# SLOVENSKI STANDARD
# SIST EN ISO 23418:2022

**01-september-2022**

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**Mikrobiologija v prehranski verigi - Sekvenciranje celotnega genoma za tipizacijo in genomsko karakterizacijo bakterij - Splošne zahteve in smernice (ISO 23418:2022)**

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

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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)

**Ta slovenski standard je istoveten z:** **EN ISO 23418:2022**

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**ICS:**

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|---|---|---|
| 07.100.30 | Mikrobiologija živil | Food microbiology |

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

# EN ISO 23418

June 2022

ICS 07.100.30

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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## European foreword

This document (EN ISO 23418:2022) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 463 “Microbiology of the food chain” the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

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INTERNATIONAL STANDARD

**ISO 23418**

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

*Microbiologie de la chaîne alimentaire — Séquençage de génome entier pour le typage et la caractérisation génomique des bactéries — Exigences générales et recommandations*

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# Foreword

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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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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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**3.1**
**adapter sequence**
DNA with a known sequence that is added to the end of a DNA library fragment to facilitate the sequencing process (e.g. annealing to a flow cell)

**3.2**
**annotation**
process of identifying genes and other features on genome *assemblies* (3.4)

**3.3**
**antibiogram**
summary of antimicrobial susceptibility testing results performed for a specific microorganism, usually represented in tabular form

**3.4**
**assembly**
output from process of aligning and merging sequencing *reads* (3.38) into larger contiguous sequences (*contigs* (3.10))

**3.5**
**base calling**
process of assigning nucleotides and quality scores to positions in sequencing *reads* (3.38)

**3.6**
**bioinformatics**
collection, storage and analysis of biological data including sequences

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**3.7**
**bioinformatics pipeline**
individual programs, scripts or pieces of software linked together, where output from one program is used as input for the next step in data processing

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**3.8**
**carryover-contamination**
sample contamination linked to previous experiments, transferred to the current analysis (e.g. carryover-contamination from amplification products in prior polymerase chain reaction (PCR) experiments to the current PCR analysis, or carryover-contamination of previously sequenced samples from one sequencing run to another)

**3.9**
**Chemical Entities of Biological Interest Ontology**
**ChEBI**
*ontology* (3.35) for describing small chemical compounds

**3.10**
**contig**
contiguous stretch of DNA sequence that results from the *assembly* (3.4) of smaller, overlapping DNA sequence *reads* (3.38)

**3.11**
**controlled vocabulary**
finite set of values that represent the only allowed values for a data item

[SOURCE: ISO 11238:2018, 3.18, modified — Note 1 to entry deleted.]

**3.12**
**coverage**
number of times that a given base position is read in a sequencing run

Note 1 to entry: The number of *reads* (3.38) that cover a particular position.


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[SOURCE: ISO 20397-2:2021, 3.6, modified — Admitted term “coverage depth” deleted.]

**3.13**
**cross-contamination**
contamination of a sample (bacterial *isolate* (3.23) or DNA) with other samples during the preparation of a sequencing run

**3.14**
**DNA sample**
portion of DNA extracted from the processed sample

**3.15**
**draft assembly**
*de novo* genome *assembly* (3.4) consisting of *contigs* (3.10) with no implied order, typically generated using whole genome shotgun sequencing with a short-read technology

**3.16**
**Environment Ontology**
**EnvO**
*ontology* (3.35) for describing environmental features and habitats

**3.17**
**FoodEx2 Ontology**
**FoodEx2**
standardized food classification and description system developed by the European Food Safety Authority (EFSA)

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**3.18**
**Food Ontology**
**FoodOn**
*ontology* (3.35) for describing food products, animal feed and food processing

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**3.19**
**Gazetteer Ontology**
**GAZ**
*ontology* (3.35) for describing geographical locations

**3.20**
**index**
oligonucleotide sequences used in the process of library preparation to tag or barcode DNA from specific samples, so that multiple samples (i.e. multiple *libraries* (3.25)) can be combined (multiplexed) in a pool of libraries and analysed in a single sequencing reaction

**3.21**
**International Nucleotide Sequence Database Collaboration**
**INSDC**
initiative operated by the DNA Database of Japan (DDBJ), the European Molecular Biology Laboratory, European Bioinformatics Institute (EMBL-EBI) and the National Center for Biotechnology Information (NCBI)

**3.22**
**International Organization for Standardization whole genome sequencing slim**
**ISO WGS Slim**
*ontology* (3.35) slim containing interoperable fields and terms pertaining to the use of *WGS* (3.49) for microbiology of the food chain

**3.23**
**isolate**
population of bacterial cells in pure culture derived from a single *strain* (3.45)

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