



# Consequences of ECJ ruling on Plant Breeding sector

7 November 2019

9th MEACB, Berlin

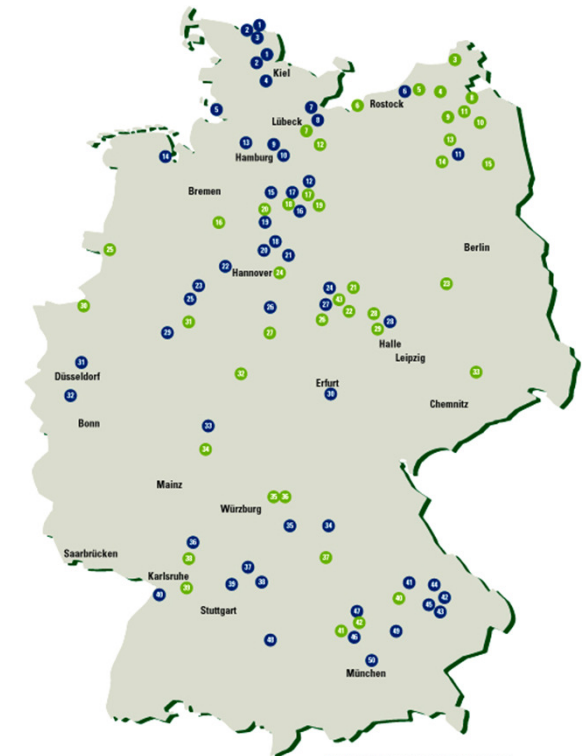
Anja Matzk

German Plant Breeders Association BDP

# Diversity in Plant Breeding

## Plant Breeding Companies in Germany

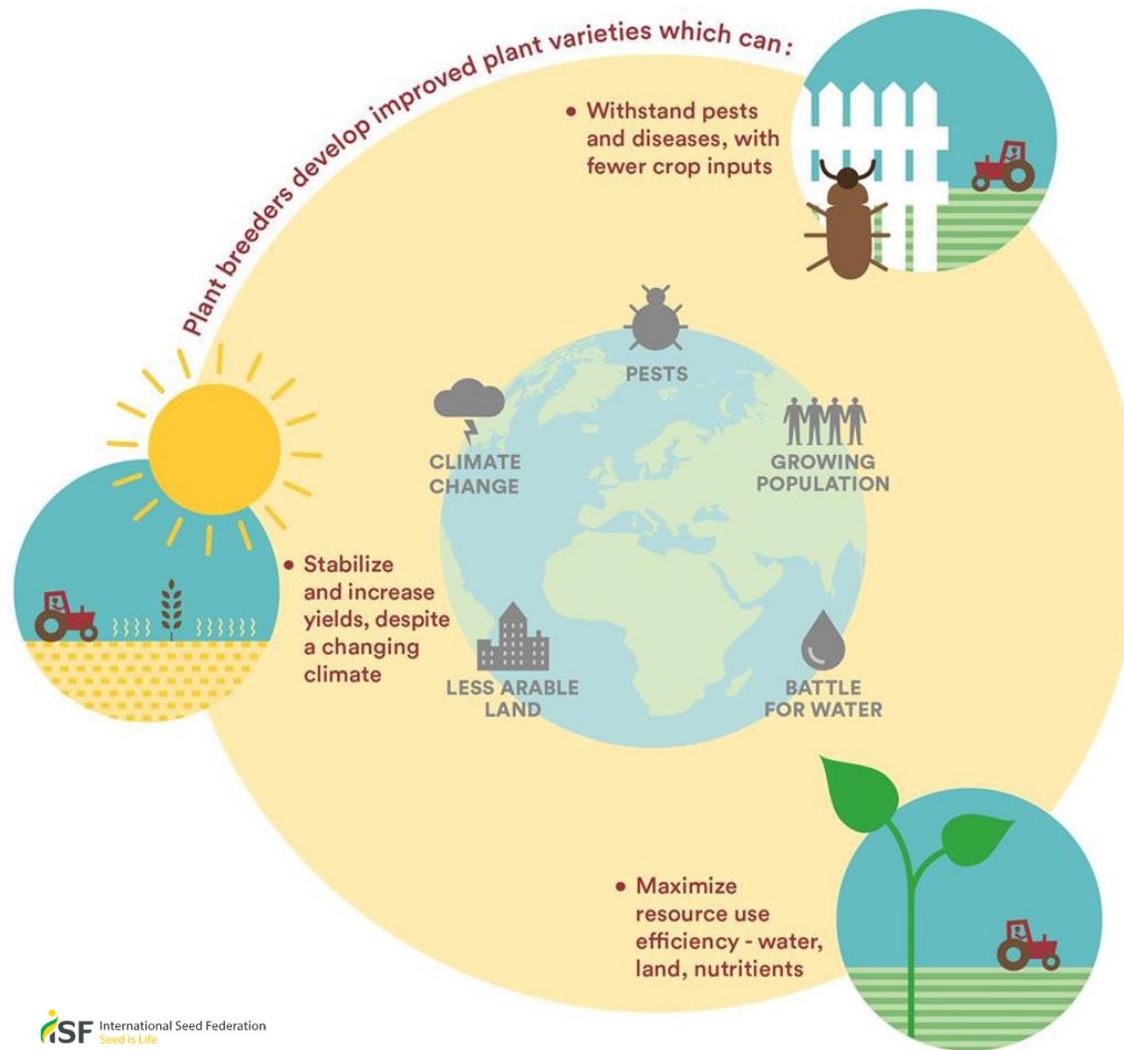
- **130** Plant breeding and seed trade companies
  - Among those 58 breeding companies with own breeding programs
- **EUR 900 million** turnover in Germany
- **5,773 employees**, among those 2,364 active in research & development
- **15.1 %** R&D share
- More than **3.000** varieties registered at Federal Plant Variety Office



