




Basic information	
<p>2023/0226(COD)</p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p>	Awaiting Council's 1st reading position
<p>Plants obtained by certain new genomic techniques and their food and feed</p> <p>Amending Regulation 2017/625 2013/0140(COD)</p> <p>Subject</p> <p>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</p> <p>Legislative priorities</p> <p>Joint Declaration 2023-24</p>	

Key players				
European Parliament	Committee responsible		Rapporteur	Appointed
	ENVI Environment, Climate and Food Safety		POLFJÄRD Jessica (EPP)	24/07/2024
			Shadow rapporteur	
			CLERGEAU Christophe (S&D)	
			SARDONE Silvia (P/E)	
			HAZEKAMP Anja (The Left)	
	Former committee responsible		Former rapporteur	Appointed
	ENVI Environment, Climate and Food Safety			
	Former committee for opinion		Former rapporteur for opinion	Appointed
	AGRI Agriculture and Rural Development (Associated committee)			
Council of the European Union				
European Commission	Commission DG		Commissioner	
	Health and Food Safety		KYRIAKIDES Stella	

Key events

Date	Event	Reference	Summary
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	CRE link	
07/02/2024	Decision by Parliament, 1st reading	T9-0067/2024	Summary
07/02/2024	Results of vote in Parliament		
07/02/2024	Matter referred back to the committee responsible for interinstitutional negotiations		
24/04/2024	Decision by Parliament, 1st reading	T9-0325/2024	Summary
24/04/2024	Results of vote in Parliament		
13/11/2024	Committee referral announced in Parliament, 1st reading		

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_o Treaty on the Functioning of the EU TFEU 043 Treaty on the Functioning of the EU TFEU 168-p4 Treaty on the Functioning of the EU TFEU 114
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

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE754.658	25/10/2023	
Amendments tabled in committee		PE756.106	14/11/2023	

Amendments tabled in committee		PE755.986	19/11/2023	
Amendments tabled in committee		PE756.242	19/11/2023	
Amendments tabled in committee		PE756.244	19/11/2023	
Amendments tabled in committee		PE756.243	19/11/2023	
Amendments tabled in committee		PE754.735	23/11/2023	
Committee opinion	AGRI	PE757.371	08/01/2024	
Committee report tabled for plenary, 1st reading/single reading		A9-0014/2024	29/01/2024	Summary
Text adopted by Parliament, partial vote at 1st reading /single reading		T9-0067/2024	07/02/2024	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0325/2024	24/04/2024	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2023)0411 	05/07/2023	Summary
Document attached to the procedure	SWD(2023)0411 	06/07/2023	
Document attached to the procedure	SEC(2023)0411 	06/07/2023	
Document attached to the procedure	SWD(2023)0412 	06/07/2023	
Document attached to the procedure	SWD(2023)0413 	06/07/2023	
Commission response to text adopted in plenary	SP(2024)394	08/08/2024	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	NL_SENATE	COM(2023)0411	25/10/2023	
Contribution	PT_PARLIAMENT	COM(2023)0411	27/10/2023	
Reasoned opinion	CY_PARLIAMENT	PE756.210	20/11/2023	
Reasoned opinion	HU_PARLIAMENT	PE756.209	20/11/2023	
Contribution	RO_SENATE	COM(2023)0411	20/11/2023	
Contribution	DK_PARLIAMENT	COM(2023)0411	22/11/2023	
Contribution	HR_PARLIAMENT	COM(2023)0411	27/11/2023	
Contribution	CZ_SENATE	COM(2023)0411	04/12/2023	
Contribution	IT_SENATE	COM(2023)0411	14/12/2023	
Contribution	IT_CHAMBER	COM(2023)0411	07/02/2024	
Contribution	FR_SENATE	COM(2023)0411	03/04/2024	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofR	Committee of the Regions: opinion	CDR4545/2023	17/04/2024	

Additional information

Source	Document	Date
EP Research Service	Briefing	28/05/2024

Meetings with interest representatives published in line with the Rules of Procedure

