



2023/0226(COD)

19.5.2026

AMENDMENTS

1 - 37

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

(17037/1/2025 – C10-0102/2026 – 2023/0226(COD))

Amendment 1
Anja Hazekamp

Council position

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Council position

Amendment

The European Parliament rejects the Council position at first reading.

Or. en

Justification

Council's position fails to incorporate important element of the position of the European Parliament, adopted on 7 February 2024 (OJ C, C/2025/3751, 17.9.2025), notably on patents and traceability. It thereby risks jeopardising farmers, consumers and the environment.

Amendment 2
Martin Häusling

Council position

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Council position

Amendment

The European Parliament rejects the Council position at first reading.

Or. en

Justification

By creating a category of NGTs to which apply neither impact assessment, nor traceability, the Council position does not respect the precautionary principle. This is made even more problematic by the unlimited length of the authorizations and the absence of safeguard clause for that category (See Georg Buchholz, 2023, Kommissionsvorschlag einer Verordnung über neue genomische Techniken (NGT): zur Verletzung des Vorsorgeprinzips, as well as the 2018 Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). Furthermore, there is no scientific basis that the list of conditions to determine if a NGT fulfils the criteria of equivalence to conventional plants guarantee a lower level of risks. The Council position also contradicts the Cartagena Protocol on Biosafety, which notably obligates its signatories to clearly identify living modified organisms (including NGT grains) when exporting them to another signatory country, and to carry out risk assessments in a "scientifically sound manner". The Council position completely ignores the specific issues linked to the diffusion of patented material

without proper traceability, or the potential issues linked to coexistence with non NGT productions. Finally, this position decreases drastically the information available to consumers and citizens by exempting NGTs from labelling on products, a rule that is still extremely popular among EU citizens. The extent of the exemptions given to NGTs are not only barely supported by scientific arguments, they are also disproportionate when compared to the alleged benefits of NGTs, the extent of which are extremely difficult to evaluate.

Amendment 3
Anja Hazekamp

Council position
Recital 1 a (new)

Council position

Amendment

(1a) Allowing for new genomic techniques and their results to be patented risks giving multinational seed companies even more power over farmers' access to seeds. In a context where large companies already have a monopoly on seeds and increasingly control natural resources, this would deprive farmers of all freedom of action by making them dependent on private companies. For this reason, patents on these products must be banned.

Or. en

Justification

Reinstates Amendment 167 of the position at first reading, adopted on 5 May 2010 (OJ C 279 E, 30.7.2010). The European Parliament has repeatedly voiced its concerns regarding patentability of plants and genetic traits. The patent framework does not provide sufficient clarity and safeguards on the patentability of genetic traits that may also occur naturally or be achieved through conventional breeding. Concerns relate in particular to access to genetic resources, freedom to operate and possible market concentration in the seed sector.

Amendment 4
Martin Häusling

Council position

Recital 1 a (new)

Council position

Amendment

(1a) Allowing for new genomic techniques and their results to be patented risks giving multinational seed companies even more power over farmers' access to seeds. In a context where large companies already have a monopoly on seeds and increasingly control natural resources, this would deprive farmers of all freedom of action by making them dependent on private companies. For this reason, patents on these products must be banned.

Or. en

Justification

This amendment reflects the Parliament's previously adopted position. The trilogue outcome goes in the opposite direction by allowing patentability of NGTs. This risks disproportionately affecting SMEs due to administrative burdens and licensing costs, while favouring large operators. It may also create legal uncertainty where patented traits occur unintentionally, reducing seed diversity, increasing costs for farmers and hindering innovation.

Amendment 5 Martin Häusling

**Council position
Recital 15 a (new)**

Council position

Amendment

(15a) NGT plants with the potential to persist, reproduce or spread in the environment, within or beyond fields, should be evaluated with the highest level of scrutiny in respect of such plants' impact on nature and the environment.

Or. en

Justification

This amendment reflects the European Parliament's initial position. NGTs are applied in many species, including wild plants native to the EU that can survive, reproduce and spread.

