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MEETING DOCUMENT

From:	Presidency
To:	Counsellors/Attachés (Agri - Genetic Resources and Innovation in Agriculture)
Subject:	Presidency non-paper in relation to the NGT proposal

In view of the meeting of the Counsellors/Attachés (Agri - Genetic Resources and Innovation in Agriculture) of 29 October 2025, delegations will find in annex a Presidency non-paper.

At the meeting, the Presidency will invite delegations to express their initial views on the questions highlighted in the last paragraph of the sections on sustainability and patents.

Non-paper by the Presidency

in relation to the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

This non-paper has been prepared by the Presidency to aid the discussions among delegations at the Attaché meeting on 29th of October 2025. The focus is on two of the outstanding issues in the negotiations, which are expected to be on the agenda of the 3rd trilogue, planned for 13th of November 2025, namely sustainability and patents.

Sustainability

In the Commission's proposal, sustainability criteria are included as regulatory incentives for NGT-2 (i.e., faster authorisation processes, pre-submission advice, exemption of fees for SMEs; see Article 22). Furthermore, sustainability is defined by a list of seven sustainability criteria in Annex III, Part 1 and a list of exclusion criteria in Annex III, Part 2. The only addition regarding sustainability made by the Council in its mandate is in the definition of a NGT-1 plant in Art. 3(7)(a) where the Council excluded tolerance to herbicides as an intended trait from the NGT-1 category. The European Parliament included an amendment in their mandate that plants can only be verified as NGT-1 if they meet at least one of the sustainability criteria cf. Annex III, Part 1 and none of the exclusion criteria cf. Annex III, Part 2.

In addition to its mandate, the Parliament during the negotiations has proposed a two-step NGT-1 verification process with regards to sustainability. In step one, the applicant shall submit a sustainability declaration in relation to the verification process in Art. 6. In step two, at a later stage and to obtain market access, the applicant shall provide data to demonstrate that sustainability criteria are met in the resulting plants bearing the verified trait. To this end, the Parliament also suggests that random checks be carried out by Competent Authorities to ensure NGT-1 plants deliver on sustainability.

For the Council, NGT-1 verification shall only be based on the criteria of equivalence. However, in an effort to reach a compromise the Presidency has suggested that sustainability criteria could trigger incentives for NGT-1 plants, as is the case with NGT-2 plants. In addition to this, the Presidency has emphasised that sustainability can only be addressed at trait level in the NGT proposal and not in the resulting variety. The latter is addressed in the PRM legislation and should not be duplicated in the NGT proposal, as it would be burdensome and lead to legal uncertainty for operators working with plants that have successfully passed the NGT-1 verification.

The trilogue on 14th of October 2025 concluded that three possible options for a compromise should be explored at technical level:

- 1) “Positive list”: NGT-1 status should be conditional on compliance with (at least one) sustainability criteria as set out on a broad, dynamic and non-exhaustive positive list of traits,
- 2) “Negative list”: NGT-1 status should be conditional on not having any of the exclusion criteria as set out on a negative list of traits,
- 3) “Incentives”: NGT-1 status should not be conditional on compliance with sustainability criteria, but these (positive) criteria/traits will be used as a trigger for incentives.

The Parliament has reiterated their demand for a follow-up demonstration that sustainability criteria are met at the latest interinstitutional technical meeting. This was once again rejected by the Presidency who in return has proposed to introduce a specific horizontal sustainability monitoring plan as part of the general monitoring and evaluation in Article 30. At the latest interinstitutional technical meeting it was mentioned that a compromise with Parliament would be difficult to reach on the third option regarding incentives, as Parliament does not deem this sufficient to ensure sustainability in NGT-1.

At the trilogue it was made clear by the Presidency that either compromise option on sustainability would depend on the compromise reached regarding the patent issue.

The Presidency is seeking the views of delegations on their order of preference among the three compromise options, as well as whether any delegation would have a red line against one of the options.

