



Legal issues relating to the use of high tech – as exemplified by novel plant breeding technologies

ICA Forum - Wageningen

25-10-2018



## ESA European Seed Association: who we are



- ✿ 38 national seed associations  
**(ESA Association Members)**
- ✿ 40 direct company members  
**(ESA Individual Members)**
- ✿ 29 associate company, association et.al. members  
**(ESA Associate Members)**

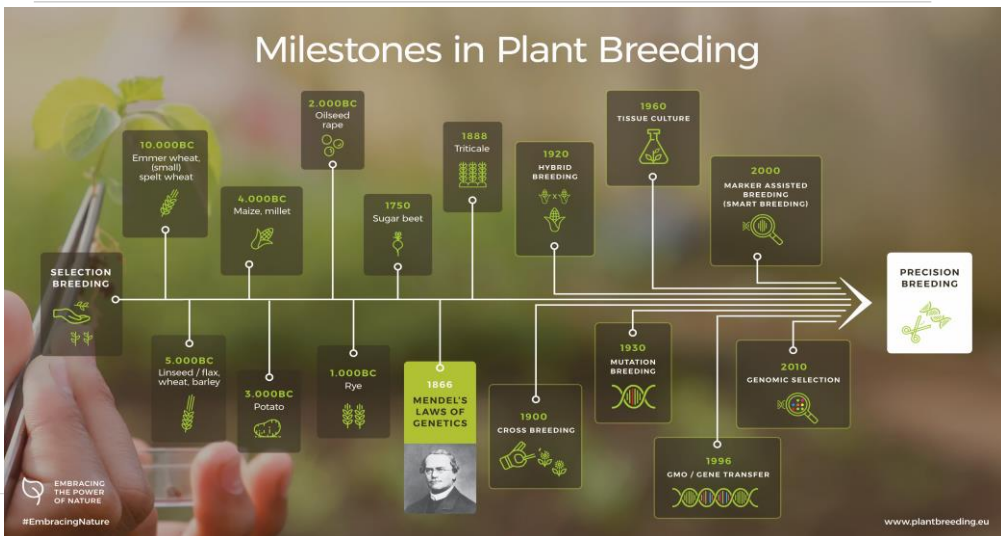


## EU SEED MARKET – KEY FACTS AND FIGURES

Item	Figure
Value EU seed market	~20-25% of the 50 bn Global Seed Market
Number of seed companies	> 7.000
Employment	~ 52.000
Annual R&D Spending	up to 20% (of turnover)
New varieties	~3500/year

