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

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

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

Republika Hrvatska ponovno ističe svoje stajalište da Prijedlog uredbe Europskog parlamenta i Vijeća o biljkama dobivenima određenim novim genomskim tehnikama te o hrani i hrani za životinje od njih i o izmjeni Uredbe (EU) 2017/625, treba biti primjereno razmotren s tri glavna aspekta: poljoprivrednog, okolišnog i zdravstvenog. Također je potrebno uzeti u obzir javno mnijenje te osigurati odgovarajuću zaštitu potrošača i njihovo pravo na „slobodu izbora”.

Republika Hrvatska podržava postupak donošenja odluka koji se temelji na znanstvenim spoznajama i procjeni mogućih koristi. Istodobno, treba očuvati visoku razinu zaštite zdravlja ljudi, zdravlja životinja i okoliša, uz osiguravanje održive poljoprivrede i proizvodnje hrane.

Republika Hrvatska želi istaknuti sljedeće temeljne zabrinutosti koje ima i koje je iznosila tijekom pregovora o tekstu:

1. U skladu s načelom supsidijarnosti, državama članicama treba omogućiti da odluče o ograničenju ili zabrani uzgoja NGT biljaka na svojem teritoriju.
2. Načelo predostrožnosti, radi osiguravanja zaštite potrošača, označavanja i sljedivosti svih NGT proizvoda, nije na odgovarajući način zajamčeno.
3. Nisu utvrđene mjere za sprječavanje mogućeg onečišćenja okoliša NGT biljkama niti mehanizmi naknade štete u slučaju nastanka štete, osobito u odnosu na ekološku proizvodnju.

Stoga Republika Hrvatska ne može podržati usvajanje Uredbe o biljkama dobivenima određenim novim genomskim tehnikama te o hrani i hrani za životinje od njih, budući da navedeni elementi nisu na zadovoljavajući način riješeni.

Courtesy translation in English

The Republic of Croatia reiterates its position that the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 should be adequately considered from three main aspects: agricultural, environmental and health. It is also necessary to consider public opinion and to ensure adequate consumer protection and their right of “freedom to choose”.

The Republic of Croatia supports a decision-making process based on scientific knowledge and the assessment of potential benefits. At the same time, a high level of protection of human health, animal health and the environment should be preserved, while ensuring sustainable agriculture and food production.

The Republic of Croatia would like to highlight the following fundamental concerns it has and which it had been raising in the course of the negotiations on the text:

1. According to the subsidiarity principle, Member States should have the possibility to decide on the limitation or ban of NGT plants to be cultivated on their territory.
2. The precautionary principle, in order to ensure consumer protection, labelling and the traceability of all NGT products, is not adequately ensured.
3. The measures to prevent possible NGT plant contamination of the environment and to define compensation mechanism in the case of damage, especially in relation to organic production, are not established.

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

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

Magyarország fontosnak tartja az innovációt a mezőgazdaságban, ideértve új technológiák alkalmazását is, amelyek alkalmasak az olyan kulcsfontosságú kihívások kezelésére, mint az éghajlatváltozás, az élelmezésbiztonság és a fenntarthatóság. Az új génkezelési eljárások kapcsán elismerjük egy egyértelmű, átlátható és szilárd jogi keret létrehozásának szükségességét, ami biztosítja, hogy az ezen új eljárásokkal létrehozott szervezetek felhasználása ne jelentsen kockázatot a környezetre, az emberi és állati egészségre, illetve megfelelően figyelembe vegye mind a fogyasztók, mind a termelők érdekeit.

A tervezet vitája során az elmúlt három évben Magyarország azon az állásponton volt, hogy a tervezet koncepcionálisan hibás, hiszen az NGT1 és NGT2 kategóriába tartozó növények elkülönítése kapcsán nem a növény újonnan létrehozott tulajdonságait és/vagy azok lehetséges kockázatait veszi figyelembe, hanem kizárólag molekuláris alapon, a módosítások típusán, mértékén és számán alapuló megkülönböztetést alkalmaz. Magyarország mindvégig jelezte a tervezettel kapcsolatos aggályait és következetesen kérte az alábbi kulcsfontosságú elemek beépítését a szabályozási javaslatba:

- Az elővigyázatosság elvének figyelembe vétele, és esetről esetre történő megközelítés alkalmazása, ami biztosítja, hogy minden NGT-növényt a forgalomba kerülés előtt tudományos kockázatértékelésnek vessenek alá;
- Az összes NGT termék kötelező jelölése a nyomonkövethetőség biztosítása és a fogyasztók tájékozott választáshoz való jogának garantálása érdekében;
- Magyarország nemzetközi szerződésben vállalt kötelezettségeinek való megfelelés biztosítása;
- A szubszidiaritás elvének figyelembe vétele, a tagállami önrendelkezés biztosítása minden NGT növény esetében;

Mivel a tervezet végleges szövege nem ad megfelelő válaszokat az általunk felvetett aggályokra Magyarország nem tudja támogatni annak elfogadását.

