



Draft regulation on plants obtained by NGTs

Analysis of amendments to the provisional compromise of the trilogue approved by the Council, tabled on 30 April by Clergeau (S&D), Hausling (Greens) and Hazekamp (Left)

A series of amendments have been tabled for the vote in the Environment Committee, scheduled for early June, ahead of the plenary vote on the proposal on plants obtained by NGTs, which should take place on the 17 of June 2026. Many of these amendments concern patents, which are one of the major concerns of farmers and small seed companies in this file. Patents are also a concern for many MEPs, who voted in the 2024 first reading vote in favour of clarifying the implementation of EU patent law.

As an organisation representing small farmers, **the European Coordination Via Campesina (ECVC) analysed these amendments and details below which should be supported in priority to protect farmers and small seed producers as effectively as possible from the risks of abusive extension of the scope of NGT patents. These priority amendments will therefore also have to be tabled for the plenary vote scheduled for mid-June.**

We also explain why some amendments are legally ineffective, and therefore we do not advise to support them at this stage of the negotiations. Finally, we consider that some of these amendments will not translate into binding obligations, and therefore will have no real effect.

I. REJECTION AMENDMENT (AMENDMENTS HAZEKAMP N°1 AND HAUSLING N°2)

ECVC considers that this legislative proposal is in many aspects incompatible with the rights of farmers, consumers and of the majority of European seed producers, who reject patents. It is also incompatible with the European Union's international obligations on GMOs (Cartagena Protocol, ITPGRFA). The abolition of the documentary and analytical traceability of NGTs, of the labelling for food products, of risk assessment and post-market monitoring will have irreversible economic, health and environmental consequences that are particularly harmful to the survival of the GMO-free and organic sectors, whose combined commercial production represents €160 billion. In addition, this draft regulation has been strongly criticised by several national food safety agencies for its lack of scientific rigour, in particular as regards the two categories of NGTs, established according to criteria considered as arbitrary, as well as for the derogations concerning risk assessment of plants obtained by NGT1. Finally, there is the risk that patents on NGTs will extend to conventional non-patentable seeds and products from their harvest, in turn increasing the concentration of the seed market. Those patent risks will be developed in more detail in this document.

For European farmers, rejecting this proposal is the only acceptable solution. ECVC will continue to mobilise against this regulation, even if it is adopted. However, if the rejection amendment is not adopted, we support a number of necessary modifications, detailed below.

II. AMENDMENTS WHICH SHOULD BE GIVEN PRIORITY SUPPORT

- 1) Limitation of the scope of patents: Amendments Clergeau N° 36, Hausling N° 33 and Hazekamp N° 34 – Article 37a (new) – paragraph 2 – taken over from N° 13 – recital 65a (new)**

Those amendments, already adopted by the European Parliament at first reading, seek to limit the scope of protection of patents on NGTs to products which are derived from the patented invention, thus

cancelling any possibility of extending their scope to 'native traits' and products obtained by conventional non-patentable breeding. This limitation implies an obligation to publish the analytical traceability processes of these products.

According to the industry itself, the development of NGTs is possible only thanks to the patents guaranteeing the return on investment. Those amendments restore the analytical traceability of patented products obtained by NGTs, to prohibit the abusive extension of the scope of patents on 'traits' (biological material or genetic information and their function) obtained by NGTs to 'native' traits, or to products containing and expressing the same 'traits', but not derived from the patented process. The new implementing rule of Article 8 of Directive 98/44/EC proposed by these amendments is unfortunately incomplete because it does not mention the obligation to distinguish NGT products from any product which was not derived from the patented invention, which is, however, mentioned in Article 9 thereof.

Contrary to the first paragraph 1 of amendments 33 and 34, these amendments (paragraph 2) do not amend the European Patent Convention or Directive 98/44/EC, but rather update their implementing rules to include the developments in genetic techniques since its adoption in 1998, i.e. before the emergence of NGTs yielding products that in some cases cannot be distinguished from products which have not been obtained by patented NGTs with current detection and identification protocols adapted to transgenic GMOs. These protocols will therefore have to be updated, taking into account the fact that patent holders have the methods allowing them to identify possible infringements.

Those amendments were set aside during the trilogue, on the pretext of avoiding the reopening of Directive 98/44. However, they do not necessarily imply such a reopening. They may, if necessary, be the subject of a reformulation as an explicit proposal for new implementing rules of the European Patent Office prior to the application of the NGT Regulation, completed as indicated above for biological materials (Article 8 of 98/44), in plenary and/or during any subsequent trilogue conciliation stage.

2) Reversal of the burden of proof, involving the publication of analytical traceability processes: Amendments Clergeau N° 17, Article 4 a (new) and N° 12, Recital 65

Paragraph 2 of this amendment complements the previous amendments by cancelling the reversal of the burden of proof in the case of infringement proceedings. Such proceedings are therefore impossible in the absence of presentation to the court, and therefore of publication, of the identification methods of patented plants.

Paragraph 1 of this amendment is a transposition of the French law cancelling the patent protection in case of incidental or accidental presence of patented genetic information. Unfortunately, it ignores in this first paragraph the incidental or accidental presence of patented biological materials. This amendment puts the entire burden of proof of any infringement solely on the patent holder, and adds that the mere presence of patented biological material is not sufficient to prove that infringement. Whether or not it is adopted by the ENVI Commission, it can be completed and presented for the EP plenary vote. If it is adopted without this addition by the EP, it can still be complemented at the subsequent trilogue conciliation stage.

