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From:	Presidency
To:	Delegations
Subject:	Regulation on New Genomic Techniques (NGT) – Presidency non-paper on the main issues

With a view to the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) of 19 July 2024, delegations will find in annex a Presidency non-paper summarising the main issues that have emerged to date in the discussions on 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.

ANNEX

Non-paper by the Presidency

on the work of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture)

in relation to 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

In preparation for the meeting of the Working Party on 19 July 2024, delegations will find attached a non-paper drawn up by the Presidency in order to facilitate the discussions and to structure the work on 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".

On 5 July 2023 the Commission proposed a legislative draft[1] on plants obtained by certain new genomic techniques and their food and feed. The examination is ongoing in the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture). No qualified majority could be reached so far in the Council and a deadlock has developed. In order to move further with the dossier the Presidency believes that more discussion is needed on several elements of the draft as there was not enough time to discuss them properly and to find an appropriate solution. Therefore this non-paper prepared by the Presidency summarises the main issues that have emerged in the discussions to date as well as identifies possible avenues to overcome the concerns expressed by Member States.

[1] 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 (doc. 11592/23 + ADD 1)

1. Annex I. - Criteria of equivalence of NGT plants to conventional plants

The proposal establishes two categories of NGT plants. The distinction between these two categories is based on the criteria for equivalence to conventional plants as defined in Annex I to the proposal. A number of Member States and stakeholders expressed their concerns with regard to the proposed criteria. They point out that the proposed set of criteria do not make the distinction between the two groups based on traits and/or their possible risks but simply based on the type, size and number of modifications made. Without taking into account the resulting traits and thus the possible risks of modifications, the scientific basis of the distinction between the two categories of plants could be questioned.

According to the rationale for the equivalence criteria in Annex I prepared and presented by the Commission, the analysis of type, size and number of mutations are considered as sufficient for assessing "equivalence". This, however, might not be sufficient for establishing similarity of category 1 NGT plants in terms of their risks with existing conventionally produced plants that are used for comparable purposes with a long safety record according to recital 17 of Directive 2001/18/EC[2].

The information which, according to the proposal, should be submitted for verification of the status of a category 1 NGT plant might not prove to be appropriate to evaluate possible impacts associated with the introduced modifications and not sufficient to assess whether category 1 NGT plants are equivalent to conventionally produced plants.

Based on the above-mentioned concerns, the Presidency seeks the views of Member States on what the basis could be on which certain NGT plants are considered to be equivalent to those produced by conventional techniques, beyond the current criteria set out in Annex I.

[2] "(17) This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record."

2. Risk assessment for category 1 NGT plants and products

One of the main objectives of the proposal is to maintain a high level of protection of human and animal health and of the environment. Environmental considerations with regard to category 1 NGT products are entirely missing from the proposal. The argument behind is to follow a more holistic approach highlighting the interlinkages of the Commission's proposal for a Regulation on production and marketing of plants reproductive material in the Union (Regulation on plant reproductive material[3] - PRM) and also the fact that category 1 NGT plants and products are considered to be equivalent to conventional plants and products. While understanding the close linkages of the two proposals, the PRM proposal is dealing only with seeds/plant reproductive material of a limited list of cultivated plants, leaving other plants and all processed products out of its scope. In addition, the assessment of value of sustainable cultivation and use (VSCU) within EU PRM legislation is currently not meant to assess risks *per se*.

A number of Member States highlighted that another main objective of the proposal is to steer developments towards contribution to sustainability goals in a wide range of plant species, especially for the agri-food system, and try to create an enabling environment for research and innovation. According to them, these objectives can only be achieved by simplifying or eliminating the application procedure for certain plants and products. In contrast, another group of Member States called for at least a simplified risk assessment and management framework also applicable to category 1 NGT plants and products in order to assess possible risks prior to marketing and to ensure the proper surveillance after releasing them into the environment.

