# EuropaBio contribution to the Calls for Evidence on the implementation of the Regulation (EU) 2026/1388 on plants produced by certain new genomic techniques (September 2026)

EuropaBio welcomes the opportunity to provide feedback on the delegated and implementing acts supporting the implementation of Regulation (EU) 2026/1388 on plants produced by certain new genomic techniques (NGTs). As discussions move from legislative framework to practical application, it is essential that the resulting system is science- and product-based, proportionate, predictable and workable for innovators, authorities and operators across the value chain. Effective implementation should demonstrate that such a regulatory approach can enable biotechnology innovation in the EU while ensuring a high level of protection for human health and the environment. A key implementation benchmark will be whether startups, scale-ups and SMEs can apply the framework in practice without disproportionate regulatory burdens and under internationally competitive conditions.

NGT crops are an important driver of a more sustainable and resilient bioeconomy, from agricultural production to downstream processing. At the same time, the underlying genome engineering techniques are enabling technologies with relevance across a wider range of biological systems and biotechnology value chains, including industrial biotechnology and fermentation, food and feed production, environmental applications, and sustainable manufacturing. This cross-sectoral relevance is growing as international competition in biotechnology increasingly takes place between integrated innovation ecosystems that connect traditionally separate biotechnology applications through shared technologies, data, infrastructure and scale-up capabilities. Greater legal certainty and workable implementation of the Regulation (EU) 2026/1388 can therefore unlock innovation well beyond plant breeding.

The implementation of the NGT framework will set an important precedent for future EU biotechnology legislation. It represents one of the first major attempts in the EU to adapt biotechnology regulation to scientific and technological progress. The choices made in the implementing and delegated acts should therefore establish a coherent and workable model that can serve as a reference for future biotechnology legislation across sectors and applications.

Central to the implementation framework must be a science-based, product-based and proportionate regulatory approach that ensures consistency across sectors and applications. Regulatory decisions should be guided by the characteristics and risk profile of the resulting organism or product rather than by the technology used to develop

it. This approach supports legal certainty while maintaining a high level of safety, ensuring that products with comparable risk profiles receive comparable regulatory treatment. This principle is also relevant for micro-organisms.

In its opinion of 19 June 2024, EFSA emphasized that possible hazards relate to the changes introduced into a microorganism, regardless of the method used to introduce them, and that risk assessment should therefore be based on the characteristics of the product containing or consisting of micro-organisms.

As the EU considers the future regulatory approaches for micro-organisms and other biotechnology applications, it should draw on the experience of implementing Regulation (EU) 2026/1388 while accounting for the distinct characteristics of different sectors and applications. Effective implementation of the NGT Regulation can thus provide an important reference point for coherent, science-based, product-based and proportionate biotechnology regulation across the EU.

In this context, adaptations to the current framework, including the proposed amendments to the Directive 2001/18/EC under the EU Biotech Act I, should foster innovation, enhance competitiveness, and provide legal certainty, while continuing to ensure a high level of protection for human health and the environment. In the longer term, a dedicated regulatory framework for micro-organisms should address the structural challenges of the current genetically modified organisms (GMO) framework, with oversight focused on the characteristics and risk profile of the micro-organism.

Ultimately, effective implementation of the NGT Regulation should not only support crop innovation but also demonstrate how a modern, predictable science- and product-based biotechnology framework can contribute to European competitiveness, sustainability and strategic resilience. By creating regulatory conditions that enable innovation across biotechnology value chains, the implementation framework can support the wider bioeconomy in line with the objectives of the EU Bioeconomy Strategy.