



# Plant breeding innovation- implications of the current regulatory situation

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# Who we are?

**34**

**National member associations** from EU Members States and beyond, which in turn represent many thousand seed businesses across Europe.

**67**

**Direct company members** from family businesses to multi-nationals, including seed related industries.

Euroseeds has members also in other parts of the world: e.g. in the USA, Canada etc.



## Mission:

**Maintaining the EU's global leadership in seed exports** by keeping clear and workable rules and market access conditions;

**Providing a broad range of high-quality seed products for all types of agriculture, including organic**, as a result of innovative and diverse breeding and seed production programmes;

**Fostering future plant breeding innovation in the EU** by assuring investment in plant breeding and protecting inventions and plant breeders' rights.

# The EU Seed Sector

**EMPLOYMENT:**  
approx.

**52.000**

**ANNUAL R&D  
SPENDING:**

up to: **20%**

(of the companies'  
turnover)

**R&D  
STATIONS:**

**750**

## SEED MARKET IN THE EU:

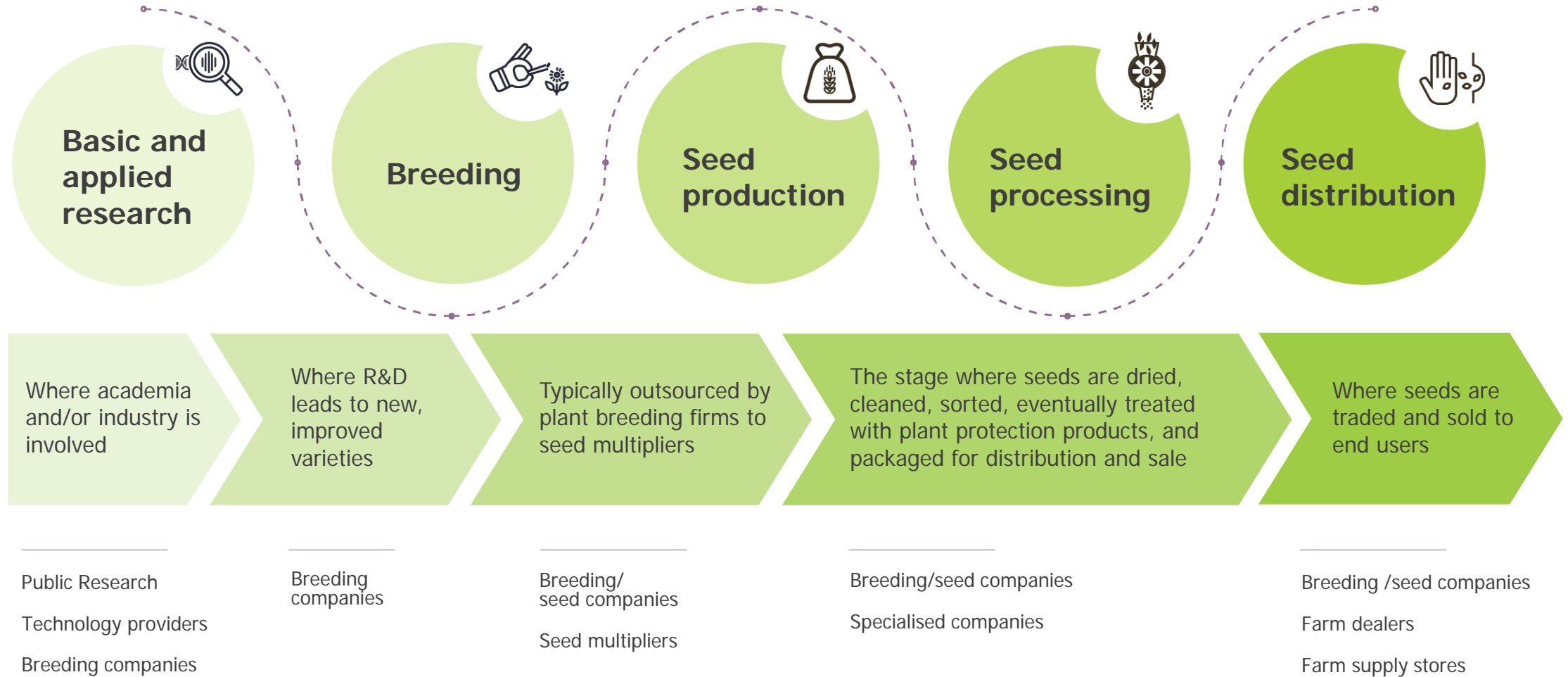
**COMMERCIAL  
SEED MARKET**  
value: **€ 10 bn\***

