



# L'iniziativa della Commissione Europea sulle piante ottenute tramite alcune nuove tecniche genomiche

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Nuove Tecniche Genomiche per migliorare la sostenibilità delle colture agrarie: potenzialità applicative e sviluppi normativi – Ciclo di webinar sulla Strategia Farm to Fork – Regione Emilia Romagna  
21 Ottobre 2022



# The European Commission



Proposes and enforces legislation; implements policies and the EU budget

## Directorate General for Health and Food Safety (SANTE)

### Objectives:

- protect human, animal and plant health,
- promote a high level of food and animal feed safety,
- contribute to the Union's efforts to ensure sustainable food systems and
- enable the health and food sectors to achieve their full economic potential.

Our mission supports the Commission's priorities for sustainability, growth, and competitiveness in two of the EU's most important economic sectors – health and food.



# What are New Genomic Techniques (NGTs)?

- Techniques, capable of altering the genetic material of an organism, that have emerged or have been developed since 2001, when Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted
- Diverse group of techniques to achieve different results, from limited changes that could also occur in nature or with conventional breeding to multiple and more extensive modifications.



## Mutagenesis

Changes without insertion of genetic material

## Cisgenesis

Insertion of genetic material from organisms that are sexually compatible

## Transgenesis

Insertion of genetic material from other organisms that are sexually incompatible

# Context of the Commission initiative



## Farm to Fork Strategy



April 2021 - Commission study  
on new genomic techniques

# Commission study on new genomic techniques\*

- ✓ Strong interest in the EU and globally in NGT products
- ✓ Current regulatory oversight and risk assessment requirements are not tailored to diverse risk profiles and have implementation and enforcement challenges.
- ✓ NGTs can contribute to Green Deal and Farm to Fork objectives, as well as to a more competitive economy.
- ✓ Reported concerns on possible negative impacts on the environment, consumers' right to information and coexistence with the organic and GM-free sector.

\* [https://ec.europa.eu/food/system/files/2021-04/gmo\\_mod-bio\\_ngt\\_eu-study.pdf](https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf)

# Scope and objectives of the Commission's initiative



## Scope

Plants, and their food and feed products, produced by targeted mutagenesis and cisgenesis

