BRIEFING
EU Legislation in Progress

European Parliament

Plants produced by new genomic techniques

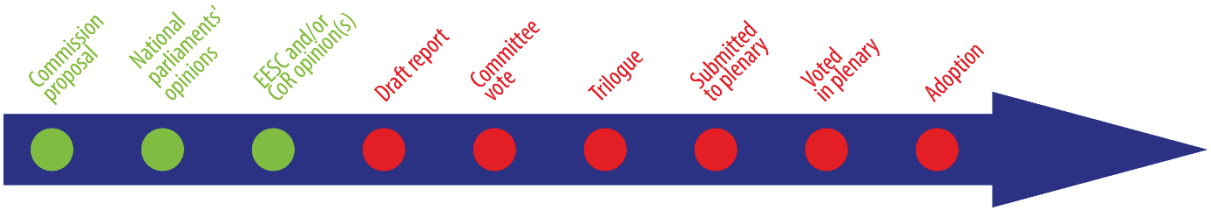
OVERVIEW

On 5 July 2023, the Commission tabled a proposal for a regulation on certain new genomic techniques (NGTs). It establishes two categories of plants obtained by NGTs: plants comparable to naturally occurring or conventional plants, and plants with modifications that are more complex. The two categories will be subject to different requirements to reach the market, taking into account their different characteristics and risk profiles.

Feedback from stakeholders is mixed. While industry interest groups hailed the 'game-changing proposals' bringing innovation in plant breeding, the organic food and farming movement criticised the Commission's plan to take NGTs out of the existing legal framework, as it could leave organic food systems unprotected.

In Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file under the co-decision procedure.

Proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625		
Committee responsible:	Environment, Public Health and Food Safety (ENVI)	COM(2023) 411 final 05.07.2023
Rapporteur:	Jessica Polfjärd (EPP, Sweden)	2023/0226(COD)
Shadow rapporteurs:	Christophe Clergeau (S&D, France) Pietro Fiocchi (ECR, Italy) Silvia Sardone (ID, Italy)	Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
Next steps expected:	Publication of draft report	



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Context

Plant breeding is an ancient activity, dating back to the very beginnings of agriculture. In the mid-1800s, Gregor Mendel outlined the principles of heredity using pea plants and thus provided the necessary framework for scientific plant breeding. The further development of genetic inheritance laws in the early 20th century sped up their application in plant breeding. Advances in biotechnology in the late 1970s allowed conventional breeding techniques – used to hybridise plants – to evolve, with the use of novel techniques able to introduce genetic changes. The term 'established genomic techniques' refers to those techniques developed before 2001. A variety of new techniques have been developed over the past 20 years based on advances in biotechnology and for which the term 'new genomic techniques' (NGTs) is now widely used. Whereas established genomic techniques generate random sequence alterations in the genome, NGTs allow changes to be directed to a selected genomic location, thus enabling more precise editing of the genome.

What are new genomic techniques?

Mutagenesis, cisgenesis and intragenesis

These genetic engineering techniques allow the genetic structure of an organism to be altered by adding, deleting or altering Deoxyribonucleic acid (DNA) – the molecule inside cells that contains the genetic information responsible for the development and function of an organism – with the aim of enhancing its genetic properties.

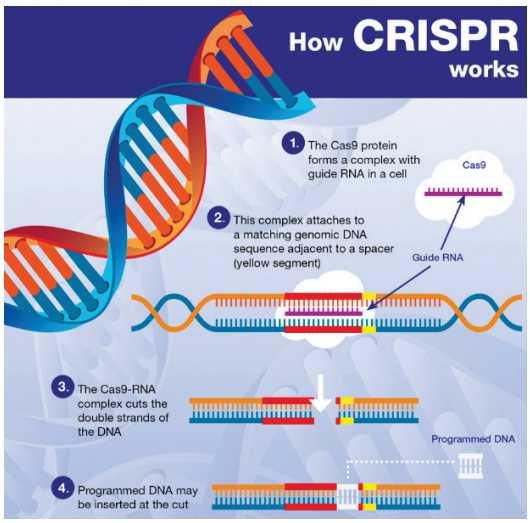
- **Mutagenesis** is a set of techniques, allowing modifications of the genome without the insertion of foreign DNA. Prior to 1990, only conventional or random methods of mutagenesis were applied *in vivo* to entire plants. Later on, technical progress led to the emergence of *in vitro* mutagenesis, which made it possible to target the mutations (**targeted mutagenesis**) in order to create organisms with specific traits, or investigate the effects of genetic changes.
- **Cisgenesis** is a modification of the genetic material of an organism with a sequence from the same species or one closely related. The new sequence is an **exact copy** of the sequence already present in the breeders' gene pool, which is the set of all genetic information for a given species.
- **Intragenesis** is a modification of the genetic material of an organism with a combination of different sequences from the same species or one closely related. The new sequence is a **re-arranged copy** of sequences already present in the breeders' gene pool.

