

January 13, 2025

## Comments on the Polish Presidency 's proposal for the regulation of certain plants derived from new genomic techniques (NGTs)

---

On January 7, 2025, the Polish Presidency of the EU distributed a draft proposal for discussion at the next meeting of the dedicated Council Working Party on Genetic Resources and Innovation in Agriculture, to be held on 20 January 2025<sup>1</sup>.

In our view this is an extremely important and favorable change in orientation by Poland which in recent months had raised objections and voted against the Commission's NGT proposal.

In this new document the Polish Presidency keeps all the modifications agreed under the Spanish and Belgian presidencies and adds limited new provisions to deal with the question of patents, which, to date, has been the single most important question preventing a qualified majority of member states in favor of the Commission's proposal.

In this note we chose to comment on the most important changes proposed by Poland, as follows:

### 1. The Polish presidency recognizes in new recitals the importance of innovation protected by the patent system and plant breeders' rights:

*"(14 quater) Subject to exclusions, patents may be granted on any inventions, whether products or processes, in accordance with Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights []. According to Article 28 of the agreement, where the subject matter of a patent is a product, that patent grants its owner exclusive rights to that product, while where the subject matter of a patent is a process, that patent grants its owner both exclusive rights to that process and to the product obtained directly from that process."*

*"(14 quinques) The balance between effective protection of invention and stimulation of research and development and the expectations of breeders to have free access to varieties for the development of new varieties should be maintained."*

*"(14 sexies) Free access to all varieties for the purpose of breeding or discovering and developing of new varieties known as breeders' exemption is guaranteed by Union rules on Community plant variety rights which aims to ensure freedom of action and is known to promote innovation in European plant breeding. It also provides "open access" to the biodiversity needed to produce new varieties. This legal framework ensures that diversity is maintained in the European seed market."*

**Comment:** The recitals reflect existing law in the EU which applies to all techniques used in breeding, not only NGTs. The question is raised whether these recitals are pertinent in a *lex specialis* intended to determine the *regulatory* treatment of plants resulting from the use of directed mutagenesis and cisgenesis.

### 2. In order to accommodate the interests of patent holders and those of breeders who need access to breeding material, the Polish Presidency believes it is justified to impose additional marketing conditions on Category 1 plants:

*"(14 octies) Striking a balance between the legitimate interests of innovators seeking protection and the legitimate interests of third parties seeking access to breeding material requires that additional conditions apply to the placing on the market of plant reproductive material of category 1 NGT plants protected by one or more product patents or process patents where the process results in a specific characteristic (trait)."*

**Comment:** If such a recital is justified, why should NGT-1 plants be treated differently from conventionally bred plants, to which they are equivalent, considering that conventionally-bred plants obtained through technologies such as random mutagenesis, TILLING, cell fusion etc., can also result in a specific trait, subject to patent coverage, and are not subject to additional marketing conditions?

**3. The Polish Presidency in a new recital proposes that plant reproductive material (“PRM”) covered by a patent be subject to identification/labeling requirements for the patent status:**

*“(24 bis) An additional labelling requirement for NGT 1 plant reproductive material which is protected by a patent followed by the inclusion of such information in the commercial documentation of such material and in the databases where it is offered for sale and in the catalogues of varieties referred to in Article 3 of Directive 2002/53/EC27 on the common catalogue of varieties of agricultural plant species shall be provided in order to ensure traceability, transparency and choice for breeders using NGT 1 plant reproductive material in breeding programs and will distinguish between patented and non-patented NGT 1 plant reproductive material.”*

**Comment:** If there is justification for such a requirement (indeed we agree that there is), is this regulation the right instrument for the requirement (versus the PRM legislation<sup>2</sup>), and why should this requirement be limited to NGT-1 plants versus all varieties covered by a patent, and why should the requirement not also apply to species not included in the catalogues?

**4. In another new recital the Polish Presidency considers that it may be necessary for member states to restrict the cultivation of patent-protected NGT-1 plants:**

*“(24 ter) In certain cases, such as placing on the market of category 1 plant reproductive material protected by a patent, it may be necessary for Member States to take appropriate measures on their territory to prevent the unintended use of patented category 1 plant reproductive material for cultivation in all or part of their territory, for reasons related to the socio-economic impact of the presence of patented plant reproductive material on the market on the breeding sector and agricultural policy objectives.”*

**Comment:** If this recital is considered to be necessary, it does not explain why “appropriate measures” may be required for patented Category 1 PRM and not for patented conventionally bred PRM.

