SLOVENSKI STANDARD
oSIST prEN ISO 20976-2:2021

01-november-2021

Mikrobiologija v prehranski verigi - Zahteve in smernice za vodenje izzivnega preskusa pri kmetijskih pridelkih in živilskih proizvodih - 2. del: Izzivni preskus za raziskavo inaktivacijskega potenciala in kinetičnih parametrov (ISO/DIS 20976-2:2021)

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/DIS 20976-2:2021)

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/DIS 20976-2:2021)

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 kinétique (ISO/DIS 20976-2:2021)

Ta slovenski standard je istoveten z: **prEN ISO 20976-2**

ICS:

07.100.30	Mikrobiologija živil	Food microbiology

oSIST prEN ISO 20976-2:2021 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 20976-2

ISO/TC **34**/SC **9**

Secretariat: **AFNOR**

Voting begins on:
2021-09-13

Voting terminates on:
2021-12-06

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 microbiologique —

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

ICS: 07.100.30

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 20976-2:2021(E)

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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

Published in Switzerland

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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).

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

The committee responsible for this document is 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.

Introduction

Under the general principles of the Codex Alimentarius on food hygiene, it is the responsibility of the Food Business Operators (FBO) to control microbiological hazards in foods and to manage microbial risks. Therefore, the FBO shall implement validated control measures, 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 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 may 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, this International Standard consists of two parts, under the general title Microbiology of the food chain — Requirements and guidelines for conducting challenge-test:

— 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.

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

1 Scope

This document sets out 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 terminological databases for use in standardization at the following addresses:

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

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

3.1
bacterial spore
resistant form of bacteria which is dormant until the germination step

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

3.2
batch
group or set of identifiable food obtained through a given process under practically identical circumstances and produced in a given place within one defined production period

Note 1 to entry: The batch is determined by parameters established beforehand by the organization and may be described by other terms, e.g. lot.

[SOURCE: Regulation (CE) n°2073/2005 [7]]

3.3
bulk product
products that are not separated into individual items or units

[SOURCE: ISO/TS 17728:2015, 3.3.1]

3.4
challenge test
study of the growth or inactivation of microorganism(s) artificially inoculated in a food

[SOURCE: ISO 20976-1:2019, 3.5]

3.5
control unit
unit of food identical to the test unit (3.34) but not artificially inoculated (used as a blank)

[SOURCE: ISO 20976-1:2019, 3.4 modified- "contaminated" has been replaced by "inoculated"]

3.6
D value
decimal reduction
time or dose required to achieve reduction of 90 % of the tested microorganism under stated conditions (e.g.: temperature, pH or chemical composition) in case of Log linear inactivation kinetics

3.7
δ value
first decimal reduction
time or dose required to achieve the first reduction of 90 % of the tested microorganism under stated conditions (e.g.: temperature, pH or chemical composition) in case of non Log linear inactivation kinetics

3.8
experimental datapoint
result of analysis of a test unit per unit weight, per unit volume, or per unit area

Note 1 to entry: Note to entry: the enumeration results may be expressed in $\log_{10}$ or Most Probable Number (MPN)

[SOURCE: ISO 20976-1:2019, 3.6]

3.9
germination
mechanism in which a bacterial spore (3.1) initiates its transformation to a vegetative cell (3.31)

[SOURCE: ISO 20976-1:2019, 3.9 modified "starts becoming a vegetative cell" replaced by "initiates its transformation"]

3.10
inactivation kinetics
change over time in the concentration of the target microorganism subjected to an inactivation process

3.11
inactivation parameters
mathematical estimates that describe the resistance/sensitivity of the target organism to the treatment, obtained by fitting primary and secondary models.

Note 1 to entry: Note to entry examples of these parameters are D, δ, p for the primary models and z for the secondary models.

3.12
inactivation potential
□ value
log kill
log reduction
difference in the log concentration (log_{10} cfu/g or ml or cm^2) of the target microorganism between an earlier and a later time point expressed as log_{10}

3.13
inactivation process
treatment used to kill or inactivate the target microorganism

3.14
inoculum
microbial suspension at the desired concentration used to contaminate test units

[SOURCE: ISO 20976-1:2019, 3.12]

3.15
k value
slope of the inactivation curve

3.16
p value
parameter describing the shape of the inactivation curve

3.17
pH value
measure of the concentration of acidity or alkalinity of a material in an aqueous solution

[SOURCE: ISO 5127:2001:2019, 6.2.29]

3.18
primary model
mathematical model describing the changes of microbial counts as a function of time

[SOURCE: ISO 20976-1:2019, 3.16]

3.19
organizing laboratory
laboratory with responsibility for managing the challenge tests

[SOURCE: ISO 20976-1:2019, 3.17]

3.20
pilot facility
a manufacturing location used to run an experiment or test before introducing more widely

3.21
processing facility
location where products are made on a larger scale

3.22
sampling
selection of one or more units or portions of food such that the units or portions selected are representative of that food

[SOURCE: ISO 20976-1:2019, 3.18]

3.23
sampling point(s)
time(s) at which the test units are taken for analyses

Note 1 to entry: Note to entry: when assessing inactivation kinetics these are represented as experimental datapoints on the inactivation graph

[SOURCE: ISO 20976-1:2019, 3.19]

3.24
secondary model
mathematical model describing the effects of the inactivation process factors (such as temperature, pH, a_w) on the parameters of the primary model (3.18) (e.g.: D, δ)

[SOURCE: ISO 20976-1:2019, 3.20 modified – environmental factors have been changed by inactivation process factors]

3.25
sporulation
mechanism by which vegetative cell forms spore

[SOURCE: ISO 20976-1:2019, 3.21]

3.26
surrogate
non pathogenic microorganism that has similar or more robust survival capability compared to the pathogen of concern both in the matrix and under the processing conditions being studied

3.27
survival
state of continuing to live or exist without significant increase or decrease in viability

3.28
target reduction level
target inactivation level expressed in $\log_{10}$

3.29
t_0
time at which the treatment starts

3.30
t_{end}
time at which the treatment is finished

3.31
t_{inoc}
time at which the microorganism is inoculated in the food

3.32
txD
time of treatment needed for x log reduction of the target microorganism