



Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in case C-528/16

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Seminar with Third Countries on Farm to Fork – Study on new genomic techniques

30 June 2021

The context



**EU Court of Justice's judgment
in Case C-528/16**

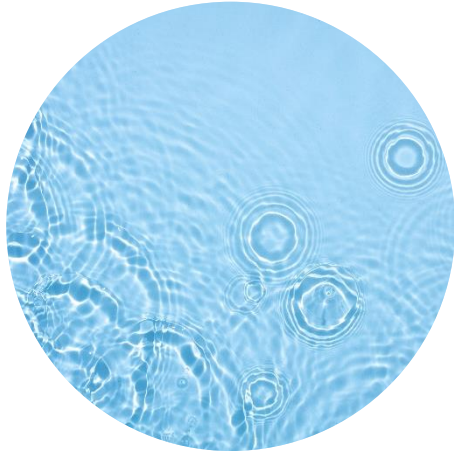


**Council Decision
(EU) 2019/1904**

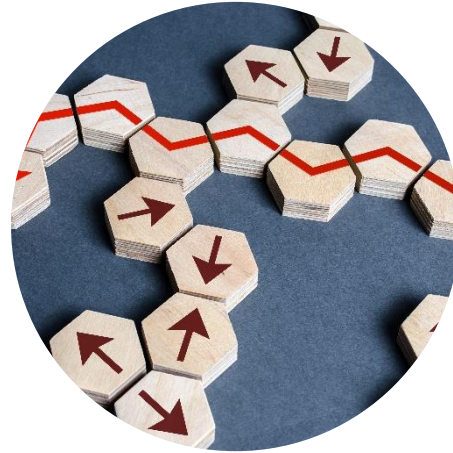


**The Commission's
study on NGTs**

Objective and scope



**Provide clarity on
NGTs**



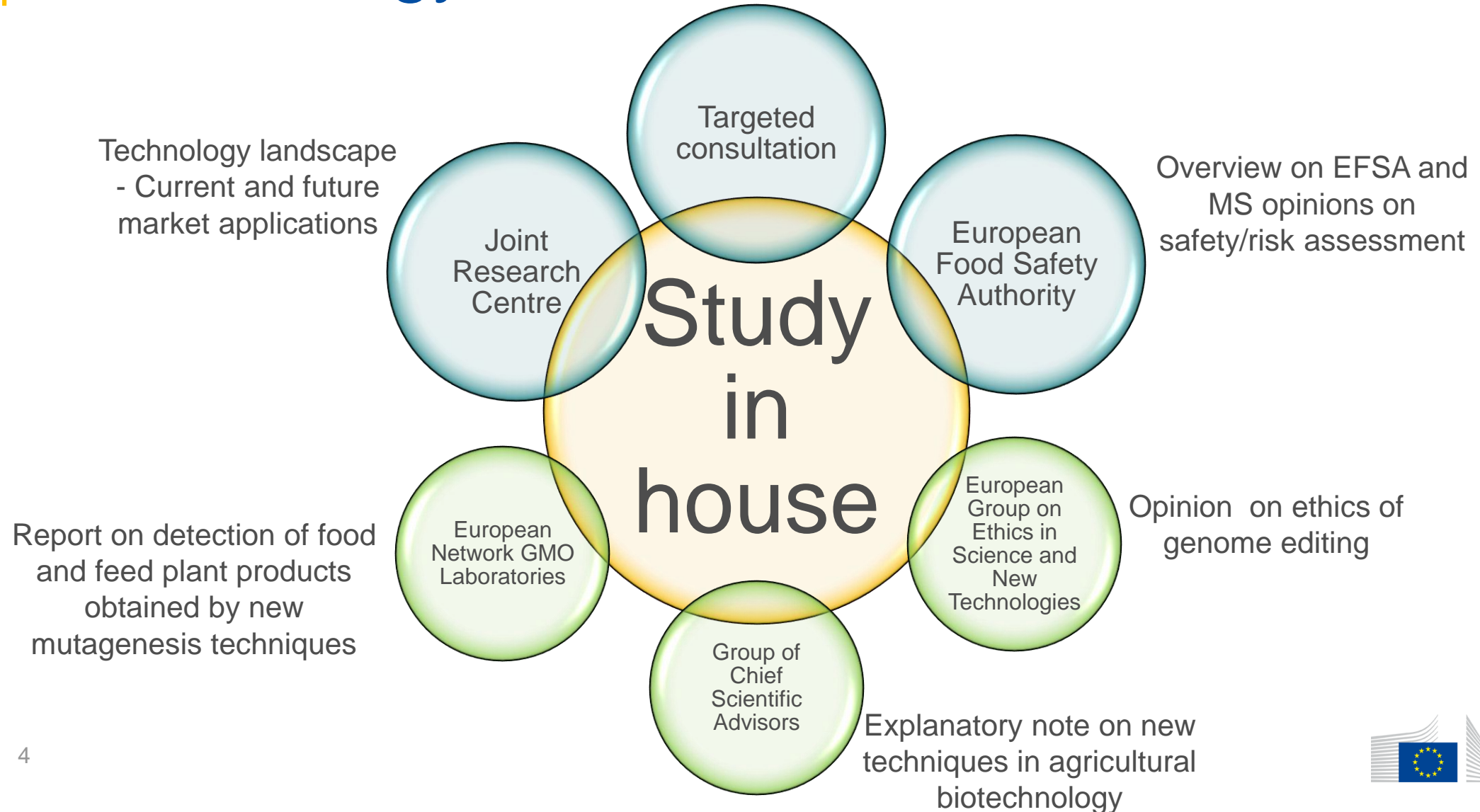
**Assist in deciding, any
further action in this policy
area, if appropriate**



