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SENSITIVE*

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 Directives 68/193/EEC, 1999/105/EC, 2002/53/EC, 2002/55/EC, and
Regulation (EU) 2017/625**

(Text with EEA relevance)

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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

New genomic techniques (NGTs)¹ provide new opportunities to alter the genetic material of an organism allowing the rapid development of plant varieties with specific characteristics. NGTs constitute a diverse group of techniques, each of which can be used in various ways to achieve different results. In many cases, these new techniques can lead to more targeted and precise changes than conventional breeding or established genomic techniques² and they may produce modifications that could or could not be obtained in nature or by conventional breeding.

The scope of this initiative are plants produced by targeted mutagenesis³ and cisgenesis⁴ (including intragenesis) and their food and feed. Targeted mutagenesis and cisgenesis are considered NGTs and are different from established genomic techniques because they have introduced novel features (e.g. higher precision and speed, introduction of genetic material from a crossable⁵ species). They do not introduce genetic material from a non-crossable species (transgenesis), which is the case with established genomic techniques. In certain cases, genetic modifications introduced by NGTs cannot be differentiated from other products by analytical methods, while this is always possible for established genomic techniques.

The choice of the scope is based on several reasons. Numerous advanced and early R&D applications concern plants, and several plant products are already on or very close to the market. Similar plants can be obtained in certain cases with conventional breeding and targeted mutagenesis and cisgenesis. Safety data are mainly available for plants obtained by targeted mutagenesis and cisgenesis, whereas it is at this stage difficult to draw relevant conclusions on other NGTs and applications in animals and micro-organisms.

The European Food Safety Authority (EFSA) concluded that, as regards risks for human and animal health and the environment, there are no new hazards specifically linked to targeted mutagenesis or cisgenesis compared to conventional breeding and transgenesis on a case-by-case basis, and due to how these novel techniques work, a lesser amount of data might be needed for the risk assessment of the relevant products compared to transgenesis. EFSA also concluded that in targeted mutagenesis, the potential for unintended effects, such as off-target effects, may be significantly reduced compared to transgenesis or conventional breeding.

There is significant demand in the EU and globally for NGT plants, because of their potential to contribute to addressing current challenges in the agri-food system.

¹ An umbrella term used to describe a variety of techniques that can alter the genetic material of an organism and that have emerged or have been developed since 2001, when the existing GMO legislation was adopted.

² Genetic modification techniques developed prior to 2001, when the existing GMO legislation was adopted.

³ An umbrella term used to describe newer techniques of mutagenesis that induce mutation(s) in selected target locations of the genome without insertion of foreign genetic material

⁴ Insertion of genetic material (e.g. a gene) into a recipient organism from a donor that is sexually compatible (crossable). The exogenous genetic material can be introduced without (cisgenesis) or with modifications/rearrangements (intragenesis).

⁵ Crossable means that there are no natural barriers to the interbreeding of two plants from the same or different species.

Climate change and biodiversity loss have put the focus on long-term resilience and the need for a transition to more sustainable agriculture and food systems. In this context, the European Green Deal's Farm to Fork Strategy⁶ specifically refers to NGTs as a possible tool for increasing sustainability, provided they are safe for consumers and the environment and bring benefits for society as a whole. NGTs have been identified as also potentially contributing to food security⁷.

The Covid-19 pandemic and Russia's war of aggression against Ukraine have also revealed the EU's external dependencies. In its Trade Policy Review Communication⁸, the Commission has stressed the role of trade openness within the concept of "Open Strategic Autonomy", recalling the importance of an open and fair trade with well-functioning, diversified and sustainable global value chains. NGTs are applied to a far larger range of crop species than established techniques and can thereby contribute, for example, to decreasing the EU's dependence on imports of plant proteins. Their technical accessibility (low entry and operating costs) could also support the diversification of developers and users, if access to and affordability of the technologies is assured.

The Council, in Decision (EU) 2019/1904 of 8 November 2019, requested the Commission to submit, by 30 April 2021, a study in light of the Court of Justice of the European Union's judgment in Case C-528/16⁹ regarding the status of novel genomic techniques under Union law, and a proposal (accompanied by an impact assessment), if appropriate in view of the outcomes of the study. The Commission delivered the requested study¹⁰ on 29 April 2021.

It concluded that there are strong indications that the current EU GMO legislation is not fit for purpose for NGT plants obtained by targeted mutagenesis or cisgenesis, and their food and feed, and that it needs to be adapted to scientific and technological progress. It identified the following problems:

- The authorisation procedure and risk assessment requirements of the current GMO legislation are not adapted to the variety of potential plant products that can be obtained by targeted mutagenesis and cisgenesis, and as a result are disproportionate or inadequate in certain cases.
- The current GMO legislation raises implementation and enforcement challenges for certain plants produced by targeted mutagenesis or cisgenesis, in particular NGT plants for which a specific detection method cannot be provided.
- The current GMO legislation applied to NGTs is not conducive to developing innovative beneficial products.

The problems identified above affect numerous operators across the agri-food system, especially breeders, the agricultural biotechnology innovation and research

⁶ A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system. COM/2020/381 final

⁷ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of The Regions, Safeguarding food security and reinforcing the resilience of food systems. COM (2022) 133 final.

⁸ Trade Policy Review - An Open, Sustainable and Assertive Trade Policy. COM/2021/66 final

⁹ Judgement of the Court of Justice of 25 July 2018, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, C-528/16, ECLI:EU:C:2018:583.

¹⁰ SWD(2021) 92

sector, farmers, bio-based industry, consumers, traders, and EU and national authorities. Regulatory oversight has been adapted to NGT plants in various non-EU countries already; there is a risk that the EU would be to a significant extent excluded from the technological developments and economic, social and environmental benefits potentially generated by these new technologies. This would lead in turn to the weakening of the EU's strategic autonomy.

Therefore, the objectives of the proposal are the following:

General objectives

- Maintain a high level of protection of human and animal health and of the environment, in accordance with the precautionary principle;
- Enable 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;
- Ensure the effective functioning of the internal market and enhance the competitiveness of the EU agri-food sector at the EU and global level, providing a level-playing field for its operators.

Specific objectives

- Procedures for the deliberate release and placing on the market ensure that NGT plants and their food and feed are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden;
- Deliberate release and placing on the market of NGT plants and their food and feed that feature a wide range of plant species and traits by various developers;
- NGT plants released or placed on the market feature traits that can contribute to a sustainable agri-food system.

- **Consistency with existing policy provisions in the policy area**

NGT plants fall under the scope of the current EU legislation on GMOs (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC). This proposal proposes new measures specifically for plants obtained by targeted mutagenesis and cisgenesis and their food and feed. It shares the objectives of the GMO legislation to ensure a high level of protection of human health and of the environment in accordance with the precautionary principle and to ensure the functioning of the internal market, while addressing the specificity of NGT plants. The proposal is coherent with the existing framework.

- **Consistency with other Union policies**

The proposal is part of the overall policies of the European Green Deal and related strategies: the Farm to Fork Strategy, the Biodiversity Strategy, the EU Strategy on adaptation to climate change and the planned initiative on a legislative framework for a sustainable food system, and it is consistent with their objectives.

NGT plants could be among the tools that contribute to the reduction target on the use and risk of pesticides set out in the Farm to Fork and Biodiversity Strategies and in the proposal for a regulation on the sustainable use of plant protection products¹¹.

¹¹ COM (2022)305 final, 2022/0196 (COD), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0305&qid=1674645473396>

The placing on the market and cultivation of plant and forest reproductive material derived from NGT plants will also have to comply with EU legislation on the marketing of seeds and other plant and forest reproductive material (PRM, FRM). The aim of the on-going revision of the PRM/FRM legislation is to ensure the availability of PRM and FRM of high quality and diversity of choice that is adapted to the current and projected future climatic conditions and that contributes to food security, sustainable production and protection of biodiversity and that are adaptable to climate change. The objectives of the NGT initiative and the PRM/FRM revision are therefore fully compatible.

This proposal shares objectives related to sustainable agriculture and food production with the EU legislation on organic production (Regulation (EU) 2018/848¹²) ('Organic Products Regulation'). However, this Regulation bans the use of GMOs and GM food and feed in organic production and the proposal maintains this approach for all NGT plants in its scope.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

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)) and a high level of human health protection in the veterinary and phytosanitary fields (Article 168(4)(b)).

- **Subsidiarity (for non-exclusive competence)**

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 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.

¹² OJ L 150, 14.6.2018, p. 1–92.

- **Proportionality**

The principle of proportionality has been reflected in the comparison of different options evaluated in the impact assessment. The proposal does not go beyond what is necessary to achieve its objectives.

The procedures for the deliberate release and placing on the market have been designed to cater for the diversity of risk profiles of products obtained with NGTs. The proposal provides for a notification procedure for NGT plants that could also occur naturally or be produced by conventional breeding and an authorisation procedure with a risk assessment adapted to the risk profile of the plant for all other products. They allow verifying that NGT plants and their products are as safe as their conventional counterparts, but are not stricter than necessary to ensure that the potential risks are properly identified and evaluated.

- **Choice of the instrument**

The policy instrument is a Regulation. The authorisation procedure as well as the notification system are based on fully harmonised criteria and requirements and procedures that should lead to the authorisation or acceptance of a notification 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 is the most appropriate legal instrument to embody such procedures and to achieve a uniform implementation of the policy intervention, which has an important internal market component.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

Two external studies on the EU GMO legislation were carried out for the Commission in 2010 (on GM food and feed)¹³ and 2011 (GMO cultivation and placing of GMOs on the market)¹⁴. They noted concerns that the legislative framework was only focused on risks and not suited for the EU to take advantage of new developments in biotechnology. They also referred to detection challenges resulting from the fact that products of targeted mutagenesis might not differ from those obtained via conventional breeding. The studies concluded that, as the rate of innovation in the global biotechnology sector was unlikely to slow down, ensuring that legislation remained relevant was likely to be an ongoing challenge, especially if the focus was on the techniques used rather than on the final products. The Commission NGT study of 2021 confirmed that the findings of the previous studies remain relevant today and that the challenges have grown, especially as regards plants produced by targeted mutagenesis and cisgenesis.

