

February 14, 2025

## Comments on the Polish Presidency's second proposal to regulate certain plants derived from new genomic techniques (NGTs)

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On 6 February 2025, the Polish Presidency of the EU circulated a new 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 14 February 2025. We were able to access a copy of this document.

Still motivated by the general interest of arriving at a text that can obtain a qualified majority, the Polish Presidency has taken into account comments provided in response to its 7 January draft and, as a result, has revised it considerably.

In its second draft, the Polish Presidency retains all the changes agreed under the Spanish and Belgian Presidencies. It adds new provisions to address patent-related issues, but without the constraints of the first draft.

As in our note of 13 January, we have chosen to comment on the most important changes proposed by Poland, namely:

- 1. In the recitals, the Polish Presidency emphasizes (1) the need to achieve transparency on patents covering NTG plants, (2) access for breeders to these plants on FRAND (fair, reasonable and non-discriminatory) terms and (3) the usefulness of having guidelines for breeders to determine their freedom to operate:**

New recital 14 (c): *"The balance between effective protection of invention and stimulation of research and development on the one hand and wide access to varieties serving the development of new varieties on the other hand should be maintained. Making NGT plants available to breeders on fair, reasonable and non-discriminatory terms is likely to contribute to the development of new varieties, and to further encourage the development and placing on the market of plants and their products obtained by NGTs."*

Sentence inserted at the end of recital 16: *"For the same reason, in order to ensure transparency for breeding activities prior to deliberate release, including placing on the market, declarations of the type of patent protection for category 1 NGT plants should be submitted. At the same time, the existence of patent protection does not affect the obtainment of category 1 NGT status, which is based solely on scientific equivalence criteria."*

Sentence inserted at the end of recital 21: *"For transparency reasons, the patent information should also be included in the database [intended to house information on the status of the NGT-1 plant and its identification number]"*.

New recital 46(c): *"Breeders can benefit from guidelines to help them navigate the plant intellectual property landscape. The Commission should therefore publish guidelines to assist operators, in particular breeders, in navigating the plant intellectual property landscape."*

**Comment:** These recitals address intellectual property issues, including the transparency needed for patent applications that may cover plants containing traits that can be obtained by various techniques. In substance, AFBV and WGG agree with the need to create transparency for patents that may cover plants – but the place for such measures is elsewhere than in the Commission's draft: such measures must be taken in a more

appropriate text such as the draft Regulation on Plant Reproductive Material (PRM)<sup>1</sup> and must apply to all techniques used to obtain plant traits, and not just NGTs.

- 2. In order to create transparency on the patents that may cover NTG-1 plants, the Polish Presidency proposes at the time of the verification procedure (1) to oblige the Developer to submit a declaration identifying the presence or absence of patents for products or processes covering plant traits of the plant subject to the verification, and (2) optionally, a statement by the patent owner indicating its agreement to license the subject matter of the patent on FRAND (fair, reasonable and non-discriminatory) terms applicable in the EU territory.**

Insertion of paragraphs 3x and 3xx in Article 6:

"3x. The requester shall submit a written statement (patent information):

(a) identifying patents for products claiming modifications of biological material resulting in particular traits; or

(b) identifying patents for processes claiming modifications of biological material resulting in particular traits; or

(c) confirming the absence of patents referred to in letters (a) and (b)."

"3xx. The requester may submit a written declaration of a patent holder confirming his willingness to licence the protected subject under fair, reasonable and non-discriminatory conditions, which is applicable within Union territory (licence declaration)."

Similar requirements are inserted in paragraphs 2x and 2xx of Article 7.

**Comment:** As mentioned above, such requirements are justified, but, it seems to us, through a different legal instrument<sup>1</sup> than the Commission's proposed NGT Regulation and should apply to all *varieties* covered by a patent and not only those derived from NTG-1 plants. It should be noted that in the above wording information is required at the time of the verification procedure which, in fact, is not the right time to require this information, because the plant submitted for verification is not accessible to breeders. It is the registered variety, once marketed, that is accessible to breeders, and it is for the latter that the information related to patents is necessary.

