



## Developing and supporting New Breeding Techniques: a key priority for the Agriculture and Progress Platform

*The agricultural community in the EU faces several challenges: produce sufficiently for a growing population, produce sustainably to address environmental and climate change issues in a very short time lapse, and ensure competitiveness in a sector that is exposed to international markets whilst generating a decent income for farmers. To face these challenges and the short timing ahead, the development of New Breeding Techniques (NBTs) is crucial not only for the agricultural community but also for the downstream industry chain and ultimately for the consumer.*

*The Agriculture and Progress Platform has duly taken note of the ECJ ruling on Case C-528/16 clarifying the legal status of mutagenesis. The ruling finds that mutagenesis leads a priori to products subject to EU GMO legislation. Member States can legislate the issue further, which may lead to diverging rules throughout Europe. We therefore believe that the consequences of this ruling could be particularly detrimental for farmers, including maize and beet growers, and the downstream production chain. The European Commission has been tasked by the Council of the EU to conduct a study on NBTs in light of this ruling by 30 April 2021 and submit a proposal, if appropriate, accompanied by an impact assessment.*

*The Commission Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16 SWD(2021) 92 issued late April 2021 highlights : the current regulatory uncertainty, the rapid development of such NGTs and their products in many parts of the world and the considerable interest in research o NGTs taking place outside the EU, the potential of some NGTs to contribute to the objectives of the EU's Green Deal and Farm to Fork strategy and to the UN Sustainable Development Goals for more resilient and sustainable food systems. Furthermore, EFSA has not identified any new hazards compared to both conventional and targeted mutagenesis and cisgenesis.*

*This provides an important backdrop to continue and advance discussion between decision-makers and stakeholders on this important issue, in view of developing an adapted and workable regulatory framework that addresses the specificities of NBTs. This framework must, and in our view can, combine state-of-the-art scientific expertise and evidence whilst guaranteeing safe and high-quality food with improved properties to consumers. The Agriculture and Progress Platform is keen to continue to play an active role in these discussions in order to generate legal and economic certainty as soon as possible.*

### **NBTs, a crucial tool for further reduction of the use of Plant Protection Products (PPPs)**

History shows that when faced with challenges, society has always turned to innovation. Notably the agricultural sector has proven that the use of innovative techniques is the path to progress. With plant protection products (PPPs) being criticised and a general call to reduce their use, NBTs are an efficient and necessary tool to accompany a new agricultural evolution. Many crop varieties on the market are the product of mutation technologies. Genome-editing can be used to make exactly the same changes as these older, unregulated mutagenesis technologies but with less time and cost.

Reducing the use of PPPs is an objective that maize and beet growers have set themselves already years ago by committing to Integrated Pest Management. This in turn has led to the use of techniques such as coated/pelleted seeds, optimising crop rotation, and precision farming. More recently, the development of robotics and digital farming have also started complementing the agricultural toolbox.

With climate change and - especially in the short to medium term - the reduction in the availability of effective tools to control pests and diseases (fewer PPPs available to growers), and the resulting year-to-year variability in crop performance, there are very rapid changes in requirements. The regions most affected by these changes so far are located in France, the UK, the Netherlands and Germany, as well as in Belgium. Emerging pests are more and more difficult to

combat in countries like Austria, Hungary, Italy, France, Germany and Poland. Some of these pests can inoculate several viruses and bacteria and lead to co-infestations/infections that are extremely difficult to manage and control without appropriate tools. The Platform supports the objectives laid out in the EU's Biodiversity 2030 and Farm to Fork strategies, but targets to reduce the use of PPPs are putting increasing pressure on farmers. NBTs can ease that pressure, contributing to the farmers' ever-shrinking toolbox. Indeed, traditional breeding by often making large-scale genetic changes can be a slow and expensive process. Genome editing technologies allow to make just a few changes to the existing DNA at very specific sequences and the end product may be indistinguishable from one made using older, unregulated technologies like also for example chemical mutagenesis.

NBTs, including mutagenesis, are key complementary tools that will allow meeting society's demand to reconcile agricultural production with sustainability and respect for the environment. Today, the need for rapid adaptation and targeted responses to challenges that arise in the current and future context cannot be managed with remaining active substances and PPPs alone, especially since resistance of weeds, pests and/or diseases to PPPs has to be managed carefully by farmers. NBTs can substantially contribute to farmers responding more rapidly and in a more targeted manner, by providing them with suitable varieties in a shorter period than would be possible via conventional breeding. The use of NBTs can also help farmers by breeding varieties with agronomically desirable traits, thereby improving yields and quality while reducing losses – a very important contribution to enhancing the sustainability of European agriculture.

The number of successful crop varieties obtained using NBTs is slowly increasing in particular in third countries. Examples include drought-stress tolerant maize and biotic-stress resistant sugar beet varieties. But the investments in terms of R&D and the time required to overcome technical barriers are so high that the uncertainty currently generated at EU level risks preventing NBTs from becoming mainstream and a permanent part of the plant breeders', and ultimately of the agricultural, toolbox of European farmers. Plant breeding has already proven to be an innovative and powerful tool in improving the sustainability of European agriculture, it is crucial that it could continue to do so.

