BioTech Brief

Regulation

1 | 2025

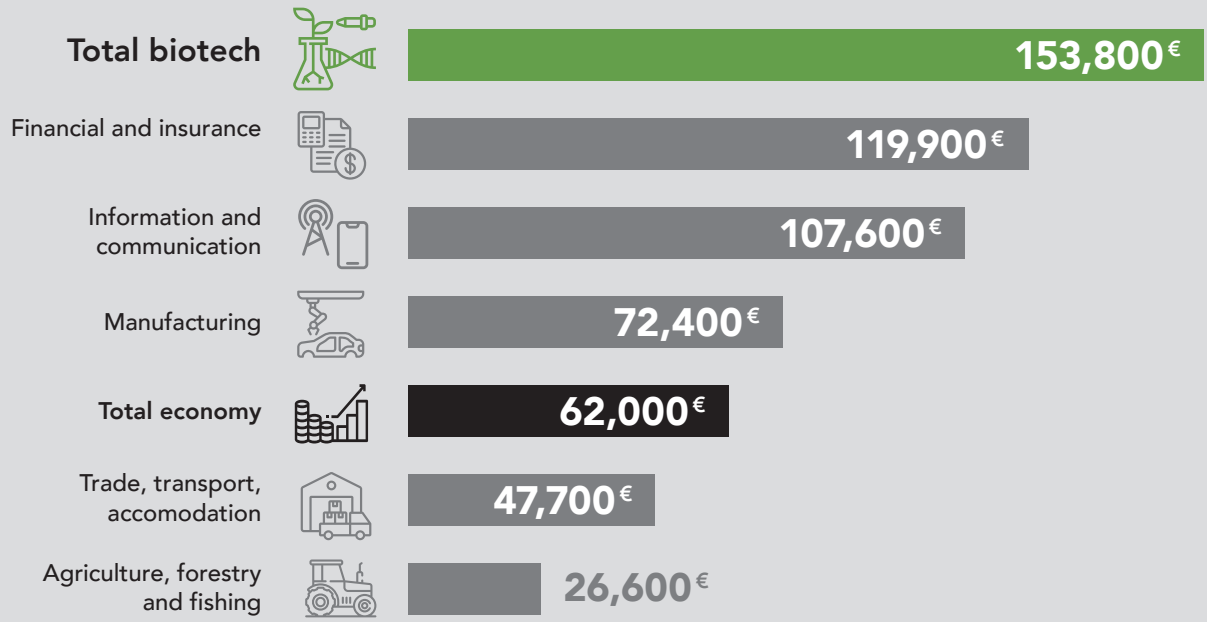
Deutsche Industrievereinigung Biotechnologie

Biotech regulation: Making Europe fit for the future

In early September 2024, Mario Draghi, the EU's special representative for competitiveness, presented a dramatic analysis. The key message: Europe urgently needs more innovation and investment in future-oriented economic sectors. The continent must overcome its static industrial structure and massively increase its productivity. The EU initiative „Boosting Biotechnology and Biomanufacturing" is a unique opportunity for the EU and its Member States to take urgent and immediate action to support and expand biotechnology and biotech manufacturing in the EU.

Biotechnology is characterised by the fact that it uses biological systems as the basis for developing new processes and products that were previously not possible with other technologies. By harnessing the potential of nature, biotechnology offers revolutionary solutions in health, agriculture and industrial processes with unrivalled efficiency, precision and sustainability. However, the technology has not yet been able to reach its full potential, in particular due to outdated and uncoordinated regulations. It is therefore essential to create an internationally competitive regulatory environment in the EU that allows investment in research, development, production and market uptake.

Labour productivity
EU-wide labour productivity per person employed per year by sector, 2021 data



Source: WiFOR, 2023

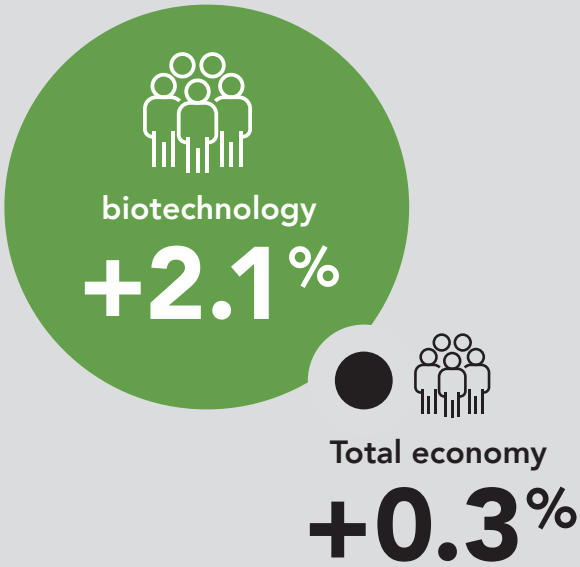
The European Commission has recognised this and wants to remove all obstacles that slow down biotechnology in the EU. The main packages of measures are:

