



The EU legislative framework and potential impact of EU legal clarification

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ESA MEMBERS TODAY



- 🌱 38 national seed associations
(ESA Association Members)
- 🌱 40 direct company members
(ESA Individual Members)
- 🌱 29 associate company
members
(ESA Associate Members)



EU SEED MARKET – KEY FACTS AND FIGURES

3.500

New varieties

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

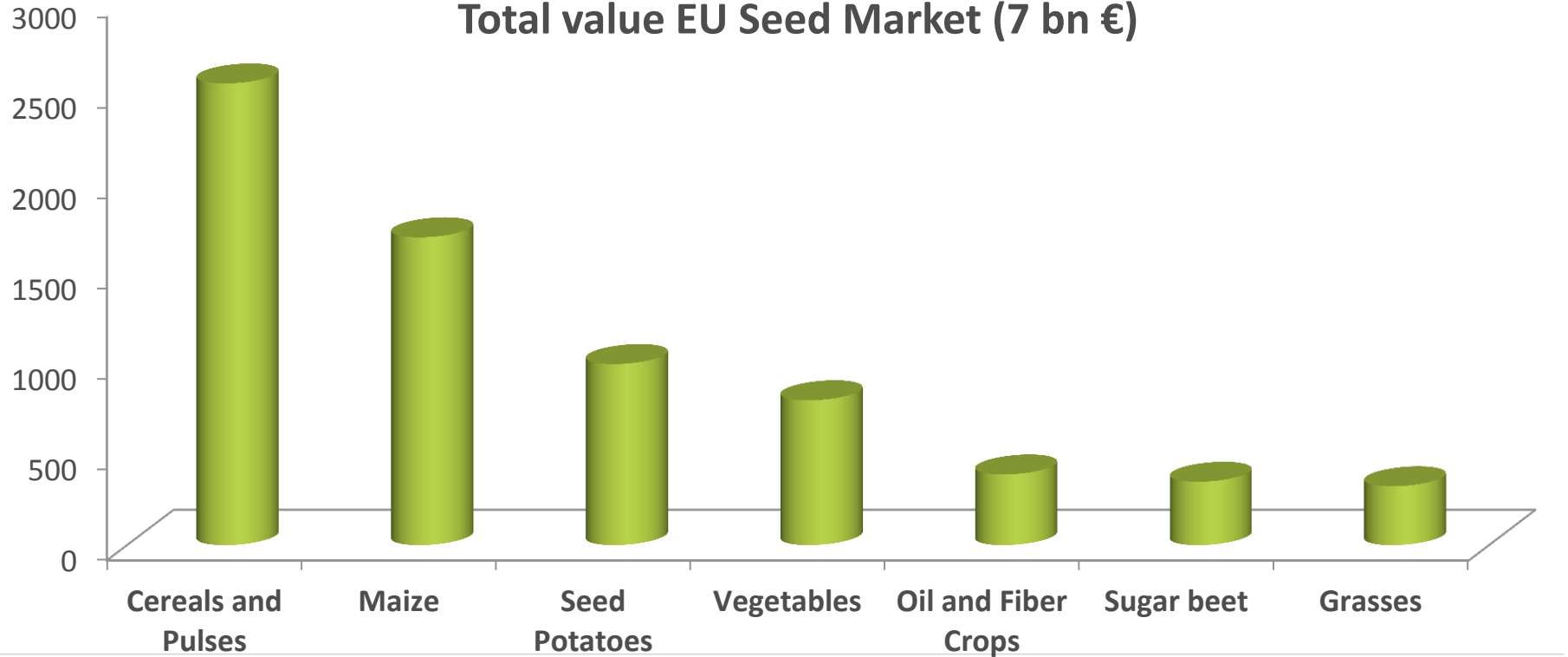
42.000

Different varieties

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

EU SEED MARKET – KEY FACTS AND FIGURES

Total value EU Seed Market (7 bn €)



