



Scientific Recommendations by the German Science Academies and the German Research Foundation

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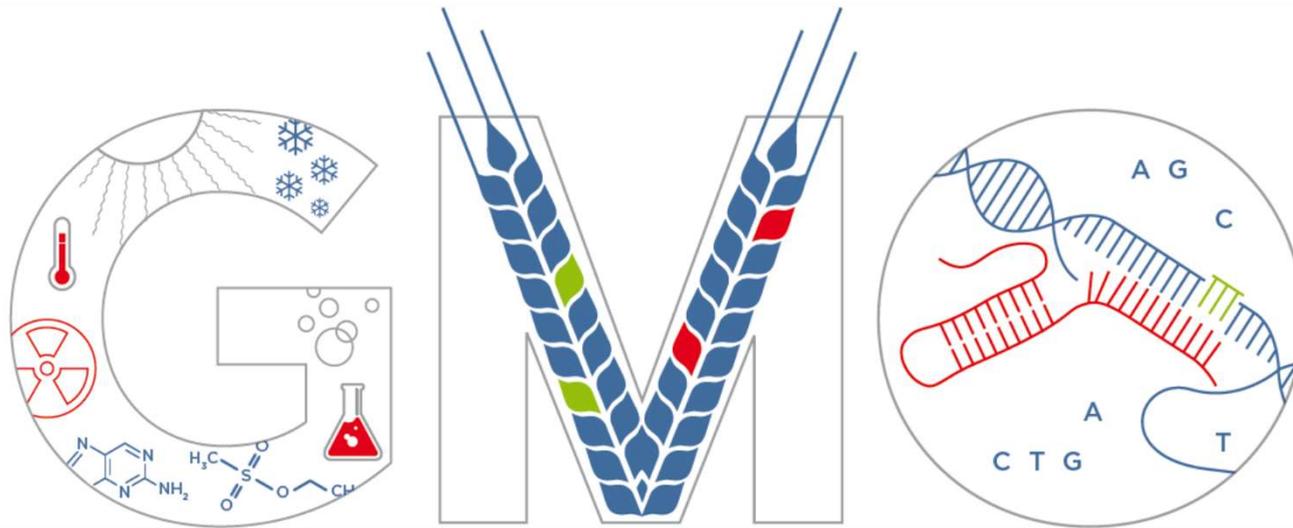


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Towards a scientifically justified, differentiated regulation of genome edited plants in the EU



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ECJ Judgment of July 25, 2018 Case C-528/16, *Confédération paysanne et al.*

- Questions submitted by French Conseil d'État concerning interpretation of Directive 2001/18
 - Mutagenesis organisms = GMOs?
 - Scope of „mutagenesis exemption“?
- Structure of Directive 2001/18
 - ‚Front door‘: GMO definition (Article 2(2) Directive 2001/18)
 - ‚Back door‘: exemption (Article 3(1) Directive 2001/18)
 - „Techniques/methods ... : 1. mutagenesis, ...“ (Annex I B(1) Directive 2001/18/EC)



ECJ Judgment of July 25, 2018

Case C-528/16, *Confédération paysanne et al.*

➤ Answers of the Court

- GMO definition („front door“)
 - Mutagenesis organisms = GMOs
- Exemption („back door“)
 - Not: „techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted [i.e. on March 12, 2001]“ (para. 51)
 - i.e. not: „techniques/methods of directed mutagenesis involving the use of genetic engineering“ (para. 47), „such as
 - oligonucleotide-directed mutagenesis or
 - directed nuclease mutagenesis“ (para. 23)



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ECJ Judgment of July 25, 2018 Case C-528/16, *Confédération paysanne et al.*

- Genome edited organisms (GEOs; i.e. ODM- + SDN-organisms) = regulated GMOs
- Applicability of all rules on deliberate release, placing on the market, labelling and traceability of GMOs
- Irrespective of whether genetic modification could have occurred naturally or been obtained through traditional breeding techniques



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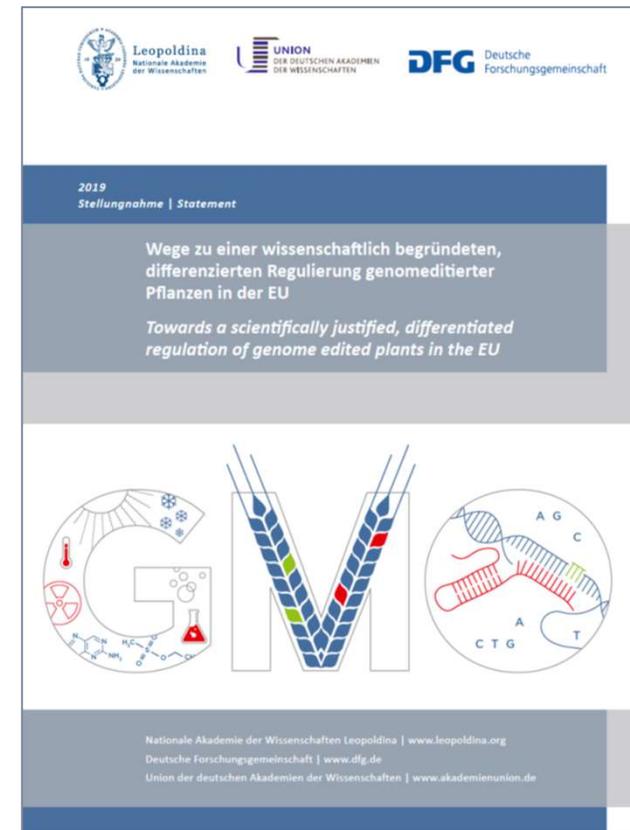
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Statement