**FARM  
GATE** value  
of agricultural  
products:  
**> € 100 bn**

**PROCESSED  
AGRICULTURAL  
PRODUCTS**  
value:  
**> € 1.000 bn**

*\*Source: OECD (2018), Concentration in Seed Markets: Potential Effects and Policy Responses, OECD Publishing, Paris.*

# UNDERSTANDING THE SEED VALUE CHAIN



# Guardians and Creators of Biodiversity

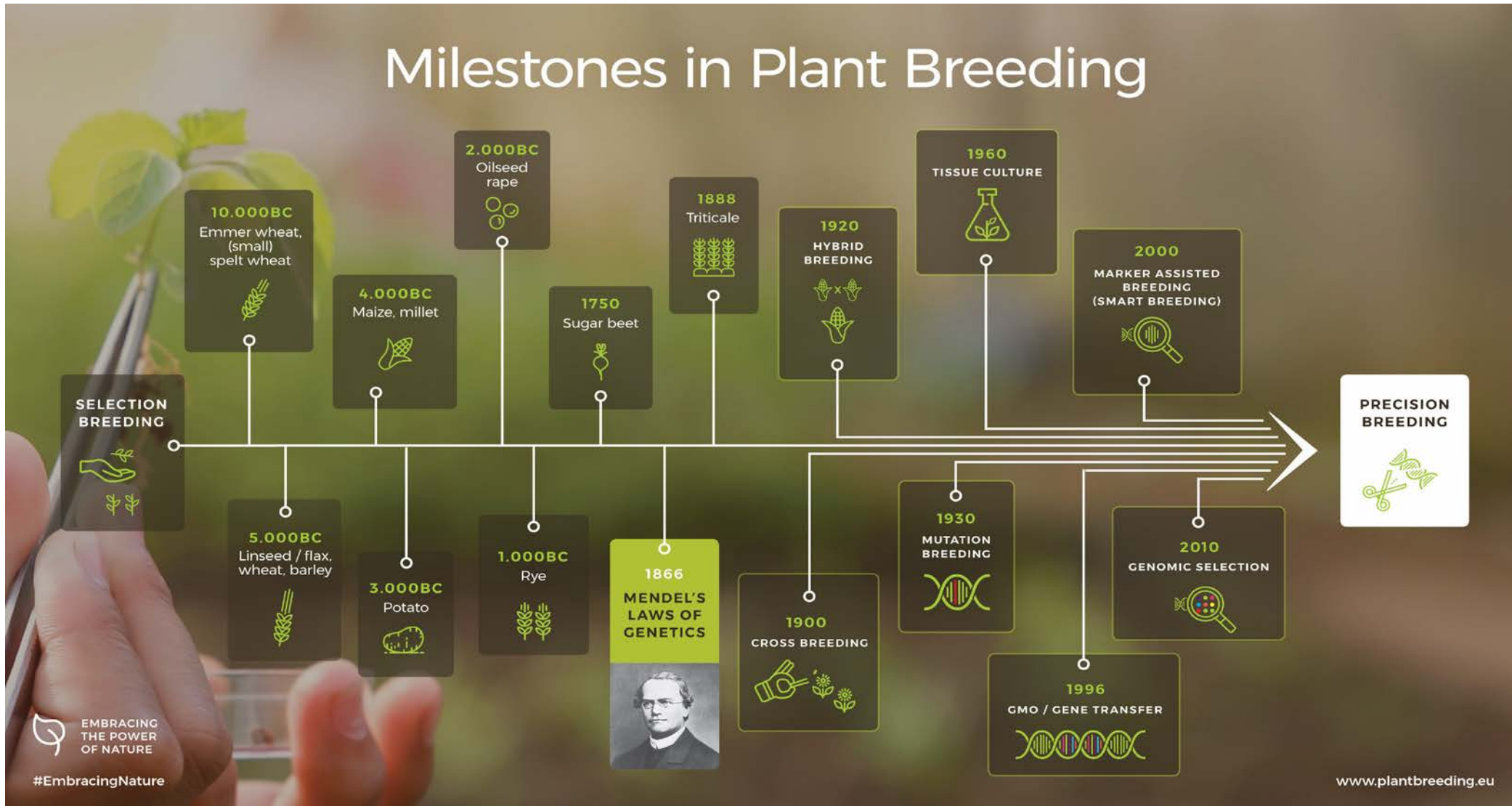
**3.500** NEW  
VARIETIES

of agricultural and vegetable  
species come to the  
EU market **EVERY YEAR\***.

**42.000** DIFFERENT  
VARIETIES

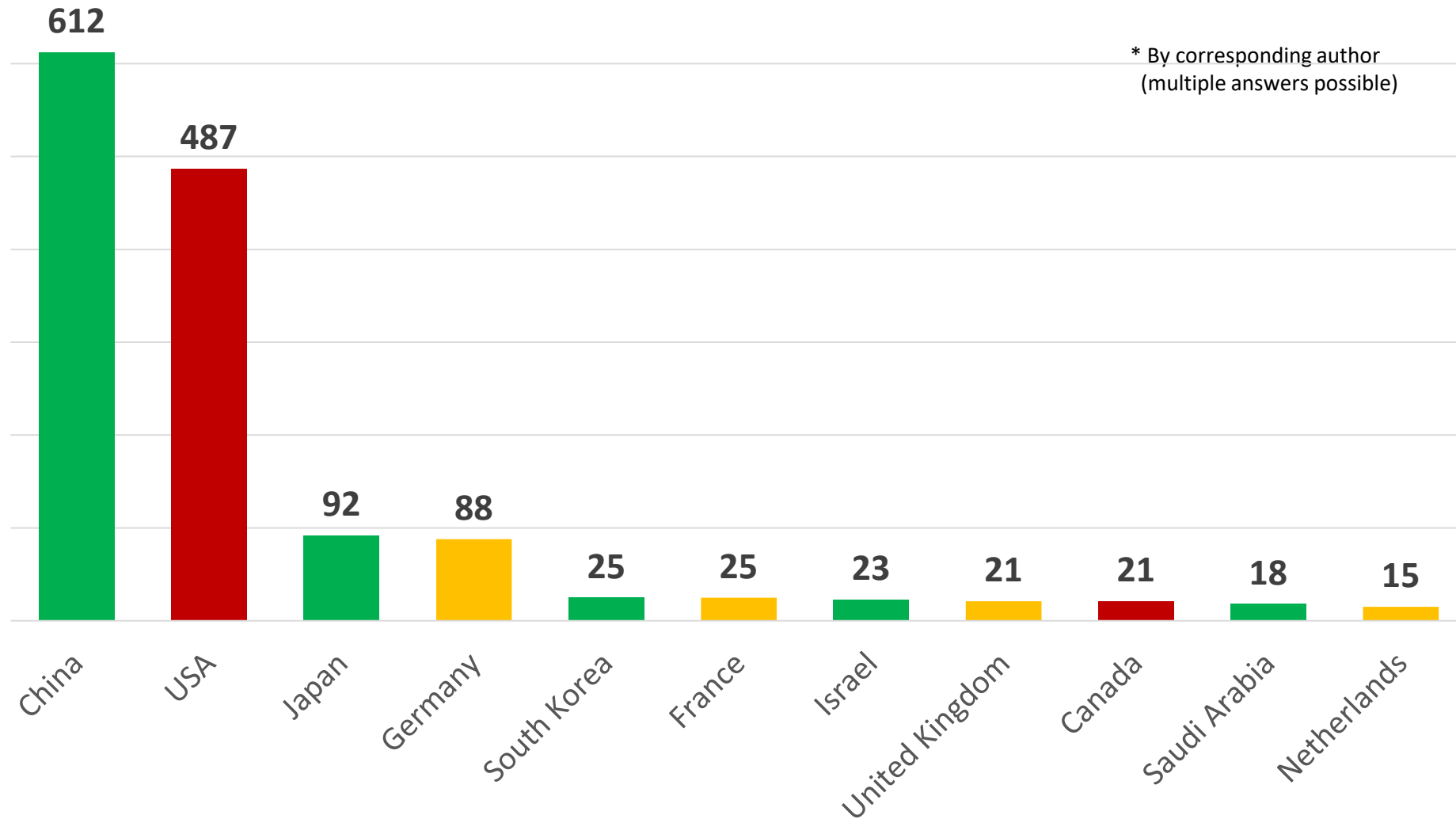
of agricultural and vegetable  
species are available to EU  
farmers **TODAY\***.