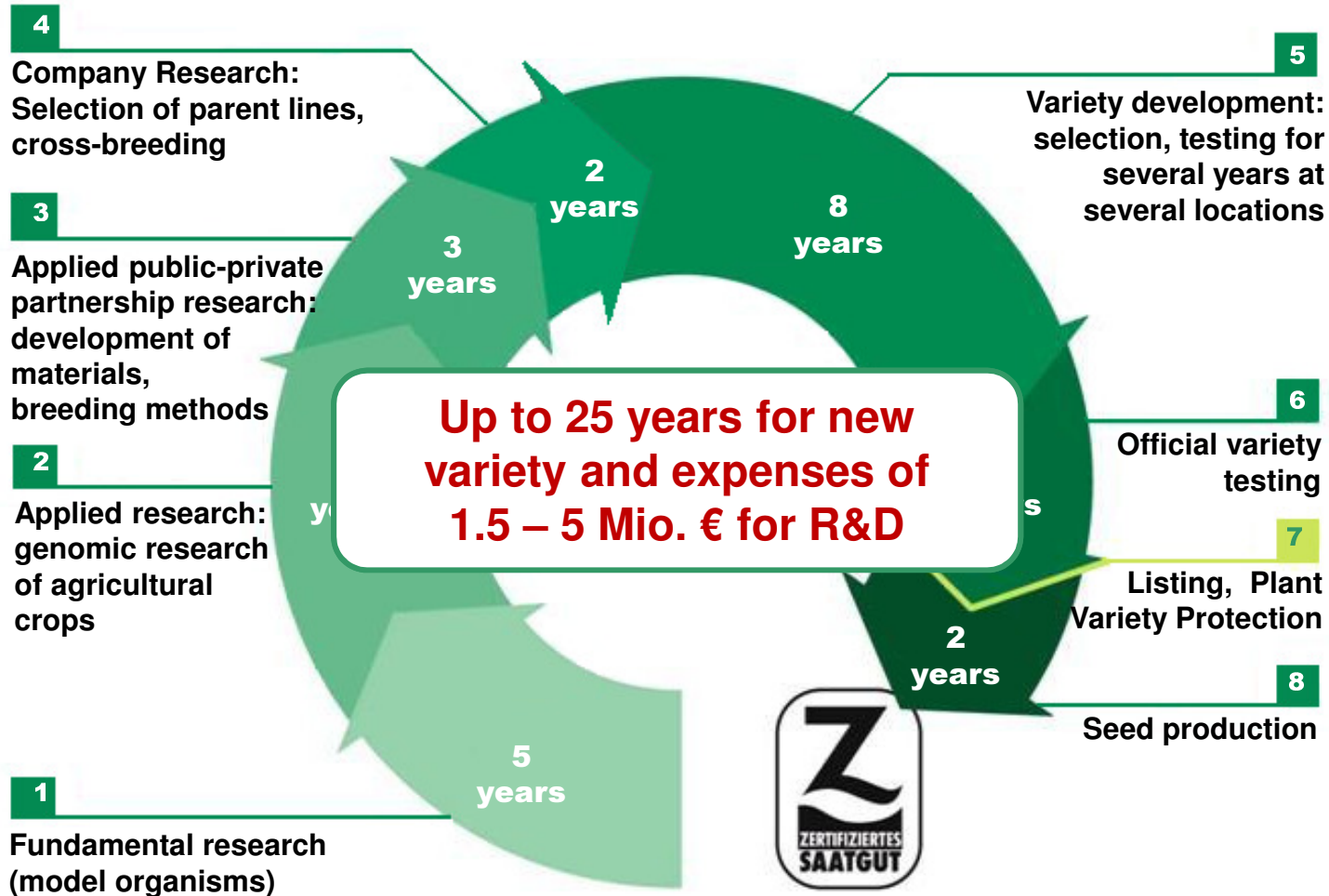
*Plants – The Basis of Life*

# Future Challenges in Plant