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From:	General Secretariat of the Council
To:	Delegations
Subject:	Regulation on new genomic techniques (NGT) – comments from Austria, Belgium, Cyprus, Germany, Denmark, Estonia, Greece, Finland, France, Luxembourg, the Netherlands, Romania, Slovenia

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (01.08.2023)

Delegations will find in annex submissions from delegations on the above subject, concerning questions and comments on the proposal for a Regulation on new genomic techniques (NGT) and on the accompanying impact assessment.

AUSTRIA

AT – Questions and comments on the proposal for a Regulation on new genomic techniques (NGT) and on the accompanying impact assessment, as of 19 July 2023

Austria appreciates the possibility to provide questions and comments to the regulatory proposal and the accompanying impact assessment. However, due to the limited time available, and the necessary national coordination, we are not in position to deliver a final statement regarding the proposal**. Thus, Austria files a general scrutiny reservation on the proposal.** The following comments and questions relate to some basic issues that need to be clarified. **Austria reserves the right to submit additional questions and comments at a later time.**

General comment:

For Austria there are several crucial aspects, which are touched upon in the proposal of the European Commission: The omission of any risk assessment for category 1 NGTs, the lack of traceability and labelling requirements – neglecting the right of consumers and producers regarding freedom of choice, requirements for organic forming, i.e. the prohibition to use NGT plants, which are impossible to implement, and finally the distribution of responsibilities and possibilities between the Member States and the European Commission, regarding coexistence, national prohibitions and possibilities to change criteria laid down in the Annexes of the proposal.

In our point of view the proposal does not provide solutions or even clarity for any of these aspects but instead leads to more open questions.

In the following, we provide more specific comments on some of these aspects:

Categorisation of NGT plants and risk assessment requirements

The EC argues that the proposal represents a scientifically justified, objective approach that maintains a high level of protection of health and the environment. However, we doubt whether an approach that is solely built on technical, process-oriented criteria and which leads to the exemption

of a large group of NGT products with a wide range of different traits from a case-by-case risk assessment can ensure the intended level of protection.

Furthermore, we believe that the equivalence criteria proposed in Annex I are not scientifically justified with regard to this objective. E.g. the scientific justification for the number of genetic modifications present in a NGT plant (20) as well as the number of nucleotide changes which may be introduced by substitution or insertion at a specific genome locus (20) remains unclear. We therefore urge the EC to specify and explain the scientific basis for this approach.

Traceability and labelling, Freedom of choice and organic farming

For category 1 NGTs, no labelling or traceability requirements are foreseen. In our understanding also those products are genetically modified and should be labelled accordingly. Consumer polls show clearly that freedom of choice is very important to them. How will the EC ensure that consumers' interests and their right of freedom of choice are not neglected?

One of the objectives of the proposal is to "[…] enhance the competitiveness of the EU agri-food sector […], providing a level-playing field for its operators". Part of the agri-food sector is also organic production, a sector quite important for Austria and which should be strengthened according to the European Green Deal. It remains unclear, how the new legislation can ensure the competitiveness or even the survival of this sector, taking into account the envisaged changes regarding detection and traceability. The EC expects "reduced burden and costs" for "breeders, operators, especially SMEs". Does this also hold true to the organic and GM-free breeders and operators, especially SMEs?

Responsibilities of and restrictions for Member States, Delegated and Implementing Acts

The goal "to facilitate the cultivation of NGT plants in the EU" (recital 37) is not shared by all Member States, stakeholders, and not all parts of civil society, as became quite clear during the consultations in preparation of this proposal. A restriction of Member States' possibilities to prohibit cultivation of NGT plants, is therefore not justified.

Member States are required to establish coexistence measures for category 2 NGT plants. No coexistence measures are foreseen for category 1 NGT plants. We believe that harmonised measures are necessary for all NGT plants, which need to be decided upon at a EU level, in order to guarantee equal market conditions for all farmers across the EU and to accommodate cross-border

issues. Such harmonized measures need to be developed by the European Commission in close cooperation with Member States.

The proposal includes several provisions for delegated and implementing acts, empowering the Commission to decide on crucial aspects, as the information to be provided by the applicant or criteria for the determination of equivalence for category 1 NGTs. Member States authorities are not or only to a minor extent involved in the development of these acts. We believe that this equires further discussion.

ANNEX II

BELGIUM

List of written questions on the NGT proposal for the written procedure

GMO General Debate of 7 July

DELETED

Questions & Answers

Annex I (Category 1 NGT Plants)

1. **Question for clarification on the statement '*No more than 20 genetic modifications*' in Annex I. Will off-target mutations be included in the maximum of 20?**

2. **Why is there in a reference to '*insertion*' in (1) in Annex I? Should this be interpreted as insertions of maximum 20bp? This is unclear and conflicting with the rest of the text which explicitly mentions insertions (of cisgenes that are likely longer than 20bp).**

3. **Question for clarification on '*does not interrupt an endogenous gene*' in (3) of annex I. What is the aim of the explicitly mentioning this 'non-interruption'? If you, for example, substitute a gene, can you at the same time disrupt a gene?**

4. **Question for clarification on '*any other targeted modification of any size, on the condition that the resulting DNA sequences already occur*' in (5) of Annex I. Can the European Commission give an example? Is this, for example, chromosome fragments?**

Novel Foods (Category 1)

5. **Question for clarification on the What is meant by '*affects*' in the (22) of the proposal? Should this be interpreted as a fork interval?**

Category 2 plants

6. **Question for clarification on the case by case approach of risk assessment mentioned in (26) of the proposal: how does the commission see the differentiated risk assessment for the diversity within Category 2 plants?**

Transparency, traceability, labeling

7. **Question for clarification on (24, 32) in the proposal: How will this proposal relate to the discussions on labeling in the Green Claims directive and the sustainable food system framework?**

Contained use of plant cells

8. **Question for clarification on whether or not plant or plant cell cultures falling under Cat. 1 should be exempted from the contained use legislation. Although Directive 2009/41/EC only applies to genetically modified micro-organisms (GMM), most Member States have extended the scope of the contained use legislation to all genetically modified organisms (including plants). Can the Commission clarify how GMM plant cell cultures and plants classified as category 1 are to be considered under contained use legislation?**

Links with other legislative frameworks

9. **During the working party of 10 July, the Commission made some links with the PRM-file, for example relating to pesticide resistance, where these sorts of traits can be managed on a more holistic scale. Processed imports, for example cattle feed made from herbicide resistant soy, do not fall under the PRM regulation. How does the Commission see other legislation where this herbicide resistant trait would be or is taken into account on a holistic scale?**

Other comments

10. **The Belgian delegation wishes to comment that the use of the terms NGT product/plant are not used consistently throughout the text.**

11. **One commonly refers to 'familiarity' in risk assessment, not 'familiarity for the environment'.**

CYPRUS

Accopanying text:

I am sending to you attached the initial comments of Cyprus on the new proposal on new genomic techniques. Please note that we still have scrutiny reservation on the proposed text pending its analysis by our experts.