Source: *\*Source: EU common catalogues of varieties of agricultural plant and vegetable species*





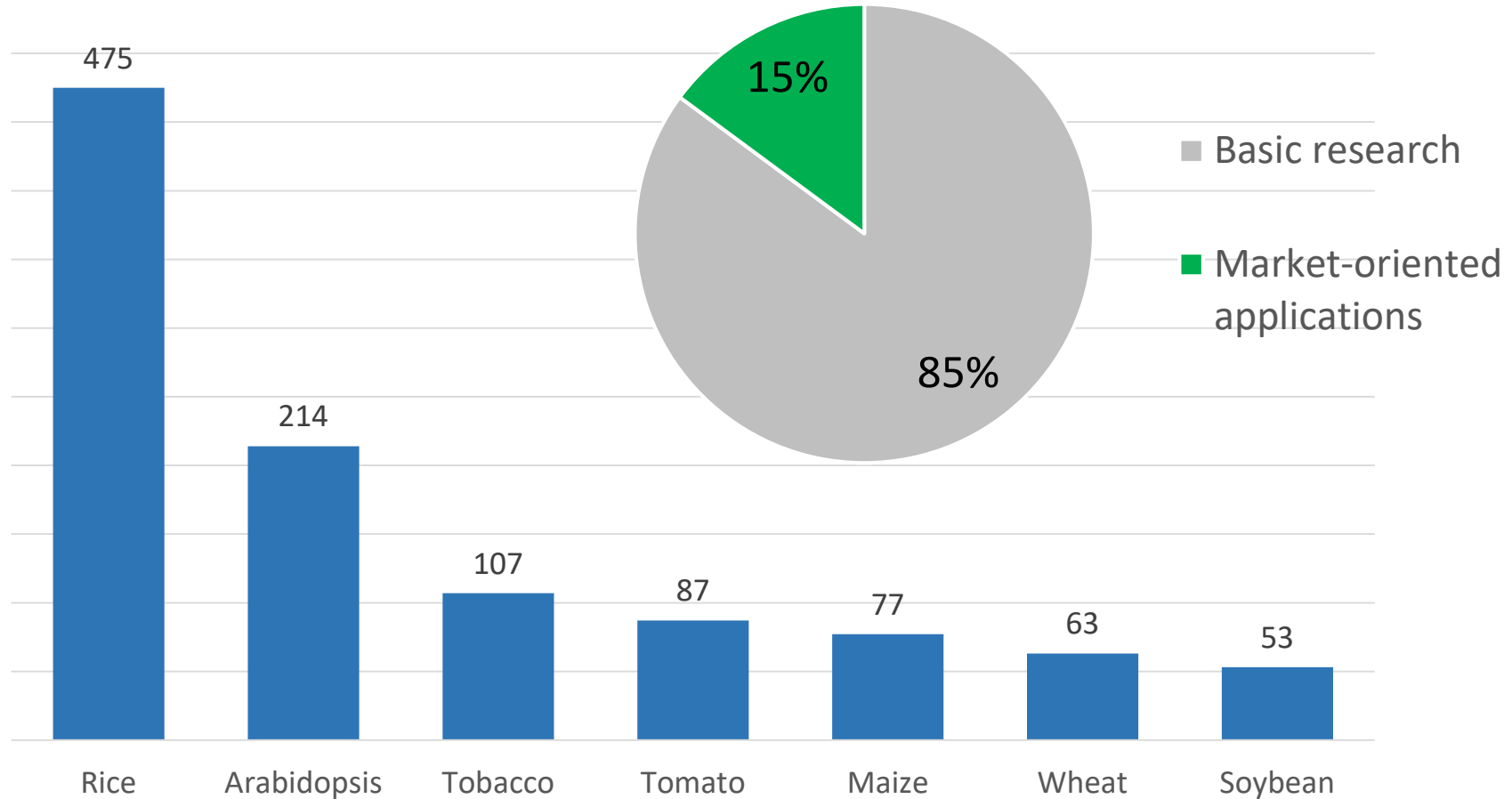
# China and the US leading in applications of Genome Editing\*



