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GMO/NGT Regulation: civil society organisations concerned about the outcome of the trilogue

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As the trilogue on the regulation of new genomic techniques (NGT) continues, civil society organisations are expressing their concerns about the outcome of the discussions, particularly on the issue of patents. This is evidenced by two recent position statements: those of the European Coordination Via Campesina (ECVC) and Arche Noah, which illustrate their mobilisation around this crucial debate at a key moment when European decisions are being made.



The outcome of the ongoing trilogue (negotiations between representatives of the Parliament, the Council and the European Commission) on the NGT regulation remains uncertain, particularly with regard to patents covering GMOs obtained through these techniques. ECVC and Arche Noah[i] have analysed the positions of the European Parliament and Council. Each organisation presents its opinion in its own briefing note [ii],[iii]. These briefs come at a strategic moment in the trilogue, when

decisions are being made and the impact studies on patents requested by the European Commission in July 2023[iv] could either reduce or reinforce their concerns. We highlight two aspects of these briefs that are important in the debate: the "*breeder's exemption*" and the traceability of products derived from NGTs.

Extending the "*breeder's exemption*"

The ongoing discussions concern a fundamental issue relating to patents, which has recently become more prominent: the "*breeder's exception*"[v]. In plant variety rights law, this exception allows breeders to freely use varieties covered by a plant variety right (PVR) to select new varieties, without seeking authorisation from the rights holder or paying licence fees. This principle guarantees open access to plant material and, at first glance, encourages diversity in the commercial supply of new seeds. However, in European patent law, this exception is currently limited to experimentation and research. However, this remains insufficient to preserve freedom of selection in the face of the expansion of patents on genetic sequences or information present in plants derived from peasant or traditional selection. Thus, the idea of creating a "*total exemption for breeders*", leaving breeders free to use patented biological material to select and market new varieties, is gaining ground. This mechanism is described as follows by German lawyers Metzger, Hertz and Kock[vi] : "*While the use of a patented process for making of a NGT plant still requires a license, the use of the NGT plants by breeders, who create and commercialise new plant varieties, would not be covered by the patent. The limitation will apply to all existing patents and patent applications*".

Arche Noah supports this proposal for a total exemption for breeders. The association criticises the current European patent system for ignoring the breeder's exemption by preventing the use of patented material (containing, for example, a gene associated with pest resistance) to develop and market new varieties. Arche Noah believes that this restriction hinders innovation and limits crop diversity. In its briefing note, the NGO clarifies its position on total exemption: "*Breeders would no longer be require authorisation from the patent holder or need to pay license fees if they develop (or have developed) a variety with the same characteristics, provided they have not used the patented process and they use essentially biological processes such as crossing or selection (but not exclusively)*". Arche Noah extends its position to the situation of farmers: "*In the same spirit, farmers who multiply or propagate a variety with the same characteristics as the patent claim but obtained without using the patented process, may also do so without authorisation of the patent owner*".

It is on this last point that ECVC, as a farmers' organisation, places particular emphasis. It considers that patents on seeds threaten not only the work of breeders, but also the fundamental rights of farmers to save, exchange and reuse their seeds. For ECVC, the concentration of power in the hands of a few multinational seed companies increases farmers' dependence and undermines food sovereignty. The organisation, which has always opposed the International Union for the Protection of New Varieties of Plants (UPOV) since its 1991 reform, cites, without endorsing it, the existence of this request for total exemption for breeders made by many seed companies and taken up by Arche Noah. It refers to the fact *of* "*aligning patent law with the European Unitary patent and UPOV provisions that allow a breeder to freely reuse a variety covered by a PVR to select a new one. The variety may then only be marketed after removal of the patented biological material or genetic information*". ECVC points out that this solution, "*while this solution does have merits for the seed sector, it does not in any way resolve the major risks that farmers will face if NGTs are deregulated: being banned from using and reusing their own seeds, an obligation to pay royalties for certain species, biopiracy, risk of infringement proceedings and seizure of their harvest, etc*".

Limiting the scope of patents *via* this "*total exception*" can be considered without having to amend the European Patent Convention. Such a revision is, in any case, unrealistic in the short term[vii]. This would involve introducing articles specifying a new rule for the application of patent law that takes into account recent developments in genetic modification techniques, directly into European Directive 98/44 (supplementing Articles 8 and 11) and/or into the national patent laws of EU Member States. Such a change would affect all patents already granted as well as pending patent applications.

Traceability and infringement

Another aspect of the subject of "*patents and NGTs*" appears unsurprisingly – because it is fundamental – in the ECVC technical note: the obligation of "*analytical traceability*" for plants derived from NGTs. As the organisation points out, the removal of the obligation to publish the methods for detecting and identifying GMOs – as currently required by European Directive 2001/18 and which the proposed new NGT regulation aims to remove – would allow "*abusive extension of the scope of patents to peasants' or conventional seeds that have been accidentally contaminated, or that present a trait similar to the patented trait without having used the patented invention*". Such a measure would effectively place farmers, small seed producers and the GMO-free sector in a situation of serious legal uncertainty: they would not know whether they were growing or marketing patented plants or seeds and, moreover, they could see their traditional seeds confiscated by new patents covering their "*native traits*". This would have a fundamental impact on their work and their income. This abuse of patents would place most of them in an impossible situation: having to prove that they have not used a patented process to obtain their seeds. This is known as "*reversing the burden of proof*".

