BioTech Letter

Bioeconomy

2 | 2024

Deutsche Industrievereinigung Biotechnologie

Bioeconomy: Keeping the legislation workable

The EU is striving to become a world leader in the bioeconomy in order to conserve resources and to develop a sustainable economy. Microorganisms play a key role in this process. They enable essential amino acids and vitamins to be produced in a sustainable and economic way. Microorganisms are also essential for the production of enzymes, which are used for example in the production of biofuels or food flavors. But at the EU level, we are facing the threat of a ban on biotechnologically enhanced microorganisms. It is important to safeguard the regulations that have been in place for decades.

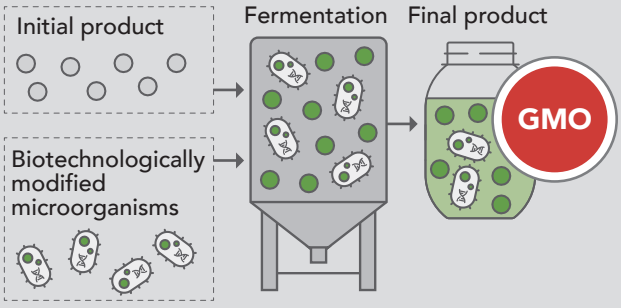
Microorganisms have been modified since the 1930s. Initially, radioactive radiation and chemicals were used, but since the 1990s, targeted biotechnological methods have also been put to use. The advantage is that the microorganisms can be specifically optimized to produce the desired products in a more efficient way while at the same time reducing the ecological footprint.

End products are not genetically modified

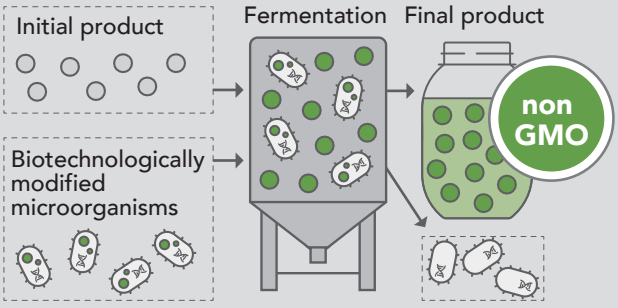
In the end products (amino acids, vitamins, enzymes, etc.), the bioengineered microorganisms themselves play no role. Once the fermentation process is complete, the inactivated microorganisms are removed. Regardless of whether they have been biotechnologically enhanced or not. Therefore, the final products are not considered genetically modified and are not subject to the regulation on genetically modified organisms (GMOs).

The microorganisms are always used in closed systems. The final products may contain unavoidable traces of modified DNA. However, the residual DNA is not relevant to the safety of human or animal health and does not adversely affect the environment, as scientists and regulators have established for decades.

Resulting product **contains** biotechnologically modified microorganisms.



Resulting product is **manufactured through the use** of biotechnologically modified microorganisms.



Paradigm shift on the horizon
Now, a zero-tolerance position is being discussed in the EU. This would put an end to this proven approval practice for food and feed. End products containing even the smallest traces of DNA from genetically modified microorganisms would be subject to GMO Regulation 1829/2003. Lengthy and costly authorisation procedures would then apply to these products. This is completely incomprehensible from a scientific perspective.

Zero tolerance is not an option
The consequences of an inappropriate regulatory approach would be devastating.

- **Burden for greater sustainability:** Biotechnologically engineered microorganisms play an important role in the production of amino acids, enzymes, vitamins and flavors worldwide. These microorganisms increase yields, improve performance and reduce environmental impact. In most cases, there are no alternative production processes and/or non-GMO production strains to produce vital, high-quality food and feed additives in the quantities needed and in a sustainable manner.

- **Production on the verge of shut down:** Companies producing food and feed with biotechnologically optimized microorganisms would have to cease production and marketing of such products in Europe. Production is always where the markets are. Billions in gross value added are at stake across Europe. A total of 53,000 jobs are at risk. It would also affect the second health market, which includes vitamin products.

- **The entire bioeconomy is at risk:** Bioengineered organisms are used to produce products beyond food and feed, such as bio-based materials/specialty chemicals. In addition, the future of biotechnology „made in Europe" is threatened by the „residual DNA" debate: If legislators treat biotech processes with a generalized suspicion that is far removed from a risk-based perspective and change established regulations in a quasi-arbitrary manner, companies will not be able to advance this key technology in Europe.