Uncontrolled dissemination may introduce persistent genetic variants with potential impacts on ecosystems, food systems and biodiversity.

Amendment 6
Anja Hazekamp

Council position
Recital 18 a (new)

Council position

Amendment

(18a) The European Parliament has called for the Union and its Member States not to grant patents on biological material and to safeguard the freedom to operate and the breeders' exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT plants, which by definition are not transgenic plants. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (breeder's exemption). As current provisions in patent law do not provide for a full breeder's exemption, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Hence, NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption. NGT plants, their derived seeds, their plant material, associated genetic material such as genes and gene sequences, and plant traits should therefore be excluded from patentability. The exclusion from patentability should be applied in a consistent manner across legislation. Furthermore, in order to avoid patents being granted or patent applications being submitted between the date of the entry into force of this Regulation and the

application of its provisions, it should be ensured that plant material is excluded from patentability from the day of entry into force of this Regulation. For patents already granted or pending patent applications covering plant material, the effects of patents should be further limited. In addition, the Commission should assess and address, in the forthcoming study, how the broader problem of patents being granted, directly or indirectly, on plant material despite previous efforts to close loopholes, should be further addressed. The assessment should address in particular the role and impact of patents on breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, as well as on innovation and in particular on opportunities for SMEs. The report of the Commission should be accompanied by the appropriate legislative proposals in order to ensure further necessary adjustments are made to the intellectual property rights framework.

Or. en

Justification

Reinstates Amendment 23 of the position at first reading, adopted on 5 May 2010 (OJ C 279 E, 30.7.2010). The European Parliament has repeatedly voiced its concerns regarding patentability of plants and genetic traits. The patent framework does not provide sufficient clarity and safeguards on the patentability of genetic traits that may also occur naturally or be achieved through conventional breeding. Concerns relate in particular to access to genetic resources, freedom to operate and possible market concentration in the seed sector.

Amendment 7 **Anja Hazekamp**

Council position **Recital 25 a (new)**

Council position

Amendment

(25a) Traceability requirements for food and feed produced from NGTs should be

established to facilitate the accurate labelling of such products, in accordance with the requirements of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner, as well as to enable control and verification of labelling claims. Requirements for food and feed produced from NGTs should be similar in order to avoid discontinuity of information in cases of change in end use.

Or. en

Justification

Reinstates Amendment 243 of the position at first reading, adopted on 5 May 2010 (OJ C 279 E, 30.7.2010). Without sufficient traceability of NGT plants and products thereof, damage will occur in value chains that need to or wish to remain free of the use of genetic modification techniques, including the organic sector.

Amendment 8 Martin Häusling

Council position Recital 25 a (new)

Council position

Amendment

(25a) Traceability requirements for food and feed produced from NGTs should be established to facilitate the accurate labelling of such products, in accordance with the requirements of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner, as well as to enable control and verification of labelling

claims. Requirements for food and feed produced from NGTs should be similar in order to avoid discontinuity of information in cases of change in end use.

Or. en

Justification

The Parliament supported full traceability for both NGT1 and NGT2. The trilogue outcome limits traceability to seeds, which is insufficient. Without full traceability, consumer choice cannot be ensured and organic labelling may be undermined. NGTs are excluded from organic production, but in the absence of mandatory traceability, it means that organic operators would bear full responsibility and costs.

Amendment 9
Christophe Clergeau

Council position
Recital 34

Council position

(34) 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. That database should contain, inter alia, information on the techniques used to obtain the traits. For transparency reasons, the patent information and the licence declarations provided by the requester should also be included in the database and be kept up to date, without any responsibility on the part of the Commission for the accuracy of that information and subject to the caveat that this information is limited only to what the requester was aware of. To ensure traceability, transparency and choice for operators, during research and plant breeding, when selling seed to farmers or

Amendment

(34) 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. That database should contain, inter alia, information on the techniques used to obtain the traits **as well as detection methods**. For transparency reasons, the patent information and the licence declarations provided by the requester should also be included in the database and be kept up to date, without any responsibility on the part of the Commission for the accuracy of that information and subject to the caveat that this information is limited only to what the requester was aware of. To ensure traceability, transparency and choice for operators, during research and plant

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.

