Fact sheet: The regulatory status of plants resulting from New Breeding Techniques in the EU

Executive Summary

Following the definition of the European GMO legislation, we come to the conclusion that in most cases, unless the plant's genetic material has been altered in a way which is not capable of occurring naturally, New Breeding Techniques (NBTs) do not lead to plants that should be considered to be genetically modified. We believe that this legal assessment will bring clarity to the current European debate on NBTs as these methods for plant breeding could have a large positive impact towards more sustainable food production.

I. Introduction

The global population is growing rapidly, whilst the amount of arable land is shrinking and natural resources are spread thin. Together with the challenges that climate change produces, the task at hand is to produce twice as much food with an environmental footprint that is reduced by half. In order to meet this challenge, major innovations need to take place in the whole value chain.

The European plant breeding sector will play a major role in this transition towards more sustainable production of food with much higher productivity. With the advent of genetic sequencing a more detailed understanding of the process of plant breeding has emerged.

In the wake of this body of knowledge, scientists have discovered novel ways to obtain plants with certain desired properties, in a less intrusive and more precise way. The products resulting from these New Breeding Techniques (NBTs), as these are called, could in principle also be achieved with classical breeding yet in a much shorter timeframe. The difference between using NBTs and classical breeding is like driving a car in a foreign country, respectively with or without GPS navigation.

Plant breeding with such a high degree of accuracy and control has the potential to make big leaps in taste and nutritional value while

decreasing the environmental footprint as less natural resources, fertilizer and pesticides are necessary. The effects of climate change might also be mitigated as plants can be made more resistant to extreme weather events such as floods or droughts.

Currently viewed as the principal New Breeding Techniques are:

- Site Directed Nucleases,
- Oligonucleotide Directed Mutagenesis,
- Cisgenesis,
- RNA-directed DNA Methylation,
- Grafting on a GMO rootstock,
- Reverse Breeding, and
- Agro-infiltration

II. Current legal status of New Breeding Techniques

The European Directive 2001/18/EC (from here on 'the Directive') determines in summary that a plant is a Genetically Modified Organism (GMO) when a GMO-technique (listed in the Directive) is used or determined by the fact that the genetic material of the plant has been altered in a way which is not capable of occurring naturally. A GMO plant is thus one which cannot be obtained by mating and/or natural recombination.

NBT Platform

The NBT-platform teamed up with several legal experts to elucidate the regulatory status of plants developed with NBTs. Their full analysis and results are available in the Legal Briefing Paper¹.

The main conclusion of the legal analysis is that in most cases, unless the plant's genetic material has been altered in a way which is not capable of occurring naturally, the New Breeding Techniques do not lead to plants that should be considered to be genetically modified. For an in-depth analysis of each technique, please refer to the full Legal Briefing Paper.

III. The need for clarity on the regulatory status of plants resulting from New Breeding Technologies

The current decision making process means that there is currently no clarity on the regulatory status of NBTs, effectively prohibiting their use.

Given the huge potential benefits of the New Breeding Techniques, the NBT-platform favours a clear regulatory status of plants resulting from these techniques. The current debate on the legal status of NBTs, though necessary for a thorough evaluation, deters major investments in NBTs in Europe. This situation can only be remedied by clear and proportionate regulation of NBTs.

About the NBT Platform

The NBT Platform is a coalition of SMEs, large industry and prominent academic and research institutes which strives to bring clarity to the European debate on NBTs. Its aim is to provide policy makers and stakeholders with clear and precise information on NBTs and to generate awareness about their widespread benefits for the European economy and society as a whole.

More information on www.nbtplatform.org, or contact us via info@nbtplatform.org

¹ 'Legal Briefing Paper - The regulatory status of plants resulting from NBTs', developed by the NBT Platform. Please contact the Secretariat at info@nbtplatform.org for more information.