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**Mikrobiologija v prehranski verigi - Zahteve in smernice za vodenje preskusa ustreznosti kmetijskih pridelkov in živilskih proizvodov - 2. del: Preskus ustreznosti za študijo inaktivacijskega potenciala in kinetičnih parametrov (ISO 20976-2:2022)**

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 (ISO 20976-2:2022)

Mikrobiologie der Lebensmittelkette - Anforderungen und Leitfaden zur Durchführung von Challenge-Tests bei Lebensmitteln und Futtermitteln - Teil 2: Challenge-Tests zur Untersuchung von Inaktivierungspotenzial und kinetischer Parameter (ISO 20976-2:2022)

Microbiologie de la chaîne alimentaire - Exigences et lignes directrices pour la réalisation des tests d'épreuve microbiologique - Partie 2: Tests d'inactivation pour étudier le potentiel d'inactivation et les paramètres de cinétique (ISO 20976-2:2022)

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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 (ISO 20976-2:2022)

Microbiologie de la chaîne alimentaire - Exigences et  
lignes directrices pour la réalisation des tests  
d'épreuve microbiologique - Partie 2: Tests  
d'inactivation pour étudier le potentiel d'inactivation  
et les paramètres de cinétique (ISO 20976-2:2022)

Mikrobiologie der Lebensmittelkette - Anforderungen  
und Leitfaden zur Durchführung von Challenge-Tests  
bei Lebensmitteln und Futtermitteln - Teil 2:  
Challenge-Tests zur Untersuchung von  
Inaktivierungspotenzial und kinetischer Parameter  
(ISO 20976-2:2022)

This European Standard was approved by CEN on 19 September 2022.

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## European foreword

This document (EN ISO 20976-2:2022) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 463 "Microbiology of the food chain" the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.

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## Endorsement notice

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**Microbiology of the food chain —  
Requirements and guidelines for  
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feed products —**

Part 2:

**Challenge tests to study inactivation  
potential and kinetic parameters***Microbiologie de la chaîne alimentaire — Exigences et lignes  
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## ISO 20976-2:2022(E)

## 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](http://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](http://www.iso.org/patents)).

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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](http://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](http://www.iso.org/members.html).

## 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.