→ Studies from **33 different** countries

Source: Thorben Sprink/JKI; published in:  
Modrzejewski et al. (2018), *Environ Evid* 7 (1), S. 11. DOI: 10.1186/s13750-018-0130-6.  
Modrzejewski et al. (2019), *Environ Evid* 8:27 <https://doi.org/10.1186/s13750-019-0171-5>

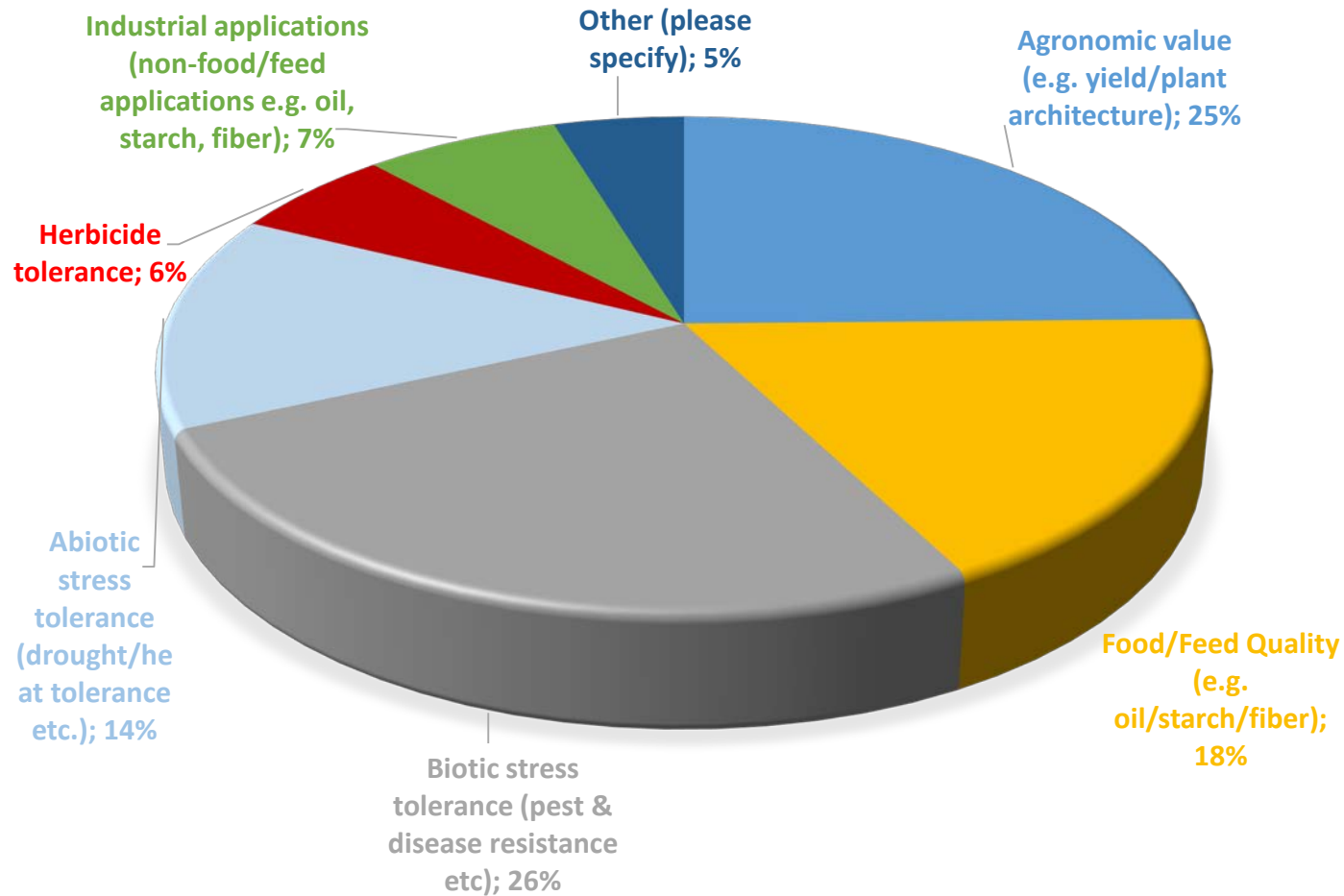
# 15 % of the studies in crops are market oriented



