European Decision Regarding Gene Editing

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AEIC 2023 Spring Meeting

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The EU Seed Sector – Facts & Figures

EMPLOYMENT:
approx.
52.000

ANNUAL R&D SPENDING:
up to: **20%**
(of the companies' turnover)

R&D STATIONS:
750

4.000 **NEW VARIETIES**
of agricultural and vegetable species come to the EU market **EVERY YEAR*.**

51.000 **DIFFERENT VARIETIES**
of agricultural and vegetable species are available to EU farmers **TODAY*.**

***https://ec.europa.eu/food/plant-variety-portal/**

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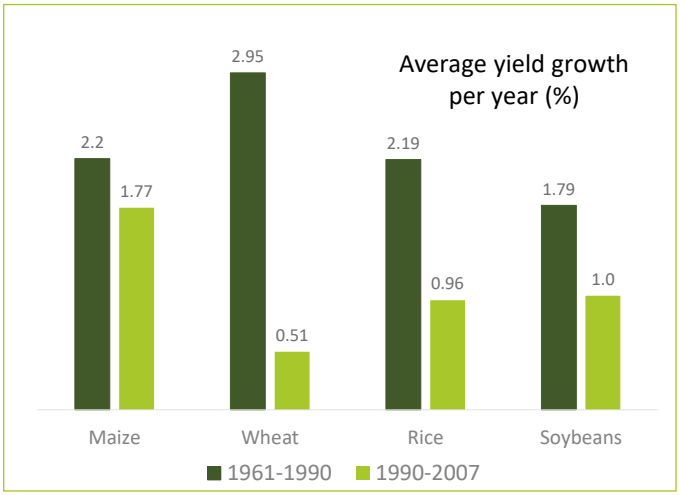
Global crop yield growth rates

Plant breeding has contributed more than 50% to agricultural productivity in the past but yield gain is slowing down

- The pace of change in the environment and pest pressures are accelerating
- An increase in yield gain is needed to keep pace



Reference: The Shifting Global Patterns of Agricultural Productivity (2009) JM Beddow, PG Pardey, JM Alston. Choices: 24(4)

Plant breeding is responsible for approximately 66 percent of annual productivity growth

The EU Policy Framework: Plant Breeding Innovation & The EU Farm to Fork & Biodiversity Strategy

- **- 50%** Pesticide use
- **- 20%** Fertilizer use
- **- 10%** productive farmland
- **> 25%** under organic production

https://ec.europa.eu/food/farm2fork_en

- On average, hectare-weighted, production losses of more than **23 percent** might be the outcome for the EU in total if the strategies are fully implemented by 2030
- Plant breeding until 2040 at current pace will only be able to partially compensate for market losses
- **Plant Breeding needs to speed up!**

Source: https://hffa-research.com/wp-content/uploads/2021/05/HFFA-Research-The-socio-economic-and-environmental-values-of-plant-breeding-in-the-EU.pdf