- **Stakeholder consultations**

A consultation strategy¹⁵ was prepared for this initiative, to gather views and evidence from several key stakeholder groups: the general public; operators active in the agri-food and feed system; operators of plant and bio-based industries active in sectors other than the agri-food sector; academic and research stakeholders active in

¹³ Food Chain Evaluation Consortium (2010)

¹⁴ GHK Consulting (2011)

¹⁵ https://food.ec.europa.eu/system/files/2022-09/sc_modif-genet_consultation-strategy-ngts.pdf

the field of biotechnology in general and agricultural/plant biotechnology; civil society/non-governmental organisations with interest in the topic; EU Member States' and third country public authorities; EU institutions; third country food safety agencies; other stakeholders such as consultancies and think-tanks with interest in the topic.

The following consultations took place:

- Feedback on the Commission's Inception Impact Assessment¹⁶ (24 September 2021 - 22 October 2021);
- Commission's public consultation (29 April 2022 - 22 July 2022)¹⁷;
- Targeted stakeholder survey (28 June 2022 – 05 September 2022);
- Interviews (June 2022 – December 2022);
- Focus groups on sustainability and traceability (22 and 23 September 2022).

The majority of stakeholders in academia/research, breeders, farmers (except organic and GM-free), other agri-food chain operators and public authorities called for the adaptation of the current legislation to a more enabling framework. Conversely, a majority of environmental organizations, non-governmental organisations (NGOs), and retail and consumer organisations support maintaining the status quo. The consultation activities attracted considerable citizen interest, reflecting different views (large campaign advocating for the preservation of the current system during the inception impact assessment; majority of citizens' contributions in the public consultation - and non-campaign replies in the inception impact assessment - favoured the adaptation of legislation).

Some respondents (majority academia/research institutions, biotechnology/bio-based industry, farming, feed, food processing/manufacturing, ornamental plants sector, plant breeding/seeds, plants protection products/fertilisers, trade sectors and public authorities) argue that the current risk assessment requirements are disproportionate for plants produced through targeted mutagenesis or cisgenesis; some of these respondents (public authorities, academic/research institutions, a majority of citizens in the public consultation) believe that risk assessment should have requirements adapted to the characteristics and risk profile of a plant, while others (biotechnology/biotech industry, ornamental plants sector, plant breeding/seeds, plant protection products/fertilisers, feed and trade sector) believe that risk assessment is not needed when these plants could have been produced through conventional plant breeding or classical mutagenesis. Conversely, a majority of non-governmental organisations (NGOs), consumer and environmental organisations consider that the current legislation is fit for purpose and effective in terms of risk assessment.

A significant share of stakeholders (agri-food chain operators, NGOs, consumer and environmental organisations) do not support inclusion of sustainability provisions in the future legislation and advocate a systemic approach to sustainability, suggesting that it should not be linked solely to the plant breeding process and in particular not to a single trait. However, such provisions are supported by a majority of

¹⁶ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

¹⁷ 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

academic/research institutions, citizens, as well as nearly half of the public authorities.

In terms of sustainability, traits affecting the better use of resources, abiotic stress tolerance (e.g., drought, heat), and biotic stress (e.g. plant pests) are favoured, as well as yield or other agronomic characteristics and better composition (e.g., better content of nutrients or lower content of toxic substances/allergens), while herbicide/insecticide tolerance and quality-related characteristics (e.g. colour, flavour) score lowest.

Responses regarding traceability and information for plants produced by targeted mutagenesis and cisgenesis vary. Consumer organisations and the majority of environmental organisations, NGOs, the organic and GM-free sectors call for physical labels on the final product; remaining stakeholders prefer alternative solutions such as public databases and registries. Furthermore, the view that transparency about the technique is unnecessary for NGT plants that could have been obtained conventionally was expressed by some academic/research institutions, and the majority of farmers (except organic and GM-free), biotechnology/biotech industry and plant breeding/seeds sectors.

Coexistence with the organic and GM-free sectors has also been raised prominently in the consultations. The organic and GM-free sectors call for the status quo to be maintained, with NGT plants remaining subject to the current GMO requirements, in particular as regards traceability and labelling, and for strengthened provisions on coexistence and harmonised rules on liability. Other stakeholders (in particular from the research, breeding and farming sectors) consider that NGT plants, when they could have been obtained conventionally, should be treated as conventional products including for the purposes of organic production.

The issue of patents on NGTs is raised by many stakeholders. Concerns have been expressed by breeders and farmer organisations on the need to ensure breeders' access to patented genetic material and the accessibility of PRM for farmers, and also in relation to the fact that certain NGT plants are undistinguishable from plants obtained by conventional breeding.

- **Collection and use of expertise**

The following external studies were conducted to support the impact assessment:

- Technopolis Group, Arcadia International and Wageningen UR. Study to support the impact assessment of legislation for plants produced by certain new genomic techniques. Impact Assessment Report. XXX 2023
- JRC case studies to analyse the potential economic, environmental and social (health) impacts of selected NGT plants in the development pipeline¹⁸; the impact assessment also relies on the two JRC reports (on market applications)¹⁹

¹⁸ Schneider, K., Barreiro-Hurle, J., Kessel, G., *et al.*, 2023. Economic and environmental impacts of disease resistant crops developed with cisgenesis. EUR 31355, Publication office of the European Union, Luxembourg; Sánchez, B., Barro, F., Smulders, M. J. M. *et al.* 2023. Socioeconomic impact of low-gluten, celiac-safe wheat developed through gene editing, EUR 31380 EN, Publications Office of the European Union, Luxembourg.

¹⁹ Parisi, C. and Rodriguez Cerezo, E., Current and future market applications of new genomic techniques, EUR 30589 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-30206-3, doi:10.2760/02472, JRC123830.

and latest scientific developments relating to NGTs²⁰) supporting the Commission NGT study.

- Two mandates were given to EFSA to support this impact assessment (statement on criteria for risk assessment²¹ and update of EFSA’s 2012 opinion on cisgenesis²²). Other, previous relevant EFSA opinions (referenced in the impact assessment) also underpin the impact assessment.

- **Impact assessment**

This proposal is based on an impact assessment which received a positive opinion from the Regulatory Scrutiny Board on 26 May 2023²³.

After screening the potential measures, they were grouped into five policy options):

1. **Baseline:** plants obtained by targeted mutagenesis and cisgenesis would continue to be subject to the current requirements of the GMO legislation (risk assessment, authorisation, traceability and labelling) with no change.
2. **Option 1:** plants obtained by targeted mutagenesis and cisgenesis would require (as today) an authorisation. The risk assessment would be adapted to cater for their diverse risk profiles and to address detection challenges. Traceability and labelling would be maintained as in the baseline.
3. **Option 2:** plants obtained by targeted mutagenesis and cisgenesis would require (as today) an authorisation. The risk assessment would be adapted to cater for their diverse risk profiles and to address detection challenges. Measures would be introduced to incentivise plant products that could contribute to a sustainable agri-food system. Traceability would be maintained as in the baseline. Several labelling alternatives were considered: a GM label accompanied by a sustainability label, a factual statement on the trait introduced, or no GMO label if the NGT trait has the potential to contribute to sustainability.
4. **Option 3:** plants obtained by targeted mutagenesis and cisgenesis would require (as today) an authorisation. The risk assessment would be adapted to cater for their diverse risk profiles and to address detection challenges. Traceability and labelling would be maintained as in the baseline. In addition, applicants for authorisation would be required to show that the introduced trait is not detrimental to sustainability.
5. **Option 4:** notification procedure for plants obtained by targeted mutagenesis or cisgenesis that could also occur naturally or be produced by conventional breeding. Such plants would be treated similarly to conventional plants and would not require authorisation, risk assessment, traceability and labelling as

²⁰ Brothhaerts, W., Jacchia, S., Angers, A. *et al.*, New Genomic Techniques: State-of-the-Art Review, EUR 30430 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-24696-1, doi:10.2760/710056, JRC121847; European Commission, Directorate-General for Research and Innovation, New techniques in agricultural biotechnology, Publications Office, 2017, <https://data.europa.eu/doi/10.2777/574498>

²¹ EFSA Panel on Genetically Modified Organisms, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. <https://doi.org/10.2903/j.efsa.2022.7618>

²² EFSA Panel on Genetically Modified Organisms, 2022. Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 2022;20(10):7621, 33 pp., <https://doi.org/10.2903/j.efsa.2022.7621>

²³ [\[add link\]](#)

GMOs; a transparency register would be established for these plants. This option is intended to apply in combination with the baseline or options 1, 2 or 3 (for plants not fulfilling the criteria for notification).

The preferred option is a combination of **option 4** for products that could also occur naturally or be produced by conventional breeding and of **option 2** for all other products. This combination ensures to the largest possible extent that NGT plants and their food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden, that NGT plants and derived food/feed products featuring a wide range of plant species and traits by various developers are placed on the market and that these plants feature traits that can contribute to a sustainable agri-food system. The preferred option creates an enabling framework to meet the demands of farmers for the development of new varieties and the commercialisation plant reproductive material with beneficial traits to respond to the constraints of their agroecological context.

The notification procedure achieves safety while ensuring that requirements are proportionate to risk. It has by far the strongest positive impact on the development and placing on the market of NGT products, as it results in a higher degree of simplification and reduction of administrative burden for applicants and authorities. This option also shows the highest potential to facilitate the contribution of NGTs to sustainability of the agri-food system, in the light of the development pipeline. It is the most advantageous for SMEs, as administrative and compliance costs will substantially decrease, it has the strongest impact on competitiveness and would be least disruptive of trade.

An authorisation procedure with adapted risk assessment for NGT plants not covered by the notification procedure ensures safety, while ensuring proportionality by adapting the data requirements for risk assessment. It would bring an additional improvement concerning attractiveness to develop such NGT plants in the EU. Regulatory incentives would help steering the development of NGTs towards traits with sustainability potential and would support the competitiveness of SMEs.

NGT plants subject to authorisation would also remain subject to traceability and labelling as GMOs. The existing GM label will be complemented with the possibility to inform of the purpose of the genetic modification to allow operators and consumers to make informed choices. This is expected to drive market demand for products with beneficial traits. The content of this statement on the purpose of the modification will be determined in the authorisation, but its use will be voluntary for operators, to address concerns identified during the impact assessment linked to its burden if made mandatory (especially in certain circumstances where it would require further segregation, e.g. for commodity consignments which are mixed or processed with others). In any case, the GM label remains mandatory.