[3] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material; doc. 11502/23 + ADD 1)

Furthermore, the proposal states that it has been developed in line with the precautionary principle. However, the criteria for equivalence as described in Annex I are not related to any case-specific safety considerations, but solely to technical/molecular parameters. The European Court of Justice in its judgement in case C-528/16[4] confirmed the need to base any exemptions on Recital 17 of Directive 2001/18/EC, meaning that exceptions can only be granted for "organisms which have conventionally been used in a number of applications and have a long safety record". Some Member States consider that no sufficient scientific justification has been provided to conclude that all category 1 NGT plants are associated with a significantly lower risk than category 2 NGT plants, and there is only extremely limited experience with the use of NGT plants. Consequently, they do not have a long safety record.

Therefore, the Presidency asks Member States whether they see a possibility to consider a simplified risk assessment procedure in relation to category 1 NGT products and seeks their views and flexibility on whether some common aspects of a possible simplified risk assessment procedure could be agreed on.

2.1. Scope of the regulation - wild plant species

The scope of the proposal covers NGT plants (apart from micro algae) and plant products without making any distinction between plants. Therefore not only agricultural plants but also wild species are covered by the proposal, including annual and perennial plants, trees, bushes, macro algae (seaweed), etc. Some Member States raised concerns that the use of NGT with regard to wild plants could have impacts on ecosystems that are not known in advance.

The Presidency sees two options with regard to wild plant species. If the regulation covers wild plants obtained by new genomic techniques, this should be complemented with a thorough environmental risk assessment in order to avoid irreversible changes in ecological systems. An alternative is to limit the scope of the regulation to agricultural plants only.

The Presidency is seeking the views of Member States on how to handle the issue of wild plants obtained by new genomic techniques.

[4] Judgement of the Court of Justice of 25 July 2018, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, C-528/16, ECLI:EU:C:2018:583

3. Labelling of category 1 NGT food and feed products

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

According to the proposal, only seeds and propagating material of category 1 NGT plants are subject to the labelling requirement. A number of Member States expressed that the labelling requirement for category 1 NGT plants should be extended to food, feed and other products in order to ensure transparency along the entire production chain, while others agreed with the proposal.

According to the organic sector's opinion expressed and also indicated in the impact assessment[5] of the proposal, the use of new genomic techniques is not compatible with the wider objectives of organic production and with consumers' perception of organic products.

The reason why the proposal in its current form seems not to address the interest of the organic sector is that the sector is not limited to organic farming and the production of raw commodities on the farm, but does also cover food and feed production. Although the intention of the proposal was to create the possibility for the organic sector to exclude category 1 NGTs from their production, its practical implementation raises serious concerns.

Based on the opinions of Member States already expressed, the Presidency believes that, basically, there are two possible ways to deal with category 1 NGT plants and products in relation to organic farming. As a first option, if Member States choose to protect the organic sector's concept, i.e. to guarantee the exclusion of category 1 NGT plants from organic farming, while agreeing with and keeping the current concept of the whole proposal, not only seeds and propagating material but also food and feed products along the chain should be labelled. The second option, which was raised by some Member States, is to allow the use of category 1 NGT plants in organic farming. In this case no labelling of any product would be needed. This might however contradict the current concept of the organic production and also the goals of the European Green Deal's Farm to Fork Strategy[6] and Biodiversity Strategy for 2030[7].

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5 Commission staff working document - impact assesment report accompanying the document 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 (doc. 11592/23 ADD 4)

6 A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system. COM(2020) 381 final, https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=CELEX:52020DC0381

7 EU Biodiversity Strategy for 2030. Bringing nature back into our lives. COM(2020) 380 final, https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=celex:52020DC0380

In summary, the Presidency is asking Member States which option they prefer, or if they see any other options.

4. Detection and identification of NGT plants and products

In order to ensure proper traceability, transparency and informed consumer choice, reliable detection and identification methods for NGT plants and products are needed. The Presidency believes that this is one of the main challenges all Member States are facing. Finding a solution is crucial in order to establish appropriate legislation for NGT plants and products.

The European Union Reference Laboratory for GM food and feed (EURL GMFF) and the European Network of GMO Laboratories (ENGL) issued a report on the detection of food and feed plant products obtained by new mutagenesis techniques in 2019[8]. At that time, they concluded that it is not feasible to differentiate a specific NGT product from conventional ones that contain the same modification(s). The ENGL updated its report in 2023[9] and concluded that limitations have been identified for the development and validation of robust, event-specific detection methods for different types of genomic modifications in plants resulting from targeted mutagenesis or cisgenesis. It is stressed that products that have identical DNA sequences but have been developed either naturally or by conventional breeding or by using new genomic techniques cannot be distinguished by analytical methods. For an effective market control of such products, and especially for unknown products entering the European Union, analytical detection will need to be complemented by other enforcement measures. It is furthermore predicted that the current analytical enforcement system will suffer from an increased workload if food, feed and seed samples have to be analysed using individual methods for all known mutation events.

