Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2023/0226(COD)
Plants obtained by certain new genomic techniques and their food and feed Amending Regulation 2017/625 2013/0140(COD) Subject 3.10.08.01 Feedingstuffs, animal nutrition 3.10.09.02 Plant health legislation 3.10.09.06 Agro-genetics, GMOs 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety Legislative priorities Joint Declaration 2023-24	Awaiting Council's 1st reading position

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		28/08/2023
		POLFJÄRD Jessica	
		Shadow rapporteur	
		CLERGEAU Christophe	
		HUITEMA Jan	
		HÄUSLING Martin	
		SARDONE Silvia	
		FIOCCHI Pietro	
		HAZEKAMP Anja	
	Committee for opinion	Rapporteur for opinion	Appointed
	AGRI Agriculture and Rural Development (Associated committee)		28/08/2023
		VRECIONOVÁ Veronika	
Council of the European Union			
European Commission	Commission DG	Commissioner	

European Economic and Social Committee European Committee of the Regions	Health and Food Safety	KYRIAKIDES Stella

Key events

05/07/2023	Legislative proposal published	COM(2023)0411	Summary
19/10/2023	Committee referral announced in Parliament, 1st reading		
19/10/2023	Referral to associated committees announced in Parliament		
24/01/2024	Vote in committee, 1st reading		
29/01/2024	Committee report tabled for plenary, 1st reading	A9-0014/2024	Summary
06/02/2024	Debate in Parliament		
07/02/2024	Decision by Parliament, 1st reading	T9-0067/2024	Summary
07/02/2024	Matter referred back to the committee responsible		
24/04/2024	Decision by Parliament, 1st reading	T9-0325/2024	

Technical information

Procedure reference	2023/0226(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2017/625 2013/0140(COD)
Legal basis	Rules of Procedure EP 57; Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 043
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	ENVI/9/12591

Documentation gateway

Legislative proposal		COM(2023)0411	05/07/2023	EC	Summary
Document attached to the procedure		SEC(2023)0411	06/07/2023	EC	
Document attached to the procedure		SWD(2023)0411	06/07/2023	EC	
Document attached to the procedure		SWD(2023)0412	06/07/2023	EC	
Document attached to the procedure		SWD(2023)0413	06/07/2023	EC	
Committee draft report		PE754.658	25/10/2023	EP	

Amendments tabled in committee		PE755.986	19/11/2023	EP	
Amendments tabled in committee		PE756.242	19/11/2023	EP	
Amendments tabled in committee		PE756.243	19/11/2023	EP	
Amendments tabled in committee		PE756.244	19/11/2023	EP	
Committee opinion	AGRI	PE757.371	08/01/2024	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0014/2024	29/01/2024	EP	Summary
Text adopted by Parliament, partial vote at 1st reading/single reading		T9-0067/2024	07/02/2024	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0325/2024	24/04/2024	EP	

Plants obtained by certain new genomic techniques and their food and feed

PURPOSE: to establish a specific regulatory framework for new genomic techniques (NGT) plants and their products.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: New Genomic Techniques (NGTs) are innovative tools that can help increase the sustainability and resilience of food systems and support the goals of the European Green Deal and the Farm to Fork Strategy. They allow precise and efficient development of improved plant varieties that can be climate resilient, pest resistant, require less fertilisers and pesticides, or ensure higher yields.

Since the adoption of the EU's GMO legislation in 2001, and especially in the last decade, a variety of new genomic techniques (NGTs) have been developed based on advances in biotechnology.

NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications.

To have a better understanding of all these recent advances, the Council requested the Commission in November 2019 to provide a study on NGTs. The 2021 Commission study concluded that the current rules - mainly the existing GMO legislation - lag behind scientific and technological progress and do not sufficiently facilitate the development and placing on the market of innovative NGT products. The EU needs an adapted framework for safe NGT plants benefitting farmers, consumers, and the environment.

