Considering microorganisms and New Genomic Techniques: on the need for a new GMO legislation in the European Union

Context and key messages

- Based on its 2021 study on New Genomic Techniques (NGTs), the European Commission has initiated a policy action on plants produced by targeted mutagenesis and cisgenesis. For microorganisms, the Commission has outlined that it will continue to build up scientific knowledge.
- Hundreds of fermentation products developed using microorganisms have been evaluated and approved since the early 1980s. Furthermore, biotechnological applications are highly advanced in microorganisms, due to their smaller and simpler genomes, shorter replication cycles and high growth rate, and ease of sequencing their entire genomes. Several dozens of species are used on a routine basis for microbial production. As policy action on NGTs for plants will evidently have implications also for microorganisms, it is crucial to consider them in parallel from the outset.
- NGTs provide significant opportunities to create new processes and products and improve existing ones, marking a shift away from the petrochemical era as we seek to achieve the EU Green transition. A future-proof, product-centric regulatory framework for all products of biotechnology where the requirements are predictable and proportionate to risk will be key to enable biotechnology innovation to contribute to this achievement.

Industrial Biotechnology and relevance to Green Deal objectives

Industrial biotechnology plays a key role in sectors such as food and feed production, agriculture, cosmetics, health, biofuel production and the chemical industry. These have successfully used microorganisms (yeasts, fungi, bacteria) and fermentation products in bio-based innovations for decades. Key advantages include reduced CO_2 emissions, improved resource-efficiency of industrial processes and provision of sustainable alternatives to fossil-based products. Important microbial products for human and animal health include probiotics, prebiotics like human milk oligosaccharides, and micronutrients like vitamins and amino acids. Microbes can help meet the growing global demand for protein whilst reducing impacts on the environment. Industrial biotechnology also provides solutions to foster a less resource-demanding, more sustainable agriculture, such as phytase enzyme to decrease the need for phosphorus supplementation of animal feed, or biological plant protection products. Industrial biotechnology thus strongly supports the Green Deal objectives.

Some innovations in industrial biotechnology rely on the genetic improvement of production microorganisms. This is accomplished using constantly evolving techniques, tools and methods. The biotechnological optimization of microorganisms results in both efficiency and sustainability benefits, such as higher yields of the intended molecules (e.g. amino acids, vitamins, or enzymes), elimination of genes that are of potential safety concern, improvements in the utilization of nutrients, energy and water, and a lower environmental footprint. The improvements can contribute to the elimination of toxic chemicals and allow mild, environmentally friendly process conditions supporting the Commission´s Chemicals Strategy for Sustainability and safe and sustainable-by-design concepts.

New genomic techniques

Gene technology[1] (also known as genetic engineering) provides ample opportunities to create new and/or improved processes and products. Within the gene technology concept, new

[1] Gene Technology is a set of tools that allow targeted changes of the genome of an organism. NGTs are a subset of the whole gene technology toolbox.

genomic techniques (NGTs) are defined by the EU Commission as techniques capable of changing or altering the genetic material of an organism and that have emerged or have been developed since 2001, when the existing GMO legislation was last updated. NGTs are highly attractive, precise state-of-the-art techniques and offer multiple benefits for both deliberate release and contained use applications.

Burdensome regulatory procedures, however, prevent some innovative products of industrial biotechnology from entering the market. At the same time, in other parts of the world, NGT products are not seen as different from their conventional counterparts if they also could have been obtained with classical techniques.

In 2021 the EU Commission published a study assessing the role of NGTs and their status under Union law, encompassing NGT use in plants, animals and microorganisms for agri-food, industrial and pharmaceutical applications. A key conclusion of the Commission´s NGT study was that current EU GMO legislation is not fit for purpose: it does not fit the significant advances in technology and has impacted Europe's global competitiveness. The study also shows that NGT products can contribute to sustainable food systems and thus also Green Deal and Farm to Fork objectives.

Microorganisms must be included in future policy actions on NGTs

In follow-up to the study the Commission has initiated a targeted policy action on plants derived from certain NGTs (cisgenesis and targeted mutagenesis). For other NGTs or for applications including microorganisms, the Commission considers that the necessary scientific knowledge is still limited or lacking, especially on safety aspects.

As a matter of fact, many highly advanced genetic engineering techniques, including e.g. CRISPR/Cas9, were initially developed in microorganisms and are already actively used in contained use applications, for a variety of reasons:

- Microorganisms have smaller and simpler genomes than plants and are more amenable to genetic modification.
- Microorganisms have high growth rates, therefore allowing a quick examination of the outcomes of the modifications.
- Whole-genome sequencing allows the identification of potential off-target effects of genetic modifications in microorganisms, and thus the selection of the desired modifications.

Any policy action on NGTs for plants will inevitably set the ground for future policy, thereby also impacting microorganisms. Therefore, advanced knowledge on microorganisms can and should contribute to policy action on NGTs – for all organisms including plants and microorganisms. For a cohesive approach, microorganisms should be considered in parallel to the ongoing policy action for plants.

Beyond NGTs, the long-term perspective for innovative biotechnology in Europe should also consider a significant modernization of the EU's GMO legislation (Directives 2001/18 and 2009/41, and Regulation EC (No) 1829/2003). To keep up with the fast pace of innovation in this sector, the legislation should be based on the characteristics of the organisms (or their products) rather than on the techniques used to develop them. Organisms that cannot be distinguished from one another can be obtained using different methods like conventional techniques or NGTs. By regulating these organisms in an identical way, the legislation will be transparent, fair, and enforceable.

A future-proof, product-centric regulatory framework for products of biotechnology where regulatory requirements are proportionate to safety risk is imperative for the EU biotechnology sector to secure its global competitiveness, building on the long record of EU excellence in biotechnological innovation, whilst further contributing towards the EU green transition for a more sustainable future.

EuropaBio *aisbl*
Avenue des Arts 53, 1000 Brussels
+32 2 735 03 13
www.europabio.org
VAT BE0477520310