**5. In a separate recital Poland considers that Member States need to inform the Commission about patents or patent applications that could be an obstacle to granting a verification decision:**

*“(24 quater) The verification whether a plant is protected by one or more product patents or process patents where the process results in a specific characteristic (trait) requires research in multiple databases established by various patent offices. A patent application can also be published after a verification request has been filed. Published patent applications limit the freedom to use the plant reproductive material and as such shall constitute an obstacle to the placing on the market of such material. Therefore, Member States need to be able to inform the Commission about patents or patent applications that would be an obstacle to granting a verification decision.”*

**Comment:** This recital does not explain why a patent verification process should be required for NGT-1 plants versus other plants obtained by other techniques which are not subject today to a patent verification process and does not provide justification why Member States should be required to undertake research in patent databases to verify the patent status (this is better left to directly involved stakeholders).

**6. In a separate recital and in a new Article 11bis, Poland proposes that the Commission be given the power to remove PRM from the market in the event of non-compliance by the holder of patent disclosure requirements:**

*“(24 octies) The Commission should have the ability to remove plant reproductive material from the market if it has been placed on the market in violation of the provisions of this regulation, even if the requester did not seek to obtain a decision stating that such material was not protected by a product patent or a process patent, where the process results in a specific characteristic (trait), or if an application for such a decision was rejected, or if such a decision was revoked.”*

**Comment:** if there is an omission or other failure to divulge a relevant patent or patent application in the labelling of the PRM or in a variety database, a more proportionate remedy would be the unenforceability of such patent against third parties.

**7. Poland creates a new section 2 in Article 4 clarifying that if a Category 1 plant or product satisfying Annex I has gone through a verification procedure resulting in a decision by the Commission that it is not covered by a patent, it can be marketed without any restrictions in the entire EU. (In Article 7bis, not reproduced below, Poland proposes a patent verification procedure to be managed by the Commission.)**

*“2. If, following a patent verification request in accordance with Article 7 bis, the plant is the object of a decision of the Commission finding that it is not protected by one or more product patents or process patents, where the process results in a specific characteristic (trait) or patents for use of biotechnological material, where the use results in a specific characteristic (trait) of the NGT 1 plant, and that no application for such a patent was published in any Member State, Articles 7 ter and 10 bis shall not apply.”*

**Comment:** Instead of a patent status verification decision process requiring the Commission to perform an exercise which it currently does not carry out for patented plants resulting from other genetic modification techniques (conventional or GM), would it not be simpler to make it mandatory to divulge the patent status in all appropriate variety databases and PRM labelling, with the failure to divulge resulting in unenforceability of the patent? If mandatory disclosure and labeling were adopted, should this not apply to all patented plants and should not the PRM legislation<sup>2</sup> be the correct instrument for this change?

**8. In proposed Article 7 ter, Poland describes the reasons a Member State could invoke to restrict the marketing of a patented NGT-1 plant:**

*“1. A Member State may adopt measures restricting or prohibiting use for cultivation of reproductive material of a category 1 NGT plant that has not obtained the decision referred to in Article 4(2) in all or part of its territory.*

*2. The measures referred to in paragraph 1 shall be based on grounds related to: (a) socio-economic impacts, including the economic impact on the breeding sector; (b) agricultural policy objectives. Those grounds may be invoked individually or in combination, depending on the particular circumstances of the Member State, region or area in which those measures will apply.”*

**Comment:** The Commission and EFSA consider NGT-1 plants to be scientifically *equivalent* to conventionally bred plants. If these two groups of plants are to be treated the same way from a regulatory standpoint, what is the justification for empowering member states to take action to restrict commercialization of NGT-1 *patented* plants, when no such empowerment is considered necessary in the case of patented *conventionally bred* plants?

## **9. In a new Article 10bis the Polish Presidency proposes mandatory labelling and transparency of information on patented category 1 NGT PRM:**

*“Labelling and transparency of information on reproductive material of a category 1 NGT plant referred to in Article 4(2)*

*1. The reproductive material of a category 1 NGT plant that has not obtained the decision referred to in Article 4(2) shall be labelled according to Article 10, followed by the additional information, accordingly, ‘patent protected’ or ‘patent pending’.*

*2. Member States shall ensure that varieties of category 1 NGT plants protected by patents referred to in Article 4(2), whose status has been confirmed under Article 6 or 7, are clearly described in national catalogues of varieties referred to in Article 3 of Directive 2002/53/EC. 3. Information mentioned in paragraph 2 must appear in the accompanying commercial documentation and catalogues in which these varieties are entered.”*

**Comment:** There is ample justification for requiring such labeling and transparency of information. However, such mandatory labeling should apply to all patented PRM, to avoid unnecessary discrimination with other patented PRM obtained through other conventional techniques. In addition, for varieties not covered by the EU catalogues, this requirement should be made to apply to the CPVO database. Finally, if we consider that this provision should indeed apply to all PRM, then the proper instrument for this proposed article is the PRM legislation<sup>2</sup>.

