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Microbiology of the food chain - Whole genome sequencing for typing and genomic characterization of bacteria - General requirements and guidance (ISO 23418:2022)

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ICS 07.100.30

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23418

June 2022

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English Version

Microbiology of the food chain - Whole genome sequencing for typing and genomic characterization of bacteria - General requirements and guidance (ISO 23418:2022)

Microbiologie de la chaîne alimentaire - Séquençage de génome entier pour le typage et la caractérisation génomique des bactéries - Exigences générales et recommandations (ISO 23418:2022)

Mikrobiologie der Lebensmittelkette - Vollständige Genomsequenzierung zur Typisierung und genomischen Charakterisierung von Bakterien in Lebensmitteln - Allgemeine Anforderungen und Leitfaden (ISO 23418:2022)

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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of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

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Endorsement notice

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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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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).

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Introduction

Next generation sequencing (NGS) provides rapid, economical and high-throughput access to microbial whole genome sequences and is being applied to an expanding number of problems in food microbiology. Whole genome sequences are representations of the biological potential of the sequenced organism at single base resolution. Whole genome sequencing (WGS) offers significant advantages over existing technologies (e.g. serotyping, pulsed field gel electrophoresis, antibiotic resistance phenotype) for many applications. WGS-based analyses are used by public health laboratories to detect outbreaks, and to detect mutations, genes and other genetic features to characterize virulence and survival potential. Within the food industry, there is interest in using whole genome sequences to characterize bacterial isolates from ingredients and environmental surfaces, to better understand their origin and ecology, and to update procedures to reduce risk. Some companies have developed, or are developing, the capacity to collect and analyse whole genome sequence data. Others are turning to third-party laboratories to perform these services, as they have done for other microbiological analyses.

This document provides guidance for both the laboratory and bioinformatic components of whole genome sequences and associated metadata for bacterial foodborne microorganisms sampled along the food chain (e.g. ingredients, food, feed, production environment). Although microbiology of the food chain includes viruses and fungi, this document is only intended for bacteria. This document is intended to be applicable to all currently available next generation DNA sequencing technologies. It may be applied to analysis of whole genome sequence data with proprietary, open-source or custom software. It is not intended to specify sequencing chemistries, analytical methods or software. This document defines laboratory, data and metadata stewardship practices to ensure that analyses are clearly reported, transparent and open to inquiry. This document is for use by laboratories to develop their management systems for quality and technical operations. Laboratory customers and regulatory authorities can also use it in confirming or recognizing the competence of laboratories. This document can also be applied in other domains (e.g. environment, human health, animal health).

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Microbiology of the food chain — Whole genome sequencing for typing and genomic characterization of bacteria — General requirements and guidance

WARNING — In order to safeguard the health of laboratory personnel, it is essential that handling of bacterial cultures is 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 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 specifies the minimum requirements for generating and analysing whole genome sequencing (WGS) data of bacteria obtained from the food chain. This process can include the following stages:

a) handling of bacterial cultures;

b) axenic genomic DNA isolation;

c) library preparation, sequencing, and assessment of raw DNA sequence read quality and storage;

d) bioinformatics analysis for determining genetic relatedness, genetic content and predicting phenotype, and bioinformatics pipeline validation;

e) metadata capture and sequence repository deposition;

f) validation of the end-to-end WGS workflow (fit for purpose for intended application).

This document is applicable to bacteria isolated from:

— products intended for human consumption;

— products intended for animal feed;

— environmental samples from food and feed handling and production areas;

— samples from the primary production stage.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

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

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

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