Rapporteurs, Shadow Rapporteurs and Committee Chairs

Name	Role	Committee	Date	Interest representatives
CLERGEAU Christophe	Shadow rapporteur	ENVI	19/11/2024	Testbiotech
POLFJÄRD Jessica	Rapporteur	ENVI	18/09/2024	Euroseeds
CLERGEAU Christophe	Rapporteur	ENVI	24/04/2024	Akiko Frid Chloe Mathurin Mute Schimpf June Rebekka bresson Peter Sudovský Gebhard Rossmannith Hervé le Meur Eva Corral Astrid Osterreicher Diederick Sprangers Fukumoto Shuhei Guy Kastler Maria Zintl Claire Robinson Nina Holland
CLERGEAU Christophe	Rapporteur	ENVI	04/04/2024	Akiko Frid Chloe Mathurin Mute Schimpf June Rebekka bresson Peter Sudovský Gebhard Rossmannith Hervé le Meur Eva Corral Astrid Osterreicher Diederick Sprangers Fukumoto Shuhei Guy Kastler Maria Zintl Claire Robinson Nina Holland
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
LINS Norbert	Committee chair	AGRI	30/11/2023	IG Saatgut
POLFJÄRD Jessica	Rapporteur	ENVI	30/11/2023	Permanent Representation of the Czech Republic to the European Union
LINS Norbert	Committee chair	AGRI	29/11/2023	Bund Ökologische Lebensmittelwirtschaft e.V.
LINS Norbert	Committee chair	AGRI	29/11/2023	Testbiotech
OLEKAS Juozas	Rapporteur for opinion	AGRI	29/11/2023	Plants for the Future European Technology Platform
LINS Norbert	Committee chair	AGRI	23/11/2023	International Federation of Organic Agriculture Movements EU Regional Group
VRECIKOVÁ Veronika	Rapporteur	ENVI	22/11/2023	Euroseeds
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	22/11/2023	Euroseeds
CHRISTENSEN Asger	Shadow rapporteur for opinion	AGRI	17/11/2023	DAKOFO
CHRISTENSEN Asger	Shadow rapporteur for opinion	AGRI	16/11/2023	Bayer AG
HUITEMA Jan	Shadow rapporteur	ENVI	16/11/2023	Covestro AG
HUITEMA Jan	Shadow rapporteur	ENVI	14/11/2023	Coöperatieve Vereniging Bionext UA
POLFJÄRD Jessica	Rapporteur	ENVI	14/11/2023	Permanent Representation of Denmark to The European Union
POLFJÄRD Jessica	Rapporteur	ENVI	14/11/2023	CEJA - European council of young farmers
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	14/11/2023	COCERAL
POLFJÄRD Jessica	Rapporteur	ENVI	13/11/2023	Corteva Agriscience International SARL
POLFJÄRD Jessica	Rapporteur	ENVI	09/11/2023	Lantbrukarnas Riksförbund
POLFJÄRD Jessica	Rapporteur	ENVI	08/11/2023	Svenska Livsmedelsföretagen
ŠOJDROVÁ Michaela	Shadow rapporteur for opinion	AGRI	08/11/2023	Plants for the Future European Technology Platform
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	07/11/2023	EuropaBio
HUITEMA Jan	Shadow rapporteur	ENVI	07/11/2023	Bayer AG
POLFJÄRD Jessica	Rapporteur	ENVI	06/11/2023	Permanent representation of Belgium to the EU
CHRISTENSEN Asger	Shadow rapporteur for opinion	AGRI	06/11/2023	Novo Nordisk Foundation
HUITEMA Jan	Shadow rapporteur	ENVI	06/11/2023	Permanent Representation of Finland to the EU

CHRISTENSEN Asger	Shadow rapporteur for opinion	AGRI	03/11/2023	Landbrug & Fødevarer - Danish Agriculture and Food Council
CHRISTENSEN Asger	Shadow rapporteur for opinion	AGRI	03/11/2023	Dansk Planteværn
CHRISTENSEN Asger	Shadow rapporteur for opinion	AGRI	03/11/2023	Inari Agriculture NV
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	02/11/2023	Biodynamic Federation Demeter International e.V.
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	26/10/2023	European Non-GMO Industry Association, AISBL
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	26/10/2023	IFOAM
CLERGEAU Christophe	Shadow rapporteur	ENVI	26/10/2023	Biodynamic Federation Demeter International e.V. European Coordination Via Campesina Friends of the Earth Europe Greenpeace European Unit POLLINIS FRANCE Verbraucherzentrale Bundesverband Kammer für Arbeiter und Angestellte GLS Save our Seeds
CLERGEAU Christophe	Shadow rapporteur	ENVI	26/10/2023	Universiteit Maastricht
CLERGEAU Christophe	Shadow rapporteur	ENVI	26/10/2023	ALTERMIND BASF SE Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofouritures de l'U.E. CropLife Europe EPPA SA European agri-cooperatives European farmers Euroseeds
CHRISTENSEN Asger	Shadow rapporteur for opinion	AGRI	24/10/2023	Confederation of Danish Industry
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	24/10/2023	Testbiotech
HUITEMA Jan	Shadow rapporteur	ENVI	24/10/2023	Bayer AG CropLife Europe
HUITEMA Jan	Shadow rapporteur	ENVI	24/10/2023	Friends of the Earth Europe
HUITEMA Jan	Shadow rapporteur	ENVI	24/10/2023	IFOAM
ŠOJDROVÁ Michaela	Shadow rapporteur for opinion	AGRI	23/10/2023	European Sustainable Agriculture through Genome Editing
HUITEMA Jan	Shadow rapporteur	ENVI	18/10/2023	KMC
SARDONE Silvia	Shadow rapporteur	ENVI	17/10/2023	COCERAL
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	17/10/2023	CESPU - European Potato Starch Producers
POLFJÄRD Jessica	Rapporteur	ENVI	11/10/2023	KWS SAAT SE & Co. KGaA
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	11/10/2023	Novozymes A/S
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	11/10/2023	KWS
HUITEMA Jan	Shadow rapporteur	ENVI	06/10/2023	COCERAL
OLEKAS Juozas	Shadow rapporteur for opinion	AGRI	05/10/2023	Inari Agriculture NV Rud Pedersen Public Affairs Brussels
ŠOJDROVÁ Michaela	Shadow rapporteur for opinion	AGRI	03/10/2023	Inari Agriculture NV

