












Procedure file

| Basic information | |
|---|---|
| COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 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 Parliament's position in 1st reading |

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

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 | |
| 07/02/2024 | Matter referred back to the committee responsible | | |

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 | Treaty on the Functioning of the EU TFEU 043; Treaty on the Functioning of the EU TFEU 114; Rules of Procedure EP 57; Treaty on the Functioning of the EU TFEU 168-p4 |
| Mandatory consultation of other institutions | European Economic and Social Committee European Committee of the Regions |
| Stage reached in procedure | Awaiting Parliament's position in 1st reading |
| 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 | |

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.

| | | | | |
|----------------------------|-------------------------------|------------|--|--|
| 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 | 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) | |
| | | | | |

| | | | | |
|--|--------|------------|------------------------------------|--|
| | Member | 17/01/2024 | Union française des semenciers, | |
|--|--------|------------|------------------------------------|--|