Breeding

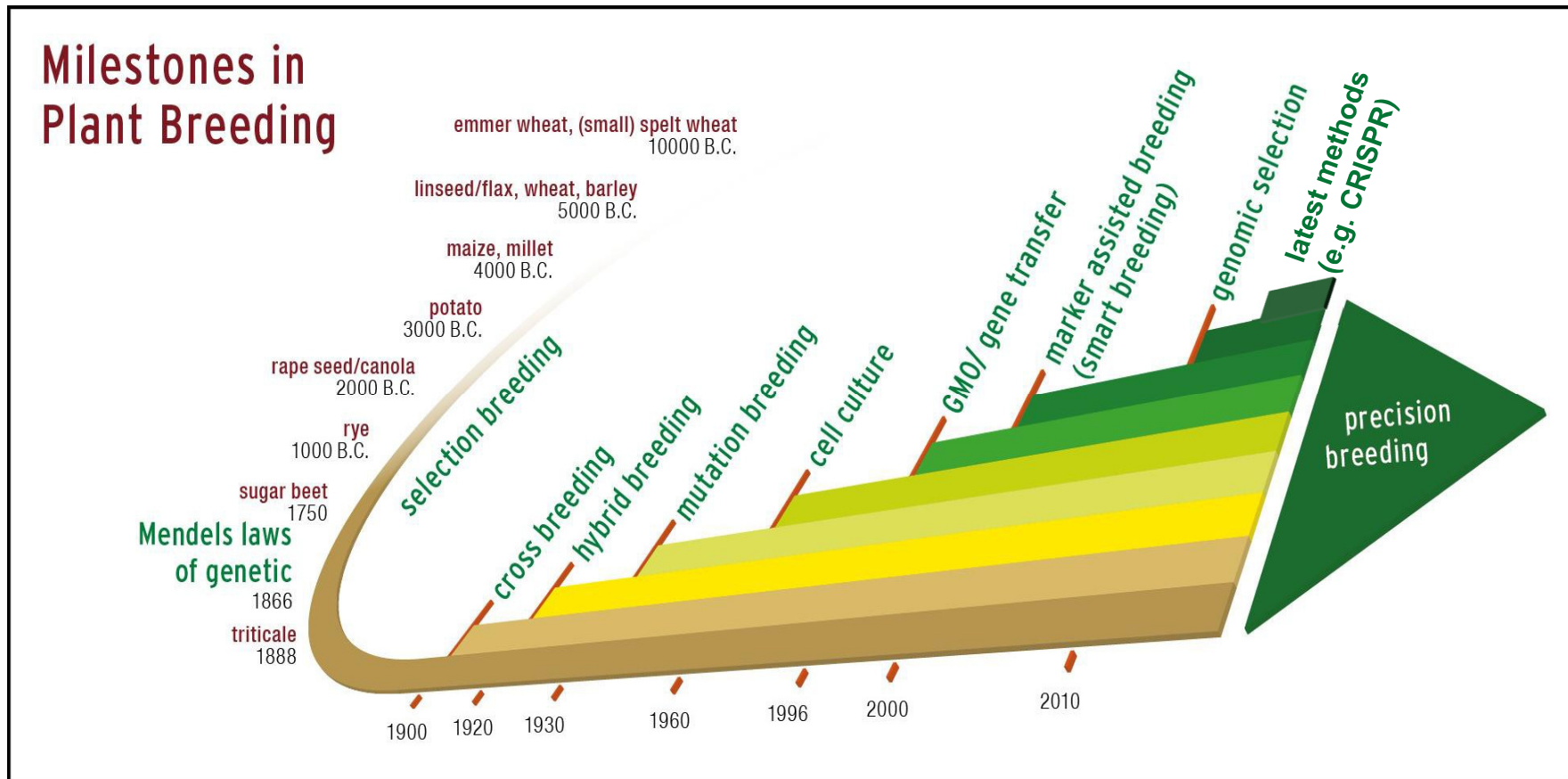
## Adapting crops to varying environmental conditions



