
**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**

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*Microbiologie des aliments — Lignes directrices pour la préparation et
la production des milieux de culture —*

*Partie 1: Lignes directrices générales d'assurance qualité pour la
préparation des milieux de culture en laboratoire*



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Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	1
3.1 General.....	1
3.2 Culture media	2
3.3 Test microorganisms.....	5
4 Quality assurance 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 Preservation and maintenance of control strains	10
5.1 General.....	10
5.2 Control strains from commercial sources	10
5.3 Laboratory-prepared reference stocks.....	10
5.4 Stock cultures	10
5.5 Working cultures.....	11
6 Performance testing of finished culture media	11
6.1 General.....	11
6.2 Physical quality control	11
6.3 Microbiological quality control.....	11
Annex A (informative) Designation of the components of the culture media in standards on microbiological analysis of food and animal feeding stuffs	13
Annex B (informative) Preparation of reference stock and working culture.....	15
Annex C (informative) Quality assurance of culture media — Troubleshooting	17
Bibliography	18

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.

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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 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;
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An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 11133-1 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 275, *Food analysis — Horizontal methods*, in collaboration with Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/TS 11133-1:2000), which has been technically revised.

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 guidelines on performance testing of culture media*

Introduction

Culture media are used in all traditional culture techniques and also for many alternative techniques. In the microbiology laboratory, many tests and procedures depend upon culture media being consistent and providing reproducible results. Many formulations of dehydrated culture media are commercially available and many more, designed for specific growth purposes, are described in the literature. In laboratories carrying out microbiological examinations of foods and feedstuffs, 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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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

1 Scope

This part of ISO/TS 11133 provides the general terminology related to quality assurance and specifies the minimum requirements for the preparation of culture media to be used for the microbiological analysis of products intended for human consumption or animal feeding.

It is also applicable to culture media to be used for the microbiological analysis of all kinds of water.

These requirements are applicable to four 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 to be remelted, supplemented and distributed;
- media prepared from commercially available dehydrated formulations;
- media prepared from their individual components.

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 7218, *Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations*

ISO 11133-2:2003, *Microbiology of food and animal feeding stuffs — Guidelines on preparation and production of culture media — Part 2: Practical guidelines on performance testing of culture media*

3 Terms and definitions

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

3.1 General

3.1.1

quality control

(food and feedstuffs) technical operations and activities that are used to fulfil the requirements for quality

3.1.2

batch of culture media

homogeneous and 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 performance testing, and which has been produced within one defined production period, having been assigned the same number

3.1.3

performance of culture media

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

3.2 Culture media

3.2.1

culture medium

formulation of substances, in liquid, semi-solid or solid form, which contain natural and/or synthetic constituents intended to support the multiplication (with or without inhibition of certain microorganisms), identification or preservation of viability of microorganisms

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

3.2.2

chemically defined medium

culture medium consisting only of chemical constituents of known molecular structure and degree of purity

3.2.3

chemically undefined medium

partially undefined medium

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

NOTE Harmonized designations for various chemically undefined components used in culture media are specified in Annex A.

3.2.4

liquid medium

culture medium consisting of an aqueous solution of one or more constituents

EXAMPLES Peptone water, nutrient broth.

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

NOTE 2 A liquid medium in tubes, flasks or bottles is commonly called “broth”.

3.2.5

solid medium

semi-solid medium

liquid medium containing solidifying substances (e.g. agar-agar, gelatin) in different concentrations

NOTE 1 Due to the worldwide use of media solidified with agar-agar, the shortened term “agar” is often used synonymously for solid media and therefore in connection with nouns, e.g. “plate count agar”.

NOTE 2 Solid media poured into Petri dishes are commonly called “plates”. Solid media poured into tubes or small bottles that are kept in slanted positions while the media are solidifying are often called “slants” or “slopes”.

3.2.6

transport medium

medium designed to preserve and maintain the viability of microorganisms without permitting significant multiplication in 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 maintenance, e.g. Stuart's or Amies's transport medium.

3.2.7**preservation medium**

medium designed to 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

EXAMPLES Dorset egg medium, nutrient agar slopes.