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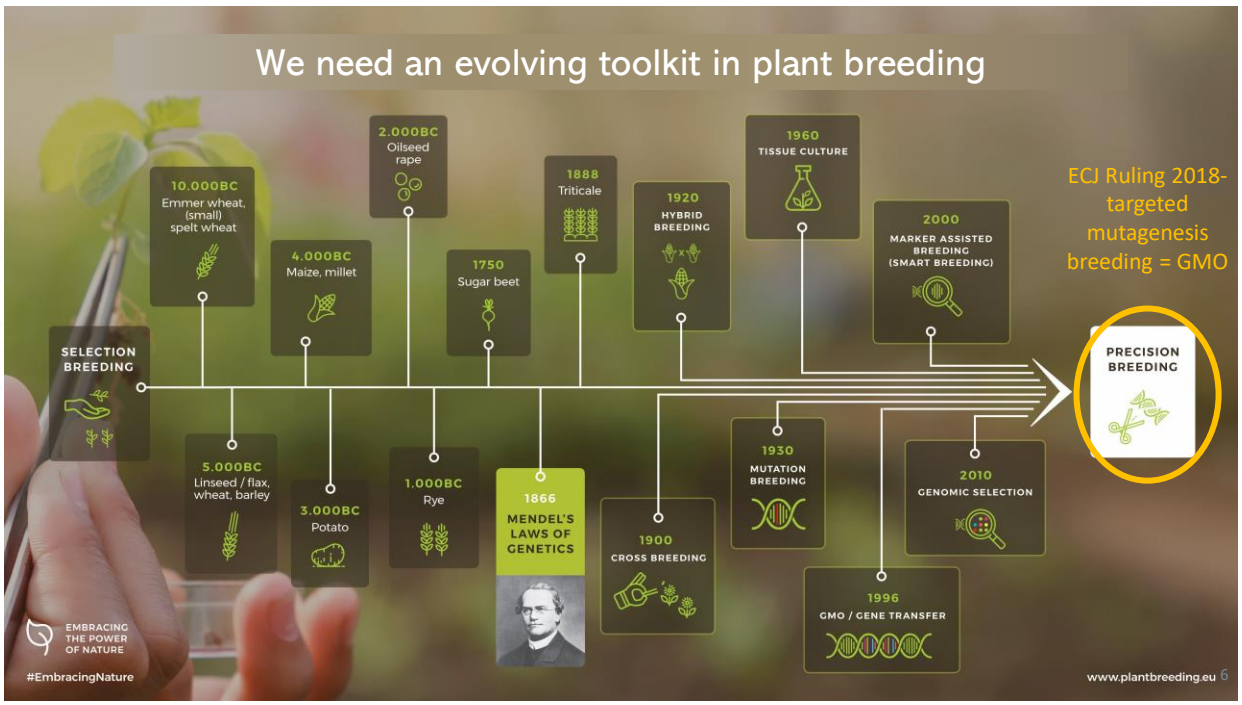

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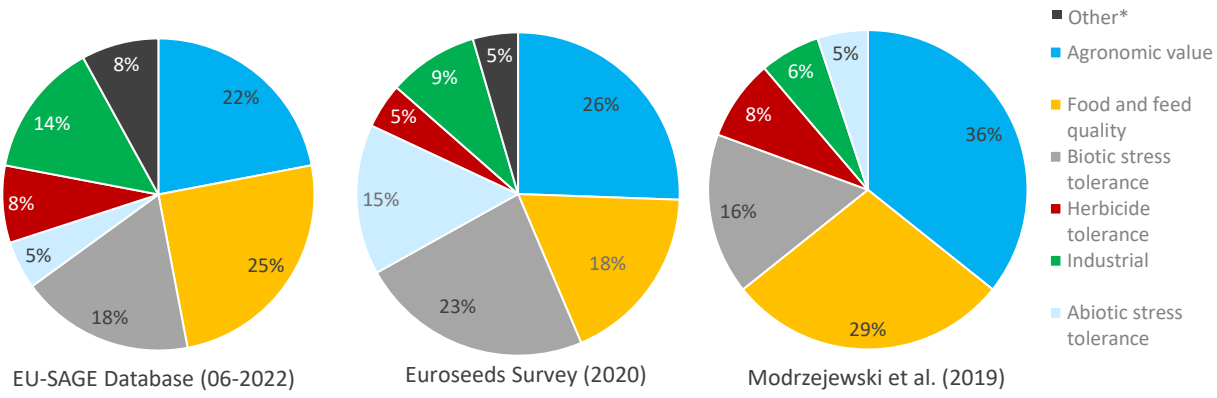
Traits that are addressed in R&D with New Genomic Techniques…



EU-SAGE Database (06-2022) | Euroseeds Survey (2020) | Modrzejewski et al. (2019)

Traits mentioned under "other" relate to flavor, shelf-life, digestibility, ornamental value (flower color), and post-harvest quality.