# The Long Way to a New Plant Variety

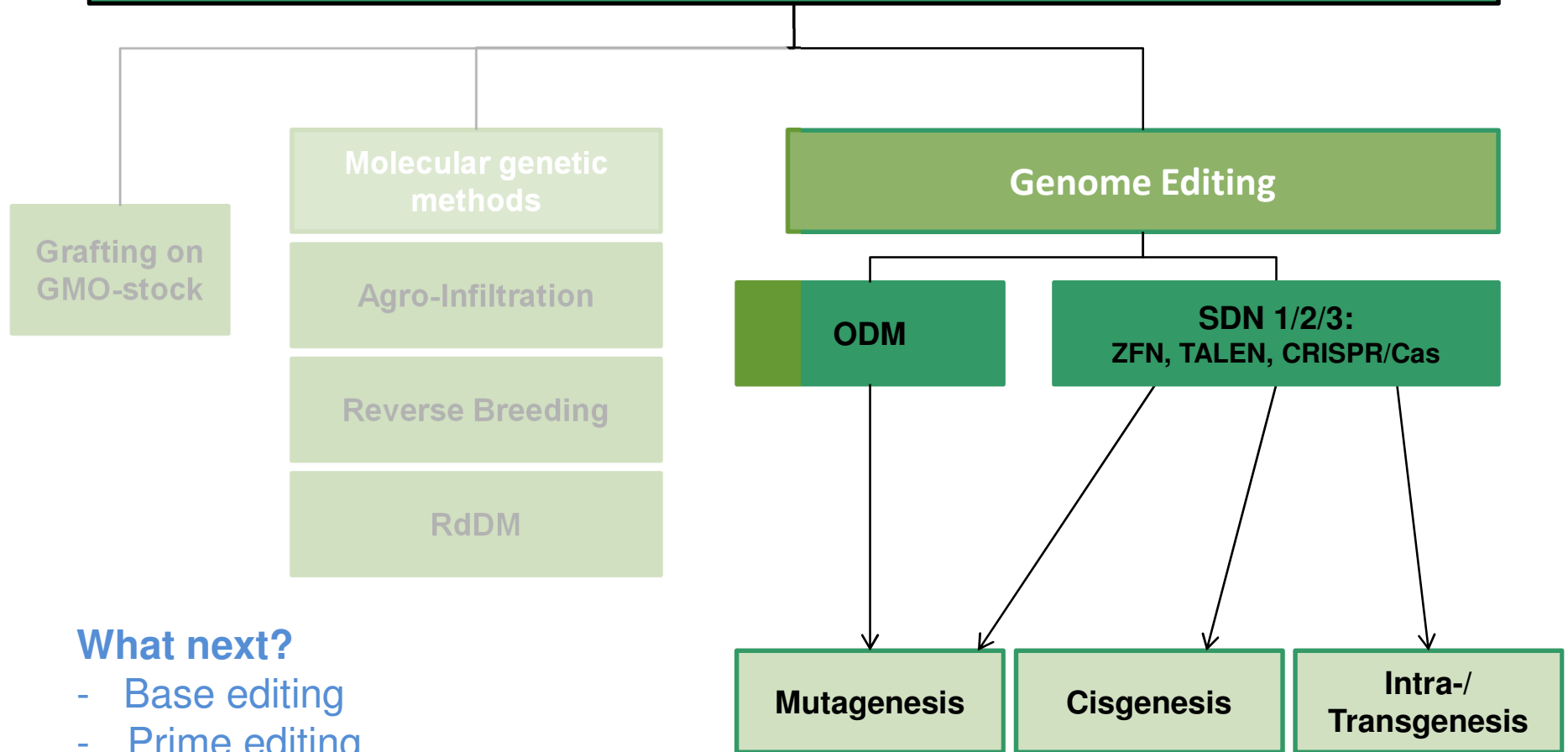


# Milestones in Plant Breeding Innovation



# Plant Breeding Innovation

## Latest Plant Breeding Methods



### What next?

- Base editing
- Prime editing
- .....



Plants - The Basis of Life

# Latest Plant Breeding Methods

- Complement the plant breeder's toolbox
- Enable
  - the generation of **genetic variation**
  - **precise** and **intended** alteration of a defined plant property
  - **improved efficiency** of the breeding process:
    - no labor and time consuming back crossing
    - reduced time necessary for R&D
- Methods can be **applied for most crops**
- Limit alterations to intended effects
- Accessible and cost-effective
  - **important for all companies!**

# Organisms resulting from mutagenesis are GMO

## Exemption for classical mutagenesis



Press and Information

