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Dutch Proposal to Legislate NBTs

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Report Highlights:
On September 7, 2017, the Dutch Government presented a proposal to the European Commission (EC) and EU Member States on how products derived from new plant breeding techniques (NBTs) could be regulated. The proposal holds the view that plants resulting from NBTs should be exempted from Directive 2001/18/EC if they are at least equally safe as plants obtained by traditional breeding.

The difference between GMOs and plants produced with a NBT

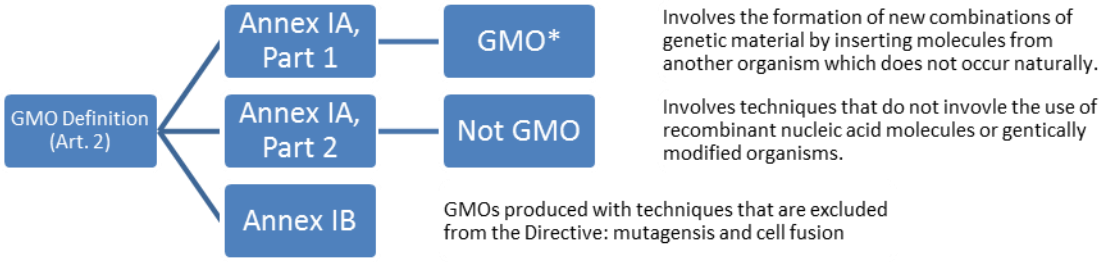
The popular term GMO or genetically modified organism is often used in the media to describe a plant or animal that has been altered through the manipulation of its genes. The type of genetic engineering (GE) that the public is most familiar with is transgenic, where a gene is moved from one *non*-closely related species to another. These types of changes generally do not occur naturally.

Newer gene editing techniques, such as CRISPR/Cas9, which gives scientists the ability to modify DNA in a very specific way by turning genes on or off, are referred to as innovative biotechnologies or new breeding techniques (NBTs) as they have only been developed in the last decade. In the European Union (EU), new seed traits resulting from NBTs have fallen through the cracks of the regulatory system and are not being regulated as GMOs because no foreign DNA has been introduced. Proponents of NBTs argue that although the mutations generated may not have occurred naturally, they could have.

The European Commission (EC) has delayed making a decision on how to legislate NBTs

Directive 2001/18/EC

*Only these products are required to be labeled.



In the EU, the deliberate release of GMOs is regulated by Directive 2001/18/EC. Currently, there is no reference to NBTs in this Directive. For the past ten years, there has been little progress made in regulating NBTs. In the meantime, the amount of uncertainty among scientists, regulators and plant breeders has increased. In October 2007, upon the request of EU Member States, an expert working group was established by the EC to assess whether NBTs should be regulated by the GMO legislation. The working group completed its work in 2012, but a final report was never made public nor was a subsequent legal interpretation published detailing how NBTs would be regulated through the existing EU GMO Directive.

The European Court of Justice (ECJ) is expected to provide an opinion on whether mutagenesis, currently exempted in Annex 1B, should be legislated as a GMO. A final verdict by the ECJ is expected in the first half of 2018. The ECJ recently ruled that EU governments cannot stop the cultivation of GE crops if there is no serious risk to human health. The ruling also noted that the precautionary principle is not grounds to ban GE crops since those foods have already gone through a full scientific assessment before being placed on the market. Although this judgment does not reference NBTs, it does make clear that the ECJ does not intend to use the precautionary principle to block all innovation.

The Dutch Government proposes to amend Annex IB of the GMO Directive

On September 7, 2017, the Dutch Government presented a discussion paper to the EC and permanent representatives of the Member States (MS) in Brussels on how products derived from NBTs could be regulated. The proposal states that plants resulting from NBTs, provided that they are at least equally safe as plants derived by traditional plant breeding, should fall under Annex IB of the GMO Directive and thus be exempt from the Directive. The proposal states that currently exempted techniques (mutagenesis and cell fusion) will remain exempted. However, it recommends not listing all possible exempted techniques on a case-by-case basis as was done in the past, but rather to set forth criteria that would be based on the final product rather than the technique used to develop it. Not all products using a specified NBT, such as CRISPR/Cas9 would necessarily be exempted. The Netherlands National Institute for Public Health (RIVM) developed two possible criteria for an exemption:

1) No genetic material is introduced into the resulting plant other than genetic material from the same plant species or from a plant species with which it can exchange genetic material through traditional breeding methods.
2) Recombinant nucleic acid molecules that are used for or during modification are no longer present in the resulting plant that is meant for deliberate introduction into the environment.

The proposal also shifts the burden from the government to companies to conduct normal safety and quality tests on their product. Companies would no longer have to ask the government for permission. However, if the government suspects the product does not conform to the above criteria, they could ask the company to provide the data that would prove that it does.

The full proposal is available in English at Netherlands Proposal for Discussion.

Why did the Dutch Government put this proposal forward?

The application of NBTs is a dossier which has the keen attention and support of the Dutch Government. This support is based on the use of NBTs as an important propagation tool for the Dutch plant breeding sector, which is globally ranked as a top exporter. The Dutch Ministry of Economic Affairs (MEA) has stated that NBTs can support Dutch policy objectives such as sustainability, food security and food safety, and provided examples of pest resistant rice and potato varieties.

An Uncertain Path Forward

The proposal faces several obstacles. The seed and agriculture sectors are eager to use NBTs for a wide range of purposes, such as developing varieties that are resistant to drought, and many agree with the content of the proposal. However, reopening the EU GMO legislation, even if only to revise the Annex, could take many years to negotiate. In the meantime, stakeholders would face uncertainty about the outcome and the possibility of a national interpretation rather than international equivalence. The proposal is reportedly also opposed by the Dutch organic sector and environmental NGOs as being not restrictive enough towards NBTs. In addition, the timing might be premature as the EU is not likely to take up the Dutch proposal before the final ECJ verdict on the status of mutagenesis.