8 European Network of GMO Laboratories (ENGL), 2019. Detection of food and feed plant products obtained by new mutagenesis techniques. JRC116289, https://gmocrl.jrc.ec.europa.eu/doc/JRC116289-GE-reportENGL.pdf

9 European Network of GMO Laboratories, 2023. Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis, Publications Office of the European Union, Luxembourg, JRC133689, https://data.europa.eu/doi/10.2760/007925

To avoid getting stuck in the current situation and also to have a clearer and more up-to-date picture of the current developments in research and innovation in the field of detection and identification of NGT plants and products, the Presidency finds that further analysis and also continuous horizon scanning of this specific issue would be useful during the negotiations within the Council, including having feedback from the EU funded DETECTIVE and DARWIN projects, specifically launched this year with the aim of developing detection methods for NGTs.

The Presidency asks whether the Member States have any ideas on possible other measures that could ensure traceability and whether they consider horizon scanning beneficial.

5. Sustainability

The European Green Deal's Farm to Fork Strategy specifically identified new techniques, including biotechnology, as a possible tool to increase sustainability of agri-food systems and contribute to guaranteeing food security. There is no question that sustainability is a key component in the agri-food sector, thus, Annex III is a very important element of the proposal, as it lists in its Part 1 traits that are expected to be useful for a more sustainable agriculture, having less negative impact on the environment. However, in the proposal, sustainability appears only in relation to category 2 NGT plants and products, and only in relation to the incentives. According to the Commission, real policy measures were not included in the proposal itself because sustainability should be handled horizontally.

Since environmental considerations constitute an essential part of sustainability [i.e. assessment of abiotic stress tolerance (e.g. drought, heat), biotic stress (e.g. plant pests), climate change mitigation, protection of biodiversity], a complete exemption of sustainability check and ecological assessment of category 1 NGT plants and products would contradict one of the main objectives of the proposal.

It was noted during the discussions that the traits listed in Annex III are described in very general terms. Some Member States stressed the need of developing criteria and data requirements in conjunction with beneficial traits, or wished to have further clarification and/or scientific justification on the suggested traits relevant for sustainability, in order to be able to appropriately evaluate the contribution of the given plant/product to sustainability. It was also made clear that sustainability can never be claimed by looking at only one specific trait of a plant or product. Environmental, social and economic circumstances should also be taken into account in connection with the planned application/use of the plant or product.

The Presidency believes that in order to fulfill the goals of the European Green Deal's Farm to Fork Strategy, a genuine sustainability approach needs to be established and implemented in relation to the plants and products obtained by new genomic techniques. Sustainability of a certain product also needs to be assessed following a common, data based approach. Thus, the Presidency seeks the views of the Member States whether this issue should be dealt with within the frame of the NGT proposal or within a wider horizontal approach, e.g. in the announced "legislative framework for sustainable food systems".

The Presidency would like to see the preferences of Member States, as well as any idea on the possible content of sustainability criteria and possible ways to assess them.

6. Exports to third countries - equivalence criteria with conventional seeds regarding third countries

During the negotiations, a Member State raised the issue of equivalence of conventional and category 1 NGT products. Certain third country trading partners do not necessarily consider category 1 NGT products to be conventional, which could create trade barriers. Consequently, in order to guarantee international trade in conventional plants and their products with third countries, the equivalence of category 1 NGT plants with conventional plants has to be widely accepted to ensure the commercial flow. In order to maintain the flow of commercial trade and to ensure the equivalence of category 1 NGT plants with conventional plants, not only by the European Union, but also by third parties, a global trade impact assessment might need to be conducted.

The Presidency, therefore, encourages Member States to liaise with their national trade experts and collect information from their third country trading partners to explore whether they might face the same problems as described above. As a follow up, the Presidency asks Member States to provide feedback on their findings.