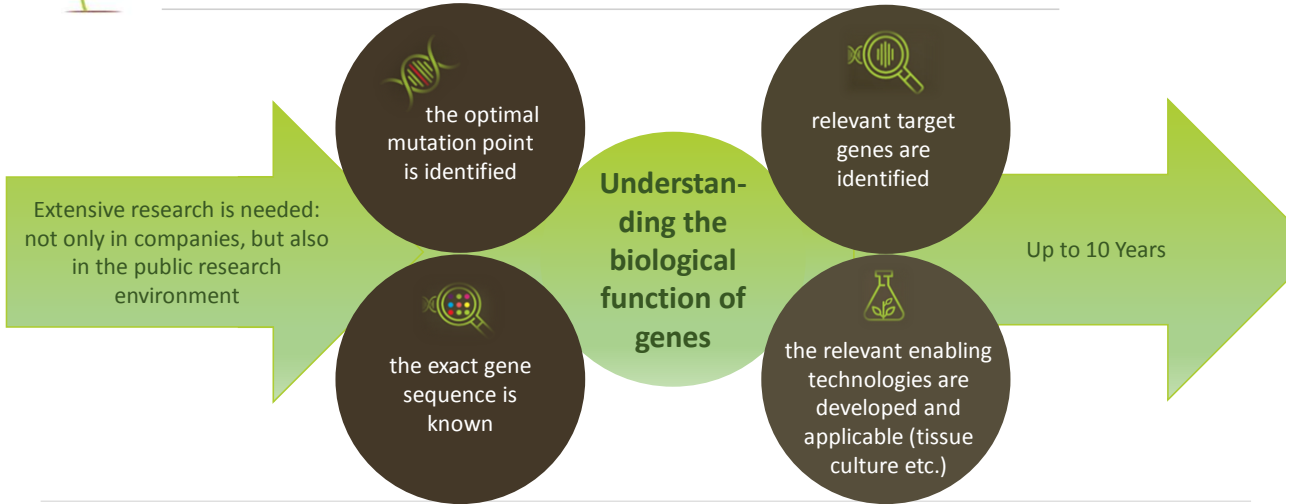


## The Breeders' Toolbox – Why talking about Plant Breeding Innovation?



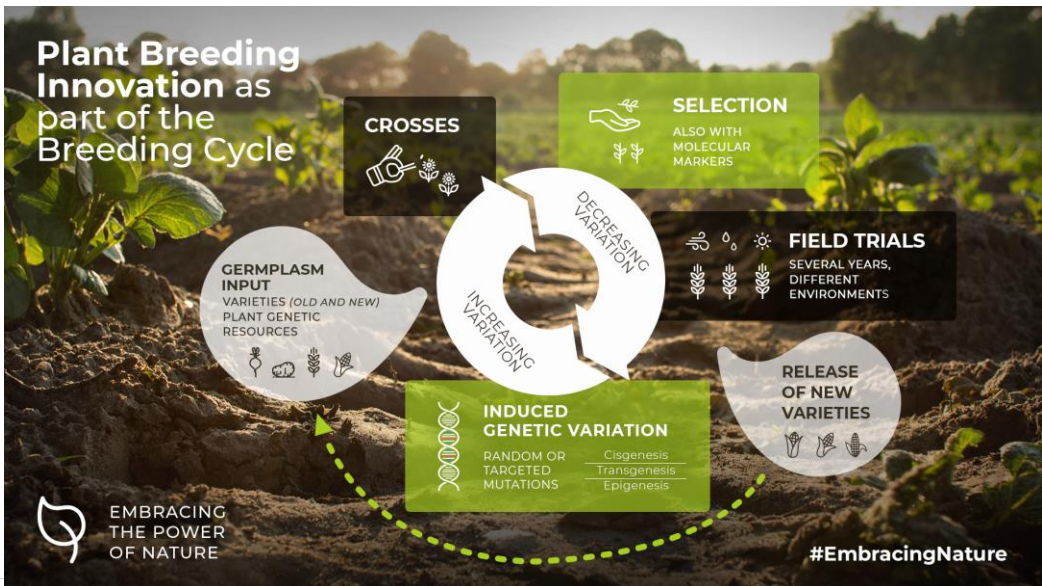


We need excellence in basic and applied plant science!



5

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6

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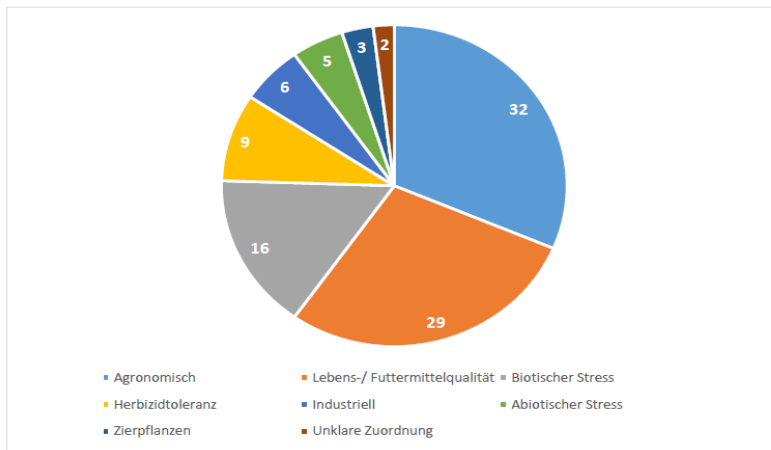


7

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### Study on Application oriented Research with Genome Editing



Σ 102 applications of genome editing in 33 species with Agricultural, Food or Industrial focus

