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**Agriculture Committee**

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**EUROPEAN COMMISSION**

**Ms Stella Kyriakides, Commissioner for Health and  
Food Safety**

Madam Commissioner,

On October 27, 2023, at the 114<sup>th</sup> session of the Agriculture Committee of the Croatian Parliament, the Committee members discussed the Position of the Republic of Croatia on the Proposal for a Regulation of the European Parliament and the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625.

The Agriculture Committee concurs with the Position of the Republic of Croatia, which emphasizes that the risk assessment should be carried out for both categories of NGT plants and products in order to maintain consumers' confidence and ensure the traceability of products on the market. The Regulation needs to ensure a uniform approach and legal certainty throughout the EU with clearly defined rules and procedures concerning NGT plants. Furthermore, a unique framework related to safety, impact on the environment and biodiversity, risk assessment and product traceability should apply to both categories of NGT plants and products, fully taking into consideration the existing agricultural legislation, good agricultural practices as well as coexistence with conventional and organic farming. The Republic of Croatia is in favour of prohibiting the use of category 1 NGT plants in organic farming.

The Regulation should allow member states to make independent decisions regarding restrictions or bans on the cultivation of NGT plants on their own territory or part of the territory, with the aim of protecting their biodiversity, environment and human and animal health. The Republic of Croatia considers that the criterion concerning 20 nucleotides in Annex I of the Proposal is not scientifically substantiated and therefore needs additional clarification. With regard to category 1 NGT products, consumers and producers should be given the right to freedom of choice, so adequate monitoring and labelling of the said products should be ensured. We emphasize that before passing the Regulation, it is necessary to identify the potential risks of patenting plant reproductive material obtained by these techniques, in accordance with the provisions of the Directive 98/44/EC of the European Parliament and the Council of July 6, 1998 on the legal protection of biotechnological inventions and thus avoid the privatization of genetic resources and the creation of monopolies. In this sense, we kindly ask you to provide us with information on the ways foreseen by the European Commission to avoid the privatization of genetic resources and limit the possibility for individual producers to create monopolies.

The other question that arises is the status of patents because NGT plants/seeds can be patented, which is not the case with products of conventional breeding, including breeding by random mutagenesis, so it is necessary to identify the potential risks of patenting plant reproductive material obtained by NGTs.

The proposed provisions of the Regulation in no way guarantee that it will not be possible to use NGTs to patent heterogeneous, preserved or amateur-breeders' seeds. Seeds are not covered by plant variety legislation, and therefore will be subject only to patent law. We kindly ask you to tell us whether this will entail the cancellation of the fundamental right of farmers to use the seeds saved on their farms (farmer's seeds), and whether, according to the currently valid European patent law, this will enable the placing on the market of new patented GMOs and organisms obtained by NGTs. We underline that all GMO processes destabilize the entire genome of plants, which also affects the homogeneous varieties. In addition, given that new commercial categories of seeds are not subject to the obligations of homogeneity and stability of the Common Catalogue and the rights concerning plant varieties, this could increase the presence of patented GMOs and organisms obtained by NGTs on the market.

Since new obligations are imposed on the member states' competent authorities, particularly regarding deciding on the status of certain NGT plants, which require specific knowledge, special attention should be directed towards strengthening the member states' administrative capacities, which necessitates additional financial costs. In addition, it is necessary to establish a monitoring system for all NGT products and provide resources to strengthen the infrastructural capacities of the member states for the purposes of official controls, along with the implementation of new product monitoring methods such as sequencing. In this sense, we would appreciate if you could provide us with information about the possible financial framework (funds) planned/intended to strengthen the administrative and technical capacities for deciding on the status of certain NGT plants, official controls and new methods of monitoring NGT products.

We consider it extremely important to regulate the relation between crops and products of both categories of NGT on the one side, and conventional and ecological agriculture products on the other, to differentiate between them and to define the issue of liability, that is, compensation for damages in the event of unwanted spread of NGT plants in the environment. Due to all of the above, the Republic of Croatia does not agree with the wide powers given to the Commission by this act. In addition to the above, we kindly ask you, taking into account the objectives of the European Green Deal and the Farm to Fork Strategy, to provide us with a clear and unambiguous answer on the criteria on the basis of which coexistence of production of NGT plants and conventional and organic cultivation will be managed.

In order to protect human health and the environment, special attention must be given to the control of the risks arising from the deliberate release of NGT plants into the environment. The exclusion of risk assessment as a safety parameter in category 1 of NGT plants, as proposed by the Proposal for the Regulation, may adversely affect biodiversity, the environment and human and animal health. At the same time, it should be taken into account that the effects of intentional release of NGT plants into the environment can be irreversible, so in this sense, risk control should be a key provision of this legislative proposal. Likewise, it is unclear from Annex I of the Regulation which criterion was used to establish the number of maximum 20 modifications for category 1 NGT plants to be considered equivalent to conventional plants, and why such plants are completely exempt from the risk assessment procedure in accordance with the principle of precaution regarding possible effects on biodiversity, the environment, human and animal health. We would appreciate if you could provide us with a more detailed explanation of this issue and inform us about the ways/measures of regulating by legislation the liability for damage in the event of unwanted spread of NGT plants, as well as the degree of liability of the potential producer of NGT plants and/or users/growers of NGT plants.

Also, taking into account that there are no analytical methods for the detection, identification and quantification of NGT plants, it is not entirely clear how member states can take measures to avoid the unintentional presence of “category 2 NGT plants” in products in order to avoid unwanted contamination. We would kindly ask you to provide us with information on the ways to resolve this issue.

We would like to remind you that while discussing this topic at the Inter-Parliamentary Conference organized by the Agriculture Committee last September and attended by representatives of 24 parliaments, the representatives of national parliaments expressed their fears about such a proposal of the European Commission.

Furthermore, the Croatian Parliament passed the Declaration on GMO-free Alps-Adriatic-Danube Region, reconfirming the fact that the Republic of Croatia is a country free from genetically modified organisms, and that we want it to remain such for generations to come. In this sense, the Agriculture Committee is of the opinion that the European Commission should respect the right of member states to decide for themselves on the ban of GMOs in their territory.

In its judgement from 2018, the European Court of Justice equated GMOs and organisms obtained by NGTs, while emphasizing that NGT regulations should be an integral part of the GMO Directive. We kindly ask you to provide us with a detailed comment on this.

On the subject of the European Commission's decisions to approve the registration of new GMOs, in disregard of the European Parliament's opinion, it was said in the discussion that for the Republic of Croatia, as a country free from genetically modified organisms, it is extremely important to limit the further registration of new GMOs.

It was pointed out during the discussion that the deregulation of new methods of genetic engineering violates the requirements of the Treaty of Lisbon (TFEU) and the Cartagena Protocol on Biosafety, because the precautionary principle is ignored and not implemented. Therefore, we kindly ask you to provide us with an explanation of the legal soundness of the Proposal in question in relation to the internationally adopted binding requirements and the European legal order.

The members of the Agriculture Committee await with interest the European Commission's answers and we would be grateful if you could provide them as soon as possible.

Sincerely,

COMMITTEE CHAIRWOMAN

Marijana Petir

CC:

European Commission  
Mr Janusz Wojciechowski  
Commissioner for Agriculture