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Standard Recommendation
S.R. CEN ISO/TS 11133-1:2009

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 11133-1:2009)

S.R. CEN ISO/TS 11133-1:2009

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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/TS 11133-1:2009)

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 (ISO/TS 11133-1:2009)

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/TS 11133-1:2008)

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The period of validity of this CEN/TS 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 CEN/TS can be converted into a European Standard.

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Part 1:

**General guidelines on quality assurance
for the preparation of culture media in the
laboratory**

*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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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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;
- 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 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.

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

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