Defined as 'techniques capable of changing the genetic material of an organism and that have emerged or have been developed since 2001',[1] NGTs are based on gene transfer (mutagenesis/cisgenesis/intragenesis) or rely on the accuracy of genome (or gene) editing.

The most prominent gene-editing tool is based on the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology. CRISPR uses artificially engineered enzymes called nucleases that act as molecular scissors to split open the DNA double-stranded helix, allowing the cell's own machinery to repair the break (see Figure 1). This technique is quick, precise and cheap, and has been used as a platform for many other NGTs.

CRISPR's developers – French microbiologist Emmanuelle Charpentier and US biochemist Jennifer Doudna – were awarded the 2020 Nobel

Figure 1 – CRISPR-Cas9 in gene editing



Source: Cambridge Core, 2016.

Prize in Chemistry. Expected benefits of gene-edited crops include enhanced nutrition, improved food safety, greater resistance to disease, weeds and pests, and better climate resilience, including tolerance to drought.

Currently, over 500 products are being developed worldwide using CRISPR and are at different stages of development, ranging from basic research to advanced R&D and near-commercialisation. In 2021, a Japanese company commercialised the first CRISPR-edited food – a gene-edited tomato, containing high levels of gamma-aminobutyric acid, an amino acid expected to help lower blood pressure. It was followed the same year by two species of fish gene edited to grow bigger. The green leafy vegetable range Conscious™ Greens, modified to enhance its flavour and colours, is expected to enter the US market in 2023. Data show that the global genome-edited product market was worth over US$5 billion in 2021 and is projected to be worth nearly US$12 billion by 2026.

On 3 October 2023, the Commission presented a Recommendation on critical technology areas for the EU's economic security, for further risk assessment with EU countries. Out of the 10 critical technology areas, four are considered highly likely to present the most sensitive and immediate risks related to technology security and technology leakage, among which are biotechnologies.

Existing situation

EU legal framework on genetically modified organisms

The EU legislation on genetically modified organisms (GMOs) is one of the strictest in the world. It has two main objectives: protecting human and animal health and the environment in accordance with the precautionary principle,[2] and ensuring the functioning of the internal market. Stringent procedures exist for the safety assessment, risk assessment and authorisation of GMOs before they can be placed on the market. To enable consumers as well as professionals to make informed decisions, labelling and traceability are also ensured.

Authorisation and cultivation of GMOs in the EU

The only GMO authorised for cultivation in the EU is maize MON 810, grown in Spain and Portugal, but 18 out of 27 EU countries have restricted or prohibited its cultivation in all or part of their territories. Directive (EU) 2015/412 gives EU countries more flexibility to decide on the cultivation of genetically modified crops on their territory, under certain conditions, at two distinct points in time:

- during the authorisation procedure: an EU country can ask to **amend the geographical scope of the application** to ensure that its territory will not be covered by the EU authorisation;
- after a GMO has been authorised: an EU country may **prohibit or restrict the cultivation of the crop** based on grounds related, among other things, to environmental or agricultural policy objectives, or other compelling grounds such as town and country planning, land use, socio-economic impacts, co-existence and public policy.

While the market for genetically modified food in the EU is small, the EU makes use of a substantial amount of genetically modified feed, as it is a major importer of high protein agricultural commodities from countries where production is dominated by GMOs, such as Brazil.

The EU's GMO legislation stems from 1990, when the first two directives regulating the use of GMOs[3] came into force. These main pieces of legislation are supplemented by a number of implementing rules or by recommendations and guidelines on more specific aspects. Both original directives have since been updated,[4] but the definition of a GMO has remained unchanged, which makes the continuum between genetic engineering and conventional breeding difficult to accommodate.

Whether an organism obtained through NGTs is considered a GMO depends on the interpretation of the current GMO definition. Article 2(2) of Directive 2001/18/EC defines a GMO as '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'.

