



What can the new plant breeding techniques be used for and how shall they be regulated?

March 2018 The new plant breeding techniques should be considered as a kind of toolbox for the development of new plant varieties for agriculture. The techniques allow us to quickly develop new crops that for example, have greater nutritional value or greater water absorption.

This discussion paper describes the possibilities associated with the new plant breeding techniques and how they shall be regulated.

The new techniques provide new possibilities

The new plant breeding techniques should be considered as a kind of toolbox for the development of new plant varieties for agriculture. The toolbox's capabilities and applications are by its very nature, difficult to predict. The following text provides some examples of the obvious possibilities in terms of the application of the techniques in agriculture:

- **Cultivation value**
The new techniques provide plant breeders with the ability to develop crops faster, cheaper and more targeted compared to the current methods. Using the techniques, you can now for example more quickly make wheat that is resistant to fungal disease such as mildew and mould. This will mean that conventional agriculture will need less antifungal agents.
- **Nutritional value**
The techniques provide producers with the possibility of increasing the content of different nutrients and ingredients in food and feed. For example, they could increase the content of phytase in wheat used for feed. This would mean that less phosphorus would

be required to be added to the feed compared to current requirements.

- **Quality**
The techniques can contribute to improving the quality of the protein and starch in crops such as wheat for bread and to making the oil composition of oil crops more healthy.
- **Structure**
The techniques can contribute to reducing demand on global water resources, because they can be used to develop crops with longer roots. Longer roots means greater water absorption and reduces the need for the watering of crops during dry periods because the plant can draw on water from deeper layers.
- **Domestication**
The process of changing a wild species to a cultivated crop (also known as domestication) will become shorter using faster and more precise breeding techniques, and the techniques can lead to a wider spectrum of cultivated crops because more species will be able to be domesticated. Greater variation in the availability of crops that the farmer can choose between will benefit biodiversity and can potentially make Denmark less dependent on the import of for example, protein feeds, because additional Nordic crops can be included in the crop rotation. For consumers, it means more choices with more locally produced crops available to choose from.

Regulation of the new breeding techniques is not clarified

How the use of the new breeding techniques shall be regulated within the EU has not yet been clarified. The central question is whether the plants that have been developed with one of the new plant breeding techniques is covered by the EU's full GMO regulation or whether they are exempted from this. It will also be decided whether the existing GMO legislation in the EU – its central parts date from 2001 – actually is suitable for dealing with the new techniques, all of which were developed after the current legislation was established.

The future regulation of the new breeding techniques will have a crucial impact on who and how the techniques will be used. From a technical perspective, a number of the new techniques are both relatively simple, cheap and fast to use. The techniques' spread will therefore primarily be determined by how they are regulated.

GMO regulation in the EU

The EU's current GMO legislation is in general based on technique. The regulation of a given plant depends on which technique was used to develop the plant in question. This approach was set out in the EU's Directive on the deliberate release into the environment of genetically modified organisms¹ and runs through the other EU legislation on GMO.

The EU legislation differentiates between two types of GMO, which are regulated differently:

1) GMOs that are covered by the full GMO regulation

If a plant has been developed by using actual gene modification techniques (cf. Directive 2001/18/EC Appendix 1A, part 1) then the plant is a GMO, and so must meet a large number of requirements before it can be grown in the EU. Among other things, there is a requirement on a comprehensive environmental and health risk assessment. There is also a requirement on traceability and labelling. Plants in this category are subject to a risk assessment and a political approval process with participation of representatives from all of the member states.

2) GMOs that are exempted from the regulation

Plants that have been developed using certain techniques for genetic modification (cf. Directive 2001/18/EC Appendix 1B), are exempted from the

GMO regulation. This applies to for example, plants that have had random mutations included in their genome through radiation or chemical treatment (known as traditional mutagenesis). No risk assessment or political approval process is carried out for this type of plant, but instead the standard variety protection process is used. This exemption provision in the EU's GMO regulation is called the "mutagenesis exemption."