- **Streamlining regulation:** Due to superimposed and complex regulation, approval procedures for biotech innovations in Europe take many years. The EU wants to systematically remedy this situation and speed up market access. Based on a comprehensive study, the EU plans to develop proposals to streamline regulatory procedures, including authorisations and approvals.

- **Driving investment:** Compared to other regions of the world, Europe has significantly lower levels of venture capital. The Commission is analysing how the various public financial instruments and funding opportunities can help mobilise much more capital for early-stage investment. It is also examining the possibility of creating targeted investment incentives through tax credits.

- **Simplify technology transfer:** Europe has an excellent research landscape and is still one of the international pioneers in many areas of biotechnology. However, the transfer of research results into the development of innovative products is unsystematic, especially compared to the US. To identify the key drivers of innovation on the one hand and the barriers to applications on the other, the EU Commission has launched a study.

Increase in employment
Average annual EU employment growth rates, 2008-2021



Quelle: WiFOR, 2023

EU recognition

The EU's recognition of biotechnology as a critical technology is an acknowledgement of its role in transforming traditional industrial ecosystems towards a sustainable and climate-friendly future, where international competitiveness and security play a key role. In a global race, countries and companies that establish themselves as leaders in the full use of biotechnology will win.

- **Stimulating market demand:** It is crucial for bio-based products to demonstrate their advantages in terms of sustainability and lower environmental impact compared to fossil-based products. The EU therefore plans to review the assessment of fossil-based and bio-based products in the light of the latest scientific evidence, to ensure fair and equal treatment.

- **Strengthening competences:** The EU wants to increase support for the development of critical technologies. In addition to deep-tech innovation, this explicitly includes biotechnology. This includes: Streamlining regulation, simplifying technology transfer, stimulating market demand and closing the skilled labour gap.

DIB explicitly welcomes the initiative of the EU Commission. As promised by the EU, it can indeed develop into a booster for biotechnology made in Europe and provide the EU and its member states a considerable boost as a centre of innovation. The success of the initiative is a cornerstone for Europe's continued prominence as an industrial destination.

Getting biotechnology on track: EU study lays foundation for effective rules

According to the EU Communication, biotechnology needs to be freed from an overly complex and innovation-hampering regulatory environment; lengthy approval and licensing procedures – for example, very slow and complicated procedures for approval of production facilities – need to be massively shortened and streamlined in favour of Europe as a location for investment and production.

This broadly underscores the requirement for political steps to be taken. A significant overhaul and harmonization of regulations are needed at European and national levels. Europe needs a predictable framework that strongly supports research, development and production of biotechnological solutions and offers companies planning security. A study to be carried out at the beginning of the new European Commission's term of office will provide the necessary basis for decision-making.

