



2023/0226(COD)

30.4.2026

AMENDMENTS

1 - 16

Draft recommendation for second reading

Jessica Polfjärd

(PE787.765v01-00)

Plants obtained by certain new genomic techniques and their food and feed,
and amending Regulation (EU) 2017/625

Council position at first reading

(17037/25 -- C10-0102/2026 – 2023/0226(COD))

Amendment 1
Christophe Clergeau on behalf of the S&D group

Council position
Article 4a(new)

Council position

Amendment

Article 4a (new)

***Incidental and accidental presence of
patented NGT material***

- 1. The protection conferred by a patent on NGT biological material shall not apply in the case of the incidental or accidental presence of patented genetic information in seeds, plant propagation materials, plants and parts of plants.***
- 2. In any proceedings concerning alleged patent infringement involving NGT biological material, the patent holder shall bear the full burden of proof to demonstrate intentional use or deliberate incorporation of the patented material by the farmer, and the mere presence of patented biological material shall not in itself constitute evidence of infringement.***

Or. en

Justification

This amendment aims to reach a compromise between the Council and Parliament. This amendment protects farmers from legal proceedings in cases of incidental or accidental presence of patented NGT material in their fields or products. Farmers should not be held liable or bear the burden of proof for unintended contamination beyond their control, in line with existing legal approaches in several Member States.

Amendment 2
Christophe Clergeau on behalf of the S&D group

Council position
Article 6 – paragraph 3 - point da(new)

Council position

Amendment

(da) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the category 1 NGT plant. In cases where it is not feasible to provide an analytical method that identifies and quantifies, if duly justified by the person intending to undertake such a deliberate release, the modalities to comply with analytical method performance requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (c)

Or. en

Justification

This amendment aims to reach a compromise between the Council and Parliament on the issue of traceability of NGTs. This amendment ensures the technical traceability of NGTs through the publication of detection, identification and quantification methods. This is the minimum requirement to enable monitoring of NGTs, support transparency and allow operators wishing to maintain NGT-free supply chains to do so. It provides the necessary technical basis for competent authorities to detect and verify the presence of NGT material in the context of official controls.

Amendment 3
Christophe Clergeau on behalf of the S&D group

Council position
Article 7 – paragraph 2 - point da(new)

Council position

Amendment

(da) methods for sampling (including references to existing official or standardised

sampling methods), detection, identification and quantification of the category 1 NGT plant. In cases where it is not feasible to provide an analytical method that identifies and quantifies, if duly justified by the person intending to undertake such a deliberate release, the modalities to comply with analytical method performance requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (c)

Or. en

Justification

This amendment aims to reach a compromise between the Council and Parliament on the issue of traceability of NGTs. This amendment ensures the technical traceability of NGTs through the publication of detection, identification and quantification methods. This is the minimum requirement to enable monitoring of NGTs, support transparency and allow operators wishing to maintain NGT-free supply chains to do so. It provides the necessary technical basis for competent authorities to detect and verify the presence of NGT material in the context of official controls.

Amendment 4 **Christophe Clergeau on behalf of the S&D group**

Council position **Article 9 – paragraph 1 - point da(new)**

Council position

Amendment

(da) methods for sampling, detection, identification and quantification as referred to in Article 6(3) and Article 7(2);

Or. en

Justification

This amendment aims to reach a compromise between the Council and Parliament on the issue of traceability of NGTs. This amendment ensures the technical traceability of NGTs through the publication of detection, identification and quantification methods. This is the minimum requirement to enable monitoring of NGTs, support transparency and allow operators wishing to maintain NGT-free supply chains to do so. It provides the necessary technical basis for competent authorities to detect and verify the presence of NGT material in the context of official controls.

Amendment 5
Christophe Clergeau on behalf of the S&D group

Council position
Article 27 – point c

Council position

(c) adapted arrangements for complying with analytical method performance requirements referred to in Article 14(1), point (1), and Article 20(2).

Amendment

(c) adapted arrangements for complying with analytical method performance requirements referred to in **Article 6(3), point (da), Article 7(2), point (da)** Article 14(1), point (1), and Article 20(2).

Or. en

Justification

This amendment aims to reach a compromise between the Council and Parliament on the issue of traceability of NGTs. This amendment ensures the technical traceability of NGTs through the publication of detection, identification and quantification methods. This is the minimum requirement to enable monitoring of NGTs, support transparency and allow operators wishing to maintain NGT-free supply chains to do so. It provides the necessary technical basis for competent authorities to detect and verify the presence of NGT material in the context of official controls.

