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NOTE

From: General Secretariat of the Council
To: Delegations

Subject: Regulation on new genomic techniques (NGT) – comments from Denmark, Estonia, Finland, France, Greece, Italy and Poland

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (16.02.2024)

Delegations will find in annex submissions from delegations on the above subject, concerning comments put forward after the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 27-28 November 2023.

DENMARK**Ministry of Food, Agriculture
and Fisheries of Denmark**

29 November 2023

Danish comments for room documents on NGT put forward by the Presidency (WK 15807/23, WK 19560/23 and WK 19561/23)

Denmark would like to thank the Spanish Presidency for the continued good and thorough work on the NGT proposal.

Recalling the presentation and debate on the three room documents on herbicide tolerance, opt-out, and labelling of category 2 NGT at the meeting in the Council working group on 28 November 2023, Denmark has carefully scrutinized the three documents.

The texts entail compromises on substantial issues, especially regarding the possibility for opt out on category 2 NGT. As also expressed at the meeting, this is not Denmark's preferred option, as it risks undermining the internal market and negatively affect the level playing field.

Some Member States have asked for a change on Article 10, with the aim of introducing full labelling of category 1 NGT products in the entire production chain. For Denmark, it is essential that the text of Article 10 is not changed. Denmark cannot support extension of labelling for category 1 NGT to cover food and feed products to the final users/consumers. Such a labelling would increase the costs of food and feed due to the need for traceability and separation in all parts of the value chain.

Denmark would also like to reiterate our position that the organic sector should have the chance to benefit from the advantages of category 1 NGT's. Therefore, the best solution is to delete Article 5(2). Alternatively, it has to be explored how the potential burden on the organic sector due to the proposed ban can be eased.

Denmark is willing to positively consider the compromise texts on herbicide tolerance, opt-out, and labelling of category 2 NGT under the condition that no further substantial concessions on the proposal are given that undermines the use and marketing of NGT's. This includes changes to Article 10.



1 December 2023

Danish comments for room documents on NGT put forward by the Presidency (WK 15958/2023)

Denmark would like to thank the Spanish Presidency for the continued good and thorough work on the NGT proposal.

Denmark supports that the regulation of patents on plants is handled in the European Patent Legislation. Denmark furthermore supports the Commission's initiative to put forward a study on the consequences of patents on plants.

Denmark suggests to remove the study's focus on the impact that patenting may have on innovation in the EU biotechnology sector to the EU plant breeding sector. The biotechnology sector is functioning on a patent based way to protect their inventions. The organisms they use are mostly microorganisms and there is no alternative to patents to protect their inventions and rights.

The plant breeding sector operates with the System of Plant Variety Protection to protect their inventions and rights. This system is well functioning and takes the special aspects of plants, plant breeding and innovation into account.

As the plant breeding sector has an alternative intellectual property rights in place, Denmark believes that the study should primarily focus on the consequences for this part of the sector as well as the innovative and economic consequences for other affected sectors and society as a whole.

Regarding the release of the report, Denmark would prefer an earlier date. Preferably by 31 December 2024 and no later than 30 June 2025.

ESTONIA

EE comments NGT working group 27-28.11.2023.

- 1) Annex III: Bioremediation: How about algae that belong to a different taxonomic group? Maybe bioremediation would be a more general term?
- 2) Revised Presidency compromise text on Articles 1-34 and Annexes I-III: Under the preambular points 21 and 24 please insert clarification for database.
- 3) Room document on coexistence and opt out: Is not an easy and ideal compromise, but we are ready to go for it to find a common and suitable solution for everyone.
- 4) Room document on voluntary labelling: We have no problem with optional labeling of NGT2 and we are flexible here.
- 5) Room document on herbicide tolerance: *scr. res.*
- 6) Room document on a study on the impact of patenting: the speedier roll-out of the survey is welcome.
- 7) Art10 is a red line for us. We support labelling on NGT1 for seeds and other reproduction material only. It is supported by both our breeders and researchers. NGT1 is equal to the conventional plants, and it is not proportionate to label products made from them differently. Labeling of seeds and other reproduction material already gives producers the choice to use or avoid it.
- 8) Delegated act to amend annex 1 is also red line for us. It is extremely important to be up to date in scientific progress and not to lock the potential of EU breeding sector.

EE comments on Patents in plant biotechnology

We thank presidency for today's informative videoconference on patents in plant biotechnology.