CONTENT: the Commission is proposing this draft regulation to establish a regulatory framework for NGT plants, and their products. It proposes different procedures for the placing on the market of NGT plants.

The main objectives of the proposal are:

- maintaining a high level of protection of health and the environment;

- steering developments towards contribution to sustainability goals in a wide range of plant species, especially for the agri-food system;

- creating an enabling environment for research and innovation, especially for SMEs.

This proposal only concerns plants produced by targeted mutagenesis and cisgenesis and their food and feed products. Targeted mutagenesis induces mutations in the genome without insertion of foreign genetic material (e.g., changes are made within the same plant species). Cisgenesis is an insertion of genetic material into a recipient organism from a donor that is sexually compatible with the recipient organism (e.g., changes are made between naturally compatible plants).

The proposal does not include plants obtained by NGTs that introduce genetic material from a non-crossable species (transgenesis). Such techniques remain subject to the existing GMO legislation.

More specifically, the proposal seeks to:

- establish two categories of plants obtained by NGTs. Both categories will be subject to different requirements to reach the market taking into account their different characteristics and risk profiles.

1. Category 1 NGT plants: NGT plants comparable to naturally occurring or conventional plants. The plants from the first category will need to be notified. Information on category 1 NGT plants would be provided through the labelling of seeds, in a public database and through the relevant catalogues on plant varieties.

2. Category 2 NGT plants: NGT plants with more complex modifications. The plants from the second category will go through the more extensive process of the GMO directive. They would be subject to risk assessment and authorisation before could be put on the market. They would be traced and labelled as GMOs, with the possibility of a voluntary label to indicate the purpose of the genetic modification. The risk assessment, detection method and monitoring requirements would be adapted to different risk profiles and regulatory incentives would be available for NGT plants featuring traits that can:

- contribute to sustainability goals;

- give incentives to steer the development of plants towards more sustainability;

- ensure transparency about all NGT plants on the EU market (for e.g., through labelling of seeds);

- offer robust monitoring of economic, environmental and social impacts of NGT products.

Budgetary implications

Overall, the proposal will be budget neutral. The costs of this proposal, estimated at EUR 2.434 million will be fully covered by redeployments within existing financial envelopes of the current MFF.

The budgetary implications are mainly related to additional tasks to be carried out by EFSA in terms of new scientific and administrative tasks as regards the adapted risk assessment, the verification procedure for certain NGT plants and pre-submission advice. The Commission proposes to reinforce the budgetary envelope of EFSA by EUR 2.334 million from the unallocated margin of Heading 2b, which will be compensated through a reduction of the Single Market Programme, whose objectives are directly linked to those of this initiative, resulting in an increase of the unallocated margin of Heading 1.

In addition, new IT tools and database are also needed to implement the legislation. An amount of EUR 100 000 is foreseen under the Single Market Programme to integrate the NGT plants/products in the already existing Food Innovation Platform (FIP) and E-Submission Food Chain (ESFC) system.

Plants obtained by certain new genomic techniques and their food and feed

The Committee on the Environment, Public Health and Food Safety adopted the report by Jessica POLFJÄRD (EPP, SE) on the 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.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Subject

The Regulation should establish, in accordance with the precautionary principle, specific rules applicable to the deliberate release into the environment, for any purpose other than placing on the market, of plants obtained through certain new genomic techniques ('NTG plants') and to the placing on the market of food and feed consisting of, containing or produced from such plants as well as products, other than food and feed, consisting of or containing such plants.

The Regulation should ensure a high level of protection of human and animal health and the environment.

Status of category 1 NGT plants

The Commission is empowered to adopt delegated acts amending the criteria of equivalence of NGT plants to conventional plants in order to adapt them to scientific and technological progress as regards the types and extent of modifications which can occur naturally or through

conventional breeding.

The amended text stated that the adventitious or technically unavoidable presence of category 1 NGT plants, reproductive material or parts thereof in organic production, or in nonorganic products authorised in organic production in accordance with Regulation (EU) 2018/848 on organic production and labelling of organic products, should not constitute non-compliance with that Regulation.

Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products

The implementation, enforcement and application of this Regulation should not have the object or effect of preventing or impeding imports from third countries of NGT plants and products that meet the same standards as those laid down in this Regulation.

Labelling

The amended text stated that plant reproductive material, including for breeding and scientific purposes that contains or consists of category 1 NGT plant or plants and is made available to third parties, whether in return for payment or free of charge, should bear a label and a reference to a variety register automatically transmitted to the EU common register indicating the words cat 1 NGT, followed by the identification number of the NGT plant or plants it has been derived from.

Exclusion from patentability

A new article has been included stipulating that NGT plants, plant material, parts thereof, genetic information and the process features they contain should not be patentable.

Ensuring science-based verification processes

The proposed regulation also introduces verification procedures for NGT 1 prior to the deliberate release of plants for this category.

The report noted that the verification process should be based on the scientifically approved criteria set out in the annex defining a category 1 plant and, where appropriate, in close consultation with the European Commission and the European Food Safety Authority.

It is stated that the other Member States and the Commission may make reasoned objections to the verification report, as regards the fulfilment of the criteria set out in Annex I, within 20 days from the date of receipt of that report.

Reporting

The implementation report should identify and address any issues regarding biodiversity and environmental, human and animal health, changes to agronomic practices as well as socio-economic and ethical issues that may have arisen with the application of this Regulation.

By June 2025, the Commission should submit a report on the role and impact of patents on breeders' and farmers' access to varied plant reproductive material, as well as on innovation and, in particular, on opportunities for SMEs.

Plants obtained by certain new genomic techniques and their food and feed

The European Parliament adopted by 307 votes to 263, with 41 abstentions, amendments on the 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.

The matter was referred back to the committee responsible for inter-institutional negotiations.

Subject matter

This proposed regulation, in accordance with the precautionary principle, lays down specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by certain new genomic techniques (NGT plants) and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants, ensuring a high level of protection of human and animal health and the environment.

Release

An NTG plant may only be deliberately released into the environment for purposes other than placing on the market, and an NTG product may only be placed on the market if:

- the plant is a category 1 NTG plant that has been the subject of a decision declaring this status;

- the plant is a category 2 NGT plant, and has been granted consent or has been authorised.

Ban on all patents filed for NGT plants

Members included a new article stating that NGT plants, plant material, parts thereof, genetic information and the process features they contain should not be patentable. They also request a report by June 2025 on the impact of patents on breeders' and farmers' access to varied plant reproductive material as well as a legislative proposal to update EU rules on intellectual property rights accordingly.

NGT 1 plants

A NGT plant is considered equivalent to conventional plants if certain conditions are met. Members, therefore, amend the rules concerning the size and number of modifications needed for a NGT plant to be considered equivalent to conventional plants. The Commission should establish and maintain a database listing the decisions declaring the category 1 NGT plant status.

Members called for the database to be publicly available, and in an online format.

Seven years after the entry into force of this Regulation, the Commission should present a report on the evolution of the consumers' and producers' perception, accompanied, where appropriate, by a legislative proposal.

Labelling

According to Members, category 1 NGT plants should bear a label indicating the words New Genomic Techniques. In the case of plant reproductive material, it should be followed by the identification number of the NGT plant(s) it has been derived from.

Appropriate document-based traceability for NGTs should be provided by the transmission and holding of information that products contain or consist of NGT plants and product, and the unique codes for those NGTs, at each stage of their placing on the market.

Verification procedure of category 1 NGT plant status

To obtain the declaration of category 1 NGT plant status, before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release should submit a request to verify whether the criteria set out in Annex I at least one of the traits referred to in Annex III, Part 1, and the exclusion criteria in Annex III, Part 2, are met.

That request should contain information on:

- a description of the trait or traits and characteristics which have been introduced or modified, including information on the technique or techniques used to obtain the trait or the traits and including disclosure of the sequence of genetic modification;

- any patent or pending application for a patent that covers the whole or part of Cat.1 NGT plant.