As a variation of the notification procedure as designed in the impact assessment, herbicide-tolerant NGT plants, even if fulfilling the notification criteria, will remain subject to authorisation and related requirements in order to be able to assess their impacts on human, animal health and the environment in the medium and long term. There is evidence showing that herbicide-resistant weeds may arise from the combined use of herbicide-tolerant varieties and overuse of the associated herbicide with potential health and agroecosystem impacts. This choice further contributes to the achievement of the initiative's objective of contribution to the sustainability

objectives of the European Green Deal and of the Farm to Fork and Biodiversity Strategies.

Two possible sub-options were considered for NGT products that, after the notification procedure, meet the criteria to be considered equivalent to conventional breeding: to treat them as GMOs or as conventional products for the purposes of organic production. Based on the majority position of the organic sector, the former scenario has been chosen. As a consequence, these NGT plants will remain prohibited in organic production. To allow choice at the beginning of the supply chain to support maintaining organic production free from NGTs and preserve consumer trust, in addition to the information in public registries considered in the impact assessment, an additional measure is proposed: the indication of the use of NGTs in the labelling of seeds (PRM/FRM).

In full alignment with the ‘do no harm’ principle, the preferred option includes procedures to ensure that NGT plants are only released or placed on the market if they are considered as safe as their conventional counterparts.

Under the European Climate Law²⁴, it has been acknowledged that a better use of genetic diversity and non-harmful plant genetic resources for adaptation based on the latest science is among the urgently needed solutions to help farmers and land managers tackle climate risks. In this context, by enabling the development and marketing of NGTs, the current proposal responds to the objective of climate neutrality.

The proposal has the potential to contribute towards the implementation of several SDGs: SDG2 (End hunger), SDG3 (Good Health and Well-being), SDG9 (Industry, Innovation and Infrastructure); SDG12 (Responsible consumption and production), SDG13 (Take urgent action to combat climate change and its impacts) (see section 1.1 of the impact assessment).

The impact assessment was screened by the RSB and received a positive opinion with reservations on 26 May 2023²⁵. The comments of the Board concerned the need for further information on the notification procedure and criteria, further clarity in the preferred option regarding the use in organic production of NGT plants/products fulfilling the notification criteria, and a comprehensive overview of benefits and costs. They have all been addressed (see box 1 in Annex 1 of the impact assessment).

- **Regulatory fitness and simplification**

The proposal represents an important simplification of the current authorisation procedure, notably through the adapted risk assessment and the new notification procedure for products that fulfil the criteria for equivalence to conventional breeding, and will lead to a considerable reduction in costs for developers of NGTs and to the accelerated development of new products. NGTs are considered relatively accessible tools for plant breeding compared to established genomic techniques. In this regard, NGTs are expected to lead to a lowering of technological barriers to entry of the plant breeding sector, benefitting SMEs in particular.

Notification: Compared to the current situation, breeders are expected to experience a considerable reduction in administrative burdens and in compliance costs, primarily due to the change in data requirements for the notification (data to show compliance

²⁴ Regulation (EU) 2021/1119

²⁵ [\[add link\]](#)

with the notification criteria instead of data for a risk assessment and detection method).

Authorisation: Regulatory incentives linked to the authorisation of NGT plants are expected to bring positive impacts in terms of steering research and development towards traits with sustainability potential by facilitating access to and navigation of the regulatory framework, especially for SMEs, supporting their competitiveness. Compared to the current situation, breeders are expected to experience a reduction in compliance costs linked to the data requirement for the adapted risk assessment. The savings can be in the range from negligible to around 85% of the current costs.

The proposal is expected to support competitiveness of the European plant breeding and farming sectors. In major trading partners of the EU, NGT plants, and their food and feed, that can also result from conventional breeding are not subject to GMO regimes. The European seed sector is the largest exporter in the global seed market and the ability of using innovative technologies is a prerequisite for maintaining competitiveness. The proposal is also expected to have an impact on strategic autonomy and resilience of the EU food system as NGTs are expected to be applied to a large range of crop species and traits by a diverse set of actors.

- **Fundamental rights**

The initiative is based on the application of the precautionary principle and the proposal contributes to achieving a high level of human health protection and is therefore consistent with Article 35 of the Charter of Fundamental Rights of the EU. Regulatory oversight procedures apply to ensure that only NGT plants that are considered as safe for human health and for the environment as their conventional counterparts are released or placed on the market. Labelling of products subject to the requirements of risk assessment and authorisation remains in order to guarantee consumers' right to information (Article 38 of the Charter).

Adapting data requirements to the risk profile of a NGT product will reduce the complexity, duration and costs of the application for authorisation and the notification procedure will nearly eliminate administrative and compliance costs for operators. This will support the freedom to conduct business of both SMEs and large operators in the agri-food, biotechnology and research sectors (Article 16 of the Charter).

4. **BUDGETARY IMPLICATIONS**

The budgetary implications are set out in the legislative financial statement attached to the proposal.

Budgetary implications are mainly related to additional tasks to be carried out by the EFSA in terms of providing scientific and administrative as regards the new, adapted risk assessment, the notification procedure for certain NGT plants and pre-submission advice.

In addition, new IT tools and database are also needed to implement the legislation. This will be done through integration of the new tools in the already existing Food Innovation Platform (FIP) and E-Submission Food Chain (ESFC) system.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

In order to monitor and evaluate the progress made towards the objectives of this proposal and its economic, environmental and social impacts, a first monitoring report should be presented no sooner than 3 years after the first products have been notified/authorised, to ensure that enough data is available after full implementation of the new legislation, and at regular intervals thereafter. An evaluation should be carried out no sooner than 2 years after the first monitoring report has been published.

- **Explanatory documents (for directives)**

n/a

- **Detailed explanation of the specific provisions of the proposal**

Title I (Arts. 1-4) lays down the subject-matter, scope and the principle of *lex specialis vis-a-vis* the GMO legislation. It makes the deliberate release and placing on the market of NGT plants subject to one of two procedures: notification to establish equivalence with conventional products (Title II) or authorisation in accordance with Directive 2001/18 or Regulation 1829/2003 (Title III).

Title II provides for a notification procedure to verify whether products obtained by targeted mutagenesis or cisgenesis could also occur naturally or by conventional breeding, based on the criteria of Annex I. It excludes from this regulatory route herbicide-tolerant NGT plants. NGT plants determined to meet the notification criteria ('category 1 NGT plants') are exempted from the requirements of the GMO legislation and subject to the provisions applicable to conventional products. However, they are treated as GMOs for the purposes of organic production (Art. 5)

In case of notification prior to field trials, the verification of the criteria is done at Member State level; the national decision has EU-wide effects and applies to the product for any use (field trials and placing on the market) (Art. 6). For the placing on the market where no field trials have been carried out in the EU, including imports, the decision is taken by the Commission, following verification of the criteria by EFSA (Art. 7).

Transparency about category 1 NGT plants is ensured in a public database, through the labelling of seeds (Arts. 10-11) and in the variety catalogues of the PRM/FRM legislation (Arts. 36-39).

Title III applies to products which do not meet the criteria of the Title II procedure ('category 2 NGT plants'). The procedures of the GMO legislation apply, with adaptations: chapter 1 (Art. 15) adapts the authorisation procedure of Directive 2001/18 for the deliberate release for purposes other than placing on the market; chapter 2 (Arts. 16-20) adapts the notification procedure of Directive 2001/18 for the placing on the market of products other than food and feed, and chapter 3 (Arts. 21-24) adapts the procedures of Regulation 1829/2003 for the placing on the market of food and feed. The main adaptations are a risk assessment based on Annex II; waiver of the requirement for an event-specific detection method if the applicant can justify that developing a detection method that can, not only detect, but also differentiate a specific NGT product from conventional ones is not technically possible; and the possibility to tailor monitoring and renewal requirements.

Regulatory incentives (Art. 25) apply for category 2 NGT plants containing traits listed in Annex III Part 1 (traits that could contribute to the overall performance of varieties as regards sustainability), provided they do not contain traits listed in Annex III Part 2 (herbicide-tolerant).

Category 2 NGT plants and products remain subject to traceability and labelling as a GMO with the possibility to add a factual statement on the intended purpose of the genetic modification (Art. 26). Member States are required to adopt coexistence measures to avoid the unintended presence of such NGT plants in other products (Art. 27). The possibility for Member States to restrict or prohibit cultivation pursuant to Directive 2001/18 does not apply to such NGT plants.

Title IV contains the provisions on delegated and implementing acts (Arts. 29-32), guidance (Art. 33), monitoring, reporting and evaluation (Art. 34) and amendments of other legislation (Arts. 35-40).

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 Directives 68/193/EEC, 1999/105/EC, 2002/53/EC, 2002/55/EC, and Regulation (EU) 2017/625

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article [...] thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Since 2001, when the centerpiece of the current Union legislation on genetically modified organisms (GMOs) was adopted, significant progress in biotechnology has led to the development of new genomic techniques (NGTs), most prominently gene editing techniques that enable changes at precise locations to be made to the genome.
- (2) NGTs constitute a diverse group, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications similar to what can be obtained by conventional breeding methods or in organisms with more complex modifications.
- (3) NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal ⁽³⁾ and of the ‘Farm to Fork’ ⁽⁴⁾ and Biodiversity ⁽⁵⁾ Strategies and to global food security ⁽⁶⁾ and to the EU’s strategic autonomy ⁽⁷⁾.

¹ OJ C [...], [...], p. [...].

² OJ C [...], [...], p. [...].

³ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM/2019/640 final.

⁴ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM/2020/381 final.

⁵ Communication from the Commission to the European Parliament the Council, the European Economic and Social Committee and the Committee of the Regions, EU Biodiversity Strategy for 2030: Bringing nature back into our lives, COM/2020/380 final.

