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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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} - {SEC(2023) 411 final} - {SWD(2023) 412 final} - {SWD(2023) 413 final}

Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
The proposal is based on Articles 43, 114 and 168(4)(b) of the Treaty on the Functioning of the European Union (TFEU). These articles provide the legal basis for the EU to adopt measures which have as their objective to implement the common agricultural policy (Article 43), and to ensure the good functioning of the internal market (Article 114(1)) while maintaining a high level of human health protection in the veterinary and phytosanitary fields (Article 168(4)(b)).
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In this policy area, the Union's competence is shared with the Member States.
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[1]: - Has there been a wide consultation before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?
The impact assessment takes into account the input from a range of stakeholder consultation activities. A public consultation[2] was held between 29 April and 22 July 2022 (2300 contributions). It was complemented by a range of targeted consultation activities: • Stakeholder interviews (25) to receive input on the initiative and on the impacts of policy options, including on costs. • A targeted survey (from 28 June to 5 September 2022) to which 397 stakeholders and Member State authorities were invited. 123 responded and self-categorised as business associations (32), NGOs, environmental, consumer and other civil society organisations (28), public authority/body (23), large company/business (11), academic/research organisation (9), SMEs (8), other (12). • Two expert focus groups on sustainability and traceability on 22 and 23 September 2022. • Regulatory cost interviews (23) to map regulatory costs of operators developing and marketing NGT plants as well as to assess costs of risk assessment and enforcement authorities. Furthermore, DG SANTE held meetings of a working group with the GMO national competent authorities to discuss specific aspects of the initiative. At the request of a number of stakeholders, DG SANTE held bilateral meetings and also attended relevant events of stakeholders. Finally, some stakeholders and national competent authorities submitted to DG SANTE opinions on specific matters. A summary of all these activities and their outcomes is provided in the Annex 2 – Synopsis report, of the Impact Assessment Staff working document. The explanatory memorandum and the impact assessment (chapter 3) contain a section of the principle of subsidiarity.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

Plants obtained by targeted mutagenesis and cisgenesis are living organisms which, as any other plant, when released into the environment for experimental purposes or as commercial products, may reproduce in the environment and cross-national borders. It is essential to achieve a harmonised, high level of protection of human and animal health and the environment in relation to these plants and of food and feed derived from them so that they may circulate freely within a smooth-functioning internal market. In addition, the EU Farm to Fork Strategy recognises the potential of NGTs as a possible tool to increase sustainability of the food system and bring benefits to society as a whole.
The requirements for the deliberate release and the placing on the market of NGT plants and their derived food and feed are already harmonised at EU level under the existing legal framework applicable to GMOs but need to be adapted to the specificities of plants obtained by these new techniques. Carving out NGT plants from the current EU legal framework and leaving it to Member States to regulate them would likely lead to different regulatory requirements and levels of protection in the EU Member States. Differing national requirements for NGT plants would hinder the free movement of these products, fragment the internal market and lead to uneven competition between economic operators.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

Absence of EU level action to provide for specific rules on NGT plants would leave those products under the current GMO rules, which are not fit for purpose as concluded by the Commission NGT Study of April 2021. Specific, EU-level rules are necessary in order to enable those plants and related products to deliver and contribute to the sustainability goals of the Green Deal and F2F and Biodiversity strategies.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The plants and products placed on the market would be authorised at EU level and allowed to be placed on the market in the EU The proposal ensures free movement of NGT products in the internal market while maintaining a high level of human health protection in the veterinary and phytosanitary fields throughout the EU.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[3] or significantly damage the interests of other Member States?

The planned measure concerns the placing on the market of products containing or consisting of NGT plants and of food and feed produced from such plants. Therefore, the proposal directly affects the internal market as regards NGT products. Those products are GMOs and therefore they are already regulated at present under the GMO legislation. Therefore, national action regulating the placing on the market of such products would not be legally possible. Absence of EU level action to provide for specific rules on NGT plants would leave those products under the current GMO rules, which the Commission NGT Study of April 2021 showed not to be fit-for-purpose and in need of modification in order to enable those plants and related products to deliver and contribute to the sustainability goals of the Green Deal and F2F and Biodiversity strategies.

[3] https://europa.eu/european-union/about-eu/eu-in-brief_en

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

NGT plants are GMOs. The rules on the deliberate release into the environment and placing on the market of GMOs are already harmonised at EU level by Directive 2001/18/EC, Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003. Therefore, Member States' ability to enact national measures in those areas is framed within the limits and under the conditions allowed by that legislation.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

The problems and causes are the same across the national, regional and local levels of the EU regarding the current legislation not being fit for purpose and raising implementation and enforcement challenges. However, the problem of current legislation not being conducive to developing innovative beneficial products might have different intensity in different Member States and at regional and local level especially with regard the different impacts from climate change.

(e) Is the problem widespread across the EU or limited to a few Member States?

The planned measure aims to tackle three problems, i.e. the inadequacy of the current risk assessment and authorisation requirements for the variety of potential NGT plant products; implementation and enforcement challenges regarding NGT plants, in particular those for which an event-specific detection method cannot be provided; and the inability of the current GMO legislation to support the development of innovative beneficial products. All these problems have an EU dimension as they are directly caused by shortcomings in the existing Union legislation and concern the breeding and placing on the market of NGT plants, which are activities that can be carried out anywhere in the EU.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

The planned measure is aimed at making the current EU rules more fit-for-purpose for the diversity of NGT plants, facilitate their enforcement and enable the development of new plants and related products that can bring sustainable benefits to society. All the proposed rules will therefore make the implementation and enforcement tasks of Member States better adapted to the specificities of these plants and reduce rather than increase the demands on Member States' resources.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

There is a general agreement between Member States that clarification on the legal status of NGT products is needed (Council Decision (EU) 2019/1904). The views vary on the level of regulatory oversight required (e.g. whether a full risk assessment is needed for all NGT products, level of requirements for traceability and labelling).