Amendment 6
Christophe Clergeau on behalf of the S&D group

Council position
Article 37a(new) – paragraph 1

Council position

Amendment

Article 37a
Amendments to Directive 98/44/EC¹

1. **Article 4 of Directive 98/44/EC on the legal protection of biotechnological inventions is amended as follows:**

(a) **In paragraph 1, the following points are added:**
‘(c) NGT plants, plant material, parts thereof, genetic

information and process features they contain, as defined in Regulation (EU) .../... [O.J. please insert the number of this Regulation];

(d) plants, plant material, parts thereof, genetic information and process features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B to that directive.'

(b) the following paragraph 4 is added:

'4. Paragraphs 2 and 3 shall be without prejudice to the exclusions from patentability covered in paragraph 1.'

Or. en

Justification

This amendment aims to restore wholly or partly the position adopted by Parliament at its first reading. This amendment will help farmers and SME seed companies by preventing exclusive control of key plant traits by patent holders and providing absolute legal certainty. It keeps seeds accessible for breeders and farmers, and supports fair innovation.

Amendment 7

Christophe Clergeau on behalf of the S&D group

Council position

Article 37a(new) – paragraph 2

Council position

Amendment

- 2. In Article 8 of Directive 98/44/EC, the following paragraph is added:**
- '3. By way of derogation from**

paragraphs 1 and 2, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological material possessing the same characteristics that is obtained independently of the patented biological material and from essentially biological processes, or to biological material obtained from such material through propagation or multiplication.'

3. *In Article 9 of Directive 98/44/EC, the following paragraphs are added:*
 2. *By way of derogation from paragraph 1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.*
 3. *By way of derogation from paragraph 1, the protection conferred by a patent on a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which*

can be obtained by an essentially biological process.

4. *The protection conferred by a patent on a technical process that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.'*

Or. en

Justification

This amendment aims to restore wholly or partly the position adopted by Parliament at its first reading. The amendment limits exclusive rights over plant patents where traits occur in nature or can result from conventional breeding methods such as crossing and selection. Such traits should remain freely accessible to breeders and farmers. Patent protection should apply only to traits not obtainable through natural processes. The amendment supports innovation, competition and farmers' rights, and is compatible with the European Patent Convention.

Amendment 8

Christophe Clergeau on behalf of the S&D group

Council position

Article 30 – paragraph 1

Council position

The Commission, in cooperation with the Member States, shall ***oversee the drawing-up*** of a code of conduct at Union level to enhance the transparency of information relating to patents on plant biological material, to facilitate breeders' access to such material and to enhance legal certainty for breeders and farmers ('code of

Amendment

The Commission, in cooperation with the Member States, shall ***draw-up*** of a code of conduct at Union level to enhance the transparency of information relating to patents on plant biological material, to facilitate breeders' access to such material and to enhance legal certainty for breeders

conduct’).

and farmers (‘code of conduct’).

Or. en

Justification

This amendment amends a part of the text of a Council position which was not included in - or differs in content from - the proposal submitted at first reading. This amendment strengthens the code of conduct and licensing platform framework to ensure fair and non-discriminatory access to patented genetic resources, in particular for SMEs, breeders and farmers, while improving legal certainty and preventing market concentration.

Amendment 9

Christophe Clergeau on behalf of the S&D group

Council position

Article 30 – paragraph 3 – introductory part

Council position

The Commission shall aim that the code of conduct include the following commitments by patent owners:

Amendment

The code of conduct **shall** include the following commitments by patent owners:

Or. en

Justification

This amendment amends a part of the text of a Council position which was not included in - or differs in content from - the proposal submitted at first reading. This amendment strengthens the code of conduct and licensing platform framework to ensure fair, transparent and non-discriminatory access to patented genetic resources, in particular for SMEs, breeders and farmers, while improving legal certainty and preventing market concentration.

Amendment 10

Christophe Clergeau on behalf of the S&D group

Council position

Article 30 – paragraph 3 – point(b)

Council position

(b) arrangements for the licensing of patents under fair and reasonable conditions, **including through the voluntary platforms referred to in**

Amendment

(b) arrangements for the licensing of patents under fair and reasonable conditions,

paragraph 2;

Or. en

Justification

This amendment amends a part of the text of a Council position which was not included in - or differs in content from - the proposal submitted at first reading. This amendment strengthen the code of conduct and licensing platform framework to ensure fair, transparent and non-discriminatory access to patented genetic resources, in particular for SMEs, breeders and farmers, while improving legal certainty and preventing market concentration.