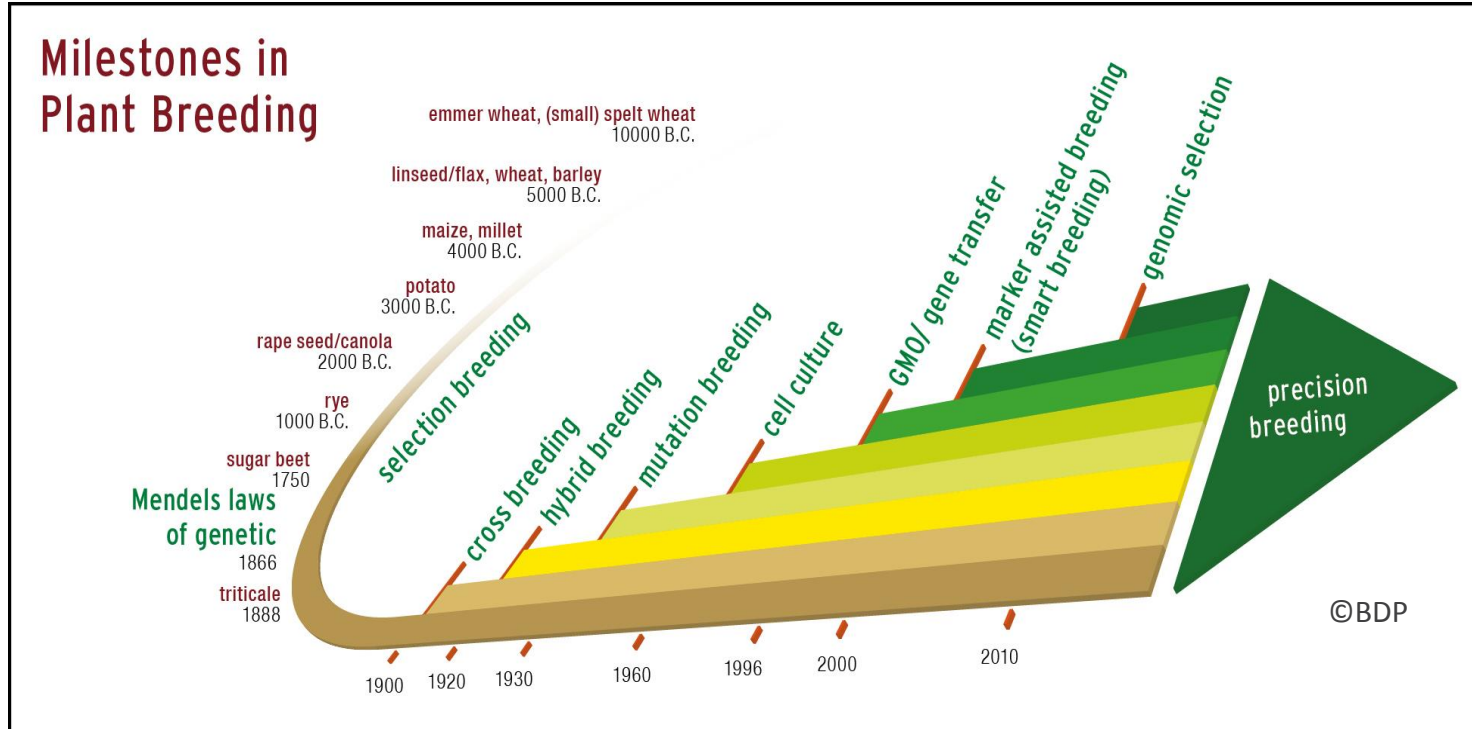


Why Plant Breeding Innovation ?

Producing sufficient quality Food, Feed, Fiber and Fuel for All

- 🌱 Healthy and Safe Food/Feed
- 🌱 Adaptation of agriculture to Climate Change
- 🌱 Ressource efficiency and reduced environmental impact
- 🌱 Reduction of Waste (pre-and post-harvest)
- 🌱 New products (Bioeconomy)

Milestones in Plant Breeding - A history of constantly improved Breeding Methods





Gene Editing: Importance to Private Breeders

- Methodologies can be used across all agriculturally important crops

- Efficient and precise
 - Reduces R&D and breeding time
 - Important for plants with long generation times
 - Important for crops with rapidly evolving diseases and pests