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Source:
https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full
https://doi.org/10.1186/s13750-019-0171-5
https://doi.org/10.1016/j.tplants.2022.05.002

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The GMO Directive and the ECJ Court Case C-528/16 in a nutshell

Dir. 2001/18

GMO Definition: "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;

Annex IB: Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, …….:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

ECJ Ruling 2018

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

- **all plants obtained by any form of mutagenesis breeding are GMOs** as defined by Article 2(2) of the GMO Directive 2001/18

2) Are all organisms obtained through mutagenesis exempted from regulatory obligations according to Annex IB of the GMO 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**

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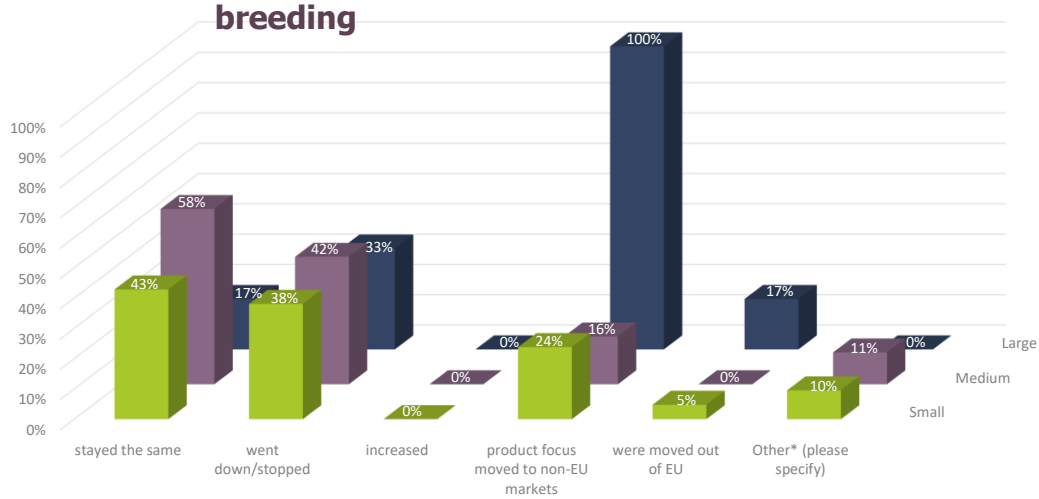
The Commission's NGT Study - Conclusions

- Several of the plant products obtained from NGTs have the **potential to contribute to the objectives of the EU's Green Deal and in particular to the 'farm to fork' and biodiversity strategies** and the United Nations' sustainable development goals (SDGs) for a more resilient and sustainable agri-food system.

- NGTs constitute a **diverse group of techniques, each of which can be used in various ways** to achieve different results and products. Therefore, **safety considerations** depend on the technique, how it is used and the characteristics of the resulting product and **cannot be made on all techniques as a whole**.

Euroseeds Members: Change of R&D activities with NBTs after the 25 July 2018 ECJ ruling on mutagenesis breeding



Effect of the ECJ ruling on NBT-related R&D activities of companies. Percentages as to the total number of companies per company size group. Multiple answers were possible, because the situation within companies might differ depending on the crop species and the projects. In addition, and under "other*" companies commented: all projects were re-evaluated, some projects were put on hold and activities were modified in specific cases. These include discontinuation, reduction of scope, change in market focus and re-evaluation of timelines; We will keep watching the future transition in the EU; some programs did not start as a consequence of the ECJ decision; After the decision of the ECJ, we decided to use the technology only for gene discovery and validation and not for product development with partners anymore.

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Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

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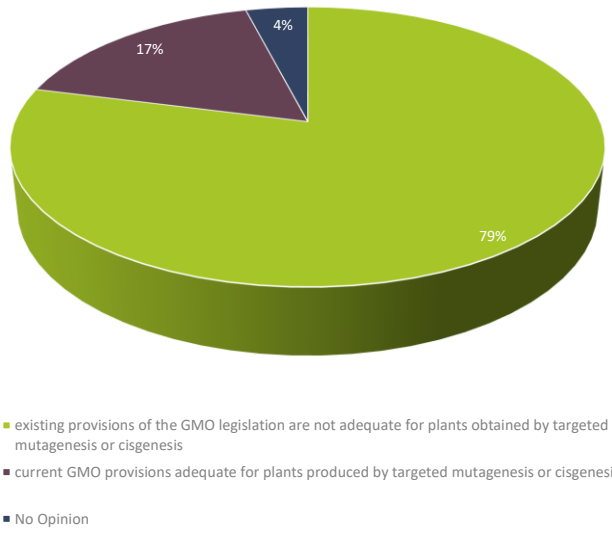
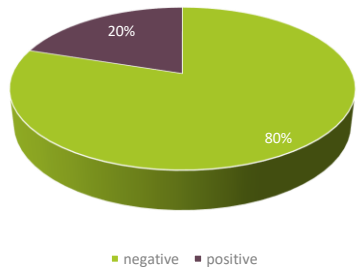
Commission announced a Policy Initiative

