



Standard Terminology Relating to Biotechnology¹

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1. Scope

1.1 This document is composed of terms, definitions of terms, descriptions of terms, and acronyms used in ASTM documents related to the field of biotechnology. Terms that are adequately defined in a general dictionary are not defined in this terminology standard.

1.2 This standard includes terminology used in biotechnology areas, such as, but not limited to: biological drug products, materials for biotechnology, characterization and identification of biological systems, aseptic sampling, preservation of biological samples, membrane filters, molecular biology, biomass conversion, fuel manufacturing facilities, and fuel analysis.

2. Referenced Documents

2.1 ASTM Standards:²

- E869 Test Method for Performance Evaluation of Fuel Ethanol Manufacturing Facilities
- E870 Test Methods for Analysis of Wood Fuels
- E1117 Practice for Design of Fuel-Alcohol Manufacturing Facilities
- E1126 Terminology Relating to Biomass Fuels³
- E1285 Guide for Identification of Bacteriophage Lambda (λ) or Its DNA
- E1286 Guide for Identification of Herpes Simplex Virus or Its DNA
- E1287 Practice for Aseptic Sampling of Biological Materials³
- E1298 Guide for Determination of Purity, Impurities, and Contaminants in Biological Drug Products
- E1342 Practice for Preservation by Freezing, Freeze-Drying, and Low Temperature Maintenance of Bacteria, Fungi, Protista, Viruses, Genetic Elements, and Animal and Plant Tissues³

- E1344 Guide for Evaluation of Fuel Ethanol Manufacturing Facilities
- E1357 Test Method for Determining the Rate of Bioleaching of Iron From Pyrite by *Thiobacillus Ferrooxidans*³
- E1493 Guide for Identification of Bacteriophage M13 or Its DNA
- E1531 Practice for Detection of Mycoplasma Contamination of Cell Cultures by Growth on Agarose Medium
- E1532 Practice for Detection of Mycoplasma Contamination of Cell Cultures by Use of Bisbenzamide DNA-Binding Fluorochrome
- E1533 Practice for Indirect Detection of Mycoplasma in Cell Culture by 4'-6-Diamidino-2-2 Phenylindole (DAPI) Staining
- E1535 Test Method for Performance Evaluation of Anaerobic Digestion Systems³
- E1536 Practice for Detection of Mycoplasma Contamination of Bovine Serum by Large Volume Method
- E1564 Guide for Design and Maintenance of Low-Temperature Storage Facilities for Maintaining Cryopreserved Biological Materials
- E1565 Guide for Inventory Control and Handling of Biological Material Maintained at Low Temperatures
- E1566 Guide for Handling Hazardous Biological Materials in Liquid Nitrogen
- E1567 Guide for Biopharmaceutical Facilities Architectural Design Considerations³

2.2 Federal Standards:

- Title 21, Code of Federal Regulations (CFR), Parts 210 and 211⁴

3. Terminology

3.1 Definitions:

- accessible**—permitting close approach or contact that could include requiring removal or opening of an access panel or door. **E1117**
- aerobic**—able to live, grow, or take place only where free oxygen is present. **E1126**
- aerobic fermentation**—fermentation processes that require the presence of air. **E1126**

¹ This terminology is under the jurisdiction of ASTM Committee E48 on Biotechnology and is the direct responsibility of Subcommittee E48.91 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.

³ Withdrawn. The last approved version of this historical standard is referenced on www.astm.org.

⁴ Available from Standardization Documents Order Desk, DODSSP, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5098, <http://dodssp.daps.dla.mil>.

