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From:	General Secretariat of the Council
To:	Delegations
Subject:	Regulation on new genomic techniques (NGT) – comments from Austria, Belgium, Czechia, Denmark, Finland, Germany, Greece, Ireland, Latvia, Lithuania, the Netherlands, Romania, Slovakia, Spain and Sweden

Delegations will find in annex submissions from delegations on the above subject, put forward after the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 19 July 2024.

AUSTRIA

Austrian Statement to the Presidency non-paper

Overall Statement:

Austria highly appreciates the initiative of the Hungarian Presidency, which is presented in the non-paper.

Austria is of the opinion that more time for discussion is needed on several elements of the draft Regulation, as highlighted by the Presidency. The elements identified by the Presidency are essential points of the draft and also essential points for Austria.

Therefore, Austria supports the non-paper and looks forward to further discussions on these topics.

Detailed Statements according to the points of the non-paper:

1.) Criteria of equivalence of NGT plants to conventional plants:

Austria still has reservations on the proposed criteria laid down in Annex I. These criteria are not scientifically based and the technical criteria laid down are not linked to any potential risk of the NGT, as a potential risk is always linked to the trait and the environment in which the NGT is used. In addition, the given number of 20 genomic changes is arbitrarily and not scientifically sound. Furthermore, the information which should be submitted is not sufficient to prove that NGT plants are equivalent to conventionally produced plants.

Austria therefore asks for further discussions on this point.

2.) Risk assessment for category 1 NGT plants and products:

Austria is of the opinion that the omission of a mandatory risk assessment for category 1 NGT plants and products, as foreseen in the proposal, is not in line with the precautionary principle and the Cartagena Protocol.

Austria understands the underlying principle of the draft proposal, that if a NGT 1 plant or product is equivalent to a conventional plant and product, there is no more risk associated. However, any classification of equivalence based on the criteria in Annex I is just an assumption. We are of the

opinion that besides the criteria of Annex I, also the issue of how to prove equivalence needs further discussion.

Austria is flexible to discuss a simplified risk assessment for NGT1 plants and products as long as there is a mandatory risk assessment for all NGT plants.

2.1) Scope of the Regulation – wild plant species:

Austria is of the opinion, that this Regulation should be limited to agricultural plants.

As there is no history of save use nor enough experience or data to assess possible risks, and the environmental effects may be quite significant, wild plant species should be excluded from this Regulation.

3.) Labelling of category 1 NGT food and feed products.

Labelling of category 1 NGT plants and products along the entire production chain is essential to ensure traceability, information and the freedom of choice for producers retailers and consumers.

The labelling of NGT 1 seeds and reproductive material is strongly supported by Austria. Nevertheless, this only ensures NGT free cultivation. Organic and GMO-free production are not limited to cultivation, but also cover food and feed production. Since NGT are not allowed in organic production, a non-labelling of NGT 1 products would cause additional burden and costs for the organic sector.

Therefore, Austria reiterates the request for a mandatory labelling of NGT1 products along the whole food and feed production chain.

4.) Detection and identification of NGT plants and products:

Austria is of the opinion, that detection and identification methods of NGT plants and products are essential to ensure traceability, transparency and freedom of choice for consumers. Therefore, Austria asks for EU-wide efforts to develop analytical methods.

In addition alternative methods for traceability, e.g. paper based traceability or separated production chains should be explored and their costs be evaluated. Austria therefore thinks that a horizon scanning exercise could be very useful.

Furthermore, Austria strongly recommends, that companies that want to bring category 1 NGT plants onto the market must be obliged to submit detection methods, reference material and data on genetic modifications.

5.) Sustainabillity:

Austria stated several times that sustainability could never be claimed by looking at only one specific trait of a plant or product, as suggested by the list in Annex III. Sustainability is a broad concept including environmental, social and economic aspects. All those should be taken into account in connection with the planned application/use of the NGT plant or product. Any claim of sustainability needs to be substantiated by a solid, data based assessment.

Currently there are no criteria nor methods to assess the sustainability of NGT plants or products. Austria therefore believes that either such criteria need to be developed within the discussion on the current proposal, or – preferably – discussed within a broader framework, such as the envisaged sustainable food systems framework.

6.) Exports to third countries – equivalence criteria with conventional seeds regarding third countries:

The responses (USA, CAN, ARG and BRA) to the draft Regulation in the context of the WTO notification indicate that there is some concern about the potential for disruption to global trade in the event of asymmetric regulation of NGTs.

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

Austria is of the opinion that the deadlines proposed to the MS to complete the verification process are too short. Within the proposed timeframe, it is almost impossible to verify the information given by the applicant and to make a proper assessment. In addition, this short period of time will presumably not be sufficient to carry out all the necessary analyses and tests to determine a possible NGT 1 status.

Therefore, Austria reiterates the request for longer timeframes.

8.) Empowerment of the Commission for adopting delegated acts:

Austria is of the opinion, that especially Annex I of the draft Regulation is an essential part of the whole Regulation. Therefore, amendments to this Annex should not be the subject of a delegated act.

Since there are contradicting opinions between the Member States, Austria strongly asks for a written statement by the Council Legal Service, in order to provide legal certainty.

9.) Compliance with the Cartagena Protocol on Biosafety:

Austria is of the opinion, that the compliance with the Cartagena Protocol on Biosafety is a mayor issue, as the EU and its Member States are bound to the requirements laid down in the Protocol. These requirements include, among others, a mandatory risk assessment and labelling for all LMOs, as well as a reporting obligation on all LMOs authorized for placing on market.

We interpret the definition of LMOs as given in the Protocol to include also NGT plants and products. Therefore, we believe that some compliance issues might arise, if NGT1 plants are exempted from requirements such as risk assessment and labelling.

BELGIUM

Disclaimer: this document represents the shared position by the Belgian administrations in relation to the proposal on plants obtained by certain New Genomic Techniques. In this document, the Belgian administrations want to address some of the issues raised in the Hungarian Presidency non-paper. This position, however, might be subject to change and does not per se reflect the final Belgian position, due to the fact that since the June elections not all governments have been installed at present.

The Belgian administrations acknowledge the fact that there is a need for a specific legislative framework for plants obtained through New Genomic Techniques. Therefore, the Belgian administrations acknowledges the need for the legislative proposal and the opportunity to engage. The Belgian administrations look forward to a concrete text to continue negotiations and encourage the Presidency to keep on moving forward with the file.

The Belgian administrations support a differentiated approach for products and plants obtained with NGT. We therefore support, in general terms, dividing plants into two categories; NGT plants category 1 and 2. The Belgian administrations think that criteria should be predictable and unambiguous.

The Belgian administrations recognize, as a first step principle, that Category 1 NGT plants should be considered as "equivalent to conventional plants, i.e. mutants found in nature or obtained by technologies existing before 2001, and therefore are not subject to the legislation outlined in Directive 2001/18".

The Belgian administrations believe that farmers should be informed and free in their choice of seed or planting material. It sees in the mandatory labeling of seed and planting material as "NGT 1" a possible solution to meet this principle.

At present, the Belgian administrations have no knowledge of a molecular detection method that can identify the presence of a plant altered with a NGT (i.e. that a certain mutation was generated via a NGT). Therefore, according to the Belgian administrations, enforcing the presence or absence of plants generated via NGTs based on these methods is impossible today. As an alternative, the Belgian administrations are open to discuss a proportional and voluntary system of (paper-based)

traceability throughout the chain of category 1 NGTs. This system should allow freedom of choice within the food production and processing chain and allow those who wish to operate without NGTs to do so. The Belgian administrations acknowledge that a subset of the NGT plants can contribute to a more sustainable agriculture.

In the assumption that the categorization based on molecular criteria is kept in the text, the Belgian administrations wish to propose as a second step principle an additional categorization, for example as a subcategorization of Category 1 NGT plants, regarding sustainability. Those plants that contain introduced phenotypic traits that may not contribute to more sustainable agriculture but that do meet the molecular criteria of Annex I can undergo an appropriate assessment. The administrations wish that insect-resistant plants are considered for this assessment and that insect-resistant plants can only be marketed if it can be demonstrated that there is no expression of insecticide in the pollen, nectar or moisture at guttation above an unacceptable level, which is defined in advance.

The Belgian administrations wish that the verification procedure for field trials is conducted at the national level. We wish that this leads to a temporary status and be confirmed at a later stage.

The Belgian administrations question whether the comitology procedure to confirm the equivalence status to category 1 NGT is the most efficient way of working and wants to help think constructively about alternative ways of working.

CZECHIA

Prague, August 20, 2024

CZECHIA´s comments on Presidency non-paper related to draft regulation on New Genomic Techniques (NGT)

In general, the Czech Republic welcomes efforts to continue in negotiation of the draft regulation on the NGT. We are open to further discussions and firmly hope that the Council's general approach will be adopted as soon as possible. We find the compromise text of February 2024, which had the greatest support from Member States, as a good negotiating starting point.

We have dealt with the HU PRES non-paper very properly and set out CZ position/findings below:

1. Annex I - Equivalence criteria for NGT plants to conventional plants
The Annex I has been for CZ one of the essential parts of the draft Regulation. Our experts dealt with this part very intensively. During several negotiations we made many concessions and came almost to the limit of our flexibility. The text of Annex I of February 2024 is an acceptable compromise proposal for us, which was also as supported by 17 MS

This issue has been successfully concluded from our point of view. The compromise text takes into account the EFSA's scientific opinion that targeted mutagenesis products are equivalent to conventional plants and is also a very good starting point for negotiations with the European Parliament. Any interference with this part of the proposal could lead to lose the support of many MS and this will make negotiations on the draft regulation in the trialogues more difficult.

2. Risk assessment for category 1 plants NGT and its products
One of the objectives of the draft Regulation is to place NGT category 1 plants, which are equivalent to conventional plants, on the market under the same conditions as their conventional counterparts. The testing and risk assessment of these plant varieties prior to their placing on the market will be subject to the legislation for conventional plant breeding and cultivation. In this respect, we consider further risk assessment for category 1 NGT plants to be a non-standard requirement which would burden these plants administratively, time and financially. We consider this requirement to be discriminatory and going against the purpose of the proposed regulation.

2.1 Proposal for a Regulation - wild plant varieties
Plant breeders routinely work with wild plant varieties to obtain novel traits or to recover features that have been lost during the plant breeding process. In the text of the draft Regulation, we refer many times to the so-called "gene pool", which ensures compliance with conventional breeding practice. It is also necessary to mention existing European legislation for the protection of wild plant varieties (e.g. Directive 43/92/EEC). From our point of view, this is not a topic for further discussion that could move negotiations of draft regulation forward.

3. Labelling of food and feed from NGT plants of category 1

We support the wording of Article 10 in the compromise text of February 2024. From our perspective, labelling of seeds of NGT category 1 plants can maintain consumer confidence in agricultural production, preserve farmers' choice of farming system and at the same time protect organic farming. In our point of view, this can be ensured by labelling NGT seeds.

We consider the obligation to label food and feed from NGT category 1 plants to be inconsistent, discriminatory and difficult to implement, as these plants are indistinguishable from their conventional counterparts due to the detection limits of current analytical methods. In addition, such obligation would have serious impact on food producers and might lead to increase of prices.

4. Detection and identification of NGT plants and products

The Czech Republic could support the introduction of only control instruments that would allow the competent authorities to fully implement detection and identification controls at national and European level in such a way that European producers are not disadvantaged.

The requirements in this area set out in the February compromise text are in line with current scientific developments and detection capabilities and therefore the Czech Republic is in favour of maintaining this text, which was supported by 17 MS.

5. Sustainability

The Czech Republic supports faster placing on the market of demonstrably sustainable products from NGT under predefined conditions and maintaining a high standard of food safety. As this is a very complex issue, we prefer to address it in a relevant legal framework dealing with sustainability. Breeding techniques are only one of many tools that can have an impact on sustainability within food systems.

In our view, sustainability assessments are carried out comprehensively for varieties of all major agricultural crops prior the placing on the market. This would duplicate the sustainability assessment in the context of NGT verification.

6. Exports to third countries - equivalence criteria with conventional seed for third countries

According to the discussions so far, we have not seen a specific negative reaction from third countries to the development of the legislative framework on NGT in the EU.

The EU proposal is stricter than the legislation of some other third countries where NGT plants have been deregulated. Compared to the EU, only a part of NGT plants (so-called category 1) will be regulated as conventional plants and an obligation to label these seeds as NGT will be introduced.

7. Verification procedure (increasing administrative burden on Member States and possible impact on operators)

We support a simple, efficient and harmonised procedure for verifying the NGT status of plants on science based. In our view, the way to achieve this is primarily through verification at the national level.

We consider this issue to have been sufficiently debated and from our perspective it is a closed point. CZ support the verification procedure proposed in the February 2024 compromise text which reflects different views and approaches of MS to the verification process.

8. Empowerment of the Commission to adopt delegated acts

We support maintaining the current text presented in February 2024. In our view, the Regulation should serve as a flexible instrument to allow reflection of the boost scientific developments in the future.

In our view, this issue has been sufficiently discussed and we consider it as a closed point.

9. Compliance with the Cartagena Protocol on Biosafety

The internal EU discussions on the proposal for a regulation on new genomic techniques are still ongoing and the outcome is unclear so it is premature to predict what it will be. In our view, there is no reason why the ongoing negotiations on European legislation should be discussed at international working conferences such as COP MOP 11 until the NGT legislation is adopted in final form.

DENMARK

20 August 2024

Danish comments to the Presidency non-paper 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

Denmark finds the NGT proposal to be of great importance for the EU agri-food sector. It is important that the sector as soon as possible can take advantage of the NGT techniques. Our current European regulation is not fit for purpose as the Commission study has clearly shown. This proposal will maintain a high level of food and feed safety.

The overall approach in the compromise text discussed during Coreper in February 2024 (document 16714/20) is the best starting point for continued negotiations. This compromise text is the outcome of constructive negotiations under the Spanish and Belgian Presidencies, which began more than one year ago.

The text, supported by a majority of 17 Member States, represents a robust and equitable resolution that reasonably accommodates the diverse interests of all the Member States.

In our view, the issues presented in the Hungarian non-paper have already been thoroughly discussed in the council working group, COREPER and AGRIFISH meetings and have been incorporated into the February 2024 compromise text.

Therefore, the discussions on a General Approach should be based on the February 2024 compromise text. To move forward, the focus for up-coming discussions should be on finding solutions that preserve its main elements and avoiding a repetition of previous debates. It will also be important to reach an agreement on how the relation to patents should be addressed.