In a **process-based interpretation** of this definition, the mere use of a technique of genetic modification suffices for a resulting organism to be considered a GMO. In a **product-based interpretation**, the resulting organism must contain a new combination of genetic material in order to qualify as a GMO. A third possible interpretation combines both criteria. However, the definition is commonly interpreted as process-based and currently does not reflect the progress made in NGTs.[5]

The annexes to the directive further define the techniques that:

- result in genetic modification (listed in Annex I A, Part 1);
- are not considered to result in genetic modification (Annex I A, Part 2);
- result in genetic modification but yield organisms that are excluded from the scope of the directive (Article 3 and Annex I B). These techniques are **mutagenesis** and **cell fusion** (a technique where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally).

In addition, recital 17 states that the directive 'should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a **long safety record**'.

In replies to parliamentary questions, the Commission has stressed that the decision to include or exclude a technique from the scope of Directives 2001/18/EC and 2009/41/EC (on the contained use of GMOs) depends on the interpretation of the definition of GMOs and of the conditions for exemption provided for in the two directives. The Commission has also noted that the evaluation is complex, because the definition of a GMO under EU legislation refers both to the characteristics of the organism obtained and to the techniques used.

International legal instruments

The Convention on Biological Diversity – an international legal instrument ratified by 196 nations and in force for the past 30 years – covers biodiversity at all levels (ecosystems, species and genetic resources, including biotechnology) through its Cartagena Protocol on biosafety. The Protocol seeks to protect biological diversity from the potential risks posed by GMOs and is grounded in the precautionary principle. It notably allows countries to ban GMO imports and requires exporters to label shipments containing genetically altered commodities such as corn or cotton. The EU signed and ratified the Protocol in 2002 and its current definition of a GMO is in line with it. However, leading producers of GMO, such as the US, Argentina and Canada, have not signed the treaty. International discussions in the framework of the more recent Nagoya Protocol – in force since 2014 – include, inter alia, the regulatory status of genome-editing techniques.

Is gene editing comparable to conventional breeding?

The legal status of NGTs has raised questions in the EU as well as worldwide.

In 2018, the Court of Justice of the European Union delivered a judgment in which it held that organisms obtained by **targeted mutagenesis** are GMOs – since mutagenesis alters the genetic material of an organism in a way that does not occur naturally – and therefore such organisms come within the scope of EU-wide authorisation, traceability and labelling rules. On the question of whether the EU GMO legislation applies to organisms obtained by NGTs, the Court considered that the risks linked to the use of these techniques are similar to those of **transgenesis** – the introduction of a foreign gene into an organism – since the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects.

The **precautionary principle** has thus been the most influential argument for placing techniques of targeted mutagenesis under the EU legislation governing GMOs. The Court's ruling also reaffirmed the EU's doctrine of regulating the **process** used to create GMOs rather than focusing on the characteristics of the final **product(s)**, as is typically the case in the US, for example (see Table 1).

Table 1 – Top five global producers of GMO crops

Country	Commercial cultivation 2019 (million hectares)	Regulatory concept	Ratification of Cartagena Protocol
USA	71.5	Product	No
Brazil	52.8	Product	Yes
Argentina	24	Product	No
Canada	12.5	Product	Yes
India	11.9	Product	No

Source: ISAAA Brief 55, Biotech crops, 2019.

However, the Court exempted the varieties that were created through 'mutagenesis techniques which have conventionally been used in a number of applications and have a **long safety record**'.

In 2019, the Council asked the Commission to submit a study on the status of NGTs under EU law in light of the Court's ruling. The study, published in 2021, concluded that organisms obtained through NGTs, notably **targeted mutagenesis**, **cisgenesis** and **intragenesis**, are GMOs.

Comparative elements

Regulation of NGTs among main non-EU producers of GMO crops

In the **United States**, food and agricultural products are regulated by three governmental agencies – the US Department of Agriculture, the Food and Drug Administration and the Environmental Protection Agency (USDA, FDA and EPA) – under the 1986 US Coordinated Framework for Biotechnology that ensures these products are safe for the environment and human health. The three agencies regulate the characteristics of the products themselves rather than the process used to develop them. Even though the precautionary principle forms part of the US law on biotechnology, the process during which a GMO is produced is not considered to be dangerous *per se* and neither is the transfer of genetic material between organisms. In 2018, the USDA issued a statement on plant-breeding innovation, clarifying that the Agency did not have plans to regulate plants 'produced through innovative new breeding techniques which include techniques called genome editing'. In 2020, the USDA enacted the SECURE rule focusing on the properties of the plant rather than its method of production. The FDA, for its part, offers a voluntary premarket consultation programme for developers of new plant varieties to obtain early feedback on potential food safety considerations. In 2020, the EPA stated its intention to modify its oversight of plant-incorporated pesticides in order to exempt products made with newer biotechnologies,[6] such as gene editing.