⁶ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Safeguarding food security and reinforcing the resilience of food systems, COM (2022) 133 final; Food and Agriculture

- (4) The type of plant applications that feature prominently in the research and development pipeline, coupled with the fairly easy and speedy applicability of these new techniques, could deliver benefits to farmers, consumers and to the environment. Research using these techniques concerns a wider variety of crops and traits compared to the transgenic organisms authorised in the EU or globally so far. This includes plants with improved tolerance or resistance to plant diseases and pests, plants with improved tolerance or resistance to climate change effects and environmental stresses, improved nutrient and water-use efficiency in plants, plants with higher yields and resilience and improved quality characteristics.
- (5) The deliberate release, including the placing on the market, of organisms obtained by NGTs, including products consisting of or containing them, as well as the placing on the market of food and feed produced from them, are so far subject to the Union's GMO legislation, notably Directive 2001/18/EC of the European Parliament and of the Council ⁽⁸⁾, Regulations (EC) No 1829/2003 ⁽⁹⁾, and 1830/2003 ⁽¹⁰⁾ of the European Parliament and of the Council. Although mutagenesis techniques are exempted from the requirements of this legislation, the judgment of the Court of Justice of 25 July 2018 in Case C-528/16, *Confédération paysanne and Others* ⁽¹¹⁾ clarified that this exemption does not apply to new mutagenesis techniques.
- (6) The Council, in Decision (EU) 2019/1904 of 8 November 2019, requested the Commission to submit a study regarding the status of novel genomic techniques under Union law, in the light of that judgment. The Commission's study on new genomic techniques ⁽¹²⁶⁾ concluded that GMO legislation is not fit for purpose for certain plant applications of new genomic techniques.
- (7) The authorisation procedure and risk assessment requirements are not adapted to the variety of potential organisms and products that can be obtained by targeted mutagenesis, cisgenesis and intragenesis, and as a result they can be disproportionate or inadequate. The study showed that this is particularly the case as regards plant applications, where considerable scientific evidence is available. The legislation also raises implementation and enforcement challenges for certain NGT organisms and their products because, in certain cases, genetic modifications introduced by NGTs are indistinguishable from natural mutations or from modifications introduced by conventional breeding methods with analytical methods, while this is generally

Organisation of the United Nations (FAO), 2022, Gene editing and agrifood systems, Rome, ISBN 978-92-5-137417-7.

⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Trade Policy Review - An Open, Sustainable and Assertive Trade Policy, COM(2021)66 final.

⁸ 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 (OJ L 106, 17.4.2001, p. 1).

⁹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

¹⁰ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

¹¹ Judgment of the Court of Justice of 25 July 2018, *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, C-528/16, ECLI:EU:C:2018:583, paragraphs 39 to 54.

¹² Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) 92 final.

possible for transgenesis. The GMO legislation applied to NGTs so far is also not conducive to developing innovative beneficial products that could contribute to sustainability, food security and resilience goals.

- (8) It is therefore necessary to adopt a specific legal framework for certain NGT organisms and their products.
- (9) This Regulation should be limited to NGT applications in plants, i.e. organisms in the taxonomic groups archaeplastida or phaeophyceae, leaving microorganisms and animals out of the scope, based on the current scientific knowledge. For the same reason, this Regulation should only cover plants obtained by targeted mutagenesis, cisgenesis and intragenesis (hereinafter, ‘NGT plants’), but not by other new genomic techniques. Such NGT plants do not carry genetic material from a non-crossable species. The use of new genomic techniques introducing genetic material from a non-crossable species (transgenesis) should remain subject to the current GMO legislation, since the resulting plants might bear specific hazards associated to the transgene and there is no indication that current requirements in the GMO legislation need adaptation in the same way as for NGT plants.
- (10) The framework should share the objectives of the GMO legislation to ensure a high level of protection of human and animal health and of the environment in accordance with the precautionary principle and to ensure the smooth functioning of the internal market, while addressing the specificity of NGT plants. In addition, it should enable 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 enhance the competitiveness of the EU agri-food sector at the EU and global level.
- (11) This Regulation follows a *lex specialis – lex generalis* approach. It introduces specific provisions for NGT plants and their products. Where there are no specific rules in this Regulation, NGT plants and their products should be subject to the rules which apply to GMOs.
- (12) Risk profiles associated to NGT plants are very diverse, from plants with risk profiles similar to conventionally bred plants to plants with various types and degrees of hazards and risks that might be similar to those of plants obtained by established techniques of genetic modification. This Regulation should therefore adjust the level of regulatory oversight according to this variety of potential risks posed by NGT plants and products.
- (13) This Regulation should thus distinguish between two categories of NGT plants. For NGT plants that could also occur naturally or be produced by conventional breeding and not harbour traits that can have a negative impact on sustainability, this Regulation should provide for a procedure determining that the genetic modifications made and traits achieved are indeed of such a nature (notification procedure), thereby classifying them as category 1 NGT plants. For all other NGT plants (category 2 NGT plants), it should provide for adaptations of the different authorisation procedures of the current GMO legislation, in particular a risk assessment adapted to the risk profile of the plant.
- (14) The notification procedure should rely on science-based criteria to verify whether a plant could also occur naturally or be produced by conventional breeding. These criteria should cover the type and extent of plant genetic modifications that can be observed in nature or with conventional breeding techniques. They should aim at ensuring that only plants with a risk profile comparable to that of naturally occurring

or conventionally bred plants are not subject to the requirements of the current GMO legislation. They should be applicable in a clear and uniform manner thus providing legal certainty to operators and authorities. To this end, the criteria should be complemented by thresholds for both size and number of modifications, ensuring that plants featuring complex sets of modifications continue to be under the regulatory oversight of the GMO legislation. The criteria should be subject to possible revision in view of scientific and technical progress.

- (15) Evidence shows that herbicide-resistant weeds may arise from the combined use of herbicide-tolerant varieties and overuse of the associated herbicide with potential health and agroecosystem impacts ⁽¹³⁾. The Farm to Fork Strategy proposes specific targets to reduce the use of – and risk from – chemical pesticides and more hazardous pesticides by 2030. EU regulation in this area is a crucial tool to achieve the targets outlined in the Farm to Fork Strategy and should therefore be strengthened. This Regulation should also contribute to these objectives, by maintaining appropriate regulatory oversight on NGT plants with traits that can have a negative impact on environmental, economic and social sustainability. These plants should therefore remain subject to authorization, traceability, labelling and monitoring requirements in order to be able to assess their impacts on human and animal health and the environment in the medium and long term.
- (16) NGT plants that, after a notification procedure, have obtained a determination that they meet the criteria of equivalence to conventional plants and that they do not harbour the aforementioned traits, the progeny derived from such plants by way of traditional breeding (jointly referred to as ‘category 1 NGT plants’) and their respective products should not be subject to the rules and requirements of the GMO legislation. This should include GMO related provisions in legislation not specific to GMOs and the use of plant cells under containment conditions. However, the GMO legislation should apply in the absence of such a determination, comprehensive of the penalties for the deliberate release of GMOs without authorisation.
- (17) Despite the fact that category 1 NGT plants will not be subject to the rules and requirements of the EU GMO legislation, they should remain subject to the prohibition of use of GMOs in organic production to meet the demand of the sector.
- (18) Operators should be able to seek determination of whether a NGT plant meets the conditions for category 1 NGT plants either prior to conducting experimental releases (deliberate release for any other purpose than placing on the market) or prior to the placing on the market of a NGT plant or related products, because not all NGT plants undergo field trials in the EU. Since the criteria are unrelated to the type of activity involving the NGT plant, the determination that a NGT plant meets the criteria should have the same effect of exempting the plant from the requirements of the GMO framework regardless of the stage at which the determination of equivalence is made, and a determination made prior to carrying out field trials should also be valid for the placing on the market of that NGT plant.
- (19) While the effects of the procedure determining that the conditions for category 1 NGT plants are met should be the same at both stages, the determination procedure should be adapted to the specificities of each stage. In view of the high uncertainty existing at the field trial stage about the product reaching the market and the likely involvement of smaller operators in such releases, the procedure of determination of equivalence at

¹³ Food and Agriculture Organisation of the United Nations (FAO), 2022, Gene editing and agrifood systems, Rome, ISBN 978-92-5-137417-7, p. 17–18.

that stage should be made in the first instance by national authorities as this would be less administratively burdensome, and a decision should only be taken at EU level in case of disagreement between Member States. Prior to the placing on the market of NGT plants which have not yet been classified as category 1 NGT plants by way of a notification procedure, the notification procedure should be conducted at EU level from the outset in order to ensure the smooth functioning of the internal market.

- (20) The competent authorities of the Member States, the Commission and the Authority should be subject to strict deadlines to guarantee a smooth processing of notifications.
- (21) Decisions to determine whether a NGT plant meets the criteria of equivalence to a conventional plant are of technical nature and do not involve any risk assessment or risk management considerations. Therefore such implementing decisions should be adopted by the advisory procedure.
- (22) To achieve the goal of ensuring the effective functioning of the internal market, category 1 NGT plants and related products should benefit from the free movement of goods, provided they comply with the requirements of other Union law.
- (23) Category 1 NGT plants should remain subject to any regulatory oversight that applies to conventionally bred plants. As is the case for conventional plants and products, those NGT plants and related products will be subject to the applicable sectoral legislation on seed and other plant reproductive material, food, feed and other products, and horizontal frameworks, such as the nature conservation legislation and environmental liability. In this regard, NGT food falling out of the scope of Regulation 1829/2003 as a consequence of the equivalence determination but featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances of the food will fall into the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council ⁽¹⁴⁾ and will be risk assessed in that context.
- (24) Provision should be made to ensure transparency and freedom of choice to breeders and farmers as regards the use of category 1 NGT varieties, to support production chains that wish to remain free of NGTs and to preserve consumer trust. To this end, NGT plants that have obtained a determination that they meet the conditions for category 1 NGT plants should be listed in a publicly available database. Seed and other plant reproductive material of category 1 NGT plants should be labelled as NGT when supplied to a third party, irrespective of their use for breeding or cultivation purposes. Varieties and forest basic material obtained from them should be indicated as NGT varieties/basic material in the registers subject to the Regulations on plant reproductive material and forest reproductive material [*Publications office please insert reference to proposal for a Regulation on plant reproductive material and to Regulation on forest reproductive material, PLAN/2020/7576*].
- (25) As regards category 2 NGT plants, i.e. plants that do not fulfil the criteria to be classified as category 1 NGT plants, the procedures under Directive 2001/18 and Regulation 1829/2003 should be adapted to the specificity of these NGT plants and products.