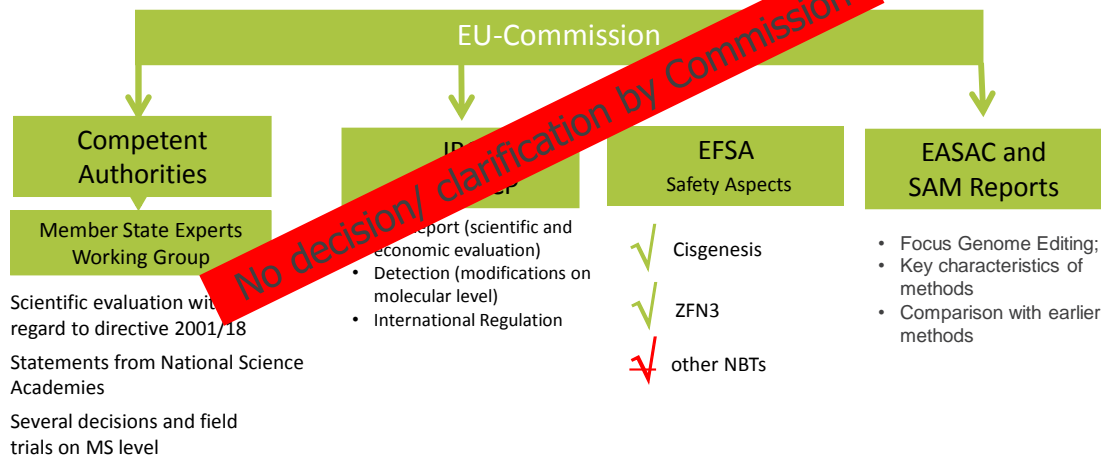
8

[https://www.dialog-gea.de/application/files/4315/3864/5414/180920\\_Anwendungen\\_von\\_Genome\\_Editing\\_in\\_Kultur-\\_und\\_Zierpflanzen\\_aktualisiert\\_bis\\_Mai\\_2018.pdf](https://www.dialog-gea.de/application/files/4315/3864/5414/180920_Anwendungen_von_Genome_Editing_in_Kultur-_und_Zierpflanzen_aktualisiert_bis_Mai_2018.pdf)

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Political framework - Lots of Activity since 2007 but no Guidance by EU-Commission



→ French ECJ Courtcase

9

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Directive 2001/18 on the deliberate release into the environment of genetically modified organisms

Article 2

Definitions

For the purposes of this Directive:

(1) .....

(2) "**genetically modified organism (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**;

Article 3

Exemptions

1. This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

10

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## Directive 2001/18 on the deliberate release into the environment of genetically modified organisms

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### 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.**



## ESA's basic principle for regulatory requirements

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*Plant varieties developed through the latest breeding methods should **not be subject to different or additional regulations** if they **could also have been produced through earlier breeding methods** or by **natural processes** without human intervention.*





## Questions to the Court

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- I. Do organisms obtained by mutagenesis (old and new) constitute GMO's?
- II. Are all organisms obtained through mutagenesis exempted?
- III. What room for Member States to legislate "conventional" mutagenesis?



## The ECJ Ruling in a Nutshell

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### The CJEU concludes on **MUTAGENESIS** that

- organisms obtained by means of mutagenesis (old and new) **must be considered to be GMOs as defined in article 2(2)** of the GMO Directive
- the mutagenesis **exemption only applies to organisms** obtained by methods of mutagenesis **which have conventionally been used in a number of applications and have a long safety record**
- the mutagenesis exemption cannot be interpreted as preventing Member States from legislating in that area. Member States are **entitled to subject such organisms to the obligations laid down in the GMO Directive or to other obligations** as long as such obligations **comply with EU law** and in particular with the rules on the **free movement of goods**.
  - 3,281 varieties resulting from radiation or chemical mutagenesis listed in [Joint FAO/IAEA Mutant Variety Database](#) (and database is incomplete)



Open Questions

What does it mean (“conventionally” – “number” – “long” – “safety”)?

When does the exemption apply? All mutagenesis techniques before 2001?

Where does recital 17 come from and what was it meant to cover?

