

## Feedback HollandBIO to the Legislation for plants produced by certain New Genomic Techniques

HollandBIO is the Dutch biotechnology industry association and welcomes the opportunity to deliver input on the inception impact assessment regarding legislation for plants produced by certain New Genomic Techniques (NGT).

The roadmap clearly describes the context and benefits these techniques can deliver to the EU Green deal, Farm to Fork and biodiversity strategies. While the current legislation is not fit for purpose and outdated, the scope of this roadmap is limited and unfortunately only includes plants. And although the described overall objective is to create a future-proof regulatory framework, the objectives of this initiative do not appear to be highly ambitious and well-balanced.

Points we agree with:

- The aim to enhance competitiveness of the EU agri-food sector. This is crucial for business to operate at a level playing field, especially with the current developments in the UK and elsewhere in the world.
- Risk assessment and approval requirement to be proportionate to the risk involved. As the use of NGTs can be considered as safe as traditional mutagenesis we are in favour of comparable approval requirements (= no risk assessment and approval requirements).
- Reduction of current costs and administrative burden.
- Flexibility to rapidly adjust elements of the legislation and its implementation over time, for a future-proof regulatory framework.

Points for improvement:

- Extension of scope
  - To extend the scope and include microorganisms in addition to plants, i.e. to include the many applications of industrial biotechnology as these are a central pillar of innovation in Europe, used in sectors as food and feed, materials and chemicals, agriculture, bioenergy and many more, having high potential to contribute to EU Green Deal objectives. Data on safety of NGT in microorganisms exist and are assessed on a national level (contained use applications).
  - To extend the scope to include all genomic techniques, including transgenesis.
- Balancing objectives
  - The introduction of sustainability-related requirements or incentives should have a positive impact on innovations. The inclusion of such requirements should not create an additional hurdle in the approval process, and it would be discriminative to apply this additional requirement to NGTs only.
  - While safety for human and animal health and the environment remains crucial and undisputed, the roadmap seems primarily skewed in this direction while NGTs can be applied as safe as traditional non-regulated techniques. A future-proof policy should be in balance with the other policy objectives; stimulating innovation and sustainability, enhancing competitiveness and providing legal clarity.
  - Full transparency via labelling to consumers can only be achieved when including all, also traditional, methods of breeding and genetic modification.

Overall, the contours of the proposed future policy seem to be no different than the policy aims that led to the current GMO legislation, besides the addition of sustainability requirements. Without a clear paradigm shift, from technology-based towards product-based regulation, the current deadlock will prevail. It is unclear to us how this roadmap will break the status quo and result in balanced, future-proof regulation, establishing a global level playing field for innovation, enabling European biotechnology to make life better, contributing to the objectives of the EU Green Deal and UN SDGs.

Instead of discriminating against the specific technique with which a product is made, the roadmap should rather focus on the characteristics of the final product, its application as well as sensible practices on the usage of products for future legislation.

Yours sincerely,  
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