One thing is clear:

- Biotechnologically optimized microorganisms have been perfected for the respective fermentative production process and are officially approved for use in biotechnological plants.

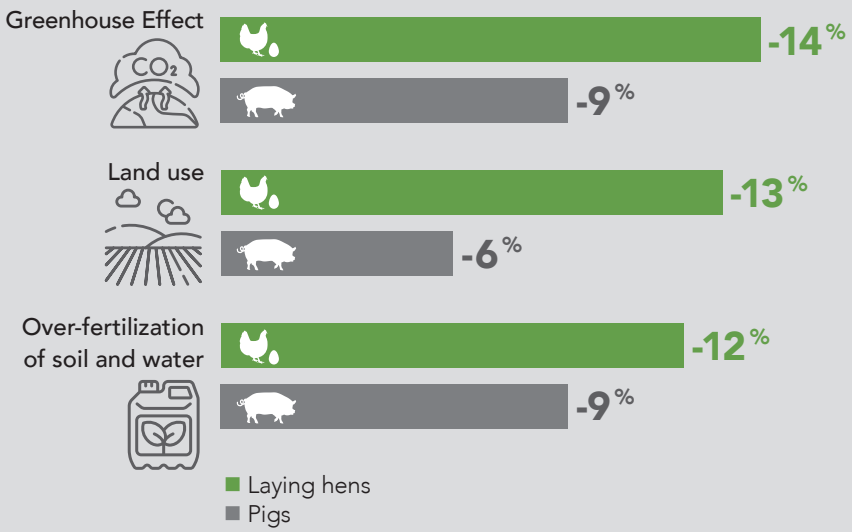
- Genetically modified microorganisms are only approved for food and feed production if they are considered safe for humans, animals and the environment.

- Viable, genetically modified microorganisms do not remain in the final products. They are therefore not subject to the GMO Regulation.

- Food and feed produced with the help of biotechnologically optimized microorganisms are subject to the relevant application law, e.g. for feed additives or enzymes, and are continuously monitored.

Ensure a reliable regulatory framework in Europe
DIB and its member companies strongly reject the zero tolerance plans of the EU Commission. Instead, it is necessary to maintain the existing and proven regulatory requirements for product approval where no viable cells of the optimized microbial production strain are present in the final product. The regulatory requirements also need to be in proportion to the actual risks involved. Similarly, the balance between allowing innovation and ensuring safety must be maintained.

Producing more sustainable animal feed with biotechnologically optimized microorganisms
Livestock production currently accounts for more than 14 percent of greenhouse gas emissions and one third of global nitrogen emissions. Microbially enhanced feeds have enormous potential for more sustainable agriculture.



Source: Evonik, audited by TÜV Rheinland

Fermentation: Thousand-year-old technology in a new form

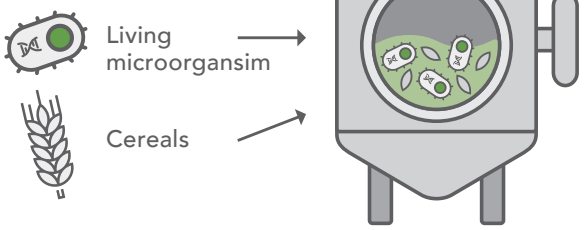
For thousands of years, microorganisms have been used in fermentation processes to turn milk and fruit into cheese and beverages. Industrial fermentation relies on organisms that are optimized for efficiency and sustainability, and that are safely inactivated and removed after fermentation in closed systems.

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.