**Court of Justice of the European Union**

**PRESS RELEASE No 111/18**

Luxembourg, 25 July 2018

Judgment in Case C-528/16

Confédération paysanne and Others v Premier ministre and Ministre de  
l'Agriculture, de l'Agroalimentaire et de la Forêt

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### **Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive**

*However, organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt from those obligations, on the understanding that the Member States are free to subject them, in compliance with EU law, to the obligations laid down by the directive or to other obligations*



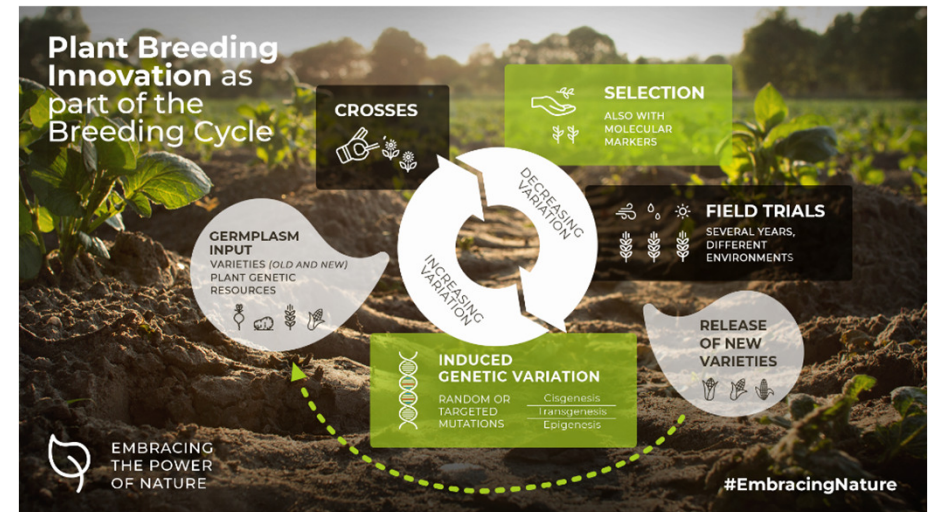
# European Court of Justice

## Consequences

- Plants with the same mutation will be subject to very different authorization requirements
- SMEs have halted any research into usage of CRISPR/ genome editing

