IBISBA
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Policy NOTE

Navigating Biotech-related terminology: pointers for European policymakers

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Biotechnology is strategically valuable for Europe's competitiveness, sovereignty, and sustainability, as it enables biomanufacturing to deliver cutting-edge solutions across key sectors such as energy, chemicals, materials, agrifood and health. However, economic and regulatory barriers hinder the advancement of biomanufacturing in the EU. Encouragingly, the European Union is preparing a Biotech Act to spur biotechnology development and accelerate the deployment of biomanufacturing, ensuring that Europe maintains its leading position in the global marketplace. This legislation seeks to address the regulatory gaps and hurdles hampering progress, while better acknowledging the benefits of biomanufactured products compared to fossil-based ones.

Whether for the Biotech Act or other policy and regulatory purposes, it is strongly recommended that key terms are defined and explained in the relevant official documents and publications to avoid unnecessary ambiguity and uncertainty.

To ensure that new legislation is efficient and fit for purpose, it must be evidence-based and grounded in precise terminology. Unfortunately, current use of some fundamental terms is often confusing, with these being the subject of sector-specific perspectives. For example, despite decades of usage, assigning a rigorous definition to the term biotechnology remains challenging, whereas the term biomanufacturing is still used hesitantly and inconsistently.

Other terms emerging in business contexts suffer from vagueness and interchangeable usage.
Drawing upon the content of a recently published scientific article [1], this IBISBA policy brief offers European policymakers an overview of the historical context and meanings that underpin some commonly used terms in the biotechnology realm. Additionally, IBISBA presents a set of definitions for policymakers to consider when preparing the Biotech Act.

[1] Ancelin et al (2025) New Biotechnology. https://doi.org/10.1016/j.nbt.2025.04.010

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Biotechnology: a generic technology toolbox

Biotechnology refers to the study and use of living organisms or their components to benefit society. In this respect, the use of biotechnology is broadly enabling and not restricted to any single application. Indeed, the term describes a versatile toolbox of technologies that can be applied to many sectors.

While the generic and enabling nature of biotechnology is rather obvious to specialists, it is not always the case for laypeople who are influenced by sector-specific business-to-business discourse. Moreover, the "rainbow code of biotechnology" [2], created to conveniently categorise biotechnology for specialists and non-specialists, may give the incorrect impression that there are distinct versions or types of biotechnology. In this code, Green usually refers to plant biotechnology and the use of biotechnology in the agricultural sector, Red relates to biotechnology in healthcare, with further colours representing other sectors [3]. Although this classification system is easy to understand and illustrates the breadth of biotechnology and its applications, it is neither standardised nor universally used and thus is probably unsuitable for use in policy documents.

In fact, the perceived differences in biotechnology stem from production processes and products, rather than from the foundational knowledge that underpins biotechnology. The production processes that use biotechnology as a core technology vary from one sector to another because the products for different markets are subject to different quality criteria and regulatory frameworks. Therefore, if a colour scheme is considered desirable for communication purposes, it would be more appropriate to colourise manufacturing processes, products and markets rather than types of biotechnology per se.

BIOTECHNOLOGY

The practical use of living organisms, as well as parts, products and models of them, for human purposes, and the body of knowledge that pertains to this endeavour.

BIOTECHNOLOGY IS A CORNERSTONE OF THE BIOECONOMY

Biotechnology can be used to manufacture many of the products that are identified as products of the bioeconomy. When considering biotechnology, much of the knowledge and tools relate to the use of microorganisms, including bacteria, fungi and microalgae. These act like miniature factories that, with the right information and ingredients, can fulfil a vast array of functions. When deployed in appropriate process conditions, they generate numerous products and services.