Comments of Cyprus in relation to the proposal on new genomic techniques

(WP 10 July 2023)

- Η Κύπρος ήταν πάντοτε διστακτική ως προς τους γενετικά τροποποιημένους οργανισμούς, εγείροντας σοβαρές ανησυχίες σε σχέση με την επαρκή ασφάλεια τους για την ανθρώπινη υγεία και τα ζώα. Παρόλο που διατηρούμε κάποιες από τις επιφυλάξεις μας, προσεγγίζουμε την πρόταση Κανονισμού με θετικό πρόσημο.

- Θα πρέπει όμως να εξεταστούν και να συμφωνηθούν αρκετές διασφαλίσεις προτού εφαρμοστεί, που να διαμορφώνουν συνθήκες προστασίας των γεωργών και των μικρών επιχειρήσεων στον τομέα της γεωργίας. Σημαντικό σημείο για μας είναι η αποφυγή της ιδιωτικοποίησης των γενετικών πόρων (μέσω διπλωμάτων ευρεσιτεχνίας) σε οποιαδήποτε διάσταση αυτής της προσπάθειας. Μια τέτοια εξέλιξη θα είχε ως αποτέλεσμα να μην υπάρχει ελεύθερη πρόσβαση των γεωργών στις νέες ποικιλίες καθώς επίσης και πιθανή μείωση της βιοποικιλότητας.

- Οι γεωργοί θα πρέπει να μπορούν να χρησιμοποιούν τους σπόρους της δικής τους παραγωγής από τον αρχικό σπόρο που προήλθε από νέες γονιδιωματικές τεχνικές και οι μικρές σποροπαραγωγικές εταιρίες να έχουν την κατάλληλη πρόσβαση για παραγωγή νέων εμπορικών ποικιλιών.

CURTESY TRANSLATION

• Cyprus has always been hesitant about genetically modified organisms, raising serious concerns regarding their adequate safety for human and animal health. Although we maintain some of our reservations, we approach the Regulation proposal positively.

• However, a number of safeguards should be considered and agreed upon before implementation, creating conditions for the protection of farmers and small businesses in the agricultural sector. An important point for us is to avoid the privatization of genetic resources (via patents) in any dimension of this effort. Such a development would result in farmers not having free access to the new varieties as well as a possible reduction in biodiversity.

• Farmers should be able to use seeds produced by them from the original seed derived from new genomic techniques and small seed companies should also have adequate access to produce new varieties.

GERMANY

Erste Fragen der Bundesrepublik Deutschland zum Vorschlag der EU-Kommission zur Regulierung neuer genomischer Techniken im Nachgang zur Ratsarbeitsgruppe zu genetischen Ressourcen und Innovation in der Landwirtschaft (Sitzung vom 10.07.2023)

Wie im Rahmen der oben genannten Sitzung angekündigt, hat die ESP-Präsidentschaft dazu eingeladen, Fragen und Kommentare zum Vorschlag der EU-Kommission für eine Verordnung über neue genomische Techniken (NGT) und zur begleitenden Folgenabschätzung (bis zum 19. Juli 2023) einzureichen. Wir möchten uns für die Einräumung dieses Angebots, welches wir sehr gerne nutzen, bedanken und übermitteln Ihnen die folgenden Fragen. Bitte haben Sie Verständnis dafür, dass in diesem frühen Stadium, unmittelbar nach Vorstellung des Vorschlags, die nachstehend zusammengestellten ersten Fragen nicht abschließend und außerdem rein fachlicher Natur sind, also keine Positionierung seitens der Bundesregierung darstellen. Wir freuen uns, auf die weiteren Beratungen.

I. Kategorie 1 NGT (Kat-1 NGT)

Kriterien

1. Der Vorschlag sieht bezüglich der Verifikation von Kat-1 NGT-Pflanzen eine Prüfung auf Grundlage der in Annex I festgelegten Kriterien vor. Diese beziehen sich ausschließlich auf die DNA-Sequenz der Pflanze.

   Auf welchen wissenschaftlichen Grundlagen bzw. welchen Erkenntnissen wurden die Kriterien zur Einstufung in Kategorie 1 (Annex I) festgelegt, insbesondere die Beschränkung auf 20 Basenpaare für Substitutionen oder Insertionen und auf 20 genetische Veränderungen, wenn man bedenkt, dass eine durch chemische Stoffe oder Strahlung hervorgerufene Mutation wahrscheinlich ein Vielfaches an Mutationsereignissen verursacht?

2. Worauf beruht die Annahme, dass Nachkommen von Kat-1 NGT-Pflanzen selbst wieder Kat-1-NGT-Pflanzen sind (Artikel 4 (1) (b))? Müssen Kreuzungen von Kat- 1 NGT nicht mehr den Anforderungen des Annexes I entsprechen (Artikel 3(7) vs. Artikel 4(1))?

3. Werden Kat-1 NGT-Pflanzen der ersten Generation von der KOM als Teil des Genpools des Züchters für die Erzeugung von Kat-1 NGT-Pflanzen der zweiten Generation betrachtet?

4. Annex I (5): Welche gentechnischen Veränderungen sind in diesem Teil des Annex I mit *„any other targeted modification of any size*“ gemeint, insbesondere in Abgrenzung zur Cisgenese? Umschließt Annex I die Intragenese?

5. Annex I (3): Wie wird "*does not interrupt an endogenous gene*“ definiert? Umfasst ein Gen in diesem Zusammenhang nur die kodierende Sequenz oder sind auch andere vor- und nachgeschaltete Elemente wie Promotoren, Terminatoren, Cis-regulierende Elemente, Trans-regulierende Elemente, Introns usw. eingeschlossen?

6. Aufgrund des sehr allgemeinen Charakters von Annex I (3) ist diese Regelung geeignet, die Inaktivierung von Genen/Proteinen zu verhindern, die den Pflanzen bestimmte ungünstige Eigenschaften verleihen. Dies gilt z. B. für bestimmte Oberflächenproteine, von denen bekannt ist, dass sie als Eintrittspforte für bestimmte Krankheitserreger, entweder Pilze oder Bakterien, dienen. Wurde dies beim Entwurf berücksichtigt?

