Reasoned Opinion of the Standing Committee on Agriculture and Natural Resources of the House of Representatives of the Republic of Cyprus

Submitted to the Presidents of the European Parliament, the Council and the European Commission, pursuant to Article 6 of Protocol (No 2) on the application of the principles of subsidiarity and proportionality of the Treaty on European Union.

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].

1. The Treaty framework for the application of the principles of subsidiarity and proportionality

1.1 Article 5(3) of the Treaty provides that:

"Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.

The institutions of the Union shall apply the principle of subsidiarity as laid down in the Protocol on the application of the principles of subsidiarity and proportionality. National Parliaments ensure compliance with the principle of subsidiarity in accordance with the procedure set out in that Protocol."

1.2 Moreover, in accordance with Article 2 of Protocol (No 2) of the Treaty, the European Commission must consult widely before submitting a proposal for a legislative act, taking into account, where appropriate, the regional and local dimension of the proposed measures.

1.3 Article 5 of Protocol (No. 2) to the Treaty provides that:

“Draft legislative acts shall be justified with regard to the principles of subsidiarity and proportionality. Any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality. This statement should contain some assessment of the proposal's financial impact and, in the case of a directive, of its implications for the rules to be put in place by Member States, including, where necessary, the regional legislation. The reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators. Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved.”

1.4 Finally, as provided for in Articles 5(3) and 12(b) of the Treaty, national Parliaments shall ensure that the principle of subsidiarity is respected, in accordance with the procedure laid down in Protocol (No 2), i.e. the procedure for delivering a reasoned opinion within eight (8) weeks of the date of transmission of a draft legislative act in all the official languages of the European Union.

1.5. The guidelines, in relation to how the subsidiarity principle is applied, were laid down in the Amsterdam Treaty and in particular in the Protocol on the application of the principles of subsidiarity and proportionality. It should be noted that these guidelines continue to be useful tools in the exercise of the check under review.

In particular, the guidelines concern the following:

- whether there are transnational aspects to the issue under consideration that cannot be effectively addressed by national measures,
- whether national measures or lack of action by the Union would conflict with the requirements of the Treaties of the European Union or would be detrimental to the interests of the Member States; and
- where Union action compared to action by Member States offers clear advantages in terms of the scale at which it will be carried out or its results.

Furthermore, in order to decide whether or not a Union action is compatible with the proportionality principle, the following elements are examined:

- the instrument used must be appropriate to achieve the objective of an action,
- the means must not go beyond what is necessary to achieve the objective of an action.

The relevant Protocols, of both Amsterdam and Lisbon, place certain restrictions on the EU when it is called upon to apply the proportionality principle:

- the form of Union action must be as simple as possible and when the European Union legislates, it must prefer Directives to Regulations,
- the need to reduce administrative or economic costs for Member State governments, national economic actors and citizens must be taken into account,
- Union action should allow as much scope as possible for national decision-making

2. The substance and objectives of the proposal for a Regulation under consideration

2.1 The current legislative proposal, as presented by the European Commission, lays down specific rules for the deliberate release into the environment of plants produced by certain new genomic techniques (hereinafter 'NGT plants') and for the placing on the market of food, feed and other products containing, consisting of or produced from such plants. The scope of the legislative proposal is limited to genetically modified plants produced by targeted mutagenesis or homogenisation, or a combination thereof. The proposal creates two categories of NGT plants with different regulatory requirements for each category. Category 1 NGT plants include plants which are produced by targeted mutagenesis or cisgenesis and which could also have been produced naturally or by conventional improvement techniques, based on the criteria set out in Annex I of the proposal. Such plants would require notification before being placed on the market, but no further authorisations or risk assessments would be required. The legislative proposal introduces the obligation to label plant propagating material containing or consisting of Category 1 NGT plants. Category 2 NGT plants include plants produced by the same techniques, but which do not fall into category 1, provided that they do not contain "foreign DNA". For this category, the

requirements of the current legislation on Genetically Modified Organisms (GMOs) will apply with some adaptations for detection methods, risk assessment methodologies and monitoring/traceability requirements. At the same time, it is proposed to introduce regulatory incentives (Article 22), which will be provided to applicants for the authorisation of NGT category 2 plants with characteristics that have the potential to contribute to a sustainable agri-food system, provided that they do not have herbicide-resistant characteristics. Additional incentives are also provided where the notifier or applicant authority is a small and medium-sized enterprise (SME), by granting fee exemptions for the validation of detection methods and by providing more extensive pre-application advice. Finally, the legislative proposal prohibits the use of NGT plants in organic production and provides that Member States may not restrict or prohibit the cultivation of NGT category 1 and 2 plants on their territory.