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

The proposed legislation replaces existing Union legislation and thereby provides legal clarity for NGTs. This provides a certain, uniform regulatory framework allowing developers of NGTs in the EU to harness the potential benefits of NGTs. Economies of scale provided by the large EU market allow NGT developers and producers to benefit from cost advantages through efficient production.

(a) Are there clear benefits from EU level action?
A large market with a uniform regulatory regime is the best possible way support the achievement of the potential benefits of NGTs. It also ensures the same level of human health protection in the veterinary and phytosanitary fields throughout the EU.
(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?
Development of new traits and of new varieties is costly, leading to large sunk costs and to economies of scale, where costs can be spread over a larger production volume of the same product for a larger market with a uniform regulatory regime. The objectives can best be achieved with action at EU level.
(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?
The planned measure will replace existing Union legislation.
(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?
The planned measure will replace existing Union legislation. Member States will keep the same competences as today as regards the implementation of the planned measure (e.g. carrying out the environmental risk assessment of NGT plants, deciding on whether to authorise experimental releases).
(e) Will there be improved legal clarity for those having to implement the legislation?
The proposal addresses specific implementation challenges related to NGTs. These were raised in the Council Decision (EU) 2019/1904 that asked the Commission to carry out a study on regarding the status of novel genomic techniques under Union law, and a make proposal, if appropriate in view of the outcomes of the study. The EU GMO legislation currently requires applicants to provide an analytical laboratory method that is specific to the product for which they seek authorisation, i.e. it can both detect it and differentiate it from other products. If, however, the genetic alteration is not unique for the relevant product, a specific detection method cannot be provided. When the same alteration can be introduced by NGTs or conventional breeding methods, the detection method may be able to detect it, but will not allow determining whether the product is a GMO subject to the GMO legislation or not. In such cases, applicants will be unable to comply with an authorisation requirement, and other food chain operators and authorities will not be able to implement or enforce the legislation. Furthermore, plants produced by targeted mutagenesis and cisgenesis, which could also occur naturally or be produced by conventional breeding, need to comply with the traceability and labelling requirements of the EU GMO legislation. Consequently, in certain cases, plant products with similar genetic modifications might be subjected to different labelling and traceability requirements, depending on the breeding technique that was used to obtain them. The proposal addresses these challenges with requirements tailored to the specific characteristic of targeted mutagenesis and cisgenesis.
3. Proportionality: How the EU should act
3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the

proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

As discussed in Chapter 7.4 of the impact assessment accompanying this proposal, the measures proposed are limited to actions that need to be taken at EU level in order to achieve the objectives. The adapted risk assessment will be proportionate as it is intended that the criteria (and subsequent data requirements based on them) for the risk assessment of different NGT plants and derived food and feed are not stricter than necessary to ensure that the potential risks are properly identified and evaluated. This approach of adapted risk assessment would ensure proportionality for all NGT plants except those that could have been obtained naturally or by conventional breeding, where a verification regime is provided for. The verification regime is designed to reflect the equivalence of the NGT plant with plants that could occur naturally or be obtained by conventional breeding methods, and (complemented by data requirements linked to those criteria) is adequate to ensure proportionality.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

Based on the impact assessment, it is expected that the proposal will provide uniform, predictable and efficient rules, in the form of a Regulation, for the development and placing on the market of NGT plants and their products, creating a level playing field for operators and ensuring the availability to farmers, food operators and consumers in the entire EU of plant varieties that can cope with challenges of a global nature such as climate change and biodiversity loss. The initiative is furthermore expected to create significant cost reductions for operators, in particular breeders.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

Compared to individual action by Member States, EU intervention would provide uniform rules for the development and placing on the market of NGT plants and their food and feed products. Harmonised EU-wide rules on the marketing of such products would ensure a level-playing field for operators within the single market and a more predictable and efficient regulatory oversight. Furthermore, there is an urgent need to ensure availability to farmers, food operators and consumers of plant varieties that can cope with challenges of a global nature such as climate change and biodiversity loss, which have been further aggravated by the present geopolitical and energy crisis in Europe, and to secure food security in the future.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

The instrument chosen is a Regulation. The planned measure consists of fully harmonised criteria, requirements and procedures that will lead to decisions valid for the whole EU, ensuring the same level of protection of health and the environment and the availability of the products concerned across the EU. A Regulation appears to be the most appropriate legal instrument to embody such procedures, as well as to achieve a uniform implementation of the planned measure, which has an important internal market component.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum

standards or use a less stringent policy instrument or approach?)
The planned measure has an internal market component, and therefore it leaves limited scope for national action in order to ensure the smooth functioning of the internal market. Scope of national action is warranted, as in the current GMO framework, in deciding on the deliberate release of NGT plants for any purposes other than their placing on the market (e.g. field trials) and in the carrying out of the environmental risk assessment of such plants. As regards NGT products to which GMO authorisation, labelling and traceability requirements will not apply any more as a result of the proposed verification regime for certain NGT plants, Member States cannot adopt national rules on such products, as this would obstruct their free circulation in the internal market.
(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
The initiative is expected to create significant cost reductions for operators, in particular breeders. Total savings for notified plants are estimated to range from EUR 99 520 000 to 111 710 000 per year. Total savings for authorisations are estimated to range from EUR 0 to 51 825 000 per year.
(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
The proposal and the accompanying impact assessment take organic agriculture into account and take into consideration that the share of organic area differs between Member States. The mandatory coexistence measures thus remain on a general level to allow Member States to take into account the diversity of farm structures and farming systems, and the economic and natural conditions under which farmers operate in the Member States.