



# **Plant Breeding Innovation – political and regulatory developments on European and international level**

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Workshop on Plant Breeding Innovation in Finland

2 October 2019, Helsinki



## EU SEED MARKET – KEY FACTS AND FIGURE

Item	Figure
Value EU seed market	€ 10 bn
Number of seed companies	7.200
Employment	52.000
Annual R&D Spending	≤ 20% (of turnover)
R&D Stations	750
R&D Employees	12.500
Seed production	1.6 bn ha

Source: Euroseeds

## 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.

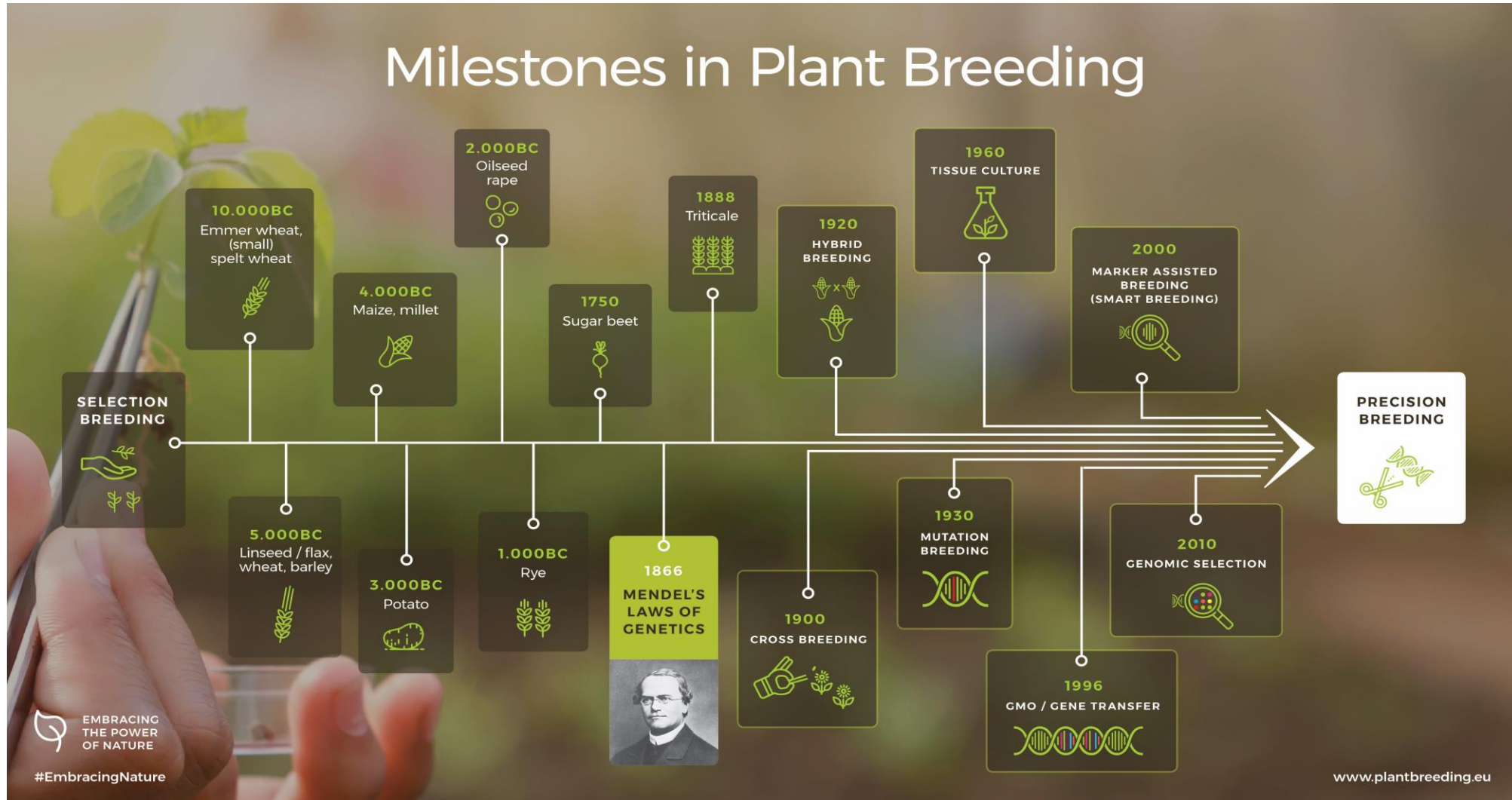
Source: Euroseeds

## INNOVATION AND IMPACT

Value seed market EU	€ 10 bn
Farm gate value agric. Products EU	> € 100 bn
Value processed agric. Products EU	> € 1000 bn

Source: Euroseeds

## PLANT BREEDING INNOVATION: A HISTORY OF PROGRESS





## The CRISPR 'Scissor' is Not Enough: High Investments in R&D needed

- How to get the 'scissor' into the cell?
  - ✓ Using tissue culture, transformation
- Which genes to target and how?
  - ✓ Understanding the biological function of genes and gene sequences
- How to grow a plant from a single edited cell?
  - ✓ Regeneration from tissue culture
- How to measure the effects of small change
  - ✓ High-precision phenotyping



- Extensive research is needed, not only in companies, but also in public research.
- Integration of new breeding methods in breeding programs is necessary.
- As a consequence, the R&D intensity will increase even further.

## Examples and benefits of (targeted) mutagenesis breeding products



**Waxy corn or potato**



- Less chemical and energy use during starch processing
- Clean Food Label



**Non-browning mushroom**



- Less food waste



**Powdery mildew-resistant wheat**

**Gluten-free wheat**



- Less pre-harvest losses and less pesticides
- Avoid food intolerance



**High Oleic Acid Soybean Oil\***



- No Trans Fatty Acids – healthier Food

