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Standard Terminology for Industrial Biotechnology[1]

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)**

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.

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[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.

bioeconomy, *n*—the segment of the economy driven by innovation in agriculture and biotechnology.

DISCUSSION—
Focused on sustainable production of goods and services from renewable and waste feedstocks.

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.

enzyme activity, *n*—Catalytic activity associated with enzymatically-active protein.

DISCUSSION—
Defined as the ability to convert a given amount of substrate to product per unit time. Expressed as units (U) of enzyme activity.

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)**

genetically engineered microorganism (GEM), *n*—a microorganism where one or more sequences of DNA has been intentionally altered relative to the parent microorganism.

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).

glycoform, *n*—A specific glycoprotein variant, where both polypeptide and associated glycan structure(s) are defined.

interactome, *n*—The set of all interactions between molecules within a cell, tissue, organism or ecosystem.

DISCUSSION—
The interactome includes all molecular interactions that comprise life processes and represents an essential element of Systems Biology.

intron, *n*—any nucleotide sequence within a gene that is removed by mRNA splicing during maturation of the final RNA product.

lignocellulosic biomass, *n*—biomass consisting predominantly of lignin, cellulose, and hemicellulose, for example, wood and structural vegetative components, such as plant stems.

metabolic engineering, *n*—the process of altering one or more metabolic pathways of an organism with the intent of changing chemical processes within the cell.

DISCUSSION—
Metabolic engineering uses genetic tools to alter the levels or function of key proteins within a cell, including the introduction of heterologous enzymes and transport proteins with new functions. Several metrics are used to assess the performance of pathway engineered strains, including the titer of product made (g/L), the rate at which product is made (g/L/hr), and the yield of substrate conversion to product (mol or wt%).

metabolome, *n*—~~The~~the set of all small molecules within a cell that transfer energy and act as biochemical precursors and collectively represent material flow and overall physiological status.

metabolomics, *n*—the science of determining the metabolite profile at a specified time under specific environmental conditions.

microbiome, *n*—the collective microorganisms inhabiting a specified environment.

molar yield, *n*—amount of reaction product converted from a defined input chemical expressed in moles.

mutagenesis, *n*—the addition, deletion or substitution of at least one base within an organism's genome.

DISCUSSION—
Mutagenesis can occur under either natural or artificial means.

percent of theoretical yield, *n*—amount of product, or products, obtained from a process, or multi-step process, given as a percentage of the theoretical yield from the defined input material.

process yield, *n*—amount of product output of interest from a single- or multi-step process expressed as a percentage of the amount of input material either as moles or mass.

promoter, *n*—a non-coding region of DNA that controls transcription of a particular gene, or set of genes.

proteome, *n*—the set of all proteins within a cell, tissue, organism or ecosystem.

proteomics, *n*—The science of protein structure, function and interaction within organisms.

regulatory elements, *n*—non-coding genetic regions that influence the expression of a gene, or set of genes.

remediation, *n*—removal of pollution, or contaminants, from environmental media such as soil, groundwater, sediment, or surface water, or degradation to non-toxic or benign status.

specific activity (of a sample), *n*—the specific activity of a sample is the enzyme activity per mass of total protein in that sample (U/mg total protein).

DISCUSSION—
The observed specific activity of a sample is a function of both enzyme purity and the intrinsic catalytic efficiency of the enzyme of interest under the particular assay conditions used.

specific activity (of an enzyme), *n*—the specific activity of an enzyme is the enzyme activity per mass of active enzyme protein in that sample (U/mg active enzyme protein).

DISCUSSION—
The observed specific activity of an enzyme is a function of the intrinsic catalytic efficiency of the enzyme of interest under the particular assay