Patents

The issue of patents was not addressed in the Commission’s proposal. The European Parliament introduced in their mandate a full ban on the patenting of NGT plants and an amendment of the Biotech Directive (98/44/EC) to this effect. In the mandate of the Council, a balanced compromise was reached in order to take into account the divergent views of Member States on this issue. The Council mandate entails the following provisions on patents:

- Information on patents/patent applications shall be given and included in a public database as part of the process for verification of an NGT-1 plant, Articles 6 and 7. Moreover, a declaration on the willingness to licence on equitable terms is optional.
- Commission shall publish guidelines to assist operators in navigating the IP-landscape, including by describing existing licensing platforms and databases and by giving information on relevant legislation, including regarding compulsory licensing and exemptions.
- Commission shall establish an expert group on patents and conduct a study of the impacts of patents on NGT-plants. If adverse effects are identified, the Commission shall follow up with a legislative proposal, if appropriate.

At the trilogue on 14th of October 2025 the Parliament signaled willingness to reconsider their demand for a ban on patents, provided that a number of safeguards were introduced to ensure fair access to plant material for breeders and farmers. Most of the safeguards are already addressed in existing EU legislation, international agreements or the Council mandate.

Firstly, the Parliament is asking for more legal certainty to make it clear which traits are protected by a patent. This safeguard is similar to the amendment in Council mandate, where an obligatory submission of a statement on the presence or absence of patents or patent applications ("patent information", see Articles 6(3a) and 7(2a)) is required. Furthermore, the Council mandate includes an obligation for the Commission to publish guidelines for the purpose of assisting operators, in particular breeders, in navigating the plant intellectual property landscape (see Article 29(2a))

Secondly, in relation to the demand above, the Parliament also wants to make it clear that patents should not be granted for genetic sequences or characteristics that occur in nature or that can be achieved through conventional breeding methods without technical invention. The Presidency considers that this is addressed through the practice of the European Patent Office to either refuse such patent applications, or to ensure with a "disclaimer" that the protected subject-matter does not extend to plants obtained by essentially biological processes.

Thirdly, the Parliament also wants safeguards that prevent market concentration and ensure fair competition, particularly for SMEs. According to the Council mandate (Article 30a), the Commission shall establish a patent expert group to survey and exchange information on a regular basis as regards the effect of patent law and the implementation practice on access to modified genetic resources, transparency of the patent landscape and innovation in the field of NGT plants. The reports from the expert group shall be taken into account in the Commission study on the impacts of patents and if appropriate, may lead to the presentation of legislative proposals.

Fourthly, the Parliament wants to protect farmers' rights to save and replant seeds covered by a patent. This is already provided for in the Biotech Directive (described as a "farmers' privilege", see Article 11(1)) with a reference to the Plant Variety Rights Regulation (2100/94, see Article 14), and with the same extent and conditions of the farmers' privilege in both acts.

Fifthly, the Parliament is asking for a licensing system to be available under fair, reasonable and non-discriminatory conditions. The issue of licensing was also addressed in the Council mandate where a requester of an NGT-1 status voluntary can declare their willingness to license the protected trait under equitable conditions (see Articles 6(3b) and 7(2b)). An additional suggestion from the Presidency could be to task the Commission to exert oversight of existing licensing platforms to ensure that certain expectations are met (licensing conditions, scope, performance, terms of membership etc.), possibly in the form of a "Code of Conduct". There are precedents of such Commission oversight in other sectors.

Finally, the Parliament is calling for the guarantee of the breeders' exemption to ensure access to genetic material for further breeding and avoid restriction of experiment. This is also called a "limited breeders' exemption" as it allows breeders to freely use plant material with patented traits to develop and breed new varieties. If the breeder wants to commercialise a new variety, the consent of the patent holder is required. The limited breeders' exemption is provided for in the Agreement on a Unified Patent Court (UPCA, see Article 27(c)), which 18 Member States have implemented. Similar provisions exist in national patent law in several Member States.

The issue of patents is still to be further explored at an interinstitutional technical meeting, however the Presidency is interested to hear if delegations see any problems with the Presidency's approach to the Parliament's demands on their safeguards.