In **Brazil**, safety standards for GMOs are set by the National Technical Commission for Biosafety (CTNBio). The risk level of each newly developed plant or food is evaluated on a case-by-case-basis. As in the US, the assessment focuses on the characteristics of the final product rather than the process used to create it. Gene-edited crops obtained through NGTs which do not contain foreign DNA are thus regulated as conventional plants and are exempt from the GMO regulatory framework.

In 2015, **Argentina** became the first country in the world to develop regulatory criteria establishing whether a crop obtained through NGTs is or is not a GMO. The 'Argentina model' consists of only regulating genome-edited plants with permanent insertion of foreign DNA. All gene-edited products are examined on a case-by-case basis by the Argentine Biosafety Commission.

The regulation of plants in **Canada** is based on the 1990 Plant Protection Act and solely considers the novel trait of a plant, regardless of which technology was used to produce it. A novel trait is defined by the Canadian Food Inspection Agency as 'a trait which is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to

the environment and human health. These traits can be introduced using biotechnology, mutagenesis, or conventional breeding techniques.' The Agency provides pre-market assessments for novel foods, novel feeds, and plants with novel traits, offering early feedback on potential issues.

In **India**, GMOs are regulated under the 1989 'Rules for the manufacture, use, import, export and storage of hazardous microorganisms, genetically engineered organisms or cells'. The Rules are supported by a series of guidelines on contained research, biologics, confined field trials, food safety assessment, and environmental risk assessment. In 2022, India's Ministry of Environment, Forest and Climate Change announced the exemption of genome-edited plants without foreign genes from biosafety assessment.

Parliament's starting position

In a 2014 resolution on 'Plant breeding: what options to increase quality and yields', Parliament noted that it was important to develop and use new plant-breeding techniques that respond to societal and agricultural demands and to be open to the technologies available. In addition, MEPs expressed concern at the Commission's delay in assessing new breeding techniques, and called on the Commission to clarify their regulatory status. The same year, in another resolution on 'The future of Europe's horticulture sector – strategies for growth', Parliament urged the Commission to differentiate between cisgenic and transgenic plants and to create a different approval process for cisgenic plants.

Conversely, during the 2014-2019 term, Parliament systematically objected to every authorisation of 'traditional' genetically modified food and feed, demanding the suspension of all GMO approvals until their authorisation process has been revised. Similarly, in a 2020 resolution on COP15 to the Convention on Biological Diversity and in a 2021 resolution on the EU biodiversity strategy for 2030, Parliament called for a global moratorium on releases of gene drive organisms into nature.

In October 2021, Parliament outlined its initial views on NGTs in an own-initiative report on the EU's farm to fork strategy. While noting the potential benefits from science and innovation in terms of NGTs, Parliament underscored the precautionary principle and the need to ensure transparency and freedom of choice for farmers and consumers. Similarly, the resolution stressed the importance of risk assessments and a comprehensive overview of options for traceability and labelling to ensure proper oversight and provide consumers with relevant information, including for products from third countries.

Commission study on NGTs

While the study clarified that organisms obtained through NGTs are subject to the EU GMO legislation, it concluded that recent developments in biotechnology, combined with the ambiguity of definitions, still impede the interpretation of some concepts, thus leading to regulatory uncertainty. Importantly, as NGTs constitute a highly heterogeneous group, safety considerations depend on the particular technique, its use and the characteristics of the resulting product. The study also confirmed that the current regulatory system involves implementation and enforcement challenges, relating in particular to the detection of NGT products that contain no foreign genetic material. This is an issue both for enforcement authorities and for applicants. Indeed, the availability of reliable detection methods is a prerequisite for a GMO market authorisation. Complementary traceability tools do not appear to offer a solution to this particular challenge and present a number of limitations.

Council starting position

Considering that the 2018 ruling by the Court of Justice brought legal clarity as to the status of NGTs, but also raised practical questions both for national authorities and the plant-breeding sector, the Council requested the Commission to prepare a study (see box). The Commission study was published in April 2021 and the Agriculture and Fisheries Ministers held a debate on its conclusions in May 2021. The ministers responded positively to the study and appreciated the need to modernise the current legislation, while also recognising the particular challenges presented by such modernisation. They discussed the importance of reflecting the latest scientific developments when conducting risk assessments on NGTs, and the need to raise awareness and provide education on these issues.