## **10. In Article 30bis4, Poland proposes that the Commission deliver its ongoing patent study one year after entry into force of the NGT regulation.**

Comment: we are aware that the Commission’s patent study is actually ongoing, under the supervision of DG GROW. The Commission had previously committed to delivering the study in 2025. Under the Polish proposal the study would most likely not be delivered before the end of 2028. Considering the concerns that have been raised by stakeholders, the earlier the study is delivered, the better.

## **11. Additional final comments**

We are very pleased with the new Polish proposal which opens the door to constructive discussions in order to overcome obstacles that may be caused by existing and future intellectual property covering PRM.

In our joint note dated December 20, AFBV and WGG suggested four measures to alleviate certain intellectual property concerns that are also raised by the Polish Presidency:

- 1) Amend the proposed PRM Regulation<sup>2</sup> making it mandatory to publish with regular updates the status of patents that may cover a marketed variety in the Official Catalogue of Species and Varieties of Cultivated Plants of the EU<sup>4</sup>, for species covered by this regulation, and, for other species not covered in the Catalogue, in the CPVO database<sup>5</sup>, referring to the relevant articles of Regulation 2100/94/EC<sup>6</sup> and Council Directive 2002/53/EC<sup>7</sup> of 13 June 2002. Later, if the patent legislation were to be modified, it could be envisaged that the failure to disclose patent status or the absence of publication of the status of a patent covering a variety would render it unenforceable against third parties.**

*The aim of this proposal is to create greater transparency around patents that may cover commercially accessible varieties, in order to facilitate freedom to*

*operate analysis and the possibilities for negotiating licences, as existing databases (PINTO<sup>8</sup> and ILPV<sup>9</sup>) are neither exhaustive nor binding.*

Our proposal fully addresses the concerns of Recital 24bis and Article 10bis of the Polish Presidency proposal.

- 2) **Clarify in an interpretative notice covering IP applicable to plants<sup>10</sup> that in Art. 27(c) of the Agreement on a Unified Patent Court (UPCA)<sup>11</sup> the term "biological material" includes the NGT tools used to create the NGT plant and the variety derived from it, and that the regulatory and legal procedures for the protection and registration of varieties may be carried out within the framework of the exemption provided for in this article, while patents are still in force, as well as seed production that precedes commercialization.**

*The objective of this proposal is to create greater certainty and clarity on the scope of the breeder's exemption which, in order to meet the needs of breeding, must include germplasm itself, tools needed to improve and modify germplasm, all regulatory steps prior to marketing, and commercial seed production prior to launch.*

Our proposal is consistent with the Polish Presidency's vision of the breeder's exemption expressed in Recital 14 sexies.

- 3) **Specify in the same interpretative notice that in the case of compulsory licenses, the criterion of "considerable economic interest" used in Article 12, para. 3 (b) of Directive 98/44/EC<sup>3</sup> as well as the criterion of "public interest" used in Article 29 of Regulation 2100/94/EC<sup>6</sup> are satisfied by the registration of a variety having a trait obtained by NGT with a known and measurable economic advantage (e.g. disease resistance) or increased tolerance to measurable environmental factors (e.g. drought resistance), compared to other registered varieties, and that FRAND (fair, reasonable and non-discriminatory) conditions should apply to compulsory licenses under the above articles for plants obtained by NGT (i) that are covered by a patent or (ii) which are varieties considered to be essentially derived from a variety protected by Plant Breeder's Rights ("PBR").**

*The objective of this proposal is to create predictable and fair conditions for the marketing of patent-dependent varieties and for NGT varieties that depend on a PBR-protected variety, both of which need a license to be marketed under fair, reasonable and non-discriminatory conditions, as is already the case for patent-covered varieties in the PINTO and ILPV databases.*

Our proposal addresses positively the questions raised by patent dependency or PBR dependency in the case of essentially derived varieties. This seems preferable to Member State-imposed marketing restrictions or bans.