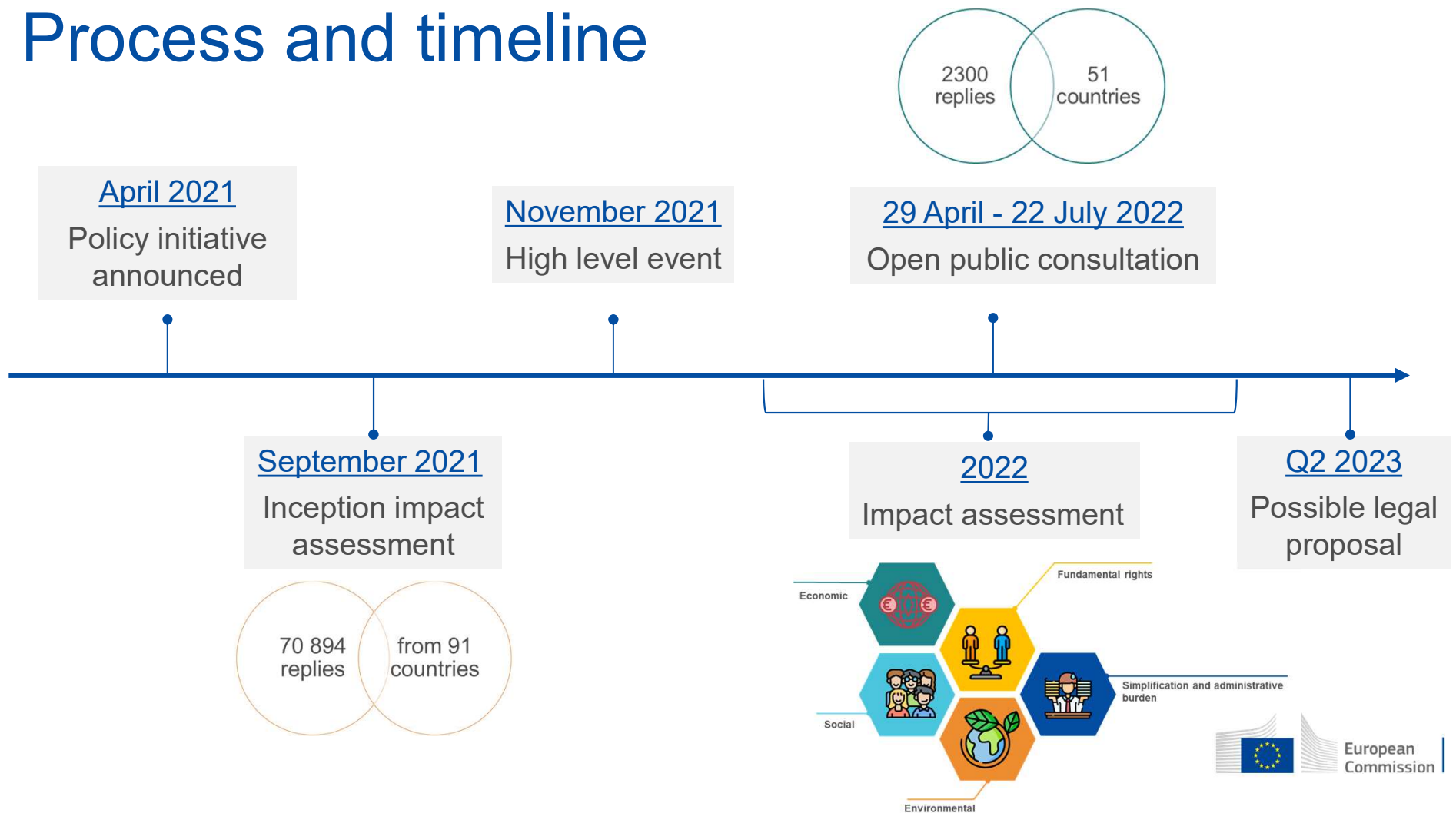


## Objectives

Ensure high level of protection of human and animal health and the environment

Reap benefits from innovation, in particular to contribute to the goals of the Green Deal and Farm to Fork Strategy