3.2.8**suspension medium**

medium designed to separate microorganisms from a test product into a liquid phase without multiplication or inhibition during the time of contact

EXAMPLE Peptone saline solution.

NOTE 1 Suspension media are also used for dilution purposes.

NOTE 2 Suspension medium is commonly called "diluent".

3.2.9**resuscitation medium**

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

EXAMPLE Buffered peptone water.

NOTE This may also be used as a pre-enrichment medium.

3.2.10**pre-enrichment medium
enrichment medium**

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

3.2.11**selective enrichment medium**

enrichment medium which allows the multiplication of specific microorganisms whilst partially or totally inhibiting the growth of other microorganisms

EXAMPLE Rappaport-Vassiliadis soya medium.

3.2.12**non-selective enrichment medium**

enrichment medium which allows the growth of a wide variety of microorganisms

EXAMPLE Nutrient broth.

3.2.13**isolation medium**

solid or semi-solid medium which allows the growth of microorganisms

EXAMPLE Plate count agar.

3.2.14**selective isolation medium**

isolation medium which allows growth of specific target microorganisms, while inhibiting other microorganisms

EXAMPLE XLD agar.

3.2.15

non-selective isolation medium

isolation medium which is not intended to selectively inhibit microorganisms

EXAMPLE Plate count agar.

3.2.16

**differential medium
characterization medium**

medium which permits the testing of one or more physiological/biochemical characteristics of the microorganisms for their identification

EXAMPLE MacConkey agar.

NOTE Differential media which can be used as isolation media are referred to as isolation/differential media, e.g. XLD agar, lactose TTC agar.

3.2.17

identification medium

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

EXAMPLE Bile esculin agar, TBX agar.

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

3.2.18

enumeration medium

selective or non-selective culture medium which enables a quantification of the microorganisms

NOTE An enumeration medium can include the properties of a resuscitation and/or enrichment medium.

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3.2.19

confirmation medium

medium which contributes partly or wholly to the identification or to the characterization of the microorganisms following a preliminary resuscitation, isolation and/or enrichment stage

EXAMPLE Kligler agar.

3.2.20

medium having multiple uses

medium assigned to several categories

EXAMPLE Blood agar is a resuscitation medium according to 3.2.9, an isolation medium according to 3.2.13 and a differential medium according to 3.2.16 used for detection of haemolysis.

3.2.21

ready-to-use medium

liquid, solid or semi-solid medium which is supplied in containers in ready-to-use form or ready-to-use after remelting

EXAMPLES Plates, tubes or other containers:

- complete ready-to-use medium;
- medium to be remelted, e.g. for use in pour-plate technique;
- medium to be remelted and dispensed before use, e.g. to be poured into Petri dishes;
- medium to be remelted, supplemented and dispensed before use, e.g. TSC medium, Baird Parker RPF agar.

3.2.22**medium prepared from commercially dehydrated formulations**

medium in dry form which requires rehydration and processing prior to use

EXAMPLES Powders, granules, lyophilized products, resulting in one of two kinds of media:

- a complete medium;
- an incomplete medium to which supplements are added before use.

3.2.23**medium prepared from individual components**

medium entirely produced from the complete formula of its specific ingredients

3.3 Test microorganisms**3.3.1****test organisms**

microorganisms generally used for performance testing of culture media

NOTE Test organisms are further defined according to their source (see 3.3.2 to 3.3.5).

3.3.2**reference strain**

microorganism obtained directly from an official culture collection and defined to at least the genus and species level, catalogued and described according to its characteristics and preferably originating from food or water as applicable

3.3.3**reference stock**

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

3.3.4**stock culture**

primary subculture from a reference stock

3.3.5**working culture**

subculture from a reference stock or stock culture or a reference material, certified or not

NOTE Reference material is a material containing a quantity of revivable microorganisms in a homogeneous, stable concentration. A certified reference material is a reference material for which the concentration is certified.

4 Quality assurance of culture media**4.1 Documentation****4.1.1 Documentation from manufacturer or producer**

The following details should be available from the manufacturer or producer:

- name of the medium, individual components and any supplements and their product codes;
- batch number;
- target pH of the complete medium;