In March 2023, at the EU Environment Council meeting, Austria, supported by Cyprus and Hungary, voiced its concerns about the safety of plants derived from NGTs. The three delegations called for the application of the precautionary principle, as previously requested by the Environment Ministers in December 2021.

Preparation of the proposal

Various studies were conducted to support the impact assessment, including case studies and reports by the Commission's Joint Research Centre and the European Food Safety Authority (EFSA).

Criteria for the risk assessment of plants obtained by mutagenesis or cis-genesis

In October 2022, following a request by the European Commission, the EFSA published a statement on the criteria for the risk assessment of plants obtained by mutagenesis or cisgenesis. The core of these criteria is the concept of '**history of safe use**', which was originally developed for food risk assessment and has always been heavily debated regarding its use in environmental risk assessment. The EFSA stated in the document that, before the proposed risk assessment criteria could be applied, many aspects required further development and definition, including the concept of 'history of safe use'. Particularly with regard to environmental risk assessment, many questions remain open, as the EFSA considers them to be overly vague.

The views and evidence gathered from various key stakeholder groups were based on a dedicated consultation strategy. The impact assessment (IA) was informed by stakeholder consultation activities, including a collection of feedback on the Commission's Inception IA (24 September – 22 October 2021, 70 894 contributions), a public consultation (29 April - 22 July 2022, 2 300 contributions), a targeted stakeholder survey (28 June – 5 September 2022), interviews (June-December 2022) and focus groups on sustainability and traceability (22 and 23 September 2022). The consultation activities attracted considerable interest from citizens, reflecting mixed views. The majority of stakeholders from academia, breeders, farmers (except organic and GM-free), agri-food chain operators and public authorities called for the adaptation of the current legislation to a more enabling framework. Conversely, a majority of environmental organisations, non-governmental organisations (NGOs), and retail and consumer organisations support maintaining the status quo.

The proposal was accompanied by an impact assessment, which received a positive opinion with reservations from the Regulatory Scrutiny Board on 26 May 2023. Similarly to the 2021 Commission study on NGTs, the IA concluded that the current EU GMO legislation is not fit for purpose for plants obtained by NGTs. The IA pointed to three issues:

- the authorisation procedure and risk assessment requirements of the current EU GMO legislation are not adapted to the variety of potential NGT plant products, and as a result are disproportionate or inadequate in certain cases;
- the current EU GMO legislation raises implementation and enforcement challenges for certain plants produced by NGTs;
- the current EU GMO legislation applied to NGTs is not conducive to developing innovative products.

The changes the proposal would bring

On 5 July 2023, the European Commission tabled a proposal for a regulation on plants obtained by certain NGTs aiming at maintaining a high level of protection of human health, while encouraging the development of varieties that help to fight climate change and reduce use of pesticides.

Categories of plants and definitions

The regulation follows a *lex specialis – lex generalis* approach. In other words, where there are no specific rules foreseen, NGT plants and their products would be subject to the rules which apply to GMOs. The Commission's proposal is structured around a distinction between two categories of

plants. The aim is to distinguish varieties 'considered equivalent to conventional plants' – 'category 1 NGT plants' – from all other plants obtained through NGTs (category 2 NGT plants), namely, targeted mutagenesis, cisgenesis and intragenesis.[7] This fundamental distinction permeates the text as a whole and determines the different provisions envisaged by the Commission.

Annex I to the Commission proposal indicates that a 'NGT plant is considered **equivalent to conventional plants** when it differs from the parent plant by **no more than 20 genetic modifications**'. These 'genetic modifications' are listed exhaustively. They include, for example, nucleotide deletion, targeted reversal of a DNA sequence, but also 'any other targeted modification, regardless of size, provided that the resulting DNA sequences already exist [...] in a species of the breeder's genetic heritage'.

According to Article 29 of the proposal, the Commission reserves the right to use delegated acts to 'adapt this list [of genetic modifications] to scientific and technological progress' up to five years after the entry into force of the text. Beyond these criteria, the Commission states that plants whose characteristic trait obtained through NGTs is 'herbicide tolerance' are excluded from 'category 1 NGT plants'. 'Category 2 NGT plants' are defined by default: they include all other varieties obtained through these new breeding techniques.

Notification, authorisation and placing on the market

The deliberate release and placing on the market of NGT plants would be subject to one of two procedures: **verification** to establish equivalence with conventional products (Chapter II), or **authorisation** in accordance with Directive 2001/18 on the deliberate release into the environment of GMOs or Regulation 1829/2003 (Chapter III) on genetically modified food and feed.

