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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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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

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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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3.24
kmer
possible sequence of length *k* that is contained in a whole genome sequence

3.25
library
collection of genomic DNA fragments from a single *isolate* (3.23) intended for determining genome sequence(s)

Note 1 to entry: A collection of libraries, each of a single isolate, is called a "pool of libraries" and is loaded on a sequencer to be analysed. This multiplexing of libraries would still provide the result for a single isolate if unique indices are used for each individual single isolate's library preparation.

Note 2 to entry: A library of mixed DNA, i.e. originating from a mixture of multiple species, can be made. However, this is not within the scope of this document as this refers to metagenomics sequencing.

3.26
management system
quality, administrative and technical systems that govern the operations of an organization

Note 1 to entry: For the purposes of this document, "organization" refers to the laboratory.

3.27
mapping
use of software to align sequencing *reads* (3.38) to reference sequences

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3.28
metadata
data that defines and describes other data

[SOURCE: ISO/IEC 11179-1:2015, 3.2.16]

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3.29
minimal data for matching
MDM
information required to describe the sample source and provenance of a genomic sequence, as defined by the Global Microbial Identifier[1], and implemented by the *International Nucleotide Sequence Database Collaboration* (3.21)

3.30
multi-locus sequence typing
MLST
method of genomic analysis that identifies nucleotide variants within predefined sets of loci

Note 1 to entry: Originally used for seven loci, it is now also applied to either core genome loci for cgMLST or whole genome loci for wgMLST.

3.31
N50
length (N) such that sequence *contigs* (3.10) of N or longer include half the bases in the *assembly* (3.4)

3.32
NCBITaxon
automatic translation of the National Center for Biotechnology Information (NCBI) taxonomy database into obo/owl

3.33
NG50
length (N) of DNA such that sequence *contigs* (3.10) of N or longer include half the bases in the genome

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3.34
Open Biological and Biomedical Ontology Foundry
OBO Foundry
collection of *ontologies* (3.35) created by a collective of ontology developers that are committed to collaboration and adherence to shared principles

3.35
ontology
controlled vocabulary (3.11) arranged in a hierarchy, where the terms are connected by logical relationships

3.36
ontology slim
set of ontology fields and terms annotated as part of a particular collection, often for a specific purpose, which may be extracted to create a file distinct from the original *ontology* (3.35)

3.37
Phred sequence quality score
Q
measure of the probability (*P*) that a base is incorrectly assigned at a given position in the sequence expressed as:

$$Q = -10 \lg P$$

Note 1 to entry: A score of Q30 indicates that there is a 1 in 1 000 chance that a base is incorrectly assigned (i.e. the base call is 99,9 % accurate).

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3.38
read
nucleotide sequence inferred from a fragment of DNA or RNA

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3.39
sequence repository
database in which *whole genome sequencing* (3.49) datasets are stored and managed

Note 1 to entry: A public repository allows unrestricted access to the data, while a private or federated repository restricts access to the data.

3.40
sequencing replicate
<biological> sequencing a different colony from the same *isolate* (3.23) obtained from the same sample material, to assess biological variation

3.41
sequencing replicate
<technical> resequencing of the same biological sample or *library* (3.25) to assess sequence variation due to instrumentation and protocol

3.42
serotype
classification scheme based on the antigenic protein detection or sequence-based detection of genes encoding bacterial surface molecules

3.43
single nucleotide polymorphism
SNP
single nucleotide variant (3.44) that passes a particular quality or frequency threshold

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3.44
single nucleotide variant
SNV
differences between the nucleotides at the same genomic position of two or more *isolates* (3.23)

3.45
strain
descendants of a single isolation in pure culture, usually derived from a single initial colony on a solid growth medium

Note 1 to entry: A strain may be considered an *isolate* (3.23) or group of isolates that may be distinguished from other isolates of the same genus and species by phenotypic and genotypic characteristics.

Note 2 to entry: See Reference [2].

3.46
validation
establishment of the performance characteristics of a method and provision of objective evidence that the performance requirements for a specified intended use are fulfilled

[SOURCE: ISO 16140-1:2016, 2.81]

3.47
validated data entry
automated process ensuring that data entered into a repository are correct

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3.48
verification
demonstration that a validated method functions in the user's hands according to the method's specifications determined in the validation study and is fit for its intended purpose

[SOURCE: ISO 16140-3:2021, 3.21, modified — Note 1 to entry deleted.]

