



# New plant breeding techniques – is there a risk?

**March 2018** In recent years, a number of new plant breeding techniques have been developed. Industry, the EU and other groups are discussing how these techniques shall be regulated legally, including in particular whether the new techniques shall be covered by the EU's full GMO regulation. There is also an ongoing discussion about the need for a completely new legislation that can cover the new techniques.

**This discussion paper deals with an important aspect of the discussion about the new plant breeding techniques, i.e. on whether the use of the techniques carries risk. Is there a risk for undesirable and harmful effects to human health and the environment can arise? And what are the consequences should this be the case?**

The answers to these questions have an impact on how we determine what the future regulation of the new plant breeding techniques will be, since the regulation must mirror the potential risk.

The current EU regulation is based on techniques: If certain techniques for genetic modification are used there is a requirement for a risk assessment.

On the other hand, there is broad scientific agreement that it is solely a plant's characteristics and not the way those characteristics are generated that constitutes whether the plant presents a risk or not. Plants that have been developed by man may present a risk – regardless of the method used to develop them. And it is the same with wild plants.

In this context, the risk must be broadly understood. It also concerns whether the use of the new techniques, for example may include a risk of an increased monopolisation of the food supply.

Among other things, the discussion deals with the questions:

- 1) How great is the risk associated with the new plant breeding techniques?
- 2) How great is the risk associated with the plants that are produced using the new techniques?
- 3) How should any potential risk be dealt with?

## **1) How great is the risk associated with the new plant breeding techniques?**

The term "new plant breeding techniques" covers a number of very different techniques, which work very differently and which have different potential and risks. The individual techniques are described in a separate discussion paper "New plant breeding techniques – what is that?"

Regardless of the technique, one may differentiate between the risks that arise from the intended effects and the risks that arise from unintended effects. In the discussion about the new plant breeding techniques, it is the risk of unintended and unexpected effects that dominates the discussion in particular.

### 1. Risk of unintended changes?

A number of the new techniques lead to much more precise and targeted changes compared to the methods that plant breeders use today, and which is known to cause many unintentional changes, cf. the illustration of precision mutagenesis in figure 1a and traditional mutagenesis in figure 1b.

Figure 1a: Illustration showing precision mutagenesis, which is more precise and targeted.

