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

DG Health and Food Safety: Unit E3 Biotechnology

Ad hoc Advisory Group - 19.5.2021

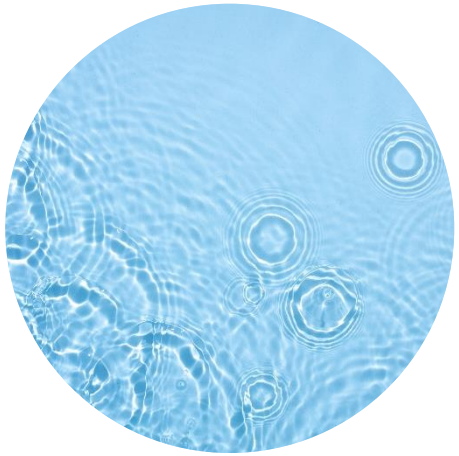
The context

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

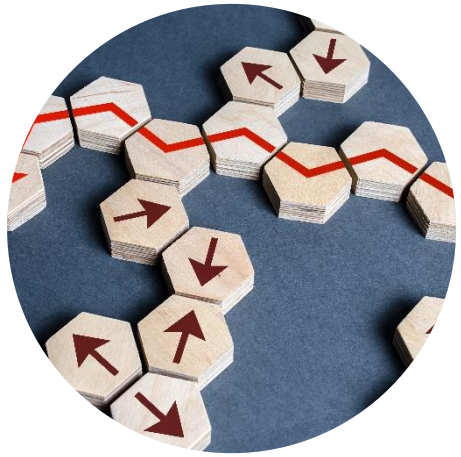
Council Decision (EU) 2019/1904

The Commission's study on NGTs

Objective



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

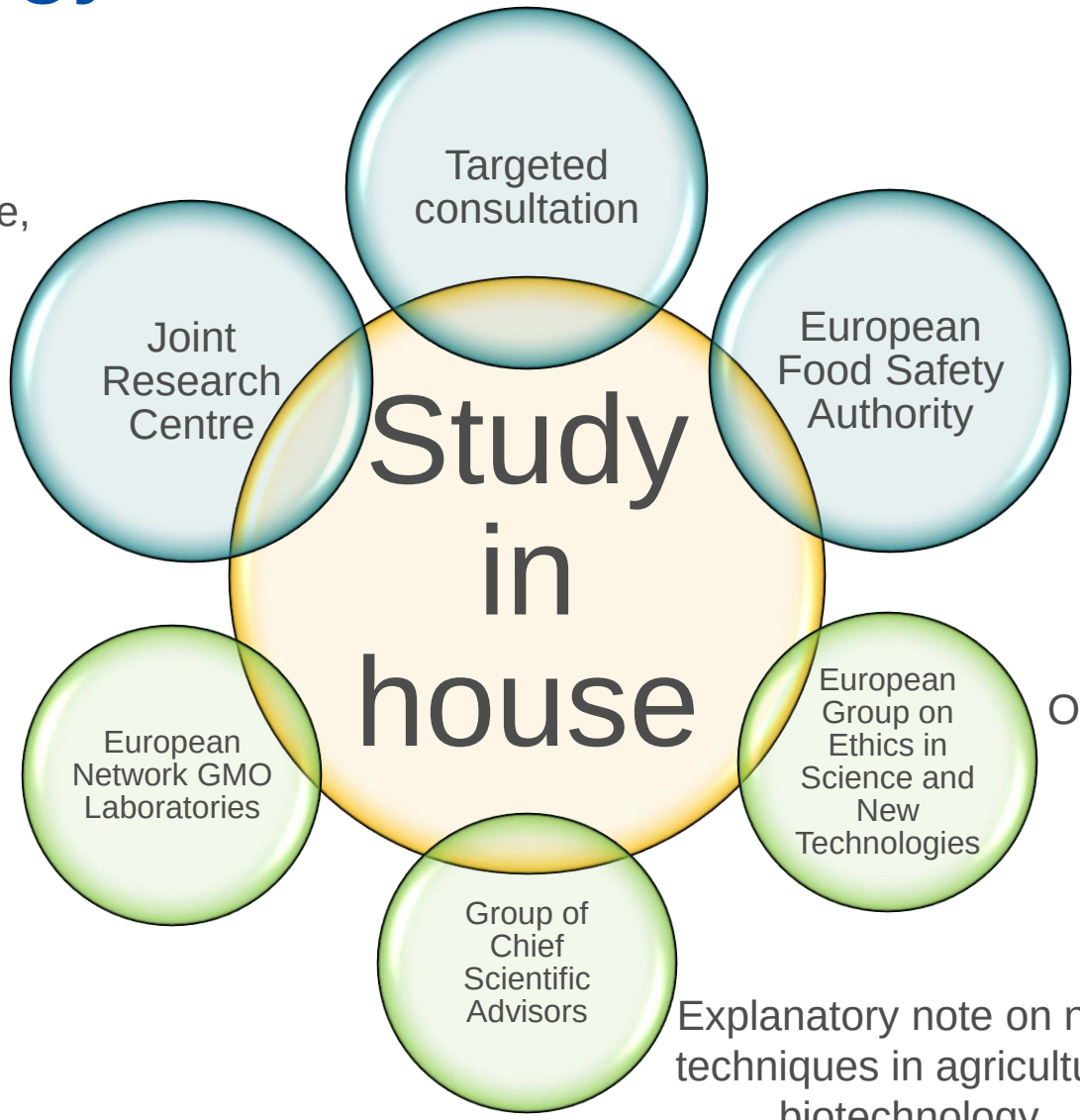
Scope

Use of NGTs in plants, animals and micro-organisms, in a broad variety of potential applications, including in the agri-food, medicinal and industrial sectors.

New genomic techniques (NGTs)

Techniques that are capable of altering the genetic material of an organism and that have emerged or have been developed since 2001, when the current GMO legislation was adopted.

Methodology



Technology landscape, current and future market applications

Overview on EFSA and MS opinions on safety/risk assessment

Report on detection of food and feed plant products obtained by new mutagenesis techniques

Opinion on ethics of genome editing

Explanatory note on new techniques in agricultural biotechnology

Targeted consultation methodology

- EU Member States
