



The importance of Plant Breeding Innovation for the EU Seed Sector

13.09.2018 -Prague

New Breeding Techniques (NBT) -

Hope for Agriculture and Food Chain

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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)
R&D Stations	750
R&D Employees	ca 12.500

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EU SEED MARKET – KEY FACTS AND FIGURES

3.500

New varieties

are authorized for marketing within the European Union **each year**.

42.000

Different varieties

of agricultural and vegetable species are available to **farmers** in the European Union.

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

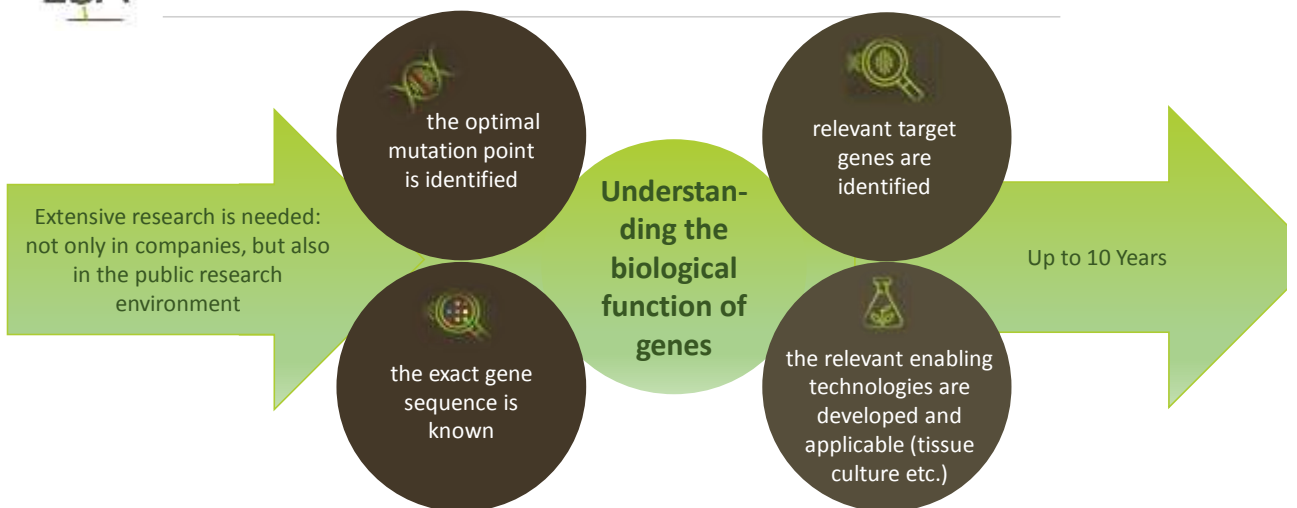


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We need excellence in basic and applied plant science!

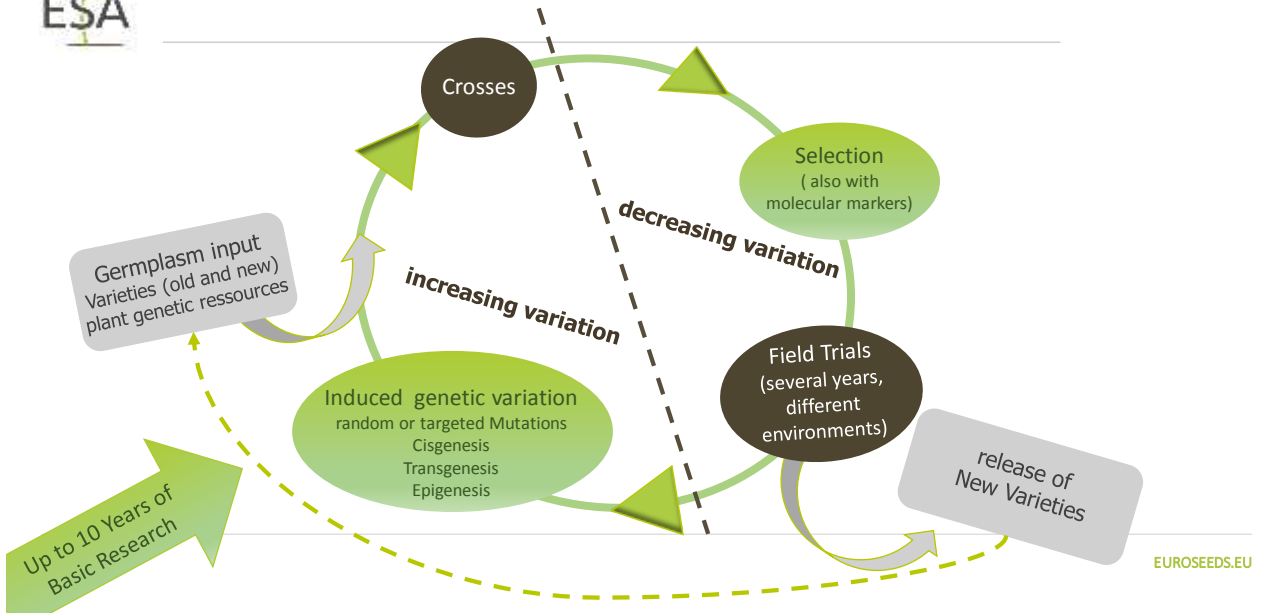


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Plant Breeding Innovation needs to be integrated to the Breeding Cycle