**European Green Deal
Farm to Fork strategy
Pharmaceutical strategy**

Use of NGTs in plants, animals and micro-organisms in the agri-food, medicinal and industrial sectors

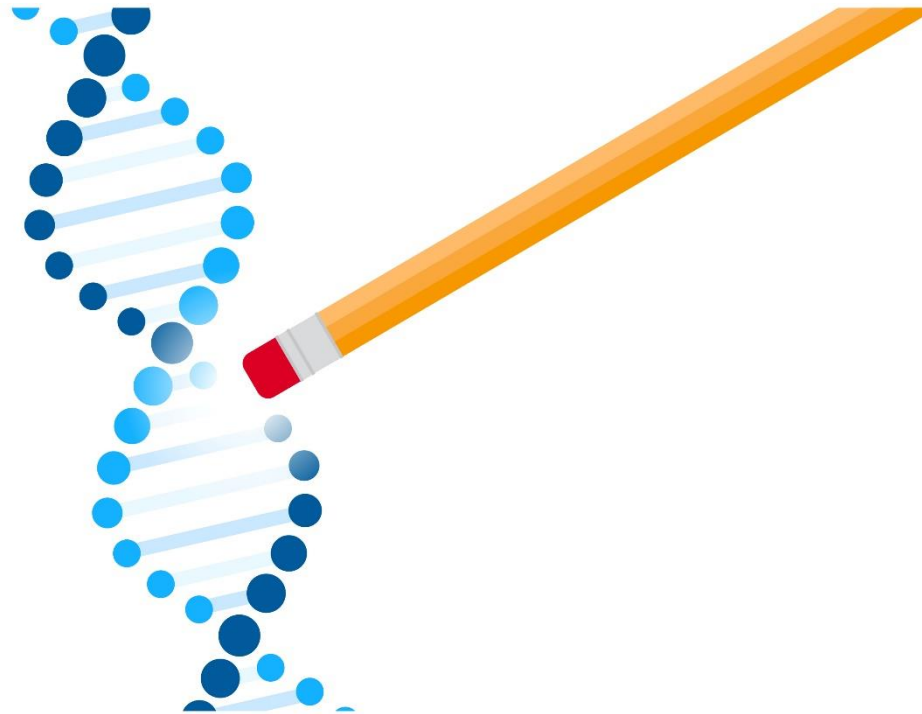
Methodology



Main findings

What are NGTs?

A diverse group of techniques to achieve different results, from limited changes to multiple and more extensive modifications



Mutagenesis

Changes without insertion of genetic material

Cisgenesis/Intragenesis

Rearrangement of genetic material of same organism or insertion of genetic material from organisms that can cross in nature

Transgenesis

Insertion of genetic material from other organisms that are sexually incompatible

Main findings: research and development (source: JRC)

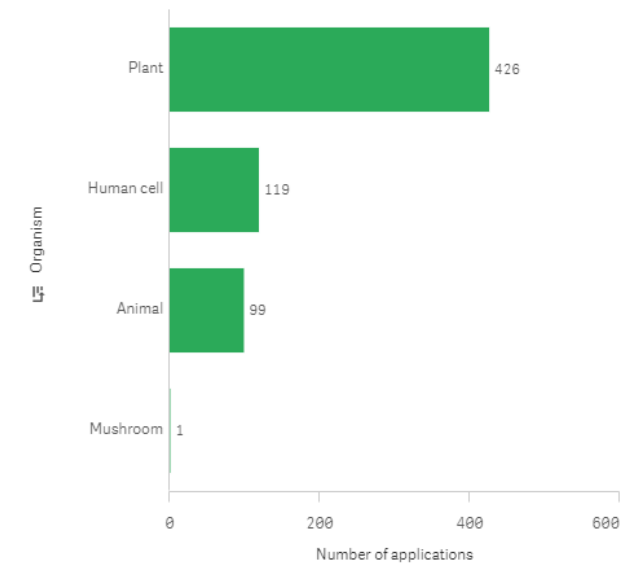


No selections applied

Selections

- Organism
- Species group
- Country classification
- Technique
- Development stage
- Trait category
- Type of company/institution
- Country