Applications identified in **46 different crops and model organisms**

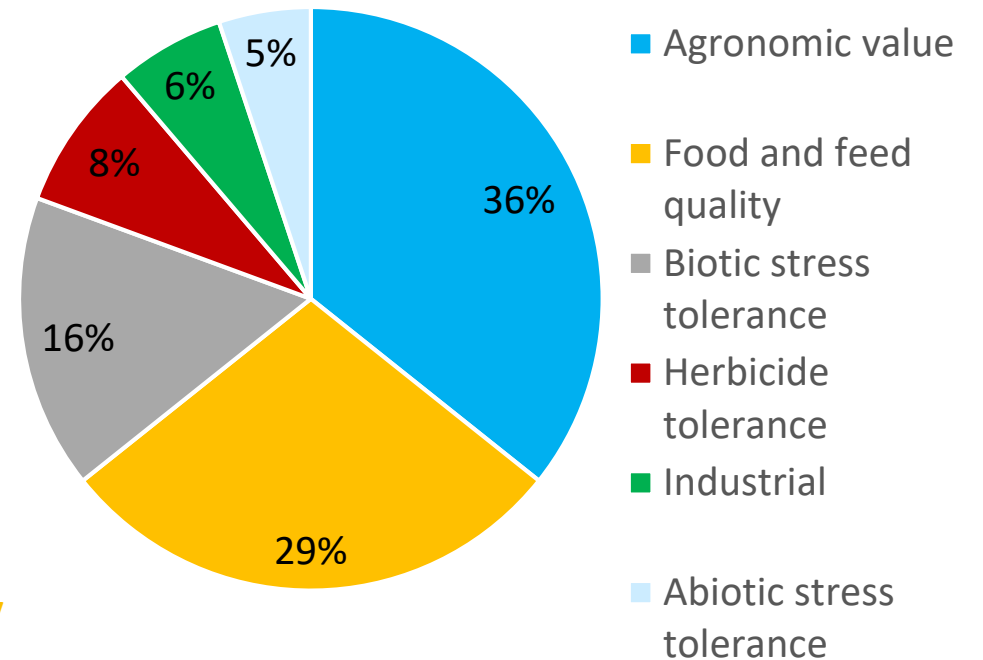


# Comparison of Euroseeds Survey with Results from the JKI study



Euroseeds Members

Other: Flavor related traits, shelf-life related traits



JKI Study 1996-2018

Source: Thorben Sprink/JKI; published in:  
 Modrzejewski et al. (2018), *Environ Evid* 7 (1), S. 11.  
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# 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

