EuropaBio response to the inception impact assessment for legislation for plants produced from certain new genomic techniques

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EuropaBio welcomes the opportunity to comment on the inception impact assessment for legislation for plants produced from certain new genomic techniques (NGTs) following the conclusion of the Commission study that the current EU regulatory framework is not fit for purpose.

EuropaBio considers that the Commission should develop and implement a regulatory approach incorporating the latest scientific findings, where organisms are regulated based on their characteristics, not the technology used to develop them. Only a science-based, proportionate, and predictable policy approach, providing equal regulatory treatment to products with equivalent risk profiles irrespective of their production method, will enable to leverage the full potential of biotechnology, including gene technology to benefit citizens, the economy, and the environment.

Overall, organisms developed with NGTs must not be subject to regulation as a GMO, when they are equivalent to products obtained through conventional breeding or classical mutagenesis or could simply result from spontaneous processes in nature. The safety of a product depends on and should be assessed based on what has been modified, not as a function of the technology used or when the technique used was invented (i.e., before or after 2001). We indeed note that when it comes to plants, EFSA does not differentiate in risk profile between older and newer technologies.

This new initiative aims to take sustainability considerations of using NGTs into account, in addition to maintaining high standards of human and environmental health. We share the view that NGTs can contribute to achieving the objectives of the European Green Deal as well as the UN SDGs. The approval should however continue to be based exclusively on the safety assessment of a product. After market introduction, sustainability aspects could be part of labeling schemes supporting an informed purchase decision of consumers. In this context, all three pillars of sustainability should be considered without preference for certain technologies. Sustainability related requirements considering environmental, social, and economic dimensions of sustainability should not be applied discriminatively to some products while others are exempt.

We regret that the new initiative excludes microorganisms. Genetically Modified Microorganisms (GMMs), including those developed using NGTs, are widely used in the manufacturing of everyday products and pharmaceuticals; for instance,

enzymes are used in a wide range of applications in the food, feed, biofuel, and detergent industries. GMMs used to manufacture fermentation products, as well as GMMs used as products have the potential to contribute to EU Green Deal objectives, both in terms of the manufacturing process as well as in the availability of the fermentation product on the market.

The degree of understanding of the microbial genomes, the ability to modify them with accuracy, the laboratory selection tools, and the characterization methods (e.g., using bioinformatic tools such as Whole Genome Sequence analysis) have been tremendously improved over the past 10-20 years. This led and continues to lead to a deeper understanding of the genomic modifications being carried out.

For this reason, we would encourage the Commission to extend the scope of this initiative to also include microorganisms as production strains and as live products. In addition, we would welcome the opportunity to share and contribute to the Commission's required scientific knowledge. While it is true that EFSA has not yet reported extensively on NGT use in microorganisms, it is also worth pointing out that new techniques are often first developed in microorganisms.