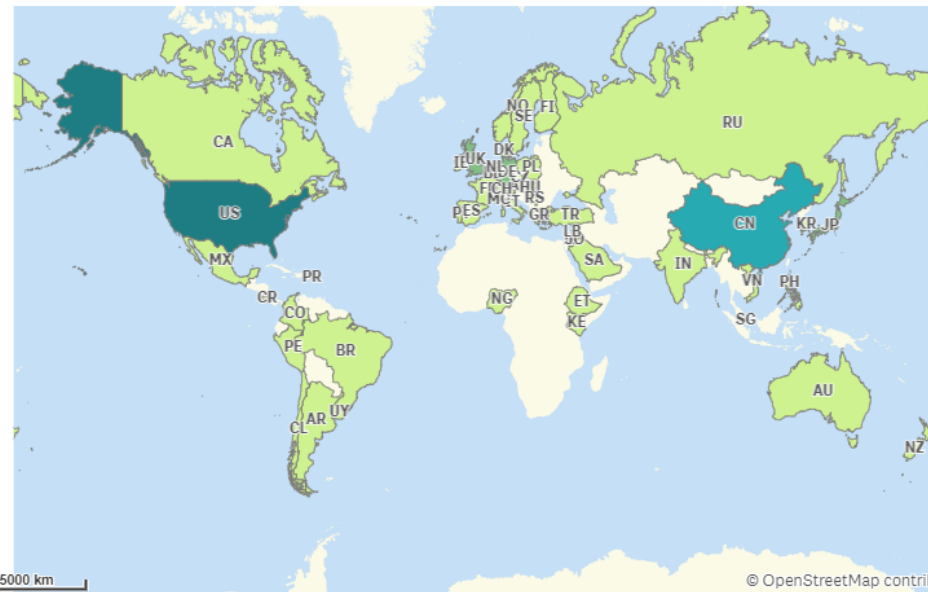
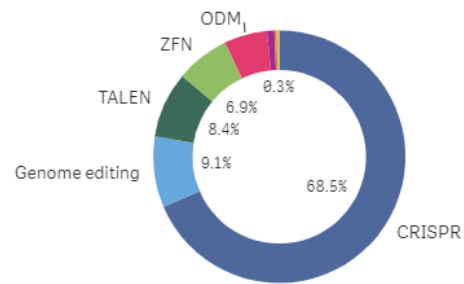
Organism and species groups



