Dear Chair,

The Commission would like to thank the Agriculture Committee of the Hrvatski sabor for its consideration of 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 (COM(2023) 411 final).

This proposal forms part of a broader package of ambitious measures for a sustainable use of plant and soil natural resources, which will also strengthen the resilience of EU food systems and farming. More specifically, it aims at maintaining a high level of protection of human and animal health and of the environment in accordance with the precautionary principle, enabling the development and placing on the market of plants and plant products contributing to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies, and ensuring the effective functioning of the internal market and enhancing the competitiveness of the agri-food sector at the EU and global level.

The proposal would establish two categories of plants obtained by certain new genomic techniques (NGTs): NGT plants comparable to naturally occurring or conventionally bred plants (category 1 NGT plants in the proposal), and NGT plants with more complex modifications (category 2 NGT plants in the proposal). Each category would be subject to different requirements, adapted to their characteristics and risk profile.

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The Commission has carefully analysed the Opinion of the Agriculture Committee of the Hrvatski sabor and would like to provide the following clarifications.

The Opinion requests that risk assessment should be carried out for both categories of NGT plants. The Commission would like to emphasise that the rules contained in the proposal maintain a high level of protection of human, animal health and of the environment. The proposal is based on the current scientific knowledge about the safety of NGT plants. The European Food Safety Authority has concluded that there are no new hazards specifically linked to the genomic modification produced via certain NGTs as compared with conventional breeding or established genomic techniques. They have considered that certain types of modifications introduced with NGTs can also take place naturally or through conventional breeding. The above conclusions warrant a proportionate approach based on the different risk profiles that result from the diversity of NGTs and of the plants obtained with them, while ensuring that all NGT plants on the EU market will be as safe as conventionally bred varieties. This is fully compatible with the precautionary principle. In addition, by adapting the regulatory burden to the level of risk, the proposal is intended to support innovation and facilitate the arrival on the EU market of safe plants and plant products for farmers and consumers.

The Opinion states that 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 Commission would like to emphasise that the ‘opt-out’ possibility in Article 26 of Directive 2001/18/EC cannot be used to address risks for human or animal health or the environment arising from genetically modified organisms, because such risks are already assessed through a scientific assessment harmonised at EU level. Therefore, the ‘opt-out’ can only be used to cater for other aims, such as the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability, or maintenance of local biodiversity, or certain types of natural and landscape features, as well as specific ecosystem functions and services.

In that regard, the Commission would like to stress that, while the proposed rules on NGT plants rest on robust scientific evidence as regards their safety, the exclusion of the ‘opt-out’ possibility for category 2 NGT plants in the NGT proposal is unrelated to safety considerations of such plants, precisely because category 2 NGT plants will only be authorised if they are safe. That measure aims to facilitate cultivation and placing on the market of safe category 2 NGT plants in the EU, which requires predictability for breeders and farmers as regards the possibility to place on the market and cultivate such plants, and thereby contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity strategies.

The Opinion asks the Commission to provide clarification concerning the criteria defining the equivalence of category 1 NGT plants with conventional plants, in particular as regards the threshold of 20 modifications. The rationale for the equivalence criteria has been presented to Member States in a technical paper prepared by the Commission,
which is publicly available\(^2\). Scientific evidence shows that the total number of mutations in a single plant caused by conventional breeding methods can be high — the typical range is 30 to 100 mutations — but in view of the relative novelty of NGT plants and the lower probability of achieving certain combinations of mutations with conventional methods, the Commission has taken a conservative approach when setting the threshold.

The Opinion expresses concerns about freedom of choice for consumers, due to the fact that category 1 NGT plants would be treated like conventional plants and would therefore not be labelled as genetically modified organisms. Imposing the genetically modified organism label for such plants would not accurately reflect the fact that the same product can be obtained by conventional means. The same rules apply already today to plants obtained by random mutagenesis, which have always been exempt from GMO labelling requirements. It is the Commission’s view that plant products with similar genetic modifications should not be subjected to different labelling and traceability requirements, depending on the technique that was used to obtain them. Nevertheless, the Commission proposes to label the seeds of such NGT plants, allowing GM-free supply chains to exclude them. Consumers wanting to avoid NGT plants can rely on the organic label as the organic sector will not be allowed to use plants obtained by NGTs.

The Opinion asks the Commission, taking into account the objectives of the European Green Deal and the Farm to Fork Strategy, to clarify how coexistence of production of NGT plants and conventional and organic cultivation will be managed. The Commission would first like to stress that addressing the challenges faced by the agrifood systems calls for a variety of responses and tools, and these include both, organic production and the use of biotechnology to deliver plants with e.g., improved resistance to diseases and pests and tolerance to climate change impacts. In this regard, plant varieties with specific traits developed using NGTs can be a tool to contribute to social, environmental and economic aspects of sustainability. In this context, the proposal intends to strike the right balance to support organic production and the use of NGTs.

Concerning coexistence, a distinction has to be made between category and category 2 NGT plants. With regard to category 1 NGT plants, the proposal includes a variety of transparency measures (a public register of all NGT plants that have gone through the verification procedure, the labelling of seeds as obtained by NGTs, and the indication of NGT status in the common catalogues of varieties). In order to minimise the risks of adventitious presence of NGT plants in organic products, the organic sector would be able to rely on those transparency measures as well as the organic traceability requirements and the preventive measures provided for in the Organic Production Regulation\(^3\). In the view of the Commission, any further measure would not be justified for NGTs plants that are comparable to conventional plants. Moreover, the impossibility


of differentiating analytically certain NGTs from conventionally bred varieties would make the enforcement of strict coexistence measures very difficult or even impossible.