Patents are a natural part of the economic landscape and play a crucial role in fostering innovation. Plant breeders have both options- patentable as well as patent-free opportunities for creation of crops that are more resilient, nutritious, and sustainable. This, in turn, ensures a more reliable and diverse food supply, addressing the ever-growing demands of our global population. It is also important to keep in mind that patents provide a recognition of the inventor's contribution to science and a protection for the intellectual property associated with innovative inventions. Patents are instrumental in encouraging researchers and scientists to invest expertise, time, and resources into developing these innovative solutions. Patents also provide positive commercial opportunities for breeders and developers and diversify the markets. New and better varieties can be more expensive, of course, and it is the same with all other areas, for example, pharmaceuticals. This is the price of innovation, and, with the increasing selection of better varieties, the market is going to set and regulate the prices. We emphasize the importance of monitoring the impact of patents along with all other impacts in the monitoring survey, which will provide us with valuable information about the functioning of the market.

GREECE

Greece fully supports Presidency's room documents WK 15961/23 and WK 15960/23, as they stand. Regarding room document WK 15807/23, we fully support and we support Malta's, Cyprus, Croatia's, Italy's and others proposal about article 5 "Article 5 (2 bis)Articles 26a(1) and (2) of Directive 2001/18 shall apply to Category I NGT plants and products produced from or by such plants in respect of islands with a total UAA under 150000 Ha", as well.

Regarding room document WK 15958/2023 INIT, Greece amendment is the following:

“Article 30 bis

External study

The Commission shall conduct a study on the impact that the patenting *of plants* and related licensing and transparency practices may have on innovation in plant breeding, on the breeder's access to genetic material and techniques and on availability of plant reproductive material to farmers as well as the overall competitiveness of the EU biotechnology industry.

The Commission shall report on its findings *before the date of application of this Regulation*.

Where appropriate, the report shall be accompanied by a legislative proposal amending the legal framework on the protection of biotechnological inventions (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998)."

FINLAND

As regards the proposal for a Regulation on plants obtained by certain new genomic techniques (NGT) and their food and feed products, discussed at the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 27-28 November, and taking into account the room documents put forward by the Presidency (WK 15807/23, WK 15958/23, WK 19560/23 and WK 19561/23)

Finland supports the proposal considering following points:

- herbicide tolerance: Finland can accept the changes proposed in the meeting by the presidency
- voluntary labeling: Finland can accept the changes proposed in the meeting by the presidency. Although in order to avoid misleading or confusing indications, it would be important that the labelling should be specified in the authorisation.
- opt-out and coexistence: Finland can accept the changes proposed in the meeting by the presidency, provided that NGT1 –plants are not included

We would also like to point out a few typos and inconsistencies in 15205/2/23 REV 2:

- Page 17 last sentence: *coexistence* -> *coexistence*
- Article 15 bis (1): *assesment* –*assessment*
- Article 27(e): *performace* ->*performance*
- page 53 first line: *exposure assesment.* -> *exposure characterization* (The term has been fixed in all the other parts of the text)

FRANCE



Paris, le 4 décembre 2023

**NOTE DES AUTORITÉS FRANÇAISES
À LA PRÉSIDENTIE DU CONSEIL DE L'UNION EUROPÉENNE**
[REDACTED]
et au **Secrétariat général du Conseil**
[REDACTED]

Objet : Commentaires de la France sur la proposition de compromis sur les brevets, présentée par la Présidence lors du groupe des 27-28 novembre 2023.

Concernant la proposition de compromis présentée par la Présidence lors du groupe des 27-28 novembre, les autorités françaises soutiennent le principe d'une disposition donnant un mandat clair à la Commission pour la réalisation de l'étude et l'inclusion de solutions possibles dans cette étude. Elles souhaiteraient toutefois que le délai pour remettre cette étude soit avancé à 2025 au maximum, de manière à pouvoir engager le cas échéant les actions nécessaires avant la mise en application du règlement NGT.

Les amendements suivants sont proposés (reproduits ci-dessous dans la proposition de compromis) :

- Avancer le délai de remise de l'étude à 2025 au maximum, et de préférence en amont de cette date ;
- Remplacer "competitiveness of the EU biotechnology industry" par "competitiveness of the EU seed sector";
- Préciser l'objectif des mesures possibles : remplacer «to follow up the study » par « to solve or prevent the potential negative impacts identified on the objectives mentioned above ».

