ICS 07.100.30 SLOVENSKÁ TECHNICKÁ NORMA Október 2019

STN	**Mikrobiológia potravinárskeho reťazca Požiadavky a pokyny na sústreďovanie záťažových skúšok potravinárskych výrobkov a krmív Časť 1: Záťažové skúšky na štúdium rastového potenciálu, časového oneskorenia a maximálnej miery rastu (ISO 20976-1: 2019)**	**STN EN ISO 20976-1** 56 1001

Microbiology of the food chain - Requirements and guidelines for conducting challenge tests of food and feed products - Part 1: Challenge tests to study growth potential, lag time and maximum growth rate (ISO 20976-1:2019)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 09/19

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English Version

Microbiology of the food chain - Requirements and guidelines for conducting challenge tests of food and feed products - Part 1: Challenge tests to study growth potential, lag time and maximum growth rate (ISO 20976-1:2019)

Microbiologie de la chaîne alimentaire - Exigences et lignes directrices pour la réalisation des tests d'épreuve microbiologique - Partie 1: Tests de croissance pour étudier le potentiel de croissance, le temps de latence et le taux de croissance maximal (ISO 20976-1:2019)

Mikrobiologie der Lebensmittelkette - Leitfaden zur Durchführung von Challengetests bei Lebensmitteln und Futtermitteln - Teil 1: Challengetests zur Untersuchung von Wachstumspotential, der Verzögerungszeit und maximaler Wachstumsrate (ISO 20976-1:2019)

This European Standard was approved by CEN on 21 January 2019.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 20976-1:2019) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 275 “Food analysis - Horizontal methods” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by October 2019, and conflicting national standards shall be withdrawn at the latest by October 2019.

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

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Endorsement notice

The text of ISO 20976-1:2019 has been approved by CEN as EN ISO 20976-1:2019 without any modification.

INTERNATIONAL STANDARD

ISO 20976-1

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

Part 1: Challenge tests to study growth potential, lag time and maximum growth rate

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

Partie 1: Tests de croissance pour étudier le potentiel de croissance, le temps de latence et le taux de croissance maximal

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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).

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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*.

A list of all the 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.

Introduction

Under the general principles of the Codex Alimentarius on food hygiene, it is the responsibility of food business operators (FBOs) to control microbiological hazards in foods and to manage microbial risks. Therefore, FBOs implement validated control measures[11] within the hazard analysis and critical control point (HACCP) system, and conduct 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 for consumers.

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

As growth and inactivation kinetics 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 growth potential, lag time and maximum growth rate*

— *Part 2: Challenge tests to study inactivation potential and kinetics parameters* (to be developed)

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. Even though many mathematical models are available to describe and predict bacterial growth, the gamma-concept (γ-concept)[22] is particularly useful for further simulations using the data generated from the challenge test, e.g. to assess the growth at storage temperatures other than the one(s) tested, or in helping to design better food formulations and storage conditions, and thus improving the microbial quality and/or safety of the food under consideration.

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

INTERNATIONAL STANDARD **ISO 20976-1:2019(E)**

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

Part 1:
Challenge tests to study growth potential, lag time and maximum growth rate

1 Scope

This document specifies protocols for conducting microbiological challenge tests for growth studies on vegetative and spore-forming bacteria in raw materials and intermediate or end products.

The use of this document can be extended to yeasts that 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 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*

ISO 18787:2017, *Foodstuffs — Determination of water activity*