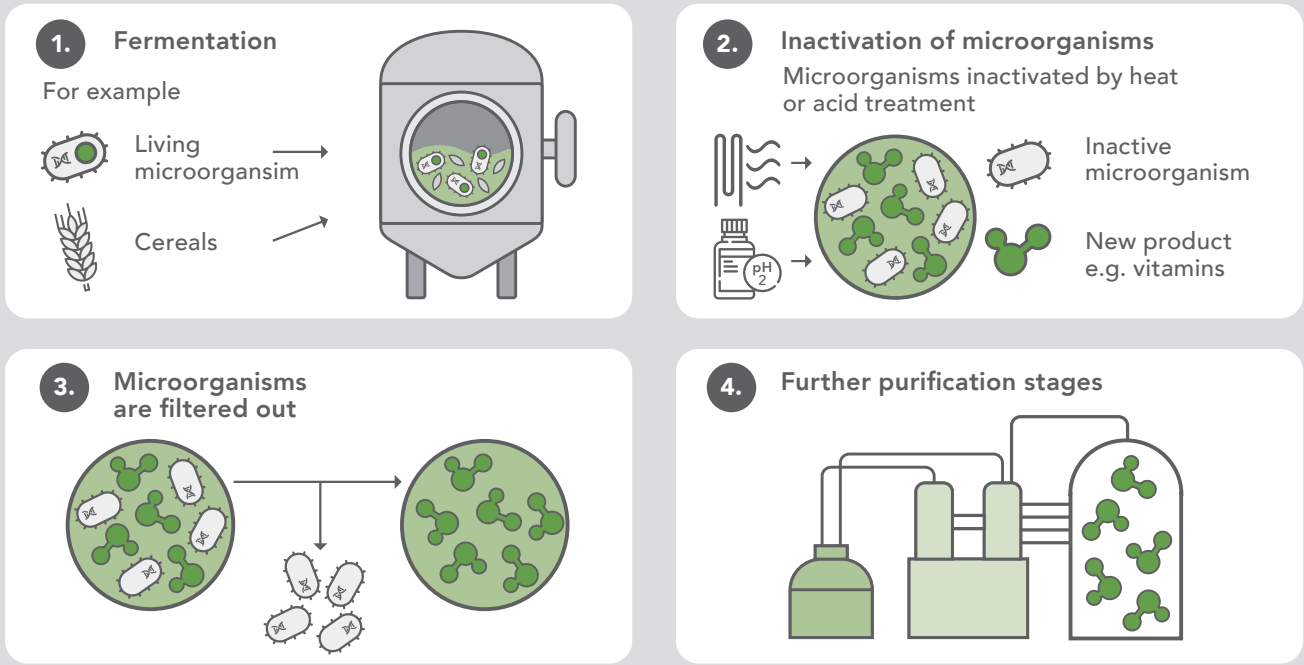
From the point of view of the biotech industry, it is important that the study is designed to take a comprehensive look at the complex field of biotechnology. It must address all the key issues in order to create the conditions for EU-wide harmonised, science-based and innovation-friendly regulation – this would be a major step forward.

Microorganisms: Rejecting scientifically unfounded over-regulation

Microorganisms enable the sustainable and economic production of essential amino acids and vitamins. They are also essential for the production of enzymes, e.g. for the production of biofuels or food flavourings. The current new EU approach is that fermentation products (e.g. amino acids, vitamins, enzymes) produced in contained use with genetically modified micro-organisms (GMMs) as processing aids do not fall under the scope of Regulation (EC) No 1829/2003, provided that no viable

Fermentation at a Glance

Industrial fermentation is subject to the most stringent of regulations. Production facilities and processes undergo specific EU approval procedures before being put into operation. All manufacturers of fermentation products have quality management systems in place. These systems ensure consistent product quality and safety. Independent auditors continuously review and certify quality systems for regulatory compliance.



GMM cells are present in the final product. This good practice has been proven to be safe for decades.

However, a new interpretation of the legislation threatens to jeopardise this success story. Some EU Member States are calling for the use of traces of recombinant DNA (rDNA) as a new marker for the classification of such products under Regulation (EC) No 1829/2003. This ignores the scientific evidence that even the tiniest traces of rDNA pose no risk to health or the environment.

Certain EU Member States' reinterpretation has resulted in products containing traces of rDNA being flagged as unauthorised in the EU Rapid Alert System, despite their longstanding presence on the EU market under existing product authorisations. Should these DNA traces be classified as regulatory markers, these products would immediately lose their authorisation, jeopardising both established practices and Europe's capacity for innovation in sustainable biotechnology.

It is therefore crucial to maintain the existing science-based regulation, as is the practice in other countries such as China and Brazil. Enzymes and other fermentation products are a cornerstone of modern, resource-efficient production processes and should not be jeopardised by scientifically unfounded over-regulation.

Explore more in a related BioTech Letter
Bioeconomy

Support for novel foods
Food products that were not significantly consumed in Europe before 1997 are considered novel and are subject to the EU authorisation procedure. This includes a wide range of new food products- from seeds such as chia seeds to foods based on innovative production processes. The problem is that the approval process is complex and can take up to four years. That is why the Netherlands has allowed early tasting of novel foods since 2023.

Sensory evaluations are an essential part of the authorisation process. They serve to ensure the economic potential in terms of consumer acceptance and market feedback, innovation and competitive advantage, investment and financing, as well as the environmental potential of this new technology in terms of sustainability, environmental awareness and resource conservation. The EU Commission is invited to facilitate tastings based on the Dutch model.