7. Im Vergleich zum Leak ist Herbizidtoleranz nicht als Ausschlusskriterium bezüglich der Einstufung in Kategorie 1 vorgesehen. Sind andere Ansätze vorgesehen, um mögliche Auswirkungen des Anbaus von herbizidtoleranten Pflanzen auf die Biodiversität zu verhindern oder zu begrenzen?

Verifikation

8. Inwieweit ist in dem vorliegenden Vorschlag vorgesehen, dass die Antragsteller*innen vollständige Sequenzinformationen der NGT-Pflanzen vorlegen, wenn sie deren Einstufung in Kategorie 1 oder Zulassung in Kategorie 2 beantragen?

9. Welche Handlungsmöglichkeiten haben nationale Behörden, wenn sie bei ihrer Prüfung den Eindruck gewinnen, dass im Einzelfall - unter Beachtung des Vorsorgeprinzips - eine vertiefte Betrachtung notwendig ist, die etwa auch mögliche aus den Sequenz-Veränderungen resultierende Eigenschaften berücksichtigt?

Koexistenz und Kennzeichnung

10. Über Artikel 24 werden die Mitgliedstaaten verpflichtet, bezogen auf Kat-2 NGT-Pflanzen Koexistenzregelungen zu treffen. Zu Koexistenzmaßnahmen für Kat-1 NGT- Pflanzen sind im Entwurf keine Aussagen zu finden.

    Welche Möglichkeit für Koexistenzmaßnahmen der Mitgliedstaaten hinsichtlich Kat-1 NGT-Pflanzen und gentechnikfreier, insbesondere auch ökologischer Landwirtschaft sieht die Kommission, wenn sie andererseits festlegt, dass nur Saatgut gekennzeichnet werden muss, keine Nachweis- oder Identifizierungsmöglichkeiten von Antragsteller*innen gefordert werden und „Opt-out“ ausgeschlossen wird?

11. Hat die Kommission im Rahmen ihrer Folgenabschätzung die wirtschaftlichen und sozioökonomischen Kosten einer Aufhebung der Koexistenzregeln für den ökologischen Landbau, für welchen ein Nutzungsverbot von Kat-1 NGT-Pflanzen vorgesehen ist, als auch für den konventionellen Landbau erfasst? Wie hoch sind diese und im welchem Verhältnis stehen sie im Vergleich zu den Kosten zur Aufrechterhaltung der Koexistenz über die ganze Wertschöpfungskette? Wurden dabei auch mögliche Auswirkungen auf das Ziel, bis 2030 einen Anteil von 25% Biolandbau zu erreichen, berücksichtigt?

12. Nach unserem Verständnis des vorliegenden Entwurfes wäre ein Hinweis zur Anwendung von NGT zwar im Gemeinsamen Sortenkatalog und eine Kennzeichnung auf der Verpackung verpflichtend e. Darüber hinaus besteht jedoch keine Pflicht zur Kennzeichnung auf Ebene der Saatgut-Verkäufer/Händler, also in deren Katalogen, auf deren Webseiten und ähnlichen. Ist das richtig?

13. Welche weiteren Maßnahmen sieht der Entwurf vor, Wahlfreiheit und Transparenz bei Kat-1 NGT-Produkten für alle zu ermöglichen?

Marktrelevanz

14. Ist der Kommission bekannt, wie viele NGT-Pflanzen, die sich in der Entwicklung befinden, erforscht werden oder bereits kommerziell verfügbar sind und angebaut werden, die in Anhang I formulierten Kriterien erfüllen oder erfüllt haben?

    Wie groß ist nach Meinung der Kommission der Anteil der Kat-1 NGT-Pflanzen im Vergleich zu den unter Kat-2 fallenden auf dem Markt zu erwartenden NGT-Pflanzen?

II. Kategorie 2 NGT (Kat-2 NGT)

15. Der Begriff „*risk profile*“ ist zentral für den Umfang der (Umwelt-)Risikoprüfung für Kat-2 NGT-Pflanzen. Welche unterschiedlichen Risikoprofile gibt es und wie sind sie definiert? Welche Anforderungen ergeben sich aus diesen Risikoprofilen nach Annex II Teil 2 und 3?

16. Wie sollen die Anforderungen an eine „hinreichende Begründung“ der Antragssteller*innen ausgestaltet sein, um zu begründen, dass es nicht möglich ist, eine Analysemethode bereitzustellen, mit der die NGT-Pflanze nachgewiesen, identifiziert und quantifiziert werden kann?

17. Eine Wiederzulassung muss i.d.R. nur noch einmal beantragt werden, danach wäre die Zulassung unbeschränkt gültig. Was ist in diesem Zusammenhang in Vorbemerkung (30) mit „Proportionalität“ gemeint?

18. Annex II: Werden „*putative traits*“, die nicht unter Teil 1 oder Teil 2 aufgeführt sind, ausgeschlossen oder einbezogen, in Bezug auf die Anreize?

19. Annex III: Was sind die Anforderungen um nachzuweisen, dass die veränderten Eigenschaften zur Nachhaltigkeit der Pflanze beitragen?

20. Warum kommen NGT-Pflanzen mit herbizidtoleranten Eigenschaften nicht für Anreize in diesem Rahmen in Frage - insbesondere im Vergleich zu Pflanzen mit herbizidtoleranten Eigenschaften, die durch konventionelle Pflanzenzüchtung oder klassische Mutagenese erzeugt wurden?

Monitoring

21. Was sind die Anforderungen für ein Monitoring bei experimentellen Freisetzungen? (Kap III, Art 13 c, v)

    Welche alternativen Maßnahmen sieht die KOM, um ein Monitoring der Umweltwirkungen bei experimentellen Freisetzungen aufzubauen, wenn für experimentelle Freisetzungen von Kat-2 NGT-Pflanzen keine Nachweismethode benötigt wird (Kap. III, Art 13 c im Vergleich zu Art 14 1 (I))?

    Wie können die Ergebnisse eines solchen Monitorings sicherstellen, dass negative, kumulative, langfristige und unerwartete Auswirkungen auf die menschliche Gesundheit und die Umwelt beobachtet werden?