Denmark remains committed to working constructively with the Presidency towards a General Approach. With this in mind, Denmark has the following comments on the nine specific topics listed in the Presidency non-paper:

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

Denmark does not find it necessary to go beyond the criteria of equivalence in the current compromise text. Denmark does not agree with the text in point 1 in the non-paper, which does not seem to acknowledge a key concept in the NGT proposal, namely the fact that category 1 NGT plants are equivalent to plants obtained with conventional techniques. This fact was one of the main reasons that it was deemed necessary to make new legislation on NGT plants in the first place.

EFSA has in its recent scientific opinion[1] (23 June 2024), which was requested by the Parliament, confirmed that "it is scientifically justified to consider category 1 NGT plants as equivalent to conventionally bred plants with respect to the similarity of genetic modifications and the similarity of potential risks".

If the lines suggested in the non-paper were adapted, the EU would end up in a situation where plants with identical genetic modifications were regulated differently, depending on whether the modification was introduced with conventional methods or with NGT. This is not proportionate and therefore not acceptable to Denmark.

2) Risk assessment for category 1 NGT plants and products

Denmark does not agree that category 1 NGT plants and their food and feed should undergo risk assessment. This would run counter to the above-mentioned key concept of the NGT proposal, namely that category 1 NGT plants are equivalent to plants obtained with conventional techniques and therefore should be regulated similarly.

2.1) Scope of the regulation - wild plant species

Again, category 1 NGT plants are equivalent to conventionally bred plants so category 1 NGT plants should not be treated differently from conventionally bred plants. The same approach should be taken with regard to wild plant species.

3) Labelling of category 1 NGT food and feed products

Denmark does not agree to the labelling of NGT-1 on food and feed as this would impose unnecessary burdens and expenses on the whole food chain, including consumers. Such labelling would also run counter to the above-mentioned basic concept of the NGT proposal, that is the equivalence between category 1 NGT plants and conventional plants.

When it comes to conventional breeding, consumers are not informed about the techniques used if mutations were created by the use of irradiation or chemicals. EFSA has assessed that, compared to conventional breeding and conventional genetic modification such as transgenesis, there are no new risks to human and animal health and the environment associated with the use of certain novel genomic techniques. EFSA has also assessed that the risk of unintended effects, such as off-target effects, may be significantly reduced compared to transgenesis and conventional breeding. In our opinion, NGT labelling on food and feed products is not meaningful to consumers and consumers might come to the erroneous conclusion that it is not as safe as products without this labeling. Thus, it could potentially be misleading information.

When it comes to the use of NGT1 in organic production (including farming), Denmark prefers option 2 in the non-paper, i.e. that it should be allowed to use category 1 NGT plants and their food and feed in organic agriculture. Organic farming should benefit from the advantages of the category 1 NGT plants in the same way as they today can grow conventional bred varieties, including varieties developed using conventional mutagenesis.

[1] Scientific opinion on the ANSAS analysis of Annex 1 of EC proposal COM 2023 411 (EFSA-Q-2024-00178) of 19 June 2024

Firstly, NGT-1 techniques can be used to develop more sustainable crops that may benefit the organic sector. Secondly, due to the small size of the organic sector, the organic sector is highly dependent on plant varieties developed for the conventional sector. Once the conventional sector adapts the category 1 NGTs, it may become difficult for the organic sector to get access to new plant varieties. Consequently, there is a risk that the organic sector in Europe will be left behind with outdated varieties (genetics) if conventional agriculture adopts NGTs that give higher yields and are more sustainable.

According to information from the Commission, the situation is handled differently by the organic movements in those third countries that have decided that category 1 NGT plants are not GMOs. If only the EU put a ban on category 1 NGTs in organic farming, but exporting countries do not, there will be different interpretations of the issue across the world, which could influence consumers trust in organic products in Europe and the trade situation negatively.

4) Detection and identification of NGT plants and products

Again, the non-paper does not seem to acknowledge the situation which led to the current NGT proposal. As mentioned previously, category 1 NGT plants are equivalent to plants developed by conventional breeding methods. For such plants, it is not possible to detect whether the genetic modification is made with NGTs or with conventional methods. Denmark considers it very positive that the proposal appropriately addresses the challenges posed by the current GMO regulation in relation to detection and identification, because it is not possible to detect which technique that was used to develop a change. The non-paper does not seem to recognize this fact.

Denmark does not agree that further analysis and horizon scanning on this specific issue is needed. Denmark does not see a need to trace and detect products from category 1 NGT and distinguish them from conventional products, as they per definition are equivalent to conventional products. As already mentioned above it would significantly increase consumer prices for food and feed. Denmark does not find it necessary to invest resources in this issue.

As to labelling of category 1 NGTs, the Commission has proposed, that category 1 NGT plants must be listed in a publicly accessible database and seeds and propagating material of category 1 NGT plants must be labeled when transferred, but not harvested food and feed products. This is a balanced compromise, which gives commercial growers the choice to deselect crops of category 1 NGT, if they prefer not to grow NGT, e.g. if the ban for organic farmers is upheld.

5) Sustainability

Denmark agrees that NGTs are a possible tool to increase the sustainability of agri-food systems and contribute to food security. Denmark also agrees to the incentives concerning sustainability that are included in the proposal. And this is exactly why there is an urgent need to put new regulation in place that will allow the agri-food sector to benefit from these techniques. A permissive regulation on NGT plants will be an important contribution to a more sustainable agri-food system in the EU.

Sustainability is however a concept that does not just involve NGTs. Policy measures regarding sustainability that go beyond the previously mentioned incentives should therefore be dealt with in a wider horisontal approach and not in the frame of the NGT proposal.

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

Denmark does not see the need for the suggested action. Whenever you export seed, food or feed products to a third country, you have to follow the regulations of that country. Furthermore, and as pointed out by the Commission at previous meetings, no third countries have mentioned this issue during the WTO hearing about the NGT proposal. Denmark therefore sees no need for further action regarding this matter.

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

Denmark's main priority in this regard is that the verification procedure should be relatively fast, simple, and based on science. Denmark is open to discuss what the administrative set-up should be, i.e. who should do what.

8) Empowerment of the Commission for adopting delegated acts

Denmark believes that the main priority should be to ensure that amendments to the criteria of equivalence can be made relatively fast, simple, and based on scientific developments. Denmark supports the wording of article 5(3) of the proposal and thus the empowerment to the Commission to adapt delegated acts.

Denmark trusts, that the amendments being empowered to the Commission will be based on solid scientific proof that adapts the criteria to scientific and technological progress. Denmark finds, that this is the best approach to ensure that the regulation is future-proof and can be adjusted to scientific and technical developments in the future.

9) Compliance with the Cartagena Protocol on Biosafety

Denmark does not agree to the non-paper concerning the alleged lack of legal clarity and possible conflict between the NGT proposal and the Cartagena Protocol. The Commission has previously explained that it has assessed that the NGT proposal is not in conflict with the Cartagena Protocol. Therefore, Denmark does not see the need to question the Commission's assessment at this point.

The Commission also mentioned that several parties to the Cartagena Protocol had already implemented legislation on NGT organisms that exempted some of these from the GMO regulation. In some cases, these legislations went further than the Commission's NGT proposal. Denmark is not aware that these regulations are being questioned due to a possible conflict with the Cartagena Protocol.

FINLAND

Finland warmly welcomes the Commission's proposal for a regulation on plants obtained by certain new genomic techniques. The focus of the up-coming discussions should be on finding solutions that preserve the main elements of the proposal and avoiding a repetition of previous debates. We believe that the overall approach considered in the compromise text discussed in February 2024 (ST16714) is the best starting point for continued negotiations, as it is the outcome of long and constructive negotiations under the Spanish and Belgian Presidencies. The key goal is to maintain the general principles of the proposal to move towards a more sustainable and competitive agri-food sector while maintaining a high level of protection of health and the environment.

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

In our view, the equivalence criteria have already been discussed thoroughly in the council working groups, COREPER and AGRIFISH meetings and have been incorporated into the February compromise text. Finland can accept the February compromise proposal in this respect, and no additional criteria are needed.

2. Risk assessment for category 1 NGT plants and products

Finland does not see justified even a simplified risk assessment procedure for category 1 NGT products, as they have already been verified to be equivalent to conventional plants (conventionally bred or naturally occurring plants), for which the current EU legislation does not require a risk assessment. Also, such a requirement without a solid justification could be challenged in the WTO as a technical barrier to trade.

2.1. Scope of the regulation - wild plant species

Finland has not yet discussed this topic nationally.

3. Labelling of category 1 NGT food and feed products

In our view, the issue has already been thoroughly discussed in the council working groups, COREPER and AGRIFISH meetings and has been incorporated into the February compromise text. Finland cannot accept labelling of end products derived from category 1 NGT plants (food, feed,

and other products). For the currently expressed needs pertaining to organic production, labelling of seeds and propagating material is considered sufficient.

4. Detection and identification of NGT plants and products

The fact is that with the current analytical methods (both PCR and sequencing based methods) it is not feasible to differentiate a specific NGT product from conventional ones that contain the same modification(s). The issues of detection are further complicated by higher analysis costs per sample (if done by large sequencing efforts), the difficulty of analysis (including very heavy bioinformatics protocols and lack of harmonization within) and lack of reference materials and sequence databases for officials. Thus, enforcement methods would therefore be largely based on document control. However, it is always necessary to monitor the changes in the operating environment, including development of analytical methods, so that decision-making remains science-based.

5. Sustainability

In our view, the issue has already been thoroughly discussed in the council working groups, COREPER and AGRIFISH meetings and has been incorporated into the February compromise text. We find that the trait listing in Annex III Part 1 is a good basis for evaluating the sustainability of a category 2 NGT plant in comparison with its conventionally bred counterparts. Naturally, the cultivars currently most widely used should be used as a reference in the evaluation of sustainability. We are also open to discussions how to develop incentives for breeding sustainability traits also into category 1 NGT plants.

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

International trade aspects have been taken into account in the impact assessment and the Commission has also duly notified two different WTO committees of the proposed regulation according to normal practices. All countries have had an equal opportunity to comment, and separate inquiries, studies or assessments are not deemed necessary.

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

Finland is ready to continue discussing the verification procedure especially in case of academic research and field trials. Currently the GMO field trial notifications are handled and approved by national competent authorities according to the subsidiarity principle.

8. Empowerment of the Commission for adopting delegated acts

As we already have heard the opinion of the Council Legal Service on this point. Finland considers that the matter has been resolved and it is clear from a legal point of view.

9. Compliance with the Cartagena Protocol on Biosafety

Finland has not yet had a national discussion concerning this topic.

GERMANY

NGT Dossier, WP 19.07.2024 – Questions from Germany 31.07.2024

Thank you very much for the non-paper submitted by the Presidency and for the opportunity to resume the discussion on important points of the NGT dossier. Views on the NGT dossier still differ within the Federal Government. We are therefore unable to take a stance at the moment and hereby submit in writing the questions we already asked orally at the above-mentioned session.

We would like to pose the following questions regarding the content of the paper and additional thematic points:

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

"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"

To HUN: From the Presidency's point of view, what are the arguments in favour of discussing the equivalence criteria from Annex I and what scientific arguments are there for this?

To the COM: Annex I states: "An NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools." We already questioned the wording "a DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools" beforehand. It is still not clear to us what exactly is meant by this - and how this requirement could be checked in practice. We would therefore appreciate it if the Commission could , once again, go into this in greater detail.

According to Hungary, criteria for equivalence and risks are not linked in points 1 and 2. It is being discussed whether NGT category 1 applications, such as RNAi constructs, harbour comparable risks to transgenic plants due to possibly identical mechanisms. Could the COM explain its position on the question of potential risks?

Question on the way forward: The previous EP requested an EFSA opinion by July on the opinions delivered by the French Authority for Food Safety, Environmental Protection and Occupational Health and Safety (ANSES). We would welcome it if EFSA could also present its opinion here in the WP in due time. How does the Presidency categorise the opinion?

2. Risk assessment NGT

"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"

From the point of view of the Presidency and the COM, what are the arguments in favour of a risk assessment of NGT- 1 products based on the previous Commission proposal? How does this relate to the most recent EFSA opinion?

To the COM: The Commission proposal for a regulation on plant reproductive material, PRM, envisages, on the one hand, an extension of the existing assessment of the value of arable crops for sustainable cultivation and sustainable use (VSCU) to cover fruits and vegetables. On the other hand, a new option has been envisaged of imposing requirements for cultivation on herbicide-tolerant plants and other plants with specific characteristics. What is the state of play on this dossier in the Council? How are these proposals being debated in the relevant Council working group?

2. 1. Scope of the regulation – wild plant species

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

To the COM: At present, little is known about the use of NGT in wild plants and their release. We would like to better understand the importance of wild plants in this dossier. The public debate tends to focus more on agricultural crops. What are the arguments in favour of including all types of plants except microalgae within the scope of application? It is being discussed whether there are potential ecological risks related to non-domesticated wild plants. In general, plants differ in terms of generation times, potential for outcrossing and possible invasiveness. Perhaps the Commission could go into this in greater detail? The COM is requested to explain possible risk aspects and whether and to what extent these should be taken into consideration.

3. Labelling

"The Presidency is asking Member States which option they prefer, or if they see any other options"

Question on the way forward: The option mentioned of labelling along the entire chain could also result in a reassessment of coexistence, a subject under debate. What is the Commission's position on this? We would like to know whether the Presidency will open the debate on this issue even disregarding the issue of the labelling requirement. We wonder whether and in what way the Presidency will take up the issue of coexistence.

4. Detection and identification

"*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"*

We believe that it makes sense to incorporate current and further research findings into the debate within the WP.

5. Sustainability

"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

"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"

To what extent are the Commission, the Presidency or individual Member States aware of problems in relation to the export of these plants from countries that have already partially deregulated or facilitated the cultivation of NGT plants - and if so, what impact has this had on the agricultural sector? (e.g. USA, Canada)

7. Verification procedure

"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"

Hungary explains under point 7 that the proposed time for the verification procedure is very short. In addition, no specific risk analysis is planned in the draft. We would like to ask the COM for more information on how risks to human health or the environment that are identified despite the classification under category 1 can be taken into account. What options for action would the competent authority undertaking or suggesting the classification have in the event of substantiated concern if the criteria laid down in Annex 1 are being met at the same time? How could the status of a category-1 plant - comparable to the emergency clause included in Art. 23 of Directive 2001/18 - be withdrawn later on if required?