Amendment 11

Christophe Clergeau on behalf of the S&D group

Council position

Article 30 – paragraph 4 – introductory part

Council position

The Commission shall aim that the code of conduct include the following commitments by **voluntary** platforms for the licensing of plant biological material:

Amendment

The code of conduct **shall** include the following commitments by platforms for the licensing of plant biological material:

Or. en

Justification

This amendment amends a part of the text of a Council position which was not included in - or differs in content from - the proposal submitted at first reading. This amendment strengthens the code of conduct and licensing platform framework to ensure fair, transparent and non-discriminatory access to patented genetic resources, in particular for SMEs, breeders and farmers, while improving legal certainty and preventing market concentration.

Amendment 12

Christophe Clergeau on behalf of the S&D group

Council position

Article 30a(new)

Council position

Amendment

Article 30a(new)

Obligations for licencing platforms

and NGT patent holders

1. *Platforms for the licensing of plant biological material operating in the Union shall abide by the code of conduct referred to in Article 30(1).*
2. *Platforms referred to in paragraph 1 shall notify the Commission of measures adopted in their internal rules of procedures to ensure the code of conduct is effectively applied.*
3. *The Commission shall establish a list of the platforms referred to in paragraph 1 and make it available to the public online*
4. *Holders of a patent on an NGT plant biological material covered by a decision declaring the category 1 NGT plant status adopted in accordance with Article 6(12) or (14) or Article 7(10) shall be registered on a platform referred to in paragraph 1.*

Or. en

Justification

This amendment aims to reach a compromise between the Council and Parliament in link with a part of the text of a Council position which was not included in the proposal submitted at first reading. This amendment strengthens the code of conduct and licensing platform framework to ensure fair, transparent and non-discriminatory access to patented genetic resources, in particular for SMEs, breeders and farmers, while improving legal certainty and preventing market concentration.

Amendment 13
Christophe Clergeau on behalf of the S&D group

Council position
Recital 24

Council position

(24) Provision should be made to ensure transparency as regards the use of category

Amendment

(24) Provision should be made to ensure transparency as regards the use of category

1 NGT plant varieties, to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard consumer trust. NGT plants that have obtained a category 1 NGT plant status declaration should be listed in a publicly available database. To ensure traceability, transparency and choice for operators, during research and plant breeding, when selling seed to farmers or making plant reproductive material available to third parties in any other way, plant reproductive material of category 1 NGT plants should be labelled as category 1 NGT.

1 NGT plant varieties, to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard consumer trust. NGT plants that have obtained a category 1 NGT plant status declaration should be listed in a publicly available database ***including information on the technique or techniques used to obtain the trait or traits, as well as detection methods.*** To ensure traceability, transparency and choice for operators, during research and plant breeding, when selling seed to farmers or making plant reproductive material available to third parties in any other way, plant reproductive material of category 1 NGT plants should be labelled as category 1 NGT.

Or. en

Justification

This amendment aims to reach a compromise between the Council and Parliament on the issue of traceability of NGTs. This amendment ensures the technical traceability of NGTs through the publication of detection, identification and quantification methods. This is the minimum requirement to enable monitoring of NGTs, support transparency and allow operators wishing to maintain NGT-free supply chains to do so. It provides the necessary technical basis for competent authorities to detect and verify the presence of NGT material in the context of official controls.

Amendment 14

Christophe Clergeau on behalf of the S&D group

Council position

Recital 60

Council position

(60) The Commission, in cooperation with the Member States, should ***oversee the drawing-up of*** a Union-level code of conduct to support transparency on patents on plant biological material, breeders' access to such material and legal certainty for breeders and farmers. ***The Commission should aim that*** the code of conduct include commitments by patent owners to provide clear and publicly accessible

Amendment

(60) The Commission, in cooperation with the Member States, should ***draw-up*** a Union-level code of conduct to support transparency on patents on plant biological material, breeders' access to such material and legal certainty for breeders and farmers. ***The code of conduct should*** include commitments by patent owners to provide clear and publicly accessible information on patents, to license patents

information on patents, to license patents under fair and reasonable conditions, and to seek the amicable settlement of patent disputes with breeders that are SMEs and with farmers in the case of unintentional **minor** presence of patented biological material in their fields. In the latter case, patent owners could consider refraining from enforcing their patent rights. **The Commission should also aim that** the code of conduct include commitments by **voluntary** licensing platforms to promote cost-attractive participation for SMEs, standard licence agreements and fair mechanisms for resolving disagreements. The Commission should monitor and evaluate the rate of participation in and the functioning of the code of conduct, and, if the evaluation observes constant or aggravated non-compliance with the provisions covered in the code of conduct, it should take appropriate actions including, where appropriate, proposing legislative measures to safeguard the good functioning of the sector, in particular access to patented NGT plant biological material for primary users, including farmers.

