



Ministry of Environment
and Food of Denmark
The Danish
Agricultural Agency

The status of GMO and precision breeding (New Plant Breeding Techniques (NPBT))

Danseed Symposium 2018

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Regulation of the new plant breeding techniques

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key questions:

How are we to regulate the use of new plant breeding techniques in the EU?

- *vis-a-vis* the current GMO-legislation?
- is new regulation needed?

Content of the presentation

- 1) Danish stakeholder involvement and activities
- 2) New Plant Breeding Techniques – a short overview
- 3) Current EU-legislation on GMOs
- 4) Different opinions on how to include the New Plant Breeding Techniques in the current EU-legislation
- 5) The expected clarification of the scope of the GMO-directive by the European Court of Justice
- 6) Next steps

Working group on new plant breeding techniques

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Danish stakeholder involvement and activities

- The working group on new plant breeding techniques held five meetings (June-December 2017)
- The following topics were discussed:
 - Introduction and background
 - Theory and Methods
 - Practical use
 - Risks, safety and detection
 - Socio-economic considerations, the consumer and the political landscape
 - Dilemmas and ethics
- Public Conference on new plant breeding techniques (30 January 2018)
- Fruitful and balanced discussions at working group meetings and at the conference
- No consensus on future regulation, but identification of some principles to guide further work



*Scientific Advice
Mechanism (SAM)*

New techniques in **Agricultural Biotechnology**

*High Level Group of Scientific Advisors
Explanatory Note 02/2017*



New Plant Breeding Techniques – a diverse group of techniques...

- Oligonucleotide Directed Mutagenesis (ODM)
- Site Directed Nucleases (SDN) (eg. CRISPR/Cas9)
 - SDN1 (insertion of random mutations in precise locations)
 - SDN2 (insertion of nonrandom mutations in precise locations)
 - SDN3 (insertion of genes in precise locations)
- Cisgenesis and intragenesis
- Agroinfiltration
- Epigenetic modification: RNA-dependent DNA methylation
- Grafting on GM-rootstock
- Reverse breeding
- ...?

New Plant Breeding Techniques – proposal for categorisation of techniques

- Transgenesis
- Cisgenesis/intragenesis
- Mutagenesis
- (Others: eg. epigenetic modifications)

New Plant Breeding Techniques – proposal for categorisation of techniques

Technique	Introduced genetic change	Could the change occur naturally or by using conventional breeding methods?	Can the change be detected by analysing the resulting plant?
Transgenesis	Insertion of foreign genes	No	Yes
Cisgenesis and intragenesis	Insertion of genes from the same or closely related species	Yes/No	Yes/No
Mutagenesis	Induced mutations	Yes	No

Cultivation of GM-crops in the EU: Some important directives and regulations

- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
- Regulation (EC) No 1829/2003 on genetically modified food and feed
- Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

Authorisation of GM-crops for marketing for cultivation in the EU: Important requirements

- Individual application and (political) approval proces for each GM-construction
 - Step-by-step introduction into the environment
 - Harmonised case-by-case environmental risk assessment
 - Harmonised case-by-case safety assessment (food and feed)
 - Unique identifier
 - Traceability and labelling
 - Post-market environmental monitoring
- *In Denmark, additional requirements in the national legislation on co-existence also apply.*

Current status and experiences on authorisations of GMOs for marketing for cultivation in the EU

Status:

- One GM-crop (GM-maize Mon 810) authorised for marketing for cultivation in the EU
- Commission has submitted draft proposals for decision on authorisation/renewal of authorisation for three GM-maize (1507, Bt11 og Mon 810). No qualified majority to neither approve nor reject the proposals.
- 19 Member States or regions (including DK) have geographical cultivation exemptions for the three GM-maize

Experiences:

- Strong opinions against cultivation of GM-crops in many Member States
- Difficult for the EU to reach decisions, i.e. either to approve or reject GM-applications
- Drawn out processes on authorisations (several years)
- Documentation requirements etc. make it very costly to obtain an authorisation for marketing of a GM-crop for cultivation in the EU

How is a GMO defined in directive 2001/18/EC on deliberate release of GMOs?