22. Das Monitoring der Umweltwirkungen soll laut Freisetzungsrichtlinie auch die von der Risikobewertung nicht vorhergesehenen Umweltwirkungen aufdecken. Wie wird dies gewährleistet, wenn die Entscheidung, ob ein Monitoring bei Marktzulassung durchgeführt wird, von den Ergebnissen der Risikobewertung abhängt? (bezugnehmend auf Erwägungsgrund 29)

23. Die Kommission möchte indikatorenbasierte Untersuchungen etablieren, um u.a. Auswirkungen auf die Umwelt und die menschliche Gesundheit festzustellen. Gibt es schon Indikatoren, die geeignet sind, Auswirkungen von GVO auf die Umwelt und die menschliche Gesundheit festzustellen und gibt es Baseline-Werte? (Art 30 Abs. 1; 3 und 4). Gibt es eine wissenschaftliche Begründung für den Start des Monitorings nach frühestens 3 Jahren? (II Art 30 (1))

III. Weitere Fragen

24. Delegierte Rechtsakte dürfen sich nach Art. 290 Abs. 1 AEUV nur auf nicht wesentliche Vorschriften des betreffenden Gesetzgebungsaktes beziehen. Wie begründet die Kommission vor diesem Hintergrund die in Art. 5 Abs. 3 vorgesehene Befugnis zur Anpassung des Annex I (durch welchen eine Definition des Anwendungsbereichs des EU-Gentechnikrechts vorgenommen wird)?

25. In den FAQs der Kommission zum Vorschlag wird erwähnt, dass bezüglich der Auswirkungen der möglichen Patentierung von NGT-Zuchtmaterial bis 2026 ein Bericht vorgestellt werden soll. Was sind die Beweggründe für diese Entscheidung und Terminierung? Wie soll der Erarbeitungsprozess dieses Berichts aussehen und welche inhaltlichen Aspekte - unter Berücksichtigung welcher potentieller Folgemaßnahmen - sollen bewertet werden? Wie werden die Mitgliedstaaten hierbei beteiligt?

26. Wann ist mit der für ein gemeinsames Verständnis wichtigen noch fehlenden Definition zentraler Begriffe wie „*risk profile*“, „*sequence similarity*“, „*breeders gene pool*“, „*similar plants*“ zu rechnen?

DENMARK

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

To the Spanish Presidency

July 19, 2023

Via Delegates Portal

Initial and preliminary comments to the Commission's 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 thanks the Presidency for the opportunity to comment and ask questions on the impact assessment and the proposal. Below follow our preliminary views under a parliamentary scrutiny reservation.

Comments on the impact assessment and the proposal
The impact assessment is very thorough and covers all necessary aspects and areas, and we agree with the choice of preferred policy option.

We find the proposal both balanced and proportionate. We support that NGT plants that could also occur naturally or by conventional breeding (category 1 NGT plants), based on suitable and clear equivalence criteria, should be treated like conventional plants and exempted from the requirements of the GMO legislation.

We agree that food and feed products from category 1 plants should not be labelled to the final consumer/user with information about the employed breeding method. If labelling of category 1 plants was required, the current situation in Europe would not be improved due to the lack of control possibilities. Furthermore, the introduction of such labelling scheme could increase the prices of food and feed products in Europe, and could potentially be confusing or even misleading to the consumers/users because the same products could also have been produced by conventional breeding methods.

Other NGT plants (category 2 plants) should remain under the current GMO legislation with adapted risk assessment, requirements for traceability and labelling as GMOs, and the possibility of voluntary labelling to indicate the purpose of the modification.

We expect to provide further comments as regards the criteria of equivalence (Annex I) and the principles for risk assessment of category 2 NGT plants after consultations with our scientific advisors.

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Questions to the proposal

Legal clarity and simplification
Organic production is currently regulated through Regulation (EU) 2018/848. However, the ban on the use of category 1 NGT plants in organic production is not placed in Regulation (EU) 2018/848. Instead, this ban is placed in the NGT-proposal itself.

All regulation on organic production at EU-level is based upon the framework within the Regulation 2018/848, including the use of various techniques such as the ban on chemical solvents, techniques authorised for use in the processing of feed products, use of food and feed additives, flavourings and GMO. It would thus seem reasonable to have the rules on the use of NGTs in organic production placed within the same regulation.

Could the Commission explain/elaborate on why the material ban of NGT-plants in organic production is placed in the NGT-regulation and not in regulation 2018/848?

An alternative could in our view be to have an article in the NGT-proposal which amends regulation 2018/848 and introduce the ban there. We notice such an "amendment approach" is used in article 33 of the NGT-proposal, where Regulation (EU) 2017/625 is proposed amended. We also notice that the PRM-proposal, which was presented simultaneously with the NGT-proposal, makes amendments to Regulation 2018/848 using this approach. This approach would seem to correspond better with the objectives of the Better Regulation agenda.

We are aware that the NGT-proposal constitutes a *lex specialis* which in principle overrules Regulation 2018/848. However, despite this fact it should be possible to find a solution that will allow us to have the ban on the use of category 1 NGT-plants placed in Regulation 2018/848.

Specifying the ban on category 1 NGT plants in organic production through an amendment of Regulation 2018/848 would also make it simpler for organic farmers to navigate the rules regarding organic production as it would compile all existing rules on organic production in one regulation. Furthermore, this approach would ensure that any future discussions on revision of organic production and the use of GMOs will be held in the appropriate DG/forum in the Union.

Committees
We would welcome a clarification on how the Regulatory Committee under directive 2001/18 would be involved in the new NGT-regulation and in the adoption of implementing acts.

Background
Under the current GMO legislation, two Committees are involved: The PAFF Committee (section genetically modified food and feed) and the Regulatory

Committee under 2001/18, both of which could be relevant in relation to this proposal.

The proposal gives the Commission the power to adopt implementing acts in accordance with articles 27 and 28, whereas the Commission shall be assisted by the committee set up by article 58 of Regulation 178/2002 (the PAFF Committee). Currently, NGT plants (not for food or feed use) have to be approved in accordance with directive 2001/18/EF. According to article 18(1) of directive 2001/18/EF the Commission shall be assisted by the regulatory Committee under 2001/18/EF in case of objections raised and maintained by a CA or the Commission. However, the proposal states that in case of objections, the Commission shall be assisted by the PAFF committee - also for plants or plant products not intended for food or feed.

ANNEX VI

ESTONIA

Questions and comments on NBT proposal 19.07.23, Estonia

As of 19.07.23, we do not have the Government's positions yet. However, we do have scrutiny reservations and we would like justification on the following points and questions:

1) Why is there limit of 20 nucleotides for NGT1? (Random mutagenesis (e.g. chemical mutagenesis) generates thousands or tens of thousands mutations.)

2) Could the definition criteria for NGT1 be more clear? May 20 x 20 nucleotides be inserted and replaced? May any number of nucleotides be deleted and reversed? May a total of 20 modifications be made, including combinations, as mentioned in points 1–5 of the Annex 1?

3) What is the situation and the rules on the patenting of technology, patenting of biological material and plant variety protection with regard to NGTs?