2.2 The legal basis for this proposal is Articles 43, 114 and 168(4)(b) of the Treaty on the Functioning of the European Union.

2.3 The main objectives of the proposal, according to the European Commission, are as follows:

- To contribute to a high level of protection of human and animal health and the environment, in accordance with the precautionary principle;
- to enable the development and marketing of plants and plant products that contribute to the innovation and sustainability objectives of the European Green Deal, the farm-to-fork strategy and the biodiversity strategy; and
- To ensure the effective functioning of the internal market for NGT plants and products and food and feed containing, consisting of or produced from NGT plants, and to enhance the competitiveness of the Union's agri-food sector at EU and global level, including a level playing field for operators.
- Ensure that NGT plants released or placed on the market have traits that can contribute to the sustainability of the agri-food system.

3. Compatibility with the principle of subsidiarity

After examination of the proposal for a regulation in question, the Standing Committee on Agriculture and Natural Resources, has concluded that the proposal in question does not comply with the principle of subsidiarity. In particular, the said committee decided that there is insufficient justification of the need for action at European Union level, in breach of the subsidiarity principle, and, as will be explained below, questions concerning compliance with the proportionality principle in certain aspects of the proposal exist.

4. Justification

4.1 The Standing Committee on Agriculture and Natural Resources has doubts as to whether the criteria foreseen for the verification of Category 1 NGT plants are sufficient to ensure the safety of health and the environment, taking into account the fact that the said plants will not be subject to a risk assessment prior to their deliberate release into the environment and placing on the market.

4.2 The European Commission's Impact Assessment[1] includes four (4) different scenarios for regulation of the problem at the EU level. The European Commission concludes that the combination of scenarios 2 and 4, i.e. the proposal as it stands, is the most appropriate option. However, in the Impact Assessment, the European Commission itself states that key parts of the analysis and the studies relied upon are based on assumptions[2] or scenario-based approaches, due to, among other reasons, the admission that the available data is incomplete. In particular, the European Commission states that the data collection and analysis carried out has some inherent limitations due to the lack of historical data on the cultivation and commercial use of plants produced by targeted mutagenesis and cisgenesis, as these products have only

[1] SWD (2023) 412

[2] See Subchapter 1.2 of the Impact Analysis entitled "NGTs in the context of key EU strategies". Pp. 6, where the following is mentioned: "In this context, according to the FAO, [...] the extent of the impact is still speculative ...".

recently reached non-EU markets while there is no experience with such plants within the EU.[3]

4.3 The assumption is also made, with reference to a scientific study, that it is difficult to carry out an assessment of the long-term environmental effects of NGT use,[4] and there are reports of contradictory findings in scientific studies in relation to the safety of NGTs to health and the environment.[5] The Impact Assessment form does not sufficiently elaborate on the evidence on the basis of which it was decided that Category 1 NGT plants are as safe to health and the environment as plants that could also have been produced through plant breeding. It should also be noted that the proposed criteria for determining the equivalence of Category 1 NGTs to conventional plants allow for up to twenty (20) different genetic modifications per plant.[6] Nevertheless, the European Commission proposes as an effective measure, scenario number 4, under which Category 1 NGT plants would be deliberately released into the environment and placed on the market without a risk assessment.

4.4 In addition to the above, it is noted that in several parts of the Impact Assessment document, the Commission, while referring to the need to ensure freedom of choice for consumers[7] and to maintain the labelling of NGT products,[8] nevertheless proposes, without sufficient justification, to exempt category 1 NGT plants from the labelling obligation as an effective measure. This choice is made despite the admission that the possibility to decide not to consume category 1 NGT products will not be sufficiently safeguarded by this option.[9] Furthermore, the proposed regulation imposes a disproportionate and/or unjustified burden on consumers, who, in order to ensure that the product they consume is free from genetic modification, will have to refer to a

[3] See Chapter 6 of the Impact Analysis entitled "6. What are the impacts of the policy options?" p. 31.
[4] See Impact Assessment, Chapter 1.2., titled: “Political context - GMOs today” p. 5 – 6.
[5] See Subchapter 1.1 of Chapter 1, titled: «Opinions of scientific bodies», p. 3 – 4.
[6] See Annex I of the proposed Regulation which sets out the criteria for equivalence of NGT plants with conventional plants and specifically states the following: "An NGT plant shall be considered equivalent to conventional plants when it differs from the recipient plant/parental plant by a maximum of 20 genetic modifications [...]".
[7] See Subchapter 1.2 of Chapter 1 of the Impact Analysis titled: "NGTs in the context of key EU strategies" p. 6.
[8] See Subchapter 1.2 of the Impact Analysis titled: "Other factors affecting the development and marketing of NGTs" p. 9.
[9] See Subchapter 1.5. of Chapter 6 titled: "Analysis of option 4: Notification of products that could also occur naturally or be produced by conventional breeding" p. 57.