## The ECJ Court Case C-528/16 in a nutshell

1) Do organisms obtained by mutagenesis (old and new) constitute GMO's?

- All organisms resulting from any form of mutagenesis are GMOs as defined by Article 2(2) of Directive 2001/18

2) Are all organisms obtained through mutagenesis exempted from regulatory obligations according to Annex IB of Directive 2001/18?

- 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

3) What room for Member States to legislate on exempted mutagenesis products?

- even for those plants to which the mutagenesis exemption of Annex IB applies, **Member States may still lay down national rules** subjecting these plants to similar obligations as the GMO Directive (compliance with EU law esp. with the rules on the free movement of goods)



## What is at stake for EU-Plant Breeders? 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 or moving focus of product development with innovative breeding methods outside of Europe
- Competitive advantage to the plant breeding industries outside Europe;
- European scientific excellence (private and public), related jobs, innovation driven out of Europe

## What is at stake for EU-agriculture and consumers? Putting new mutagenesis under GMO regulations...

- 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)



## Grow scientific progress: crops matter!



### Initiative language

English (en) ▾

### Subject matter

Directive 2001/18/EC is outdated. We as students of Life Sciences consider it important to revise the current exemption mechanism stipulated in the Directive, with regards to new plant breeding techniques (NPBTs).

Support this initiative by filling in the form below

Please select the Member State you are a national of and/or you reside in:

Please select country ▾

Support

To support a European Citizens' Initiative, you must be an EU citizen (national of an EU Member State) and be old enough to vote in European Parliament elections.

