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From:	Presidency
To:	Delegations
Subject:	Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) – Meeting of 20 January 2025 – Steering note on the revised Presidency text on the Regulation on new genomic techniques (NGT)

In view of the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) of 20 January 2025, delegations will find in annex a Presidency steering note on the revised Presidency text on the Regulation on new genomic techniques (NGT) (doc. 5076/25).



Steering note for amendments to Articles 3, 4, 7bis, 7ter, 10bis, 11bis, and 30bis

of the proposal for a Regulation on Plants Obtained by New Genomic Techniques

Working Party on Genetic Resources and Innovation in Agriculture
(Innovation in Agriculture), 20 January 2025

The Polish Presidency aims at moving forward with the negotiations on the proposal for a Regulation on Plants Obtained by New Genomic Technologies (NGT). The goal is to find a qualified majority supporting an improved compromise text.

The negotiations have been ongoing since July 2023. A large group of Member States supports the text presented during Coreper on 7 February 2024, but not enough to achieve a qualified majority. During the Belgian and Hungarian Presidencies different scenarios on how to overcome this deadlock have been assessed. It is clear to the current Presidency that only by addressing the concerns linked to the existence of patents on plants obtained by NGT the qualified majority may be reached.

The Presidency has drafted amendments taking into account the fact that neither the Member States nor the Commission want to amend other legislation related to patents like the Directive on the legal protection of biotechnological inventions (Directive 98/44/EC), the Unified Patent Court Agreement (UPCA) or the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization.

The Presidency believes that 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 struck.

The amendments put forward look in general as follows:

1. The definition of 'cat. 1 NGT plant' is maintained in accordance with the COREPER text of 7 February 2024, does not depend on existence of patent(s), and is based exclusively on the biological features.
2. The definitions of 'patent', 'product patent' and 'process patent' have been introduced (Art. 3(16)-(18)).
3. There is a differentiation between process patents protecting basic technologies and process patents that result in a specific characteristic (trait) and this distinction is important for the marketing of NGT 1 plant reproductive material; the existence of patent(s) affects only the marketing of NGT 1 plant reproductive material; the existence of patent(s) does not affect the placing on the market of NGT plants or products (Art. 4).
4. The reproductive material of a category 1 NGT plant may only be placed on the market without further restrictions (see below) if 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 (Art. 4(2)).
5. It provides for a procedure to verify the existence of patent protection and for the Commission to issue a decision on the absence of such protection (or on the absence of a pending patent application) (Art. 7bis).
6. The reproductive material of a category 1 NGT plant may still be placed on the market if it is 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/or the application for such a patent was published in one or more member states; in this case the new Articles 7ter and 10bis shall apply.
7. It introduces the entitlement for a Member State to adopt measures restricting or prohibiting use for cultivation of reproductive material of a category 1 NGT plant protected by the aforementioned patent(s) in all or part of its territory (Art. 7ter).

8. It introduces an additional label to be used on the reproductive material of a category 1 NGT plant protected by the aforementioned patent(s) (Art. 10bis).

9. Subject to certain conditions and acting in the public interest, the Commission may launch the revocation of the patent verification decision and removal of patent protected category 1 NGT plant reproductive material from the market (Art. 11bis).

10. It postpones the publication of the Commission study on the impact of patenting practices (Art. 30bis); the Commission shall report on its findings one year after entry into force of the Regulation (Art. 30bis(4)).

The Presidency believes that the amendments address the concerns of the Member States related to patents. The amendments provide for a solution that can be used by certain Member States (opt-out for plant reproductive material of patented cat. 1 NGT plants), leaving other Member States the option not to apply this provision. Additional labelling of plant reproductive material of patented cat. 1 NGT plants brings clarity for the users and should not threaten the innovations.

We hope for a fruitful exchange during the Working Party!

Polish Presidency NGT Team