Nevertheless, it is important to understand that the transformative potential of biotechnology extends beyond the bioeconomy, offering a versatile toolbox that can be applied in diverse contexts. For example, the utilisation and recycling of fossil-based plastics to new "green" products using enzymes that have been created by biotechnology, or the bioconversion of off-gases (containing carbon monoxide and carbon dioxide) from fossil-powered steel mills into valuable chemicals, are also examples of biotechnology. It is also true that not all aspects of the bioeconomy involve biotechnology.

[2] Early use of this code (in 2003) is attributed to Dr. Rita Colwell, 11th Director of the U.S. National Science Foundation.

[3] Kafarski P. Rainbow code of biotechnology. Chemik 2012;66:814–6. https://www.researchgate.net/publication/287253802_Rainbow_code_of_biotechnology

Biomanufacturing: implementing biotechnology at commercial scale

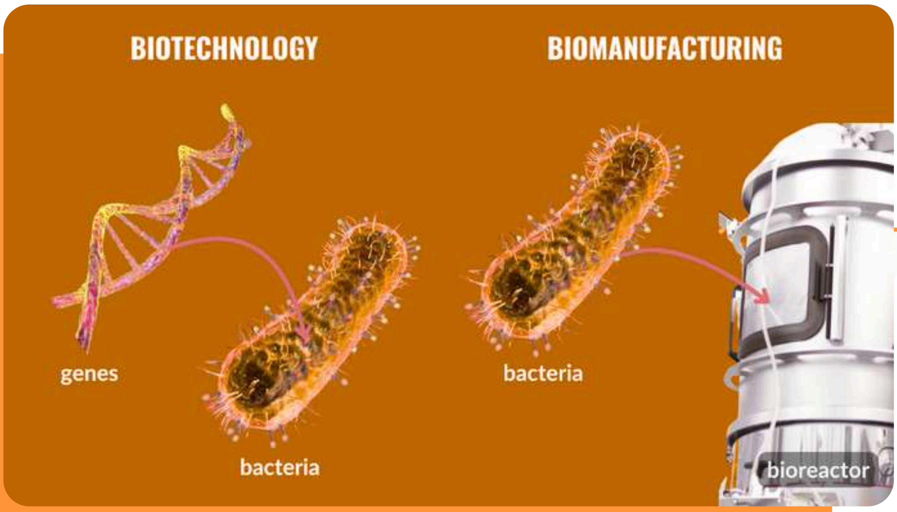
Biomanufacturing is a relatively recent term. Often mentioned alongside biotechnology, biomanufacturing and biotechnology complement each other. While biotechnology refers to the art of using living organisms or their parts, biomanufacturing places biotechnology in an industrial process to produce goods and materials at commercial scale. In that sense, biomanufacturing is a synonym of the frequently used term industrial biotechnology, defined as biotechnology used to enable the production of good and services at industrial scale.

A key point is that biomanufacturing does not refer to a single sector. Goods and materials produced through biomanufacturing include a wide range of products, such as pharmaceuticals (e.g., insulin, monoclonal antibodies and vaccines), biofuels (e.g., bioethanol and biogas), food ingredients (e.g., enzymes for baking, vitamins, microbial oils, flavours and fragrances), industrial enzymes (e.g., for feed processing and as laundry washing agents), chemicals (e.g. bio-based alternatives to chemical building blocks), materials (e.g., biodegradable plastics, silk, bio-based textiles and coatings).

BEER PRODUCTION AS AN EXPLAINER FOR HOW BIOMANUFACTURING HARNESSES BIOTECHNOLOGY

To make beer, barley grains are first malted, meaning that they are soaked in water, allowed to germinate, then dried. This seemingly simple process leads to the activation of enzymes naturally present in the grains. These convert the starch stored in the grain into simple sugars. Once malted, the barley malt is mixed with hot water to extract a sugar-loaded liquid called wort. The wort is boiled, hops are added and once cooled poured into a bioreactor (essentially, a large stainless-steel tank). Yeast is added and the fermentation process begins. Yeast cells are living organisms that possess the ability to consume the sugar using enzyme-driven biological functions to release energy. In the process, ethanol (the alcohol) and carbon dioxide (the bubbles) are also produced. Along the way yeast also makes the flavours and aromas that characterise beer.