Arche Noah refers to infringement on several occasions, also highlighting the burden of proof of non-infringement that threatens small and medium-sized breeders. However, the NGO does not explicitly link this to the issue of traceability: *"Limiting the scope of patents granted on NGTs/GMOs and applying fair proportionate rules on the burden of proof would also provide plant breeders, farmers and food processors who do not work with NGTs or regulated '*old*' GMOs the freedom to operate and innovate without concerns of patent infringement*." Seed producers who registered and marketed their varieties before a competitor claimed a new patent can easily prove that they did not use the patented invention. But this is not the case for farmers, who have no way of proving the genetic composition of seeds from their own selections that they have never sequenced or registered.

The requirement for traceability, not only in terms of documentation but also in terms of the publication of detection and identification processes, is therefore the cornerstone of the protection of farmers' rights against the risks of patent infringement, not to mention the risks resulting from accidental contamination. This requirement, introduced in Directive 2001/18, filled a gap in the "*biotech inventions*" Directive 98/44/EC. Why should it no longer be maintained today, at least in patent law, if it is unfortunately removed from GMO/NGT law?

The European debate on NGTs is at a decisive moment, with farmers and consumers potentially being led to cultivate or consume GMOs without their knowledge. While the Commission supports the position of a seed industry that wants to make these new GMOs "*invisible*" in fields and supply chains, civil society organisations are advocating for limited or total transparency requirements. Another form of invisibility affects small seed producers and farmers faced with the complexity and opacity of patents covering plant material[viii]: the persistence, until 2037, of old patents on products derived from essentially biological processes, with only new patents being - theoretically - impossible to obtain since july 2017[ix].

An outcome that is cause for concern

While Arche Noah calls for a complete overhaul of European legislation on patents on life forms, ECVC supports their total ban and, in the short term, a structural but pragmatic transformation, fuelled by the defence of farmers' rights. It should also be noted that a significant legal divergence remains between the two organisations regarding random mutagenesis. Arche Noah considers that it should be expressly excluded from patentability, as it is considered a conventional method, while ECVC warns against its impossibility without illusory short-term modification of the European Patent Convention and cautions against industry propaganda presenting this solution as the only strategic escape route[x].

As the European trilogue enters its decisive phase, ECVC and Arche Noah each hope to influence what could be the last opportunity for the European legislator to regulate the crucial issue of patents on GMOs derived from NGT or on NGT itself. The coming months will be decisive in determining whether the final text of the regulation will take into account the concerns raised by these two organisations and, more broadly, by other civil society actors. If not, it could perpetuate a system that allows for patents that are as opaque as they are powerful, effectively ignoring the breeder's exception to plant variety rights and depriving small farmers of their seed freedom.

At the last trilogue session, discussions focused mainly on the definition of NGT1 (amendments to Annex 1[xi]) and traceability. The Parliament also appears to have softened its "*anti-patent*" stance on NGT, indicating that it could "*deviate from the total ban*"[xii]. Amendments were also proposed to remove the labelling requirement, which was intended to provide simple, factual information on the presence or absence of GMOs in cultivated seeds and commercialised products covered by patent rights.

i Arche Noah, an Austrian association for the conservation and development of crop diversity, defines itself as an NGO (non-governmental organisation)
European Union, Accredited organisation, "ARCHE NOAH GESELLSCHAFT FUR DIE ERHALTUNG DER KULTURPFLANZENVIELFALT UND IHRE ENTWICKLUNG VEREIN".

ii Arche Noah, "Briefing on Patents on NGT plants and processes", September 2025.

iii ECVC, "Patents on GMOs-NGTs: State of play and solutions to protect farmers, small breeders, and the GMO-free sector", October 2025.

iv European Commission, "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions", 5 July 2023.

v Eric Meunier, "Patents and the evolution of Plant Breeder ‘s Right (PBRs)" *Inf'OGM, le journal*, No. 176, July/September 2024.

vi Axel Metzger *et al.*, "Mitigating impact of patents on plants obtained from New Genomic Technique (NGT)", 27 January 2025.

vii This type of change affecting the basic principles of the EPO (European Patent Office) patent system would require consensus among the member states of the European Patent Convention (EPC), which also includes countries that are not members of the European Union. This generally requires a diplomatic conference.

viii Denis Meshaka, "De Bolster: another Dutch SME under patent threat," *Inf'OGM*, 22 July 2024.

ix Zoé Jacquinot, "Produits issus de procédés biologiques : finalement non brevetables", *Inf'OGM*, 4 June 2020.

x Denis Meshaka, "'*Essentially biological process*', a definition shaken up", *Inf'OGM*, 22 April 2024.

xi Trilogue on GMOs/NGTs, "ANNEX I - Criteria of equivalence of NGT plants to conventional plants," October 2025.

xii Maria Simon Arboleas and Sofia Sanchez Manzanaro, "Gene-editing talks inch forward as MEPs soften on patent ban," *Euractiv*, 14 October 2025.

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