Plant Breeding Innovation - NGTs FAQs

1. Why do we need a differentiated and risk-based regulatory approach?

NGTs applications are versatile and can be used in the development of a wide range of different plant products.

Many NGT products could be obtained also by using conventional breeding techniques albeit with less precision, less efficiency and, in a much more time-consuming way. Where the resulting geno- and phenotype is comparable to results from conventional breeding, the risk on human/animal health and on environment is also like conventionally bred plants. This is why these plants would not require a specific pre-market risk assessment.

More and more countries follow the principle that plant varieties developed through the latest breeding methods should not be subject to biotech regulations if they could also be obtained through earlier breeding methods or result from spontaneous processes in nature.

Euroseeds advocates for a differentiated approach not asking to exclude all NGTs from GMO regulations, but only those applications of NGTs that result in **conventional like products**. Applications of NGTs that result in transgenic products would still be covered by the GMO legislation. Where the resulting geno- and phenotype is reasonably expectable from conventional breeding, the risk on human/animal health and on environment is also like conventionally-bred plants[1]. To evaluate the regulatory status of a plant resulting from certain NGTs, an effective verification process on a case-by-case basis should be established that based on clear and unambiguous criteria confirms either the GMO-status of the plant material in question or the non-GMO and with this conventional status.

2. How does plant breeding and, more specifically, NGT crops contribute to sustainable farming systems?

Seeds are the key input for farmers in Europe and worldwide. On average 66%[2] of all productivity gains are due to improved varieties resulting from sophisticated plant breeding. Euroseeds is convinced that to be successful, an EU Farm to Fork Strategy must place plant breeding, related scientific advances and technological innovations at the very core of its considerations and consequent supportive measures. NGTs are an additional tool to contribute to deliver the next generation of varieties that are adapted to climate change. Plant varieties, regardless of a certain breeding method, provide the genetic potential for sustainability (environmental, societal and economic sustainability). Based on the current legislative framework for plant reproductive material, crops are e.g. tested for their climate adaptation which remains a key characteristic that breeders focus on and is largely expressed by the combination of quality and yield under practical growing conditions. Such adaptation as well as other characteristics, for example resource-use efficiency like water- or nutrient-use efficiencies, disease resistances as well as yield under those specific conditions need to be regionally assessed under relevant conditions. Nevertheless, any sustainability potential is only

[1] EFSA Journal 2020;18(11):6299

[2] https://hffa-research.com/wp-content/uploads/2021/05/HFFA-Research-The-socio-economic-and-environmental-values-of-plant-breeding-in-the-EU.pdf

realized when new varieties are integrated and used in suitable production, processing, and trade systems.
Sustainability considerations for plant varieties must therefore be independent of the breeding process and in a non-discriminatory manner based on scientifically sound, and properly linked to measurable data and results in repeatable tests.

3. How can transparency and freedom of choice be ensured?

Euroseeds recognizes the importance of transparency and information sharing and supports customer/consumer choice. To practically support and facilitate informed choice also for NGT-derived varieties, Euroseeds is committed to providing information on all varieties obtained with NGTs and available on the national variety lists and the European Common Catalogues.
Already today some private organic certification standards exclude plant varieties of certain non-GMO breeding processes from their value chains[3]. These private standards are facilitated by the seed sector by providing the relevant information[4].
Such information allows full freedom of choice to those farmers and growers and value chains that do not wish to or, based on private standards, do not allow the use of conventional-like NGTs in their production. Euroseeds is of the opinion that such information should be publicly accessible without any cost to customers.

4. How can coexistence of farming systems and international trade be ensured?

The EU does not impose co-existence measures between conventional and organic farming systems, even though certain organic farming standards today already exclude plant varieties from certain non-GMO breeding methods[3]. Only potential cross-pollination with non-compliant products (e.g. regulated GMOs) would lead to the loss of the organic status. The same applies to organic or conventional farmers in the US with which the EU agreed on equivalency schemes for organic food. Imposing risk assessment and traceability and labelling requirements as well as co-existence measures for conventional-like NGT plants and products would be incompatible with regulations and organic standards in third countries like the US with which the EU has established equivalency agreements and it would put EU organic and conventional farmers in a competitive disadvantage compared to their counterparts in third countries.

5. Can conventional-like NGT plants be detected and identified for market control and consumer trust?

For market control, considering the current knowledge and state of the art of GMO testing, it is highly unlikely for enforcement laboratories to be able to detect the presence of unintended or unauthorised conventional-like NGT derived plant products in food or feed entering the EU-market without prior information on the altered DNA sequences[5]. Also, current detection methods cannot distinguish how the genetic change in a plant occurred (NGT or conventional breeding) and with that if a plant (product) in fact is a regulated GMO and/or falls under specific traceability, labelling or co-existence requirements.
To ensure that consumers can trustfully rely on traceability and labeling systems the EU should impose those measures only on products that are identifiable and where respective measures are fully enforceable. This is not the case for conventional-like NGTs. The EU risks to loose trust in regulatory systems and processes which are unenforceable and with this vulnerable to fraud.

---

[3] https://www.ifoam.bio/sites/default/files/2020-03/Breeding_position_paper_v01_web_0.pdf
[4] FiBL - Positive list of cell fusion-free vegetable varieties updated
[5] The European Network of GMO Detection Laboratories (ENGL): Report on Detection challenges with a specific view on the EU regulatory Detection Requirements.

6. Why is it important to have regulatory policies for plant breeding innovations that are globally aligned?

The seed sector is an international business. Countries should consider the global impacts that different regulatory processes may have on global seed movement, exchange and access to germplasm globally, agriculture, trade and research collaborations. If policies for plants developed through plant breeding innovations are not aligned globally, this will limit the ability of researchers and commercial developers to use the entire range of innovative plant breeding tools.

Different regulatory approaches for plants resulting from the latest breeding methods could also lead to enforcement difficulties, trade limitations and disruptions, and put some operators at a competitive disadvantage, with further negative consequences. This includes the creation of technical barriers to trade, potentially leading to disputes between countries. Regulatory barriers would particularly affect small and medium-sized enterprises (SMEs) and small-scale operators seeking to gain market access with products from new breeding methods, even though many stakeholders see opportunities for them in this sector.

7. Do off-target effects of NGTs create risks?

Off-target effects are, as the term suggests, effects other than those which are desired, resulting from the employment of a technique, like an NGT. Off-target effects can be caused by unintended mutations, which in conventional breeding result from spontaneous or classical induced mutations (irradiation, chemicals) and can be numerous, occur at random locations, and are not possible to control. With NGTs like genome editing, off-target mutations can also occur, however they are much less numerous, and can be mitigated with the proper design of genome editing reagents, which are continuously being improved. The EFSA GMO panel concluded that the analysis of potential off targets would be of very limited value for the risk assessment[6].

[6] Applicability of the EFSA Opinion on site-directed nucleasestype 3 for the safety assessment of plants developed usingsite-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6299

Avenue des Arts 52 B
1000 Brussels

www.euroseeds.eu

#GrowingTheFuture