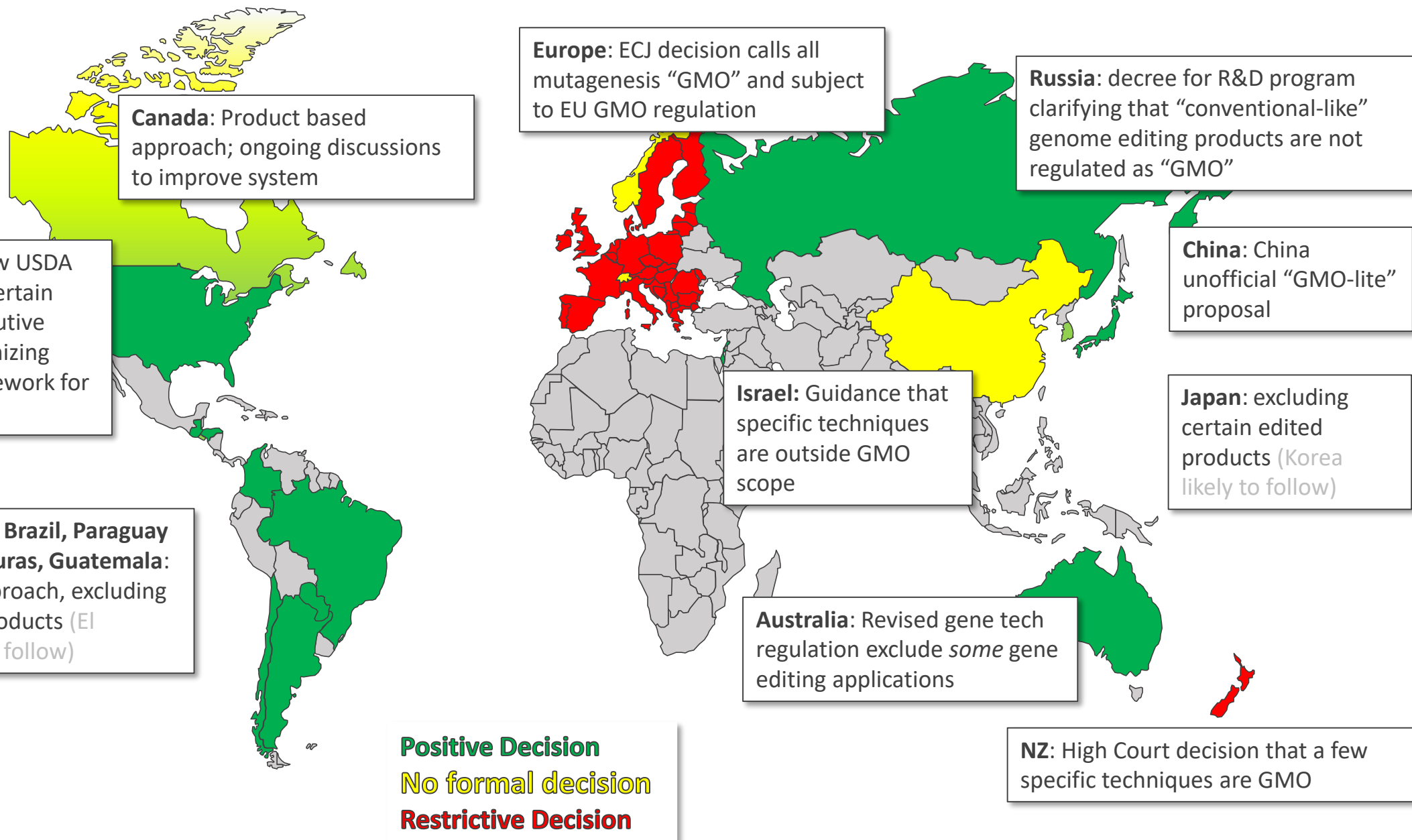
For more information on the rules and conditions for the European Citizens' Initiative <http://ec.europa.eu/citizens-initiative>