- EU-level stakeholder organisations and associations that could be directly or indirectly affected or have a potential interest in NGTs (107 invited; 71 confirmed their interest, 58 replied)

- ✓ Transparent and participatory consultation process
- ✓ Member States and stakeholders involved in the finalisation of the questionnaires
- ✓ Information on dedicated website

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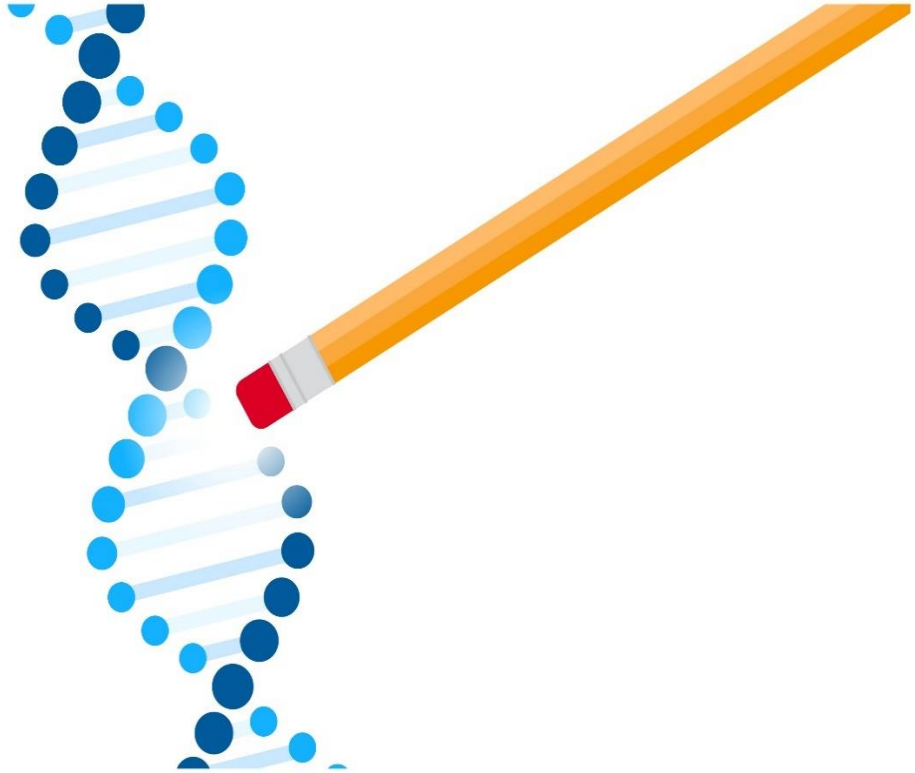
Main findings

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

Epigenomic changes

Genetic material altered without change of the nucleic acid sequence

Main findings: research and development

- NGTs and their products have developed rapidly in the last two decades in many parts of the world.
- Some applications are already on the market and more applications in different sectors are expected in the coming years.
- There is considerable interest in research on NGTs in the EU, but most of development is taking place outside the EU.
- Following the ruling of the Court of Justice of the European Union, negative impacts have been reported on public and private research on NGTs in the EU due to the current regulatory framework.

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

Vegetables 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.