- 4) **Propose to the European Patent Office (EPO) to formally confirm that the disclaimer clause of EPO Rule 28(2)<sup>12</sup> covers not only the plant containing a gene or a native trait, but also the gene and the corresponding trait.**

*The objective of this proposal is to remove any uncertainty about the scope of the disclaimer by reassuring the breeder in the event that the breeder is working on a trait found in its breeding material that could be dependent on a patent on the same trait obtained as a result of the use of NGT techniques.*

This fourth proposal (along with No. 3 above) is intended to address concerns alluded to in Poland's proposed Article 7ter (socio-economic impacts on the breeding sector).

These four proposals are likely to be acted upon more quickly than others, because they are well understood by stakeholders, three of them do not require a legislative act and another could be inserted into a text currently under discussion (the PRM Regulation<sup>2</sup>). They are necessary to create transparency on which varieties are covered by a patent, to facilitate the analysis of freedom to operate and the negotiation of licenses, to provide concrete solutions to enable the implementation of compulsory licenses, to clarify the scope of the breeder's exemption and to reassure small breeders about native genes that may be present in their gene pool.

We hope the Polish presidency will consider all four of our proposals and maintain its admirable efforts to reach a qualified majority.



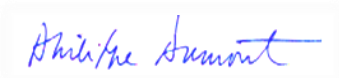
**Thierry Langin**

President  
Association Française des  
Plant Biotechnology (AFBV)  
e.mail: [afbv.secretariat@gmail.com](mailto:afbv.secretariat@gmail.com)  
Website: <https://www.biotechnologies-vegetales.com>



**Prof. Dr. Klaus-Dieter Jany**

Vorsitzender  
Wissenschaftlerkreis Genomik und  
Gentechnik e.V. (WGG)  
[jany@wgg-ev.de](mailto:jany@wgg-ev.de)  
<https://www.wgg-ev.de/>



**Philippe Dumont**

Membre du Conseil d'Administration, AFBV

**References:**

<sup>1</sup> Available online: [https://www.keine-gentechnik.de/fileadmin/user\\_upload/20250107NGT-VorschlagPolen\\_publicierbar.pdf](https://www.keine-gentechnik.de/fileadmin/user_upload/20250107NGT-VorschlagPolen_publicierbar.pdf)

<sup>2</sup> Proposal for a Regulation on the production and marketing of plant reproductive material in the Union [https://food.ec.europa.eu/plants/plant-reproductive-material/legislation/future-eu-rules-plant-and-forest-reproductive-material\\_en](https://food.ec.europa.eu/plants/plant-reproductive-material/legislation/future-eu-rules-plant-and-forest-reproductive-material_en)

<sup>3</sup> Directive 98/44/EC on the legal protection of biotechnological inventions. <https://eur-lex.europa.eu/legal-content/FR/TXT/?uri=celex%3A31998L0044>

<sup>4</sup> [https://food.ec.europa.eu/plants/plant-reproductive-material/plant-variety-catalogues-databases-information-systems\\_en](https://food.ec.europa.eu/plants/plant-reproductive-material/plant-variety-catalogues-databases-information-systems_en)

<sup>5</sup> CPVO database: <https://cpvo.europa.eu/en/applications-and-examinations/cpvo-variety-finder>

<sup>6</sup> Regulation 2100/94/EC on Community plant variety rights. <https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:31994R2100>

<sup>7</sup> Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species <https://eur-lex.europa.eu/legal-content/FR/ALL/?uri=celex:32002L0053>

<sup>8</sup> PINTO database set up by Euroseeds: <https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/>

<sup>9</sup> ILPV database: International Licensing Platform-Vegetables - <https://www.ilp-vegetable.org/>

<sup>10</sup> See Commission opinion of 8 November 2016: [https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:52016XC1108\(01\)](https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:52016XC1108(01))

<sup>11</sup> Agreement on a Unified Patent Court (UPCA): <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:175:0001:0040:fr:PDF>

<sup>12</sup> EPO Rule 28(2): <https://www.epo.org/fr/legal/epc/2020/r28.html>. See also EPO Guideline on the Disclaimer: paragraph 5.4. Plant varieties and animal breeds, essentially biological processes for the production of plants or animals - [https://www.epo.org/fr/legal/guidelines-epc/2023/g\\_ii\\_5\\_4.html](https://www.epo.org/fr/legal/guidelines-epc/2023/g_ii_5_4.html)

<sup>13</sup> Scientific opinion on the ANSES analysis of Annex I of the EC proposal COM (2023) 411 (EFSA-Q-2024-00178) <https://www.efsa.europa.eu/en/efsajournal/pub/8894>