HUITEMA Jan	Shadow rapporteur	ENVI	28/09/2023	Inari Agriculture NV
HUITEMA Jan	Shadow rapporteur	ENVI	26/09/2023	Deutscher Bauernverband
HUITEMA Jan	Shadow rapporteur	ENVI	26/09/2023	EuropaBio
POLFJÄRD Jessica	Rapporteur	ENVI	26/09/2023	Euroseeds
ŠOJDROVÁ Michaela	Shadow rapporteur for opinion	AGRI	21/09/2023	Corteva Agriscience International SARL
HUITEMA Jan	Shadow rapporteur	ENVI	20/09/2023	Covestro AG
HUITEMA Jan	Shadow rapporteur	ENVI	18/09/2023	KMC
CLERGEAU Christophe	Shadow rapporteur	ENVI	08/09/2023	Institut national de recherche pour l'agriculture, l'alimentation et l'environnement
CLERGEAU Christophe	Shadow rapporteur	ENVI	07/09/2023	European Coordination Via Campesina
CLERGEAU Christophe	Shadow rapporteur	ENVI	07/09/2023	International Federation of Organic Agriculture Movements EU Regional Group
CLERGEAU Christophe	Shadow rapporteur	ENVI	07/09/2023	Synabio
POLFJÄRD Jessica	Rapporteur	ENVI	06/09/2023	European Commission

Other Members

Name	Date	Interest representatives
HAYER Valérie	02/10/2024	Phyteis (ex Union de l'Industrie de la Protection des Plantes)
VAN BREMPT Kathleen	05/04/2024	Biotech lab KUL
LUENA César	21/03/2024	Greenpeace European Unit
LUTGEN Benoît	05/02/2024	Virginie Pissoot
ARIMONT Pascal	05/02/2024	Fédération Nature et Progrès
LINS Norbert	05/02/2024	dm-drogerie markt GmbH + Co. KG Frosta AG Andechser Molkerei Scheitz GmbH Bioland e.V. IFOAM Organics Europe
FRANSSEN Cindy	24/01/2024	VARIO - Vlaamse Adviesraad voor Innoveren en Ondernemen
LUENA César	23/01/2024	ASAJA
DE LANGE Esther	23/01/2024	Glastuinbouw Nederland
SAILLIET Laurence	23/01/2024	Eurodom
LIMMER Sylvia	18/01/2024	IFOAM Organics Europe/ Bioland e.V.
SAILLIET Laurence	17/01/2024	Union française des semenciers,
COLIN-OESTERLÉ Nathalie	17/01/2024	Union française des semenciers (UFS)
LUCKE Karsten	15/01/2024	Arbeitsgruppe ökologischer Landbau RLP / Saar & Arbeitsgemeinschaft biologische Landwirtschaft
VANDENKENDELAERE Tom	09/01/2024	BASF SE
LUCKE Karsten	09/01/2024	Testbiotech
VANDENKENDELAERE Tom	08/01/2024	Euroseeds Penta (formerly Hume Brophy) The American Seed Trade Association
LIESE Peter	18/12/2023	Deutscher Bauernverband