In beermaking, biotechnology relates to the series of biochemical reactions that occur both in the grains and inside the cells leading to the conversion of wort to what we call beer. Biomanufacturing, on the other hand, describes implementation of the entire process of beer production at commercial scale.



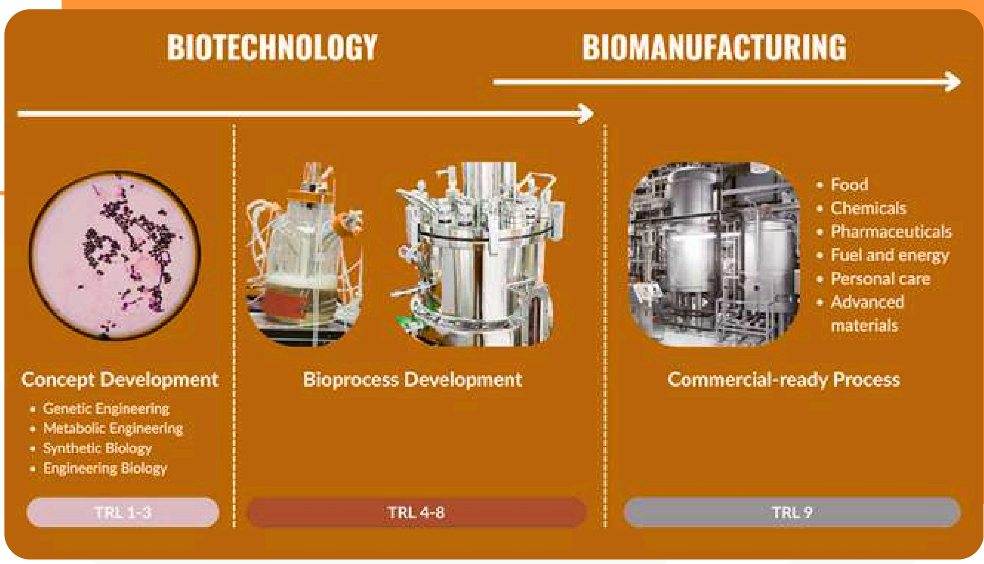
Biomanufacturing operates on an industrial scale using bioreactors – closed vessels up to millions of litres in volume – that provide environments for microorganisms to grow and produce targeted products.

By controlling factors such as temperature, pH, oxygenation and sterility, bioreactors enable optimised production conditions. This contained approach ensures that engineered microorganisms are not released into the environment. With strict safety protocols, biomanufacturing boasts an excellent safety track record with no reported industrial accidents.

BEERMAKING AND BIOETHANOL PRODUCTION: THE IMPORTANCE OF BIOPROCESS ENGINEERING

Fundamentally, bioethanol production for biofuels and beermaking are similar processes. However, depending on the type of raw material used, distinct process operations might be required to make bioethanol. For example, bioethanol made using non-food raw materials such as crop residues involves the use of an array of specialised industrial enzymes to release sugars from cellulosic raw materials, and distillation to recover pure ethanol. While first generation bioethanol production from corn or sugarcane relies on non-engineered strains, for second generation bioethanol production from lignocellulosic raw materials, the use of genetically modified yeast strains (GMO yeast) is considered beneficial to optimise the process under tight economic constraints.

In both bioethanol production and beermaking, bioprocess technology (bioprocess engineering) is deployed to design and operate a process that leverages biotechnology. This engineering discipline is a critical part of the commercial-scale, end-to-end biomanufacturing process.



BIOMANUFACTURING

The commercial scale industrial production of goods using biotechnology as a core process component.