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 10 Martin Häusling

Council position Recital 57 a (new)

Council position

Amendment

(57a) The European Parliament has called for the Union and its Member States not to grant patents on biological material and to safeguard the freedom to operate and the breeders' exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT plants, which by definition are not transgenic plants. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (breeder's exemption). As current provisions in patent law do not provide for a full breeder's exemption, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Hence, NGT plants should not be subject to patent legislation, but should for the protection of intellectual property

solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption. NGT plants, their derived seeds, their plant material, associated genetic material such as genes and gene sequences, and plant traits should therefore be excluded from patentability. The exclusion from patentability should be applied in a consistent manner across legislation. Furthermore, in order to avoid patents being granted or patent applications being submitted between the date of the entry into force of this Regulation and the application of its provisions, it should be ensured that plant material is excluded from patentability from the day of entry into force of this Regulation. For patents already granted or pending patent applications covering plant material, the effects of patents should be further limited. In addition, the Commission should assess and address, in the forthcoming study, how the broader problem of patents being granted, directly or indirectly, on plant material despite previous efforts to close loopholes, should be further addressed. The assessment should address in particular the role and impact of patents on breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, as well as on innovation and in particular on opportunities for SMEs. The report of the Commission should be accompanied by the appropriate legislative proposals in order to ensure further necessary adjustments are made to the intellectual property rights framework.

Or. en

Justification

As the trilogue outcome fails to provide a balanced compromise and departs from the Parliament's position, this EP initial amendment limits patent scope for NGTs in line with Directive 98/44/EC, ensuring safeguarding breeders' access to genetic material and

preventing market concentration in the seed sector.

Amendment 11
Christophe Clergeau

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 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

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 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

farmers.

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 12 **Christophe Clergeau**

Council position **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***

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***

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.

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 13
Christophe Clergeau**

**Council position
Recital 65 a**

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.

Amendment 14
Martin Häusling

Council position
Recital 68 a (new)

Council position

Amendment

(68a) Effective traceability, labelling and environmental monitoring rely on the availability of reliable, accurate and validated detection methods capable of identifying and quantifying relevant substances, organisms or products. The development and use of appropriate detection methods, including those enabled by NGTs, are therefore essential to ensure transparency, consumer confidence and the effective implementation of Union law.

Or. en

Justification

Such methods are already available and continuously improving, including through NGT-related innovation. Without them, enforcement would be ineffective and legal obligations could not be verified in practice, undermining transparency, consumer trust and the functioning of Union law.

Amendment 15
Anja Hazekamp

Council position
Article 4 a (new)

Council position

Amendment

Article 4a
Exclusion from patentability

***NGT plants, plant material, parts thereof,
genetic information and the process
features they contain shall not be
patentable.***

Or. en

Justification

Reinstates Amendment 33 of the position at first reading, adopted on 7 February 2024 (OJ C, C/2025/3751, 17.9.2025). The European Parliament has repeatedly voiced its concerns regarding patentability of plants and genetic traits. The patent framework does not provide sufficient clarity and safeguards on the patentability of genetic traits that may also occur naturally or be achieved through conventional breeding. Concerns relate in particular to access to genetic resources, freedom to operate and possible market concentration in the seed sector.

**Amendment 16
Martin Häusling**

**Council position
Article 4 a (new)**

Council position

Amendment

Article 4a

Exclusion from patentability

***NGT plants, plant material, parts thereof,
genetic information and the process
features they contain shall not be
patentable.***

Or. en

Justification

This amendment reflects the Parliament's previously adopted position. The trilogue outcome goes in the opposite direction by allowing patentability of NGTs. This will disproportionately affect SMEs due to administrative burdens and licensing costs, while favouring large operators. It will also create legal uncertainty where patented traits occur unintentionally, reducing seed diversity, increasing costs for farmers and hindering innovation.