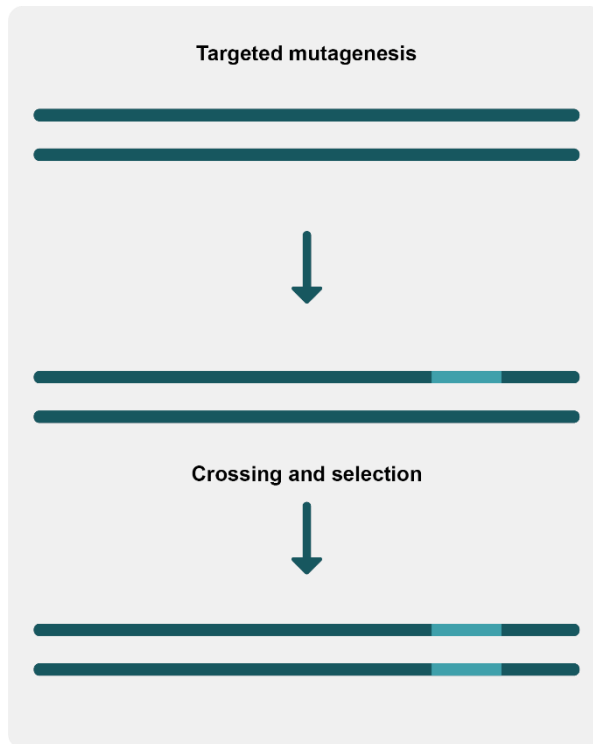
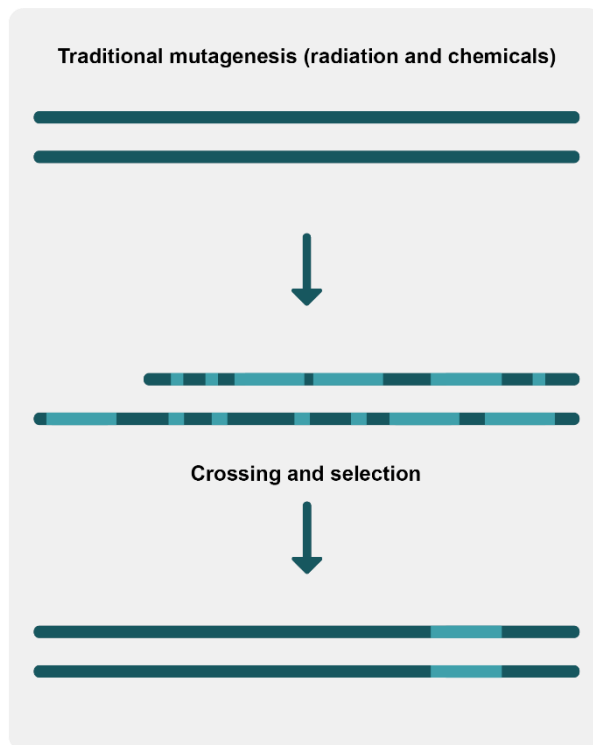
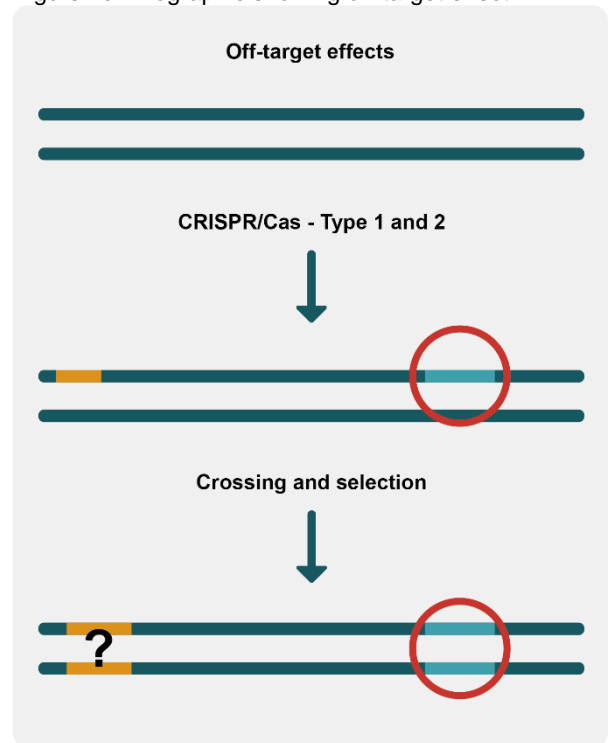


Figure 1b: Illustration showing traditional mutagenesis, where many unintentional changes occur, which are selectively removed in the subsequent process.



Even with precision techniques, unintentional changes can occur, known as off-target effects, which are illustrated in figure 1c.

Figure 1c: Infographic showing off-target effect



This leads to the question of what risks arise in relation to off-target effects? People have differing viewpoints with regard to the answer to this question.

Viewpoint 1: There are fewer unintentional changes (off-target effects) with the new techniques compared to traditional mutagenesis (cf. figure 1b), which has been used for decades without causing problems. Therefore, there is no reason to expect that the new techniques will cause problems.

Viewpoint 2: There is only limited experience with the new plant breeding techniques and thus little knowledge with regard to their unintentional effects. Therefore, you cannot compare this with the unintentional changes that arise with the familiar methods.

## 2. Risk of monopolisation?

There is also a discussion about a number of more market-related risk aspects with regard to regulation of the new plant breeding techniques.

One point of view is that the new techniques will lead to an increased monopolisation of the food supply in the same way that genetically modified (GM) crops are viewed today. The development here is dominated by a

few major companies and involves only global crops such as soya and maize.

Another viewpoint is that the new plant breeding techniques will be able to strengthen small and medium-sized plant breeding companies and lead to more diverse land use. But it will require that the new techniques are regulated in a way that allows smaller companies to be able to use them. GM crops are monopolised because the applicable GMO legislation sets out many requirements that must be met for a crop to be approved. This means that only the largest companies can meet the requirements because only they have the means and the resources.