## Industry expresses its concern with the ECJ Ruling

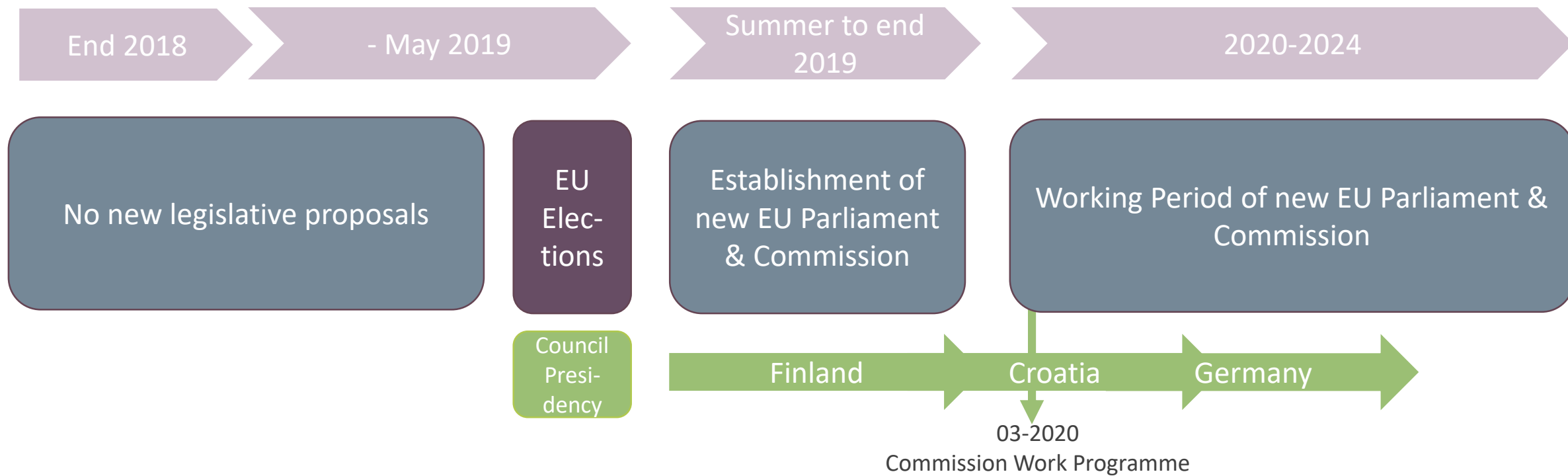


# Policy developments in different Countries around the world (09/2019)



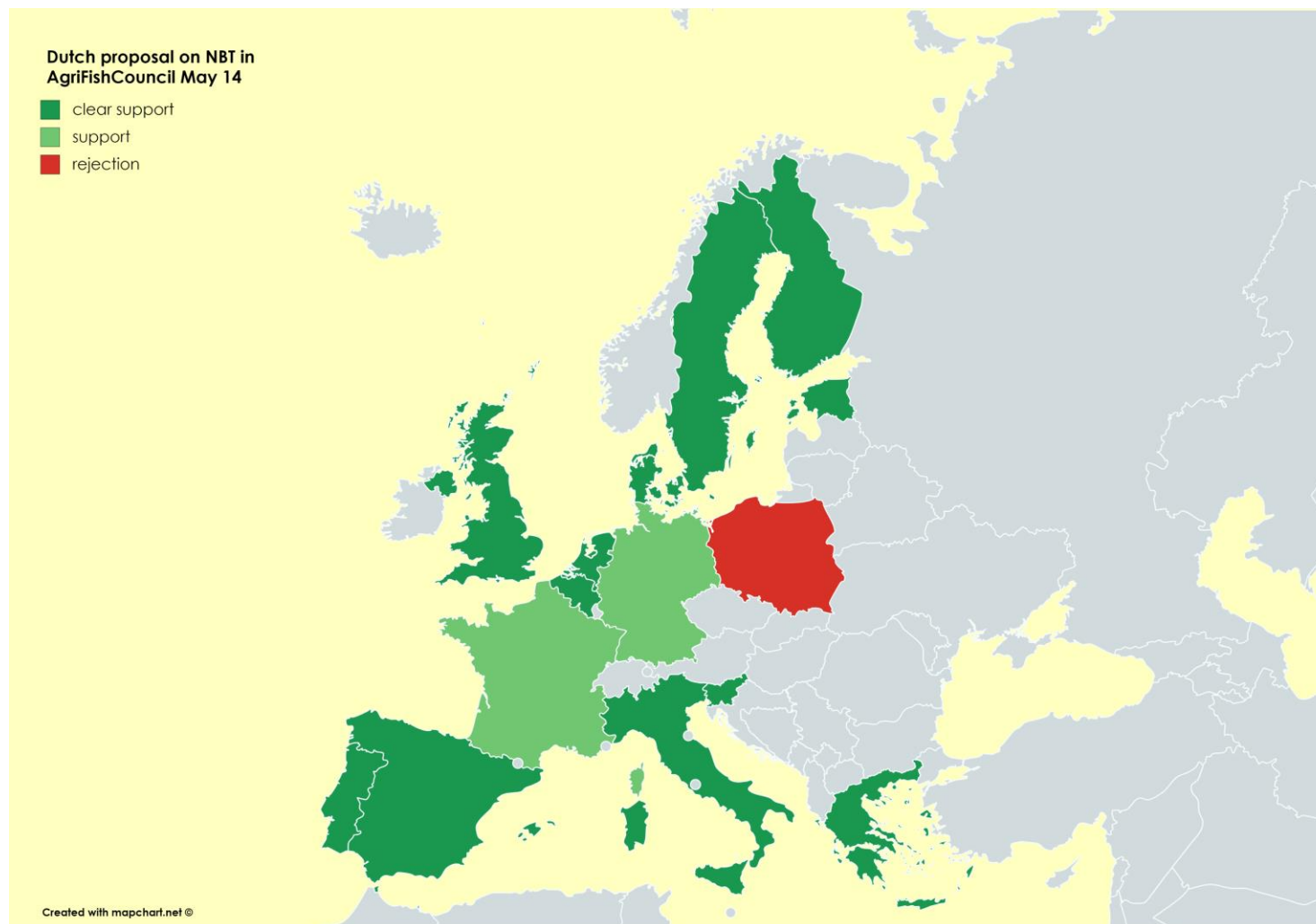


## Relevant political Developments on EU Level



## Outcome of the AgriFish Council Meeting 14 May 2019

“The Netherlands call upon the incoming new Commission to include addressing the adequacy of the European legislative framework for GMOs – and as appropriate other related legal and policy instruments – in its Programme of Work.”



