

Existing legal framework

GMOs in plant breeding:

In the EU all GMOs need authorization before being placed on the market.

Authorisation can only be granted after a comprehensive risk assessment.

Non-GMOs in plant breeding:

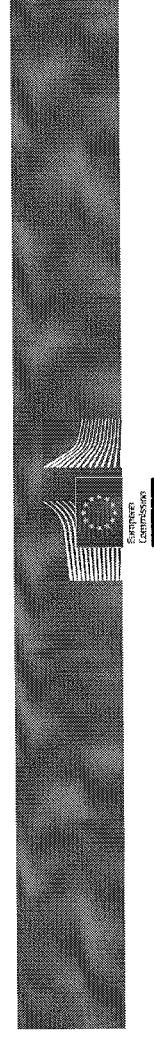
No general requirement for a pre-market risk assessment.

 The logo of the European Commission, featuring the European Union flag (a circle of twelve gold stars on a blue background) and the text "European Commission" below it.

New Breeding Techniques

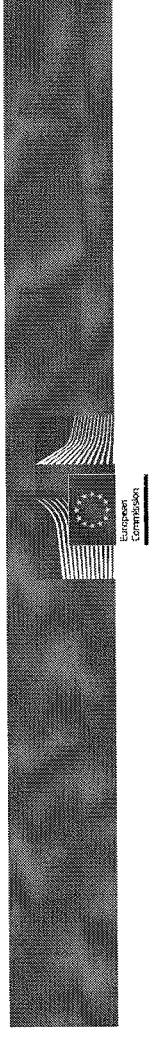
Presentation at:
 European Seed Association
 Annual Meeting
 15th October 2012
 Section Forage Plants Amenity Grasses – SFG

DG Sanco - [redacted]

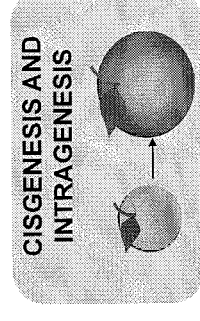


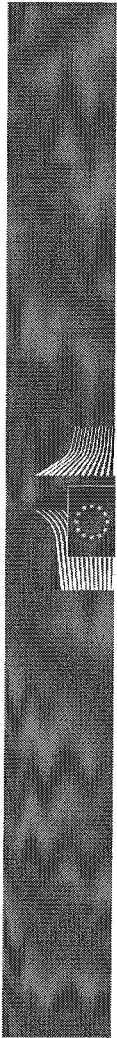
New Breeding Techniques:

- *Cisgenesis/Intragenesis*
- *Zinc finger nuclease technology*
- *Oligonucleotide-directed mutagenesis*
- *RNA-dependent DNA methylation*
- *Grafting*
- *Reverse breeding*
- *Agro-infiltration*
- *Synthetic biology*

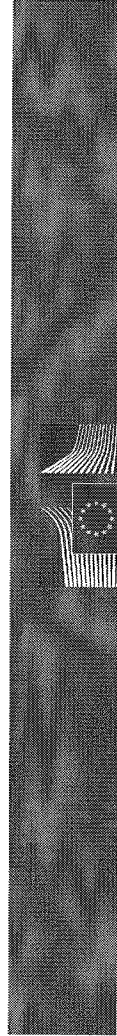
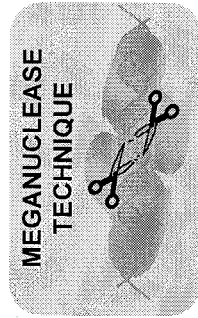
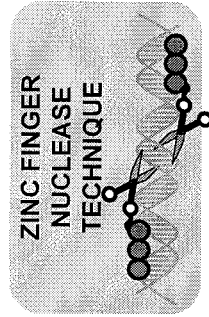


Cisgenesis and Intragenesis

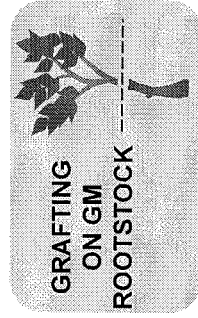


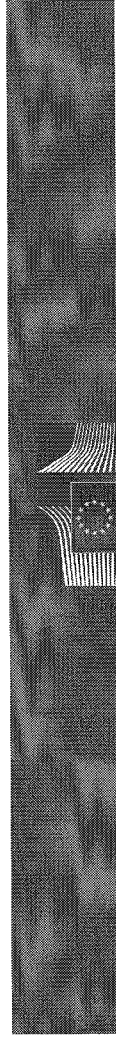


Site Directed Nucleases

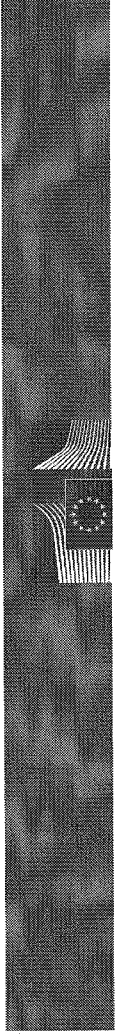
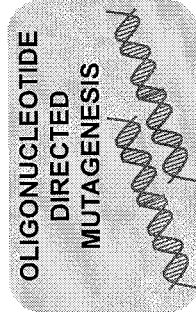