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3.49
whole genome sequencing
WGS
process of determining the DNA sequence of an organism's genome using total genomic DNA as input

4 Principle

4.1 General

WGS analyses of bacteria along the food and feed chain consists of culturing the pure bacterial isolate, DNA isolation performed in a microbiological laboratory, sequencing steps conducted in an appropriate sequencing environment and bioinformatics analysis performed in a distinct computational environment.

NOTE The microbiology laboratory, the sequencing facility and the bioinformatics facility can be the same organization.

4.2 Laboratory operation: sample preparation and sequencing

Sample preparation and sequencing should include the following steps:

a) Information about the isolates being sequenced, including barcodes for multiplexed samples, is entered into the appropriate record systems, such as a laboratory information management system (LIMS) or sample description worksheets, or both.

b) Pure isolates (identified at least to the genus level and ideally to the species level) are cultured and genomic DNA is extracted.

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c) DNA sequencing libraries are prepared from quality controlled genomic DNA (see Table A.1 for guidance on DNA quantity and quality metrics). This process should include:

   1) DNA fragmentation, if required for the applied sequencing technology;

   2) ligation of indices and adapters, consistent with the applied sequencing technology's protocols;

   3) quantification, normalization and quality control of the resulting library;

   4) pooling of libraries in the case of multiplexed sequencing runs.

d) Libraries (i.e. pool of libraries) are sequenced.

e) Quality metrics produced by the sequencing instrument are ideally recorded for each run to allow monitoring of the performance.

4.3 Bioinformatics analysis

4.3.1 General

Pipelines for bioinformatics analysis may focus on *in silico* predictions of phenotype (e.g. virulence) or detecting clusters of genetically similar isolates (i.e. same strain, sequence type or serotype). Pipelines based on comparative approaches may be used to detect the presence and states of markers in raw and assembled sequencing data to make *in silico* strain (e.g. sequence type) and phenotype predictions.

Sequence data for multiple isolates may be analysed using SNP, MLST or kmer distance analysis methods to identify clusters of closely related bacteria. Results from these analyses may be used to infer relationships between isolates, which may be illustrated with phylogenetic trees and dendrograms.

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4.3.2 SNP analyses

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For SNP analyses, reads are mapped to a reference sequence or reads are assembled into contigs that are compared. To determine SNPs, SNVs are quality-filtered to identify SNP positions.

4.3.3 MLST analyses

For MLST analyses, reads are assembled or mapped. Alleles are identified, quality-filtered and compared to a cgMLST or wgMLST database.

4.3.4 Kmer distance analysis

Sequence data for multiple isolates may be analysed using kmer distance methods to identify clusters of related bacteria. Kmer analyses have the advantage of being very fast but have some limitations, notably in terms of precision (i.e. they are applicable in species determination, but not recommended for detailed source tracking analysis of closely related strains).

4.4 Metadata formats and sequence repository deposition

Metadata records shall be created and safely stored for all sequences. Sequence data and corresponding metadata should be consistently formatted and documented. These metadata may be shared solely at the discretion of the metadata owner. Sequence data and its corresponding metadata shall be subject to security considerations, cost and benefits, intellectual property rights, confidential business information, contract restriction or other binding written agreements.

NOTE Licensing or a privacy policy, or both, can be applied to metadata or sequence data, or both, to protect private or proprietary information.

To promote data stewardship best practices[3], this document provides optional metadata reporting formats which are harmonized to a community data standard (e.g. MDM or OBO Foundry ontologies). These formats and standards facilitate reproducibility and common understanding of terminology. An

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ISO WGS Slim was created to format and provide values for the recommended metadata fields. WGS and selected metadata may be transferred (uploaded) to a publicly accessible database.

4.5 Validation and verification of WGS workflow

The entire WGS workflow shall be validated to provide assurance that the methods are fit for intended use.

NOTE More details on the validation and verification of the WGS workflow are given in Clause 10 and Table 4.

5 General laboratory guidance

5.1 Bacterial isolation and DNA extraction

Bacterial isolation and DNA extraction should be performed in a general microbiological laboratory adapted to work with the specific bacteria, including pathogens. For sequencing library preparation that involves DNA amplification using polymerase chain reaction (PCR), pre- and post-PCR steps should be carried out in different or segregated areas of the laboratory to avoid carryover-contamination.