Category 2 NGT plants would remain subject to current traceability and labelling rules of the EU legislation on genetically modified organisms. In this context, the potential limitations of analytical methods for the reliable detection, identification and quantification of category 2 NGT plants in some cases would require certain adaptations to systems of identity preservation, based on measures such as additional documentation or third-party verification. In addition, the proposal proposes stronger measures than the current GMO legislation by requiring Member States to adopt national coexistence measures adapted to local circumstances.

Matters concerning financial compensation or liability for economic damage are the exclusive competence of Member States and can, therefore, not be addressed in the proposal. Liability for certain environmental damages is addressed by Directive 2004/35/CE.

The Opinion also considers that it is necessary to identify the potential risks of patenting plant reproductive material obtained by NGTs. The Commission would like to note that the legislative proposal concerns the rules applicable to the release into the environment and placing on the market of plants obtained by certain NGTs and their products and does not concern EU rules on patents related to such plants, which are laid down in Directive 98/44/EC on the legal protection of biotechnological inventions. However, the Commission is aware that patentability of such plants is a matter of concern to many and, therefore, in its Communication of 5 July 2023 on ‘Ensuring resilient and sustainable use of natural resources’, it announced that it will assess the impact of patenting plants on innovation in plant breeding, on breeders’ access to genetic material and techniques, on availability of seeds to farmers and on the overall competitiveness of the EU biotech industry. The Commission will publish a report with its findings by 2026, which will serve as a basis to decide on any possible follow-up actions.

As regards your specific concerns about patents on traits in heterogeneous material or varieties used by amateur gardeners and breeders, Directive 98/44/EC on the legal protection of biotechnological inventions states that the conditions for the use of farm-saved seeds covered by patents correspond to the conditions for the use of seeds protected by plant variety rights, that is, farmers can use the product of their harvest for propagation or multiplication on their own farm.

With regard to the administrative capacity of Member States and the establishment of official specialised public laboratories for NGT specific testing, the Commission notes that the relevant expertise for such tasks already exists in the national reference

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laboratories, designated under Regulation (EU) 2017/625\textsuperscript{6} and Regulation (EC) 1981/2006\textsuperscript{7}, and in the European Network of GMO laboratories, as set out in Regulation (EC) 1829/2003\textsuperscript{8}. The European Union Reference Laboratory on Genetically Modified Food and Feed coordinates the work for official testing and validation of analytical methods with the Member States through this network.

The Opinion refers to the judgment of the Court of Justice of the European Union in Case C-528/16 Confédération paysanne and Others\textsuperscript{9} and asks the Commission to provide its comments on it. In that judgment, the Court held that GMOs obtained by new techniques or methods of mutagenesis that had appeared or had been mostly developed since Directive 2001/18/EC was adopted could not be considered excluded from the scope of that Directive. The Court ruling provided an authoritative interpretation of the existing EU legislation. This, however, does not prevent the co-legislators to adapt the legal framework to scientific and technical progress, if needed. In this regard, the Council recognised that the Court ruling brought legal clarity on the status of new mutagenesis techniques, but also raised practical questions on implementation and enforcement. Therefore, the Council asked the Commission to conduct a study on the status of new genomic techniques under Union law and submit a proposal (accompanied by an impact assessment), if appropriate, in view of the outcome of the study\textsuperscript{10}. The Commission study on new genomic techniques of 29 April 2021\textsuperscript{11} concluded that there were strong indications that the applicable legislation is not fit for purpose for some NGTs and their products, and that it needs to be adapted to scientific and technological progress. On that basis, the Commission announced a policy initiative on plants obtained by certain NGTs\textsuperscript{12}.

The Opinion questions the Commission decisions to authorise new GMOs and states that it is important for the Republic of Croatia to limit the further authorisation of GMOs. The authorisation in the EU of genetically modified organisms and their food and feed is based on strict, harmonised criteria and requirements. When such criteria and requirements are met, there is no reason not to authorise the deliberate release or placing on the market. The applicable EU legislation only allows Member States to restrict or prohibit cultivation of genetically modified organism under the specific conditions of the ‘opt-out’ in Article 26b of Directive 2001/18/EC, referred to above.

\begin{itemize}
\item\textsuperscript{6} https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0625
\item\textsuperscript{7} https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1981
\item\textsuperscript{8} https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32003R1829
\item\textsuperscript{9} ECLI:EU:C:2018:583
\item\textsuperscript{10} Council Decision (EU) 2019/1904
\item\textsuperscript{11} https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf
\item\textsuperscript{12} https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_letter.pdf
\end{itemize}
Finally, the Agriculture Committee of the Hrvatski sabor raises concerns about the compliance of the proposal with the EU’s international obligations under the Cartagena Protocol on Biosafety. The Commission would like to clarify that it considers that category 1 NGT plants are not within the scope of the Protocol, since they are not ‘living modified organisms’ within the meaning of Article 3, points (g) and (i) thereof. This is because category 1 NGT plants do not possess ‘a novel combination of genetic material obtained through the use of modern biotechnology’ within the meaning of the Protocol.

The points made above are based on the proposal presented by the Commission, which is currently in the legislative process involving both the European Parliament and the Council, and therefore may be amended by them.

The Commission hopes that the clarifications provided in this reply address the issues raised by the Agriculture Committee of the Hrvatski sabor and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Martoš Šefčovič
Executive Vice-President

Stella Kyriakides
Member of the Commission