Technological innovation: from genetic engineering to engineering biology

Genetic engineering, synthetic biology, engineering biology and other terms addressed in this section are technology-based. They were established by the scientific community to reflect the technical progress made over the last century from understanding genes to genome modification.

The discovery of the structure of DNA in the early 1950s engendered a new field of investigation that enabled scientists to change the genetic make-up of cells. In the late 1970s and 1980s a series of breakthroughs gave rise to recombinant DNA technology, the study and modification of genes, and their transfer between different organisms.

Gene technology enabled the isolation of individual genes and emerged from a need to understand gene function, while genetic engineering already implied a purposeful engineering of cells for specific needs.

GENETIC ENGINEERING

The purposeful and rational modification of genes including their transfer between organisms to obtain specific functions.

Building on this foundation, and enhanced by advances in knowledge of cell physiology and new analytical methods, genetic engineering inspired metabolic engineering in the early 1990s. This involves the tuning of cellular activities for specific purposes, achieving this through the modification of genes that underpin the biochemical pathways and metabolism within cells. Metabolic engineering can be used to increase or decrease the production of specific compounds, even those not naturally found in an organism.

In recent years, genome engineering gained prominence thanks to the development of CRISPR-Cas9 methodology in the 2010's. This allows for precise, site-specific manipulation of genes at single-base level, and the large-scale editing of full genomes (the complete repertoire of genes in one organism). While transformative in scope, in essence, CRISPR-based engineering can be viewed as the latest advance in genetic engineering technology.

METABOLIC ENGINEERING

The targeted modification of the genes affecting metabolic pathways of living organisms for specific purposes such as production of certain industrially relevant compounds.

With an increasing emphasis on applying engineering principles to biology, synthetic biology took off at the start of the 21st century. Leveraging advances in DNA sequencing and synthesis, genome editing tools such as CRISPR-Cas9, mathematical modelling, computer sciences, and automation, it provides the framework to progress from a limited number of gene modifications to the design and engineering of entire gene networks and large genome parts. This allows greater control over complex biological systems and processes, often using a systematic DBTL (Design-Build-Test-Learn) workflow to (re)design biological systems in an iterative manner.

SYNTHETIC BIOLOGY TO PRODUCE ARTEMISINIC ACID, A PRECURSOR OF AN ANTI-MALARIA DRUG

Artemisinin is an antimalarial compound that is traditionally extracted from the sweet wormwood plant. Using the toolbox of synthetic biology, a yeast strain was extensively engineered, introducing an array of genes from different organisms to reprogramme and extend its metabolism. This led to a yeast that produces high yields of artemisinic acid, a chemical precursor of artemisinin. This is an example of synthetic biology because it involved very extensive genetic engineering to confer an exogenous function to yeast. It is noteworthy that transferring a function from one organism to another is insufficient to qualify as synthetic biology. Indeed, if this was case one could argue that even the very first gene technology successes at the end of 1970's (e.g., the production of human insulin in bacterial cells) were examples of synthetic biology - which of course is incorrect, becuase these were far from the remarkable capabilities of today's synthetic biology.

SYNTHETIC BIOLOGY

The systematic deployment of engineering principles to design (or profoundly redesign) biological systems, endowing these with novel biological functions that are inaccessible when using conventional genetic engineering methods, or even creating new-to-nature molecules and functions.

The use of the term "engineering biology" has increased in recent years. Engineering biology is the application of engineering practice to biological systems. It relies on both understanding of the physical, chemical, and biological rules of the system at play, and uses design methods to achieve consistency and quality. For most intents and purposes, bioengineering and biological engineering are synonyms of engineering biology, although bioengineering can also refer to biomedical engineering, which covers applications in the biomedicine and healthcare spaces, for example bioengineered tissues, biomedical devices and prosthetics.

The key difference between engineering biology and synthetic biology arguably lies in their scope, with engineering biology embracing a much wider range of activities.