4) What are the justifications for the reasons for which NGT1 are prohibited in organic farming? Given that NGT1 plants are not inherently different from conventional cultivars and the challenges and difficulties of growing a healthy plant and fight diseases, weeds and pests in inorganic conditions, will the organic sector not miss the opportunities and benefits provided by NGT and innovation? With the ban of NGT1 in the organic sector, will the introduction of NGT1 varieties not give a greater advantage to conventional growers while potentially reducing the share of the organic sector in crop production?

5) What are the reasons that random mutagenesis is outside the scope of the GMO legislation while targeted mutagenesis is under GMO? Could they not be treated equally?

6) What are the reasons that random mutagenesis is allowed in organic farming and a targeted mutagen is not?

7) Since NGT1 varieties could also occur naturally, have no foreign DNA and are not inherently different from conventional varieties, what are the justifications for labelling their propagating material?

8) Could a single term "new breeding techniques" not be used instead of "new genomic techniques"? What are the justifications of using "new genomic techniques"?

GREECE

1. We consider that for the NGT plants of category 1, there should be information from the breeder regarding the detection method of the genetic modification inserted in the plants. The breeder conducts tests in order to verify that the modification is successful. Thus the breeder shall notify to the competent authorities of the member states not only his willing for the deliberate release and placing on the market of a NGT plant but also the detection method of the genetic modification of that NGT plant.
2. By this proposal, Member States cannot opt out of cultivation of category 2 NGT plants on their territory, so there is not freedom of choice, in case that in a member state there is an agreement of not cultivating the category 2 NGT plants.
3. There is a risk of creating monopoly/oligopoly situations, as the new characters created with the new genomic techniques (NGT) will be protected by patents, in accordance with the provisions of Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998, for the legal protection of biotechnological inventions. There will likely be a dependence of other breeders, seed and nursery companies and farmers, on the breeders who have patented these characters. It is noted that plant varieties are not protected by a patent, in accordance with the provisions of article 4 of the aforementioned Directive, but only by a plant variety right, in accordance with the provisions of article 1 of Regulation (EC) no. 2100/94 of the Council of 27 July 1994 on Community plant variety rights.

FINLAND

Preliminary FI comments and questions, 19.07.2023

**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**

General comments:

We thank the Commission for the NGT-proposal and for the accompanied impact assessment.

Since the drafting and adopting the Directive 2001/18/EC, there has been substantial progress in the development of new breeding techniques. The Council decision (2019/1904), prepared during the Finnish presidency, recognized the need to clarify and update the legal framework for the novel genomic techniques for the plant breeding.

We appreciate that based on the study requested by the Council decision, the Commission has submitted the NGT proposal, which intends to clarify the situation and solve the issues that have arisen because of the present EU GMO legislation was not seen fit for purpose for some NGT applications. It is important that the proposed solutions are scientifically justified, time-resistant and balanced.

Finland will work constructively on the proposal with the presidency and the other member states. We support the overall objectives of the Commission proposal. Please find below some preliminary comments and questions. Due to a short deadline for commenting, we retain the possibility for giving further comments in the later stages.

Page 4: Consistency with existing policy provisions in the policy area:

Clarification is needed in the first sentence: *"NGT plants fall under the scope of the current Union legislation on GMOs (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC)."* as NGT plants do not currently fall under the scope of Directive 2009/41/EC, only plant cell cultures.

Page 19: Point 11:

The preamble text states that *"…where there are no specific rules in this Regulation, NGT plants and products (including food and feed) obtained from them should remain subject to the requirements of the Union GMO legislation and the rules on GMOs in sectoral legislation,…"*.Would the Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms apply to both Category 1 and Category 2 NGT plants?

Page 26: Article 2:

It should be defined that the Regulation applies to the deliberate release unless the scope is also contained use. If so, inclusion of contained use should be clearly expressed and justified in the Regulation.

Page 27: Article 3:

(3) Definition of genetically modified organism (GMO). Directive 2001/18/EC excludes certain techniques and organisms developed by these techniques from the Directive, not from the definition of a GMO (see article 3 and annex I B).

(5) Definition of cisgenesis does not follow the EFSA definition. Also, cisgenesis and intragenesis could both be presented in the definitions, instead of footnote 4.

Page 29: Article 6: Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market

While the proposed verification procedure may work smoothly when the verification request for the MS competent authority (CA) contains all the necessary data at the outset, the CA agrees on it and no other MS opposes the Category 1 status for the NGT plant, problems may arise under other circumstances. Clarification is needed for e.g. the following situations:

1. The applicant is an academic research group or SME with limited resources and/or timeframe for the field trial (because of a certain grant/financing period, timing of the annual plant pest infection under study, or the short growing season in the MS). Instead of set timelines, some points of Article 6 set the timeframe for a certain procedure step as "*without undue delay*", which can be interpreted in different ways. The applicant needs to know beforehand how long the verification procedure can actually take in a worst-case scenario, i.e. when another MS comments the verification request, the Commission subsequently consults EFSA and prepares a draft decision, and a decision is made under the comitology procedure under Article 28(2).
2. If the decision in Article 6(8) or 6(10) is negative as to the Category 1 status of the NGT plant, the applicant has to send the CA a Part B notification under Article 6 of Directive 2001/18/EC. If the applicant needs to speed up the process to be able to perform the field trial, could the verification process under Article 6 and the Part B notification be handled by the CA in parallel, or should the administrative procedures be consecutive?
3. If (to save time) the applicant chooses to send a Part B notification of the intended NGT plant field trial instead of a verification request for the Category 1 status, could the applicant send a verification request afterwards? If so, and if the request would confirm the Category 1 status of the NGT plant, would the Part B Notification and information on the field trial be removed from the GMO registers afterwards?

In Northern countries, timeframe issues are crucial in the field trials, as the growing season is short. A long administrative procedure means that the field trial would have to be postponed to at least the following year. Moreover, if the outcome of the verification procedure under Article 6 would be negative, the applicant would have to submit a GMO field trial notification in accordance with Part B of Directive 2001/18/EC, which will take at least 3-4 months for the CA to process. From the point of view of both the applicant and the CA, the proposed verification procedure may not actually reduce administrative burden in all situations, and if its outcome is uncertain, it may not encourage SMEs or academic research groups to carry out their field trials in the EU.

Annex I:

Clarity of the criteria is fundamental here, in order for the verification procedure under Article 6 to work as intended. “Sequence similarity” should be defined for legal certainty, and a set percentage of sequence identity may be needed in the definition.

Clarification is needed on whether the sequence similarity criteria would be applied also to related, but non-functional pseudogenes in the plant genomes.

