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### CONTRIBUTION

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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 Cyprus, Czechia and Denmark

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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.

**CYPRUS**

Alongside the issue of coexistence, another major concern is the prevention of the privatization of genetic resources (through patents) in any dimension of this effort, and the victimization of small-scale farmers and SMEs operating in this sector. Cyprus, is strongly in favour of a free access on NGT plants, at least for SMEs and the public sector. Since these technologies are designated as a mean to combat climatic change and to produce solutions for feeding the ever growing population from hunger (UN SDG), we are of the opinion that they should be freely available,. Public sector breeders and SMEs in the field of plant breeding should be allowed for breeding new varieties free of any intellectual property restrictions. Traits of plants intended for food, that are NATURALLY available in the Breeder's Gene Pool shouldn't be patentable or restricted for breeding purposes.

Cyprus is concerned regarding farmers pertain to their protection from price increases and their ability to safeguard their own seed produced from a previous cultivation period for own use in the next growing season. Ending up with limited options for monoculture or oligoculture does not serve the goals of this proposal and the Green Deal.

We note that although the Proposal defines Category 1 as equivalent and Category 2 as partially equivalent to conventional plants, this does not seem to apply in the case of patents. We believe that the existing system for protecting varieties (CPVO/UPOV) is sufficient for safeguarding both the investments of plant reproductive material production companies and the interests of farmers and small to SMEs. Understanding that this does not fall under the authority of this working group, we propose that the Commission take the necessary actions to exempt NGT plants intended for food from the application of patent law.

Cyprus supports ensuring uniform implementation throughout the EU, promoting agricultural production, the environment, and human health. We reiterate our support for the French proposal to expedite the examination of patent issues and find quick solutions to the problems at hand.

We strongly support Wageningen’s initiative for the free availability of Crispr-Cas related patents for the wider good. Below is a statement taken directly from Wageningen’s website. Let us take this as an example for the EU and try to truly protect the Union’s Farmers, Breeders and Companies holistically.

*“Wageningen holds a portfolio of patents that are made available to the private and or public sector for further use. The CRISPR-Cas patents are made available for free and they are not trait related. They are on specific methods. The plants are not patented, only the specific breeding technology that can be applied for a wide range of plants/plant varieties. This is really quite unique for CRISPR, in the academic world and beyond. As far as we know, we’re among the first to do so regarding CRISPR-technology. We do it, because we simply and firmly believe this is the right thing to do.”*

*Two billion people face inadequate nutrition around the world in 2020. Nearly all of them are also vulnerable to the effects of climate change. So, we need a transformation to healthier, more sustainable, equitable, affordable and resilient food systems. This will also take center stage during the UN Food Systems Summit on September 23<sup>rd</sup>. CRISPR and other biosciences could accelerate this transformation.”*

## CZECHIA

### PATENTS

Patents are not the subject of the NGT legislation. However, a discussion on this topic is inevitable. From the point of view of the Czech Republic, plant varieties that may arise and occur naturally or may be produced by conventional breeding or are considered conventional plants should not be subject to Patent legislation but to Plant Variety Rights legislation, which allows the use of the so-called Plant breeders' exemption and Farm saved Seeds exemption.

The Czech Republic wants to avoid limiting access to NGT plants for small and medium-sized breeders, possible monopolisation of the sector, reduced production of varieties for local conditions and thus a decline in the entire breeding industry.

The Czech Republic sees the following main risks arising from the possible patentability of the NGT 1 category:

- restricting/preventing access to genetic resources for small breeders,
- the end of the Farm saved Seeds exemption., i.e. the end of farmer's seed, including the exemption for small farmers, as there is no exemption for patents,
- the monopolisation of the market and the increase in the price of seeds,
- difficult lawsuits due to non-existent or unreliable methods of detecting genome modifications.

