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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 Germany

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.

GERMANY**Federal Ministry of Food and Agriculture****27 October 2023****Questions on the topic of patenting plants in the context of the NGT proposal**

In the latest (5th) Council Working Party on “Innovation in Agriculture”, the Spanish Presidency offered the opportunity to submit questions to be replied to orally by DG Grow/EPO. We would like to thank for this offer and take this opportunity to submit questions as it is a very important topic for us and we think that there is still a lot of discussion needed to achieve more clarity.

1. To what extent is biopatent monitoring, similar to that in Germany, already conducted at EU level? Are there any plans to implement such monitoring on a continuous basis in the future?
2. What is the exact meaning of the terms compulsory licences, cross-licences and farmer's privilege? Who can make use of that, and how, and in which cases? What are the practical effects at present and, where relevant, in the future for the parties involved?
3. How exactly is the so-called ‘disclaimer solution’ translated into practice in the patenting of plants obtained from random mutagenesis? Have there already been litigation procedures with regard to the question whether a plant has been obtained through random mutagenesis or through other conventional breeding methods?
4. It was explained during the Council Working Party on 5/6 October, that the breeder’s exemption is only effective before the commercialisation and only in the 17 Member States that have already signed the Unified Patent Court Agreement. What does this mean in detail and what are the practical consequences for breeders?
5. Which private-sector data bases/licensing platforms are already known to the COM? Is the COM also considering the use of this tool or working towards regulating such use?
6. Which problems are known to the COM that could arise from the patentability of NGT plants for the competitiveness of small and medium-sized plant breeders and for the agricultural sector in general?
7. Has the COM examined which advantages and disadvantages could arise from increased patenting of NGT plants for the sustainability goals of the EU?
- 7.1. And has it also been examined which advantages and disadvantages could arise from increased patenting of NGT plants for achieving the sustainability goals of the UN?

8. To what extent is it envisaged to also take into account data/experiences from third countries in which NGT plants are already common, or from emerging and developing countries, in the report on the impact of the patenting of plants announced for 2026?
9. How do these third countries handle the patentability of plants that are categorised as 'equivalent to conventionally-bred plants' (comparable to Cat. 1 NGT) and are therefore not subject to genetic engineering regulation?
10. Can patent infringement proceedings be initiated even if there is no method to clearly prove that the plant or the product in question has been produced in a technological process?
11. What is meant by the principle of exhaustion? What is the effect of a patent on a plant or on a product from this plant?
12. What exactly is patented or protected by the patent? A DNA sequence? A group of plants/plant varieties containing this sequence? Products of these plants (which possibly do not contain the DNA anymore)?
13. With reference to a statement of DG GROW in the Council Working Party: To what extent are plant variety law and patent law actually comparable as regards the problems facing in cases of unintentional contamination of neighbouring fields with certain sequences/traits?
14. Based on the suggestions of several MS: What can be done to support that/if here will be no patent application or utilisation for NGT plants in the agricultural sector?
15. Which special rules for small and medium-sized enterprises already exist in patent law and which would be conceivable?
16. What would farmers have to take into account in the case of replanting farm-saved, patented seeds (the use of own crops for further reproduction)? According to your estimation, what would be the financial and legal consequences for farmers if they replant farm-saved seeds without permission or the payment of licence fees?
17. In light of the increasing number of patentable plant traits due to the latest technological developments, how does the Commission intend to ensure that the crucial contribution of plant breeding to the European goals like the Green Deal, which is based on a diverse breeding landscape of mainly small and medium-sized enterprises and the protection of new plant varieties as the primary protective right in plant breeding, will not be brought to an almost complete standstill?
18. Does the Commission see the danger of restricted access to biological material as a consequence of the increasing possibilities with regard to the patenting of plant traits? If yes, what steps could already be taken before 2026 to prevent this?

19. Does the Commission see the danger of oligopolisation in plant breeding and an ensuing decrease in the diversity of the available crop species and plant varieties as a consequence of the increasing possibilities with regard to the patenting of plant traits? If yes, what steps could already be taken before 2026 to prevent this?

20. What will be the components of the market analysis announced by the Commission and planned to be presented by 2026, and which stakeholders will be involved? Will the consequences (social, economic and environmental) for third countries, also including emerging and developing countries, be taken into consideration?

21. Which impact does the Commission expect from the announced market analysis on the influence of patented plant traits from NGT plants on plant breeding until 2026?