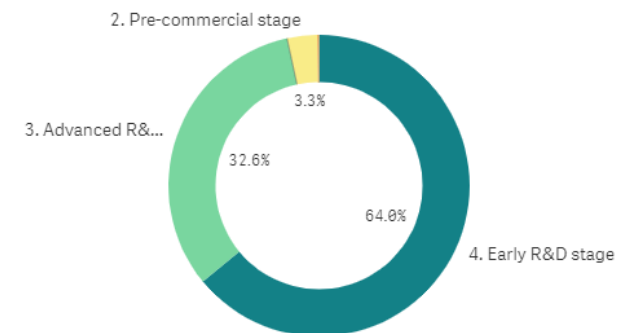
Number of applications

645

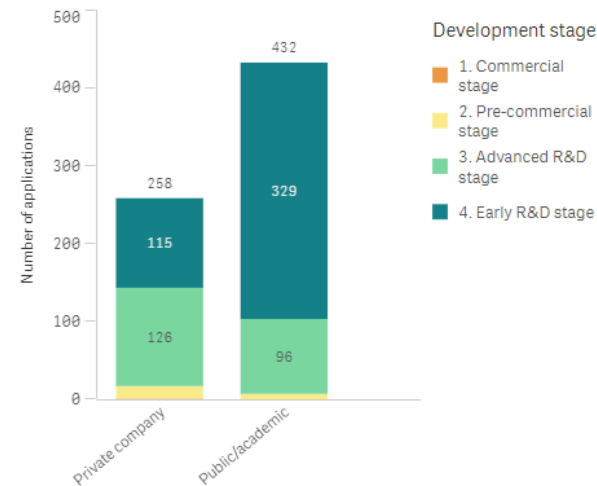
Technique share



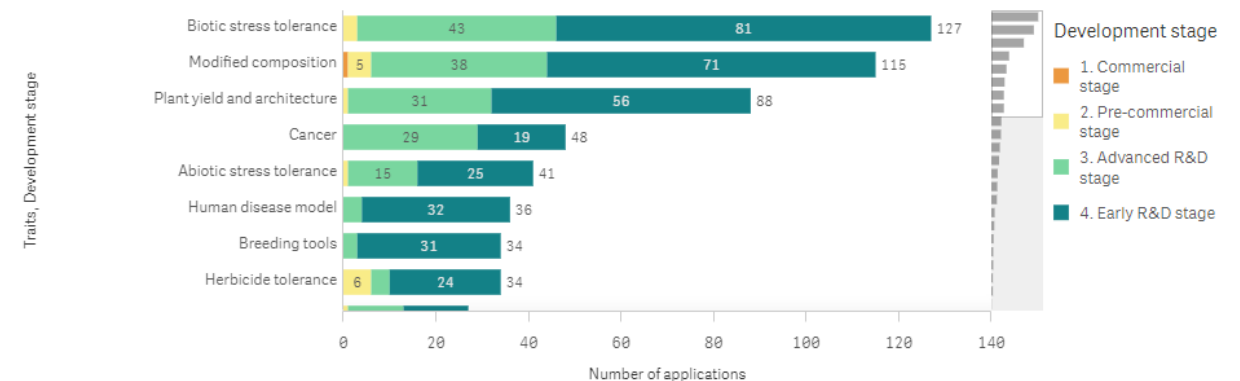
Development stage



Type of Company/Institution and Development Stage



Traits and development stage



Main findings: potential benefits



Plants resistant to effects of climate change



Reduced content of harmful substances such as toxins and allergens



Plants resistant to pests and diseases, needing less chemical pesticides



Vegetable with improved nutrient content



Farm animals resistant to certain diseases

Main findings: potential benefits

- Production of useful substances from **microorganisms**, with applications in cosmetics, biofuels, food ingredients and pharmaceutical substances
- In the **pharmaceutical sector**, NGTs can be employed for the development of vaccines and therapies for hereditary diseases and cancer.

Main findings: potential concerns

- possible risk and environmental impact
- coexistence with organic and GM-free agriculture
- labelling and consumers' right to information



Some stakeholders consider that benefits are hypothetical and achievable by other means.

Main findings: safety aspects

- NGTs constitute a diverse group of techniques and each technique can be used in various way to change the genome.
- Need for a case-by-case approach to identify potential hazards and the necessary experimental data.

EFSA opinions on targeted mutagenesis and cisgenesis in plants:

- No new hazards compared to both conventional breeding and established genomic techniques.
- Modifications introduced with targeted mutagenesis and cisgenesis in plants can also take place naturally in the environment without human intervention.

Limited information on other NGTs and microorganisms or animal applications

Main findings: implementation and enforcement



- Organisms obtained through new genomic techniques are subject to the EU GMO legislation.
- Developments in biotechnology since the legislation was adopted give rise to certain ambiguities in the application of the legislation to some NGTs.
- There are challenges relating to the detection and differentiation of certain NGT products that contain no foreign genetic material.

Main findings: regulation in non-EU countries

- Regulatory frameworks from around 30 non-EU countries screened.
- Considerable variation in GMO and NGT legislation.
- Around one third have adapted their legislation to address NGTs. All of them cover plants, some also microorganisms and animals.
- The regulatory tools often include exemptions for NGTs, based on the characteristics of the final product or the techniques used or a combination of both.
- In many, the regulatory status of NGT products is determined in a case by case approach.



Main findings

Other findings

- Ethical aspects
- SMEs
- Patents

Consumer information

- Information and labelling
- Public dialogues, awareness and perception.

Conclusions

- GMO legislation needs adaptation to scientific and technological progress to be suited to certain NGTs and their products.
- NGTs can contribute to the Green Deal and Farm to Fork objectives of innovation and sustainability of the food systems, and to a more competitive economy.
- NGT applications in the agricultural sector should not undermine other aspects of sustainable food production, e.g. as regards organic agriculture.
- Knowledge gaps identified in the study need to be addressed.
- More effort should be made to inform and engage with the public and assess their views.



Next steps

The Commission's follow-up action

The Commission's follow-up action

- ✓ The Commission plans to initiate policy action on **plants derived from targeted mutagenesis and cisgenesis**.
- ✓ The policy action will **aim at** a proportionate regulatory oversight, which would:
 - maintain a high level of protection of human and animal health and the environment
 - allow reaping benefits from innovation
- ✓ **Impact assessment**, including **public consultation**, will be carried out in the next months.
- ✓ For other organisms and other NGTs, the Commission will continue to build up the required scientific knowledge, in view of possible further policy actions.
- ✓ Considerations related to the use of NGTs in medicinal products will be addressed in the Commission's Pharmaceutical Strategy.

Thank you

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Slides 3, 6, 8, 10, 12, 14, 15, 16: Pictures, source: Gettyimages