LINS Norbert	14/12/2023	Naturland e.V. Bioland Demeter
MÜLLER Ulrike	13/12/2023	CropLife Europe
LINS Norbert	13/12/2023	CropLife Europe Green Biotech Europe Syngenta Agro GmbH
POULSEN Erik	12/12/2023	Inari Agriculture NV
SCHNEIDER Christine	12/12/2023	Inari Agriculture NV
DECERLE Jérémy	08/12/2023	Limagrain
DECERLE Jérémy	07/12/2023	Avril
ARA-KOVÁCS Attila	07/12/2023	National Society of Conservationists -Friends of the Earth Hungary (Magyar Termeszettvedok Szovetsege)
DE MEO Salvatore	06/12/2023	Corteva Agriscience International SARL
LUCKE Karsten	05/12/2023	Deutsche Forschungsgemeinschaft
LINS Norbert	29/11/2023	Organic Processing and Trade Association Europe e.V. AöL
LINS Norbert	29/11/2023	Biodynamic Federation Demeter International e.V.
POULSEN Erik	27/11/2023	Euroseeds The American Seed Trade Association
TORVALDS Nils	22/11/2023	Fediol
LUENA César	21/11/2023	Euroseeds
SKYTTEDAL Sara	17/11/2023	LRF
LIMMER Sylvia	15/11/2023	IFOAM Organics Europe/ Bioland e.V.
NOICHL Maria	15/11/2023	European Non-GMO Industry Association, AISBL
MESURE Marina	14/11/2023	France Nature Environnement
BERNHUBER Alexander	14/11/2023	ARCHE NOAH, Gesellschaft für die Erhaltung der Kulturpflanzenvielfalt und ihre Entwicklung
WIEZIK Michal	14/11/2023	Obianska iniciativa Slovensko bez GMO
MÜLLER Ulrike	14/11/2023	The EU Vegetable Oil and Proteinmeal Industry
GLÜCK Andreas	13/11/2023	Bayer AG
GLÜCK Andreas	10/11/2023	Deutscher Bauernverband
LINS Norbert	07/11/2023	COCERAL
MÜLLER Ulrike	07/11/2023	International Federation of Organic Agriculture Movements EU Regional Group
BERNHUBER Alexander	06/11/2023	IFOAM
LINS Norbert	06/11/2023	Deutscher Bauernverband
MESURE Marina	03/11/2023	Bio de Provence
LIESE Peter	02/11/2023	Internationale Vereinigung der ökologischen Landbaubewegungen
MESURE Marina	30/10/2023	POLLINIS FRANCE
SAILLIET Laurence	27/10/2023	POLLINIS FRANCE
SIDL Günther	25/10/2023	Testbiotech
LINS Norbert	24/10/2023	KWS SAAT SE & Co. KGaA
TORVALDS Nils	18/10/2023	Stora Enso Oyj
LINS Norbert	17/10/2023	BASF SE
ORVILLE Max	19/09/2023	Corteva Agriscience International SARL
SCHREIJER-PIERIK Annie	19/09/2023	Corteva Agriscience International SARL
GUSMÃO José	07/09/2023	Plataforma Transgênicos Fora

AGUILERA Clara	07/09/2023	Ecologistas en Accion
BERNHUBER Alexander	06/09/2023	GLOBAL 2000, Friends of the Earth Austria
ORVILLE Max	05/09/2023	EURODOM
POULSEN Erik	17/08/2023	Økologisk Landsforening/Organic Denmark
SCHNEIDER Christine	19/07/2023	Green Biotech Europe
TORVALDS Nils	17/07/2023	CropLife Europe
ORVILLE Max	12/07/2023	Corteva Agriscience International SARL
BERNHUBER Alexander	11/07/2023	CropLife Europe
ARENA Maria	11/05/2023	Inari Agriculture NV

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

2023/0226(COD) - 29/01/2024 - Committee report tabled for plenary, 1st reading/single reading

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

2023/0226(COD) - 24/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 336 votes to 238, with 41 abstentions, a legislative resolution 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 European Parliament's position adopted at first reading under the ordinary legislative procedure amends the proposal as follows:

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.

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.

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.

Verification procedure of category 1 NGT plant status before undertaking a deliberate release for any other purpose than placing on the market

The person intending to undertake the deliberate release should submit a request which 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.

Where a declaration of Category 1 NTG plant status has not yet been made, the person intending to place an NTG product on the market should submit an application for verification to the Authority, including the denomination of the variety and a monitoring plan for environmental effects.

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.

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

2023/0226(COD) - 05/07/2023 - Legislative proposal

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

2023/0226(COD) - 07/02/2024 - Text adopted by Parliament, partial vote at 1st reading/single reading

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.