# The CRISPR 'Scissor' is Not Enough: High Investments in R&D needed to enable the efficient and precise use of the tool

- ❑ 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

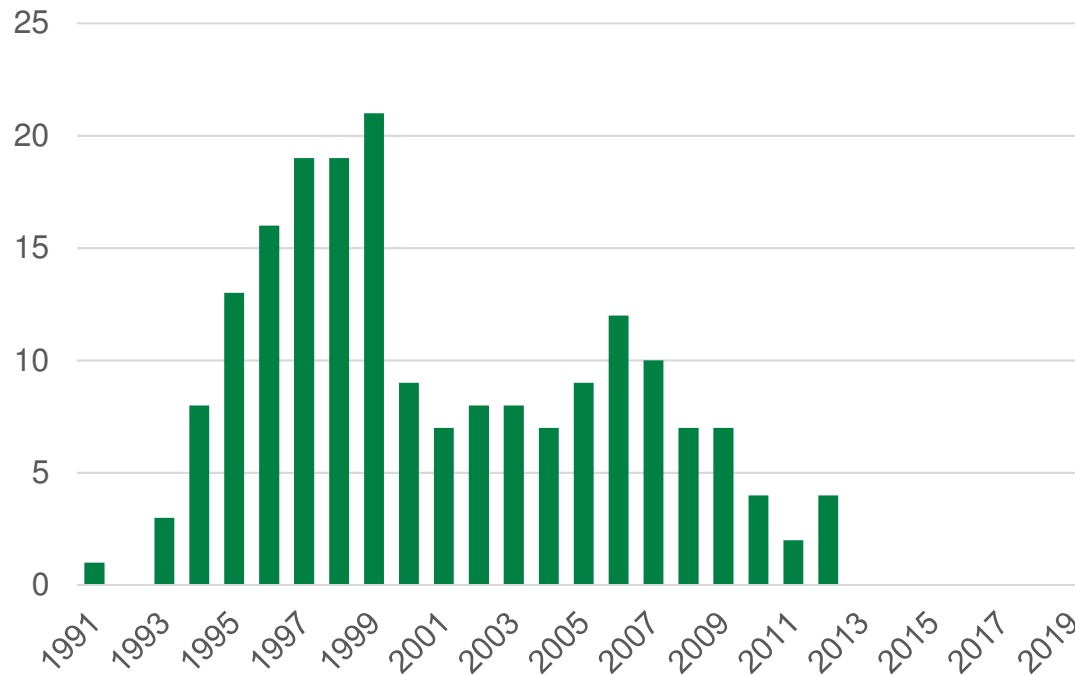


- **Extensive research is needed. As a consequence, the R&D intensity will increase even further.**
- **Integration of new breeding methods in breeding programs is necessary.**
- **Legal certainty and planning security needed.**

# European Court of Justice

## Consequences on Research

Number of Field releases in Germany



**Protected sites  
are not a solution!**

## What is at stake for German Plant Breeders?

Putting new mutagenesis under GMO regulations...