- alcohols**—series of liquid products composed of a hydrocarbon plus a hydroxyl group, such as ethanol (C₂H₅OH). **E1344**
- alpha-amylase**—enzyme that acts specifically to accelerate the hydrolysis of starch to dextrans. **E1344**
- alpha complementation**—the ability of a short amino-terminal fragment (alpha fragment) of β-galactosidase to form a functional complex with the carboxyl terminal fragment (omega fragment). **E1493**
- anaerobic**—living or active in an airless environment. **E1126**
- anaerobic bacteria**—microbes whose metabolisms require the absence of free oxygen. **E1126**
- anaerobic digester**—a chemical reactor in which anaerobic bacteria are used to decompose biomass or organic wastes to produce methane and carbon dioxide. **E1126**
- anaerobic digestion**—degradation of organic matter by microbes in the absence of air (oxygen) to produce methane and carbon dioxide (biogas). **E1126**
- anaerobic fermentation**—fermentation processes conducted in the absence of air. The following anaerobic fermentation processes are significant in obtaining useful forms of energy from biomass: (1) alcoholic fermentation, fermentation processes whereby certain microorganisms convert glucose and other substrates with alcohol as an end product, (2) methane fermentation, generally termed anaerobic digestion (See also **anaerobic digestion**). **E1126**
- anhydrous**—a material that does not contain water either absorbed on its surface or as water of crystallization; a water-free product. **E1126**
- anhydrous ethanol**—100 % ethanol, neat ethanol, 199 + proof ethanol. **E1344**
- anhydrous, without water**—term used in chemistry to denote absence of water. 199 + proof ethanol is considered anhydrous ethanol. **E1344**
- aseptic sampling**—sampling process in which no extraneous microorganisms or substances are introduced into the sample or its original bulk material as a result of the sampling system and activity. **E1287**
- ash**—inorganic residue remaining after combustion, determined by definite prescribed methods. **E1126**
- ash fusion temperature**—melting point of ash, usually expressed in degrees Fahrenheit. Variations include oxidizing atmosphere or reducing atmosphere, initial softening, or final fluid temperature. Some specifications include two intermediate points between initial softening and final fluid. **E1126**
- azeotrope**—constant boiling mixture, for ethanol-water, the azeotrope of 95.6 % ethanol and 4.4 % water (both percentages by volume) boils at one atmosphere pressure. **E1344**
- azeotropic distillation**—the use of an organic solvent to create a new constant boiling point mixture, a method used to produce anhydrous ethanol from the ethanol water azeotrope. **E1344**
- backset**—the liquid portion of the thin stillage that is recycled as part of the process liquid in mash preparation. **E1344**
- bacteriophage**—a virus that infects bacteria. **E1285**
- bagasse**—residue remaining after extraction of a sugar-containing juice from plants like sugar cane. **E1126**
- basic hydrolysis**—the chemical addition of water to a compound. **E1344**
- batch fermentation**—batch of nutrient mixture and microorganisms mixed in a vessel and allowed to ferment. **E1344**
- beer**—term used to describe the product of ethanol fermentation by microorganisms. **E1344**
- bioconversion**—a general term describing the use of biological systems to transform one compound into another. Examples are digestion of organic wastes or sewage by microorganisms to produce methane. **E1126**
- biofuel**—biomass-derived fuel. **E1126**
- biogas**—a composition of methane and carbon dioxide and minor constituents produced by the digestion of organic substrates in the absence of oxygen. **E1535**
- biomass**—total weight of living matter in a given volume. When considered as an energy source, biomass is further subdivided into: (1) primary biomass, rapidly growing plant material that may be used directly or after a conversion process for the production of energy, and (2) secondary biomass, biomass residues remaining after the production of fiber, food, or other products of agriculture, or biomass by-products from animal husbandry or food preparation that are modified physically rather than chemically. Examples include waste materials from agriculture and forestry industries (manure, sewage, etc.) from which energy may be produced. The above distinction noted between primary and secondary biomass is based on economic factors; these are defined differently in ecological science. **E1126**
- biomass**—any material, excluding fossil fuels, which is or was a living organism that can be used as a fuel directly or after a conversion process. Peat is not a biomass. **E1126**
- biomass fuel**—fuel derived from biomass. **E1126**
- capsomere**—a structural subunit of the outer protein shell (capsid) of a virus consisting of protein monomers. **E1286**
- carbohydrates**—molecules consisting of carbon, hydrogen and oxygen that include celluloses, starches and sugars. **E1344**
- centrifuge**—machine that separates a mixture of solids and liquids by centrifugal force. **E1344**
- contaminants**—all adventitious substances or microorganisms present in raw materials, bulk drugs, or final products. **E1298**
- continuous fermentation**—nonstop flow of nutrients into a fermenting vessel, with the simultaneous outflow of products, organisms, and by-products. **E1344**
- conversion efficiency**—the ratio of the actual to theoretical fuel ethanol yield per unit mass of the feedstock. **E1344**
- corn stover**—the stalks of the maize plant. **E1126**
- cryogenic temperatures**—for purposes of this practice, cryogenic temperatures are temperatures at or below –70°C. **E1342**
- cryogenic temperatures**—temperatures below or equal to –100°C. **E1564, E1565, E1566**
- cryoprotectant**—a chemical substance used to protect cells during freezing and rewarming. **E1342**