At the European level, the Novel Food Regulation needs to be brought into line with international standards and more space needs to be created for biotech innovation. The potential in terms of sustainability is considerable: For example, precision fermentation can be used to produce meat and sausage alternatives from fungal proteins with significantly lower water consumption and CO_2 emissions compared to conventional foods. At the same time, biotechnologically produced food is an important answer to opening up new food sources without requiring additional agricultural land.

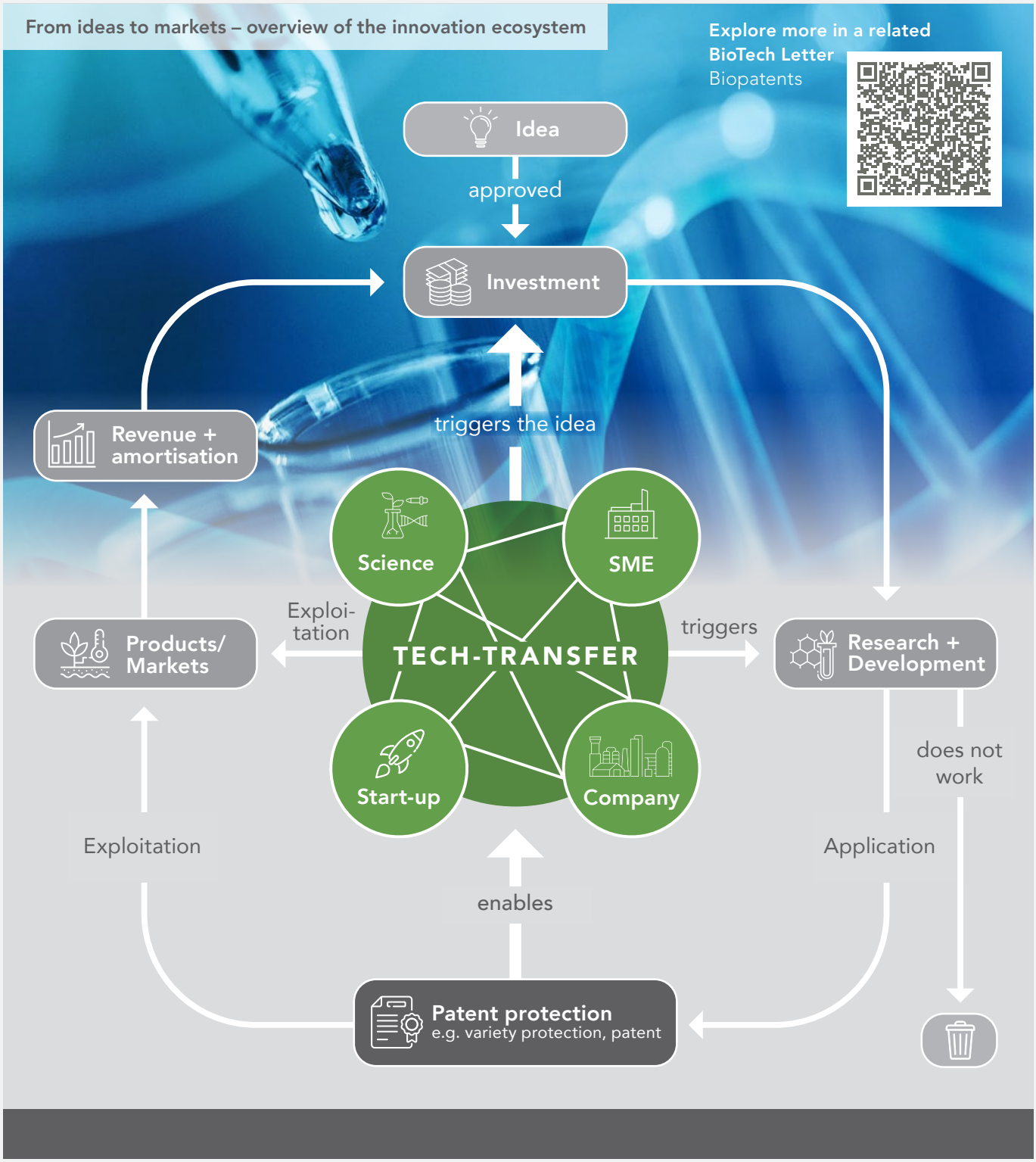
Gene editing: Liberating Innovation
Gene editing represents one of the most significant innovations in biotechnology over the past two decades. It is a set of methods – known as new genomic technologies (NGTs) – enabling the targeted modification of individual DNA building blocks. In plant breeding, for example, NGTs help to a plant's full yield potential in a targeted and sustainable way and to improve its resistance to disease. The faster NGTs are deployed – whether by start-ups, SMEs, large companies or public research institutions – the faster they can contribute to climate adaptation, sustainability and food security.