8. Empowerment of the Commission for delegated acts

"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"

We would like to reiterate our previous concern raised on this issue and request the Council's Legal Service to lay down in writing its thoughts on the proposed authorisation of the Commission in Art. 5, which have been presented orally to date.

9. Cartagena Protocol

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

How do the Commission and the Legal Service assess a possible violation of the Cartagena Protocol in the context of the proposal for a regulation on NGT?

GREECE

Comments from the Greek delegation on the Presidency non-paper (ST 11820/24):

1. **Annex 1 – Criteria for equivalence of NGT plants to plants produced by classical breeding methods**

We believe that the criteria of Annex I on the type, size and number of genetic modifications, of the proposed Regulation, are not based on science but have been set arbitrarily. Deletion of any number of nucleotides can lead to unknown and unpredictable changes. Targeted inversion of a sequence of any number of nucleotides can lead to new traits and risks, as is the case with transgenic plants. In general, category 1 plants cannot be considered equivalent to plants resulting from conventional breeding methods or from random mutations in nature, because in the 1st case the modification is targeted and random and in the 2nd only random. In addition, we believe that the information expected to be submitted by the applicant during the verification process of NGT category 1 plants, are insufficient to assess the possible effects of these amendments and to assess the equivalence of NGT category 1 plants to plants resulting from the classical breeding methods.

Regarding the Presidency's question about the basis on which certain NGT plants could be considered equivalent to those produced by classical breeding methods; we believe that it is required further experimentation.

2. **Risk assessment for category 1 NGT plants and products**

We believe that in order to minimize possible adverse effects of NGT category 2 plants, post-market monitoring should be mandatory and not optional, as provided for in the proposed Regulation. There should be no adjustments for detection methods and monitoring requirements. The existing GMO legislation should be followed for this category, as these are new techniques and there is no history of safe use of these plants and their products as well as their effects on environment (biodiversity) and human and animal health (precautionary principle). In addition, we think that the above obligation should also be extended to NGT category 1 plants as the proposed Regulation does not provide risk analysis and monitoring after placing on the market. In any case, the protection of the environment and human and animal health should be ensured by controls and not by assumptions and contradictory literature references.

Regarding the Presidency's question on whether Member States could agree to a simplified risk assessment procedure for NGT plants category 1, we believe that the process for category 1 and 2 NGT plants should be the same.

2.1 Purpose of the Regulation – wild (non-cultivated) plant species

We believe that the scope of the Regulation should be limited only to cultivated plants to ensure the protection of the environment.

3. **Labelling of category 1 NGT food and feed products:** we support the first option

4. **Detection and identification of NGT plants and products**

With new genomic techniques, changes to the genome at specific locations are possible, so these changes can be detected. Therefore, there is a method of detection and the breeder who

will notify the competent authorities of the EU Member States of his intention to release into the environment and/or on the market the NGT plants of category 1, should also communicate the relevant information to the competent authority for detection, identification and quantification of the introduced modifications. It is not possible for the competent authorities to confirm the equivalence of these plants with plants resulting from conventional breeding methods or from random mutations in nature based on the information provided by the applicant and the bioinformatics tools (they have relatively high uncertainty). In this sense, we consider that the interested party should be obliged to provide the relevant information for the detection, identification and quantification of these changes (method, primer sequences, etc.). Therefore, the breeder who will notify the competent authorities of the EU member states of his intention to release NGT plants into the environment and on the market should also notify the relevant information to the competent authority for the detection, identification and quantification of the modifications that introduced. Regarding the Presidency's question about the existence of possible other measures to ensure traceability and whether horizontal monitoring of the issue would be useful, we believe that horizontal monitoring is moving in the right direction.

5. Sustainability

We believe in principle that the horizontal approach should be qualified as the simplification and improvement of legislation will be promoted, as well as the creation of a regulatory framework that will allow the development of innovations in the agri-food sector, such as biotechnological solutions that can reduce climate and environmental impact, without reducing productivity or competitiveness. But at the same time we believe that a specific condition should be met, in the horizontal approach and more specifically the explicit reference in the specific legislative text of the obligation to observe the principle of precaution.
Adherence to the precautionary principle ensures the real protection of the consumer and therefore his trust in new and innovative products and furthermore has a positive impact on the international level, as it ensures a satisfactory level of environmental and health protection in international negotiations .

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

We support a global trade impact assessment might need to be conducted.

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

We believe that verification procedure should be carried out at EU level in order to ensure the uniformity of the procedure and reduce the administrative burden for national authorities.

8. Empowering the Commission for adopting delegated acts

We believe that the updating of the criteria should be done by the Council and the European Parliament, i.e. by the usual legislative procedure as these criteria are of high importance.

9. Compliance with the Cartagena Protocol on Biosafety

We agree with the Presidency consideration on having legal clarity in order to achieve a common understanding on the issue and to avoid any non-compliance with our international

obligations. We also agree with the proposal for a comparative analysis of the criteria of Annex I with the corresponding third countries in order to clearly reflect the situation at global level.

IRELAND

Ireland's response to Hungarian Presidency's Non-paper on the NGT Proposal

1. Ireland wishes the Hungarian delegation well during their presidency in their efforts to reach agreement on this proposal at Council.

2. Ireland has been supportive of the proposal since it was launched by the Commission in July of 2023 and believe that NGT's can contribute positively to the challenges facing the agricultural sector including those of climate change, environment and biodiversity. NGT's can play a significant role in meeting the goals of the European Green Deal and the Farm to Fork Strategy while producing food and feed that is safe and nutritious for consumers. NGT's can contribute to the sustainability of EU agriculture from social, environmental and economic viewpoints and can ensure the continued competitiveness of EU farmers with producers in 3rd countries.

3. Ireland recognises the comprehensive background work of the Commission in drafting the initial NGT Proposal in June 2023, and in particular the consultations and targeted stakeholder surveys with the general public, farming representative bodies, organic representative bodies, environmental NGO's, consumer associations while also taking into account the scientific opinions of bodies such as EFSA.

4. Ireland recognises the constructive efforts of both the Spanish and Belgian presidencies in progressing this proposal since it was published in July 2023.

5. Ireland is willing to aid the presidency, in so far as is possible, in their attempts to reach agreement on any outstanding issues. Ireland is of the view that a spirit of collaboration and constructive engagement is necessary by all in order to progress this proposal to the next stage.

LATVIA

REGULATION ON NEW GENOMIC TECHNIQUES (NGT)-HU Presidency non-paper

-Written comments from Latvian delegation-

Latvia expresses its gratitude to the HU PRES for the developed non-paper document although we also have to admit that we don't really understand the purpose of this document. PRES has highlighted 9 sensitive issues but if the aim of this document is to reopen the discussions on all these points, we think it is huge step back in respect of adoption of the proposal. We consider that huge amount of work was done by ES and BE PRES to develop finally the compromise text, and we believe it is solid basis to continue the work.

Please see below Latvia's comment on points highlighted in HU PRES non-paper document:

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

In our opinion, additional equivalence criteria are unnecessary. NGT-1 plants by definition are distinguished from classic GMOs precisely by their technical accuracy and the absence of foreign DNA. Therefore, in our opinion, it is justified that the criteria take into account only possible types of genome modification (nucleotide insertion, deletion, etc.). If the modified plant contains a similar amount and type of genomic changes as a plant obtained through traditional breeding, we think that it is enough to consider it as an NGT-1 plant.

Furthermore the EFSA opinion on the analysis by the French Agency (ANSES) concludes that "the available scientific literature shows that plants containing the types and numbers of genetic modifications used as criteria to identify category NGT-1 plants in the European Commission proposal do exist as the result of spontaneous mutations or random mutagenesis. Therefore, it is scientifically justified to consider category NGT-1 plants as equivalent to conventionally bred plants with respect to the similarity of genetic modifications and the similarity of potential risks. The EFSA GMO Panel did not identify any additional hazards and risks associated with the use of NGTs compared to conventional breeding techniques in its previous Opinions."

2. Risk assessment for category 1 NGT plants and products

Taking into account that NGT 1 plants are considered as safe as conventional we believe that a simplified risk assessment procedure is not needed for NGT-1 plants. It is clear that any breeder evaluates the characteristics and the traits of the variety he has created - be it a NGT plant or a conventional plant. There are very well-developed tests for plant varieties used in food, which allows determining undesirable traits as well as economic properties. These are field trials over many seasons as well as laboratory testing of quality characteristics.

2.1. Scope of the regulation - wild plant species

We think like sustainability issue also an issue on wild plant species is more horizontal questions when we speak about invasiveness and impact on ecosystem and it relates not only to NGT - 1 plants but also to traditional plants.

Even in Latvia it is considered we have about 50 invasive plants, and they are not NGT or GMO plants. But they have impact on our ecosystem and biodiversity equally.

3. Labelling of category 1 NGT food and feed products

We appreciate PRES for offering two options on this issue, but Latvian Organic farming association is absolutely against the possibility of using NGTs in organic sector.

So far, we haven't changed our previously stated position on this issue and we still support the proposal text according to which only NGTs seeds and plant propagating material should be labelled.

4. Detection and identification of NGT plants and products

We consider that horizon scanning could be beneficial, even maybe it could be done in the frame of DARWIN and DETECTIVe projects, but at this stage we can't sagest nothing other than already discussed instruments like – publicly available data base on NGT seeds and PPM, verification of accompanying documents, information exchange among stakeholders and etc.

5. Sustainability

We consider that sustainability is an issue to be dealt within the frame of a wider horozontal approach. It would be logically that all plants not just NGT plants be assest in respect of sustainability.

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

No comments.

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

So far we have very limited expierenc with clasical GM plants' field trials. Latvia has received just one application for field trials. Teherefore we cannot assess the situation based on practical expierence. On the other hand we have established all necesarry administrative procedures, we have staff dedicated particularly for the assessment of verification requests as well as responsible committe for risk assessment. At this moment we feel well prepared for verification procedure of NGTs at national level.

8. Empowerment of the Commission for adopting delegated acts

Latvia is satisfied with Council Legal Service oral explanation provided during one of the meetings.

9. Compliance with the Cartagena Protocol on Biosafety

Latvia would appreciate to receive the opinion of the Council Legal Service on this issue.

LITHUANIA

Lithuania ‘s comments on non-paper

drawn up 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 aRegulation 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 (hereinafter – proposal) (11820/24)

Lithuanian competent authorities together with Lithuanian Academy of Science have analysed the non-paper and Lithuania's position was prepared, which was presented during the discussion in the Council Working Party on Genetic Resources and Innovation in Agriculture on 19 July 2024:

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

Lithuania maintains its position of seeking the agreement on the proposal on the basis of the compromise text presented in February 2024. The Scientific Opinion of the European Food and Safety Authority on Annex 1 of this proposal was published on 11 July 2024. According to the criteria for equivalence to conventional plants, category 1 NGT plants are those plants that have mutations identical to those that can occur naturally or can be obtained by conventional mutagenesis. It is therefore proposed to consider the mutations that the plant has in its genome, rather than the way in which they were obtained: "*The EFSA GMO Panel concluded that scientific literature shows plants with the types and numbers of genetic modifications used to identify category 1 NGT plants do occur naturally or through random mutagenesis. Therefore, it is scientifically justified to consider category 1 NGT plants equivalent to conventionally bred plants regarding the similarity of genetic modifications*." *EFSA Journal*, 22(7), https://doi.org/10.2903/j.efsa.2024.8894; EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms) (2023).

2. Risk assessment for category 1 NGT plants and products

Lithuania maintains its position of seeking the agreement on the proposal on the basis of the compromise text presented in February 2024.

2.1. Scope of the regulation - wild plant species

The proposal is specifically adapted to plants used for food and feed, so if the text of the proposal gives reason to doubt that wild plant species will be covered, it is worth to discuss a clarification of the proposal.

3. Labelling of category 1 NGT food and feed products

Lithuania maintains its position of seeking the agreement on the proposal on the basis of the compromise text presented in February 2024.

The proposal to label only seeds and propagating material is adequate. As category 1 NGT plants have identical mutations compared to natural plants or those obtained by conventional mutagenesis, further labelling of the product does not make sense.

4. Detection and identification of NGT plants and products

Lithuania maintains its position of seeking the agreement on the proposal on the basis of the compromise text presented in February 2024.

5. Sustainability

Lithuania maintains its position of seeking the agreement on the proposal on the basis of the compromise text presented in February 2024.

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

Lithuania maintains its position of seeking the agreement on the proposal on the basis of the compromise text presented in February 2024.

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

Lithuania maintains its position of seeking the agreement on the proposal on the basis of the compromise text presented in February 2024 and would support the consideration of the possibility of a field trial verification procedure at EU level.

8. Empowerment of the Commission for adopting delegated acts

Lithuania maintains its position of seeking the agreement on the proposal on the basis of the compromise text presented in February 2024.

9. Compliance with the Cartagena Protocol on Biosafety

Lithuania maintains its position of seeking the agreement on the proposal on the basis of the compromise text presented in February 2024. The Cartagena Protocol on Biosafety parties (Japan, UK and others) have already simplified regulatory framework for the use of NGT plants and their products, and non-compliance with this Protocol has not been identified.

THE NETHERLANDS

Written comments from the Netherlands on the Presidency non-paper (doc 11820/24) and from the Council Working Group on the 19th of July.

The Netherlands appreciates the Hungarian Presidency's intention to advance the New Genomic Technique (NGT) dossier and wishes the Hungarian Presidency success in its role as mediator in furthering this dossier.

The European Commission (hereafter Commission) published the NGT proposal last July. Since then, the NGT file has been intensely discussed in the Council during the Spanish and Belgian Presidencies. Enormous progress has been made thus far. Therefore, for the Netherlands it seems appropriate to take this opportunity to reflect on the NGT dossier and the progress made so far, before delving into the specifics in the written commentary on the non-paper. The NGT proposal is a politically challenging dossier with strong proponents and opponents, yet over the past year, we have made progress and reached compromises on many aspects of the proposal, thus narrowing the differences between delegations. The Netherlands urges the new Hungarian Presidency to build upon the achievements of the previous Presidencies. For the Netherlands, the compromise text (ST16714) presented to the COREPER for a vote last February would serve as a solid starting point. The text, supported by a majority of 17 Member States, represents a robust and equitable resolution that reasonably accommodates the diverse interests of the Member States, without exceeding the limits of flexibility inherent in the negotiation process.