# Process and timeline

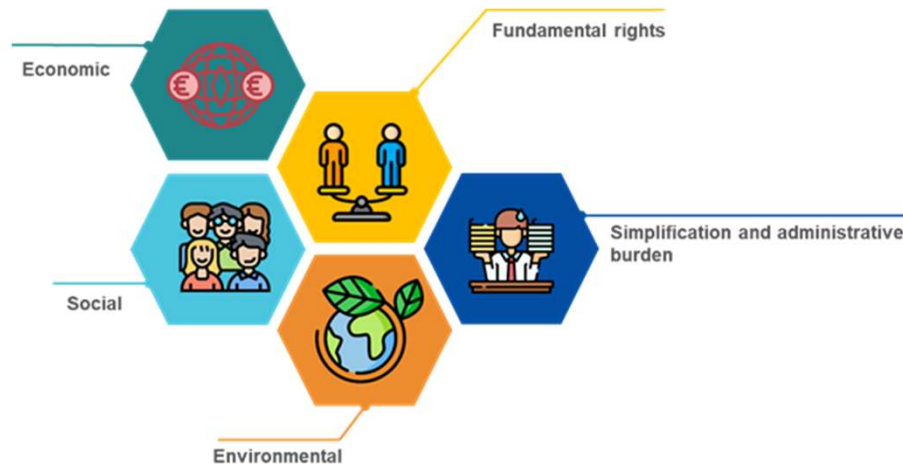


# Policy approaches examined

Risk assessment and approval	Sustainability	Traceability	Information
<ul style="list-style-type: none"><li>• As today</li><li>• Risk assessment tailored to risk; authorisation procedure</li><li>• No risk assessment if NGT product can also be obtained naturally or by conventional breeding; notification procedure</li></ul>	<ul style="list-style-type: none"><li>• As today</li><li>• Regulatory incentives for traits with potential to positively contribute to sustainability</li><li>• Regulatory requirements for traits with potential to negatively impact sustainability</li></ul>	<ul style="list-style-type: none"><li>• As today</li><li>• Not needed if NGT product can also be obtained naturally or by conventional breeding</li><li>• Additional traceability if sustainability claims</li></ul>	<ul style="list-style-type: none"><li>• As today</li><li>• No physical labelling; but transparency ensured through other means</li><li>• Introduction of labelling to reflect trait / sustainability contribution</li></ul>

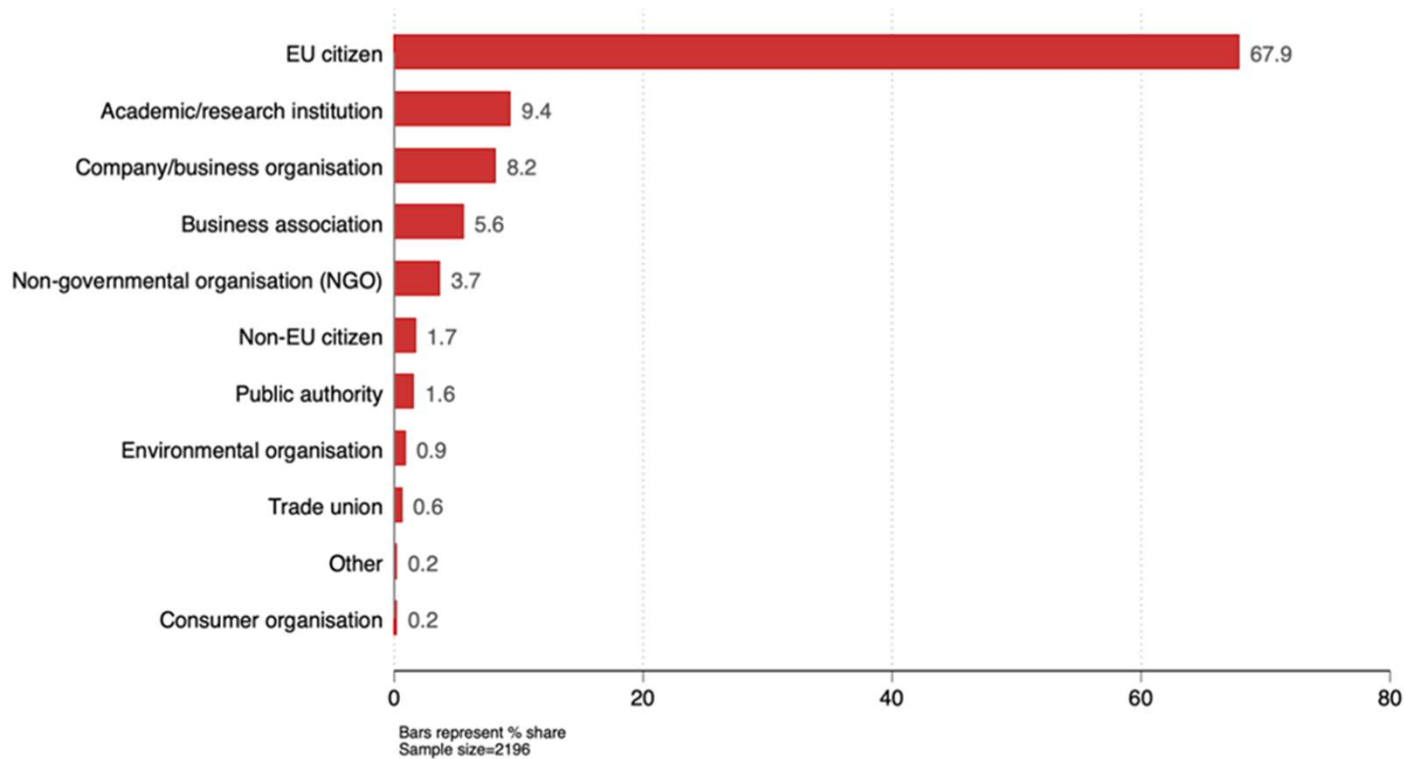


# Impact assessment



- Open public consultation
- Targeted stakeholder consultation (survey, interviews, focus groups)
- EFSA and JRC technical contributions

