

This is a preview of "ISO 20976-1:2019". [Click here to purchase the full version from the ANSI store.](#)

First edition
2019-03

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*



Reference number
ISO 20976-1:2019(E)

© ISO 2019



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of "ISO 20976-1:2019". Click here to purchase the full version from the ANSI store.

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Principle	4
4.1 General.....	4
4.2 Estimation of the growth potential.....	6
4.3 Estimation of the growth kinetics parameters (lag time and maximum growth rate).....	7
5 Apparatus	7
6 Culture media and reagents	7
7 Study design and sampling	8
7.1 General.....	8
7.2 Setting decision criteria for growth potential.....	8
7.3 Number of batches and selection criteria.....	8
7.4 Preparation of the test units.....	8
7.5 Number of test units to be inoculated.....	9
8 Selection of strains	9
9 Preparation of the inoculum	10
9.1 General.....	10
9.2 Preparation of the vegetative cell suspensions.....	10
9.3 Preparation of the spore suspensions.....	10
10 Inoculation of the tests units	10
11 Controls	11
11.1 Food controls.....	11
11.2 Control units.....	11
12 Storage of the test units	12
12.1 General.....	12
12.2 Estimation of growth potential.....	12
12.3 Estimation of growth kinetics parameters (lag time and growth rate).....	12
13 Analysis	12
14 Expression of the results	13
14.1 General.....	13
14.2 Growth potential (Δ).....	13
14.3 Growth kinetics parameters (lag time and growth rate).....	14
15 Test report	14
15.1 General.....	14
15.2 Aim of the study and type of challenge test.....	14
15.3 Experimental protocol.....	15
15.4 Sample analysis.....	15
15.5 Results.....	15
15.6 Conclusions.....	16
15.7 Reference documents.....	16
Annex A (informative) Inter-batch variability assessment based on pH and a_w	17
Annex B (normative) Minimum number of units to prepare for the challenge test study	18
Annex C (informative) Examples of protocols to prepare inocula	19

This is a preview of "ISO 20976-1:2019". [Click here to purchase the full version from the ANSI store.](#)

Annex D (informative) Examples of how to estimate growth potential, lag time and maximum growth rate from results of challenge tests	22
Annex E (informative) Use of simulation to assess a microbial population under different temperature conditions	26
Bibliography	27

This is a preview of "ISO 20976-1:2019". [Click here to purchase the full version from the ANSI store.](#)

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*.

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.