Many countries are promoting the use of NGTs in agriculture, medicine and industrial biotechnology. However, the EU remains divided, slowing down the innovation of this game-changing technology. Legislators need to put in place a workable, science-based and future-proof NGT regulation as soon as possible.

Explore more in a related BioTech Letter
Gene-Editing
(in German only)

Preserving patentability

Europe's biotechnology sector is based on an innovation ecosystem in which academia, start-ups, SMEs and large companies work closely together. Patents play a key role in this open system, ensuring that research results are protected and that the high development costs can be refinanced. Patents are particularly important for start-ups and SMEs without large amounts of capital to obtain sufficient funding for their innovation efforts. It is concerning that, as part of the legislative process on NGTs, there have been calls to exclude plants or plant material bred through these techniques from patent protection. The effects would be far-reaching: insufficient patent protection would stifle investment in this domain. Questioning the proven patentability of plant breeding could have implications for legal certainty in medical and industrial biotechnology, too. Europe must therefore continue to offer biotechnological innovations the same proven and adequate patent protection as all other commercially tradable goods.



Better framework conditions for innovative solutions – now!

Biosolutions – i.e. enzymes, microbial cultures and functional proteins – are more important than ever. They increase resource efficiency and play a key role in the transition from fossil-based to bio- and circular-based industrial value chains. They support the shift towards alternative and healthier sources of protein and help to significantly reduce the carbon footprint of food production. In short, biosolutions are part of the answer to feeding the world more sustainably.

However, the political framework is slowing down progress massively. Would you like an example? In Nienburg an der Weser, Germany, we produce cultures for organic crop protection. These cultures are in demand worldwide, especially in South America. The EU is not benefiting from this innovation because the approval process can take up to 9 years and is therefore not internationally competitive – an obstacle to par excellence!

My second example concerns the classification of enzymes as biological molecules. They are subject to the REACH chemicals regulation and are therefore treated 1:1 as chemicals. The regulation does not distinguish between these enzymes and chemicals, even though the two are fundamentally different. This leads to massive regulatory obstacles and therefore drastic consequences for the use and market introduction of enzymes in the EU. In order to realise their enormous potential for the bioeconomy, biosolutions need to be properly regulated in the EU quickly.

As if that were not enough, other restrictions are on the horizon. For example, lactic acid bacteria, which we have been using safely and successfully in various foods for decades and whose use is regulated under general food law, could soon be subject to additives regulations if some EU countries get their way. The result would be approval procedures that would delay the launch of new products by two to three years and, in the worst case, could even lead to a marketing ban. All of this goes against the principle of a sustainable and forward-looking economic policy.

Europe and Germany must finally adopt a new regulatory approach. Biosolutions should no longer be subject to a regulatory regime that focuses on chemical substances. The new EU Commission's agenda to prioritise industry competitiveness and sustainable innovation is encouraging. In my view, what is needed now is to cut red tape, create legal clarity and planning certainty for food producers, and harmonise the regulatory framework across the EU. Let us usher in a new era of transformative policy!

Michael Erkes
Trained Butcher,
Food Engineer,
Head of Business
Meat & Prepared
Food Europe by
NOVONESIS

novonesis

NOVONESIS was formed in January 2024 through the merger of Novozymes, which has almost 100 years of experience in the field of enzymes, and Chr. Hansen, which has 150 years of expertise in microbial food cultures.

NOVONESIS key data

- **Registered office:** Denmark
- **Employees worldwide:** 10.000
- **Annual global turnover:** €3.7 billion
- **Locations in Germany:** Nienburg, Pohlheim, Rheinbreitbach, Bonn and Berlin
- **Investment volume in Germany since 2022:** over €40 million

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Deutsche Industrievereinigung Biotechnologie (DIB)
im Verband der Chemischen Industrie e.V. (VCI)
Mainzer Landstraße 55
60329 Frankfurt
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Executive Director:
Dr. Ricardo Gent
Phone +49 69 2556-1459
Telefax: +49 69 2556-1620
E-Mail: gent@dib.org
Internet: www.dib.org