One important discussion topic for the Netherlands that needs further addressing is the role of patents in plant breeding, both broadly and specifically in relation to the NGT dossier. The Netherlands acknowledges concerns regarding the role of these patents and believes it is a broad issue that should be addressed comprehensively. The Netherlands therefore welcomes the Commission's investigation into this matter and urges the Commission to deliver the study as soon as possible. At the same time, the Netherlands recognizes that this creates a challenging situation for the NGT proposal. However, the Netherlands does not wish to exacerbate the potential problem through the NGT proposal. Therefore, it seems prudent to include a provision in the NGT proposal on patents and to allow time for addressing the broader question regarding patents in plant breeding. The Belgian Presidency had already made significant progress on this issue, and the Netherlands asks the Hungarian Presidency to continue exploring this matter.

Specifically concerning the Presidency non-paper, the Netherlands has reviewed the document carefully and concluded that the Netherlands respectfully disagrees with the Hungarian Presidency's assessment that the nine paragraphs mentioned are the remaining points for discussion. Nevertheless, the Netherlands will adopt a constructive approach in the discussions that the Hungarian Presidency seeks to initiate and will elaborate on its views on each paragraph accordingly.

1. *Annex I. – Criteria of equivalence of NGT plants to conventional plants*

For the Netherlands, this has been a thoroughly discussed aspect of the NGT proposal, with several improvements made in previous compromise texts. The Netherlands supports Annex I as included in the compromise text (ST16714) adopted by COREPER last February.

2. *Risk assessment for category 1 NGT plants and products*

The premise for Category 1 plants and products is that they could also have been developed through conventional breeding methods. Therefore, the Netherlands considers it disproportionate to implement a

risk assessment for these plants and products. The Netherlands would also like to highlight the recent EFSA publication (EFSA-Q-2024-00178) that supports this view.

2.1. Scope of the regulation – wild plant species

The Netherlands respectfully disagrees with the two options presented by the Presidency in the text. The Netherlands does not recognize this as an unresolved discussion in the Council Working Groups. For the Netherlands, it is desirable that wild plants also be covered under this regulation, as currently described in the compromise text (ST16714) adopted by COREPER last February.

3. Labelling of category 1 NGT food and feed products

This topic has been extensively discussed in previous Council working groups. The Netherlands does not see the need to reopen this discussion and supports the wording included in the compromise text (ST16714) adopted by COREPER last February. Labelling is already in place for starting materials and seeds, ensuring choice for professional users. For the Netherlands, this is sufficient, and there should be no requirement for labelling of end products.

4. Detection and identification of NGT plants and products

Category 1 NGT plants are comparable to plants derived from conventional breeding or occurring naturally; therefore, no labelling requirement is necessary, and tracing these plants and their products would also not be proportionate. Moreover, in some cases, it is impossible to determine whether a plant was bred using NGTs or conventional techniques. As a result, mandatory tracing of Category 1 NGT plants and their products would also be unfeasible. Therefor the Netherlands would like to again underline that it supports the compromise text (ST16714) adopted by COREPER last February.

5. Sustainability

Sustainability applies to all plants, not just NGT plants; therefore, it is more logical and proportional to implement this in horizontal legislation for plants, if we wish to do so. The PRM proposal, for example, would be a more appropriate place to discuss this, instead of the NGT proposal.

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

The Netherlands is satisfied with the work that the European Commission has done to investigate this matter and considers the WTO notification sufficient. It is import to be able to rely on the competence of third countries to respond to WTO notifications if they have objections to NGT plants and products. Therefore, the Netherlands does not consider the NGT proposal as a potential problem for our export.

7. The verification procedure

The Netherlands has a strong preference for a verification procedure conducted by the national competent authority instead of the EFSA. We disagree with the assertion that the EFSA offers an easier route for SMEs compared to a national competent authority. The language differences and limited scope for customization make the EFSA process less accessible, so we would argue that it is the other way around.

8. Empowerment of the Commission for adopting delegated acts

This topic was extensively discussed under the Spanish Presidency. The Council Legal Service provided a clear refinement in the text and offered a comprehensive oral explanation, which is sufficient for the

Netherlands to support the compromise text (ST16714) adopted by COREPER last February. The Netherlands sees no need to reopen this discussion.

9. Compliance with the Cartagena protocol on biosafety

This discussion has also taken place multiple times before in the Council Working Group, with the same conclusion each time: the NGT proposal is in line with the Cartagena Protocol. This has been confirmed by the Commission, and the Netherlands also concurs with this assessment.

ROMANIA

JULY 19TH 2024

WORKING PARTY: NEW GENOMIC TECHNIQUES

MANDATE OF ROMANIA – written comments on HU Presidency Non-paper and Annex on assessment of commodities and trade barriers of agricultural biotechnology in third countries (USDA Reports)

Romania welcomes the initiative of the Hungarian Presidency to open the agenda for all the subjects proposed by MS, issues that haven't been accepted and detailed since the launching of NGT proposal. This is a very good opportunity to work together towards a balanced reglementation of this complex proposal and towards harmonisation with the international framework that shapes and defines the production, market access and trade of agricultural goods in the third countries.

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

Romania considers that Annex 1 is the legal key of the entire proposal. It switches the entire production of the conventional crops under the definition of NGT1, stated in Article 3.

Romania underlines that, for as long as the mutations can't be identified and lack the identification methods, testing possibility, it has no categories of plant beneficial traits, no risk assessment included, the products NGT1 do not respect any international standards of production, nor international standards of trade. Thus, the opinion regarding "Criteria of equivalence of NGT1 with conventional plants" becomes a subject of legal and political approach.

We should know, briefly, what this legal equivalence with the conventional crops shall bring:

- The main consequence is the legal disappearance of conventional plants and their replacement by NGT1 category, due to the lack of coexistence measures. According to Art. 3, the defined category in the proposal is NGT1, plants and products.
- There are no elements of protection of conventional genetic material, nor of conventional small and medium breeders in relation to patent owners dominating the international markets. The patent owners are free to register the patents of any genetic material available in the gene pool.
- Legally, the entire production shall switch from conventional to NGT1s. Consequently, the control and production of the genetic material from natural sources, including conventional crops, shall switch to the patent owners ONLY.

- Due to impossibility to identify the mutations, the lack of risk assessments and other tests, the international standards of production shall be deregulated. The entire production of plants and their products will be traded only by the patent owners into the third markets that they can access (based on TRIPS Agreement only). This leads to monopoly/oligopoly of the markets of production and of the markets of export. The MS authorities will not have the possibility to trade any conventional production anymore, due to lack of standards.
- This situation shall lead to weaker bilateral trading relations between MS and third countries, the instruments of control over the production and market access being held by the patent owners.
- Losing the instruments of control for exports by the member states authorities, shall generate a weaker European Union in benefit of the companies owning the patents.
- Kindly ask you to check the ANNEX of this document for more information regarding assessment of commodities and trade barriers of biotechnology products in: Turkey, China, Morocco, UAE+GCC4, Russian Federation +EAEU, Algeria etc (USDA reports). Please note that, according to USDA assessment reports, Turkey, Algeria, Morocco completely ban the biotechnology commodities for food into their market. China, on the other hand, chose to protect its national market and forbids most of foreign biotech products for import. If the country of origin develops biotechnology crops, even the shipments of conventional may be rejected by the Chinese state. There are also other third countries that apply the same provisions.
- ***Romanian Ministry of Agriculture, on behalf of Romanian Farmers Associations, asks for freedom of choice regarding the production. Romanian farmers underlined the idea that they do not want to become dependent of the patent owner's production, nor to pay for additional fees for using reproductive material. They asked for guarantees of market access offered by the EU COM for the third countries to which they export the conventional crops.***

In regard to the elements presented above, Romania considers that ANNEX 1 of the NGT Proposal should be deleted, due to its legal consequences.

One of Romania's red lines of the mandate is the request for protection of conventional and organic crops and safeguarding their standards of production and integrity.

On our opinion, this Annex should contain the rules of coexistence with conventional and organic crops, it should shape all the necessary legal detailed provisions for lab identification of NGT1s in each MS, field tests of every new NGT1 product in every MS due to various national and regional conditions, compulsory risk assessment for each plant and product and the rules of traceability and labelling.

In the end, Romania proposes to adopt a legally balanced proposal, containing 3 main categories of crops:

1. Conventional and organic - protected by coexistence measures,

2. NGT1 – plants and products,

3. NGT2 plants and products ,

in order for the European farmers, producers and processors to be able to maintain the global trade flow and market access into all third countries.

2. Risk assessment for category 1 NGT plants and products

Romania considers that the strong risk assessment of each plant (NGT1 and NGT2) in relation to human, animal and environment is a must for all biotechnology plants and products, including microorganisms. The testing and risk assessing of each NGT product can bring only development of the scientific field and of assessment techniques.

It may also become the main vector for increasing the public's trust and for guaranteeing the health and safety of European people.

We consider that the judgement of EU Court of Justice represents both: a guide to guarantee certain standards of production and a solution to avoid creating future non-tariff barriers on foreign global trade flow.

Regarding PRM parallel negotiations, Romania insisted upon protection of conventional and organic production of seeds and crops, and for a total separation from NGT products.

2.1. Scope of the regulation - wild plant species

Regarding wild plants species, we believe that the Precautionary Principle as listed in Article 191 of The Treaty of the Functioning of European Union should apply (in the same way it was applied as a legal instrument for the use of neonicotinoids category **https://eur-lex.europa.eu/EN/legal-content/summary/the-precautionary-principle.html)**

We would like to underline the fact that lacking the risk assessment for pollinators, an endangered category who benefits of special protection, represents a major problem for the associations of beekeepers, for the bees themselves and for the integrity of crops and the environment as a whole. Romania has more than 2 million bees families, the second number in Europe.

NGT plants and products should be divided into separate categories: **for agriculture** – based on their main traits and number of events, **for forestry** – with main traits and number of events, and **for other purposes**.

All NGT products, without any difference, should be released into environment only based on complex environmental risk assessment, in line with the Precautionary Principle (Art.191 TFUE).

3. Labelling of category 1 NGT food and feed products

Romania reiterates its request regarding labelling: all NGT products must bear the label, in order to respect the consumer's rights to be informed and to choose (**Art. 169 Treaty of Functioning of European Union https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A12008E169)**. This request, together with traceability and risk assessment, is one of the red lines of our mandate.

The same labelling provisions should be applied also to the imported products within the EU territory.

- Kindly ask you to check the ANNEX of this document for more information regarding labelling, assessment of commodities and trade barriers for biotechnology products in: Turkey, China, Morocco, UAE+GCC4, Russian Federation +EAEU, Algeria etc (USDA reports). After implementing the Cartagena Protocol, the third states require labelling of the biotechnology products.

4. Detection and identification of NGT plants and products

Detection and identification are the most important aspects of biotechnology products. In order to fulfil the traceability and labelling requirements for the food chain, also the safety and protection of the seeds and breeders involved in industry, detection and identification of new genomic techniques is a cornerstone of the sector.

- Kindly ask you to check the ANNEX of this document for more information regarding detection and identification rules, assessments of commodities and trade barriers for biotechnology products in: Turkey, China, Morocco, UAE+GCC4, Russian Federation +EAEU, Algeria etc (USDA reports).

The first necessary step is to create an European chain of laboratories and biotech testing&research centers in each member state, based on the uniform capacities of testing and developing research in this area, before this regulation enters into force.

5. Sustainability

Romania shares Presidency's approach to this subject and agrees that sustainability should be introduced as one of the most important accountable elements of NGT plants and products along with the beneficial traits and risk assessment of each plant. A strategy must be based on accountable indices, that can be evaluated and monitored during the implementation.

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

Romania would like to express its gratitude for including this important subject on the agenda. Indeed, our farmers and our specialists from the Ministry of Economy and Trade submitted us this request for conventional crops protection and for an in-depth trade assessment of NGT1 category equivalent to conventional crops within the third countries markets. ***We shall refer not only to the conventional seeds category, but to the entire conventional agrifood production that is traded to third countries (crops for food, feed and processing as well).***

As we explained in point 1, the first and most important consequence of this legal decision is that conventional plants and products shall be traded under the definition of NGT1 (Article 3). ***Starting with this change of definition, there is a major possibility that third countries raise market access issues and trade barriers towards NGT1 products and conventional products together on the bilateral exports from EU countries.***

Market Access regulations: they may be sets of laws and procedures adopted by the third country regarding biotechnology products. They provide the criteria that biotech commodities should meet in order to receive the permit for import within the territory of the third country. They can be found in the national legislation framework adopted by each country or group of countries.

Non-tariff barriers to trade may be technical regulations and standards, sanitary and phytosanitary measures, customs formalities, government procurement practices that are becoming more important than customs duties or quantitative restrictions**.** Rules on non-tariff barriers are listed in GATT provisions and specific WTO agreements, particularly The Agreement on Technical Barriers to Trade (TBT Agreement) and The Agreement on Application on Sanitary and Phytosanitary Measures (SPS Agreement).

Since July 2023, Romania addressed several times to the EU COM the request regarding market access conditions and foreign trade assessment. We also asked for the guarantees of NGT1 acceptance as conventional within the territory of the third countries.

EU is one of the most important trading partners of the global flow, being well known for the top-quality exports of agri-food products, row or processed. According to the report published by DG AGRI on 5 April 2024 (please find the full report here: https://agriculture.ec.europa.eu/news/eu-agri-food-trade-achieved-record-surplus-2023-2024-04-05_en) ,the ***EU agri-food exports reached €228.6 billion in 2023***.

In 2023, the EU exported a wide variety of products, with the ***top 3 exported product categories by the EU, representing close to 30% of total EU agri-food exports.*** These top three categories were ***cereal preparations and milling products;*** dairy products; and ***wine and wine-based products***. Exports of ***preparations of fruit, nuts and vegetables had the largest increase in value in 2023***, with +€1.3 billion (+12%) compared to 2022. ***It is followed by exports of cereal preparations and milling products (+€1.2 billion, +5%) and confectionary and chocolate (+€1.2 billion, +12%).***

Please note that these commodities are traded as CONVENTIONAL AGRIFOOD PRODUCTS, under the highest standards of production and food safety (SPS Agreement).

According to the official report published by DG AGRI, there are two categories of top countries (markets) to which EU exports great volumes of agrifood goods**:**

1. ***TOP 15 export countries of EU agrifood*****:** UK, USA, ***CHINA***, SWITZERLAND, JAPAN, ***RUSSIAN FEDERATION***, NORWAY, ***TURKEY***, SAUDI ARABIA, Republic of KOREA, Canada, ***Morocco***, Australia, Ukraine, ***UAE***.
2. ***Countries with most important changes (2021-2023*****) – in value and volume of merchandise:** UK, Turkey, Ukraine, Switzerland, Serbia, Islamic Republic of Iran, Egypt, ***Algeria***, China, USA.