What about EU compliance with Cartagena Protocol/ LMO definition?

Member States can regulate exempted organisms, in compliance with rules on the free movement of goods. What does this in practice mean?

Can plants resulting from targeted mutagenesis even comply with the directive (e.g. obligation to provide “description of detection and identification techniques”)?



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VOLUME 5, ISSUE 3

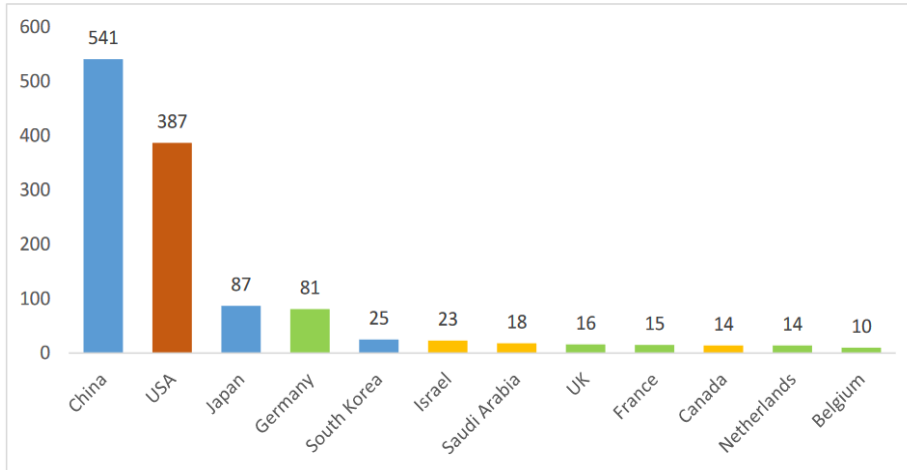


We still have hope in resurrection!





## Overview of the global applications of Genome Editing\*



\* By corresponding author (multiple answers possible)

17

→ Studies from **31 different countries**

[https://www.dialog-gea.de/application/files/4315/3864/5414/180920\\_Anwendungen\\_von\\_Genome\\_Editing\\_in\\_Kultur-\\_und\\_Zierpflanzen\\_aktualisiert\\_bis\\_Mai\\_2018.pdf](https://www.dialog-gea.de/application/files/4315/3864/5414/180920_Anwendungen_von_Genome_Editing_in_Kultur-_und_Zierpflanzen_aktualisiert_bis_Mai_2018.pdf)

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17



## Regulatory developments on international level

	No Foreign DNA					Foreign DNA	Comments
	Targeted small deletions	Targeted small additions/ edits	Targeted allele replacements	Targeted insertions	Null Segregants	Targeted Insertion	
Argentina	No	No	No	Likely Yes	No	Yes	Status: Final; Case by Case—60d Novel combination of DNA trigger
Chile	No	No	No	Likely Yes	No	Yes	Status: Case by Case—20d Novel combination of DNA trigger
Brazil	No	No	No	Likely Yes	No	Yes	Status: Final; Case by Case—90d Novel combination of DNA trigger
Colombia	Likely No	Likely No	Likely no	Likely Yes	No	Yes	Status: Proposed; Case by Case; 60 days Novel combination of DNA trigger
Canada	Using existing regulations—Novelty as trigger (discussions ongoing to provide more clarity)						
US (USDA)	No, if no plant pest	No, if no plant pest	No, if no plant pest	No, if no plant pest	No	No if no plant pest	"Ann 1 Regulated" Process Plant Pest Trigger; Secretary Perdue Issues USDA Statement on Plant Breeding Innovation 28.3.2018; FDA, EPA to be seen
Australia	Yes	Yes	Yes	Yes	Yes	Yes	Proposal to exclude SDN-1 & null-segregants
New Zealand	Yes	Yes	Yes	Yes	Yes	Yes	High court decision, only classical mutagenesis exempted
FSANZ	Yes	Yes	Yes	Yes	No	Yes	Code under review Australia/NZ Food Safety Authority
Israel	No	Likely No	Likely No	?	?	Yes	Status: Decision by GMO Committee, 2015 Novel combination of DNA trigger
EU	Yes	Yes	Likely yes	Likely yes	?**	Yes	According to ECJ ruling; ** no formal policy
Japan	Likely No	Uncertain (GMO by law, but option for exemption)	Uncertain (GMO by law, but option for exemption)	Yes	Likely No	Yes	proposal by MOE 25.09.2018, comments until 19-10 possible
China	?	?	?	Yes	?	Yes	No formal proposal yet