**Amendment 17
Christophe Clergeau**

Council position

Article 4 a (new)

Council position

Amendment

Article 4a

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 18

Christophe Clergeau

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 19
Christophe Clergeau

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 20 **Christophe Clergeau**

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 21 **Martin Häusling**

Council position **Article 10 – paragraph 1**

Council position

Amendment

1. ***Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plants and is made***

1. ***Category 1 NGT plants, products containing or consisting of category 1 NGT plant(s) plant reproductive material, including for breeding and scientific***

available to third parties, whether in return for payment or free of charge, shall bear a label with the indication '**NGT-1**', followed by the identification numbers of the NGT plants it has been derived from.

purposes, that contains or consists of category 1 NGT plants and is made available to third parties, whether in return for payment or free of charge, shall bear a label with the indication '**New Genomic Techniques**'. ***In the case of plant reproductive material, it shall be*** followed by the identification numbers of the NGT plants it has been derived from.

Or. en

Justification

This amendment reinstates the Parliament's initial position, as labelling limited to seeds is insufficient and undermines traceability. Mandatory labelling of NGT-1 plants throughout the value chain, including final products, is necessary to ensure transparency, consumer protection and informed choice. With around 90% of consumers supporting such labelling, it also strengthens consumer confidence and freedom of choice.

Amendment 22 **Martin Häusling**

Council position **Article 10 - paragraph 1 a (new)**

Council position

Amendment

(1a) Appropriate document-based traceability for NGTs shall 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.

Or. en

Justification

The Parliament supported full traceability for both NGT1 and NGT2. The trilogue outcome limits traceability to seeds, which is insufficient. Without full traceability, consumer choice cannot be ensured and organic labelling may be undermined. NGTs are excluded from organic production, but in the absence of mandatory traceability, it means that organic operators would bear full responsibility and costs.

Amendment 23
Anja Hazekamp

Council position
Article 10 – paragraph 1 a (new)

Council position

Amendment

1a) Appropriate document-based traceability for NGTs shall 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.

Or. en

Justification

Reinstates Amendment 265 of the position at first reading, adopted on 7 February 2024 (OJ C, C/2025/3751, 17.9.2025. Without sufficient traceability of NGT plants and products thereof, damage will occur in value chains that need to or wish to remain free of the use of genetic modification techniques, including the organic sector.

Amendment 24
Martin Häusling

Council position
Article 11 a (new)

Council position

Amendment

Article 11a

Withdrawal of the decision

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 referred to in Article 6(8) or statement referred to in Article 7(5). The withdrawal decision must be sent by registered mail to the beneficiary of the decision, who shall have 15 days in

which to make observations. In that case, the marketing of the NGT plant or product shall be prohibited from the day following the date of receipt of the registered letter.

Or. en

Justification

This EP initial provision ensures an effective precautionary and adaptive framework. Where monitoring results or new scientific evidence indicate a risk to human health or the environment, competent authorities must be able to act swiftly. Withdrawal of the authorisation allows timely risk management, protects health and the environment, and ensures decisions remain aligned with evolving scientific knowledge while maintaining procedural fairness for operators.

Amendment 25
Anja Hazekamp

Council position
Article 24 a (new)

Council position

Amendment

Article 24a

Measures to avoid the unintended presence of category 2 NGT plants

Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.

Or. en

Justification

Reinstates article 24 of the Commission proposal, which was also adopted in the European Parliament's position at first reading, adopted on 7 February 2024 (OJ C, C/2025/3751, 17.9.2025). To protect farmers and food chains that wish to remain free of the use of NGT plants, it is necessary to ensure that proper measures are taken by Member States to avoid accidental cross-contamination of NGT plants.

Amendment 26
Martin Häusling

Council position
Article 24 a (new)

Council position

Amendment

Article 24a

Measures to avoid the unintended presence of category 2 NGT plants

Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.