7. The verification procedure (increased administrative burden on Member States and possible effects on operators)

Swift processing of verification requests and the timely decision by Members States' authorities are crucial for the applicants, taking especially into account the period of the growing season. However, it could cause a significant burden for the relevant national authorities, taking into account their capacities. In summary, on the one hand a long administrative procedure could lead to a postponement of the planned field trial to the following year, but on the other hand the proposed time for the procedure is very tight to verify the submitted information and to prepare a meaningful scientific report that can be made available to the Member States and the Commission. This is especially true in the case of Member States that do not have staff dedicated particularly for the assessment of verification requests. As a consequence, it may discourage SMEs or academic research groups to carry out their field trials in the EU, if the outcome of the verification procedure is uncertain.

It could also be considered, as it was suggested by some Member States during the negotiations, that the verification procedure for field trials should be transferred completely to EU level. This could be a solution also to lighten the administrative burden on national authorities and could also provide a solution for the time constraints. Another idea was raised to have a simple, effective, harmonized and uniform verification procedure, regardless whether the use of these plants is for deliberate release into the environment or for placing them on the market, so that the verification procedure performed at the national level could be more beneficial for SMEs, universities and other stakeholders due to e.g. easier accessibility or elimination of language barriers.

The Presidency would like to explore the preferences of Member States with regard to the verification procedure, based on the above mentioned or any other considerations.

8. Empowerment of the Commission for adopting delegated acts

According to Article 5(3) of the proposal, the Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I in order to adapt them to scientific and technological progress as regards the types and extent of modifications which can occur naturally or through conventional breeding.

Without any doubt the distinction of the two categories of NGT plants and products is the core element of the proposal.

The criteria included in Annex I – although based on scientific literature – are, in fact, the result of a policy decision, as was confirmed by the Commission. A number of Member States expressed their concerns about the fact that criteria which were defined by a policy decision could be amended by means of a delegated act on the basis of scientific development, and they believed that the criteria should only be amended through the ordinary legislative procedure.

The Presidency believes that – despite the oral presentation given by the Council Legal Service – this question has not yet been resolved and remained unclear for a number of Member States from a legislative point of view.

9. Compliance with the Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty governing the transboundary movements of living modified organisms (LMOs) resulting from modern biotechnology. The Cartagena Protocol on Biosafety was established to address the potential risks posed by LMOs resulting from modern biotechnology.

According to the proposal, category 1 NGT products were exempted from the GMO regulations and were to be regulated as conventional products. In the light of the provisions of the proposal, its compliance with the Cartagena Protocol on Biosafety may not be guaranteed, given the potential conflict between the Protocol and the Regulation if it is adopted. This has not yet been assessed, neither in the impact assessment of the proposal, in spite of the fact that the adoption of the proposal could create a situation whereby all Member States might become non-compliant with their international obligations, which is to be avoided.

This is especially important considering that according to the European Court of Justice, international agreements concluded by the EU become part of the EU legal order.[10] It means that international agreements concluded by the EU are binding on its institutions and Member States as well. Furthermore, the ECJ elaborated that international agreements can have direct effect and their legal force is superior to that of secondary legislation, which must therefore comply with them.[11] Moreover, the Court stated that even if '*[…] the CBD contains provisions which do not have direct effect, in the sense that they do not create rights which individuals can rely on directly before the courts, that fact does not preclude review by the courts of compliance with the obligations incumbent on the Community as a party to that agreement*.'[12] Based on this, it can be reasonably assumed that Cartagena Protocol is relevant to the proposal and its requirements have to be taken into account when drafting the proposal. As the possible adoption of the proposal with its current text may be in conflict with a superior international agreement, the Presidency considers it essential to have legal clarity in order to achieve a common understanding on the issue and to avoid any non-compliance with our international obligations.

The Presidency is seeking the views of Member States on how they assess their compliance with the Protocol, should the proposal be adopted in its current form.

Furthermore, an analysis comparing the criteria in Annex I with those in third countries regulating NGTs could be useful in order to get a clear picture globally, as has been proposed by one Member State.

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10 C-181-73. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:61973CJ0181

11 C-12/86. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:61986CJ0012

12 C-377/98. para 54, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:61998CJ0377