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From:	General Secretariat of the Council
To:	Delegations
Subject:	Regulation on new genomic techniques (NGT) – comments on biotechnology patents in plant breeding from the Netherlands, Poland and Romania

Delegations will find in annex submissions from delegations on the above subject, concerning questions and comments on biotechnology patents in plant breeding put forward after the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 5-6 October 2023.

THE NETHERLANDS

The Netherlands agree with the Commission's observation that this proposal is important for innovation and has connections with intellectual property. Therefore, the Netherlands supports the Commission's intention to conduct a study on intellectual property in this context and to formulate potential policy proposals. However, the Netherlands considers it late to publish the results of this study only in 2026. Various stakeholders in the Netherlands have already expressed their concerns on this matter, both regarding access to genetic material and the preservation of a balanced intellectual property system. The Netherlands therefore urges the Commission to initiate this study more quickly and to present conclusions and policy proposals sooner.

POLAND

General position

Genetic progress cannot depend on patented varieties or patented specific traits. Licensing fees and legal barriers will discourage small and medium-sized breeders from using patented varieties, limiting biological progress, biodiversity and the ability to bring new varieties to market.

In extreme cases, such practices will lead to dominance by large breeding companies that own the patents. Market exclusivity will allow the patent holder to control supply and demand for a patented plant variety, potentially allowing them to charge higher prices that are unacceptable to farmers and consumers.

Patenting varieties with particularly valuable traits or characteristics will unbalance the seed market and result in NGT varieties being superior to conventional varieties. NGT varieties will lead to a narrowing of the gene pool, reducing agricultural biodiversity.

The patenting of plant varieties leads to legal disputes with other breeding companies, but also to restrictions on farmers' rights to use the seed produced. Concerns arise if a breeding company inadvertently infringes a patent or if a patented element spontaneously finds its way into its breeding stock (e.g. uncontrolled over-pollination, which can occur, for example, in breeding collections). In some cases, patents may be granted for plant varieties or their elements created using NGT, but similar to those found in natural resources, gene banks or regional collections. Violation of the breeder's privilege, whereby the breeder's consent is not required for the use of protected varieties to develop new plant varieties, will undermine certainty, stability and order in plant breeding.

To conclude this section, we have serious concerns that the patents used in the NGT will have a negative impact on agriculture. Only the free use of genetic resources and methodological solutions will lead to biological progress and sustainability for the entire agri-food sector. Patenting these solutions will only serve the interests of breeding and biotechnology companies.

Additional remarks to the projekt in relation to patents.

We have understood that European patent law allows patenting not only synthetic sequences or sequences altered in such a way that they do not occur in nature, but also sequences identical to natural ones if the alteration have been obtained by technical means.
According to Article 9 of Directive 98/44/EC, a patent granted for a product containing genetic information extends to all materials, in which this genetic information has been incorporated and performs its function. This means, for example, that seeds of herbicide-tolerant plants containing a protected sequence are covered by patent protection, while e.g. flour made from these seeds is not, because flour is not sprayed with plant protection agents.
Therefore, the placing on the market of seeds of varieties (even those obtained from one's own breeding) containing a patented DNA sequence will constitute an infringement of that patent.

1. **How breeders can avoid using patented sequences in their breeding programs of conventional, organic and NGT varieties** when we accept that methods for detection and identification of NGT plants (bot category 1 and category 2) might not be available?.

2. **Once patented NGT varieties are released, how to protect the rights of breeders and farmers and not expose them to legal action for patent infringement when there is a serious risk of restricting access to the gene pool?**

After entry into force of this regulation, we can expect an increased number of patents on plants. We are concerned that the level of patenting, which may be very high in the case of NGT plants, will create a serious problem for breeders, as it may cover many traits which will be difficult for breeders to detect using genetic resources, including the so-called 'breeders' gene pool'.
The category 2 NGT variety can contain a big number of patented modification (eg 100) which are located on various chromosomes (covering big part of the plant genome). Any crossing with such NGT variety will result in transferring a patented sequences to the offspring. Out segregation of such a high number (100) of patented sequencing might be practically impossible even when methods for detection of genetic modification in the NGT variety are available.
Consequently the access to the breeders gene pool not covered by patents will be limited.

ROMANIA

Romania maintains its reserve of analysis regarding the NGT regulation proposal, the consultation at the national level on different levels, being ongoing.

Romania is gratefull to The Spanish Presidency of the Council for the opportunity offered to present its point of view regarding the patenting of NGT products, a particularly important subject that could influence the economic future of European agricultural production.

It is necessary to exclude from patenting plants obtained through processes that could take place in the natural environment (NGT1), as well as plants that are already in the public domain and genes of interest that are the object of biodiversity heritage. We do not agree with the licensing of transformation processes that would have taken place, with some probability, also "in vivo". In effect, we would be licensing a targeted mutation that could occur in the nature, followed by the isolation of the individual(s) it is present on.

The patenting of the NGT1 and NGT2 varieties is protected by variety patents which in turn have a special regulated regime.

Patenting biotechnologies applied to plants should not limit breeders' access to genetic material and techniques. Also, the establishment of a compulsory licensing system should be avoided, because it could affect the availability of seeds and the economic value of the investment in production that farmers will pay.

The patenting of biotechnologies applied to plants must not have a negative impact on the competitiveness of the biotechnological industry in the EU.