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Main findings: safety aspects

- Respondents to the **consultation** expressed diverse, sometimes opposite views as regards the level of safety of NGTs and their products, and on the need and requirements for risk assessment.
- Case-by-case assessment is widely recognised as the appropriate approach.
- Need for flexibility and proportionality in risk assessment, although not all stakeholders share this view.
- Another aspect that has been raised is the need to develop risk assessment procedures that are specific to NGTs.

Main findings: safety aspects

Overview of opinions of EFSA and MS risk assessment bodies since 2012:

- Focus on plant applications of some NGTs; less information on other NGTs and microorganisms or animal applications.
- NGTs constitute a diverse group of techniques, each of which can be used in various ways to achieve different results and products with specific safety considerations.
- The different scopes and objectives of these opinions make it difficult to compare them directly and to draw general conclusions.

Main findings: safety aspects

EFSA opinions on targeted mutagenesis and cisgenesis in plants:

- No new hazards compared to both conventional breeding and established genomic techniques.
- Random changes to the genome occur independently of the technique.
- Off-target mutations potentially induced by targeted mutagenesis techniques are of the same type as, and fewer than, those mutations in conventional breeding.
- Therefore, in certain cases, targeted mutagenesis and cisgenesis carry the same level of risk as conventional breeding techniques.

Limited information on other NGTs and microorganisms or animal applications

Main findings: implementation and enforcement

Legal clarification

Organisms obtained through new genomic techniques are subject to the GMO legislation.

Remaining legal uncertainty

Developments in biotechnology, combined with a lack of definitions (or clarity as to the meaning) of key terms, are still giving rise to ambiguity in the interpretation of some concepts, potentially leading to regulatory uncertainty.

Main findings: implementation and enforcement

- There are implementation and enforcement challenges in the EU, relating in particular to the detection of NGT products that contain no foreign genetic material.
- Problems for enforcement authorities, operators and applicants.
- Different regulatory oversight for NGTs in other countries ⇒ potential impacts on trade.

Main findings

SMEs

Regulatory barriers for small and medium-sized enterprises (SMEs), even though many Member States and stakeholders see opportunities for them in this sector.

Patents

Benefits of patents and licensing in promoting innovation. However, these same aspects (together with high business concentration) can also act as a barrier to market entry for SMEs and can limit access to new technologies and to genetic material, e.g. for breeders and farmers.

Main findings

Ethical aspects

- The use of NGTs raises ethical concerns, but so does missing opportunities if not using them.
- Most of the ethical concerns raised relate to how these techniques are used, rather than the techniques themselves.

Public dialogues

- In Member States, there is interest in addressing NGT-related topics in dialogues and events carried out by various institutions, which can help to raise public awareness and understanding.

Main findings: labelling

- Consumers' understanding and awareness enable them to make informed choices, so the provision of consumer information is key.
- Stakeholders have opposing views, both on the need to continue labelling NGT products as GMOs and on the effectiveness of such labelling in informing consumers.

Conclusions

- GMO legislation:
  - implementation challenges
  - legal uncertainties
  - not fit for purpose for some NGT products
  - needs adaptation to scientific and technological progress
- It may not be justified to apply different levels of regulatory oversight to similar products with similar levels of risk
- The current risk assessment procedures are rigid and difficult to adapt to scientific progress.

Conclusions on possible follow-up

- ✓ Confirm whether and how adaptation is needed in order for the legislation to be resilient, future-proof and uniformly applied.
- ✓ Aim at enabling NGT products to contribute to sustainability, in line with the objectives of the European Green Deal, the Farm to Fork and Biodiversity Strategies, while addressing concerns.
- ✓ Consider an appropriate mechanism to evaluate benefits of NGT products.
- ✓ NGT applications in the agricultural sector should not undermine other aspects of sustainable food production, e.g. as regards organic agriculture.
- ✓ Address knowledge gaps identified in this study. More effort should be made to inform and engage with the public and assess their views.

Next steps

The Commission’s follow-up action

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The Commission’s follow-up action

- ✓ The Council requested the Commission to submit a proposal or other measures, if appropriate, as a follow-up to the study.
- ✓ NGTs can contribute to the Green Deal and Farm to Fork objectives of innovation and sustainability of the food systems, as well as to a more competitive economy, which are at the centre of current priorities of the European Union.
- ✓ The Commission plans to initiate policy action on **plants derived from targeted mutagenesis and cisgenesis**.
- ✓ For other organisms and other NGTs, 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.

The Commission's follow-up action

- ✓ 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 to examine:
  - potential policy options
  - concerns expressed during the study consultation
- ✓ The Commission will engage in a wide-ranging **communication** effort to share the results of the study and to discuss its outcome and next steps with the EU institutions and stakeholders in dedicated meetings.

Thank you

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