Bringing Innovation on the Farm and into the Field





Existing Breeding Goals can be achieved in a more efficient way

Quality Traits	Yield	Resistances
Baking quality (e.g. N-glycans modification in barley, gluten free wheat)	Corn yield (pod shatter resistant oil seed rape, grain weight and enhanced grain number in rice, parthenocarpic tomato plants)	Viruses (Cucumis: Zucchini Yellow Mosaic virus; Papaya ring spot Virus)
Brewing quality (e.g. low lox barley)	Biomass yield (improved carbon metabolism)	Bacteria
Fatty acid composition (e.g. high oleic acid soybean/ Camelina; low sat. fatty acid canola)	Starch, Protein, Sugar, Oil content (higher oil content Camelina)	Insect
Increased Vitamin content	Nutrient use Efficiency	Fungi (e.g. Powdery Mildew in Wheat and tomato, late blight potato, blast resistant rice)
Improved shelf life (improved cold storage potato, non-browning mushroom/apple/potato)	Water use Efficiency (drought tolerant soybeans)	Drought, Heat, Salt (salt stress tolerant rice, drought stress resistant corn)
Starch quality (e.g. waxy corn, amylopectin potato, high-amylose rice)		Herbicides (e.g. oilseed rape, linum, rice, potato)
Food/Feed quality (low-phytate maize, high fiber wheat)		

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ESA's basic principle for regulatory requirements

*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.*

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ESA's Position on the scope of GMO Regulation

The genetic variation in the final plant product should **NOT be covered by the scope of the legislation for GMOs** if

- ✦ there is **no novel combination of genetic material** (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct), and;
- ✦ the final plant product solely contains the stable insertion of inherited **genetic material from sexually compatible plant species**, or;
- ✦ the genetic variation is the **result of spontaneous or induced mutagenesis**.

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New Breeding Techniques (NBT) – Still hope for Agriculture and Food Chain in Europe after ECJ Ruling?

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 means of techniques/methods of mutagenesis **which have conventionally been used in a number of applications and have a long safety record**
- the mutagenesis exemption under the GMO Directive **cannot be interpreted as preventing Member States from legislating in that area**. As a result, 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**.
 - for the moment 3,281 varieties resulting from radiation or chemical mutagenesis are listed in [Joint FAO/IAEA Mutant Variety Database](#) (and database is incomplete)

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Checking ESA Position in view of the ECJ Ruling

Resulting plants which are placed on the market	Applied method	Targeted Mutagenesis via SDN1, ODM	Targeted gene edit via SDN2	Transgenesis (stable integration of DNA from a non-sexually compatible specie)	Intragenesis (Cisgene, but novel combination of genetic material)	Cisgenesis (addition of a cisgene* at different location – novel combination of genetic material)	Cisgenesis sensu stricto (replacement or addition of allele* at naturally occurring location using SDN3)	RNA-induced DNA-methylation	Reverse Breeding	Grafting on GM-rootstock	Agro-infiltration of non-reproductive tissue only	Agro-infiltration of reproductive tissue (floral dip)	Null-Segregants	Future techniques	
1. contains no novel combination of genetic material (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct) and		✓	✓				✓	✓	✓	✓	✓		✓		
2. solely contains inherited genetic material from sexually compatible plant species or		✓	✓			✓	✓	✓	✓	✓	✓		✓		
3. is the result of spontaneous or induced mutagenesis		✓	✓												
Subject to GMO Regulation		No	No	Yes	Yes	Yes	No	No	No	No fruits/seeds	Yes entire plant	No	Yes/ No depending on kind of application	No	to be assessed
ECJ Ruling		Yes	Yes												

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Regulatory developments on international level

	No Foreign DNA				Foreign DNA	Comments
	Targeted small deletions	Targeted small additions/edits	Targeted large insertions or replacements	Null Segregant	Targeted Insertion	
Argentina	No	No	Likely no	No	Yes	Status: Final Consultation—60d New combination of DNA trigger
Chile	No	No	Likely no	No	Yes	Status: Final Consultation—20d New combination of DNA trigger
Brazil	No	No	Likely no	No	Yes	Status: Final Consultation—90d New combination of DNA trigger
Colombia	No	No	Likely no	No	Yes	Status: Proposed Case by Case 60 days Foreign DNA trigger
Canada	Using existing regulations—Novelty as trigger					
US (USDA)	No	Depends	Depends	No	Depends	*"Am I Regulated" Process" Plant Pest Trigger
Australia	No	Yes	Yes	?	Yes	Proposed 1 st step in process of reviewing statutes and implementing regs
New Zealand	Yes	Yes	Yes	?	Yes	High court decision Unclear if GOZ will challenge
FSANZ	Code under review					Australia/NZ Food Safety Authority
Israel	No	No	No	?	Yes	Status: Final Consultation New combination of DNA trigger
EU	yes*	yes*	Likely yes*	Likely yes*	Yes	According to ECJ ruling
Japan	Likely no	Likely no	?	Likely no	Yes	No formal proposal yet
China	?	?	?	?	Yes	No formal proposal yet

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*according to ECJ ruling C-528/16

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

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What is at stake? Putting new mutagenesis under GMO regulations...

- Prevent esp. SME's 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 will be put at risk;
- **Disruption of Trade** (Seed and Commodity).

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europeanseed

VOULPIER & PARTNER



We still believe in resurrection!

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ESA Position

The European plant breeding sector considers the consequences of the ECJ ruling to be unacceptable not only for breeders but for the EU agri-food chain as a whole and for society at large.

ESA will therefore do whatever is needed to support and finally achieve policies and regulations that enable a facilitated development and practical use of varieties resulting from plant breeding innovation.

ESA will

- continue to outreach and advocate for Plant Breeding Innovation and lead and coordinate the respective collaborative effort.
- try to achieve the objective of a non-GM regulatory status for targeted mutagenesis techniques
- analyse in detail with its respective bodies and other stakeholders how this objective may be achieved, both from a formal, legal perspective as well as taking account of wider political considerations.

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