While engineering biology applies engineering principles to biological systems, synthetic biology specifically refers to the profound redesign of organisms, often in an iterative manner, or the creation of entirely new biological systems with functions beyond those found in nature. Policymakers must be aware of the current ambiguity surrounding these terms and carefully select and apply clear definitions.

ENGINEERING BIOLOGY

The design, construction, and/or assembly of the components of living systems to achieve an intended function or outcome. It includes the use of approaches such as genetic engineering and metabolic engineering.

Precision fermentation and cellular agriculture: tailored terminology for the food industry

Precision fermentation and cellular agriculture are food industry-derived terms. While these terms are useful for business dialogue, when used in the public space, their fuzzy definitions make them vulnerable to misinterpretation. They may also negatively affect and confuse the use of traditional and established terms in biotechnology when applied to applications that are unrelatd to the food industry. Therefore, before using these terms to craft public policy, clear definitions are required. These must be supported by well-reasoned arguments, providing the basis to determine whether a particular application falls within these definitions.

Fermentation has been used worldwide for thousands of years to produce foods and beverages. Strictly speaking, the term refers to specific biochemical processes that take place in living organisms usually in the absence of oxygen.

However, fermentation is frequently used in a more informal way by both practitioners and laypeople to describe the culturing (growing) of microorganisms irrespective of whether oxygen is present or used.

In 2019, the food industry introduced "precision fermentation", meaning the production of a particular product by a specially engineered microbe.

The word precision is used to infer the use of a genetically modified microorganism (GMM) to produce a food ingredient rather than to imply that the overall bioprocess is more precise.

Thus, while the term "precision" may serve a marketing purpose, for policymaking it is vital to understand that precision fermentation essentially refers to the application of genetically modified microorganisms to produce specific compounds for use in the food industry.

Unfortunately, the trend towards describing any application of engineered micro-organisms as "precision fermentation" will add to the confusion.

PRECISION FERMENTATION

Used in food biotechnology to describe the use of engineered microorganisms to produce specific target molecules of interest to the food industry.

CELLULAR AGRICULTURE: LAB TO FORK

Coined in 2015, the term "cellular agriculture" describes the use of cells to produce lab-grown foods (e.g., meat, seafood), food components, and plausibly even some non-food products (e.g., fungal leather). So far, the mainstream industrial use of the term refers to cultivation of animal cells to produce so-called "cultured meat", cultivated meat", or "cell-based meat" or other animal-based foods, although it is sometimes extended to the use of plant and even microbial cells for food component production. When using animal cells, these are extracted for cultivation from the animal, obviating the need for slaughter or fishing. This fact underpins the claim by some that cellular agriculture is a means to generate vegan-compatible food products, though this view is not universally accepted. As with other applications of biotechnology, in cellular agriculture, engineering biology is often used to improve cells, achieving better growth rates and nutrient absorption.

In cellular agriculture, animal cells, such as muscle cells for meat or mammary epithelial cells for milk, are grown in bioreactors that provide optimal conditions for production. For structured foods like steak, support structures (scaffolds) are used to help the cells grow into specific shapes. Other substances, such as fats and vitamins, produced by microorganisms using precision fermentation, can be added.

Considering that precision fermentation and cellular agriculture are adjacent concepts, these terms have sometimes been used as synonyms. Increasingly, however, industry users recognise a distinction whereby cellular agriculture describes the cultivation of animal (and possibly plant) cells to produce food (and non-food) products, whereas precision fermentation describes the use engineered microorganisms to produce specific food ingredients, such as proteins, fats and vitamins.

From a policy perspective the term cellular agriculture, which actually describes something that is not agriculture, is possibly troublesome in as much that, in the absence of an extremely rigorous definition, it is likely to create confusion, particularly when it is considered as an alternative to conventional agriculture.

CELLULAR AGRICULTURE

The growth of cells in contained and defined culture conditions for use in or as foods. It mostly applies to the in vitro cultivation of animal cells to generate products such as cultured meat and fish.