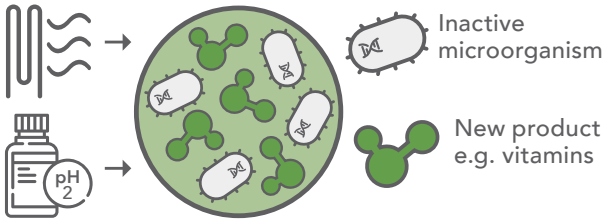
1. **Fermentation**

For example

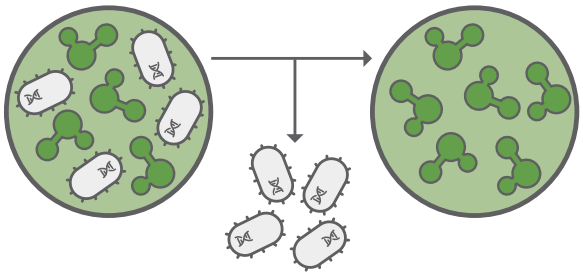


2. **Inactivation of microorganisms**

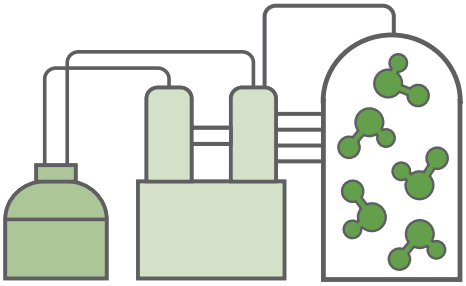
Microorganisms inactivated by heat or acid treatment



3. **Microorganisms are filtered out**



4. **Further purification stages**



5. **Final product such as:**

- **Amino acids** – promote a healthier and more balanced diet.
- **Vitamins** – support metabolism, growth and immunity.
- **Enzymes** – improve food processing and feed conversion.
- **Biosurfactants** – significantly improve the environmental performance of cleaning and cosmetic products.
- **Specialty chemicals** (e.g. hexanoic acid) – produced by bacteria from carbon dioxide (CO_2) and electricity from renewable sources, reducing dependence on fossil fuels. These specialty chemicals are starting materials for the lubricants and cosmetics industries, for example.

Industrial biotechnology: harnessing its potential

Key policy initiatives, such as the Green Deal and the Farm-to-Fork strategy, depend on biotechnological solutions: They reduce natural resource consumption, promote sustainable food and enable the transition to a bio-based circular economy.

The opportunities are also undisputed in the political arena. In early July, the Chancellor's Future Council emphasized the enormous importance of biotechnology for Germany, discussing it with Federal Economics Minister Robert Habeck and Federal Health Minister Karl Lauterbach, among others. The benefits of biotechnology are explicitly recognized by the EU Commission: „In agriculture, animal husbandry and aquaculture, biotechnology has improved animal feed." And in industrial processes, the EU Commission points out: „By using fermentation instead of traditional chemical synthesis, higher process efficiency can be achieved, reducing energy and water consumption."

USA pushes bioeconomy hard

The U.S. government has adopted a comprehensive funding and reform program for biotechnology in 2023. The main objectives are: Replace plastics and synthetic polymers with biobased alternatives, meet 30 percent of chemical needs with bioengineered products, increase cell-based drug production tenfold, and produce 11.4 billion liters of biokerosene. In order to achieve these goals, the U.S. government intends to cut red tape, fund research, and greatly facilitate the exchange of data for the bioeconomy. This example underscores the fact that global competition is intensifying. Germany and Europe must offer biotechnology a forward-looking framework.

Europe's viability is at stake!

Guest article by **Dr. Harald Schwager**, Member and Vice Chairman of the Executive Board of Evonik Industries

Ursula von der Leyen, President of the EU Commission, has said it clearly: Biotechnology is the key technology. There are two reasons for this: First, a sustainable bioeconomy and a successful fight against climate change are inconceivable without biotechnology. Second, fermentation processes will play an even greater role in global production processes in the future - economic growth and prosperity in Europe depend on them.

In a wide range of fermentation processes, such as the production of food ingredients or feed additives, biotechnology relies on the performance of genetically optimized microorganisms. Fermentation processes are also used to produce chemicals and biofuels. In addition, biotechnology enables bacteria or yeast to perform photosynthesis. However, European legislators are threatening to tighten the regulatory framework carelessly because decades of safe use of optimized microorganisms in various fermentation processes have shown that the minute traces of DNA of optimized microorganisms are no longer intact and absolutely harmless.

The zero-tolerance position is purely ideological. If it were to become law, biotechnology would have no future in Europe. Development and production would take place in America and Asia. I urge those in positions of responsibility not to gamble with Europe's future in this way. Please come and talk to the members of DIB, come and visit Evonik and find out what we are doing to create innovative, value-adding and sustainable solutions for our customers. And help us to ensure that we can continue to use our innovative strength for the benefit of the people of Europe.

With around 34,000 employees worldwide, including around 23,000 from EMEA, Evonik Industries produces specialty chemicals that are, for example, essential for fuel-efficient tires, healthier animal nutrition and a circular economy. Biotechnological processes are often fundamental to this. The company invested around 460 million euros in research and development in 2022 alone.

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