EuropaBio response to NOU 2023 -18 *Gene technology in a sustainable future*

EuropaBio welcomes the opportunity to comment on the Committee report *Gene technology in a sustainable future*. Our comments focus on the general principle of the majority's proposal and on organisms intended for food, feed and agriculture, as well as other releases for industrial, and environmental purposes (excluding GMO medicinal products).

EuropaBio considers that the Committee's general assessment of the current situation is accurate: gene technology can contribute significantly to a more sustainable future; today's regulations and their implementation create many obstacles to realise its full potential; current gene technology regulations, management and policies inhibit innovation and access to safe and useful products.

We fully agree with the recommendation of the Committee to modernise the current regulation of organisms and products developed using gene technology and advocate for similar modernisation of the EU GM framework. Furthermore, we also support the Committee's view that any new proposal for regulating products developed with gene technology should consider all living organisms, i.e. plants, animals, and microorganisms. The scope of the proposal should be clear with regard to fermentation products: products produced using genetically modified microorganisms (GMMs) should not fall in scope of the Gene Technology Act.

More specifically, EuropaBio supports the following aspects of the majority's proposal:

i. Laying down requirements for the use of the precautionary principle in the regulations to the Gene Technology Act, in the same way as in the Food Act regulations, to ensure that a precautionary measure is proportional and non-discriminatory, and that the authorities are obliged to actively obtain the necessary knowledge within a reasonable time to maintain or terminate a measure.

ii. A significant change of direction with focus on the final product/organism that will provide a more predictable, proportionate to risk and resource-efficient path from research and innovation to market, for products and organisms developed with gene technology.

iii. Different levels for approval requirements, based on the type of genetic change and the knowledge of the trait resulting from the change (as elaborated in Figures 10.1 and 10.2).

iv. The regulatory classification of changes within the species' gene pool in a similar way to those, which could also be achieved by conventional methods and the adaptation of conditions for market access accordingly (no special requirements for labeling, traceability or coexistence).

v. If the trait resulting from the change has a long history of safe use or there is existing knowledge that provides predictable low risk, the requirements for risk assessment should be reduced.

Moving away from technology-specific terminology

EuropaBio fully agrees that the modernisation of the regulatory framework for deliberate release applications to a product-centric, future-proof, science- and risk-based, proportionate, and predictable regulatory approach as proposed by the majority can provide certainty for investments in future applications. We note that the draft document uses the term "precision breeding". We recommend avoiding this term in future legislation: regulatory terminology should be science-based so as to remain clear and consistent amid changes in understanding as well as scientific and technological developments. Furthermore, 'precision breeding' applies to plants and animals, but not microorganisms. We therefore propose to replace the terms 'precision breeding' and 'genetic modification' and instead use categories to distinguish organisms based on their characteristics, for instance:

- Category I: Organisms with genetic changes within the species' [and/or genus'] own gene pool;
- Category II: Organisms with genetic changes beyond the species' [and/or genus'] own gene pool.

Biotechnology – a key enabler for the circular economy and the green transition

Biotechnology contributes to EU growth, with an average annual growth rate of 4.1%. This is more than twice as fast as the EU overall economy. Biotechnology generates highly effective value chains across Europe, outperforms highly productive industries, and contributes to growth through R&D The scientific and technological progress of the industry should be recognised and supported by enabling and pragmatic regulatory frameworks.

Industrial biotechnology uses microorganisms and their fermentation products (e.g., enzymes, vitamins, amino acids) in sectors such as food and feed production, agriculture, consumer products, health, and the chemical industry. Most innovations in industrial biotechnology rely on the genetic improvement of production microorganisms. This is accomplished using constantly evolving techniques, tools, and methods, including new genomic techniques (NGTs).

The biotechnological optimisation 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 utilisation of nutrients, energy and water, and a lower environmental footprint.

See also:

EuropaBio Position Papers:

- *European Commission proposal on New Genomic Techniques – a first step towards modernizing the EU GMO framework*
- *Considering microorganisms and New Genomic Techniques: on the need for a new GMO legislation in the European Union*