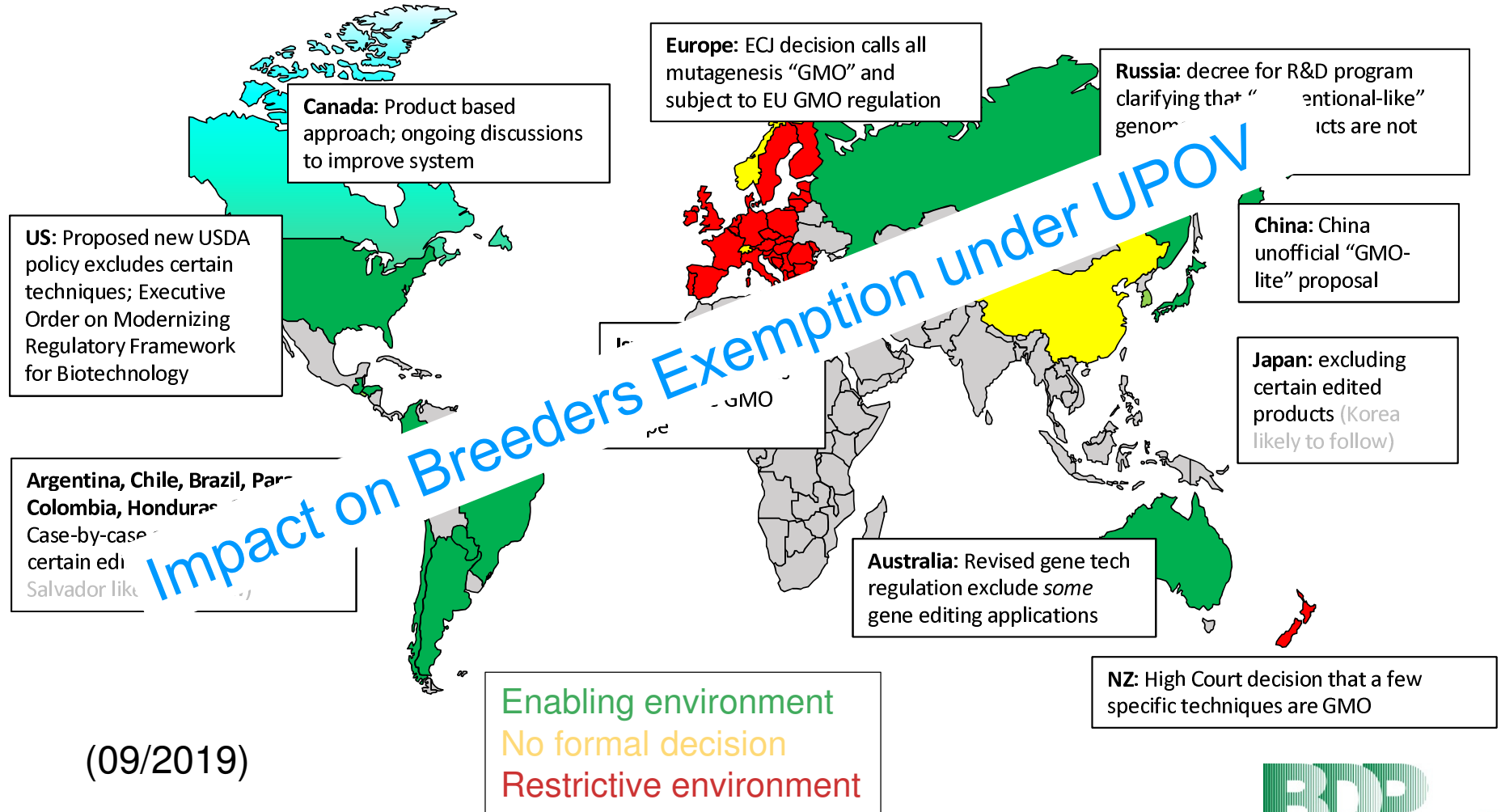
- Prevent esp. SME's from developing and using these methods;
- Eroding **competitiveness** and leading to a less diversified plant breeding sector;
- Moving focus of product development with innovative breeding methods **outside of Europe**
- **Competitive advantage** to the plant breeding companies 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)

# Regulation of Genome Editing in different Countries around the world



(09/2019)

# BDP-Position

## Criteria to assess the latest plant breeding methods

Plants that have been developed applying the latest plant breeding methods should not be subject to GMO regulation if

- 1) **the genetic variation is the result of spontaneous or induced mutagenesis,**  
**or**
- 2) the final plant product solely contains the stable insertion of **genetic material from sexually compatible plant species**  
**and**
- 3) **a novel combination** of such genetic material could **occur by natural recombination**

# European Court of Justice

## Statements from Science and Stakeholders

March 2019



“Legislative basis needs to be **adjusted** such as to take **scientific principles** into consideration and to **enable future innovations**”

<https://bit.ly/32IG1Af>

April 2019



“We therefore call upon member states and the EU Commission to initiate **a legislative change** that provides innovation-friendly rules.”

<https://bit.ly/2NELe22>



Plant varieties developed through the latest breeding methods should not be subject to different or additional regulation if they also could have been produced through **earlier breeding methods** or by **natural processes**.





**Thank you!**