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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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Biotechnology - Genome editing - Part 1: Vocabulary

生物技术 基因组编辑 第1部分:术语

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 1 of GB/T 46433, "Biotechnology - Genome Editing". GB/T 46433 has already published the following parts.

---Part 1: Terminology.

This document is equivalent to ISO 5058-1:2021 "Biotechnology - Genome editing - Part 1: Terminology".

The following minimal editorial changes have been made to this document.

---Incorporates the content of the ISO 5058-1:2021/Amd1.2022 amendment (see 3.2.5.2 and 3.3.7).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Technical Committee on Standardization of Biochemical Testing (SAC/TC387).

Introduction

Genome editing technology is a rapidly developing global field of bioscience with applications in many biotechnology areas.

Editing involves modifying nucleic acids at specific sites in the genetic code. The genetic code can be composed of DNA or RNA, and modifications include the insertion of nucleic acids.

Deletion or alteration. This technology is based on biochemical principles universally applicable to various cells. Genome editing technology is applied to human cells...

It has global significance in areas such as cell therapy, agriculture, microbial-based therapies, synthetic biology, and biomanufacturing.

While actively utilizing genome editing technology, it is necessary to internationally standardize the terminology and definitions in this field to strengthen the understanding of concepts and definitions.

Interpretation and communication of data and results.

GB/T 46433 is proposed to consist of the following parts.

---Part 1: Terminology. The purpose is to define the terminology related to genome editing technologies, applicable to cross-species genome editing.

General uses.

This document aims to provide a unified set of standard terminology and definitions to meet the needs of biotechnology stakeholders and to serve as a reference for genome editing techniques.

References for the technology. Standards in the field of genome editing aim to harmonize and accelerate the effective communication, technology development, identification, and evaluation of genome editing products.

This document is expected to improve confidence and clarity in scientific communication, data reporting, and data interpretation in the field of genome editing.

The specific requirements for the application do not include agricultural and food technologies. For specific requirements, users can refer to the relevant ISO technical committee guidelines.

Standards, such as ISO/TC34/SC16 for level methods of molecular biomarker analysis, or ISO/TC215 for health informatics.

This document provides a glossary to standardize the meaning and use of terms related to genome editing technology. This document is divided into the following sections.

Categories and subcategories.

---The concept of genome editing (3.1).

---Genome Editing Tools (3.2).

- General Tools (3.2.1);
- Specificity of regularly clustered, short palindromic repeats (CRISPR) (3.2.2);
- Broad nuclease specificity (3.2.3);
- Extensive use of megaTAL-specific chimeric nucleases (3.2.4);
- Transcription activator-like effector nuclease (TALEN) specificity (3.2.5);
- Zinc finger nuclease (ZFN) specificity (3.2.6).

---Genome editing results (3.3).

The terms in the categories are listed alphabetically. The "General Tools" subcategory contains terms applicable to all types of genome editing tools.

Other subcategories contain terms specific to the genome editing technology subcategory. "CRISPR specific" and "broadly specific nucleases".

"megaTAL specificity," "TALEN specificity," and "ZFN specificity." The index provides an alphabetical list of all terms.

The meaning should follow the English word order as much as possible.

Biotechnology Genome Editing Part 1: Terminology

1 Scope

This document defines the terminology related to genome editing technologies.

This document is intended for general use in cross-species genome editing.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Concept of Genome Editing

3.1.1

gene editing

Site-specific modifications are performed in genome engineering (3.1.3) using techniques such as nucleic acid damage, repair mechanisms, replication, and/or recombination.

Methods for integrating into one or more genes.

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

Note 2: See 3.2 and Figure 1 for genome editing tools.

Note 3: Gene editing specifically refers to the modification of the coding or regulatory regions of a gene, while genome editing covers the modification of any region of the genome (including intergenic regions).

3.1.2

Genome editing

Site-specific modifications are performed in genome engineering (3.1.3) using techniques such as nucleic acid damage, repair mechanisms, replication, and/or recombination.

Methods for integration into genomic DNA.

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

Note 2: See 3.2 and Figure 1 for genome editing tools.