5.2 Laboratory environment

Air movements, vibration, temperature and humidity can interfere with the performance of many sequencers and should be considered in the placement of the equipment in the laboratory. Laboratories should consult the sequencer manufacturer's site preparation guide for specific guidance.

5.3 Standard operating procedures and nonconforming work

Laboratories should maintain and adhere to standardized operating procedures (SOPs), workflow documents, reagent inventory controls and equipment maintenance logs. SOPs should include procedures for using positive and negative controls for the DNA extraction, sequence library preparation and sequencing steps. SOPs should include procedures for monitoring operations for run quality and errors (sample misidentification or cross-contamination).

In the case of sample misidentification or contamination, the root cause of errors in sequencing shall be investigated:

a) ensuring that runs containing misidentified samples, or samples contaminated with multiple strains, are not used for bioinformatics analysis for sample interpretation or uploaded to databases;

b) implementing measures to maintain quality and prevent recurrence of errors.

5.4 Laboratory information management system

Sample information shall be captured using a LIMS or similar system of documenting and tracking information.

5.5 Laboratory competence

Laboratories should maintain records documenting training, education and proficiency for individuals performing sequencing and bioinformatics analysis, and sample retention policy.

The laboratory should monitor its performance for WGS analysis by comparison with results of other laboratories, where available and appropriate. This monitoring should be planned and reviewed and include, but not be limited to, one of the following, ideally annually:

a) participation in a proficiency testing programme;

b) participation in interlaboratory comparisons other than proficiency testing;

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c) verification of the analytical process by introducing "blind" samples or samples whose characteristics are not known by the operator.

Data (e.g. sequence data, run metrics, result reports provided by the organizing institution) from these monitoring activities should be analysed, used to control and, if applicable, used to improve the laboratory's activities. If the results of the analysis of data from these monitoring activities are found to be outside predefined criteria, appropriate actions should be taken to prevent incorrect results from being used for sample analysis.

6 Laboratory operations

6.1 Sample preparation and storage

Any material to be sequenced (bacterial isolate or extracted genomic DNA) should be handled and stored in a way that minimizes the risk of sample degradation, misidentification and cross-contamination.

6.2 Bacterial isolates

Bacterial isolates should be stored and cultured by processes that minimize the potential for introducing genetic changes (e.g. loss of plasmids or polymorphisms introduced through culture and passaging). If the laboratory receives a bacterial isolate, the laboratory shall ensure the purity of the isolate and ideally confirm species before subsequent steps are performed. If there is concern that potentially unstable elements (e.g. plasmids) can be lost from a sample during passage, then sequences should ideally be collected from at least two biological replicates. The number of single colony passages performed after receipt of the isolate should be noted in the sample metadata. Bacterial isolates should be archived using methods such as freezing as a glycerol stock at −80 °C.

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6.3 DNA isolation

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For bacterial DNA isolation, an extraction procedure should be selected that is suitable for the respective organism and provides DNA of sufficient quality with regard to the sequencing platform used. Bacterial DNA isolation is influenced by a number of factors including cell type (Gram positive or negative), growth phase (early, mid, late log or stationary) and culture medium. The quantity and quality of DNA should be assessed and documented. Storage conditions will influence DNA integrity and library preparation for certain sequencing technologies.

NOTE Some DNA extraction methods are better than others for the recovery of plasmids. If plasmids are important for the specific application, an appropriate method can be used.

6.4 Library preparation and sequencing

6.4.1 Library preparation

The laboratory should follow the manufacturer's recommended protocol. Procedures may be adapted for specific needs, but all modifications shall be fully documented and validated.

NOTE Size-selection procedures used in some library preparation methods [e.g. in construction of large insert size (> 2 kb) single molecule real time libraries] can result in the loss of small plasmids.

PCR enrichment of libraries can result in reduced library complexity and a reduction in the number of distinct DNA molecules in the preparation. Library complexity can also be affected by the amount of DNA starting material or the amount of DNA lost during library preparation clean-up steps. Library complexity may be estimated using the method of Daley and Smith[4].

If there is a possibility that libraries will be used again, libraries shall be stored according to the manufacturer's recommendations. The laboratory shall document:

— the sample tracking method used (i.e. barcode or equivalent);

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