under fair and reasonable conditions, and to seek the amicable settlement of patent disputes with breeders that are SMEs and with farmers in the case of unintentional presence of patented biological material in their fields. In the latter case, patent owners could consider refraining from enforcing their patent rights. The code of conduct **should also** include commitments by licensing platforms to promote cost-attractive participation for SMEs, standard licence agreements and fair mechanisms for resolving disagreements. **Moreover to guarantee a fair and non-discriminatory access to patented NGT material, holders of a patent on an NGT plant biological material should be registered on a platform for the licensing of plant biological material abiding by the code of conduct.** The Commission should monitor and evaluate the rate of participation in and the functioning of the code of conduct, and, if the evaluation observes constant or aggravated non-compliance with the provisions covered in the code of conduct, it should take appropriate actions including, where appropriate, proposing legislative measures to safeguard the good functioning of the sector, in particular access to patented NGT plant biological material for primary users, including farmers.

Or. en

Justification

This amendment amends a part of the text of a Council position which was not included in - or differs in content from - the proposal submitted at first reading. This amendment strengthens the code of conduct and licensing platform framework to ensure fair, transparent and non-discriminatory access to patented genetic resources, in particular for SMEs, breeders and farmers, while improving legal certainty and preventing market concentration.

Amendment 15 **Christophe Clergeau on behalf of the S&D group**

Council position

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Recital 65

Council position

(65) In accordance with Directive 98/44/EC, the holder of the patent is to be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products. However, situations where the unintentional or accidental presence of patented biological material of NGT plants occurs during agricultural activity by farmers, as a result of natural self-replication through cross-pollination, are not comparable to the situations that could arise for non-self-reproducing products. ***This is one of the relevant factors when determining whether a patent on an NGT plant has been infringed in such situations. Even if it is concluded that a patent infringement has occurred, Directive 2004/48/EC of the European Parliament and of the Council lays down the framework for the enforcement of intellectual property rights and requires, inter alia, that measures, procedures and remedies provided by Member States be proportionate and applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse. That requirement is to apply when determining the appropriate enforcement measures, procedures and remedies in such situations.***

Amendment

(65) In accordance with Directive 98/44/EC, the holder of the patent is to be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products. However, situations where the unintentional or accidental presence of patented biological material of NGT plants occurs during agricultural activity by farmers, as a result of natural self-replication through cross-pollination, are not comparable to the situations that could arise for non-self-reproducing products. ***Therefore, farmers should not be exposed to legal liability or bear the burden of proof in cases where patented NGT material is present in seeds, plant propagation material or crops as a result of incidental or accidental contamination. Appropriate safeguards are necessary to protect farmers from disproportionate legal risks arising from circumstances beyond their control while ensuring a fair balance between patent protection and agricultural practices.***

Or. en

Justification

This amendment aims to amend a part of the text of the Council position which was not included in the proposal submitted at first reading. Farmers should not be held liable or bear the burden of proof for unintended contamination beyond their control, in line with existing legal approaches in several Member States. Council position is not offering this guarantee as it is only recalling status quo. An explicit safeguard in this Regulation is essential to provide legal certainty and to protect farmers from unjustified litigation.

Amendment 16
Christophe Clergeau on behalf of the S&D group

Council position
Recital 65a

Council position

Amendment

(65a) Patent protection should not extend to plant traits, genetic characteristics or biological material that occur in nature or that can be obtained through essentially biological processes, including conventional breeding methods such as crossing and selection. Granting exclusive rights over such naturally occurring traits would unduly restrict access to genetic resources, hamper innovation and undermine the breeders' exemption.

Or. en

Justification

This amendment aims to reach a compromise between the Council and Parliament. The amendment limits the exclusive rights granted to the holders of plant patents: If the trait occurs in nature or could result from conventional plant breeding like crossing and selection, the plant can be freely used by breeders and farmers. Full protection only applies to traits that could not be derived from natural processes. It supports innovation and competition in the sector and protects farmers. It is compatible with the European Patent Convention.