3) No NGT 1 if they can spread in the environment: Hausling amendment N° 37, Annex II, Article 3, point 13(a) (new addition)

This amendment aims to exclude plants with the potential to persist, reproduce or spread in the environment, within or beyond fields, from the NGT1 category. It thus limits the cultivation of NGT1 plants to the confined environment (closed greenhouses) and to possible NGT 'terminator' plants (which don't produce pollen or fertile seeds).

III. AMENDMENTS TO BE SUPPORTED, ALTHOUGH INSUFFICIENT

The next steps (EP plenary and possible conciliation in trilogue) may make it possible to clarify them.

1) Detection methods: amendment Clergeau 9 - Recital 34

This amendment provides for a public database of breeding techniques and detection methods. However, its translation into binding articles (below) remains rather weak. Moreover, it unfortunately only provides information on detection methods, which are essential for the organic and GMO-free sectors, but not identification methods, which are essential to avoid any abusive infringement proceedings.

2) Methods of detection and identification: Amendments Clergeau N° 18 – Article 6 – paragraph 3 – point d a (new) –, N° 20 – Article 9 – paragraph 1 – point d a (new), and N° 27 – Article 27 – point c

These amendments could transcribe into articles the recitals 24 above and 68a below, by referring to the obligation to provide, together with applications for authorisation of deliberate release, the methods for sampling, detection, identification and quantification of category 1 NGT plants. Unfortunately, they make these obligations optional by providing for derogations through Commission's implementing acts. The Commission has repeatedly stated that, in its view, it would be technically impossible to make this analytical traceability mandatory.

3) Withdrawal of NGT products in the event of post-dissemination emergence of risks to health or the environment: Hausling amendment N° 24 - Article 11 a (new)

Post-release monitoring is unfortunately not possible in the absence of an analytical traceability obligation.

4) Assessment and control of risks to health and the environment: Hausling Amendment N° 5 – Recital 15 a (new)

Risk control is not possible in the absence of an analytical traceability obligation.

5) Documentary traceability of NTG products: Hausling Amendment N° 14

Documentary traceability is particularly essential for the organic sector and all quality or origin schemes guaranteed without GMOs. However, its applicability will be uncertain in the event of a lack of analytical traceability (provided for in the following amendment).

6) Analytical traceability: Hausling Amendment N° 14 - Recital 68 a (new)

Unfortunately, this obligation is not confirmed by any binding article.

7) Labelling and documentary traceability of NGT products: Hausling Amendment N° 21 and N° 22 and Hazekamp Amendment N° 23 – Article 10(1)

Their application will not be systematic if there is no obligation for analytical traceability.

8) Member States shall take co-existence measures for NGT 2: Hausling Amendment N° 26 and Hazekamp Amendment N° 25 – Article 24 (new)

In the absence of analytical traceability, these coexistence measures will be difficult to apply at field level, and inapplicable in the rest of the value chain. In addition, organic and GMO-free sectors must also protect themselves against NGT 1, which will constitute the vast majority of authorised NGT plants, and not only against NGT 2.

IV. RELEVANT AMENDMENTS, BUT LEGALLY INADMISSIBLE

These amendments require a prior modification to the European Patent Convention, which is unrealistic in the short-term, since this Convention has also been ratified by non -EU countries. While they constitute an important political signal, at the moment they could only be the subject of a motion by the EP to start negotiations to update this Convention, for which there doesn't seem to be a political consensus.

- 1) **Plants derived from NGTs are not patentable: Amendments Clergeau N° 33 and N° 34 Hausling - Article 37(a), paragraph 1 and N° 15 Hazekamp and N°16 Hausling - Rule 4a (new)**
- 2) **No patents on NGTs (plant processes and products), only Community Plant Variety Rights (CPVR) system, subsequent Commission report: Hausling Amendment N° 10 and Hazekamp Amendment N° 6 – Recital 57 a (new) and Recital 18 a (new)**
- 3) **NGT plants or plants excluded from the scope of Directive 2001/18 are not patentable: Hausling Amendment N° 4 and Hazekamp Amendment N° 34 – Rule 37 a (new) - 1 (a) (c) and (d)**

The Paragraph 2 of the amendments concerning articles 35 a (new) are a priority because it concerns a limitation of the scope of patents (see section II. priority amendments).

V. INEFFECTIVE AMENDMENTS, SHOULD NOT BE SUPPORTED

These amendments could be widely supported by MEPs, but will not provide an effective solution against the risks of patent abuse and abusive infringement proceedings that threaten farmers and small seed producers, nor against the risks of contamination for the organic and GMO-free sectors, nor against the biosafety risks in case of post-marketing health or environmental damage. **ECVC therefore considers that their adoption would be counterproductive, because they are based on non-binding rules, and therefore asks MEPs not to support them:**

Code of conduct for licence fees: Amendements Clergeau N° 28, 29, 30, 31– Article 30

These amendments concern the establishment of a code of conduct for licensing rights, which is a tool that is useful for companies wishing to use NGTs, but doesn't address the root problem of patent abuse. Moreover, this code of conduct will not be effective, as patent holders will have no real obligation to effectively comply with it.

The same is true of **Clergeau Amendment N° 11 – recital 60 - and amendment N° 32, article 30 a (new)** on licensing platforms. Licensing platforms constitute a privatisation of European law by the few companies which hold patent rights on NGTs. They exist for the sole benefit of patent holders and make smallest actors dependent on the largest patent-holders.