INTERNATIONAL STANDARD

ISO 16577

Second edition
2022-08

Molecular biomarker analysis — Vocabulary for molecular biomarker analytical methods in agriculture and food production

Analyse de biomarqueurs moléculaires — Vocabulaire pour les méthodes d'analyse de biomarqueurs moléculaires dans l'agriculture et la production agroalimentaire

Reference number
ISO 16577:2022(E)

© ISO 2022



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

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
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2022 – All rights reserved

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
3.1 Bioinformatics 1
3.2 Immunology 2
3.3 Metrology 4
3.4 Molecular biology 20
3.5 Molecular genetics 27
3.6 Nucleic acid amplification technology (NAAT) 31
3.7 Nucleic acid sequencing 43
3.8 Pathology 46
3.9 Statistics and sampling 47
Bibliography **50**
Index **51**

© ISO 2022 – All rights reserved

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 16, *Horizontal methods for molecular biomarker analysis*.

This second edition cancels and replaces the first edition (ISO 16577:2016), which has been technically revised.

The main changes are as follows:

— definitions have been updated, and new definitions have been added;

— typographical errors have been corrected.

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.

© ISO 2022 – All rights reserved

Introduction

Molecular biomarker analytical testing methods in agriculture and food production cover a broad spectrum of molecular technologies including but not limited to the analysis of nucleic acids, proteins, lipids and glycosides for biomarker identification and quantification, variety identification and detection of plant pathogens. This document includes terminology for biomolecular methods and processes in the food chain from primary production to consumption, as well as animal and vegetable propagation materials, in particular, as applied to sampling, methods of test and analysis, product specifications, food and feed safety, quality management, and requirements for packaging, storage and transportation. It includes terms that are useful metrologically in biomarker analysis of food and food products such as those from Codex Alimentarius and those applied to genetically modified organism (GMO) testing. It is important that a harmonized compendium of terms is available so that terms are used accurately and consistently throughout this field of standardization.

The terms in this document conform to the foundational FAIR principles: findability, accessibility, interoperability and reusability. They serve as a basis for terminology applied to horizontal methods for molecular biomarker analysis of food products.

© ISO 2022 – All rights reserved

Molecular biomarker analysis — Vocabulary for molecular biomarker analytical methods in agriculture and food production

1 Scope

This document defines terms for horizontal methods for molecular biomarker analysis in agriculture and food production.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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/

3.1 Bioinformatics

3.1.1
bioinformatic analysis
bioinformatics
multidisciplinary examination of life sciences data using information technology as part of the methodology, as well as a reference to specific analytical "pipelines" to understand and interpret these biological data

Note 1 to entry: Life sciences data include genomics (including sequencing, massively parallel sequencing, metagenomics, epigenomics and functional genomics), transcriptomics, translatomics, proteomics, metabolomics, lipidomics, glycomics, enzymology, immunochemistry, life science imaging, synthetic biology, systems biology, systems medicine and related fields.

3.1.2
FASTA format
text-based format for representing either nucleotide sequences or amino acid (protein) sequences, in which nucleotides or amino acids are represented using single-letter codes

Note 1 to entry: A sequence in FASTA format begins with a single-line description, followed by lines of sequence data. The description line (defline) is distinguished from the sequence data by a greater-than (">") symbol at the beginning. It is recommended that all lines of text be shorter than 80 characters in length.

Note 2 to entry: An example sequence in FASTA format is:

>P01013 GENE X PROTEIN (OVALBUMIN-RELATED)
QIKDLLVSSSTDLDTTLVLVNAIYFKGMWKTAFNAEDTREMPFHVTKQESKPVQMMCMNNSFNVATLPAEKMKILELP-
FASGDLSMLVLLPDEVSDLERIEKTINFEKLTEWTNPNTMEKRRVKVYLPQMKIEEKYNLTSVLMALGMTDLFIPSANLT-
GISSAESLKISQAVHGAFMELSEDGIEMAGSTGVIEDIKHSPESEQFRADHPFLFLIKHNPTNTIVYFGRYWSP*

Note 3 to entry: Blank lines are not allowed in the middle of FASTA input. Sequences are represented in the standard IUB/IUPAC amino acid and nucleic acid codes, with these exceptions:

© ISO 2022 – All rights reserved

— lower-case letters are accepted and are mapped into upper-case;

— a single hyphen or dash can be used to represent a gap of indeterminate length;

— in amino acid sequences, U and * are acceptable letters.

It is common to end the sequence with an "*" (asterisk) character and to leave a blank line between the description and the sequence.

3.1.3
FASTQ format
FASTQ files
text based format for nucleic acid sequence files that includes the sequence and per base Phred or Q quality scores

Note 1 to entry: FASTQ files consist of a definition line that contains a read identifier and possibly other information, nucleotide base calls, a second description line (definition line), and per-base quality scores, all in text form.

Note 2 to entry: There are many variations of FASTQ formats.

Note 3 to entry: The following terms and formats are defined in general:

— Decimal-encoding, space-delimited: [0-9]+ | <quality>\s[0-9]+

— Phred-33 ASCII: [\!\"\#\$\%\&\'\(\)*\+,\-\.\/0-9:;<=>\?\@A-I]+

— Phred-64 ASCII: [\@A-Z\[\\\]\^_`a-h]+

Note 4 to entry: Quality string length should be equal to sequence length.

Note 5 to entry: In a limited set of cases, log odds or non-ASCII numerical quality values will succeed during a sequence read archive (SRA) submission. Files from various platforms employing this format are acceptable:

> @<identifier and expected information>; <sequence>; +<identifier and other information OR empty string>; <quality>

Note 6 to entry: Where each instance of Identifier, Bases and Qualities are newline-separated, extra information added beyond the < identifier and expected information > examples is likely to be discarded/ignored. As indicated above, the Qualities string can be space-separated numeric Phred scores or an ASCII string of the Phred scores with the ASCII character value = Phred score plus an offset constant used to place the ASCII characters in the printable character range. There are two predominant offsets: 33 (0 = !) and 64 (0=@).

3.1.4
metadata
data providing information about one or more aspects of the datasets ("data about data")

EXAMPLE Means of creation of the data, purpose of the data, file size, data quality, source of the data.

Note 1 to entry: Metadata are used to summarize basic information about data which can make tracking and working with specific data easier.

3.2 Immunology

3.2.1
antibody
Ab
host proteins produced in response to the presence of foreign molecules, organisms or other agents in the organism

Note 1 to entry: Antibodies are useful reagents that can bind with high affinity to chosen antigens.

Note 2 to entry: In animals, antibodies are synthesized predominantly by plasma cells, terminally differentiated cells of the B-lymphocyte lineage, and circulate throughout the blood and lymph where they bind to antigens.

© ISO 2022 – All rights reserved