Since 'category 1 NGT plants' are considered 'equivalent' to conventional plants, the deliberate release and placing on the market of this type of variety would be conditional on a simple verification procedure. To do so, the applicant would have to apply to the competent authority in the EU country concerned and provide it with information on the genetic modifications carried out. The verification procedure would rely on science-based criteria covering the type and extent of plant genetic modifications that can be observed in nature or with conventional breeding techniques. However, 'category 1 NGT plants' remain prohibited in organic production (Article 5).

To guarantee uniform application and legal certainty to operators, the criteria would be complemented by thresholds for both size and number of modifications, ensuring that plants featuring complex sets of modifications remain under the regulatory oversight of the GMO legislation. The criteria would be subject to possible revision in view of scientific and technical progress. Once this procedure is validated, the variety would be considered a NGT similar to a conventional variety.

The Commission intends to create a principle of free movement for 'category 1 NGT plants'. Consequently, this category is excluded from the scope of the 'safeguard clauses' that EU countries may adopt to prohibit the use of a GMO in their territories. Prior to the placing on the market of NGT plants which have not yet been classified as category 1 by way of a verification procedure, the procedure would be conducted at EU level from the outset to ensure the smooth functioning of the internal market.

For 'category 2 NGT plants', the notification procedure referred to in Article 6(1) of Directive 2001/18/EC would apply for any introduction into the environment other than placing on the market. It would include an 'environmental risk assessment' concerning, among other things, potential effects on human and animal health. When placing category 2 NGT plant products intended for human consumption on the market, the applicant must go through an authorisation procedure, i.e. a risk assessment of the product. EU countries are also required to adopt coexistence measures to avoid the unintended presence of such NGT plants in organic and conventional crops (Article 24).

Traceability and labelling

Regarding traceability, the Commission opted for a hybrid solution. For 'category 1 NGT plants', the

mandatory labelling that applies to GMOs is abandoned. At consumer level, traceability is deemed to be guaranteed through the labelling of seeds and the creation of a new, publicly accessible database listing all 'category 1 NGT plants' (Articles 10-11) and through the variety catalogues of the plant reproductive material/forest reproductive material legislation (Articles 36-39).

Mandatory labelling is created, but only for products intended for plant reproduction.

On the other hand, the Commission proposes to maintain mandatory labelling for all 'category 2 NGT plants', to indicate that the product is a GMO. The Commission leaves the possibility of specifying the characteristics brought about by the genetic modification by adding a factual statement on the intended purpose of the genetic modification (Article 26). To enable operators to use this complementary labelling in a harmonised manner and avoid misleading or confusing indications, a proposal for such labelling would be provided in the application for authorisation and would be specified in the authorisation decision.

Monitoring and oversight

Category 1 NGT plants would remain subject to any regulatory oversight that applies to conventionally bred plants. As is the case for conventional plants and products, those NGT plants and related products would be subject to the applicable sectoral legislation on seed and other plant reproductive material, food, feed and other products, and horizontal frameworks, such as the nature conservation legislation and environmental liability. In this regard, NGT food falling out of the scope of Regulation 1829/2003 on genetically modified food as a consequence of the equivalence determination but featuring a significantly changed composition or structure that affects the nutritional value of the food will fall within the scope of Regulation (EU) 2015/2283 on novel foods.

Regulatory incentives

Regulatory incentives (Article 22) would be offered to applicants for 'category 2 NGT plants' containing traits with the potential to contribute to a sustainable agri-food system, in order to steer the development towards such traits. Such incentives would consist of an accelerated procedure for risk assessment and enhanced pre-submission advice. Additional incentives would be offered to applicants from small or medium-sized enterprises (SMEs), to promote access by small players and to support diversification of the food system.

The criteria to trigger these incentives would focus on broad trait categories with the potential to contribute to sustainability (such as those linked to tolerance or resistance to biotic[8] and abiotic[9] stresses, improved nutritional characteristics or increased yield). Consequently, the Commission proposal envisages incentives, particularly in authorisation procedures, for plants with Annex III characteristics: 'resistance to plant diseases', 'climate adaptation', 'enhanced nutritional quality' or 'enhanced yield'. Based on the regulation's goal of contributing to the targets of the 'farm to fork' strategy to reduce the use of pesticides, incentives would not be available for plants featuring herbicide-tolerant traits obtained with NGTs.