- Autumn 2021: Inception Impact Assessment – road map
- Spring 2022: Public Consultation
- Summer 2022: Stakeholder Consultation(s)
- November 2022: Publication EFSA Statement – risk assessment criteria

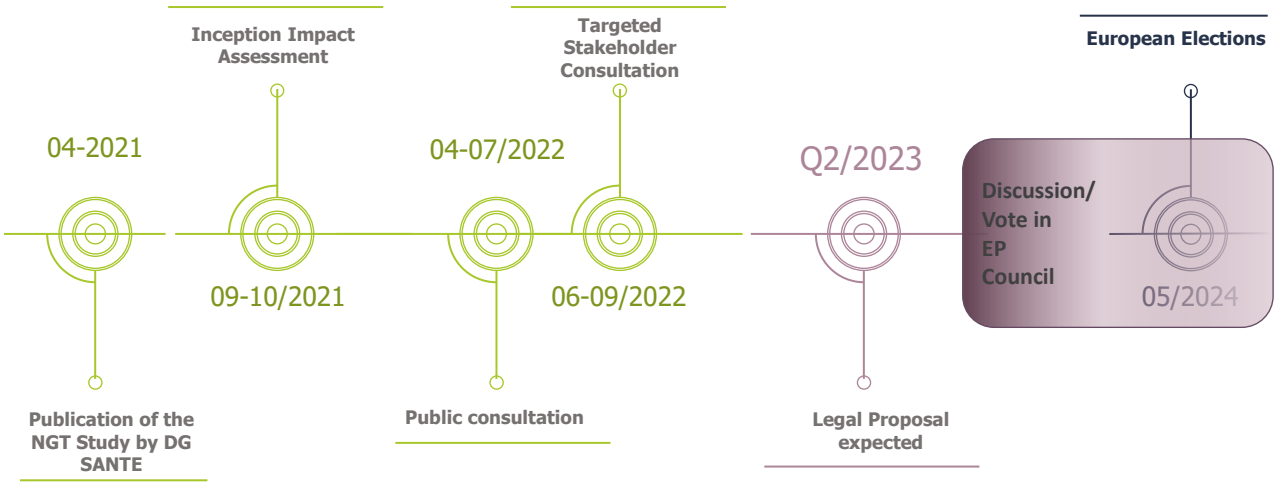
Results from the Public Consultation– Adequacy of the current legal framework



61% replied that maintaining plants produced by targeted mutagenesis and cisgenesis under the current framework is expected to have short-, medium- or long-term consequences in their activity or sector



Where are we with the policy debate on "New Genomic Techniques" in the EU?



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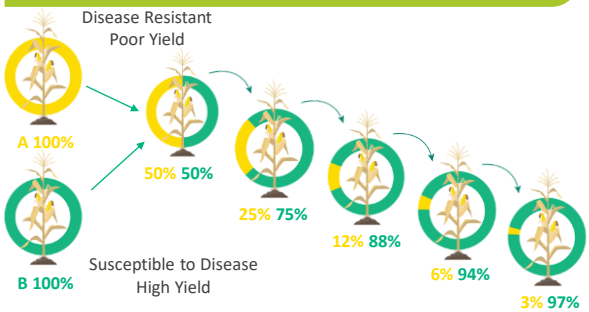
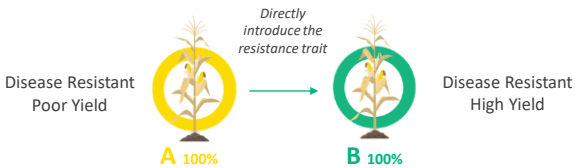
Efficiency gain might be neutralized by inefficient processes and costly regulatory approaches

Conventional Breeding : 5-7 cycles of backcrossing



Genome Editing: 1-2 cycles in elite lines



Reference: Ahmad S *et al.*, CRISPR/Cas9 for development of disease resistance in plants: recent progress, limitations and future prospects, (2020) *Briefings in Functional Genomics*, 19(1) 26–39

