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Biotechnology — Genome editing —

Part 1: Vocabulary

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Partie 1: Vocabulaire

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Contents

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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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.