public database[10] listing category 1 NGT products and/or buy organic products (which are GM-free).[11]

4.5 At the same time, the European Commission proposes to restrict the right of Member States to prohibit the cultivation of NGT plants on their territory (Article 25). This right of prohibition was granted to Member States by Directive 2001/18/EC,[12] as amended by Directive 2015/412/EU. However, the proposal to restrict this right has not been sufficiently justified and explained by the European Commission, especially with regard to Category 2 NGT plants, which for the purposes of their release into the environment and placing on the market will continue to be subject to the current regulatory framework for genetically modified organisms (Directive 2001/18/EC) albeit with certain adaptations. However, it is also noted that, while the European Commission's documents admit that it is difficult to carry out an assessment of the long-term environmental impact of the use of GMOs and that there are contradictory findings from scientific studies on the safety of GMOs for health and the environment, as mentioned in point 4.3 above, the legislative proposal in question would also allow the cultivation of GMOs in ecologically sensitive areas, such as Natura 2000 sites. It is emphasised that the cultivation of category 1 NGT plants will also be allowed in these areas, but that no risk assessment will be carried out before they are released into the environment and placed on the market.

4.6 At the same time, the Impact Assessment states that, due to the increase in the cultivation of NGT crops, the risk of mixing conventional, organic and non-GMO production with NGT products will increase, which will, in turn, increase the cost of segregation that farmers will have to bear. However, it is admitted that there are no quantitative estimates of the said cost.[13] In addition, the European Commission states that the proposed solutions are the most efficient, while at the same time admitting that organic farmers will suffer a possible, but unquantifiable increase in the costs of

[10] Article 9 of the proposal for a Regulation. See also the summary of the Impact Assessment Report - Document SWD(2023)413, p. 4.
[11] See Subchapter 1.6. of Chapter 7 titled: "Effectiveness" p. 65.
[12] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.
[13] See Subchapter 1.2. of Chapter 6 of the Impact Analysis entitled "Analysis of option 1 (Authorisation with adapted risk assessment and detection method requirements)" p. 41-42.

adaptation to risk management practices and market monitoring (for the accidental presence of GM or NGT product) due to the uncertainty of the possible presence of NGT plants in conventional seeds.[14] Given the above, the Impact Assessment should include an estimate of the level of these costs, taking into account the specificities of the Member States and adequately assessing the risk of contamination of neighbouring crops by NGT plants, particularly in areas such as Cyprus, where the main characteristic of its agricultural sector is the cultivation of many different crops on small agricultural plots.

4.7 In addition, as mentioned above, one of the main objectives of the legislative proposal is to develop and market plants and products that contribute to the objectives of, inter alia, the farm-to-fork strategy. This strategy aims to stimulate organic production to occupy at least 25% of agricultural land in the EU by 2030. The legislative proposal under consideration is expected to increase the cultivation of NGT plants in the EU, the use of which is prohibited in organic production. However, the Impact Assessment does not adequately assess the potential impact on organic production, the increased costs of segregation for organic farmers as mentioned above, and the potential reduction in the availability of seeds that could be used in organic production due to increased cultivation and production of NGTs and the risk of contamination of agricultural production and contamination from neighbouring crops.

4.8 In addition, while the Impact Assessment notes the concern of NGOs, consumer/environmental organisations,[15] business organisations and trade unions about the negative effects of a possible patenting of NGT production, and in particular the concern about the privatisation of seeds and the creation of monopolies,[16] this issue is not specifically addressed in the legislative proposal in question. At the same time, the impact of the possible patenting of NGTs on the ability of farmers to select, obtain and multiply the seeds of plants harvested with NGTs on their farms is not addressed in the Impact Assessment. In addition, the European Commission

[14] See Subchapter 8.2 titled: "Simplification and burden reduction, supporting the one-in-one-out approach", p. 75. Also see sub-chapter 1.5. of Chapter 6, titled: "Analysis of option 4: Notification of products that could also occur naturally or be produced by conventional breeding" p. 55.
[15] See. Subchapter 1.3 of Appendix 2a of the Impact Analysis, titled: "Non-Campaign Contributions" p. 119.
[16] See Subchapter 1.2 of Annex 2a of the Impact Assessment titled: "Business organisations/associations, trade unions", p. 115.

documents refer to farmers' concerns about the cost of licensing in relation to access to NGT plants and seeds and that this can be prohibitive, particularly for small-scale farmers.[17] Nevertheless, the Impact Assessment does not provide an estimate of the costs that farmers would likely incur in accessing NGT seeds or plants, nor does it assess the potential that these costs would be passed on to the consumers.