### **An EU NBT framework needs to guarantee competitiveness in global agricultural markets**

Furthermore, the EU's agricultural markets cannot be seen in isolation from global markets. Some of the EU's key trading partners (US, India, Canada, Japan and more recently the UK...) have developed or are in the process of developing a regulatory framework for NBTs. These regulatory frameworks are most often based on case-by-case assessment and do not systematically refer NBTs to the GMO framework. By doing so, these trading partners allow for innovation, for underpinning R&D and commercial development of their economy. If the EU chooses a different path or leaves too much uncertainty for too long, the impact on the plant breeding industry and the agricultural sectors will be substantial. The EU risks lagging behind the rest of the world in terms of using innovative tools that allow sustainable progress of its agri-food chain.

For example, under its biotechnology regulations, the U.S. Department of Agriculture does not currently regulate, or have any plans to regulate, plants that could otherwise have been developed through traditional breeding techniques - as long as they are developed without the use of a plant pest as the donor or vector and they are not themselves plant pests. This includes a set of new techniques that are increasingly being used by plant breeders to produce new plant varieties indistinguishable from those developed through traditional breeding methods. The newest of these methods, such as genome editing, expand traditional plant breeding tools because they can introduce new plant traits more quickly and precisely, potentially saving years or even decades in bringing needed new varieties to farmers. But while companies in the US, Canada, Brazil, and Australia are already adopting these new genome editing technologies - and starting to apply the benefits of these plant engineering techniques to increase the sustainability and profitability of agriculture - they will not be applied in Europe.

### **Ignorance breeds intolerance: explaining NBTs to a wider audience**

NBTs are mostly unknown to consumers, as is their potential to reduce e.g. food waste and the environmental impact and cost of producing food. And ignorance breeds intolerance. To raise awareness of the potential of NBTs, we look first and foremost to plant breeding companies and to the farming community. We firmly believe that decision-makers, and notably EU decision-makers, have a responsibility in reaching out to the public to contain unsubstantiated scaremongering and to give a factual explanation of what NBTs are and are not and what added-value they can bring to consumers.

## Developing an adapted, workable legal and regulatory framework for NBTs: the sooner the better

On the basis of the ECJ ruling, Member State authorities are left with concrete queries as to how they should integrate the findings of the ECJ in practical terms. While the ruling brought **legal clarity** as to the **status of new mutagenesis techniques**, it **raised issues** for the **national competent authorities**, the EU's industry (notably the plant breeding sector), research and beyond. Those questions concern, inter alia, how to ensure compliance with Directive 2001/18/EC when products obtained by means of new mutagenesis techniques cannot be distinguished, using current methods, from products resulting from natural mutation, and how to ensure, in such a situation, the equal treatment between imported products and products produced within the EU.

If not properly guided, this situation risks generating a patchwork of different situations in the various EU Member States, which is detrimental to the farming community and the downstream production chain. The Platform is awaiting the results of the European Commission's study on NBTs which will include opinions of various stakeholders, ethics, new developments and guidance to a probable legal framework.

This does not mean that the Agriculture and Progress Platform pleads for lenience when it comes to NBTs. Consumers need to be able to rely on the fact that:

- the food they consume is safe,
- a scientific body needs to assess any health and environmental concerns,
- a coherent and well-balanced regulatory process is in place.

Risk assessments that would be conducted need to be science and risk-based and should not be a barrier to innovation. Given the specific nature of NBTs, the current GMO legislative and regulatory framework is not fit for purpose. Thorough reflection and discussion are needed to work out a workable and adapted solution.

More specifically:

- **Varieties, be they conventional or not, should continue to be evaluated most and foremost in function of their value for cultivation and use (VCU) and agronomic interest**
- 'Traditional' / 'conventional' mutagenesis should remain exempt from the authorisation requirements of Directive 2001/18
- Only organisms obtained via transgenesis and containing genes from other organisms should be subject to the authorisation requirements of Directive 2001/18. A plant genetically edited for minor changes in the genome such as changing or removing a pair of bases or introducing a gene known to belong to the plant's genetic pool will be exempt.
- The list of exemptions can then be updated in function of scientific and technological progress.
- The authorisation process including risk assessments is required only if an NGT is does not categorise as 'traditional' mutagenesis or does not fall within the category of exemptions. This would apply to transgenesis for example.

We call on the EU Commission to explore, in close cooperation with Member States and stakeholders, the development of such a framework in the near future. This is becoming all the more urgent since the announcement of the UK's DEFRA (Department for Environment, Food & Rural Affairs) of a step-by-step approach for the Introduction of Genetic Technologies, starting with a Statutory Instrument by the end of 2021, to make research & development easier for plants that have been produced by genetic technologies where the resulting genetic changes could have been developed using traditional breeding methods. The Agriculture and Progress Platform has been in close cooperation with relevant technical/research institutes and will continue its mission to shed light, vis-à-vis the public and decision-makers, on the important contribution NBTs can provide. We are keen on participating in further discussions on this crucial topic.

**The Agriculture & Progress Platform is looking forward to continuing the debate on NBTs and their great potential for the European Union's agricultural sector, whilst protecting biodiversity and enhancing sustainability of EU produce. Please contact us at [platform@agriprogress.info](mailto:platform@agriprogress.info).**