GMO: means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

Within the terms of this definition:

- a) genetic modification occurs at least through the use of the **techniques** listed in Annex I A, part 1*
- b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification*

Exemption (art. 3)

*This directive shall not apply to organisms obtained through the **techniques** of genetic modification listed in Annex I B*

Categorisation of techniques and resulting organisms in the deliberate release directive (2001/18/EC)

Technique	Genetic modification cf. Annex I A, part 1 <i>(eg. recombinant nucleic acid techniques involving a vector or direct introduction)</i>	Genetic modification cf. Annex I B <i>(mutagenesis, types of cell fusion)</i>	Non-genetic modification cf. Annex I A, part 2 <i>(in vitro fertilisation, natural processes such as conjugation etc, and induction of polyploidy)</i>
Classification of existing techniques, examples	<i>Agrobacterium</i> -mediated gene transfer	Induction of mutations by radiation or chemical treatments	<i>In vitro</i> fertilisation
Resulting organism	GMO	GMO	non-GMO
Subject to the full GMO-regulation?	Yes	No <i>("mutagenesis-exemption")</i>	No

There are different opinions about how the New Plant Breeding Techniques should be regulated *vis-a-vis* the current EU regulation on GMOs

- Broad consensus that some applications of some of the new techniques result in GM-plants that should be subjected to the full GMO-regulation ("*transgenesis*")
- Disagreement about how to handle other techniques and applications (eg. "*cisgenesis and intragenesis*")
- The discussion focuses on the new techniques of targeted mutagenesis such as SDN-1 and SDN-2, particularly CRISPR/Cas9
- The discussion involves legal arguments..
- ..and other types of arguments (technical, political, "freedom of choice" etc.)

Legal disagreement on how to deal with the new techniques for targeted mutagenesis (such as CRISPR/Cas9) in the current GMO-regulation in the EU

”These techniques should be included in Annex 1A, part 1 and thus result in GMOs that should be subject to the full GMO-regulation, including *case by case* approval and risk assessment.”

or

”These techniques should be included in Annex 1B (*“the mutagenesis-exemption”*). They result in GMOs that are exempted from the requirements of the GMO-regulation.

Examples of arguments from stakeholders as to why new techniques of targeted mutagenesis (ia. CRISPR/Cas) should be subjected to the full GMO-regulation

- New techniques pose new risks – risk assessment (environment and health) is thus needed
- More research on risk is needed – will only happen if the new techniques are subjected to the full GMO-regulation
- Faster development of targeted mutations is not the solution, we need a more balanced and hollistic approach to address the challenges of agriculture
- Consumers should have the right to choose – labelling and traceability is thus needed
- Farmers should have the right to choose – need for co-existence regulation in relation to eg. organic crops

Examples of arguments from stakeholders as to why new techniques of targeted mutagenesis (ia. CRISPR/Cas) should not be subjected to the full GMO-regulation

- These techniques only introduce changes that also could have occurred naturally
- The techniques cannot comply with the GMO-regulation's requirements concerning unique identifiers and traceability
- The techniques are more targeted and result in fewer unintended changes than traditional mutagenesis techniques (which are exempted from the full GMO-regulation)
- If these techniques are subjected to the full GMO-regulation, only the very largest (multinational) companies will use them and only in large, global crops (maize, soybean etc.)
- Full GMO-regulation of the techniques will imply that the EU plant sector will be less innovative and competitive

Clarification of the relationship between the new techniques and the current GMO-regulation in the EU

- Member States have waited in several years for a clarification from the EU-Commission
- Some Member States (eg. Sweden) have made national decisions in specific cases, eg. on experimental releases of plants developed with a new technique
- The European Court of Justice (ECJ) will later this year clarify the scope of the GMO Directive's mutagenesis exemption - i.a. whether this exemption includes new mutagenesis techniques.
- Advocate General M. Bobek presented 18 January 2018 his non-binding opinion for an ECJ-ruling. The opinion included:
 - *All mutagenesis techniques are exempted from the obligations of the GMO Directive provided they do not involve the use of recombinant nucleic acid molecules or a regulated GMO*
 - *Member States can legislate on organisms obtained by mutagenesis provided they respect their overall EU law obligations*
- The binding ruling from the ECJ is expected to be issued later this year



Next steps

In Denmark

The Danish Agricultural Agency will:

- inform the minister about the outcome of the activities in the working group and at the conference,
- Develop balanced and comprehensive material that can serve as a basis for an informed discussion at the political level.

In the EU

- A binding ruling on the mutagenesis exemption is expected to be issued by the European Court of Justice in 2018
- Implications of the ruling: What does it clarify and what is not included?
- Need for new regulation?