¹⁴ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

- (26) Category 2 NGT plants should remain subject to authorisation under Directive 2001/18 and Regulation 1829/2003 prior to their release or placing on the market. However, given the wide variety of these NGT plants, the amount of information necessary for the risk assessment will vary on a case-by-case basis. Based on the Authority's statement 'Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis' ⁽¹⁵⁾, considerations on the history of safe use, familiarity and the function and structure of the modified/inserted sequence(s) may assist in determining the type and amount of data required to perform the risk assessment of these NGT plants.
- (27) The requirement for a detection method able to identify and quantify modifications should be waived if duly justified by the applicant, since when the introduced modifications are non-unique, they do not allow the differentiation of the NGT plant from conventional plants, as explained in the European Network of GMO Laboratories' report on the detection of food and feed plant products obtained by new mutagenesis techniques ⁽¹⁶⁾. [add new EURL report when published]
- (28) Monitoring requirements should be adapted to the category 2 NGT plant concerned. A monitoring plan should not be required if the NGT plant is unlikely to pose potential risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or the environment. The decision should be based on the outcomes of the environmental risk assessment, the experience in field trials and the intended use of the NGT plant as well as familiarity and history of safe use of its modifications. On the same grounds, after a first renewal, the authorisation should be valid for an unlimited period, unless decided differently at the time of that renewal based on the risk assessment and the available information on the NGT plant concerned, subject to reassessment when new information has become available in accordance with Article 20 of Directive 2001/18/EC and Article 22 of Regulation 1829/2003.
- (29) To increase transparency, operators should be allowed, on a voluntary basis, to complement the labelling as GMO with information on the purpose of the genetic modification. In order to enable operators to use this complementary labelling in a harmonised manner and avoid misleading or confusing indications, a proposal for such a labelling should be provided in the application for authorisation and should be specified in the authorisation decision.
- (30) Regulatory incentives should be offered to (potential) applicants for category 2 NGT plants containing traits with the potential to contribute to a sustainable agri-food system, in order to steer the development of category 2 NGTs towards such traits. Certain incentives should apply to all applications for products containing such traits, by assessing them in an accelerated procedure (limited to food and feed products) and by providing pre-submission advice on risk hypotheses to be tested to help developers prepare the dossier for the purpose of the environmental and health risk assessments, without affecting the general provisions in Article 32a, 32b and 32c of Regulation

¹⁵ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firkbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Fernandez A, Gennaro A, Papadopoulou N, Raffaello T and Schoonjans R, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. <https://doi.org/10.2903/j.efsa.2022.7618>.

¹⁶ European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289). [add new report]

(EC) No 178/2002¹⁷). Additional incentives should be afforded when the applicant is a small or medium-sized enterprise (SME), to promote access to the regulatory procedures by small players and to support diversification of the food system in terms of actors as well as crop species and traits targeted by NGTs, by granting fee waivers for the validation of detection methods to (SMEs) and more extensive pre-submission advice covering also the design of studies to be carried out for the purpose of risk assessment.

- (31) The criteria to trigger these incentives should focus on broad trait categories with the potential to contribute to sustainability (such as those linked to tolerance or resistance to biotic and abiotic stresses, improved nutritional characteristics or increased yield). A narrower definition of traits to focus on specific issues would fail to address local and regional specificities. Based on the goal of this Regulation to contribute to the targets of the Farm to Fork Strategy to reduce the use of – and risk from – chemical pesticides and more hazardous pesticides, incentives should not be available to plants featuring herbicide-tolerant traits obtained with NGTs.
- (32) As per the definition of the term ‘NGT plant’, category 2 NGT plants do not harbour genes from non-crossable species, and their cultivation is not expected to impact national, regional and local specific conditions and policy objectives to the same extent as transgenic crops. Therefore, the possibility for Member States to adopt measures restricting or prohibiting the cultivation in all or part of their territory set out in Article 26b of Directive 2001/18/EC would appear not justified for such plants. It would lead to uncertainty and negatively impact the interest of developers to apply for authorisation, and consequently the realisation of NGT plants potential to contribute to sustainability goals.
- (33) The adaptations to the authorisation procedure are expected to result in a higher uptake of category 2 NGT plants compared to transgenic plants. That renders necessary for Member States’ public authorities to define coexistence measures to balance the interests of conventional, organic and GM producers and thereby allow consumers and producers a choice between different types of production.
- (34) Given the novelty of the techniques, it will be important to monitor closely the uptake of NGT products and the accompanying impacts on human and animal health, the environment and environmental, economic and social sustainability. Information should be collected regularly and the Commission should carry out an evaluation of this Regulation to measure the progress made towards its objectives.
- (35) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by providing uniform rules to operators so that NGT plants and food and feed produced from them may circulate freely within a smooth-functioning internal market, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (36) As science and technology evolve very rapidly in this field, in order to provide a future-proof legislation, the power to adopt acts in accordance with Article 290 of the

¹⁷ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031 1.2.2002, p. 1).

Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the criteria to verify whether a plant could also occur naturally or be produced by conventional breeding and the adaptation of the lists of traits with a potential to contribute to sustainability or to have a negative impact on sustainability, respectively, to scientific and technological progress and new scientific evidence relating to sustainability implications of traits.

- (37) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁽¹⁸⁾. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the information required to demonstrate that a plant is a NGT plant, as regards the preparation and the presentation of the notification for determination that the criteria set out in Annex I are met, and as regards the methodology and information requirements for the environmental and health risk assessments. Those powers should be *exercised* in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽¹⁹⁾.
- (39) The Commission should regularly collect information in order to assess the performance of the legislation against the objectives it pursues and in order to inform an evaluation of the legislation. A broad set of indicators have been identified [*ref to IA SWD*] and should be periodically reviewed by the Commission. The indicators should support monitoring of potential risks to health or the environment, impact of NGT plants on environmental, economic and social sustainability as well as impacts on organic agriculture and on consumers acceptance of NGT products. A first monitoring report should be presented no sooner than three years after the first products have been notified/authorised, to ensure that enough data is available after full implementation of the new legislation, and at regular intervals thereafter.
- (40) The Commission should carry out an evaluation of this Regulation no sooner than two years after the first monitoring report has been published, in order to allow for the impacts of the first notified/authorised products to fully materialize.
- (41) The legislation on seed and other plant reproductive material, Council Directives 68/193/EEC ⁽²⁰⁾, 1999/105/EC⁽²¹⁾, 2002/53/EC⁽²²⁾ and 2002/55/EC⁽²³⁾ should be

¹⁸ OJ L 123, 12.5.2016, p. 1

¹⁹ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

²⁰ Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15).

²¹ Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17).

²² Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

²³ Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

amended to identify, as a further measure of transparency, varieties of category 1 NGT plants in the catalogues of varieties and forest basic material of such NGT plants in the registers of basic material subject to that legislation.

- (42) Certain references to provisions of the GMO legislation in Regulation (EU) 2017/625 of the European Parliament and of the Council ⁽²⁴⁾ need to be amended to include the specific provisions in this legislation applicable to NGT plants,

HAVE ADOPTED THIS REGULATION:

TITLE I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down specific rules for the deliberate release into the environment, including the placing on the market, of plants obtained by certain new genomic techniques ('NGTs') and of products containing or consisting of such plants, and for the placing on the market of food and feed produced from such plants.

Article 2

Scope

This Regulation applies to:

- (a) NGT plants;
- (b) food and feed containing or consisting of NGT plants or produced from NGT plants;
- (c) products, other than food and feed, containing or consisting of NGT plants.

The rules in Union legislation which apply to GMOs, in so far as they are not derogated from by this Regulation, shall continue to apply to these plants and products.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (1) the definitions of 'organism', 'genetically modified organism', 'deliberate release', 'placing on the market' and 'product' set out in Directive 2001/18/EC, those of 'food' and 'feed' set out in Regulation (EC) No 178/2002, that of 'traceability' set out in Regulation (EC) No 1830/2003, that of 'plant' set out in Regulation (EU)

²⁴ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

2016/2031⁽²⁵⁾ and that of ‘plant reproductive material’ set out in [*Publications office please insert reference to Regulation on plant reproductive material and to Regulation on forest reproductive material, PLAN/2020/7576*];

- (2) ‘NGT plant’ means a genetically modified plant obtained by targeted mutagenesis, cisgenesis, intragenesis, or a combination thereof, on the condition that the NGT plant does not contain any genetic material originating from outside the breeders’ gene pool that temporarily may have been inserted during the development of the NGT plant;
- (3) ‘NGT plant for food use’ means a NGT plant that may be used as food or as a source material for the production of food;
- (4) ‘NGT plant for feed use’ means a NGT plant that may be used as feed or as a source material for the production of feed;
- (5) ‘NGT food’ means food containing, consisting of or produced from a NGT plant;
- (6) ‘NGT feed’ means feed containing, consisting of or produced from a NGT plant;
- (7) ‘produced from a NGT plant’ means derived, in whole or in part, from a NGT plant, but not containing or consisting of a NGT plant;
- (8) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at precise locations in the genome of an organism;
- (9) ‘cisgenesis’ means techniques of genetic modification resulting in the insertion, in the genome of an organism, of an exact copy of genetic material already present in the breeders’ gene pool;
- (10) ‘intragenesis’ means techniques of genetic modification resulting in the insertion, in the genome of an organism, of a re-arranged copy of genetic material composed of two or more DNA sequences already present in the breeders’ gene pool;
- (11) ‘breeders’ gene pool’ means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;
- (12) ‘small or medium sized enterprise’ (SME) means SME within the meaning of Commission Recommendation 2003/361/EC².

Article 4

Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of products containing of or consisting of such plants and food and feed produced from such plants

Without prejudice to other requirements of Union law, a NGT plant may only be deliberately released into the environment for any other purpose than for placing on the market, and a product containing or consisting of a NGT plant as well as food and feed produced from it may only be placed on the market, if:

- (1) it is a category 1 NGT plant in accordance with Title II;

²⁵ Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

- (2) the deliberate release or placing on the market of the NGT plant or related product referred to in Article 2 is authorised in accordance with Title III of this Regulation and the relevant provisions of Directive 2001/18/EC or Regulation 1829/2003.

TITLE II

CATEGORY 1 NGT PLANTS

Article 5

Status of category 1 NGT plants

1. The rules which apply to GMOs in Union legislation shall not apply to
 - (a) NGT plants that have been determined, by a decision adopted in accordance with Articles 6 or 7, to
 - (i) fulfil the criteria of equivalence to conventional plants set out in Annex I and
 - (ii) have intended characteristic(s) or property(ies) conveyed by the genetic modification other than those listed in Part 2 of Annex III.
 - (b) the progeny of the NGT plants referred to in point (a), including progeny derived by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC(hereinafter ‘category 1 NGT plants’).
2. By derogation from paragraph 1, Article 11 of Regulation 2018/848 applies to category 1 NGT plants.

