ISO/FDIS 23691:2025(E(en)

ISO/TC 34/SC 9/WG 19

Secretariat: AFNOR

Date: 2025-05-2708-11

Microbiology of the food chain — Determination and use of cardinal values

FDIS stage

ISO Copyright Office
CP 401 • CH-1214 Vernier, Geneva
Phone: + 41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org
Published in Switzerland.

Contents

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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).

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 the food business operators (FBOs) to control microbiological hazards in foods and to manage microbial risks. Therefore, it is the responsibility of the FBO to 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. Predictive microbiology is one of the recognized scientific 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, procedures and calculations to estimate the cardinal values of a microorganism of concern and use them in combination with challenge test results to simulate and predict its growth in raw materials, intermediate products or end products under reasonably foreseeable food processes, storage and use conditions.

To do so, this document includes the following sections:

— to identify the environmental factor(s) in scope (e.g. temperature, *pH*, a_w, organic acids);

— to define the appropriate experimental design;

— to estimate the cardinal values of a microorganism in broth medium;

— to perform a challenge test in the matrix of interest and derive the food correction factor and the maximum microbial population density;

— to use the cardinal values and the food correction factor to predict the growth of the studied microorganism in different conditions of interest (e.g. changes in time and temperature throughout the chill chain, changes in formulation with addition of organic acids or preservatives).

Regulatory authorities can have specific recommendations, and these differences have been included as much as possible in this document. It is, however, possible that additional requirements are needed to get a regulatory approval of the study.

The use of this document involves expertise from the organizing laboratories in relevant fields such as food microbiology, predictive microbiology and statistics. This 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 microbiology.

Microbiology of the food chain — Determination and use of cardinal values

WARNING — In order to safeguard the health of laboratory personnel, it is essential that tests for detecting target microorganism(s) are only undertaken in properly equipped laboratories, under the control of a skilled microbiologist, and that great care is taken in the disposal of all incubated materials. Persons using this document should be familiar with normal laboratory practice. This document does not purport to address all of the safety aspects, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices.

1 Scope

This document establishes basic principles and specifies requirements and methods to determine the cardinal values of bacteria and yeast strains and use them to predict microbial growth.

The four main steps of the approach are: ~~(1) Determination of the cardinal values in culture medium, (2) Determination of the correction factor in the target food, (3) Validation of the model and (4) Simulations.~~

a) determination of the cardinal values in culture medium;

b) determination of the correction factor in the target food;

c) validation of the model;

d) simulations.

Four environmental factors are considered: temperature, *pH*, a_w and inhibitors (e.g. organic acids).

NOTE 1 Microbial competition is not considered as an inhibitor in this document and can be addressed by proper modelling approaches.

The determination of cardinal values is performed in a two-step approach:

— the determination of maximum specific growth rates of the studied strain grown in broth under a defined range of values of the studied environmental factor(s);

— the use of recognized predictive microbiology secondary models to fit the obtained experimental data to obtain the cardinal values.

The use of cardinal values in microbial growth simulation is based on predictive microbiology primary and secondary models. The cardinal values are combined with challenge test data to consider the matrix effect. Depending on the goal of the growth simulation, it is important to account for variation of cardinal values between strains within a bacterial or yeasts species.

Cardinal values are a good indicator of a strain growth ability for the studied environmental factors. They are therefore used as criteria to select strains, in addition to their origin and virulence, when performing growth challenge tests (see ISO 20976-1) or in methods validation (see ISO 16140 series).