Clarification is needed for a situation where NGT plants may be categorised differently according to the ploidy level of their genomes. This could lead to a situation where a NGT plant with a certain trait would fulfill the criteria for Category I NGT plant if its genome is diploid, while a plant with the same trait would be considered a Category 2 NGT plant if its genome has a higher number of gene copies (polyploidy), such as wheat (hexaploid) and strawberry (octoploid).

A study comparing the criteria in Annex 1 with those in third countries regulating NGTs would be useful.

Point (1). Further scientific justification is needed for the number (20 nucleotides). Can these nucleotides derive from outside the breeder’ gene pool i.e. any organism, not only plants? If yes, this could lead to a situation where 400 nucleotides in a category 1 NGT plant could derive from outside the breeders’ gene pool.

Point (3). Does the text “does not interrupt an endogenous gene” mean that intragenic plants belong to category 2 NGT plants? If yes, this should be clearly stated to clarify this particular criterion.

Please clarify the status of a) category 1 NGT plants and b) plants bred through conventional methods, when the number of modified nucleotides exceeds the number of nucleotides (20) mentioned in point (1).

Annex II:

Part 1, paragraph 2 (The environmental risk assessment of category 2 NGT plants and the risk assessment of category 2 NGT food and NGT feed shall consist of the following). The terminology used here is not from Directive 2001/18/EC but from Directive (EU) 2018/350 that amends Directive 2001/18/EC as regards the environmental risk assessment of genetically modified organisms. Reference to Directive (EU) 2018/350 should be included here and in other parts of the regulation where risk assessment is discussed.

Impact assessment:

Resources needed for border controls in different policy options are not covered.
Administrative costs for the different outcomes of the verification procedure under Article 6 were not evaluated.

FRANCE

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

Paris, le 19 juillet 2023

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

Objet : Questions posées par la délégation française sur le projet de règlement relatif aux nouvelles techniques génomiques, lors la réunion du groupe de travail sur les ressources génétiques et l'innovation en agriculture du 10 juillet 2023

Lors de la réunion du groupe de travail sur les ressources génétiques et l'innovation en agriculture du 10 juillet 2023, la délégation française a posé les questions suivantes, sans préjudice de la future position de la France sur le projet de règlement et d'un examen plus approfondi du projet.

- Critères d'équivalence pour les plantes NGT de catégorie 1 - Sur quelle base scientifique les critères ont-ils été établis (le seuil de 20 modifications génétiques et les 5 types de modification permises) ? Pour quelles raisons la liste de critères est-elle limitée à des considérations génétiques, sans prendre en compte la fonctionnalité des traits introduits ?
- Intragenèse - Pourquoi aucune définition de l'intragenèse n'est-elle prévue dans le projet de texte ?
- Tolérance aux herbicides - Dans la version qui a circulé préalablement à la présentation officielle du projet de règlement, la tolérance aux herbicides était exclue de la catégorie 1. Quelles sont les raisons de la suppression de cette disposition dans la proposition finale ? Quelles mesures alternatives sont-elles envisagées sur cette question, afin de s'assurer que les variétés obtenues par NGT seront cohérentes avec les objectifs de durabilité ?
- Contrôles - Pour la catégorie 2, des dérogations sont prévues pour la méthode de détection, dans le cas où il ne serait pas possible de fournir une méthode de détection, d'identification ou de quantification. Etant donné que les obligations relatives à la traçabilité et à l'étiquetage sont maintenues pour cette catégorie, comment les contrôles seront-ils réalisés et comment leur sécurité juridique sera-t-elle assurée dans cette situation ?
- Articulation entre les propositions NGT et PRM (matériel de reproduction des plantes) - Des dispositions relatives aux NGT figurent dans le projet de règlement PRM, pour l'inscription des variétés NGT au catalogue (déclaration du recours à une NGT). Comment les calendriers des deux propositions vont-ils s'articuler ?
- Propriété intellectuelle - Les enjeux relatifs aux brevets sont mentionnés dans l'étude d'impact (risque de frein à l'accès des PME aux techniques, possible prolifération de brevets sur les plantes), toutefois aucune disposition n'est prévue dans la proposition sur cette question. Quelles actions sont-elles envisagées pour anticiper et éviter les risques identifiés ?

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- Subsidiarité - L'article 8 du projet qui avait circulé préalablement signifiait que les États membres ne pouvaient interdire ni limiter la diffusion ou la mise sur le marché des plantes NGT de catégorie 1 et des produits connexes. Quelle sont les raisons de sa suppression dans la version officielle du texte transmise le 5 juillet ?
- Entrée en application - Dans la version qui avait circulée préalablement à la présentation officielle du projet de règlement, l'entrée en application de certaines parties du texte n'était prévue qu'après l'adoption des actes d'exécution nécessaires à leur bonne mise en œuvre. La version présentée le 5 juillet prévoit désormais une entrée en application 24 mois après l'entrée en vigueur du texte. Quelles sont les raisons de ce changement ? Cette nouvelle formulation est-elle à même d'assurer que le texte n'entre pas en application tant que les actes d'exécution nécessaires n'auront pas été adoptés ?

Les autorités françaises remercient la Commission pour ses réponses et se tiennent à la disposition de la Présidence pour toute précision qui lui serait utile.

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COURTESY TRANSLATION

NOTE OF THE FRENCH AUTHORITIES

Subject : questions asked by the French delegation on the draft regulation on new genomic techniques during the meeting of the Working Party on genetic resources and innovation in agriculture on July 10, 2023

During the meeting of the Working Party on genetic resources and innovation in agriculture on July 10, 2023, the French delegation asked the following questions, without prejudice to France's future position on the draft regulation and a further examination of the project:

- Equivalence criteria for category 1 NGT plants - On what scientific basis were the criteria established (the threshold of 20 genetic modifications and the 5 types of modification permitted)? Why is the list of criteria limited to genetic considerations, without taking into account the functionality of the introduced traits?

- Intragenesis - Why is no definition of intragenesis provided for in the draft text?

- Tolerance to herbicides - In the version that had been circulated prior to the official presentation of the draft regulation, tolerance to herbicides was excluded from category 1. What are the reasons for the deletion of this provision in the final proposal? What alternative measures are envisaged on this issue, in order to ensure that the varieties obtained by NGT will be consistent with sustainability objectives?

- Controls - For category 2, exemptions are provided for the method of detection, in the event that it is not possible to provide a method of detection, identification or quantification. Given that the obligations relating to traceability and labelling are maintained for this category, how will the controls be carried out and how will their legal certainty be ensured in this situation?