Courtesy translation in English

Hungary recognises the importance of innovation in agriculture, including the use of new technologies that can address key challenges such as climate change, food security and sustainability. In the context of new genomic techniques, we recognise the need for establishing a clear, transparent and robust legal framework to ensure that the use of organisms created by these new processes does not pose a risk to the environment, human and animal health and takes due account of the interests of both consumers and producers.

During the negotiations on the draft, over the past three years, Hungary maintained the position that the draft is conceptually flawed, since, with regard to the distinction between NGT category 1 and 2 plants, it does not take into account the newly created characteristics of the plant and/or their potential risks, but applies a distinction based solely on molecular criteria, and applies a distinction based on the type, extent, and number of modifications. Hungary has always expressed its concerns about the draft and has consistently requested the inclusion of the following key elements in the regulatory proposal:

- taking into account the precautionary principle and apply a case-by-case approach to ensure that all NGT plants are subject to a scientific risk assessment before being placed on the market;
- mandatory marking of all NGT products to ensure traceability and guarantee consumers' right to an informed choice;
- ensuring compliance with Hungary's international obligations;
- taking into account the principle of subsidiarity and providing the possibility for an opt-out by Member States for all NGT plants;

As the final text of the draft does not adequately addresses our concerns, Hungary cannot support its adoption.

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

Österreich erkennt grundsätzlich die möglichen Potenziale der neuen genomischen Techniken (NGT) an, jedoch sind diese auch mit möglichen Risiken behaftet.

Positiv bewertet Österreich, dass bei NGT-Pflanzen der Kategorie 2 ein Opt-out vom Anbau weiterhin möglich ist. Demgegenüber werden jedoch zentrale, von Österreich wiederholt vorgebrachte Bedenken im finalen Text weiterhin nicht ausgeräumt. Nachfolgend werden diese Bedenken dargelegt:

- Aus österreichischer Sicht widerspricht der Verzicht auf eine Risikobewertung von NGT-Pflanzen der Kategorie 1 und deren Produkten dem Vorsorgeprinzip sowie dem Cartagena-Protokoll.
- Darüber hinaus ist Österreich der Auffassung, dass Konsumentinnen und Konsumenten ein Recht auf Information und Wahlfreiheit haben. Das Fehlen einer Kennzeichnungspflicht für Produkte von NGT-Pflanzen der Kategorie 1 (mit Ausnahme von Pflanzenvermehrungsmaterial) schränkt diese Wahlfreiheit erheblich ein und wird daher als nicht vertretbar angesehen.
- Das vorgesehene Verbot der Verwendung von NGT-Pflanzen und deren Produkten in der biologischen Landwirtschaft wird von Österreich ausdrücklich begrüßt. Allerdings stellt sich die Frage, wie dies ohne Kennzeichnung der Produkte von NGT-Pflanzen der Kategorie 1, inklusive Futtermittel, ohne massiven Mehrkostenaufwand für die Landwirtschaft bewerkstelligt werden soll.
- Die Möglichkeit, dass NGT-Pflanzen patentiert werden können, lässt befürchten, dass es zu nachteiligen Auswirkungen auf kleine und mittlere Züchtungsunternehmen kommen könnte und diese vom Markt verdrängt werden. Die im finalen Text vorgesehenen Transparenzbestimmungen in Bezug auf Patente beseitigen aus österreichischer Sicht weder die grundlegenden Bedenken in dieser Frage noch schaffen sie Rechtssicherheit.
- Österreich betrachtet die Äquivalenzkriterien nach Anhang I als nicht wissenschaftlich fundiert. Trotz wiederholt geäußerter Bedenken wurde bislang keine fundierte wissenschaftliche Begründung dafür gegeben, warum diese Kriterien, einer konventionellen Züchtung entsprechen sollten. Österreich möchte außerdem darauf hinweisen, dass Anhang I hinsichtlich der Äquivalenzkriterien wesentlich vom Verhandlungsmandat des Rates abweicht. Dies betrifft insbesondere die Ausnahme von genetischen Veränderungen in Intronen und regulierenden Sequenzen von der festgelegten Obergrenze. Aus österreichischer Sicht hätte dies vor der finalen Abstimmung über den Text weitere Diskussionen erfordert.