Article 6

Notification procedure prior to the deliberate release for any other purpose than placing on the market of category 1 NGT plants

1. Any person may, before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, submit a notification for determination that this NGT plant fulfils the conditions set out in Article 5(1) to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place.
2. Where a person intends to undertake such a deliberate release of a NGT plant simultaneously in more than one Member State, that person shall submit the notification to one of those Member States.
3. The notification referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include:
 - (a) the name and the address of the notifier;
 - (b) the designation of the NGT plant;
 - (c) a description of the trait(s) and characteristics which have been introduced or modified;
 - (d) the information necessary to demonstrate that

- (i) the plant is a NGT plant, including that, where genetic material other than that originating from the breeders' gene pool is inserted in an intermediate step during the development of the NGT plant, this genetic material has been completely removed from the plant;
 - (ii) the NGT plant meets the criteria set out in Annex I;
 - (e) in the cases under paragraph 2, an indication of the Member States in which the notifier intends to undertake the deliberate release;
 - (f) an identification of the parts of the notification and any other supplementary information that the applicant requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 12 of this Regulation and Article 39 of Regulation (EC) No 178/2002.
4. The competent authority shall acknowledge receipt of the notification to the notifier without undue delay, stating the date of receipt. It shall make available the notification to the other Member States and to the Commission without undue delay.
 5. If the notification does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a notification. It shall inform the notifier, the other Member States and the Commission without undue delay of the inadmissibility of the notification and shall provide the reasons of its conclusion.
 6. If the notification is not deemed inadmissible in accordance with paragraph 5, within 30 working days from the date of receipt of a notification, the competent authority shall verify whether the notified NGT plant fulfils the criteria set out in Article 5(1) and prepare a verification report. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.
 7. Another Member State and the Commission may make comments or present reasoned objections to the verification report within 30 days from the date of its transmission.
 8. In cases where a reasoned objection is raised by another Member State or the Commission within the deadline laid down in paragraph 7, the competent authority that prepared the report shall forward the reasoned objection(s) to the other Member States and the Commission. The competent authorities and the Commission may discuss any outstanding issues within 30 days.
 9. In the absence of any reasoned objection from a Member State or the Commission or if outstanding issues are resolved within the period referred to in paragraph 8, the competent authority that prepared the report shall, within 10 working days from the deadlines referred to in paragraph 7 or, in the case outstanding issues are resolved, in paragraph 8, adopt a decision establishing whether the NGT plant fulfils the conditions set out in Article 5(1). It shall transmit the decision without undue delay to the notifier, the other Member States and the Commission.
 10. In cases where a reasoned objection is raised and maintained by another Member State or the Commission, the competent authority that prepared the report shall forward the verification report, and the reasoned objection(s) to the European Food Safety Authority ('the Authority') without undue delay. The Authority shall deliver a statement on whether the notified NGT plant fulfils the conditions set out in Article

5(1) no later than 30 working days from the date of the referral. The Authority shall make available the statement to the Commission and the Member States.

11. Where the Authority is consulted in accordance with paragraph 10 of this Article, it shall, in accordance with Article 38(1) of Regulation (EC) No 178/2002, make public without delay the notification, relevant supporting information and any supplementary information supplied by the notifier, as well as its statement, with the exception of any information to which the competent authority has granted confidential treatment in accordance with Article 12 of this Regulation.
12. The Commission shall prepare a draft decision on whether the notified NGT plant fulfils the conditions set out in Article 5(1) within 30 working days from the date of receipt of the statement of the Authority, taking the latter into account. The decision shall be adopted in accordance with the procedure laid down in Article 32(2).
13. The Commission shall publish a summary of the decisions referred to in paragraphs 9 and 11 in the *Official Journal of the European Union*.

Article 7

Notification procedure prior to the placing on the market of products containing or consisting of type 1 NGT plants or food or feed produced from such plants

1. Before placing on the market a product containing or consisting of a NGT plant or food or feed produced from a NGT plant for which no decision has been already adopted in accordance with Article 6, any person may submit a notification to the Authority for determination that this NGT plant fulfils the conditions set out in Article 5(1).
2. The notification referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include:
 - (a) the name and the address of the notifier;
 - (b) the designation of the NGT plant;
 - (c) a description of the trait(s) and characteristics which have been introduced or modified.
 - (d) the information necessary to demonstrate that
 - (i) the plant is a NGT plant, including that, where genetic material other than that originating from the breeders' gene pool is inserted in an intermediate step during the development of the NGT plant, this genetic material has been completely removed from the plant;
 - (ii) the NGT plant meets the criteria set out in Annex I;
 - (e) an identification of the parts of the notification and any other supplementary information that the applicant requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 12 of this Regulation and Article 39 of Regulation (EC) No 178/2002.
3. The Authority shall acknowledge receipt of the notification to the notifier without delay, stating the date of receipt. Without undue delay after receipt of the notification, the Authority shall make the notification available to the Member States and to the Commission.

4. If the notification does not contain all the necessary information, the notification shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a notification. It shall inform without undue delay the notifier, the Member States and the Commission of the inadmissibility of the notification and shall provide the reasons of its conclusion.
5. If the notification is not deemed inadmissible in accordance with paragraph 4, within 30 working days from the date of receipt of a notification, the Authority shall assess whether the notified NGT plant fulfils the criteria set out in Article 5(1) and prepare a draft statement. The Authority shall make the draft statement available to the Member States and the Commission without undue delay.
6. Member States and the Commission may make comments on the draft statement of the Authority within 30 days from the date when it was made available to them.
7. The Authority shall deliver its statement on whether the notified NGT plant fulfils the conditions set out in Article 5(1), taking into account the comments received from Member States and the Commission, within 30 days from the deadline referred to in paragraph 6. The Authority shall make available the statement to the Commission and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its statement public, after deletion of any information identified as confidential in accordance with Article 12 of this Regulation.
8. The Commission shall prepare a draft decision on whether the notified NGT plant fulfils the conditions set out in Article 5(1) within 30 working days from the date of receipt of the statement of the Authority, taking the latter into account. A decision shall be adopted in accordance with the procedure laid down in Article 32(2).
9. The Commission shall publish a summary of the decision in the *Official Journal of the European Union*.

Article 8

Free movement

Member States shall not prohibit or restrict the deliberate release or placing on the market of type 1 NGT plants and related products referred to in Article 2 through requirements that are specific to type 1 NGT plants or related products.

Article 9

System of exchange of information between Member States, the Commission and the Authority

The Commission shall set up and maintain an electronic system for the submission of notifications and the transfer and exchange of the information under this Title.

Article 10

Database of NGT plants that have been determined to meet the conditions of Article 5(1)

1. The Commission shall establish and maintain a database listing all NGT plants that have obtained a positive decision referred to in Article 6(9) and (12) and Article 7(8). The database shall contain the following information:

- (a) name and the address of the notifier;
 - (b) the designation of the NGT plant;
 - (c) a summarised description of the technique(s) used to obtain the genetic modification;
 - (d) a description of the trait(s) and characteristics which have been introduced or modified;
 - (e) an identification number, and
 - (f) the summary of the decision referred to in Article 6(9) and (12) and Article 7(8), as relevant.
2. The database shall be publicly available.

Article 11

Labelling of category 1 NGT plant reproductive material, including breeding material

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words “new genomic technique category 1”, followed by the identification number of the NGT plant(s) it has been derived from.

Article 12

Confidentiality

1. The notifier may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this Title as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.
2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request submitted by the notifier.
3. Upon request of a notifier, the competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the notifier to potentially harm its interests to a significant degree:
 - (a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;
 - (b) DNA sequence information; and
 - (c) breeding patterns and strategies.
4. The competent authority or the Authority, as appropriate, shall, after consultation with the notifier, decide which information is to be treated as confidential and shall inform the notifier of its decision.
5. Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged under this Title is not made public.

6. The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.
7. In the event of a withdrawal of the notification by the notifier, Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the withdrawal of the notification takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.

TITLE III

CATEGORY 2 NGT PLANTS

Article 13

Scope

This Title applies to NGT plants other than category 1 NGT plants ('category 2 NGT plants'), to products containing or consisting of such plants and food and feed produced from such plants.

Article 14

General Rule

Save as otherwise provided in this Title, Directive 2001/18/EC and Regulation 1829/2003 as appropriate apply to all notifications/applications for the authorisation of category 2 NGT plants, products containing or consisting of such plants and food and feed produced from such plants.

CHAPTER 1

Deliberate release of category 2 NGT plants for any other purpose than for placing on the market

Article 15

Authorisation procedure

By way of derogation from Article 6(2) of Directive 2001/18/EC, the notification referred to in Article 6(1) of that Directive shall include:

- (a) the name and the address of the notifier;
- (b) the designation of the NGT plant;
- (c) a description of the trait(s) and characteristics which have been introduced or modified.
- (d) a copy of the studies, which have been carried out and any other available material to demonstrate that the plant is a NGT plant, including that, where genetic material other than that originating from the breeders' gene pool is inserted in an intermediate

- step during the development of the NGT plant, this genetic material has been completely removed from the plant;
- (e) a technical dossier supplying the information necessary for carrying out the environmental risk assessment of the deliberate release of a NGT plant or combination of NGT plants, in particular:
 - (i) general information including information on personnel and training,
 - (ii) information relating to the NGT plant(s),
 - (iii) information relating to the conditions of release and the potential receiving environment,
 - (iv) information on the interactions between the NGT plant(s) and the environment,
 - (v) a plan for monitoring in order to identify effects of the NGT plant(s) on human health or the environment,
 - (vi) where relevant, information on control, remediation methods, waste treatment and emergency response plans,
 - (vii) a summary of the dossier;
 - (f) the environmental risk assessment carried out in accordance with the principles set out in parts 1 and 2 of Annex II to this Regulation.