- 3. In a new paragraph of Article 29 (Guidance), the Polish Presidency proposes the publication of regularly updated guidelines to assist operators, including breeders, in navigating the IP landscape:**

Insertion of paragraph 3 at the end of Article 29:

"3. The Commission shall publish, review and update if needed, guidelines for the purpose of assisting operators, in particular breeders, in navigating the plant intellectual property landscape. The Commission shall consult the competent intellectual property offices of the Member States when drafting the guidelines. The guidelines shall at least specify:

(a) existing plant licencing platforms and their members;

(b) existing public organisations that have the purpose of assisting plant breeders with intellectual property-related questions;

(c) existing databases allowing operators to identify the intellectual property rights which apply to a given plant;

(d) basic information on the forms and conditions of protection of intellectual property in plants, including information on compulsory licencing and exemptions."

**Comment :** While such information is useful for operators, the draft PRM<sup>1</sup> Regulation, which addresses all varieties of all species, seems a more appropriate instrument to address these information needs. Freedom to operate analysis is an exercise that each operator must carry out for itself, assisted by a competent counsel in the field of intellectual property. The question arises as to whether the Commission is the appropriate competent

authority to provide the assistance referred to in points (a) to (d) rather than another competent EU institution such as the Community Plant Variety Office.

**4. In Article 30bis4, Poland continues to propose that the Commission deliver its ongoing study on patents one year after the entry into force of the NGT Regulation.**

**Comment:** We have learned that the Commission's study on patents is currently underway, under the supervision of DG GROW. We continue to believe that it would be preferable for the Commission to publish the results of its study as soon as possible, rather than wait three years (since it will take two years after adoption for the Regulation for it to come into force).

**5. Additional concluding observations**

The Polish Presidency has made very constructive proposals on the subject of patents for NGT-1 plants. However, these proposals should apply to all patents that may cover plants, regardless of the technique used and, for this reason, should be addressed more appropriately in the draft PRM<sup>1</sup> Regulation.

We hope that the discussions initiated by the Polish Presidency will lead to a qualified majority in favour of the Commission's draft.

In the table below, we briefly summarize the four proposals previously suggested by AFBV and WGG on the subject of intellectual property:

<p><b>Proposal No. 1: make mandatory the publication of the patent status covering a variety :</b></p> <ul style="list-style-type: none"> <li>→ in the Official Catalogue of Species &amp; Varieties of the EU</li> <li>→ and in the CPVO database</li> <li>→ Optionally on PRM (seed bags)</li> </ul>	<p><b>Proposal No. 2: interpret the UPCA so that the breeder's exemption covers:</b></p> <ul style="list-style-type: none"> <li>→ genetic material,</li> <li>→ tools to improve and modify it (Crispr Cas 9)</li> <li>→ all regulatory steps prior to sales</li> <li>→ seed production prior to launch</li> </ul>
<p><b>Proposal No. 3: For cases requiring a compulsory license,</b></p> <ol style="list-style-type: none"> <li>1. Interpret the criterion of "considerable economic interest" and "public interest" as satisfied by the registration of a variety having a trait with             <ul style="list-style-type: none"> <li>→ a known and measurable economic advantage (e.g. disease resistance) or</li> <li>→ increased tolerance to measurable environmental factors (e.g. drought resistance) and</li> </ul> </li> <li>2. FRAND (fair, reasonable and non-discriminatory) conditions apply.</li> </ol>	
<p><b>Proposal No. 4: reassure small breeders by requesting the EPO to confirm formally that the disclaimer clause (§ 28(2) ) covers</b></p> <ul style="list-style-type: none"> <li>→ the plant containing a gene or a native trait, and</li> <li>→ the gene and the corresponding trait.</li> </ul>	

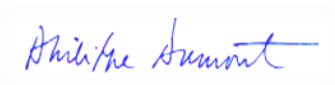
We reiterate our wishes for the success of the Polish Presidency's efforts to obtain a qualified majority in favor of the proposal.



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<sup>1</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)