DG AGRI & DG TRADE are the EU Directorates that should elaborate a detailed assessment in regard to market access and conformity assessment of the new defined NGT1s as conventional products. After one year of negotiations, we have received only 4 examples of answers on behalf of ***USA, Canada, Argentina and Brazil*** regarding the acceptance of NGT products.

Please, check the ANNEX attached to this document for more information regarding assessments of commodity, market access conditions and trade issues in the field of plant biotechnology and other new production technologies – Turkey, China, Morocco, UAE+GCC4, Russian Federation +EAEU, Algeria etc.

In the light of the ANNEX,

And taking into consideration that since July 2023, the EU COM has declared that there is no need of assessments of biotechnology commodities and that there are no trade barriers in relation to any third country; according to the EU Commission's opinion: no foreign market shall be lost,

We would like to receive the written opinion of DG AGRI&DG TRADE regarding 2 aspects:

1. ***market access conditions &trade barriers for NGT1 under provisions of the proposal,***
2. ***market access conditions & trading of the conventional crops if they are mixed with NGT1s,***

Both related to third markets territories and possible trade barriers that may be encountered.

Romanian Ministry of Agriculture, at the request of the Associations of Romanian Farmer's, has decided to approach it's traditional bilateral trading partners, in order to accomplish the trade assessment and to find out if our third country partners shall accept the NGT1s as conventional merchandise, under the new definition and if the conventional production shall be accepted for exports under new legal conditions.

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

The verification procedure is crucial in the development of the future crops of NGT plants.

As we all know, each member state has its own characteristics: specific flora, different soil types, different structure of the environment, specific chemistry of waters, pests and specific plant diseases etc. ***Each member state should be given the possibility to select the NGT plants suitable for its territory to avoid secondary consequences that may be difficult to repair.***

Referring to unwanted consequences and taking into consideration that biotech products defined as NGTs in this proposal represent patents developed and owned by companies, we would like to address you the following question: ***who will pay for the unwanted consequences of the NGT crops, that may produce damages in certain areas? The Member State? The farmers? Or the company that owns the patent?*** We raise this problem under this subject, because some member states requested and I quote "to have a simple, effective, harmonized and uniform verification procedure, regardless of whether the use of these plants is for deliberate release into the environment or for placing them on the market".

Romania underlines the fact that once we agree to create a simple and uniform system of verification, we should create a separate chapter that should treat the fees and payments, the legal

consequences, for damages produces in various situations. ***We need to know who will pay for the potential damage produced by NGT plants.***

This chapter should also refer to the imported biotechnology goods from third countries, including the undeclared genetically engineered events.

8. Empowerment of the Commission for adopting delegated acts

We think that the most important aspect is to receive the written opinion of the Council Legal Service, in order for each member state's Legal Departments to be able to analyze it properly.

The Commission's empowerment of amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I ***should be granted by implementing acts, not by delegated acts***.

9. Compliance with the Cartagena Protocol on Biosafety

Cartagena Protocol on Biosafety, which has been developed under the Convention on Biological Diversity (Article 19 (3)), is the principal instrument for creating the legal framework of international regulation of biotechnology and genetically modified organisms at the global level. The Protocol entered into force in 2003 and has ***173 parties, including the European Union (https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-a&chapter=27&clang=_en).***

In the light of Cartagena Protocol, which regulates also the transboundary movement of biotechnology products, an official written opinion of the World Customs Organisation should be provided.

A number of states that play key roles in biotechnology have not ratified the Protocol, including Argentina, Australia, Canada, Israel, Singapore, and the United States.

According to EU COM declarations made several times during the WP NGT, the target of the NGT proposal is to harmonize the production of new biotechnology products with the legislation implemented by Argentina, USA, Canada, Argentina being the most used example by EU COM.

In conclusion, the EU COM wants to implement a legislation framework harmonized with non-signatories of Cartagena Protocol, in order to produce and export biotechnology products into the markets of signatories of Cartagena Protocol (172 countries + EU).

There are a number of ***other international agreements*** that also contain ***relevant obligations*** in the context of regulating risks resulting from the application of biotechnology:

- The ***International Plant Protection Convention*** and the measures adopted within its framework seek to prevent the spread of plant pests, which under certain circumstances may include LMOs.
- The ***World Organization for Animal Health*** serves a similar objective with respect to animal diseases.
- The ***Codex Alimentarius*** is a set of standards on food safety and also addresses foods obtained from modern biotechnology.
- The ***United Nations Convention on the Law of the Sea*** is relevant with regard to the protection of the high seas beyond the limits of national jurisdiction.
- ***International regulations on the transport of hazardous goods and substances*** also address safeguarding measures for LMOs.
- When a biotechnology product causes a transmissible disease in humans, ***international health law*** becomes relevant.
- Certain applications of biotechnology may also fall within the scope of the ***Biological Weapons Convention and rules of humanitarian international law***

Annex

Assessments of commodity and trade issues in the field of plant biotechnology and other new production technologies – *Turkey, China, Morocco, UAE+GCC4, Russian Federation +EAEU, Algeria and other third countries*.

Please note that EU COM declared since July 2023 that there is no need of assessments of biotechnology commodities and that there are no trade barriers in relation to any third country. According to the EU Commission's opinion: no foreign market shall be lost.

The assessment has been prepared ***based on the USDA public reports,*** written by the USA experts in the third countries***. USDA is one of the most reliable sources of information due to USA's development, experience and professionalism on this field***. They present in detail the conditions of market access for genetically engineered products, the national legal frameworks of each third country and the potential trade barriers that may occur if the legal granting market access conditions are fulfilled.

Conclusions related to NGT proposal:

- Due to equivalence criteria of Annex1, the conventional crop production, just as NGT1, shall be regulated under the international legislation framework of agricultural biotechnology products (TRIPS Agreement) and shall fall under Cartagena Protocol framework for biosafety, implemented differently by each third country. ***Each genetically engineered event shall need the approval of the Governmental bodies designed by the targeted third country***.

- ***Conventional production shall be impossible to be guaranteed for export to several markets, due to lack of coexistence measures with NGT1 plants and products and due to Annex 1 of the proposal (equivalence).***
- ***NGT1 legal provisions*** - Lack of identification keys of the genetically engineered events, lack of testing and monitorisation of 1 to 20 genetically engineered events, lack of risk analyses for NGT1 may be considered equal to lack of health guarantees for human, animal and environment. Lack of traceability & labelling of genetically engineered events shall make NGT1 category, together with conventional crops impossible to sell on most valuable foreign markets. ***The conditions of granting the market access by the third countries assessing bodies shall not be accomplished***.

- The NGT proposal doesn't grant any protection tools of EU market, nor for small and medium developers of biotechnology. Clear rules regarding the imported commodities should be included within NGT proposal.

- Financial support of farmers, producers and processors of biotech crops should be provided: amounts of payments in order to cover the coexistence measures, the rules of traceability and labelling, private storage and transport.

General conclusions of the USDA reports:

- ***Patent developers:*** - third countries that allow the access of patented seeds and products within their territory, allowed only the most important global developers in the field; ***there are no foreign medium or small developers of biotechnology products allowed by those governments to access the markets.***
- ***Legal framework: the national legal frameworks of the third countries are shaped under the GMO international legal framework. There is no legal framework that accepts biotechnology products as conventional products.***
- ***Identification & testing:*** most third countries accepting imports of biotechnology products imposed rigorous market access regulations, analysing and testing the genetically engineered event one by one; the tests are based on number of events and the traits of the biotech products.
- ***Field trials:*** most countries involved in producing and trading biotechnology products run field trials, which may take up to 5 to 10 years until assessing the biotech product and issuing the permit for import, if they decide to accept it into their market (***See: China, South Africa, Indonesia, etc***).
- ***Risk assessment for human, animal & environment:*** all countries involved in developing biotech products and imports of GE commodities ask for risk assessment of each product and many of them run their own risk assessments before allowing those products to be imported within their territory.
- ***Traceability & labelling:*** all countries adopted national legal framework regarding mandatory labelling of biotechnology products.
- ***Granting the market access for foreign biotechnology products:*** the legal frameworks of national or regional alliances of states, according to their level of development and market protection policy implemented, do not approach the global flow of biotechnology goods in the same way they accept the global trade of conventional crops and products.
- ***Assessment of NGT1 category: in none of the third countries that we have analysed, there were any biotechnology products accepted as conventional products.***

- There are several countries that ***ban biotechnology products for FOOD completely*** and accepting only a limited number of patented products ***for feed only***, under strict monitoring (examples: Turkey, Morocco, Algeria).

According to the official report published by DG AGRI, ***TOP 15 export countries of EU agrifood*****:** UK, USA, ***CHINA***, SWITZERLAND, JAPAN, ***RUSSIAN FEDERATION***, NORWAY, ***TURKEY***, SAUDI ARABIA, Republic of KOREA, Canada, ***Morocco***, Australia, Ukraine, ***UAE***, to which EU exports great volumes of agrifood goods**. According to the USDA assessment of biotechnology commodity and trade issues, the situation is different in several countries.**

Thus, legitimate questions arise for the attention of COM EU:

- Considering the major volumes of exports of conventional products only in the countries presented below, how will COM EU guarantee the market access conditions for NGT1 and conventional products in these markets?
- What is the advantage of the farmers and producers, in the light of the NGT proposal?

We would appreciate a written answer, so it could be presented to the associations of Romanian Farmers and processors, as an official answer of the EU COM.

TURKEY:

- **producer and trader of conventional products ONLY**
- **top 8 EU export partner in 2023 and one of the traditional markets for RO exports of cereals and oilseeds**
- **Turkey has over 85 million people**
- **GDP: $3.832 trillion estimated for 2024**
- **Full USDA 2023 report here: https://fas.usda.gov/data/turkiye-agricultural-biotechnology-annual**
- Turkey's Biosafety Law, which went into effect in 2010, ***prohibits the commercial production of biotech plants, also the imports of biotech plants and products for food purposes***.
- The law permits the regulated study and development of plant biotechnology for ***research purposes*** only.
- The Ministry of Agriculture and Forestry is the competent authority under the Biosafety Law.
- Currently, the Government maintains ***a cap on the total number of approved GE events at 36***, for ***feed purposes only***. Among the approved GE crops, like 15 soybean and 21 corn events for feed purpose only, there are several with approval dates from more than 10 years ago. The renewal of the approval is done only if the applicant (developer/importer) in question requests this renewal at least one year before it expires.
- ***Developers present on the Turkish market of biotech feed are:*** Syngenta, DuPont Pioneer, Dow AgroSciences LLC, Monsanto, Bayer CropScience, BASF (total of 36 events approved for corn&soybean). There are 9 more pending applications for feed from Monsanto, Bayer CropScience, Dow AgroScience LLC, Syngenta and BASF.

- ***Stacked or pyramided event approval***: Turkey treats stacked events as novel and processes their approval separately from the approval of each individual event in the stack. The Committees follow the same assessment procedures followed for individual events.

Labelling and traceability: According to Biosafety Law and implementing regulations, any imported food or feed containing, consisting of, or deriving from GE crops above the labelling threshold set by Ministry of Agriculture and Forests (0.9% - Agriculture Ministerial Directive in 2011), ***must be labelled as GMO*** - for consumers' right to know purpose. The conventional counterpart of any GE food or feed product may be labelled as ***"does not contain/consist of/derived from GMO" or "GMO free".***

Cartagena Protocol: signed and ratified October 2003 and entered into force January 2004**.**

LOW LEVEL PRESENCE (LLP) POLICY: Turkey has zero tolerance for LLP of GE events not approved in Turkey for food, feed and industrial products, subject to liability provisions of the Biosafety Law.

Trade Barriers:

- ***trade has been restricted out of concern that dust in minor LLP of GE traits in feed and food products would lead to rejection of shipments.*** Transit of GE products for food aid is allowed, but must be permitted through Min AF, which oversees document checks and monitoring. Turkey's approval process is slower than approval systems in many countries. The frequency sampling and testing imported commodities depends on the foreign CA's declaration whether the cargo in question does or does not include GE. Countries that regulate and declare GE products are subject to stringent testing.
- ***The Biosafety Law contains liability, sanction and penalty clauses that penalize noncompliance with large fines and 5 to 12 years in prison***.

CHINA

- **Top 3 agrifood export partner of EU in 2023 in the field of conventional production**
- **Type of production: both conventional crops and biotech crops, separately regulated**
- **With an area of nearly 9.6 million square kilometers (3,700,000 sq mi), it is the 3rd largest country by total land area, with a population exceeding 1.4 billion, it is the world's 2nd most populous country after India, representing 17.4% of the world population.**
- **GDP: $35.291 trillion in 2024.**

Full USDA report here: https://fas.usda.gov/data/china-agricultural-biotechnology-annual-9

The People's Republic of China (PRC) is preparing for commercial cultivation of domestically developed genetically engineered (GE) crops. Key developments include regulatory changes to facilitate variety registration of GE crops for domestic cultivation, variety registration standards for GE corn and soybeans, and the PRC's first ever regulations on gene-edited plants.

- ***The PRC favors domestic biotech developers by prohibiting foreign investment in the sector and through its approval process which lacks transparency and predictability.***
- However, except for GE cotton and papaya, the PRC has not yet approved any GE food or feed products for domestic commercial cultivation. ***The PRC continues to prohibit foreign agricultural biotechnology developers' foreign direct investment in the biotech sector and prohibits the cultivation of foreign-developed biotech products in China***.
- ***Ministry of Agriculture and Rural Affairs (MARA)*** holds the primary responsibility for the approval of biotech products for ***import and domestic cultivation***, as well as the ***development of agricultural biotech policies and regulations.***
- On January 21, 2022, the ***Ministry of Agriculture and Rural Affairs (MARA)*** released its Decree No. 2 of 2022, announcing the revised Administrative Measures for the Safety Assessment of Agricultural GMOs. The finalized Measures, which were previously notified to the WTO under (SPS N CHN 1241), came into force on January 21, 2022. ***The Measures change the nature of biosafety assessments from being on a "crop variety and event" basis to solely on an "event" basis.*** The change facilitates variety registration of GE crop varieties for domestic cultivation and may provide for the ***biosafety assessment of GE crops containing "stacked" traits***.
- On January 24, 2022, MARA issued "Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)", which for the first time establish application procedures and requirements for gene-edited plants. The Guidelines establish application procedures and requirements for ***genome-edited plants that do not introduce exogenous genes***. The Guidelines define genome-edited ***plants for agricultural use as plants and their products obtained by targeted modification of specific genomic sites with genetic engineering technology***, which are used for agricultural production or agricultural product processing.
  - On December 27, 2021, MARA issued ***biosafety certificates for 34 biotech crops approved for import as processing materials*** (including two new GE cotton events and the renewal of 32 other events), ***and 31 certificates for domestic cultivation and production*** (including 16 renewed GE cotton events, 2 renewed animal vaccines, 1 renewed feed additive enzyme, 8 new GE cotton events and 4 new GE corn events).
- On April 29, 2022, MARA issued ***biosafety certificates for 11 biotech crops approved for import as processing materials*** (including one new GE soybean event and the renewal of 10 other events), ***and 36 certificates for domestic cultivation and production*** (including 17 renewed GE cotton events, 4 new GE corn events, 6 renewed animal vaccines, and 9 new animal vaccines).