The other Member States and the Commission may make reasoned objections to the verification report, as regards the fulfilment of the criteria set out in Annex I, within 20 days from the date of receipt of that report. In the absence of any reasoned scientific objections from a Member State or the Commission, within this deadline, the national competent authority that prepared the verification report should adopt a decision declaring whether the NGT plant is a category 1 NGT plant. The national competent authority should transmit the decision within 10 working days to the requester, the other Member States and the Commission.

In cases where a reasoned objection is made by another Member State or by the Commission, the competent authority that prepared the verification report should make the reasoned objections publicly available without undue delay.

If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports this hypothesis, the competent authority may withdraw its decision declaring whether the NGT plant is a category 1 NGT plant.

Organic production

Category 2 NGT plants will be banned in organic production. However, it is necessary to clarify the status of category 1 NGT plants for the purposes of organic production.

Currently, the compatibility of the use of new genomic techniques with the principles of organic production requires further consideration. The

use of category 1 NGT plants should therefore be prohibited in organic production, until such further consideration takes place.

The amended text stipulated that the adventitious or technically unavoidable presence of category 1 NGT plants, reproductive material or parts thereof in organic production, or in non-organic products authorised in organic production in accordance with Regulation (EU) 2018/848, should not constitute non-compliance with that Regulation.

NGT 2 plants

For NGT 2 plants, Members agreed to maintain most of the requirements of the GMO legislation, which is among the strictest in the world, including the authorisation procedure.

In view of the precautionary principle, a monitoring plan for environmental effects should always be required when consent is first given. It should only be possible to waive the requirement for monitoring upon the renewal of consent, provided that it has been demonstrated that the category 2 NGT plant does not pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.

Transparency

POLFJÄRD Jessica	Rapporteur	ENVI	02/02/2024	UK Mission to the European Union
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	23/01/2024	KeyGene
CLERGEAU Christophe	Shadow rapporteur	ENVI	11/01/2024	Confédération paysanne
CHRISTENSEN Asger	Shadow rapporteur for opinion	AGRI	10/01/2024	Novozymes A/S
CLERGEAU Christophe	Shadow rapporteur	ENVI	15/12/2023	Corporate Europe Observatory Fédération Nature et Progrès Greenpeace European Unit
CHRISTENSEN Asger	Shadow rapporteur for opinion	AGRI	12/12/2023	Inari Agriculture NV
HUITEMA Jan	Shadow rapporteur	ENVI	06/12/2023	Permanent Representative of Denmark to the EU
CLERGEAU Christophe	Shadow rapporteur	ENVI	06/12/2023	COPA-COGECA
LINS Norbert	Committee chair	AGRI	06/12/2023	International Federation of Organic Agriculture Movements EU Regional Group
POLFJÄRD Jessica	Rapporteur	ENVI	05/12/2023	Copa Cogeca
LUENA César	Member	21/03/2024	Greenpeace European Unit	
LINS Norbert	Member	05/02/2024	dm-drogerie markt GmbH + Co. KG Frosta AG Andechser Molkerei Scheitz GmbH Bioland e.V. IFOAM Organics Europe	
ARIMONT Pascal	Member	05/02/2024	Fédération Nature et Progrès	
LUTGEN Benoît	Member	05/02/2024	Virginie Pissoort	

FRANSSEN Cindy	Member	24/01/2024	VARIO - Vlaamse Adviesraad voor Innoveren en Ondernemen	
LUENA César	Member	23/01/2024	ASAJA	
	Member	23/01/2024	Eurodom	
DE LANGE Esther	Member	23/01/2024	Glastuinbouw Nederland	
LIMMER Sylvia	Member	18/01/2024	IFOAM Organics Europe/ Bioland e.V.	
COLIN-OESTERLÉ Nathalie	Member	17/01/2024	Union française des semenciers (UFS)	