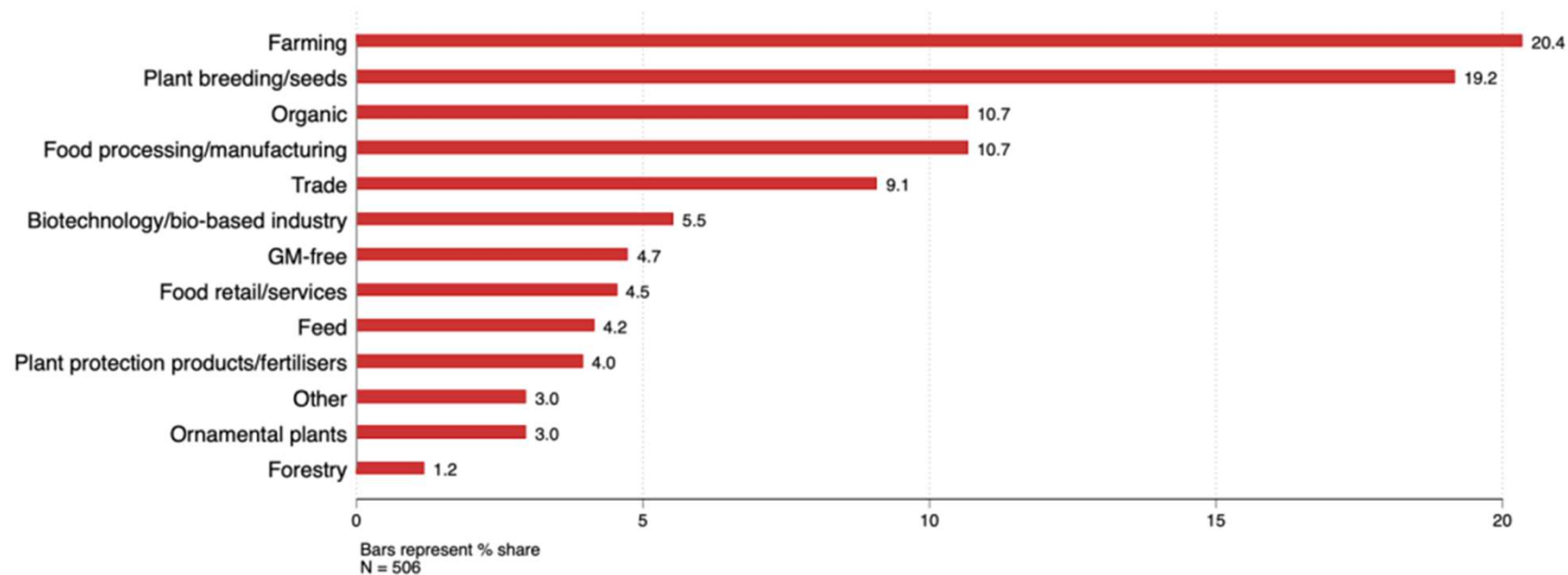
# Public consultation - overview



- From 23 Member States, majority from DE, IT, FR, ES
- 5% of respondents from third countries, mainly CH, US, UK

# Public consultation - overview

**Figure 3 - Contributions by economic sector for company business organisations, business associations and trade unions**



# Thank you

Follow the initiative at:

<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques>

[https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology\\_en](https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en)



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Slides 3 : picture, source: Gettyimages. Slide 6: icons, source: Flaticon.