- Relationship between the NGT and PRM (plant reproductive material) proposals - Provisions relating to NGT appear in the draft PRM regulation, for the registration of NGT varieties in the catalogue (declaration of the use of an NGT). How will the timetables of the two proposals fit together?

- Intellectual property - Issues relating to patents are mentioned in the impact assessment (risk of hampering SMEs' access to techniques, possible proliferation of patents on plants), however there is no provision on that question in the proposal. What actions are planned to anticipate and avoid the identified risks?

- Subsidiarity - Article 8 of the previously circulated draft meant that Member States could not prohibit or limit the distribution or placing on the market of category 1 NGT plants and related products. What are the reasons for its deletion in the official version of the text transmitted on July 5?

- Entry into application - In the version that had been circulated prior to the official presentation of the draft regulation, the entry into application of certain parts of the text was only provided for after the adoption of the implementing acts necessary for its proper implementation. The version presented on July 5 now provides for entry into application 24 months after the entry into force of the text. What are the reasons for this change? Is this new wording able to ensure that the text does not enter into application until the necessary implementing acts have been adopted?

The French authorities would like to thank the Commission for its replies and remain at the disposal of the Presidency for any clarification that may be useful to it.

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LUXEMBOURG

Comments and questions from Luxembourg

4. Cat 1 NGT plants are considered GM but are outside of the scope of GMO legislation. Therefore, the labelling of GM content above the threshold of 0.9% in the final product is not applicable for cat 1 plants. In that case, how can be avoided that cat 1 plants enter organic production? Enforcement will be impossible. In the same logic, the 0.9% threshold applies to cat 2 plants as they fall under the provisions of GM legislation. How does COM see this?
5. The scope of this initiative are plants produced by targeted mutagenesis and cisgenesis (including intragenesis) and their food and feed. This is mentioned in several recitals but does not appear in the articles of the proposal. Intragenesis is excluded form criteria of equivalence because of wording of Annex 1. Only a definition of cisgenesis is given in Art 3 (5). Does this definition include intragenesis as well? Why making a distinction in the recitals? We find this confusing.
6. This proposal sets new requirements in specifically for NGT plants obtained by targeted mutagenesis and cisgenesis. Article 2 states that the regulation will apply to:
7. NGT plants;
8. food containing, consisting of or produced **from** NGT plants, or containing ingredients produced **from** NGT plants;
9. feed containing, consisting or produced **from** NGT plants;
10. products, other than food and feed, containing or consisting of NGT plants.

How about products produced **by** NGT plants. For instance, NGT plans with a modified nutritional content accumulating vitamins to be sold as food supplements? These vitamins would be extracted from the plant prior placing on the market. In order to avoid the same discussion as for MGM is this "produced by" covered by the proposal's definition "produced from a NGT plant" (Art 3 (11))?

- The verification procedure defines a deadline of 30 working days from the date of receipt of a verification request. Especially small MS might lack the resources. Did COM take this into account? How about collaboration between MS, will this be permitted by the regulation? What if the deadline of 30 working days is not respected?

The NETHERLANDS

Technical questions for the European Commission:

Question 1

The Commission proposes two categories of NGT-plants, namely category I NGT- and category II NGT plants. The proposal also contains equivalent criteria to assess whether NGT plants are equivalent to plants created by conventional breeding techniques. Category I NGT plants and their products are exempt from the current GMO regulation when deliberately introduced in the environment and placed on the market. However, breeders might further utilize their existing category I NGT plants to further develop new plants either using conventional genetic modifying techniques or category I NGT techniques. **Do progenies of category I NGT plants with more than 20 modifications still classify as category 1 NGT?** Hence the possibilities exist that the progenies contain more than 20 modifications (sum of the modifications from parental category I NGT plant and the newly introduced modifications either using NGTs or conventional breeding methods). Do they meet the criterium of no more than 20 genetic modifications of Annex I?

Question 2

The Commission proposes that this Regulation should be limited to NGT applications in plants, including organisms in the taxonomic groups Archaeplastida or Phaeophyceae. In addition to terrestrial plants the Archaeplastida and Phaeophyceae also include aquatic plants such as red-, green-, and brown algae. The current GMO directive focuses on Spermatophytea (Gemnospermae and Angiospermae). Why are these different taxonomic groups chosen? Is there sufficient knowledge available about aquatic species in particular to estimate potential risks in advance?

Question 3

Could the Commission elaborate more on the reference in Art 5.2 to Regulation 2018/848 Art 5f and Art 11 to exclude the use of NGT-1 products from organic agriculture? What does this exclusion mean, could you elaborate as how this should be interpreted for organic operators? For example, is this to be interpreted as a best efforts obligation for organic operators and if they can show that they have taken enough effort to minimize risks it is enough? Or will this exclusion mean that there should never be any NGT content present and thus the exclusion will mean a zero tolerance policy?

Question 4

What is the scientific basis for random cisgenesis specifically to be excluded from the Criteria of equivalence, Annex 1 (3)? It is our understanding that similar processes could also occur using conventional breeding techniques or in nature, which should mean that it would fit the criteria of equivalence.

Question 5

Could you elaborate more whether intragenesis is part of category 1 NGT, while the EFSA report[1] stated additional risks for intragenesis compared to conventional breeding techniques?

[1] Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques - - 2021 - EFSA Journal - Wiley Online Library

Question 6

The Commission proposes incentives for the application of NGT-2 products by SMEs in article 22. Does the European Commission want to avoid the application for these incentives by subsidiaries of multinational plant breeders, or are they also eligible for these incentives? We foresee that this could be an easy loophole in the application procedure for large multinational companies.

Additionally could the Commission elaborate what the waiving of the financial contribution to NRLs and EURLs for SMEs, will mean for the funding of the NRLs and EURLs.

Question 7

As the Commission already remarked, the PRM/FRM proposal and the NGT proposal are very much intertwined, does the Commission foresee problems if either the NGT- or PRM/FRM legislation frameworks are delayed in their implementation?

ROMANIA

First comments on the Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed of ROMANIA

We would like to mention that this is only a draft reaction of the research area, based on the input sent by Academy of Agricultural and Forestry Sciences. We are still looking forward to consult the other factors involved in the food chain, including the farmer's sector.

