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From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

Subject: Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625 (**first reading**)
- Adoption of the Council's position at first reading and of the statement of the Council's reasons
= Statements

Croatia has requested that the following statement be entered in the Council minutes

The Republic of Croatia reiterates its position that the proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 should be duly considered from three main standpoints: agriculture, environment and health. It is also necessary to take account of public opinion and to ensure adequate protection for consumers and their right to 'freedom of choice'.

The Republic of Croatia supports a decision-making process based on scientific knowledge and the assessment of potential benefits. At the same time, it is necessary to safeguard a high level of protection of human health, animal health and the environment, while protecting sustainable agriculture and food production.

The Republic of Croatia would like to highlight the following fundamental concerns, which it also raised during the negotiations on the text:

1. In accordance with the principle of subsidiarity, Member States should be allowed to decide to restrict or prohibit the cultivation of NGT plants on their territory.
2. The precautionary principle is not adequately guaranteed in respect of consumer protection, labelling and the traceability of all NGT products.
3. There are no measures in place to prevent potential environmental contamination by NGT plants and no compensation mechanisms in case of harm, especially in relation to organic production.

Therefore, the Republic of Croatia cannot support the adoption of the Regulation on plants obtained by certain new genomic techniques and their food and feed as these elements have not been satisfactorily addressed.

Hungary has requested that the following statement be entered in the Council minutes

Hungary considers innovation in agriculture important, including the use of new technologies capable of addressing key challenges such as climate change, food security and sustainability. With regard to new genomic techniques, we recognise the need to establish a clear, transparent and robust legal framework to ensure that the use of organisms created by these new techniques does not pose a risk to the environment, human and animal health, and takes due account of the interests of both consumers and producers.

During the discussion on the draft over the past three years, Hungary has taken the view that the draft is conceptually flawed, as it does not take into account the newly created properties of the plants and/or their potential risks when separating plants into categories NGT1 and NGT2, but only discriminates on a molecular basis, based on the type, extent and number of modifications. Hungary has always expressed concerns about the draft and has consistently called for the inclusion of the following key elements in the regulatory proposal:

- Consideration of the precautionary principle and the use of a case-by-case approach, ensuring that all NGT plants undergo a scientific risk assessment before being placed on the market;
- Mandatory labelling of all NGT products to ensure traceability and guarantee consumers' right to make an informed choice;
- Ensuring compliance with Hungary's international treaty obligations;
- Consideration of the principle of subsidiarity, ensuring Member States' freedom of choice for all NGT plants;

As the final text of the draft does not adequately address the concerns we have raised, Hungary cannot support its adoption.

Austria has requested that the following statement be entered in the Council minutes

In principle, Austria recognises the possible potential of new genomic techniques (NGT). They are, however, also associated with potential risks.

Austria welcomes the fact that it is still possible to opt out of the cultivation of category 2 NGT plants. However, key concerns raised repeatedly by Austria have not been addressed in the final text. These concerns are set out below.

- In Austria's view, not carrying out a risk assessment for category 1 NGT plants and products is contrary to both the precautionary principle and the Cartagena Protocol.
- Furthermore, Austria is of the opinion that consumers have a right to information and freedom of choice. The absence of a labelling requirement for products from category 1 NGT plants (with the exception of plant reproductive material) significantly limits that freedom of choice and we therefore consider it unacceptable.
- Austria expressly welcomes the proposed ban on the use of NGT plants and their products in organic farming. However, this raises the question of how it can be implemented without the labelling of products from category 1 NGT plants, including animal feed, without incurring substantial additional costs for those in the agricultural sector.
- The possibility for NGT plants to be patented raises concerns that this could have a negative impact on small and medium-sized breeding companies, potentially forcing them out of the market. In Austria's view, the transparency provisions regarding patents included in the final text neither address the fundamental concerns surrounding this issue nor provide legal certainty.
- Austria believes that the equivalence criteria set out in Annex I do not have a scientific basis. Despite concerns having been expressed repeatedly, no scientific justification has been provided to date as to why those criteria should be equivalent to conventional breeding. Austria would also like to point out that Annex I deviates significantly from the Council's negotiating mandate with regard to the equivalence criteria, in particular concerning the fact that genetic modifications in introns and regulatory sequences are exempt from the established upper limit. In Austria's view, this would have required further discussion prior to the final vote on the text.