CHAPTER 2

Placing on the market of products containing or consisting of category 2 NGT plants for uses other than food or feed

Article 16

Notification procedure

By way of derogation from Article 13(2) of Directive 2001/18/EC, the notification shall contain:

- (a) a copy of the studies, which have been carried out and any other available material to demonstrate that the plant is a NGT plant, including that, where genetic material other than that originating from the breeders' gene pool is inserted in an intermediate step during the development of the NGT plant, this genetic material has been completely removed from the plant;
- (b) the environmental risk assessment carried out in accordance with the criteria set out in Parts 1 and 2 of Annex II;
- (c) the conditions for the placing on the market of the product, including specific conditions of use and handling;
- (d) methods for sampling (including references to existing official or standardised sampling methods), detection identification and quantification of the NGT plant. If the characteristics of the genetic modification do not allow the identification or quantification of the NGT plant, methods for identification or quantification do not have to be provided. In that case, a justification supported by evidence shall be provided;

- (e) samples of the NGT plant and their control samples, and information as to the place where the reference material can be accessed;
- (f) with reference to Article 15(4) of Directive 2001/18/EC, a proposed period for the consent, which should not exceed 10 years;
- (g) where appropriate, a plan for monitoring in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent. If, on the basis of the results of any release notified in accordance with Chapter 1, or on the basis of the environmental risk assessment, the applicant considers that the NGT plant and its use do not pose a potential risk to human health and the environment that needs to be monitored, they may propose not to submit a monitoring plan;
- (h) a proposal for labelling which shall comply with the requirements laid down in point 8 of point A of Annex IV to Directive 2001/18/EC, Article 4(6) of Regulation (EC) No 1830/2003 and Article 26;
- (i) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Cartagena Protocol);
- (j) proposed commercial names of the products and names of GMOs contained therein, and a proposal for a unique identifier for the GMO, developed in accordance with Commission Regulation (EC) No 65/2004⁽²⁶⁾. After the consent any new commercial names should be provided to the competent authority,
- (k) name and full address of the person established in the EU who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,
- (l) description of how the product and the GMO as or in product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted,
- (m) intended categories of users of the product e.g. industry, agriculture and skilled trades, consumer use by public at large,
- (n) a summary of the dossier in a standardised form.

Article 17

Assessment report

1. In addition to the task referred to in Article 14(1) of Directive 2001/18/EC, the competent authority referred to in Article 13(1) of that Directive shall examine the notification for compliance with this Regulation.
2. By way of derogation from point 5 Annex VI of Directive 2001/18/EC, the conclusion shall address the monitoring plan, if such a plan has been proposed, or the justification provided by the applicant for not proposing a monitoring plan.

Article 18

Criteria and information for specified NGT plants

²⁶ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

Article 16 of Directive 2001/18/EC shall also apply in respect of the information requirements set out in Article 16.

Article 19

Consent

1. By way of derogation from Article 19(3), point (f), of Directive 2001/18/EC, the written consent shall either specify monitoring requirements as described therein or specify that monitoring is not required.
2. In addition to Article 19(3) of Directive 2001/18/EC, the written consent shall specify the labelling in accordance with Article 26.

Article 20

Renewal of consent

1. Article 17(2), point (b), of Directive 2001/18/EC shall not apply if monitoring is not required by the consent in accordance with Article 19(1).
2. By derogation from Article 17(6) of Directive 2001/18/EC, the consent shall be valid, as a general rule, for an unlimited period, and may be limited as appropriate for specific reasons.

CHAPTER 3

Placing on the market of category 2 NGT plants for food or feed use and of their NGT food and NGT feed

Article 21

Scope

This Chapter shall apply to category 2 NGT plants for food or feed use, and their NGT food and NGT feed.

Article 22

Application for authorisation

1. By way of derogation from Articles 5(3), point (e), and 17(3), point (e), of Regulation (EC) No 1829/2003, an application for authorisation shall be accompanied by a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other available material to demonstrate that:
 - (a) the plant is a NGT plant or the food and feed are NGT food and feed, including that, where genetic material other than that originating from the breeders' gene pool is inserted in an intermediate step during the development of the NGT plant, this genetic material has been completely removed from the NGT plant.
 - (b) the food or the feed complies with the criteria referred to in Articles 4(1) or 16(1) of Regulation (EC) No 1829/2003, respectively, and this assessment shall

be carried out in accordance with the principles set out in Parts 1 and 3 of Annex II.

2. By way of derogation from Articles 5(3), point (i), and 17(3), point (i), of Regulation (EC) No 1829/2003, an application for authorisation shall be accompanied by methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant and, where applicable, for the detection and identification of the NGT plant in the food and/or in foods produced from it or in the feed and/or in the feed produced from it. If the characteristics of the genetic modification do not allow identification or quantification of the NGT plant, methods for identification or quantification do not have to be provided. In that case, a justification supported by evidence shall be provided.
3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of NGT plants or food or feed containing or consisting of NGT plants, the application shall also be accompanied by the information required in Part 2 of Annex II and, where appropriate, by a monitoring plan for environmental effects in accordance with Annex VII of Directive 2001/18/EC including a proposal for the duration of the monitoring plan. This duration may be different from the proposed period for the consent. If, on the basis of the results of any release notified in accordance with Chapter 1, or on the basis of the environmental risk assessment, the applicant considers that the NGT plant and its use do not pose a potential risk to human health and the environment that needs to be monitored, they may propose not to submit a monitoring plan.
4. The application shall also contain a proposal for labelling in accordance with Article 26.

Article 23

Opinion of the Authority

1. By way of derogation from Articles 6(1) and (2) and 18(1) and (2) of Regulation (EC) No 1829/2003, the Authority shall deliver an opinion on the application for authorisation referred to in Article 22 of this Regulation within 6 months as from the receipt of a valid application. Where the Authority or the Member State competent authority carrying out the assessment considers that additional information is necessary, the Authority shall ask the applicant to submit that information within a specified time limit. In that case, the 6-month period shall be extended by that additional period. The extension shall not exceed 6 months in total unless it is justified by the nature of the data requested or by exceptional circumstances.
2. In addition to the tasks referred to in Articles 6(3) and 18(3) of Regulation (EC) No 1829/2003, the Authority shall verify whether all the particulars and documents submitted by the applicant are in conformity with Article 22 of this Regulation.
3. By way of derogation from Article 6(3)(d) and 18(3)(d) of Regulation (EC) No 1829/2003, the Authority shall forward to the Union reference laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 the particulars referred to in Article 22(2) of this Regulation and in Articles 5(3), point (j), and 17(3), point (j), of Regulation (EC) No 1829/2003. The Union reference laboratory shall test and validate the method of detection, identification and quantification proposed by the

applicant or assess whether the conditions for not providing methods of identification or quantification referred to in Article 22(2) are met.

4. By way of derogation from Article 6(5), point (f), and 18(5), point (f), of Regulation (EC) No 1829/2003, in the event of an opinion in favour of authorising the food or the feed, the opinion shall also include:
 - (a) the method, validated by the Union reference laboratory, for detection, including sampling, and, where applicable, identification and quantification of the NGT plant and detection and identification of the NGT plant in the food and/or in foods produced from it or the feed and/or in feed produced from it;
 - (b) an indication of where appropriate reference material can be accessed.
5. In addition to the particulars mentioned in Article 6(5) and 18(5) of Regulation (EC) No 1829/2003, the opinion shall also include a proposal for labelling in accordance with Article 26.

Article 24

Renewal of authorisations

1. By way of derogation from Articles 11(1) and 23(1) of Regulation (EC) No 1829/2003, an authorisation granted in accordance with Articles 7 or 19 of Regulation (EC) No 1829/2003 for a NGT plant, NGT food or NGT feed, shall be renewable, on application to the Commission by the authorisation holder at the latest one year before the expiry date of the authorisation.
2. Once renewed, the authorisation shall be valid for an unlimited period, unless the Commission decides, on justified grounds relating to the risk assessment carried out pursuant to this Regulation, to proceed with one additional 10-year renewal.

CHAPTER 5

Common provisions for category 2 NGT plants

Article 25

Incentives for category 2 NGT plants and their NGT food and feed containing traits relevant for sustainability

1. The incentives in this article shall apply to category 2 NGT plants where at least one intended characteristic(s) or property(ies) conveyed by the genetic modification is listed in Part I of Annex III and none is listed in Part 2 of Annex III.
2. The following incentives shall apply to notifications referred to in Article 13 of Directive 2001/18/EC in conjunction with Article 16 and to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 22:
 - (a) by way of derogation from Article 23(1), the Authority shall deliver its opinion on the application within 4 months as from the receipt of a valid application.
 - (b) where the applicant is a SME, it shall be exempted from the payment of the financial contributions to the Union Reference Laboratory and to the European

Network of GMO Laboratories referred to in Article 32 of Regulation (EC) No 1829/2003.

3. The following pre-submission advice for the purposes of the risk assessment conducted in accordance with Annex II shall, in addition to Article 32a of Regulation 178/2002, apply prior to notifications referred to in Article 13 of Directive 2001/18/EC in conjunction with Article 16 and to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 22:
 - (a) The staff of the Authority shall, at the request of a potential applicant or notifier, provide advice on plausible risk hypotheses that the potential applicant/notifier has identified based on the properties of a product or hypothetical product, that need to be addressed by providing the information under Part II and III of Annex II. The advice shall not, however, cover the design of studies to address the risk hypotheses.
 - (b) Where the potential applicant or notifier is a SME, it may, in addition to point (a), notify the Authority on how it intends to address the plausible risk hypotheses that it has identified based on the properties of a product or hypothetical product, including the design of the studies it intends to perform for the purposes of Part II and III of Annex II. The Authority shall provide advice on the notified information, including on the design of the studies.
4. The following provisions apply to the pre-submission advice referred to in paragraph 3:
 - (a) such pre-submission advice provided by the staff of the Authority shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Scientific Panels. The staff of the Authority providing the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice;
 - (b) for potential notifications under Article 13 of Directive 2001/18/EC and for potential applications under Articles 5 or 17 of Regulation (EC) No 1829/2003 concerning NGT plants to be used as seeds or other plant reproduction material, the pre-submission advice shall be provided by the Authority together, or in close collaboration with the competent authority of the Member State to which the notification is going to be submitted;
 - (c) the Authority shall make public without delay a summary of the advice provided to potential applicants or notifiers at pre-submission phase in accordance with this Article once an application or notification has been considered valid;
 - (d) potential applicants or notifiers demonstrating that they are a SME can request advice referred to in point (a) of paragraph 3 at different points in time.
5. Requests for the incentives in this Article shall be submitted to the Authority at the time of request of advice referred to in paragraph 3 or together with the notification referred to in Article 13 of Directive 2001/18/EC in conjunction with Article 16 or the application referred to in Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 22, and accompanied by the following information:

- (a) the information necessary to establish that the intended characteristic(s) or property(ies) conveyed by the genetic modification meet the conditions referred to in paragraph 1;
 - (b) for the purpose of point (b) of paragraph 2 and point (b) of paragraph 3, the information necessary to demonstrate the (potential) applicant or notifier is a SME;
 - (c) for the purpose of paragraph 3, information on the aspects listed in Part I of Annex II as far as it can already be provided and any other relevant information.
6. The Authority shall lay down the practical arrangements for implementing the procedures referred to in paragraphs (3)-(5) of this Article.