Vor diesem Hintergrund kann Österreich der Annahme der Verordnung nicht zustimmen.

Courtesy translation in English

Austria recognizes the possible potential of new genomic techniques (NGT), however, they are also associated with possible risks.

Austria welcomes that for category 2 NGT plants, an opt-out from cultivation remains possible. Nevertheless, key concerns repeatedly raised by Austria have not been addressed in the final text. These concerns are outlined below:

- From Austria's perspective, the absence of a risk assessment for category 1 NGT plants and their products contradicts the precautionary principle as well as the Cartagena Protocol.
- Furthermore, Austria considers that consumers have a right to information and freedom of choice. The absence of a labeling requirement for products from category 1 NGT plants (with the exception of plant propagating material) significantly limits this freedom of choice and is therefore considered unacceptable.
- Austria expressly welcomes the proposed ban on the use of NGT plants and their products in organic farming. However, questions arise as to how this can be implemented without the labeling of products from category 1 NGT plants, including feed, without incurring substantial additional costs for agriculture.
- The possibility that NGT plants can be patented raises concerns that this could have a negative impact on small and medium-sized breeding companies, potentially forcing them out of the market. From Austria's perspective, the transparency provisions regarding patents included in the final text neither address the fundamental concerns on this issue nor provide legal certainty.
- Austria considers the equivalence criteria set out in Annex I to lack a sound scientific basis. Despite repeatedly expressed concerns, no sound scientific justification has yet been provided as to why these criteria should be equivalent to conventional breeding. Austria would also like to point out that Annex I deviates significantly from the Council's negotiating mandate with regard to the equivalence criteria. This concerns in particular the exemption of genetic modifications in introns and regulatory sequences from the established upper limit. From Austria's perspective, this would have required further discussion prior to the final vote on the text.

Against this background, Austria cannot agree to the adoption of the Regulation.

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

Slovenija meni, da dogovor o predlogu uredbe o rastlinah, pridobljenih z nekaterimi novimi genomskimi tehnikami, ter hrani in krmi iz njih ne obravnava ustrezno številnih ključnih vprašanj, zlasti tistih, ki se nanašajo na oceno tveganja, označevanje, sledljivost, razpoložljivost analitskih metod in avtonomijo držav članic pri odločanju ter pogoje pridelave.

Slovenija poudarja, da trenutno pomanjkanje ustreznih nadzornih orodij skupaj z možnostjo nenamernih genetskih sprememb zahteva uporabo previdnostnega načela ter temeljito oceno tveganja, da bi preprečili morebitne škodljive učinke na zdravje ljudi in živali, okolje ter kmetijsko proizvodnjo.

Glede na navedeno Slovenija ne more podpreti dogovora in ne more soglašati s predlagano uredbo v njeni trenutni obliki, pri čemer poudarja, da je treba inovacije uvajati odgovorno, na trdnih znanstvenih dokazih in na način, ki varuje okolje ter ohranja svobodo izbire.

Courtesy translation in English

Slovenia considers that the agreement on the Proposal for a Regulation on plants obtained by certain new genomic techniques and their food and feed does not sufficiently address several essential issues, particularly those concerning risk assessment, labelling, traceability, the availability of analytical methods, the decision-making autonomy of Member States and conditions of cultivation.

Slovenia underscores that the current absence of adequate control tools, together with the possibility of unintended genetic modifications, necessitates the application of the precautionary principle and robust risk evaluation in order to prevent potential adverse effects on human and animal health, the environment and agricultural production.

Against this background, Slovenia is unable to support the agreement and cannot endorse the proposed Regulation in its present form, stressing that innovation should be introduced in a responsible manner, firmly grounded in scientific evidence and implemented in a way that protects the environment and upholds the freedom of choice.

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

Oceňujeme pokrok vo vývine textu nariadenia, avšak vzhľadom na skutočnosť, že Slovenská republika má naďalej výhrady voči NGT rastlinám kategórie 1, najmä z dôvodu, že návrh nariadenia neumožňuje označovanie NGT rastlín kategórie 1 a produktov z nich naprieč celou výrobnou vertikálou, čím obmedzuje právo spotrebiteľa na informované rozhodnutie, **Slovenská republika bude hlasovať proti návrhu nariadenia.**

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

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

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

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

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

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