The PRC does not accept safety testing data obtained by trials conducted outside of China without conducting verification trials, which duplicate most of the safety testing conducted in third countries. This remains a major concern for foreign developers and the international community because they incur additional costs and lose control over the timeline to conduct the trials and the trial results.

Imports:

- ***China is a large importer of GE soybeans, cotton, corn, Distiller's Dried Grains with Solubles (DDGS), rapeseed/rapeseed meal/ rapeseed oil, and sugar beet pulp for feed and processing***.
- These products are imported from numerous trading partners, including the United States, Brazil, Argentina, Canada, and India, among others.
- ***China's burdensome and unpredictable approval process for GE products imported for feed and processing poses numerous challenges for foreign developers. Additionally, China's lack of a low-level presence (LLP) policy may result in detained and rejected shipments, including those that may be considered "non-GMO". China does not allow the importation of GE seeds for commercial cultivation.***
- China has not approved any major biotech food products for domestic cultivation, and all ***food aid*** is comprised of ***conventional products***.

Trade Barriers

- China's prohibition of foreign investment in the biotechnology sector remains the most significant barrier to overseas companies. The 2021 ***Special Administrative Measures for Foreign Investment Access (also known as the "Negative List"***) was jointly issued by NDRC and MOFCOM on December 27, 2021. The Measures continue the prohibition on foreign biotech developers from conducting research or seed production in China.
- On November 5, 2021, MOFCOM released the ***Catalogue of Technologies Prohibited or Restricted to be Imported***. The catalogue of technologies restricted for imports includes: "***GE plant seeds and seedlings***, seedlings of livestock and poultry, aquatic fingerings, and strains of agricultural microorganisms obtained through modern biotechnology means."

Granting the market access for imports products:

- ***China's regulatory approval process for GE traits includes several provisions that decrease the predictability and transparency of the regulatory review causing unnecessary delays and additional costs, particularly for foreign developers***. ***These include requirements that events already be approved in their country of origin and requirements for environmental safety trials and feeding trials be conducted in China by MARA designated institutions.***
- Throughout the review process, applicants are often subject to requests for additional material and data that can delay season sensitive plantings for field trials. Additionally, the National Biosafety Committee (NBC), which typically only convenes twice per year, ***frequently rejects applications or requests further information from developers resulting in some applications languishing for more than a decade in the approval process***. Subsequent applications are not reviewed by the same NBC panels and can result in new NBC members asking previously answered questions. Dates for NBC meetings are also closely held by MARA, with members themselves called to attend on short notice. Once approved by the NBC, applications must still undergo a final MARA review. Post contacts have reported that on numerous occasions, despite being approved by the NBC, MARA has returned applications to the review process for additional information.
- ***The lack of an LLP policy in China means the world's largest importer of animal feed has a zero tolerance for unapproved GE events, which is a significant barrier to trade***.
- ***Import Approval Procedures - Biosafety Certificate for Agricultural Biotech (Import) Issued to Foreign Developers*** – detailed information, page 12 of the USDA report.

- ***Biosafety Certificate for Agricultural Biotechnology (Import) Issued to Traders*** – details – page 13 of the USDA report.
- ***On January 24, 2022, MARA issued "Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)", which for the first time establish application procedures and requirements for gene-edited plants. The Guidelines establish application procedures and requirements for genome-edited plants that do not introduce exogenous genes. MARA has said that genome edited products fall within the scope of China's "GMO" regulations and will be regulated as "GMOs" but have held out the possibility of a streamlined process for gene-edited plants that do not pose a risk to food, feed, or environmental safety. More details: GAIN Report CH2022-0015 MARA Issues First Ever Gene-Editing Guidelines.***

Cartagena Protocol Ratification

The PRC signed the Cartagena Protocol on Biosafety (CPB) to the United Nation's Convention on Biological Diversity in 2000 and ratified it in 2005. In 2011, the PRC announced that the protocol would also apply to the Hong Kong Special Administrative Region. As a party to the Protocol, the PRC adopted the Biosecurity Law on October 17, 2020. The Biosecurity Law came into force on 15 April 2021. China submitted the Fourth National Reports on Implementation of 18 the Cartagena Protocol on Biosafety in October 2019, covering China's implementation of CPB from September 2015 to September 2019. ***Adopted as a supplementary agreement to the CPB, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization*** aims to contribute to the conservation and sustainable use of biodiversity by providing international rules and procedures in the field of liability and redress relating to living modified organisms. The Nagoya Protocol was adopted on October 29, 2010 and entered into force on October 12, 2014. The PRC acceded to the Protocol on June 8, 2016. The Protocol entered into force for China on September 6, 2016 and does not apply to the Hong Kong or Macao Special Administrative Regions.

MOROCCO

-12th agrifood export partner of EU in 2023; Morocco is one of the most important traditional export markets of RO for conventional cereals.

- It has a population of approximately 37 million people.

Full USDA report here: https://fas.usda.gov/data/morocco-agricultural-biotechnology-annual-8

Morocco continues to ***import*** agricultural products derived from genetically engineered (GE) technologies ***for use in animal feed products***. No GE products have been developed or

commercialized for local production in Morocco. ***GE products are not allowed for human consumption.***

Morocco neither produces nor allows importation of agricultural products derived from biotechnology for human consumption. However, Morocco does import genetically engineered (GE) products for its livestock and poultry sectors. Imports of biotech seeds for planting are currently not allowed by Morocco and standard seed imports require a ***"GMO-free certificate" for customs clearance.***

Morocco's National Office for Food Safety (ONSSA), located within the Ministry of Agriculture, Fisheries, Rural Development, Water, and Forests, is the competent authority in charge of implementing regulations and agreements related to biotechnology. In September 2012, the Ministry published guidance to clarify Morocco's position on GE products, which states that Morocco follows the precautionary principle in respect to ***justifying the ban on GE products from local cultivation and from their presence in products for human consumption***, while simultaneously recognizing their international presence and ***acceptance as an animal feed source***.

Morocco is actively engaged in agricultural biotechnology research and development as a means for addressing the country's food security challenges. This work is led by the ***National Agronomic Research Institute (INRA)*** and focused on finding solutions for Morocco's major crops, including ***cereals, tomato, forage, date palm, citrus, and olives.***

IMPORTS: Morocco is a major importer of ***soybean products*** (USA and Argentina - 55% market share), ***corn products*** (Argentina - 42%, USA 20%), ***sugar products*** (Brazil - 89%), and ***cotton products*** (Spain - 37%) in 2022. Imported ***feed ingredients*** are a necessity for Morocco's livestock and poultry industries.

TRADE BARRIERS: Morocco bans GE products from local cultivation and from products for human consumption.

Morocco Halal Labelling

- 3.8 Genetically Modified Foods (GMFs): Food and beverages containing products (and / or by-products) of Genetically Modified Organisms (GMO).

FIELD TESTING: ONSSA has not permitted open field testing of GE crops.

LABELING AND TRACEBILITY: GE labelling is not required in Morocco. ***For consumer products entering Morocco, a GE-free label may be included to avoid potentially being asked to provide a GE-free certificate.***

CARTAGENA PROTOCOL RATIFICATION:

Morocco signed the Cartagena Protocol in *May 2000, ratified it on April 25, 2011*, and it ***entered into force on July 24, 2011***. The Ministry of Energy, Mining, Water and Environment is the focal point, which serves as a liaison for information and compliance. In October 2011, ONSSA took charge of the implementation of the Cartagena Protocol. On February 15, 2013, Morocco published its National Biosafety Framework, but has not established a corresponding legal framework.

- On ***December 9, 2011, Morocco signed the Nagoya Protocol on Access and Benefit Sharing***. The Moroccan Government Council and the Ministerial Council approved the Protocol on March 22 and June 17, 2012, respectively; and ratified it on April 22, 2022.

UNITED ARAB EMIRATES & GCC-4 Gulf Cooperation Council

- ***15TH agrifood export partner of EU in 2023; UAE is one of the most important traditional export markets of RO for conventional cereals.***
- ***The Cooperation Council for the Arab States of the Gulf****, also known as the* ***Gulf Cooperation Council*** *is a regional intergovernmental, political, and economic union comprising* ***Bahrain****,* ***Kuwait****,* ***Oman****,* ***Qatar****,* ***Saudi Arabia****,* ***and the United Arab Emirates****.*
- *GCC4 consists of aprox.* ***59,620,000 people*** *and a* ***gross domestic product over $3.655 trillion****.*

FULL USDA REPORT here: ***https://fas.usda.gov/data/united-arab-emirates-agricultural-biotechnology-annual-7***

- ***Kuwait, Oman, Qatar and the UAE (GCC-4)*** permit the importation of genetically engineered (GE) food products of plant origin. GCC-4 countries have established several technical regulations that ***require labelling for both raw and further processed food and feed that may contain GE plant products. In the event "GMO Free" is claimed on a product label, the supplier must provide a GMO-free certificate from a government competent authority issued in the country of origin.***
- The United Arab Emirates (UAE) has been named one of the top three most innovative economies in the Middle East.
- The country has a chain of institutes and research centres that support research and development of biotechnology.
- Genetically engineered food with less than 0.9 percent of components derived from bioengineering may be imported.
- ***Ingredients and composition of imported or locally produced food must be registered***.
- ***DuBiotech*** is the first free zone in the Middle East to serve the ***science sector***.

- See ***GAIN Report TC2020-0024*** (https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural+Biotechnology+Annual_Dubai_United+Arab+Emirates_TC2023-0010.pdf) , "***UAE Passes New Mandatory Biotech Labelling Law***," for additional information.

IMPORTS:

- ***Federal Law No. 9 of 2020***: https://uaelegislation.gov.ae/ar/legislations/1448
- ***GAIN Report TC2020-0024***: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural+Biotechnology+Annual_Dubai_United+Arab+Emirates_TC2023-0010.pdf

In May 2020, the United Arab Emirates passed Federal Law no. (9) of 2020 and its related implementing regulations on the import, export, re-export, transit, trading, development, manufacture, production and transfer of food and agricultural products containing 0.9 percent or more in components derived from bioengineering.

This biosafety law requires that companies obtain a permit to import genetically engineered (GE) products into the UAE and requests the creation of a registry of applications. It also outlines requirements for labeling of GE food products and describes penalties if rules are broken. ***Imprisonment from not less than 3 months up to not less than 2 years is decided for breaking the national legal framework.***

LABELING AND TRACEABILITY

The importer, exporter, trader, developer, manufacturer, and producer of genetically engineered commodities or their products shall place an information label on each package. ***The label must state that the product contains "Genetically Modified Organisms or their products" and any other Information as determined by the law's implementing regulation*** (Ministerial Decree 84 of 2020).

MONITORING AND TESTING

Dubai Municipality's Dubai Central Laboratory uses real-time polymerase chain reaction technique to screen food samples to ensure the conformity of GE food with labels and local standards. The UAE has several other accredited laboratories with the capacity to monitor and test for GE products if needed: Al Hoty Stanger Laboratories ICAD, Abu Dhabi; SGS Gulf Food and Chemical Testing Laboratory, Dubai; Inspectorates International Limited, Dubai; Holistic International Testing Services, Dubai ; Advance Biotechnology Center, Dubai.

CARTAGENA PROTOCOL RATIFICATION

The UAE ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in July 2014 through Federal Decree No. (77) of 2014. More information regarding the international framework that UAE ratified can be found in the USDA report.

RUSSIAN FEDERATION & EAEU Eurasian Economic Union (Armenia, Belarus, Kazakhstan , Kyrgyzstan)

- ***Russia is listed by DG AGRI as the 6th agrifood export partner of EU in 2023;***
- ***The EAEU has an integrated single market***. As of 2023, it consists of ***183 million people*** and a ***gross domestic product of over $2.4 trillion***.
- The EAEU encourages the free movement of goods and services, and provides for common policies in the macroeconomic sphere, transport, industry and agriculture, energy, foreign trade and investment, customs, technical regulation, competition, and antitrust regulation.
- The ***EAEU is the top producer*** of ***sugar beet and sunflower,*** producing ***18.6% of the world's sugar beet and 22.7% of the world's sunflowers in 2012,*** as well as a ***top producer of rye, barley, buckwheat, oats and sunflower seed.*** It is also a ***large producer*** of ***potatoes, wheat and grain (and grain legumes)***.

- ***FULL USDA REPORT here***: https://fas.usda.gov/data/russia-agricultural-biotechnology-annual-3 - ***we recommend complete reading to those interested in selling biotechnology products on this market.***

On March 27, 2020, ***Russia's Minister of Agriculture signed Order #160 "On approval of Methodological Guidance for conducting assessments (studies) of the biological safety of genetically engineered/modified organisms used for production of animal feed and feed additives."***

The guidelines became effective on April 26, 2020 and ***establish a process for registering genetically engineered (GE) events for feed use, making it possible for those events to be imported after registration.***

The existing mechanism for registration of GE products for food use is still in effect. Per Federal ***Law No. 358-FZ of July 3, 2016***, ***Russia continues to ban cultivating and breeding GE plants and animals in the Russian Federation***.

All Russian legislative and regulatory documents use the term ***"GMO" (genetically modified organisms) or "GMM" (genetically modified microorganisms)*** instead of genetically engineered (GE) organisms/microorganisms.