In the optics of innovative breeding methods, we would like to point out the unclear relationship of Patent law vs Plant Variety Rights legislation. Therefore, as long as there is uncertainty in the interpretation of the current legislation on plant patents, there will be constant existential concerns for breeders, belong to the SME category, i.e. the category of enterprises that should be prioritised according to our government's declaration on support for small and medium-sized enterprises.

Note:

We would like to note our concern about random mutagenesis. From the point of view of the Czech Republic, all breeding procedures, e.g. **random mutagenesis**, are technological conventional procedures that only make the breeding process faster and more efficient and are necessarily followed by other processes such as crossing and selection. This is not a reason for the possibility of patenting products resulting from these processes. If we allow the patenting of biological products that are indistinguishable from those obtained naturally (and freely crossable and reproduced), we will completely dismantle the current functional system within the breeding and seed sector.

Questions:

1. The legislative proposal concerns the marketing of plants obtained by NGT but does not address the intellectual property issues of varieties produced by these methods. There are major concerns among small and medium-sized breeders about the monopolisation of this sector by a few multinationals because of the potential patentability of NGT 1 plants. How will it be ensured that NGT plants are not patented?
2. The EC will assess the impact that plant patenting and licensing can have on innovation in plant breeding. It will also assess the impact on breeders' access to genetic material and techniques, and on the availability of seed to farmers. By 2026, the EC will produce a report which should serve as a basis for decisions on possible follow-up measures. What measures does the EC have in mind if the study shows a negative impact on small and medium-sized breeders? For example, if it finds that large companies already hold a large number of patents relating to bred crops. How does the EC plan to stop or possibly reverse this negative trend? Is the EC concerned that in 3 years' time it might be too late? However, we welcome this EC initiative on the study and, like some other Member States, hope that it will be completed before 2026.
3. Please provide further explanation of the COM Notice from 2016 mentioned in the EC presentation What is the specific practice with this Notice within the EPO? What is the source of the sentence "If a technical feature is obtainable both by technical process or EBP, excluded subject-matter is to be disclaimed". What is its impact?
4. We would also welcome a more detailed explanation, including concrete benefits in practice, of the tools of Patent legislation facilitating research and access to breeding materials in the framework of the „Agreement on a Unified Patent Court (UPCA). Also mentioned in the EC presentation
- 5) Finally, we would like to know something more specific about the general criteria for patentability (novelty, inventive activity, industrial application).

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## DENMARK



Ministry of Food, Agriculture  
and Fisheries of Denmark  
Danish Agricultural Agency

### Regulation on New Genomic Techniques (NGT) – Reply from Denmark concerning questions on biotechnology patents in plant breeding

The proposal on new regulation on NGT is expected to make it more attractive to use these techniques, and thus the use of patents on plants is foreseen to rise.

Denmark finds, that an analysis of the consequences of increased use of patenting of plants for agriculture, including consequences for breeding companies as well as dealers/grocers and farmers etc., is desired. Such an analysis should at least address the following questions:

- 1) Which consequences are foreseen for the sector (breeding companies, dealers/grocers and farmers etc.), both at Member State level and aggregated EU level, from increased use of patents especially regarding their ability to compete on an international market? Focus should be particularly on SMEs. Will it, for example, in the long term reduce access to genetic material and thus limit the sectors “freedom to operate”? And will there be increased risk of patent pools and dominant positions on the market, etc., also taking into consideration that the competitive conditions and the position of companies are very different across Member States.
- 2) What will increased use of patenting mean for the behaviour and speed of development/speed of innovation in the sector (breeding companies, dealers/grocers and farmers etc.)?
- 3) What socio-economic consequences does it have for society that there will be increased use of the option to take out patents on plants, and are there financial consequences for the individual breeding companies, dealer/grocer, farmer etc. in the market, including new costs for exploiting the patenting opportunities.
- 4) Does Unitary Patents pose opportunities for securing exemptions for breeding companies?

At national level, the Danish Agricultural Agency, has contracted Copenhagen University, Department of Food and Resource Economics, to carry out an small scale analysis of similar scope to the above mentioned.