- Accessible & relatively inexpensive
 - Important to companies of all sizes



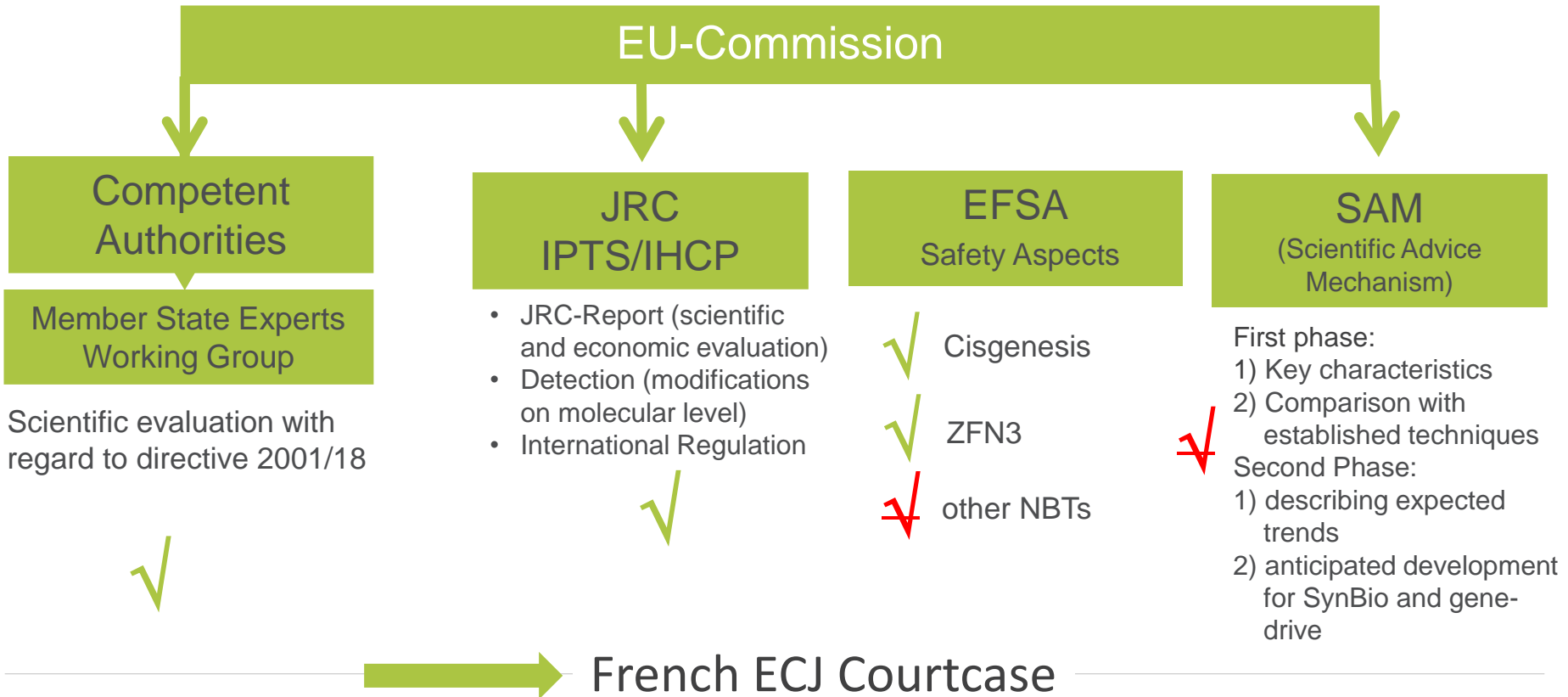
Political debate in the EU: Central Questions

- 1) Can these techniques be regulated under the current EU-GM-legislation (directive 2001/18) or is there a need to amend the directive?

- 2) If the techniques can be regulated under the current legislation: Which of the techniques fall under the regulation (lead to a gm-plant)?



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





Impact of Public Policy

- Inconsistent policies
 - Make research and breeding collaborations difficult
 - Negative impact on commercial seed trade
 - Negative impact on trade in agricultural products
 - Differential negative impact on breeding innovation across countries (level playing field)

- Determine range of improved varieties and traits for farmers and products for consumers



Growth of Seed Trade





Consistent Policies

Goal:

- To have **consistent and well defined alignment among governments** on the criterion used for the **scope of those categories of plants** developed through newer breeding methods that would be regulated under biotech/GMO regulations.
- **Consistent criteria used across countries to determine scope of regulatory oversight** for plants developed through newer breeding methods (primarily gene editing)



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.



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

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.**



Basic Principle for regulatory Requirements

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

Principles for Regulatory Requirements

The genetic variation in the final plant product is **not covered under the scope of existing regulation** 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), or;
- ✿ 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**.

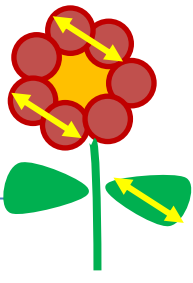
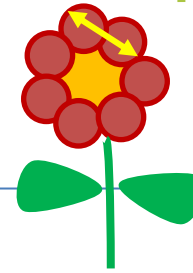
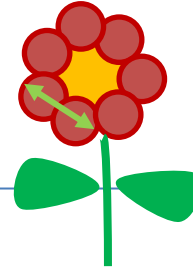
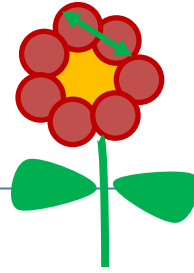
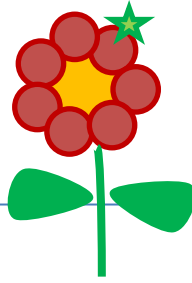
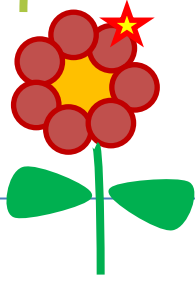
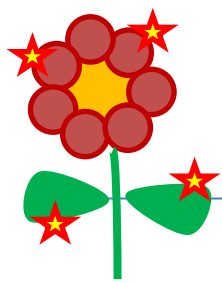
No additional need for regulation if:

- ✿ Plants or plant products are already regulated (GMO, Novel Food etc)

Classical mutagenesis

Genome editing

Classical GMO



Random Mutation

Targeted Mutation

Targeted Edit

Targeted Replacement

Targeted Insertion

Targeted Insertion

Random Insertion

small nucleotide additions or deletions

recreate or replace gene from plant's own gene pool

of gene from plant's own gene pool

of gene from outside plant's gene pool



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