Disposal of media.....	10
5 Quality control of finished product	10
5.1 Physical quality control.....	10
5.2 Microbiological quality control	10
Annex A (informative) Designation of the components of the culture media in standards on microbiological analysis of food and animal feeding stuffs products	12
Annex B (informative) Guidance on preservation and maintenance of control strains	14
Annex C (informative) Quality assurance of culture media – trouble shooting	15
Bibliography	16

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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.

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Introduction

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.

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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 diagnostic medical devices – Culture media for microbiology – Performance criteria for culture media.*

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ISO 8402:1994, *Quality management and quality assurance – Vocabulary.*¹⁾

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]

1) This is under revision and will be combined with ISO 9000-1:1994 to become ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary.*

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

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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]

3.3.1 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.

3.3.2 Culture media classified by consistency

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]

3.3.3 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]

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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]

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)

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).

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[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

3.3.4 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]

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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)

4 Practices for quality control of culture media

4.1 Documentation

4.1.1 Documentation required from manufacturer

The following details should be available from the manufacturer:

- name of the medium, individual components and any supplements, and their product codes ;
- batch code ;