## Council Working Party adopts „Finnish Proposal“ for a Commission Study on 6.9.2019



**Brussels, 6 September 2019**  
**(OR. en)**

**11347/1/19**  
**REV 1**

**LIMITE**

**AGRI 418**  
**AGRILEG 149**  
**ENV 743**

### Next steps:

- Coreper – end of October
- AgriFish Council 18 November

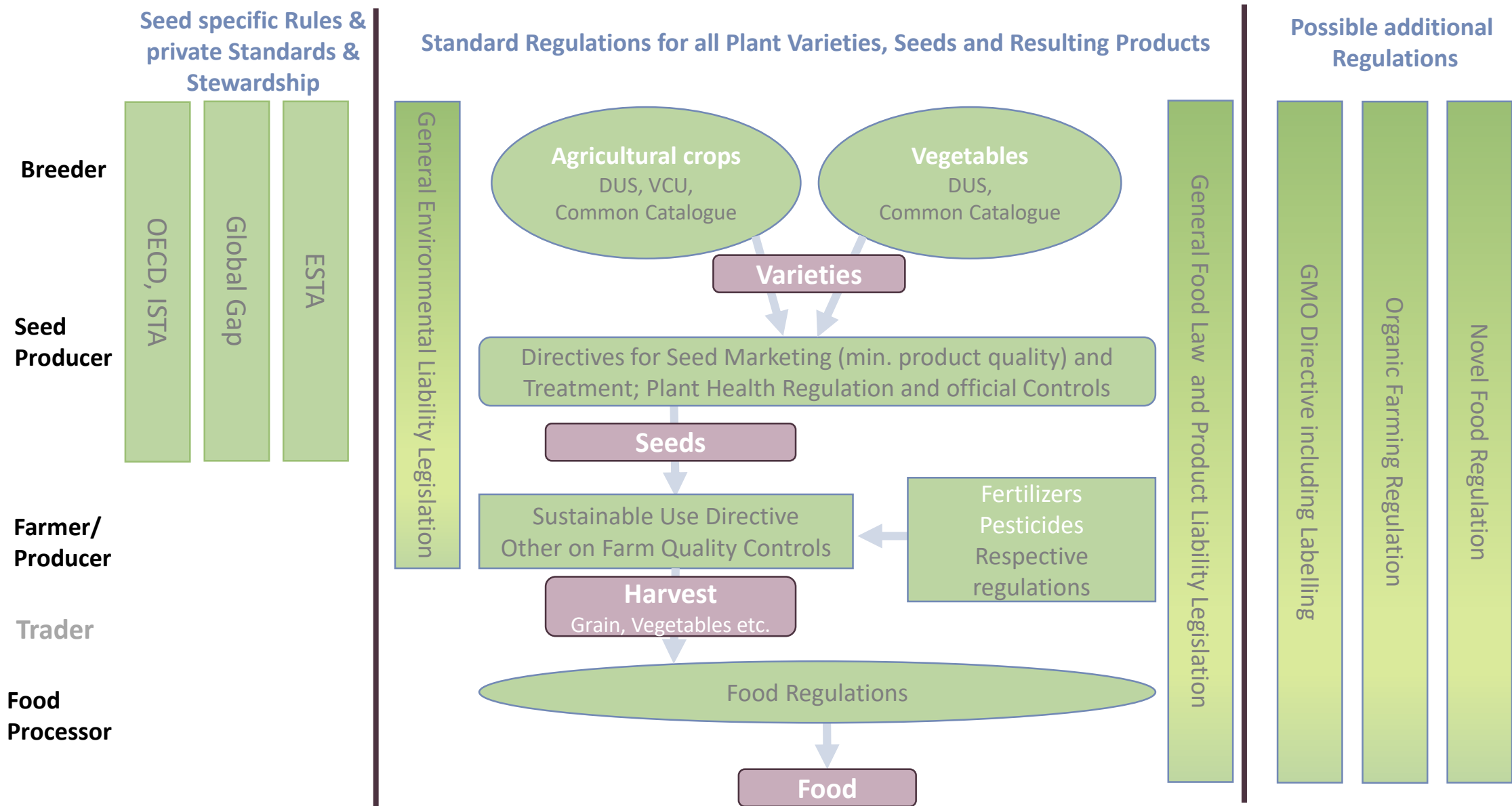
### **NOTE**

From:	Presidency
To:	Delegations
Subject:	DRAFT COUNCIL DECISION requesting the Commission to submit a study on the Union's options for addressing the legal situation of new plant breeding techniques taking into account the existing legal framework provided by Directive 2001/18/EC of the European Parliament and the Council and the Court of Justice's judgment in Case C-528/16

## Euroseeds View on the Way forward

- The ruling of the ECJ of July is not in line with intention of the legislators that wanted to set specific rules for classical GMOs (transgenes) but NOT for mutagenesis derived plants
- The interpretation of the ECJ is thus due to a lack of clarity of the provisions in Directive 2001/18
  - This clarity must now be achieved by a targeted amendment of the Directive that specifies that mutagenesis derived plants are not GMOs
  - targeted amendment of Directive 2001/18 that excludes products of old and new mutagenesis breeding from its definition;
- Alignment of the EU's policy and rules with those established and being developed in the rest of the world;
- Create legal certainty for EU operators by avoiding that Member States adopt individual national rules for products resulting from conventional, random mutagenesis.

# Responsibilities and Regulatory Framework for the primary Food Chain





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