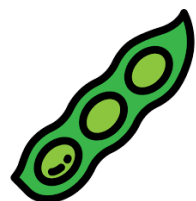


**Powdery mildew-resistant wheat**

**Gluten-free wheat**



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



**High Oleic Acid Soybean Oil\***



- No Trans Fatty Acids – healthier Food

\*first product on US-market (<http://www.calyxt.com/first-commercial-sale-of-calyxt-high-oleic-soybean-oil-on-the-u-s-market/> )

- 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)

## Euroseeds' basic principle for regulatory requirements – a differentiated approach

*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.*

In essence: Those plants that have genetic changes indistinguishable from conventional breeding or natural changes should not be subject to GMO regulation!

# What is at stake for EU-Plant Breeders? Putting new mutagenesis under GMO regulations...

- Prevent esp. SME's from developing and using these methods;
- More than 50% of Euroseeds breeding companies
  - moved focus of product development with innovative breeding methods outside of Europe,
  - stopped or reduced their activities in Europe or
  - completely moved R&D with innovative breeding methods out of Europe
- European scientific excellence (private and public), related jobs, innovation driven out of Europe
- Competitive advantage to the plant breeding industries outside Europe;
- Eroding competitiveness and leading to a less diversified plant breeding sector;
- Access to genetic diversity restricted!



## 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)





**Canada:** Product based approach; ongoing discussions to improve system

**Europe:** ECJ decision: all "new" mutagenesis are regulated "GMOs"

**Russia:** decree for R&D program clarifying that genome editing products are "conventional-like"

**US:** Proposed new USDA policy excludes certain techniques; Executive order on Modernizing Regulatory Framework for Biotechnology

**China:** unofficial "GMO-lite" proposal

**Israel:** Guidance that specific techniques outside GMO scope

**Japan:** excluding certain edited products

**India:** Draft guidelines, Tiered approach, too excessive info. needs

**Philippines:** excluding non-transgenic products

**Argentina, Chile, Brazil, Paraguay, Colombia, Honduras, Guatemala:** Case-by-case approach, excluding certain edited products (El Salvador likely to follow)

**Nigeria:** high level act final, but ongoing discussions on guidelines

**Kenya:** first draft positive

**Australia:** Revised gene tech regulation excludes some gene editing applications

**Positive Decision**  
**No formal Decision, but positive Direction**  
**Discussion started, direction unclear**  
**Restrictive Decision**

