Dear President,

The Commission would like to thank the Senatul României 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 farming¹. 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.

The Commission carefully analysed the Reasoned Opinion and would like to provide the following clarifications.


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The Commission is pleased that the Senatul României recognises that the NGT proposal respects the principle of subsidiarity and takes note that Senatul României’s Opinion on the proposal raises concerns as regards compliance with the principle of proportionality. The Commission will explain how this principle has been taken into consideration, when addressing certain of the concerns raised by the Opinion.

The Opinion recalls the judgment of the European Court of Justice of 25 July 2018 (in case C-528/16), and notes that certain NGT plants and their products will be excluded from the current rules applicable to genetically modified organisms (GMOs) and genetically modified food and feed. In that regard, the Commission would like to note that, following that judgment, the Council of the European Union requested the Commission to carry out a study on the status of new genomic techniques under Union law {Council Decision (EU) 2019/1904}2. That study, published on 29 April 2021 {SWD(2021) 92 final}3, concluded that the current legislation is not fit-for-purpose and needs to be adapted for some NGTs and their products, in particular as regards NGT plants containing genetic modifications that can also occur naturally or be obtained by conventional breeding methods. The NGT proposal contains measures to address the shortcomings of the current legal framework.

The Reasoned Opinion expresses the view that the exclusion of plants obtained by means of new mutagenesis techniques from the scope of Directive 2001/18/EC would not respect the precautionary principle. The Commission proposal aims at maintaining a high level of protection of human, animal and environmental health and is based on the current scientific knowledge about the safety of NGT plants. The European Food Safety Authority (EFSA) has concluded that there are no new hazards specifically linked to targeted mutagenesis and cisgenesis as compared with conventional breeding or established genomic techniques4. EFSA has considered that the type of modifications introduced with certain 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, that is by applying the principle of proportionality, the proposal is intended to support innovation and facilitate the arrival on the European market of safe plants and plant products for farmers and consumers.

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2 OJ L 293, 14.11.2019, p. 103.
With regard to your concerns about transparency and freedom of choice for consumers, category 1 NGT plants for which it has been verified that they are comparable to conventionally bred plants would be treated like conventional plants and would be subject to the same rules. Imposing the GMO label for such plants would not accurately reflect the fact that the same product can be obtained by conventional means. This is the same approach as taken in the past as regards GMOs exempted from the requirements of the GMO legislation, such as the products of random mutagenesis, which already today are not labelled as GMOs. 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. Information is also provided in the public register on category 1 NGT plants and in the plant variety catalogues. Consumers wanting to avoid NGTs can rely on the organic label, as the organic sector will not use plants obtained by NGTs. In order to minimise the risks of adventitious presence of NGTs in organic products, the organic sector can rely on the organic traceability requirements and the preventive measures provided for in the Organic Products Regulation.

Category 2 NGT plants which contain more complex modifications would remain subject to risk assessment and authorisation, the current traceability and labelling rules of the GMO legislation, as well as coexistence measures which all Member States would need to adopt.

In the Commission’s view, the proposal would ensure a high level of consumer protection. It would not only ensure that NGT products are safe, but also increase consumer choice of safe and sustainable products, while also providing transparency to those supply chains that cannot or do not want to use NGTs by providing for labelling of plant reproductive material seed of category 1 NGT plants.

The Commission notes the concerns of the Senatul României with regard to its grain exports to third countries. Several countries among the world’s top global grain exporters (such as Argentina, Brazil, Canada or the US) already have provisions to exempt certain NGT plants (those that could have been obtained by conventional means) from GMO requirements. The Commission proposal, with the creation of category 1 of NGT plants, is taking a similar approach which, as reported in the impact assessment, is being adopted by an increasing number of third countries.

Moreover, the proposal includes provisions to ensure the transparency of the category 1 NGT status of seeds and plant breeding material, which enables traders to establish supply chains free from category 1 NGT plants, if required by the importing country. In this way, the proposal ensures a higher level of transparency about category 1 NGT plants that the situation in various exporting countries that exempt certain NGT plants from GMO legislation with no labelling or public registers. For category 2 NGT plants, the current labelling and traceability requirements as a GMO continue to apply.

Furthermore, you ask the Commission to ensure that third countries are consulted on the verification of category 1 NGT plants in order to avoid trade frictions. The Commission
has notified the proposal to the WTO, both under SPS agreement\(^5\) and TBT agreement\(^6\). It will examine any comments received and engage with third countries as necessary. So far, no non-EU country has raised concerns in relation to the NGT proposal.

The Opinion draws attention to the need for new plant varieties obtained through NGTs to respond to the specific agricultural and technological needs of each Member State. New plant varieties obtained through NGTs are subject to the same variety registration procedure as conventionally bred varieties. According to legislation on the production and marketing of plant reproductive material, all new varieties of agricultural species have to undergo official examinations of their value for cultivation and use (VCU). Specific criteria for VCU examinations are set at the Member State level in order to ensure that the specific needs of each Member State are met.

With regard to 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 laboratories, designated under Regulation (EU) 2017/625\(^7\) and Regulation (EC) 1981/2006\(^8\), and in the European Network of GMO laboratories, as set out in Regulation (EC) 1829/2003\(^9\). 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 also considers it necessary to exclude from patentability category 1 NGT plants as well as plants that are already in the public domain and genes of interest that are the object of biodiversity heritage. In that regard, the Commission would like to note that the 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\(^10\). However, the Commission is aware that patentability of such plants is a matter of concern to many stakeholders. Therefore, in its Communication of 5 July 2023 on ‘Ensuring resilient and sustainable use of natural resources’, the Commission 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.

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\(^5\) G/SPS/N/EU/687
\(^6\) G/TBT/N/EU/1032
\(^7\) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0625
In your letter you ask the Commission to provide the scientific basis for the criteria defining the equivalence of category 1 NGT plants with conventional plants, in particular 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\textsuperscript{11}. 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 with regard to setting the threshold.

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 Senatul României and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Executive Vice-President

Stella Kyriakides
Member of the Commission