In light of the above, Austria cannot agree to the adoption of the Regulation.

Slovenia has requested that the following statement be entered in the Council minutes

Slovenia considers that the agreement on the proposal for a Regulation on plants obtained by certain new genomic techniques and their food and feed does not adequately address a number of key issues, in particular concerning risk assessment, labelling, traceability, the availability of analytical methods, and Member States' autonomy in decision-making and in respect of conditions of production.

Slovenia underlines that the current lack of appropriate control tools, together with the possibility of unintended genetic modifications, necessitates the application of the precautionary principle and a thorough risk assessment to prevent potential adverse effects on human or animal health, on the environment or on agricultural production.

In view of the above, Slovenia cannot support the agreement and is unable to agree to the proposed Regulation in its present form, and wishes to emphasise that innovation must be introduced in a responsible manner, on the basis of sound scientific evidence, and in a way that protects the environment and preserves freedom of choice.

Slovakia has requested that the following statement be entered in the Council minutes

We appreciate the progress made in drafting the Regulation, yet, due to the fact that the Slovak Republic still has reservations regarding Category 1 NGT plants, particularly because the draft Regulation does not allow for the labelling of Category 1 NGT plants and their products across the entire production chain, thereby limiting the consumer's right to make an informed decision, **the Slovak Republic has decided to vote against** the draft Regulation.

The European Commission has requested that the following statement be entered in the Council minutes

The European Commission reiterates its full commitment to protecting the functioning of the internal market and the plant breeding sector, in particular small and medium-sized enterprises (SMEs).

To this end, in accordance with the provisions of the compromise agreement, the Commission recalls the following measures included in the text to be adopted by the Council as its position at first reading:

1. The Commission will closely monitor the impact of the NGT regulation on SMEs in the European seed sector, with the objective to avoid that the development of NGT plants, and in particular their patenting, leads to negative impacts on the plant breeding market, such as the exclusion of SMEs.
2. The Commission will oversee the drawing up of a code of conduct which will be ready as soon as possible and no later than 6 months before entry into application of the regulation.
3. The Commission will assess the functioning of licensing platforms and their use by the seed sector, to ensure transparency on patents and facilitated access to licences for SMEs under fair and reasonable conditions.
4. The Commission will ensure that SMEs have access to support and guidance on patent matters relating to plants, in order to balance the relations between different players in the plant breeding market.
5. The Commission will fulfil all its reporting obligations, which include a report on the implementation of the regulation every 5 years (Article 32(1)), an assessment of the impact of the regulation (Article 32(3)), an assessment of the impact of NGT plant patenting practices (Article 31(4)), and a report on the functioning of the code of conduct every 5 years (Article 30(7)).

6. As part of its assessment under Article 31(4), the Commission will consider the appropriateness of updating or supplementing its interpretative notice 2016/C 411/03 on certain articles of Directive 98/44/EC on the legal protection of biotechnological inventions. In particular, the Commission will assess whether it would be appropriate and legally feasible to further precise and clarify the patentability criteria for inventions relating to plant genetic information, the concept of essentially biological processes and the conditions for compulsory cross-licensing set out in Article 12 of that Directive, without prejudice to the legal framework provided for in the Directive and in full compliance with the international commitments of the EU.

7. In the event that the system is not functioning smoothly, in particular as regards SMEs, the Commission will consider, where appropriate, the establishment of mandatory conditions or safeguards as part of the review clause provided for in Article 31(10), in full compliance with the international commitments of the EU.