≥8-10 years to get to field trials

Disease Resistant
High Yield

<4 years to get to field trials

Disease Resistant
High Yield

Variety registration
2-3 years
Variety turnover in many vegetables and some agricultural crops 2-4 years

efficiency gain via NGTs of 2-6 years depending on crop/trait & NGT application

Timelines for regulatory process for NGTs in the EU:
Current GMO import approvals:
5 years average EFSA assessment
0.7 years average EC process
Cultivation approval???
+ costs!!!
+
Variety registration
2-3 years

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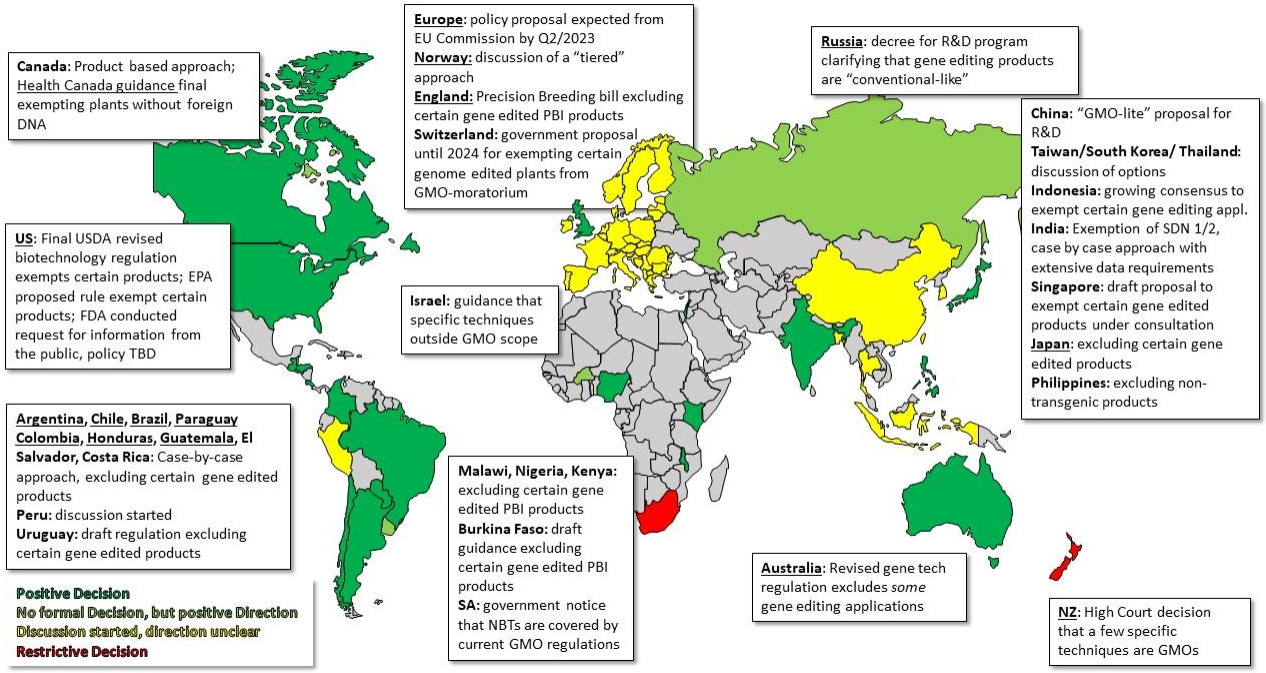
Policy developments around the world (03/2023)



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Conclusions

- Plant breeding has a proven track record of boosting sustainability options for agriculture
  - Environmental: e.g. reduction of inputs by disease resistance, climate adaptation, reduction of land use
  - Societal: e.g. improved quality, health effects
  - Economic: e.g. improved income by improved yields and quality
- NGTs provide additional opportunities to support sustainability:
  - Reduction of breeding time
  - More targeted breeding approaches reducing complexity in breeding
- NGT applications are versatile and can be used in the development of a wide range of different plant products with many different characteristics:
  - GMO – like products
  - Conventional - like products
- Europe should join the increasing number of countries that follow a differentiated and efficient regulatory approach according to these product categories.

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