Grafting

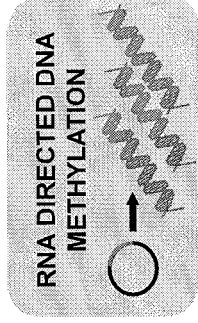


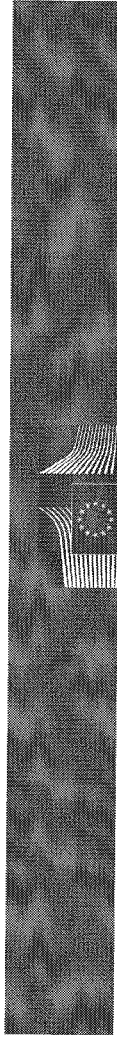


Targeted mutagenesis

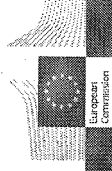
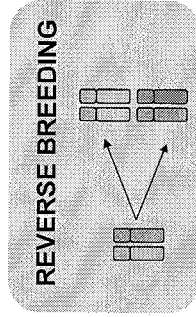


2. RNA Directed Methylation





2. Negative (null) segregants



New Breeding Techniques: Commission approach

1. JRC work on New plant breeding techniques
 - IPTS study on adoption and economic impact
 - IHCP task force on detection challenges
 - IPTS international workshop on regulatory approaches
2. EFSA input on safety aspects
3. Expert Working Group on New Techniques to report to Member States' Competent Authorities
4. Comprehensive analysis within the Commission



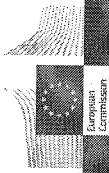
New Breeding Techniques: Commission approach

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New Breeding Techniques: Commission approach

2. EFSA input on safety aspects
 - Is current guidance appropriate?
 - Risks related to the use of new techniques
 - Compare to conventional breeding
 - Compare to current GMOs



New Breeding Techniques: Commission approach

2. EFSA input on safety aspects

Cisgenesis: completed

Intragenesis: completed

Zinc-finger nuclease: in progress

...



New Breeding Techniques: Commission approach

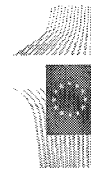
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...



New Breeding Techniques: Commission approach

3. Expert Working Group on New Techniques to report to Member States' Competent Authorities

Objective:

examine new techniques in the context of the
GMO legislation

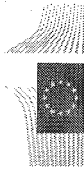
Report was finalised in December 2011



New Breeding Techniques: Commission approach

4. Comprehensive analysis within the Commission

to be completed



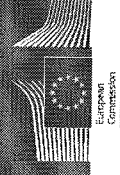
New Breeding Techniques: Challenge

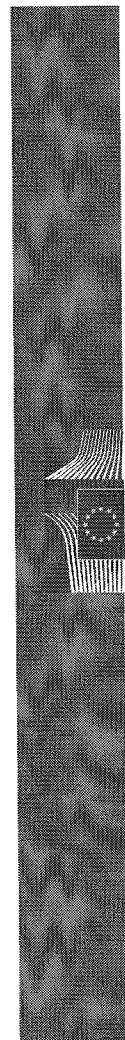
"Genetically modified organism (GMO)" according to Article 2 of Directive 2001/18/EC:

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 an/or natural recombination.

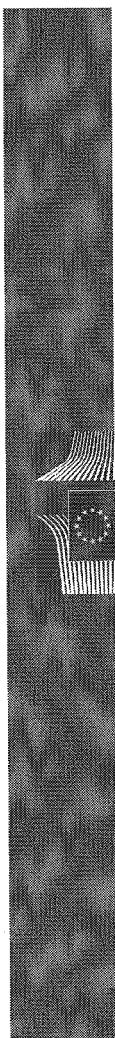
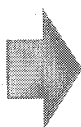
Within the terms of this definition:

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

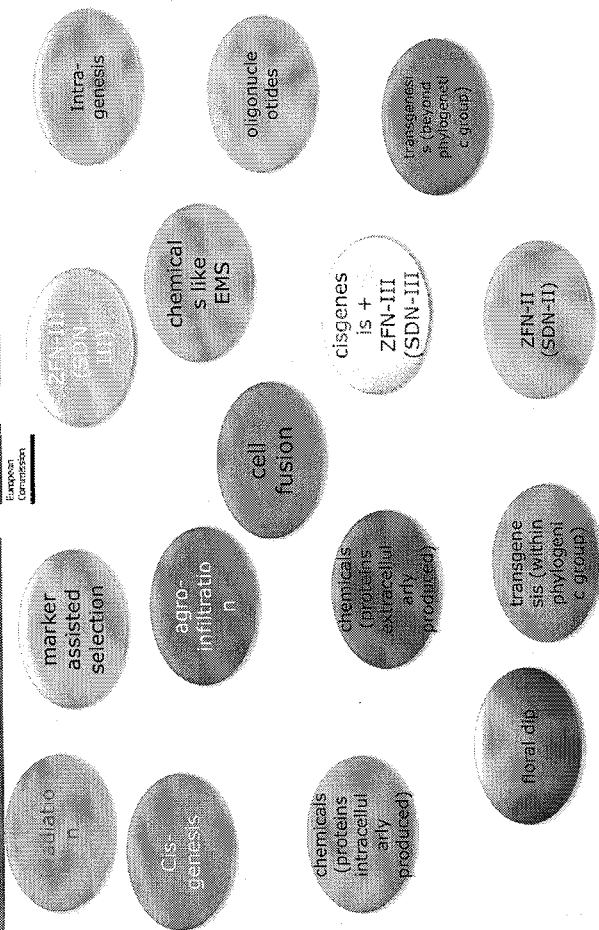


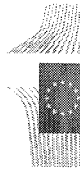


European
Commission



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Commission





New Breeding Techniques:

The analysis is ongoing.

The analysis will include:

- safety considerations,
- legal situation in the EU,
- approach in third countries,
- chances and risks involved,
- European plant breeders' views.