1. Romania supports the proposed *purpose* of the amendments to EU Regulation 2017/625, to maintain a high level of health and environmental protection and the evolution towards increasing the sustainability objectives of the agri-food and feed chains. Romania would like to underline the fact that given the creation of varieties of fundamentally new plants with characteristics obtained by targeted mutagenesis, cisgenesis and/or any variant of intragenesis (the use of endogenous genetic information), it is required that the evaluation of the changes be carried out at the MS level, from two different approaches: **a)** from the ***A****gricultural* ***V****alue (**AV**) and the* ***T****echnological* ***V****alue(**TV**)* and **b)** of the ***D****istinctness,* ***S****tability and* ***U****niformity (**DSU**)*;

2. For new varietal creations, the assessment of AV&TV and DSU should be carried out in accordance with the legislation in force at community and national levels, **by the existing specialized national authorities in the monitoring and surveillance system of the market of varieties and seeds**. Thus, the especially created varieties declared as tolerant to the incidence of environmental factors (climatic and biological), should be tested in the environmental conditions (biotic and abiotic) that imposed/generated the need to be created/improved.

3. A new provision should be introduced in the current regulation regarding New Breeding Techniques/New Genomic Techniques, previously tested AV&TV and DSU. The nationally approved varieties should benefit by the same commercial community facilities in terms of the seed market, respectively of the principle of the free movement of values and goods. They should be registered in the Common Catalogue, ***with the specification that varieties tolerant to diseases/pests/abiotic***

stress factors can be re-evaluated by the specialized authorities of the MS from the market on which they shall be sold/ used, in order to highlight the new character/s ***in relation to the incidence of races/local forms of the pathogen/pest or of the abiotic stress specific to the new culture areas*** (for example: tolerance to saline solutions of the soil, heat, the spectrum and light intensity, etc.)

4. It is necessary to be allocated the financial support by the EU to the MS for the establishment of the European accredited specialized official public laboratories, for specific NGT testing, which will operate the assessment based on specific procedures/methods, identical/unique to all MS authorities.

5. We are in favor of the establishment of two categories of NGTs, with the remark that they must be clearly defined, without confusion and/or overlapping so that, in the definition of the category, there are no doubts due to subjective interpretations or to define one of the categories as an exception to the other.

6. ***We express our reserve regarding the characterization of NGT 1 organisms through an ad-hoc numerical restriction (20 genetic modifications)*** and the ambiguity of the phrase ("*with the targeted site that can be predicted by bioinformatic tools*"). This phrase induces the idea that the tool/method used to determine the modification of a specific *locus* ("*determined position occupied by a gene or its alleles in the structure of the chromosome*") is somewhat random. Thus, we propose using the established term *"locus/loci"* instead of the term *"targeted site"*. We also propose replacing the term "bioinformatics tool" with an investigation method unanimously accepted by the MS, depending on the scientific and applied evolution of the infrastructure/apparatus, research and investigation methods.

7. ***We express our reserve about fixing/limiting the insertion to twenty nucleotides***. If we consider the fact that a codon is the unit of genetic information made up of three nitrogenous bases/three nucleotides, it follows that an amino acid (structural unit in protein synthesis) is coded by one or more codons/nucleotides. Thus, it follows that the insertion sequence must be represented by at least one codon represented by three nitrogenous bases. The corresponding amino acid/s is/are represented by informational structures with variable sizes, consisting of multiples of three, to which are added at least two nonsense codons (codons that start/end the informational sequence). ***We propose that the NGT insertion be defined by a multiple of three in order to include the nonsense codons from which information transcription begins/ends.***

8. We believe that ***the disruption of an endogenous gene*** (see Annex 1, paragraph 3), by introducing one or more nonsense codons could be accepted as NGT, if it is done for genes that encode the information of unwanted organic compounds (e.g. zein in corn, antinutrients in soy, etc.).

9. We believe that it is necessary to define the phrase ***"the breeders' gene pool"*** in order to eliminate ambiguities due to the different interpretation, in the various official European languages, of the notion *"the breeder"*, so that it appears that the phrase *"gene pool"* refers to the genetic background specific, varietal, endogenous.

10. We believe that ***the general principles relating to Annex II – NGT 2 risk assessment***, as well as the term ***"complex changes"*** - in the case of NGT 2, should be defined as in the previous case (NGT 1). We propose a conceptual revision of Annex II in order to maintain only those evaluation criteria that address the influence of NGT information molecule/genome rearrangement based on the target objective. The rest of the information is included in the category of those assumed by the applicant for testing and approval of the new variety, with the possibility of the official testing and registration authority to make extensive evaluations in case of suspicion.

11. Re-defining of the phrase ***"similar plants"*** (Annex II, part 1, point c), ***specifying that they should at least belong to the same botanical family***. We emphasize that in the living world there are no similarities ("similarity of biological, morphological, biochemical characters, etc."), except between different species (the case of NGT is excluded), but which have undergone a convergent evolution. We propose the reformulation of the factor defined in point c, in the sense of ***eliminating "similar plant species"*** and ***replacing the phrase "previous experience"*** with ***"other agricultural plant species of the same botanical family"***.

12. We believe that ***the assessment of environmental risks (Annex II, Part 1 point a-c paragraph - Assessment of environmental risks) for NGT 2 plants must be carried out at the level of the MS that wish to introduce them into cultivation***. The geostationary and agro-environmental peculiarities of the location where exploitation will take place can significantly influence the behavior of a variety, including its ***invasive capacity***. These indices may become non-existent, in the conditions of the varieties obtained by classical methods of selection and improvement. Environmental risk assessment must be mentioned as an attribute of the national authority for testing and homologation of agricultural plant varieties.

13. We believe that (Annex II, Part 1), should be restructured from the point of view of the ambiguity of paragraph and subparagraph numbering. In the current numbering of the subparagraphs about the factors to be considered, this is relatively identical to the notation of the subparagraphs defining the risk assessment.

SLOVENIA

Regulation on new genomic techniques (NGT) - SI comments:

Slovenia has not yet taken an official position on the legislative proposal and expresses a scrutiny and linguistic reservation.

Slovenia stresses that the possible long-term negative impacts of plants or products derived from new genomic techniques need to be carefully considered and taken into account when regulating this issue. It is essential that the legislative framework is based on a scientific approach, taking into account the precautionary principle.

We would like to raise the following questions on the legislative proposal:

- How will the traceability of products derived from new genomic techniques be ensured, including detection and identification, which is essential for identifying potential adverse impacts on species, ecosystems and biodiversity?
- What tools will be used to ensure that conventional and organic farming is maintained, in particular in terms of coexistence with the production of NGT plants?
- Why does the Commission foresee, in accordance with recital 36, that a specific measure for herbicide-tolerant NGT plants will be taken horizontally in the proposal for a Regulation on the production and marketing of plant reproductive material (PRM)? According to Article 2, the PRM legislative proposal only regulates the production with a view to marketing of plant propagating material and not plant production in general.
- When will the language versions of the legislative proposal be available?