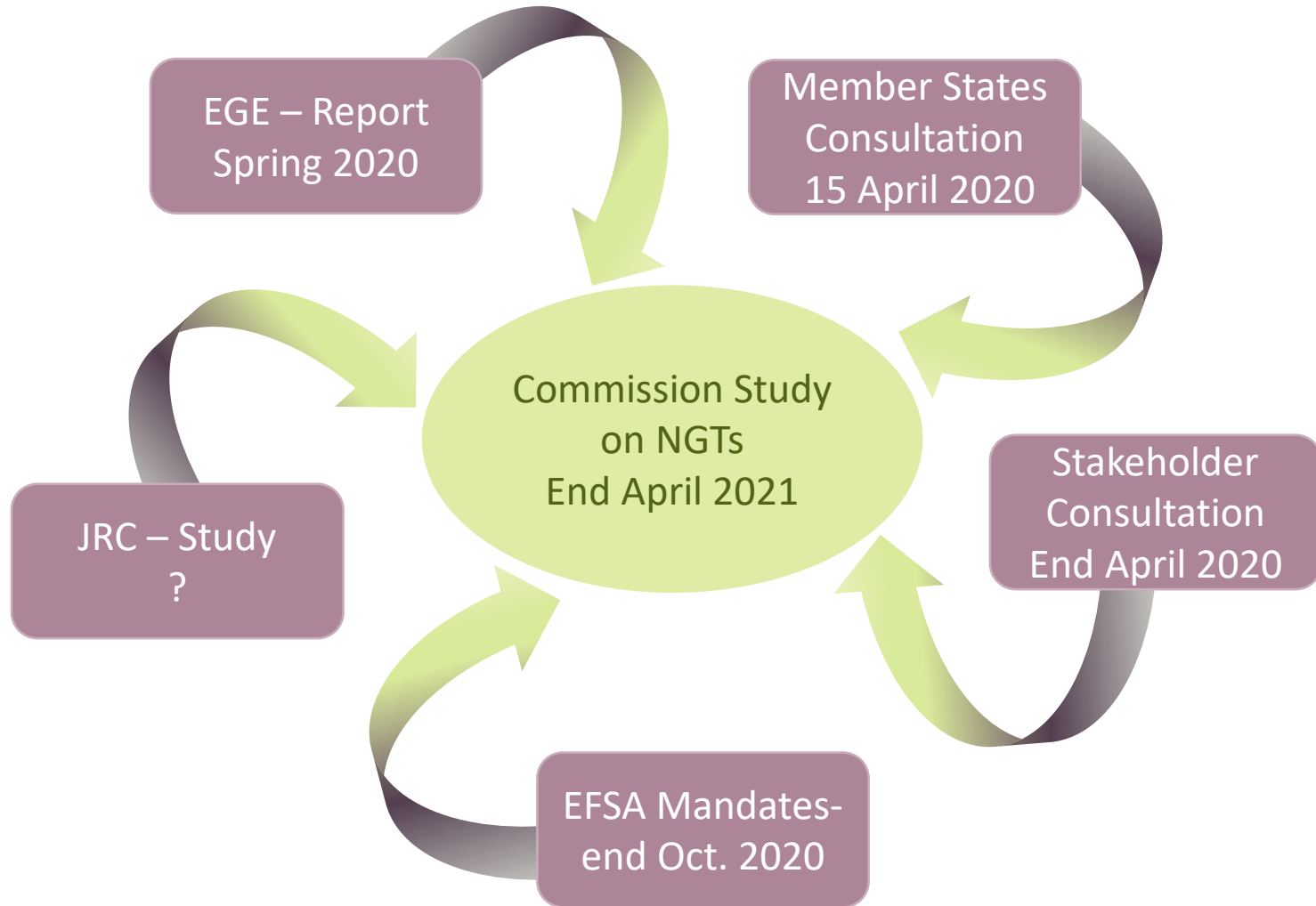
**NZ:** High Court decision that a few specific techniques are GMOs



# Growth of Seed Trade - why harmonization of regulatory oversight is key!



# Commission Study on New Genomic Techniques (NGTs)



**COUNCIL DECISION (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice’s judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study.**

# Euroseeds View on the Way forward

- A 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
- Legal certainty for EU operators by avoiding that Member States adopt individual national rules for products resulting from conventional, random mutagenesis.





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#EmbracingNature



# France: Conseil d'Etat Ruling - Summary

- **within 6 months** from notification of this decision, to amend (a) of 2° of Article D. 531-2 of the Environment Code
- HCB to set up a restrictive list of mutagenesis techniques or methods which have conventionally been used in a number of applications and have a long safety record\*
- **within 9 months:** competent authorities to identify within the common catalogue, those varieties, in particular among the HT varieties, which should have been subject in view of the technique by which they were obtained and to assess whether they are falling under the gmo-regulations (in France); and check if provision of Art 14(2) of Dir 2002/53 applies to the identified varieties (MS can ask for revocation of acceptance of varieties)
- **within 6 months:** take the necessary measures to implement the recommendations made by ANSES, in its opinion of 26 November 2019, with regard to the assessment of the risks associated with HT varieties
- to implement the procedure provided for in Article 16(2) of Directive 2002/53/EC of 13 June 2002, in order to be authorised to prescribe appropriate growing conditions for HT varieties from mutagenesis used in France

\*Reference to No 51 ECJ ruling: recital 17 of the directive, to exclude from the scope of the directive only organisms obtained by means of techniques/methods which have conventionally been used in a number of applications and have a long safety record.