INTERNATIONAL STANDARD

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Biotechnology — Genome editing —

Part 1:
Vocabulary

Biotechnologie — Édition génomique —

Partie 1: Vocabulaire

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Contents

Page

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).

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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 276, *Biotechnology*.

A list of all parts in the ISO 5058 series can be found on the ISO website.

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

Genome editing technology is a fast-growing and rapidly advancing global bioscience field with applications in many biotechnology sectors. Genome editing is used to modify the nucleic acids of a genetic code, which can be composed of DNA or RNA, in a site-specific manner. Modifications can include insertion, deletion or alteration of nucleic acids. The technology operates by biochemical principles generally applicable to every kind of cell. Examples of genome editing technology applications with global significance include human cell-based therapeutics, agriculture, microbial based therapeutics, synthetic biology and biomanufacturing.

While genome editing technology is being actively utilized, there is a need for international standardization in terms and definitions for this field, so as to enhance interpretation and communication of concepts, data and results.

This document has been developed to provide a unified standard set of terms and definitions that serve the needs of biotechnology stakeholders and act as a reference for genome editing technology. Standards in the field of genome editing are intended to harmonize and accelerate effective communication, technology development, qualification and evaluation of genome editing products. This document is expected to improve confidence in and clarity of scientific communication, data reporting and data interpretation in the genome editing field. Specific requirements for the application of genome editing technologies in agriculture and food are not included. For specific requirements, users can consult standards developed by appropriate ISO Technical Committees, e.g. ISO/TC 34/SC 16 *Horizontal methods for molecular biomarker analysis*, or ISO/TC 215 *Health informatics*.

This document provides a vocabulary that standardizes the use and meaning of terms associated with genome editing. This document is organized into categories and sub-categories as follows:

— genome editing concepts (see 3.1);

— genome editing tools (see 3.2):

    — general (see 3.2.1);

    — CRISPR specific (see 3.2.2);

    — meganuclease specific (see 3.2.3);

    — megaTAL specific (see 3.2.4);

    — TALEN specific (see 3.2.5);

    — ZFN specific (see 3.2.6);

— genome editing outcomes (see 3.3).

Terms within categories are listed alphabetically. The sub-category "General" contains terms that apply to all types of genome editing tools. Additional sub-categories contain terms specific to the sub-category of genome editing technology: "CRISPR specific", "Meganuclease specific", "megaTAL specific", "TALEN specific" and "ZFN specific". An alphabetical list of all terms is given in the index. Definitions follow English word order wherever possible.

It is also recognized that genome editing is a rapidly developing and evolving biotechnology, and additional terms and definitions will be needed as genome editing technologies mature.

Biotechnology — Genome editing —

Part 1:
Vocabulary

1 Scope

This document defines terms related to genome editing technology.

This document is applicable to general use of genome editing across species.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

3.1 Genome editing concepts

3.1.1
gene editing
techniques for *genome engineering* (3.1.3) that involve nucleic acid damage, repair mechanisms, replication and/or recombination for incorporating site-specific modification(s) into a gene or genes

Note 1 to entry: Gene editing is a subclass of *genome editing* (3.1.2).

Note 2 to entry: There are various genome editing tools (see 3.2 and Figure 1).

3.1.2
genome editing
techniques for *genome engineering* (3.1.3) that involve nucleic acid damage, repair mechanisms, replication and/or recombination for incorporating site-specific modification(s) into a genomic DNA

Note 1 to entry: *Gene editing* (3.1.1) is a subclass of genome editing.

Note 2 to entry: There are various genome editing tools (see 3.2 and Figure 1).