Or. en

Justification

This provision restores the Commission's original approach and represents a balanced middle ground. It ensures coherence with existing Union GMO and food and feed legislation, while maintaining a proportionate framework to prevent the unintended presence of category 2 NGT plants in non-GMO products. This is necessary to safeguard legal certainty, protect consumer choice and ensure the proper functioning of internal market rules and coexistence measures.

Amendment 27
Christophe Clergeau

Council position
Article 27 – paragraph 1 - point c

Council position

Amendment

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

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 (l), 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 28 **Christophe Clergeau**

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 conduct').

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 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 29 **Christophe Clergeau**

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 30

Christophe Clergeau

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 paragraph 2;**

Amendment

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

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 31

Christophe Clergeau

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 32
Christophe Clergeau

Council position
Article 30 a (new)

Council position

Amendment

Article 30a

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 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 33
Martin Häusling

Council position
Article 37 a (new) Directive 98/44/EC
Article 4, Article 8 and Article 9

Present text

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:

‘(ba) 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];

(bb) 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 3 a is added:

‘3a. Paragraphs 2 and 3 shall be without prejudice to the exclusions from patentability covered in paragraph 1.’

2. In Article 8, the following paragraph 2 a is added:

‘2a. 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, the following paragraphs are added:

‘1a. 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.

1b. 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.

1c. 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.’

¹ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13).

Or. en

Justification

As the trilogue outcome fails to provide a balanced compromise and departs from the Parliament’s position, this amendment reinstates the exclusions from patentability and limits patent scope for NGTs in line with Directive 98/44/EC, ensuring legal certainty, safeguarding breeders’ access to genetic material and preventing market concentration in the seed sector.

Amendment 34 **Anja Hazekamp**

Council position
Article 37 a (new) Directive 98/44/EC
Article 4, Article 8 and Article 9

Present text

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:

‘(ba) 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];

(bb) 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 3 a is added:

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

2. In Article 8, the following paragraph is added:

'2a. 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, the following paragraphs are added:

1a. 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.

1b. 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.

1c. 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.’

¹ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13).

Or. en

Justification

Reinstates amendments 69, 291cp1, 230/rev1 and 291cp3 of the position at first reading, adopted on 7 February 2024 (OJ C, C/2025/3751, 17.9.2025. The European Parliament has repeatedly voiced its concerns regarding patentability of plants and genetic traits. The patent framework does not provide sufficient clarity and safeguards on the patentability of genetic traits that may also occur naturally or be achieved through conventional breeding. Concerns relate in particular to access to genetic resources, freedom to operate and possible market concentration in the seed sector.

Amendment 35 **Christophe Clergeau**

Council position
Article 37 a (new) Directive 98/44/EC
Article 4

Present text

Amendment

Article 37a

Amendments to Directive 98/44/EC

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:

'(ba) 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];

(bb) 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 3 a is added:

'3 a. 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 36
Christophe Clergeau

Council position
Article 37 a (new) Directive 98/44/EC
Article 8 and Article 9

Council position

Amendment

Article 37a

Amendments to Directive 98/44/EC

2. In Article 8 of Directive 98/44/EC, the following paragraph is added:

'2a. 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:

'1a. 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.

1b. 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.

1c. 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 37
Martin Häusling

Council position
Annex II

<i>Council position</i>	<i>Amendment</i>
Traits referred to in Article 3, point (13)(a), that exclude NGT plants from category 1 status	Traits referred to in Article 3, point (13)(a), that exclude NGT plants from category 1 status
(1) Tolerance to herbicides	(1) Tolerance to herbicides
(2) Production of a known insecticidal substance	(2) Production of a known insecticidal substance
	<i>(3) Potential to persist, reproduce or spread in the environment, within or beyond fields</i>

Or. en

Justification

This is linked with recital 15a. NGT plants with the potential to persist, reproduce or spread in the environment may pose risks to biodiversity and ecosystem stability, including outside cultivation areas. Such traits increase the likelihood of uncontrolled dissemination and long-term environmental exposure of modified genetic material. Given the potential for irreversible impacts on ecosystems, these plants require higher regulatory scrutiny and should not be classified as category 1 NGTs.