Issues relating to patents and intellectual property rights

The proposal does not regulate issues of intellectual property. The Commission intends to assess, as part of a broader market analysis, the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding. It will also assess their impact on breeders' access to genetic material and techniques, on availability of seeds to farmers and on the overall competitiveness of the EU biotech industry. The Commission will report on its findings by 2026.

Advisory committees

A mandatory consultation of the European Economic and Social Committee (EESC) and the European Committee of the Regions (CoR) is envisaged under the co-decision procedure. Work by the EESC is ongoing (rapporteur Arnaud Schwartz, Diversity Europe – GR III / France).

National parliaments

The deadline for reasoned opinions on the grounds of subsidiarity is 6 November 2023. The consultation is ongoing.

Stakeholder views[10]

The deadline for stakeholders' feedback on the Commission proposal is 5 November 2023. By 6 October, 249 contributions had been received, of which 83 % were from citizens, 6 % from companies and 4 % from NGOs. The bulk of contributions came from Germany (68 %) and Austria (14 %).

There is a clear split between those in favour and those against the proposal. While industry lobbies hailed the 'game-changing proposals' for plant-breeding innovation, green interest groups adopted a critical stance, urging the Council and Parliament to reject the proposal.

The EU's largest farm lobby, **COPA-COGECA**, welcomed the Commission's proposal, arguing that NGTs are 'part of the toolbox that enables breeders to speed up their breeding programmes and bring faster and better plant varieties to the market, which must be accessible in all sectors and all regions helping European farmers, who face many challenges including the acceleration of climate change'. The umbrella body underlines that new plant varieties 'must offer additional benefits compared to existing ones', while 'knowing that these varieties have been tested and evaluated according to an already established criteria is a form of assurance for farmers'.

FoodDrinkEurope (FDE) hailed the publication of the draft regulation, which it says will 'help pave the way for NGTs', and 'enable the development of plant varieties with specific beneficial characteristics'. FDE considers that innovations such as NGTs play an important role in creating sustainable and resilient food systems 'alongside integrated pest management to help reduce farm inputs, and improve climate mitigation and adaptation'.

In a joint statement, **COCERAL** (grain traders) and **FEDIOL** (vegetable oil and protein meal industry association) argue that the proposal 'reflects a fair balance between reaping the benefits from plant breeding innovation, while maintaining a high protection of human and animal health and of the environment', which they consider is a 'move in the right direction'. Both associations praise the clarification regarding 'conventional-like varieties that could be obtained through NGTs, through a simplified notification approach'.

The **European Council of Young Farmers** (CEJA) was equally enthused by the long-awaited proposal on NGTs. CEJA hails the possibility – created by the opportunity to use targeted mutagenesis and cisgenesis – for farmers to mitigate and adapt to climate change, thanks to better-adapted varieties. The umbrella body acknowledges the 'consideration given to farmers' freedom of choice with seed labelling, but regrets that organic farmers are not granted this ability'.

Commenting on the proposal, **Euroseeds** Secretary-General Garlich von Essen welcomed the 'differentiation of conventional-like NGTs from the outdated and practically unworkable approval requirements of transgenic GMOs', which is a 'prerequisite for a proportionate framework adapted to different profiles of these plants'. This notification process 'needs to be efficient and based on clear scientific criteria' to avoid a situation whereby 'a simple administrative process becomes politicised and inconclusive.' Euroseeds supports the distinction made on the market but raises concerns about 'inconsistencies and restrictions, such as the prohibition of NGT-derived plants in organic farming'.

IFOAM Organics Europe, the umbrella body representing the organic movement, is on a completely different page, arguing the proposal is 'misguided, dangerous for European seed autonomy, and a distraction from the agro-ecological solutions needed to move agriculture towards sustainability'. The body urges MEPs and governments to 'act to protect the freedom of farmers and consumers not to use or buy products from genetic engineering, and to prevent the monopolisation of genetic resources through patents'. It welcomes the prohibition of NGTs from organic production,

which is 'in line with the position of the organic food and farming sector', but voices misgivings as it 'does not provide a clear basis to protect GMO-free and organic production with co-existence measures, nor to ensure a fair distribution of risks and burdens'.

Friends of the Earth Europe echoes this sentiment, emphasising that the proposal 'sacrifices consumer rights and puts nature at risk', as it 'abolishes labelling requirements, safety checks and any type of liability processes for new GMOs'. The NGO argues that the 'deregulation proposal' will, inter alia, allow the release of untested new GMOs into nature, adding that 'no research has been conducted on how new GMOs interact with bees and other pollinators, nor on how GMO cropping can speed biodiversity loss'. Claiming the proposal is 'based on promises made by the industry about products that are currently still in the pipeline, without baseline or independent assessment on the actual sustainability of new GMOs,' the organisation urges EU's Environment and Health Ministers and MEPs to reject this piece of legislation.