IMPORTS:

- ***Russia does not permit imports of GE planting seeds***.
- Registration of GE lines imported for processing into food and feed has become more and more difficult. This is partially due to increased regulatory scrutiny. With no finalized regulatory documents for biosafety or for the registration of GE feeds, feed additives and veterinary pharmaceuticals, ***there is a de facto suspension on new registrations of feeds and feed additives containing GE organisms or products derived from GE organisms.*** The ongoing uncertainty of the situation will continue to have a serious impact on the trade of these products, specifically in bulk crops, such as soybeans, corn, and others that may be GE, as well as processed products made with GE components.
- ***The Russian Federation allows imports of GE crops, and processed products containing GE ingredients if these crops/products have been tested and registered in Russia for food and/or feed use and are "non-viable."***
- On June 24, 2019, President Putin signed decree No. 293 extending until the end of 2020 Russia's ban on the import of agricultural products from the countries that applied economic sanctions against Russia. Soybeans, soybean meal, and corn are not on the list of banned products.
- ***In 2021 : 12 corn lines, eight soybean lines, one rice line, one sugar beet line and two potato lines were registered for food use in Russia and in the EAEU***.
- ***Feed use registrations***, handled by Rosselkhoznadzor, have only been ***granted*** for a period of ***five years***, and the registration periods for only ***2 soybean lines and 4 corn lines were still valid***. The registrations for the remaining ***13 corn and soybean lines began to expire in 2017*** and continue according to each event's expiration date. Despite efforts to re-register the lines, until a regulatory mechanism for registration of GE feeds is approved, the registration renewal process and timeline remain unclear.

TRADE BARRIERS:

- ***Russia bans the cultivation of GE crops, and this impedes exports of planting seeds of crops, such as soybeans, rapeseed, sugar beets and corn. Russia's demand for efficient, drought-resistant varieties and hybrids of planting seeds of these crops is very high, but there is no open market for these seeds***.

RESPONSIBLE GOVERNMENT MINISTRIES :

- Federal Service for Surveillance of Consumer Rights Protection and Human Welfare (Rospotrebnadzor)
- The Ministry of Agriculture (MOA) of the Russian Federation
- The Federal Service for Veterinary and Phytosanitary Surveillance (VPSS)
- The Ministry of Industry and Trade of the Russian Federation
- The Ministry of Economic Development of the Russian Federation
- The Russian Academy of Sciences (RAN)
- The Ministry Science and Higher Education
- The Eurasian Economic Union (EAEU)

LEGISLATION AND REGULATIONS:

Currently, agricultural biotech policy is regulated by the EAEU Decisions (referred to as "technical regulations" of the CU/EAEU), Russian federal laws, government resolutions and orders of the heads of the Russian ministries, agencies, and services.

- ***Decisions of the Eurasian Economic Union (EAEU):***

Since July 2010, the EAEU has adopted several technical regulations that have influenced agricultural and food biotechnology. These technical regulations came into force on July 1, 2013, and ***all regulations require marking the presence of "GMOs" on labels and informing consumers in cases when food products are processed from or with the use of a "GMO," even if there is no DNA or proteins of "GMO" components in the marketed food products.***

- ***Russia, Federal Law No. 358-FZ*** has come in force in its entirety as of July 1, 2017. This law makes an exception for the cultivation and breeding of plants and animals required for scientific expertise or research. ***Based on monitoring of the effect of "GMO," or products derived from/or containing "GMOs," on humans and the environment, the Government shall have the right to ban imports into Russia of "GMOs" intended for environmental release and (or) products derived from or containing such organisms***.
- ***Federal Law No. 86-FZ of July 5, 1996 "On the State Regulation in the Sphere of Genetic Engineering Activities" with amendments made in 2000 and in 2010.*** There were several amendments to this federal law, including the last one, made by FL No. 358-FZ of July 3, 2016, which emphasized the role of state control over the release of GE organisms into the environment, state monitoring of the effects of such release on the environment and also on the health of human beings. The amendments add the ***responsibility of control and monitoring, as well as registration, of GE organisms and products, including imported goods, to the state***.

Registration for Food Use (procedure):

- ***Rospotrebnadzor registers biotech crops and ingredients for food use for Russia and for the EAEU***. Decisions of EAEU prevail over Russian Federation regulation for GE crops/lines registration for food use. The registration for food use is implemented in compliance with Decision of EAEU No.299 dated July 26, 2010, while registration for feed use must comply with Government Resolution No. 839. Rospotrebnadzor has developed methodological guideline that conforms to requirements of Government Resolution No. 839.
- ***Laboratory tests*** required for the safety assessment take approximately ***12 months to conduct and an additional two to three months are needed to organize and prepare documents for the new GE crops***. ***Registration is only granted if the biotech product contains biotech events that have already been registered***.

Fees for registration of biotech events:

- Rospotrebnadzor's charges for ***all examinations and related services, including comprehensive studies required to register biotech events for food use***. The fee varies, depending on the range of examinations and studies plus customs clearance and other fees, but ***averages around RUB 6.3 million (approximately $99,000)*** for the approval of new events for an unlimited period. The option to register for an unlimited period began in 2006.

- ***Registration of food products that contain a previously registered biotech*** event is RUB 20,000 ($313). For registration of ***biotech events for feed use***, VPSS usually registers an event only after it has been approved for food-use. On average, ***the past charges for examination and a five-year event registration for feed use was RUB 4.5 million (approximately $70,500***). The charge for re-registration of the event every five years was RUB 3.8 million (approximately $59,500). Fees will be updated under the new Methodological Guidance.
- ***Companies that import formula feed with registered biotech components also need to register this feed as GE feed***. ***The registration is given to the company that imports this feed and VPSS requires that each feed containing a registered GE event must also be registered***.

Developers present on the Russian market: Legacy Monsanto, Syngenta, Legacy Bayer Crop Sciences Registration transferred to BASF since Aug.2020, Syngenta (Producers Syngenta /Bayer), Legacy Bayer Crop Sciences, Legacy Monsanto/KWS, Center "Bio-engineering"Russia, AO Bayer, Pioneer Hi-Bred International & Dow AgroSciences.

INNOVATIVE BIOTECHNOLOGIES: ***there is no information on the development of innovative plant biotechnologies***. According to available information, Russian research in biotechnology is limited to biological means of plant protection, growth stimulators, and microbiological fertilizer.

LABELLING: Labelling and information for consumers on the presence of GE ingredients in food products is regulated by the technical regulations of the EAEU on safety and labelling of food products. These regulations require that in ***any of the EAEU member states, products must be labelled if the presence of GE lines is over 0.9 percent***. Feed sold in Russia does not require labelling. However, ***registration of GE lines for use in feed is required if the presence of registered lines is over 0.9 percent and the presence of non-registered lines is over 0.5 percent.***

- For ***food products imported into Russia***, ***Rospotrebnadzor has the right to conduct sample tests to detect the presence of biotech components***. In order to verify the biotech-free claim, the producer or exporter may conduct its own tests at independent laboratories, but the results of these tests are not accepted by Rospotrebnadzor.
- ***for products obtained with the use of "GMOs - an inscription "GMO,"*** similar to the unified mark in form and size, should be marked next to the unified mark of products circulating on the market of the EAEU Member States.

MONITORING AND TESTING:

- In Russia, Rospotrebnadzor monitors/tests GE food products and VPSS monitors/tests grains, oilseeds for animal consumption, feed additives, and ingredients. ***GE testing requirement*** for planting seeds may hinder the process of registration of new varieties of planting seeds in Russia, which already takes ***at least two years***. There are no approved methods and/or laboratories for certification of GE-free production of corn and soybeans in Russia.

LOW LEVEL PRESENCE (LLP) POLICY: In accordance with Russian and EAEU legislation, ***imported food products are considered non-GE if the presence of GE content does not exceed levels determined by Russian and EAEU legislation: not more than 0.9 percent of registered or nonregistered GE lines in food products or ingredients, and not more than 0.9 percent of registered GE lines and not more that 0.5 percent of non-registered GE lines in feed or feed ingredients.*** However, in 2016 the attention of Russia's feed surveillance authorities to the presence of non-registered lines in feed and the absence of information on the registered lines increased. ***In several cases***, ***VPSS***, the watchdog for control of GE in feed, ***temporarily suspended imports of feed or feed additives based on finding non-registered GE ingredients***.

CARTAGENA PROTOCOL RATIFICATION: ***Russia has not ratified this protocol and is not a party to the Protocol***.

ALGERIA

- ***16th export partner of agrifood products of EU and top export partner of RO conventional cereals***
- Algeria consists of ***over 45 million people*** and a ***gross domestic product of $768.52 billion, 2024***
- ***Founder of Arab Maghreb Union, a political union and economic union trade agreement aiming for economic and future political unity among Arab countries that are located primarily in the Maghreb in North Africa.***
- ***The Arab Maghreb Union members are the nations of Algeria, Libya, Mauritania, Morocco and Tunisia***, consisting of a population of over ***102 million people***.

FULL USDA REPORT here: https://fas.usda.gov/data/algeria-agricultural-biotechnology-annual-5

- ***There is no agricultural genetically engineered product development for commercialization purposes in Algeria.***
- ***The Ministry of Agriculture's decree of December 24, 2000, prohibits all imports, production, distribution, and commercialization of genetically engineered plant materials.***
- Several Universities have centres for Biotechnology research.
- In 2001, the ***Algerian Ministry of Agriculture MOA published a decree prohibiting development of agricultural genetically engineered product for commercialization purposes***.
- ***The Ministry of Agriculture's decree of December 24, 2000 prohibits all imports, production, distribution, and commercialization as well as utilization of genetically engineered plant materials*** (live plants or pieces of live plants, including their dormant buds, tendrils, grafts, tubers, rhizomes, cuttings, shoots, and seeds intended for propagation and reproduction) except for research purposes.
- **In early 1980's**, Algeria began developing a strategy for the implementation of a biotechnology policy adapted to local needs. Universities and higher education centers designed training and research programs in a variety of sectors. Their focus targeted life sciences and biotechnology. ***Plant genomics, genetics, and bio-industry were introduced during this period***.

- The centers develop biotech solutions to domestic agricultural concerns and promote food security. ***FAS Algiers*** continues to support these institutions' biotechnology researchers with capacity building through the ***Borlaug scientific exchange program***.

PRODUCT DEVELOPMENT: The Ministry of Agriculture MOA has legislative responsibility for the domestic production of crops.

- the MOA still prohibits any biotechnology product development except for research purposes as set out in the Decree of December 24, 2000 (published in the Official Journal on January 7, 2001). ***The decree prevents agricultural genetically engineered (GE) product development, commercialization, and import into Algeria.*** Pursuant to this decree, ***Algeria does not develop agricultural GE products for commercialization purposes.***
- The biotechnology institutions in Algeria promote and carry out ***applied research in biotechnology in several fields: health, environment, bio-industry, food, and agriculture***. The centers develop biotech solutions to domestic agricultural concerns and promote food security. In addition, these multidisciplinary biotechnology research institutions ensure continuous training and provide services and expertise in the field of biotechnology. These institutions would benefit from capacity building.

IMPORTS: ***The decree prevents imports of GE products***.

TRADE BARRIERS: ***MOA issued a decree in 2000 that prohibits the importation, production, distribution, and commercialization as well as utilization of GE plant materials*** (live plants or pieces of live plants, including their dormant buds, tendrils, grafts, tubers, rhizomes, cuttings, shoots, and seeds intended for propagation and reproduction) except for research purposes.

INNOVATIVE BIOTECHNOLOGIES: The Government of Algeria (GOA) has not addressed the regulation of genome-edited agricultural products.

LABELING & TRACEABILITY: The Ministry of Commerce, which has authority for quality control and fraud prevention, regulates labelling and laboratory inspection. Currently, there are no laws regarding the labelling or testing of plant products derived from biotechnology.

CARTAGENA PROTOCOL RATIFICATION: Algeria signed the Cartagena Protocol in May 2000 and ratified it in June 2004.

INTERNATIONAL TREATIES and FORUMS: Algeria has ratified the Convention on Biological Diversity and the UN Framework Convention on Climate Change. Algeria is a member of the International Plant Protection Convention (IPPC), the Food and Agriculture Organization of the United Nations (FAO), and Codex. Algeria collaborates and reports regularly to FAO, IPPC, and Codex.

OTHER EXAMPLES OF THIRD COUNTRIES INVOLVED IN DEVELOPMENT AND TRADE OF BIOTECHNOLOGIES (legal framework, possibilities of market access, trade barriers):

INDIA: Full USDA report: *https://fas.usda.gov/data/india-agricultural-biotechnology-annual-6*

PAKISTAN: *https://fas.usda.gov/data/pakistan-agricultural-biotechnology-annual-7*

SRI LANKA: *https://fas.usda.gov/data/sri-lanka-agricultural-biotechnology-annual-1*

EGYPT: *https://fas.usda.gov/data/egypt-biotechnology-and-other-new-production-technologies-annual-1*

INDONESIA: *https://fas.usda.gov/data/indonesia-agricultural-biotechnology-annual-7*

SOUTH AFRICA: *https://fas.usda.gov/data/south-africa-agricultural-biotechnology-annual-7*

NIGERIA: *https://fas.usda.gov/data/nigeria-biotechnology-and-other-new-production-technologies-annual-0*

ETHIOPIA: *https://fas.usda.gov/data/ethiopia-agricultural-biotechnology-annual-3*

SOUTH KOREA: *https://fas.usda.gov/data/south-korea-agricultural-biotechnology-annual-7*

Japan: *https://fas.usda.gov/data/japan-agricultural-biotechnology-annual-7*

SPAIN

Dear Presidency

We thank you for the opportunity to send written comments after the July meeting of Working Party on Genetic Resources and Innovation (WP).

We refer to our oral comments during the meeting, which were shared by a majority of Member States. However, we can briefly summarise certain topics and ideas:

- We welcome the Commission proposal for a regulation on plants obtained by certain new genomic techniques, which is the result of a Council request in November 2019 and based on the main results of the Agriculture and Fisheries Council, 26-27 May 2021[2]. In this Council meeting, ministers held a debate on the conclusion of the Commission's study on new genomic techniques and in general they agreed with the finding of the study, notably the need to address legal uncertainty and to adapt the existing legislation to consider scientific and technological progress.
- Therefore, we firmly support the general principles of the Commission proposal to create two distinct pathways for the use of NGT plants and their products based on different EFSA reports. That means the **recognition of a category 1 NGT plant subjected to a verification procedure, based on scientific criteria, and that would be treated like conventional plant from a regulatory perspective in case it meets these criteria**. Spain wants to highlight the recent EFSA publication (EFSA-Q-2024-00178) that supports this view.
- The issues presented in the non-paper shared by the Presidency, even the ones related to wild plants, Cartagena Protocol or delegated acts, have already been thoroughly discussed in the council working groups, COREPER and AGRIFISH meetings, and have been incorporated into the February compromise text (ST16714). This text was supported by 17 Member States, although it didn't reach a qualified majority.