## **2) How great is the risk associated with the plants that are produced using the new techniques?**

The discussion about the possible risks with plants that have been developed using the new techniques differentiates between environmental risks and health risks. Questions under discussion, include:

### The environmental risk

Is there potentially a greater risk to nature and the environment by growing a plant that has been produced using one of the new techniques? Is there for example, a risk that the plant unintentionally spreads in the wild? Can cultivation have unintentional effects on other organisms, e.g. competitive advantage in relation to wild genus? Is the plant in conflict with what we want to protect?

### The human health risk

Does a plant that has been developed using one of the new techniques present a health risk to humans? Is there a risk that the plant for example, has become more toxic or can cause an allergy? Or is there a risk that it has acquired another nutritional value? Or is there a risk that new unknown substances are created?

There are also aspects other than environmental and human health aspects that are part of the discussion, e.g. concerning factors connected with sustainability and socio-economic questions and use. Does the plant make a positive contribution to society? Is it ethically acceptable to develop it? Is it ethically acceptable to not develop it? Does it contribute to more sustainable plant production? Will it help to solve a global problem?

## **3) How should any potential risk be dealt with?**

In the current EU legislation, the development of plants is primarily regulated on the basis of the way the plants are made (the technique). In other words, the requirements for the risk assessment and subsequent risk management depend on the production method.

In the field of plant production, the current EU legislation operates with three different categories of plants, which in relation to the risk aspect, are treated differently:

### *1) Plants that are not genetically modified.*

These plants can be marketed, without legislation placing any explicit requirements about prior risk assessment or requirements for their subsequent cultivation and use.

### *2) Genetically modified plants, which are excluded from GMO regulation.*

This type of plant is categorised in EU legislation as genetically modified but excluded from the GMO legislation's requirements and thus can be marketed on an equal footing with plants that have not been genetically modified. Plants that are developed using traditional mutagenesis, fall into this category.

### *3) Genetically modified plants that are covered by the GMO regulation.*

These plants are categorised in the EU legislation as genetically modified and may only be marketed in accordance with a comprehensive prior environmental and health risk assessment. The individual steps in the risk assessment are described in the EU legislation and implemented by the European Food Safety Authority (EFSA). Requirements are in place that establish that the subsequent cultivation and use of a GM plant must be done in a way that minimises the risk of anything adverse happening. Finally, there is a requirement for environmental monitoring of the cultivation of GM crops following their authorisation for marketing.

The plants in all three categories go through a trial in the breeding companies, and typically also a two-year trial of their cultivation properties before they can be added to the variety list and thus be marketed.

There are divided opinions about how the risk of the new plant breeding techniques best can be dealt with using the applicable EU legislation. The debate about this can be split into three main views:

Viewpoint 1: Plants developed with any of the new techniques will carry the same risk as GM plants and therefore they should be covered by the full GMO regulation – including the requirements on prior risk assessment and subsequent risk management (cf. category 2 above).

Viewpoint 2: Some uses of the new breeding techniques are a form of mutagenesis and they should – in the same way as traditional mutagenesis – be excluded

from the full GMO regulation with the requirement on risk assessment.

In other words, these uses introduce the same type of changes that traditional mutagenesis introduces, only now more targeted and with far fewer unintentional changes. Additionally, mutations that are produced by these techniques cannot be differentiated from naturally occurring mutations.

Viewpoint 3: It is proposed that the current Danish Plant Variety Protection Act must be adjusted, so that it includes a requirement for a risk assessment in the act, which is less comprehensive than the risk assessment for GM crops.

The current GMO legislation in the EU was established before the new plant breeding techniques were developed. Thus there is a need to clarify the relationship between this legislation and the new techniques. A principle case has been raised with regard to this at the Court of Justice of the EU and a ruling is expected in 2018, cf. the discussion about the new technique's possibilities and regulation.

#### **Need for a new regulation?**

It has been pointed out by others that the current legislation was set out before the existence of the new breeding techniques and thus it is not suitable to deal with them. Regardless of the outcome of the court's decision on the aforementioned case, we may expect that there will be a discussion about the need for establishing a new regulation.

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.