18

Yes=Under current biotech regulations No= Not under current biotech regulations ? = uncertain

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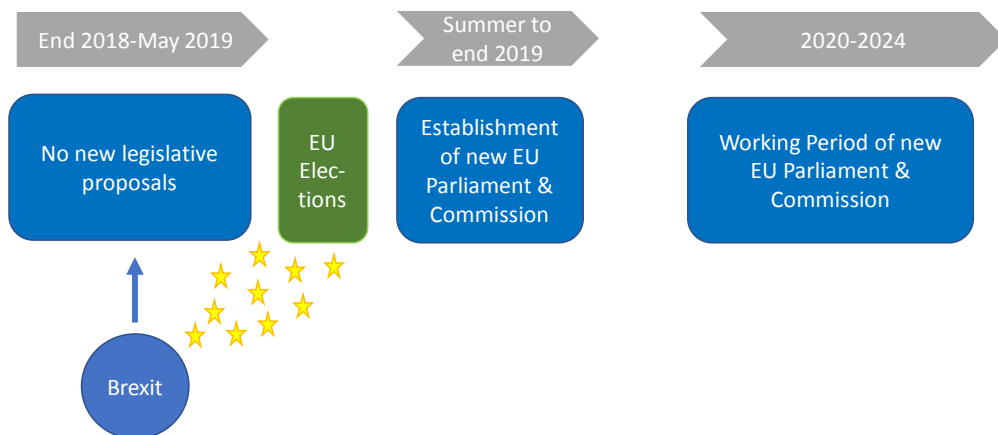


## End of the Story in the EU? - No

- The Ruling is about interpreting legislation that was established in in 1990 and updated 2001
- Ruling shows that legislation is outdated
- Now political process starts - Our interest is:
  - Avoiding individual MS regulation of classical mutagenesis
  - Supporting scientific interpretations of the ECJ judgement to exempt specific applications or interpret e.g. the “history of safe use” concept
  - Targeted amendment or change of legislative basis to exclude plants that could have also been produced by conventional breeding or nature (no novel combination of genetic material)
    - within 2001/18
    - within a separate piece of legislation



## Political Developments in the EU





## What is at stake? Putting Plant Breeding Innovation under burdensome regulation will...

- **Prevent esp. SME's and public applied research** from developing and using these methods;
- Eroding **competitiveness** and leading to a less diversified plant breeding sector;
- **Exodus** of innovative breeding companies from Europe;
- **Competitive advantage** to the plant breeding industries outside Europe;
- European **scientific excellence** (private and public), related jobs, innovation and consequently economic growth driven out of Europe;
- Small size of **niche markets** would not justify the regulatory approval costs
  - portfolio of products reduced
  - less choice in products for Europe's farmers, growers, processing industries and consumers;
- Achieving goals of **increased sustainability** of EU agriculture (new CAP) will be put at risk;
- **Disruption of Trade** (Seed and Commodity).

21

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## Regulating genome edited organisms as GMOs has negative consequences for agriculture, society and economy

PFLANZENZÜCHTUNG GEFÄHRDET

### Der Aufschrei der europäischen Gen-Gelehrten

VON JOACHIM MÜLLER-JUNG - AKTUALISIERT AM 24.10.2018 - 12:30



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<http://www.vib.be/en/news/Pages/European-scientists-unite-to-safeguard-precision-breeding-for-sustainable-agriculture.aspx>

[www.plantbreeding.eu](http://www.plantbreeding.eu)



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**CONTACT US**

ESA European Seed Association  
Avenue des Arts 52  
B 1000 Brussels

T. +32 (0)2 743 28 60

[secretariat@euroseeds.eu](mailto:secretariat@euroseeds.eu)

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