

Novozymes position on the regulatory framework for biotechnology innovation in the EU

Summary

Industrial biotechnology is a key enabling technology; it offers multiple benefits, helping address several societal challenges such as climate change, resource scarcity, pollution, etc. The future of industrial biotechnology and ability to offer solutions relies on its ability to innovate.

The regulatory framework for biotechnology innovation in the EU, in particular Directive 2001/18 on the deliberate release of GMOs, is no longer fit for purpose. Its technology-based approach prevents the use of modern biotechnology techniques, hampering innovation, and putting at risk the competitiveness of the European industry.

To ensure Europe can continue to innovate and develop sustainable solutions, a change of legislation is required. Novozymes therefore recommends revising Directive 2001/18 to adapt it to past and future innovation progress, focusing on products rather than processes.

Industrial biotechnology is a Key Enabling Technology

The EU recognizes industrial biotechnology as a Key Enabling Technology¹ because it is instrumental in modernizing European industry and driving the sustainable development of existing and new industries. Industrial biotechnology plays a crucial role in addressing societal and economic challenges and supports the development of the bioeconomy. It stimulates job creation and sustainable growth. Proven benefits of industrial biotechnology for society and the planet include, but are not limited to:

- reduced use of raw materials, water and energy
- reduced production of waste
- replacement of greenhouse gas emitting technologies with renewables
- substitution of hazardous and fossil-based chemicals
- improved human and animal health e.g. by eliminating antimicrobial resistance
- mitigation of climate change effects and improved land use in agriculture (using microorganisms).

The relevance of industrial biotechnology comes from the above multiple benefits and from the fact that it has been routinely used (as live microorganisms or fermentation products) for decades in food and feed production, agriculture, and many large industries such as cleaning products.

The future of industrial biotechnology and ability to offer solutions relies on its ability to innovate. In the past two decades, innovation progress in biotechnology has led to a variety of techniques to introduce desirable changes in organisms such as plants, and microorganisms used for food, feed, bioenergy production and more. Compared to older tools, new biotechnology techniques can make genetic changes in a more and more precise manner with limited unintended effects in the organism. They provide a growing degree of accuracy, contributing to safety and increased efficiency. They open new opportunities for the development of organisms and products at an increased speed, at a time when the challenges the planet faces have become more acute and urgent to address.

¹ European Commission, Internal Market, Industry, Entrepreneurship and SMEs: http://ec.europa.eu/growth/industry/policy/key-enabling-technologies_en

The present EU regulatory framework is no longer operational

On 25 July 2018, the Court of Justice of the European Union (CJEU) issued a judgement in Case C-528/16 ruling that targeted mutagenesis methods that have been developed after 2001 are in the scope of Directive 2001/18 (on the deliberate release of GMOs in the environment or "GMO Directive") and therefore subject to its requirements. The issue faced by the European biotechnology is not the CJEU ruling itself but the Directive it is based upon.

Directive 2001/18, and other biotech-related directives and regulations, rely on the technologies used to develop an organism, to determine its categorisation and safety evaluation procedures. This approach was developed in the 1980's, when molecular biology was evolving at a slow pace. Since the mid-2000's, innovation in biotechnology has been thriving and accelerating, providing new tools and new opportunities at a faster pace. While this acceleration must be dealt with responsibly by public and private research, it requires an adaptation of the present technology-based legislation.

In parallel, certain applications of new techniques result in microorganisms that cannot be distinguished from counterparts found in nature. This is due to the increased accuracy of modern techniques, as well as the more discrete nature of interventions being made. This constitutes a major challenge for official controls and for traceability in the present framework as recently highlighted by the European Commission Joint Research Centre (JRC)².

Directive 2001/18 is no longer fit for purpose, nor operational. This was confirmed by the European Commission's Chief Group of Scientific Advisors in November 2018.³ Its technology-based set-up prevents innovation, does not ensure a level playing field – in particular vis-à-vis products imported from third countries. It also consumes a large amount of European institutions resources, thereby not being optimal anymore for an effective protection of consumers and the environment.

Reviewing and updating Directive 2001/18 has become unavoidable to enable innovation for the achievement of sustainability and climate goals, to ensure continued competitiveness of the European biotech sector, as well as its users while maintaining a high-level of protection of citizens and the environment.

A modern and operational regulatory framework

Technology is generally not safe or unsafe by nature. In the case of modern biotechnology techniques, tools such as whole genome sequencing allow an accurate characterization of genetic changes performed on a microorganism and adequately support its safety assessment as well as categorisation.

We therefore propose that the revised legislation:

- Focuses on the organism, not on the techniques used to obtain it, in other words that it bases the containment level and safety assessment of a microorganism on its characteristics, rather than on the technology used to obtain it;
- Is based on a scale of increasing risks:
 - o an organism that is very close to a natural counterpart will undergo a proportionate, low level of safety assessment, containment and traceability, while
 - o an organism presenting higher levels of newly inserted characteristics will be subject to more stringent safety, containment and traceability requirements;

² JRC, "Technical report on detection methods", March 2019, <http://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf>. It highlights how the existing GMO detection methods are no longer adaptable as gene edited products can only be detected "when prior knowledge on the altered genome sequences, a validated detection method and certified reference materials are available". The same report further outlines how "this will have important consequences for the enforcement of the GMO legislation".

³ EC Scientific Advisory Board, "A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive", 13 November 2018, https://ec.europa.eu/info/sites/info/files/2018_11_gcsa_statement_gene_editing_2.pdf

- Allows for a proportionate and enforceable level of supervision and traceability, establishing a clear and level-playing field; for example, that does not regulate similar organisms in different ways;
- Promotes responsible innovation and stimulates the competitiveness of the EU-based industrial biotechnology and its users.

Such an approach focusing on the organism itself, with its intrinsic characteristics and backed up by scientific criteria, would preserve or increase safety for consumers and the environment, while being operational for enforcement and official control purposes.

This way, the EU regulatory framework would also be more aligned with regulatory frameworks from other major economies, allowing European industry to remain competitive.

About Novozymes

Novozymes is a Danish industrial biotechnology company and the world's largest provider of enzyme and microbial technologies. We find enzymes in nature and optimize them for use in various industries (food, feed, textile, household care, bioenergy, agriculture sectors etc). They help our customers make more from less, while saving energy and generating less waste. Like enzymes, microorganisms have natural properties that support more sustainable agriculture, animal health and nutrition, industrial cleaning and wastewater treatment.

Novozymes strives to have great impact by balancing good business for our customers and our company, while spearheading environmental and social change. As such, we are committed to using responsibly and ethically the most performing available biotechnology techniques, to develop and improve microorganisms and products that can be assessed safely for consumers and the environment.

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