Towards a scientifically justified, differentiated regulation of genome edited plants in the EU

Recommendations: to

1. amend existing EU GMO legislation in the short term
2. adopt a completely new legal framework in the long term
3. facilitate field trials
4. discuss breeding methods in a more nuanced way
5. ensure free choice
6. exploit the potential of innovations responsibly
7. increase market competition





Recommendation 1. Amendment of existing EU GMO legislation

➤ Objective

- GEOs are exempt from GMO legislation if they
 - do not contain foreign genetic information or
 - contain a combination of genetic material which could have occurred naturally or obtained through traditional breeding methods as well

➤ Means

- Narrowing the ‚front door‘: i.e. the GMO definition (options 1)
- Broadening the ‚back door‘: i.e. the exemption (option 2)



Option 1: narrowing the GMO definition (Article 2(2) Directive 2001/18)

Article 2 Definitions

For the purposes of this Directive :

...

(2) ,genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the genetic material ~~has been~~ **is altered in the shape of insertion of genetic information into the genome** 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;

...



Option 2: broadening the exemption (Article 3(1), Annex I B Directive 2001/18)

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

1. mutagenesis,
2. cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods,
3. **targeted molecular techniques which, when applied, effect a genetic modification that may have occurred naturally, in particular techniques that**
 - a) **cause deletions of DNA,**
 - b) **exchange individual base pairs,**
 - c) **do not cause stable insertion of genetic information,**
 - d) **cause the insertion, inversion or translocation in the genome of genetic information known to occur, or can occur with high probability, in the natural gene pool of the same species or closely related species**



Recommendation 2. Adoption of a completely new legal framework

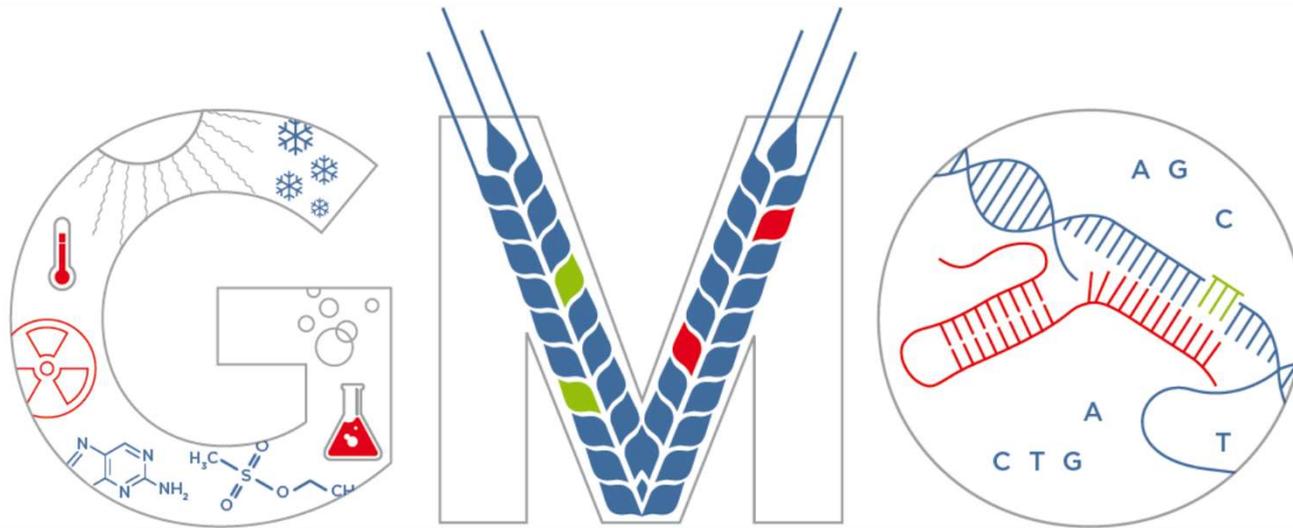
- Source of risks to human health and environment?
 - Not: process of genetic modification
 - Rather: products resulting from genetic modification and their use
- Framework should
 - be product-based: ‚novel traits‘ of an organism as regulatory trigger
 - ensure legal certainty: obligatory early consultation mechanism to clarify the regulatory status of an organism
 - be science-based:
 - risk assessment adapted to traits and their novelty
 - evaluation of the legal framework, e.g., every five years



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