Slow Food describes the move to 'no longer test new GMO plants for safety' as 'baffling', underlining that a 'large and ever-growing number of scientific studies show that new GMOs are far less precise than what is being claimed and give rise to numerous genetic errors'. The organisation underlines that researchers have previously warned of the need to test unintended mutations, 'because once new GMOs have been released into nature, it is impossible to prevent the contamination of crops nearby, and to avoid their spread'. Similarly, it argues the proposal 'will likely increase the already immense corporate control that large agrochemical companies have over our food systems'.

Pesticide Action Network (PAN) Europe also joined the chorus of opponents, describing the 'solutions' proposed by industry as 'merely wishful thinking', likening it to the 'same kind of deception that we observed earlier with conventional GMOs'. PAN Europe is convinced that the proposal 'violates the precautionary principle' and is 'not in line with the European Green Deal's promises', as the new techniques 'will only benefit the seed industry, leaving farmers, citizens and the environment unprotected'.

Corporate Europe Observatory (CEO) asserted that the 'deregulation proposal' is 'a massive give-away by the Commission to corporations like Bayer and BASF, without getting anything in return'. The organisation argued that 'this will not lead to more sustainable farming practices, on the contrary', adding that the 'assumption the Commission makes that new GMOs would lead to more sustainability was based solely on industry claims, instead of real evidence'. Similarly to other NGOs, CEO fears that patents on new GM seeds will 'erode farmers' rights and will lead to a further monopolisation of the already highly concentrated seed market'.

Legislative process

In Parliament, the report was referred to the Committee on the Environment, Public Health and Food Safety (ENVI), which appointed Jessica Polfjärd (EPP, Sweden) as rapporteur. The draft report is scheduled for presentation on 29 November 2023 and will be put to the vote on 24 January 2024.

Two meetings have taken place in the Council, on 25 July and 5 September, under the Spanish Presidency of the EU. The majority of EU agriculture ministers are in favour of the proposal, even though the coexistence of organic agriculture with gene-edited crops and the treatment of patents (currently excluded from the text) have emerged as contentious issues. The text proposed by the presidency features a new definition of NGT plants excluding the term 'genetically modified'. Instead, an NGT plant is defined as 'obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant'. The verification procedure allowing an NGT plant to be granted Category 1 status has also been modified. Any EU country and the Commission would have the possibility to file reasoned objections instead of simply making comments to the verification report. The objections should be forwarded to all the other EU countries and the Commission should duly take them into account. The presidency hopes to reach a political agreement by the end of the year.

EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

Rakstelyte A., Legislation for plants produced by certain new genomic techniques, EPRS, European Parliament, September 2023.

Study on Regulating genome editing: Societal hopes and fears, EPRS, European Parliament, 2021.

Laaninen T., New genomic techniques: European Commission study and first reactions, EPRS, European Parliament, 2021.

OTHER SOURCES

Plants obtained by certain new genomic techniques and their food and feed, 2023/0226(COD), Legislative Observatory (OEIL), European Parliament.

ENDNOTES

1 That is, after the existing EU legislation on genetically modified organisms was adopted.

2 At European level, the precautionary principle was enshrined in the Maastricht Treaty in 1992. It is now included in Article 191 of the Treaty on the Functioning of the European Union among the principles underpinning EU environmental policy.

3 Directive 90/220/EEC on the deliberate release of GMOs into the environment and Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

4 Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and Directive 2009/41/EC on the contained use of genetically modified micro-organisms. Regulation (EC) No 1829/2003, concerning genetically modified food and feed, was added in 2003.

5 NGTs are indeed capable of altering the genetic material in a target organism. However, these alterations in some cases merely result in genetic combinations that also occur in nature or through conventional breeding, while other alterations are more unlikely to occur naturally.

6 In the US, the term 'bioengineered crops' is used for GMO crops.

7 Thus, the use of NGTs introducing genetic material from a non-crossable species (transgenesis) should remain subject to the current GMO legislation, since the resulting plants might bear specific hazards associated to the transgene and there is no indication that current requirements in the GMO legislation need adaptation in the same way as for NGT plants.

8 Biotic stress includes various plant pathogens such as bacteria, fungi, viruses, nematodes, insects, and others.

9 Examples of abiotic stresses include drought, salt, cold, and heat.

10 This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'European Parliament supporting analysis'.

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