



Designation: E3072 – 19

Standard Terminology for Industrial Biotechnology¹

This standard is issued under the fixed designation E3072; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This terminology is a repository for the terms, and their standardized definitions, as relates to the technical standards generated by Committee E62 on Industrial Biotechnology. The meanings and explanations of the technical terms have been written for both the nonexpert and the expert user.

1.2 At a minimum, this terminology is updated annually (at a time corresponding to the publication of the Annual Book of ASTM Standards containing this terminology standard) to include editorially any terms approved in the committee's technical standards.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*²

E2363 Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry

3. Terminology

aerobic fermentation, *n*—fermentation processes that require the presence of oxygen. **(E2363)**

anaerobic fermentation, *n*—fermentation processes conducted in the absence of oxygen. **(E2363)**

¹ This test method is under the jurisdiction of ASTM Committee E62 on Industrial Biotechnology and Synthetic Biology and is the direct responsibility of Subcommittee E62.91 on Terminology.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

applied biology, *n*—the application of the theories and principles of biology for practical purposes.

biocatalyst, *n*—enzyme, nucleic acid, or organism capable of accelerating a chemical reaction or conversion.

biochemical, *n*—chemical produced by biological systems.

bioprocess, *n*—a process requiring a biocatalyst.

bioproduct, *n*—material or product derived from a biological source or through a biological process.

biorefining, *v*—processing systems using physical, biological (for example, fermentation), chemical methods, or combinations of these, by which biobased products are separated into partially or fully purified fractions, which may be further converted into new chemical entities.

enzyme, *n*—protein-based molecule that is capable of catalyzing a chemical reaction.

exon, *n*—part of an open reading frame that encodes any part of the final gene product.

fermentation, *n*—the biochemical reaction process where microorganisms in a nutrient medium convert a feedstock to a product. **(E2363)**

genome, *n*—the sum of all genetic material within an organism, composed of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) arranged into sequences that direct the expression and function of the proteins in the organism.

genome-edited organism, *n*—an organism containing a genome altered through the process of genome-editing.

DISCUSSION—Gene-edited organisms can be either cisgenic or transgenic, depending on the nature of the genomic alterations.

genome editing, *v*—The introduction of precise changes to the DNA sequence of an organism at defined locations within a genome.

DISCUSSION—Gene edits can involve alteration of a single base pair, or the deletion or addition of longer DNA sequences, including entire genes.

genotype, *n*—The portion of genetic material within an organism which determines the expression of a specific characteristic (phenotype).