4.9 At the same time, as stated above, one of the main objectives of the legislative proposal under consideration is to ensure that NGT plants released or placed on the market have such characteristics that render them able to contribute to the sustainability of the agri-food system. However, the European Commission notes in the Impact Assessment that the proposed regulation will have a limited positive impact on the attractiveness for farmers to develop NGT plants that contribute to sustainability objectives, because the regulation does not take into account the fact that the sustainability of a crop does not depend solely on its individual characteristics, but on the interaction of the plant with its environment and the farming system in which it is used.[18] In addition to the above, the European Commission assumes that the process of verifying how the characteristics of an NGT plant can contribute to sustainability, as well as the provision of support by the competent authorities to SMEs for the approval process of such NGT category 2 plants, is expected to increase the administrative costs of the approval process.[19] However, given the limited positive impact on sustainability that this arrangement is expected to have, an estimate of the level of administrative costs that the competent authorities will have to bear should have been included in the Impact Assessment.

4.10 In the light of the above, the Standing Committee on Agriculture and Natural Resources does not consider that the need for legislative action at the EU level is based on sufficient quantitative and qualitative indicators or on detailed justification, as required by Article 5 of Protocol (No 2) to the Treaty. In other words, the European Commission does not sufficiently justify that the proposed option is a necessity, especially in the proposed form. The taking up of regulatory action at the EU level,

[17] See Subchapter 1.2. of Chapter 1, titled: "NGTs in the context of key EU strategies" p. 8.
[18] See Subchapter 1.6. of Chapter 7, titled: "Effectiveness" p. 61.
[19] See Chapter 6, Subchapter 1.3 titled: "Analysis of option 2: Authorisation with incentives for products containing modified traits that have the potential to contribute to sustainability" p. 46.

should be based on satisfactory and convincing evidence and not on assumptions or analyses with a large margin of error, precisely because it runs counter to the principle that decisions should be taken as close as possible to the citizens.

4.11. It is undisputed that the problem that the legislative proposal in question seeks to address has a clear cross-border dimension. The European Commission considers that the current regulatory framework on genetically modified organisms (GMOs) is not appropriate for regulating NGT plants produced by targeted mutagenesis or cisgenesis and products (including food and feed) derived from them, and that this legislation needs to be adapted to scientific and technical progress in this area. However, the Commission does not sufficiently justify why it is not a satisfactory and/or effective solution to amend the current legislative framework on GMOs before intervening legislatively with a Regulation, which is the most stringent and inflexible legislative instrument, which raises the issue of respecting the principle of proportionality. Indeed, as noted above, the Impact Assessment states that, given that specific regulatory frameworks have only recently been adopted in several non-EU countries and given the limited number of products on the global market (none in the EU) very little, if any, data or assessments are available to date on the economic, social or environmental impacts of the different legislative frameworks for NGT products.[20] It should be recalled that, in accordance with the principle of proportionality, preference should be given to regulation of a given matter by directive rather than a regulation, where possible. Given the fact that the European Commission's choice of this legislative proposal is not based on satisfactory evidence, it is considered that the scope of its regulatory action in its current form is not strictly necessary to achieve the objectives set by the EU.

4.12. Having taken the above into account and considering the fact that the proposed scenarios put forward by the European Commission do not include the possibility of amending the current legislative framework on GMOs, the Standing Committee on Agriculture and Natural Resources, expresses its doubts as to whether an alternative course of action has been adequately and thoroughly explored.

[20] See Subchapter 2.2 of the Impact Analysis titled: "What is the size of the problem and who is affected?" p. 16.

Conclusion

4.13 In the light of the above, the Standing Committee on Agriculture and Natural Resources concludes that the proposal for a Regulation under consideration does not comply with the principles of subsidiarity and proportionality and that the criteria required by the Treaties, as set out above, are not sufficiently met to justify, on the one hand, the need for this regulatory action by the Union and, on the other hand, the need to regulate the matter in the present form in order to achieve the objectives pursued.