[2] https://www.consilium.europa.eu/en/meetings/agrifish/2021/05/26-27/#:~:text=The%20meeting%20was%20held%20in,of%20key%20issues%20remained%20outstanding.

- During the last meeting of the WP, various doubts, concerns and disagreements were raised on the approach of the non-paper document, the criteria followed to select the nine topics, and their content, amongst others. We share those and we want to highlight our concern and disagreement with the absence of any reference in the non-paper document to the main amendments introduced in compromise texts, as result of previous discussions. We are referring to:
    - Amendments to incorporate provisions included in the current GMO legislation (opt-out) or to address new topics (e.g., sustainability/tolerance to herbicides, intellectual property) based on the flexibility of certain delegations.
    - Amendments based on scientific criteria and suggested by a majority of Member States (e.g. annex I).
    - Amendments with a favourable opinion given (orally) in complete impartiality by the Council Legal Service, such as those related to delegated acts.
- International trade.
    - Article 207 of TFU confers on the Commission, on mandate from the Council, the powers to implement the common commercial policy, including International Treaties. Based on that, the procedures that provides guarantees on international agreement have been strictly followed for this proposal. Two notifications were submitted:
        - G/SPS/N/EU/687. Committee on Sanitary and Phytosanitary measures.
        - G/TBT/N/EU/1032. Committee on Technical Barriers to Trade.
    - No changes have been included in the compromise text ST16714 with respect to Article 10 on mandatory labeling of plant reproductive material, that contains or consists of category 1 NGT plant. This Article provides guarantees to farmers, exporters or competent authorities to be informed or to note the presence of category 1 NGT plants. Furthermore, this can also be guaranteed by Article 47 of the legislative proposal of plant reproductive material (mandatory information to register a variety). Therefore, if necessary, information on the presence of category 1 NGT plants can be provided to potential customers, including from third countries.
- Council Legal Service. We want to highlight that, as referred to in the Annual Activity Report of the Council Legal Service[3], most of the advice is given orally during the discussions on the files. **This approach based on oral advice, which was followed**

[3] https://www.consilium.europa.eu/media/w33ly0gs/2023-annual-activity-report-of-the-legal-service.pdf

during the previous works of this Working Group, has full validity and full guarantees. Furthermore, we understand that to deviate from this common procedure (oral advice), duly justified grounds, identifying topics which could not be addressed properly by oral advice, must be provided.

We remain committed and constructive to work with the Presidency towards a General Approach. To that end and considering the result of the last WP, we understand that the more successful and effective way to move forward is to recognise the work and its results, based on constructive discussion initiated in July 2023 and the need to avoid a repetition of previous debates. We call on the Presidency to consider this work and its results to have a better change to reach an agreement.

Particularly we refer to compromise text ST 1674. We think it is possible to find a balanced solution preserving its main elements, such as those related to the verification procedure and labelling and traceability provision for category 1 NGT plants. This will also ensure the consistency with Council requests from 2019 and 2021 to adapt the current legislation to the scientific and technological progress.

Madrid 19 of August 2024

SLOVAKIA

Slovak republic would like to provide the following comments to the Hungarian Presidency document 11820/24:

1/ Although the Commission has provided a rationale for the equivalence criteria, we agree that their definition should take into account the resulting features (including possible off-target mutations) and thus the possible risks. In this context, we should also take into account the first report of the agency ANSES (2023), which raises fundamental concerns in relation to the scientific basis of the Annex I criteria and is closely related to the need for mandatory risk assessment. We continue to consider it necessary for NGTs to be labelled and traceable within the framework of regulation. This reflects public opinion in Slovakia on the topic of GMOs and NGT.

2/ Based on Article 57 of the draft regulation on plant reproductive material, every application for the registration of a variety should be formally examined, therefore it is important that precise and clear rules are given for the identification and marking of NGT 1 and NGT 2. Precise rules on how this fact will be demonstrated already when applying for registration and how the tests of economic value and tests for diversity, uniformity and stability of the variety (DUS tests) will take place in the case of NGT 1 and NGT 2. One solution could be that for each application for registration the applicant also attach the results of laboratory analyses that would confirm that it is a NGT 1 or NGT 2 variety. However, not all laboratories will be able to perform this type of analysis due to their equipment and staffing. The solution could be the creation of laboratory consortia at the EU level, which would be devoted exclusively to the issue of NGT testing and analysis and would be available to the official laboratories of the EU MS.

2.1/ We agree with the Presidency that the subject of the regulation should be narrowed down to plants used in agriculture. Applying the regulation also to wild plants could have a risk for the functioning of ecosystems.

3./ We agree with the Presidency on the importance of labelling for maintaining consumer confidence and freedom of choice. It is a fundamental right of the consumer, on which the EU itself publicly builds and considers its consumer to be the most informed in the world. In relation to the NGT, we would like to emphasize all the more that trust and freedom of choice are not only important here for consumers, but for the entire EU food industry, from breeders, farmers, beekeepers, feed and food processors and retailers, who must also have the right to information about what kind of food they produce or sell. And that regardless of whether they work ecologically or conventionally. Therefore, we support the positions of those member states that promote the labelling of NGT plants also on food, feed and other products made from them. We propose a label on food or feed on the packaging in accordance with the current legislation for food labelling, as it is transparently stated in the case of GMOs.

A lengthy backward search for a possible NGT origin of a product or ingredient is difficult, imprecise, expensive and gives room to induce a competitive disadvantage. We should respect

organic agricultural production and consumers' trust in it, and therefore food and feed made from NGT category 1 plants should also be labelled.

4./ We will also appreciate feedback from DETECTIVE and DARWIN projects. However, under the Commission's proposal, companies wishing to place Category 1 NGT plants on the market will be not required to submit detection methods, reference material and genetic modification data.

One solution could also be that applicant will attach to each registration application the results of laboratory analyses confirming that it is a conventional variety and NGT 1 or NGT 2 type. Laboratory analyses should be performed in an accredited official laboratory. Such a method would speed up the process of registration and approval of the variety in view of the high number of analyses to be carried out in case of NGT. In the case of laboratory analysis (detection, identification and quantification) of NGT plants and their products, as well as NRL for GMO foods, our diagnostic workplaces in the Slovak Republic are part of the European Network of GMO Laboratories (ENGL), which is dedicated to the issue of NGT for a long time. We agree with the statement that there are currently and are being addressed problems with the development and validation of reliable methods for the detection of NGT in general. The current analytical enforcement system will suffer from an increased workload, if food, feed and seed samples have to be analysed by individual methods for all known cases of mutations. The overall time of laboratory analyses will of course be extended, which may negatively affect trading in this type of commodity and of course, the cost of laboratory analyses will increase. At the same time, not all laboratories will be able to perform this type of analysis due to their equipment and personnel. Another problem is the performance of official control according to Regulation of the European parliament and the Council (EU) 625/2017 on official controls, where laboratories performing official control must be accredited according to ISO EN 17025.

5./ We support the Presidency's proposal for "a real approach" to sustainability (...) in relation to plants and products obtained by new genomic techniques" and the need for data and evidence-based evaluation.

6./ In Slovakia is in general low acceptance of genetically modified food and feed by manufacturers, therefore NGT products without labelling might seriously harm their national and export markets.

7./ The deadlines for processing the operator's application by the Member States and for sending comments by the other Member States are very short. We recommend extending the deadlines so that the authorities cannot carry out work at the expense of quality.

8./ The Commission's right to adopt delegated acts amending the equivalence criteria set out in Annex I in order to adapt them to scientific and technical progress appears to be in conflict with Article 290 TFEU. Art. 290 of the TFEU provides that "a legislative act may to delegate the authority to adopt generally binding non-legislative acts in order to supplement or change certain non-essential elements of the legislative act". However, the criteria of equivalence seem to be the most essential element of this legislative proposal.

9./ According to the legislative proposal, any risk assessment will be abolished for NGT category 1, i.e. for 91% of plants that are in development with market potential according to the Joint Research Centre (2021)[4]. We therefore consider reasonable to obtain a legal opinion from the Council's legal service in advance, so as not to expose ourselves to the risk of violating international binding law, because according to the definition given in Art. 3 (g) of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, "living modified organism" means any living organism that has a new combination of genetic material obtained through the use of modern biotechnology.

[4] New genomic techniques; Parisi, Claudia; Rodríguez Cerezo, Emilio (2020): New genomic techniques. European Commission, Joint Research Centre (JRC) [Dataset] PID: http://data.europa.eu/89h/382e03fc-aac3-482a-9e81-9997789083b1

SWEDEN

Written comments from Sweden on the Presidency non-paper (doc 11820/24) and from the Council Working Group on the 19th of July.

Sweden appreciates the Hungarian Presidency's intention to advance the New Genomic Technique (NGT) dossier in order to find a qualified majority in the council and wishes the Hungarian Presidency success in its role as mediator in furthering this dossier.

The European Commission presented the proposal for a regulation on NGT-plants a little more than a year ago. Following from then, the NGT file has been intensely discussed in the Council during the Spanish and Belgian Presidencies. Significant progress has been made. Therefore, before going into the details of the written commentary on the non-paper, we would like to reflect on the NGT dossier, and the progress made so far. Although the NGT proposal is politically challenging with strong proponents and opponents, we have made progress and reached compromises on many aspects of the proposal, thus narrowing the differences between delegations. Sweden urges the Hungarian Presidency to build upon the achievements of the former Presidencies, rather than reopening previously negotiated compromises. For this purpose, the compromise text (ST16714) presented to the COREPER for a vote last February would serve as a solid starting point. The text, supported by a majority of 17 Member States, represents a robust and equitable resolution that accommodates the diverse interests of the Member States, without exceeding the limits of flexibility inherent in the negotiation process.

Specifically concerning the Presidency non-paper, Sweden has reviewed the document carefully and concluded that we respectfully disagree with the Hungarian Presidency's assessment that the nine paragraphs mentioned are the remaining points for discussion and a way forward to reach a qualified majority in the council. These issues have already been extensively discussed in the Council Working Group resulting in compromises supported by a majority of Member States. Nevertheless, Sweden will adopt a constructive approach in the discussions that the Hungarian Presidency seeks to initiate. We refer to our oral intervention during the working party in July but will also elaborate on each issue briefly in writing below.

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

For Sweden, this has been a thoroughly discussed aspect of the NGT proposal, with several improvements made in previous compromise texts. Sweden supports Annex I as included in the compromise text (ST16714) discussed by COREPER last February.

2. Risk assessment for category 1 NGT plants and products

The premise for Category 1 plants and products is that they could also have been developed through conventional breeding methods. Therefore, Sweden considers it disproportionate to implement a

risk assessment for these plants and products. Risk assessment would constitute a significant and disproportionate administrative burden for researchers, companies, and authorities. Sweden would also like to highlight the recent EFSA publication (EFSA- Q- 2024- 00178) that supports this view.

2.1. Scope of the regulation – wild plant species

Sweden does not agree with the two options suggested by the Presidency. Sweden considers that the scope of the regulation already has been addressed in the Council Working Groups and that this issue is resolved. For Sweden, it is desirable that wild plants are covered under this regulation, as currently described in the compromise text (ST16714) adopted by COREPER last February.

3. Labelling of category 1 NGT food and feed products

This topic has been extensively discussed in previous Council working groups. Sweden is not in favour of reopening this discussion and supports the wording included in the compromise text (ST16714) adopted by COREPER last February. Labelling is already in place for plant reproductive material, ensuring that professional users can make informed choices. For Sweden, this is sufficient, and there should be no requirement for labelling of end products. A requirement on labelling of NGT-1 products would necessitate complete separation of conventional and NGT1 production lines at prohibitingly high administrative and financial costs. Consequently, the use of gene editing in EU would be severely limited, counteracting the purpose of this proposal to foster innovation and provide EU-farmers access to new technology that enables the green transitions. The organic sector is obliged to use organic seeds and products. The organic sector would benefit if NGT1plants would equate to conventional plants also in this respect, hence no prohibition of using NGT plants is needed.

4. Detection and identification of NGT plants and products

Category 1 NGT plants are comparable to plants derived from conventional breeding or occurring naturally; therefore, no labelling requirement is necessary, and tracing these plants and their products would also not be proportionate. Moreover, in some cases, it is impossible to determine whether a plant was bred using NGTs or conventional techniques. As a result, mandatory tracing of Category 1 NGT plants and their products is not feasible, is unlikely to be legally sound and very costly for companies and authorities. Therefor Sweden would like to again underline that it supports the compromise text (ST16714) discussed by COREPER last February.

5. Sustainability

Sustainability applies to all plants, not just NGT plants; therefore, it is more logical and proportional to implement this in horizontal legislation for plants, if we wish to do so. The PRM proposal, for example, would be a more appropriate place to discuss this, instead of the NGT proposal.

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

Sweden is satisfied with the work that the European Commission has done to investigate this matter and considers the WTO notification sufficient. Sweden argues that it is important to follow standard procedures in this matter as deviating from common practice here may impact trade issues in other areas. It is important to be able to rely on the competence of third countries to respond to WTO notifications if they have objections to NGT plants and products. Therefore, Sweden does not consider the NGT proposal as a potential problem for our export.

7. The verification procedure

Sweden has a preference for a verification procedure conducted by the national competent authority instead of the EFSA, especially as regarding field trials. We disagree with the assertion that the EFSA offers an easier route for SMEs compared to a national competent authority. The language differences and limited scope for customization make the EFSA process less accessible, so we would argue that it is the other way around.

8. **Empowerment of the Commission for adopting delegated acts**

This topic was also discussed thoroughly under the Spanish Presidency. The Council Legal Service provided a clear refinement in the text and offered a comprehensive oral explanation (as is practice), which is sufficient for Sweden to support the compromise text (ST16714) adopted by COREPER last February. Sweden sees no need to reopen this discussion.

9. **Compliance with the Cartagena protocol on biosafety**

This discussion has also taken place multiple times before in the Council Working Group, with the same conclusion each time: the NGT proposal is in line with the Cartagena Protocol. This has been confirmed by the Commission, and Sweden concurs with this assessment. The Cartagena protocol defines a living modified organism as any living organism that possesses a novel combination of genetic material developed through modern biotechnology. Sweden is of the opinion that the core of the NGT-proposal, whereby only modifications that may also occur in nature or during conventional breeding are allowed in caegory1-plants, is a clear expression of adaptation to the Cartagena Protocol. Furthermore, several parties of the Cartagena Protocol have already adopted different variants of legislation regarding new genomic techniques, the current EU proposal will bring the EU more in line with them.