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Microbiology of the food chain — Requirements and guidelines for conducting challenge tests of food and feed products —

Part 2: Challenge tests to study inactivation potential and kinetic parameters

Microbiologie de la chaîne alimentaire — Exigences et lignes directrices pour la réalisation des tests d'épreuve microbiologiques —

Partie 2: Tests d'inactivation pour étudier le potentiel d'inactivation et les paramètres de la cinétique d'inactivation

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 463, *Microbiology of the food chain,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 20976 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Under the general principles of the Codex Alimentarius on food hygiene, it is the responsibility of the food business operators (FBOs) to control microbiological hazards in foods and to manage microbial risks. Therefore, FBOs implement validated control measures, within the hazard analysis and critical control point (HACCP) system, and conducts studies in order to investigate compliance with the food safety criteria throughout the food chain.

In the framework of microbial risk assessment (MRA), several complementary approaches are developed to estimate risks posed by pathogens or spoilage microorganisms in the food chain. MRA is adopted by regulators under the auspices of the international agency for setting food standards. Challenge testing is one of the recognized approaches used to validate control measures within the HACCP system, as well as to assess microbiological safety and quality of food, food production processes, food storage conditions, and food preparation recommendations dedicated to consumers.

Therefore, this document provides technical rules, calculations and approaches to investigate the ability of an inoculated microorganism of concern to grow, survive or be inactivated in the raw materials, intermediate or end products under reasonably foreseeable food processes, storage and use conditions. The objective and the scope of the study are to determine the experimental design and the selection of the study conditions, and to assess the extent of microbial inactivation. Regulatory authorities can have different recommendations, and these differences have been included as much as possible. It is, however, possible that specific requirements need to be incorporated to get a regulatory approval of the challenge test.

As the growth and inactivation studies are clearly different, the ISO 20976 series consists of two parts, under the general title *Microbiology of the food chain — Requirements and guidelines for conducting challenge tests of food and feed products*:

— *Part 1: Challenge tests to study the growth potential, lag time and the maximum growth rate*;

— *Part 2: Challenge tests to study inactivation potential and kinetic parameters*.

The use of the ISO 20976 series involves expertise in relevant areas such as food microbiology, food science, food processing and statistics. The statistical expertise encompasses an understanding of sampling theory and design of experiments, statistical analysis of microbiological data, and overview of scientifically recognized and available mathematical concepts used in predictive modelling.

For practical reasons, the term “food” includes feed.

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Microbiology of the food chain — Requirements and guidelines for conducting challenge tests of food and feed products —

Part 2: Challenge tests to study inactivation potential and kinetic parameters

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1 Scope

This document specifies the protocols for conducting microbiological challenge tests for inactivation studies on vegetative bacteria and bacterial spores in the raw materials and ingredients, intermediate or end products.

The use of this document can be extended to yeasts which do not form mycelium.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 6887 (all parts), *Microbiology of the food chain — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination*

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

ISO 11133, *Microbiology of food, animal feed and water — Preparation, production, storage and performance testing of culture media*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
bacterial spore
resistant form of bacteria which is dormant until the *germination* (3.9) step

[SOURCE: ISO 20976-1:2019, 3.1]

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