Courtesy translation :

With regard to the compromise proposal presented by the Presidency at the group meeting of 27-28 November, the French authorities support the principle of a provision giving the Commission a clear mandate to carry out the study and to include possible solutions in this study. However, they would like the deadline for submitting this study to be brought forward to 2025 at the latest, so that any necessary action can be taken before the NGT regulation comes into force.

The following amendments are proposed (reproduced below in the compromise proposal):

- Bring forward the deadline for submitting the study to 2025 at the latest, and preferably before that date;
- Replace "competitiveness of the EU biotechnology industry" by "competitiveness of the EU seed sector";
- Specify the objective of possible measures: replace "to follow up the study" with "to solve or prevent the potential negative impacts identified on the objectives mentioned above".

Article 30 bis

External study

The Commission shall conduct a study on the impact that the patenting and related licensing and transparency practices may have on innovation in plant breeding, on the breeder's access to genetic material and techniques and on availability of plant reproductive material to farmers as well as the overall competitiveness of the EU ~~biotechnology industry~~ seed sector.

The Commission shall report on its findings and possible measures required to ~~follow up the study~~ solve or prevent the potential negative impacts identified on the objectives mentioned above not later than 31 December ~~2026~~2025 ⁽¹⁾.

⁽¹⁾ At the latest and preferably before this date

ITALY

Room document on herbicide tolerance (WK 15961/2023 INIT): We agree with the Presidency compromise text proposed. The exclusion of NGT 1 is in line with the goals on pesticide reduction of the Farm to Fork strategy.

Room document on voluntary labelling (WK 15960/2023 INIT): We agree with the Presidency compromise text proposed because the voluntary regime is maintained.

Room document on coexistence measures and opt-out from cultivation (WK 15807/2023 INIT): We agree with the Presidency compromise text proposed as the proposal keeps the choice in the hands of our country.

Room document on a study on the impact of patenting (WK 15958/2023 INIT): We agree with the Presidency compromise text proposed as it adds a level of security for the effects and impact that patenting may have on various sectors.

POLAND

As regards the discussion during last WG PL would like to thank again for hard work and the proposed changes.

Poland support doc. WK 15807/23 – (opt out, coexistence).

On 1st of Dec. we send opinion on patent proposal (WK 15958/23).

Amendements related to herbicide tolerance and voluntary labeling of NGT 2 were not our priority and we dont comment on them.

However, we pay your attention to art. 5(2) in relation with art 10. We maintain our proposal submitted toogheter with AT, HU, RO and SK delegations.

Labelling of products is essential to ensure traceability, keep consumer trust by providing sufficient information and the freedom of choice for consumers.

According to the current proposal only seeds and propagating material of category 1 NGT plants are subject to the labelling requirement. As regards the breeding and farming sector this provides insufficient transparency. Traceability of category 1 NGT plants and products from operator to operator until the finall consumer can only be ensured if all the products are labelled along the whole food chain.

The use of new genomic techniques is incompatible with the concept of organic production and with consumers' perception of organic products. Therefore, according to the current proposal, the use of category 1 NGT plants remains prohibited in organic production, however the implementation of this in practice raises questions. Organic farming does not only use seeds and propagating material for its production, but also food and feed products. Consequently the exclusion of category 1 NGT plants of organic farming can only be guaranteed, if not only seeds and propagating material, but also food and feed products are labelled.

WK 15958/23 - (patents) - we thank PREZ for this proposal, it is a step in the right direction, but it does not address our fundamental concerns.

Concerns about patents have been raised by most countries in the Working Group.

Today's videoconference did not address the concerns raised by the breeder sector, and our concerns remain.

It should be emphasized that we note the unfavorable direction of the shift of the property rights on varieties contained in the UPOV Convention towards the regulations on biotechnological patents.

We strongly believe that patents should not restrict the use of NGT plants in the creative work of breeders and growers - in particular, our concerns relate to NGT Category 1 plants.

We suggest that a specific provision be added to the Draft Regulation to ensure that NGT 1 plant material is not patentable.

We propose this change by, for example, additionally amending the definition of NGT 1:

Article 3

Definitions

[...]

(7) 'category 1 NGT plant' means a NGT plant that:

(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, and does **not include tolerance to herbicides among the intended traits conveyed by the genetic modification**, or

(b) is progeny of the NGT plant(s) referred to in point (a), including progeny obtained derived by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003, or

(c) is not patented or does not include patented sequences according to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions;

Our justification is based on rule that unlimited access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (Breeder's exemption).