Previous experience with GMO regulation in the EU

The EU's GMO regulation establishes requirements for a comprehensive risk assessment and documentation before a GM crop may be grown in the EU. At the same time, the political approval process is often a protracted process.

It is therefore expensive and time-consuming getting approval for the growing of a GM crop in the EU. An estimate from 2011, shows that it costs a company about DKK 220,700,000 (USD 35.1 million) extra to have a variety approved in accordance with the GMO regulations.²

The comprehensive requirements means that today it is only multinational companies that have the means and capacity to meet the documentation requirements in the current GMO legislation.

Currently, there is only one GM crop (Mon 810 maize), which may be marketed for cultivation in the EU.

There are different wishes for the future regulation of the new plant breeding techniques

There are different wishes for the future regulation of the new plant breeding techniques among stakeholders. In particular, there is disagreement about how the new precision mutagenic techniques shall be regulated (see more about this in the discussion paper about new plant breeding techniques). There are two main viewpoints:

1) Plants that have been developed with one of the new precision mutagenic techniques should be covered by the full GMO regulation

Supporters of this viewpoint believe that the new precision mutagenic techniques produce GMOs, which must be regulated. They point out that there is a need for a final risk assessment of plants that have been developed using the precision mutagenic techniques, cf. the discussion paper about risk. There is also a need for

¹ See article 2 (2) in the Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration.

² P. McDougall, 2011: *The cost and time involved in the discovery, development and authorisation of new plant biotechnology derived traits.*

traceability and labelling, so that there is the option to not use this technique.

2) Plants that have been developed using the new precision mutagenic techniques should come under the mutagenesis exemption and therefore be excluded from the GMO regulation.

Supporters of this viewpoint believe that the new precision mutagenic techniques are comparable with traditional mutagenesis, and the new techniques just produce far fewer unintentional effects (cf. the discussion paper about risk). They also point out that a regulation under the mutagenesis exemption will mean that small and medium-sized plant breeding companies in the EU and in Denmark will be able to use the techniques – something they cannot do under a full GMO regulation.

The Court of Justice of the European Union will make a crucial ruling on some of the new plant breeding techniques

The Court of Justice of the European Union is expected to make a ruling on a principle case in the middle of 2018. The case relates to EU regulation of the new precision mutagenic techniques. The ruling is expected to establish whether the new precision mutagenic techniques are covered by the mutagenesis exemption. The ruling is the binding interpretation of current EU legislation.

In January 2018, one of the court's advocate general presented a non-binding proposal for a ruling, which among other things, proposes that plants produced using the new precision mutagenic techniques are in general exempted from the GMO regulation, and the member states have the opportunity to issue national rules in this area.

Requirement for approval of GM crops

The member states in the EU regulate crops that come under the definition for GMO in accordance with the regulation on GM food and feed or the EU's Directive on the deliberate release into the environment of genetically modified organisms². In these rules there is a requirement that a company that wishes to have a GM crop approved, must submit the necessary documentation so that the European Food Safety Authority (EFSA) can carry out an environmental and health risk assessment of the effect of growing the new crop. An estimate from 2011 shows that it costs a company about DKK 220,700,000 (USD 35.1 million) extra to have a variety approved in accordance with the GMO regulations in relation to the approval that is taken for the standard variety protection directive (Source: P. McDougall, 2011: *The cost and time involved in the discovery, development and authorisation of new plant biotechnology derived traits*).

As of 2017, only one crop has been approved for growing in the EU – Mon 810 maize. About 100,000 hectares are cultivated annually in a number of southern European countries.

This discussion paper is one of three that sheds light on different aspects of the new plant breeding techniques. The two other discussion papers deal with the techniques and the potential risks involved in their respective use. The discussion papers have been devised in consultation with a broad working group, which the Ministry of Environment and Food of Denmark has established to identify Danish stakeholders' attitudes to the issue. However, the Danish Agricultural Agency is solely responsible for the discussion papers.