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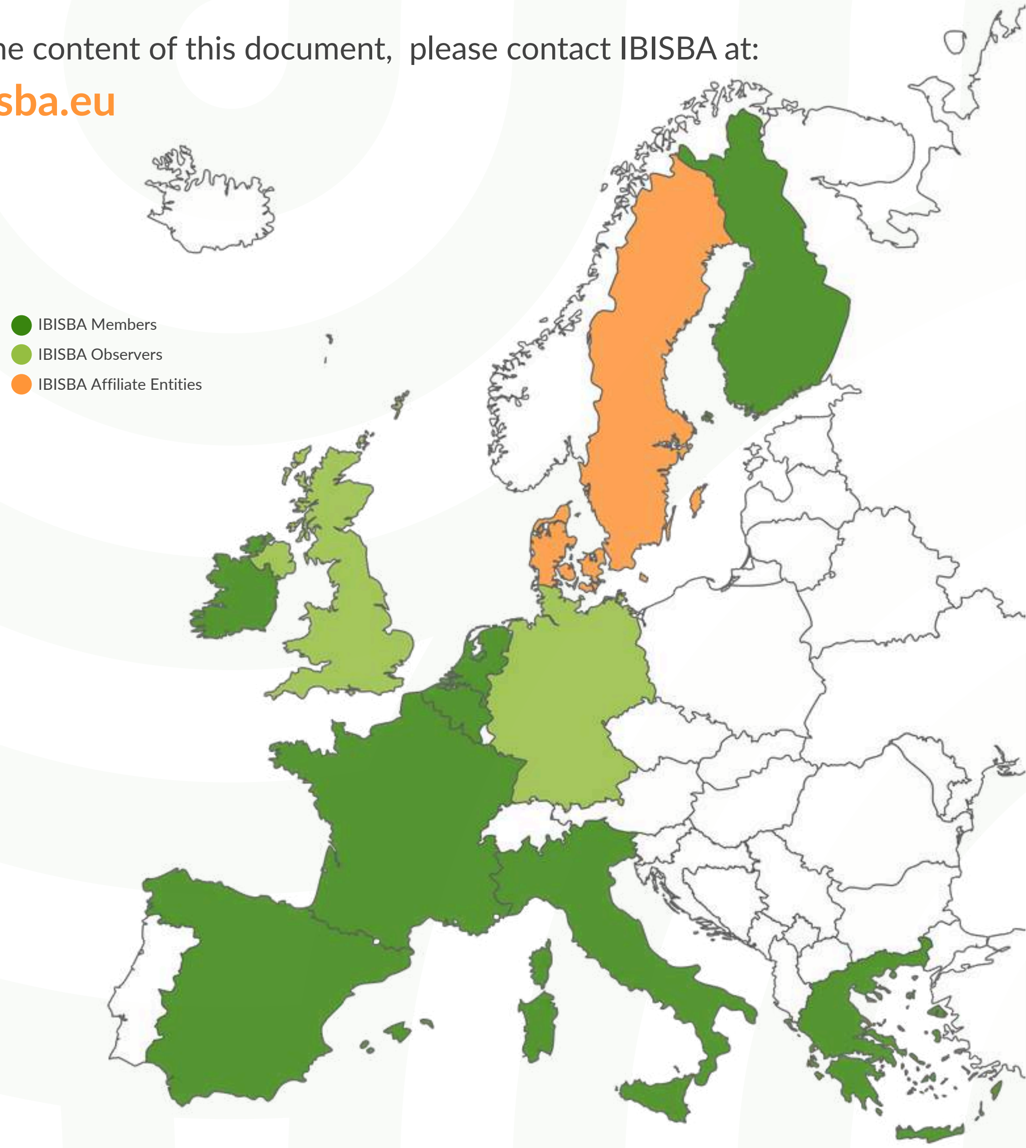

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