Article 26

Labelling of authorised category 2 NGT plants

In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003 and Article 4(6) to (7) of Regulation (EC) No 1830/2003 and without prejudice to the requirements under other Union legislation, the labelling of products containing or consisting of authorised category 2 NGT plants, and of food and feed produced from such plants, may also mention any other characteristic(s) or property(ies) conveyed by the genetic modification, as specified in the authorisation.

Article 27

Measures to avoid the unintended presence of category 2 NGT plants

By way of derogation from Article 26a(1) of Directive 2001/18/EC, Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in other products.

Article 28

Cultivation

Article 26b of Directive 2001/18/EC shall not apply to NGT plants.

TITLE IV

FINAL PROVISIONS

Article 29

Delegated acts

The Commission shall, by means of delegated acts adopted in accordance with Article 30 lay down rules concerning:

- (1) the adaptation of Annex I to scientific and technological progress;
- (2) the adaptation of Annex III to scientific and technological progress and to new evidence relating to sustainability impacts of traits.

Article 30

Exercise of the delegation

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt the delegated acts referred to in Article 2 shall be conferred on the Commission for a period of 5 years from *[date of entry into force of this Regulation]*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.
3. The delegations of power referred to in Article 29 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁽²⁷⁾.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 29 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.
7. To delegated acts referred to in point (1) of Article 29, the following additional conditions apply:
 - (a) plants having the number of genetic modifications of the types referred to in points 1 to 5 of Annex I shall be expected to arise naturally or be achieved through conventional breeding or through the techniques referred to in Annex I B to Directive 2001/18/EC;
 - (b) when adopting a delegated act, the Commission shall in particular take into account, by way of an up-to-date scientific literature review, of the number and types of spontaneously occurring DNA alterations as well as the number and types of DNA alterations introduced by conventional breeding techniques, including the techniques referred to in Annex I B to Directive 2001/18/EC;
 - (c) before adopting the delegated act, the Commission shall consult the Authority.
8. To delegated acts referred to in point (2) of Article 29, the following additional conditions apply:

²⁷ OJ L 123, 12.5.2016, p. 1.

- (a) the Commission shall take into account the monitoring of the impacts of this Regulation referred to in Article 34(3);
- (b) the Commission shall conduct an up-to-date scientific literature review of the impacts on environmental, social and economic sustainability of the characteristic(s) or property(ies) it intends to add to or delete from the list in Annex III;
- (c) where applicable, the Commission shall take into account the results of monitoring which was carried out according to Article 16, point (g), or Article 22(3), in conjunction with Annex VII of Directive 2001/18/EC, of NGT plants harbouring the characteristic(s) or property(ies) conveyed by their genetic modification it intends to add to or delete from the list in Annex III;
- (d) before adopting the delegated act, the Commission shall consult the Authority.

Article 31

Implementing acts

The Commission, having first consulted the Authority, shall adopt implementing acts concerning:

- (1) the information required to demonstrate that a plant is a NGT plant within the meaning of Article 3;
- (2) the preparation and the presentation of the notification referred to in Articles 6 and 7;
- (3) the methodology and information requirements for the risk assessment in accordance with the criteria laid down in Annex II;
- (4) the information requirements for the notification set out in Article 16, including rules concerning the preparation and the presentation of the notification.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(3).

Article 32

Committee procedure

- 1. The Commission shall be assisted by the committee set up by Article 30 of Directive 2001/18/EC.
- 2. Where reference is made to this paragraph, Article 4 of Regulation (EC) No 182/2011 shall apply.
- 3. Where reference is made to this paragraph, Article 5 of Regulation (EC) No 182/2011 shall apply.

Article 33

Guidance

Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the notifier or the applicant in the preparation and the presentation of the notification or application referred to in Titles II and III.

Article 34

Monitoring, reporting and evaluation

1. No sooner than three years after the first decision is adopted in accordance with Article 6(9) or (12) or Article 7(8) or in accordance with Chapters 2 or 3 of Title III, whichever is the earliest, and thereafter every five years, the Commission shall forward to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the implementation of this Regulation.
2. The report shall also address any ethical issues that have arisen in the application of this Regulation.
3. For the purpose of the reporting referred to in paragraph 1, the Commission, by *[insert date X months after the date of entry into force of this Regulation]* at the latest, shall establish, after consulting the competent authorities of the Member States under Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impacts of this Regulation. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.
4. No sooner than two years after the publication of the first report referred to in paragraph 1 the Commission shall carry out an evaluation of the implementation of this Regulation and its impact on human, animal health, the environment, consumer information, the functioning of the internal market, and economic, environmental and social sustainability.
5. The Commission shall present a report on the main findings of the evaluation referred to in paragraph 3 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Article 35

References in other legislation

1. With regard to category 2 NGT plants, references made in other Union legislation to Annex II to Directive 2001/18/EC shall be considered as making reference to Part 1 of Annex II to this Regulation, and references made to Annex III to Directive 2001/18/EC shall be considered as making reference to Part 2 of Annex II to this Regulation.
2. With regard to category 2 NGT plants, internal references made within Directive 2001/18/EC or Regulation (EC) No 1829/2003, respectively, shall be considered as making also reference to the relevant provisions of this Regulation.

Article 36

Amendment to Directive 68/193/EEC

Article 5f of Directive 68/193/EEC is replaced by the following:

- ‘1. Member States shall ensure that genetically modified varieties which have been accepted are clearly indicated as such in the catalogue of varieties. They shall further ensure that any person marketing such a variety clearly indicates in their vine sales catalogue that the variety is genetically modified and states the purpose of the modification.

2. Member States shall ensure that varieties containing or consisting of a category 1 NGT plant within the meaning of Article 5 of Regulation [*please insert reference to this Regulation*] are clearly indicated as varieties obtained by a new genomic technique in the catalogue of varieties. They shall further ensure that any person marketing such a variety clearly indicates in his sales catalogue that the variety is obtained by a new genomic technique.’

Article 37

Amendment to Directive 1999/105/EC

In Article 10(2) of Directive 1999/105/EC, the following point is inserted: ‘(k) in the case of material of the ‘tested’ category, whether it contains or consists of a category 1 NGT plant within the meaning of Article 5 of Regulation [*please insert reference to this Regulation*].’

Article 38

Amendments to Directive 2002/53/EC

Directive 2002/53/EC is amended as follows:

- (1) In Article 9, the following paragraph is inserted:
- ‘5a. Member States shall ensure that varieties containing or consisting of a category 1 NGT plant within the meaning of Article 5 of Regulation [*please insert reference to this Regulation*] are clearly indicated as varieties obtained by a new genomic technique in the catalogue of varieties. They shall further ensure that any person marketing such a variety clearly indicates in his sales catalogue that the variety is obtained by a new genomic technique.’
- (2) Subsection 3 of Article 17 is replaced by the following:
- ‘The published notice shall clearly indicate those varieties which have been genetically modified, including those which contain or consist of a category 1 NGT plant within the meaning of Article 5 of Regulation [*please insert reference to this Regulation*].’

Article 39

Amendments to Directive 2002/55/EC

Directive 2002/55/EC is amended as follows:

- (1) In Article 9, the following paragraph is inserted:
- ‘5a. Member States shall ensure that varieties containing or consisting of a category 1 NGT plant within the meaning of Article 5 of Regulation [*please insert reference to this Regulation*] are clearly indicated as varieties obtained by a new genomic technique in the catalogue of varieties. They shall further ensure that any person marketing such a variety clearly indicates in his sales catalogue that the variety is obtained by a new genomic technique.’
- (2) Subsection 3 of Article 17 is replaced by the following:
- ‘The published notice shall clearly indicate those varieties which have been genetically modified, including those which contain or consist of a category 1 NGT plant within the meaning of Article 5 of Regulation [*please insert reference to this Regulation*].’

Article 40

Amendments to Regulation (EU) 2017/625

Article 23 of Regulation (EU) 2017/625 is amended as follows:

- (1) in paragraph 2, point (a)(ii) is replaced by the following:
‘(ii) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of Directive 2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Article 22(3) of Regulation [*please insert reference to this Regulation*];’;
- (2) in paragraph 3, point (b) is replaced by the following:
‘(b) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of Directive 2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Article 22(3) of Regulation [*please insert reference to this Regulation*];’.

Article 41

Entry into force and application

This Regulation shall enter into force on the [*insert*] day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [XX.XX.XXXX]. However, Part III shall apply from the date of application of the implementing acts referred to in Article 31(1) and (3). Part II shall apply from the date of application of the implementing acts referred to in Article 31(1) and (2).

This Regulation shall enter into force on the [...] day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

1.2. Policy area(s) concerned

1.3. The proposal/initiative relates to:

1.4. Objective(s)

1.4.1. General objective(s)

1.4.2. Specific objective(s)

1.4.3. Expected result(s) and impact

1.4.4. Indicators of performance

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention, which is additional to the value that would have been otherwise created by Member States alone.

1.5.3. Lessons learned from similar experiences in the past

1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments

1.5.5. Assessment of the different available financing options, including scope for redeployment

1.6. Duration and financial impact of the proposal/initiative

1.7. Method(s) of budget implementation planned

2. MANAGEMENT MEASURES

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2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)

2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected**
- 3.2. Estimated financial impact of the proposal on appropriations**
 - 3.2.1. Summary of estimated impact on operational appropriations*
 - 3.2.2. Estimated output funded with operational appropriations*
 - i. Summary of estimated impact on EFSA's Human Resources*
 - 3.2.3. Summary of estimated impact on administrative appropriations*
 - 3.2.4. Compatibility with the current multiannual financial framework*
 - 3.2.5. Third-party contributions*
- 3.3. Estimated impact on revenue**

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

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 Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1946/2003, Directive 2009/41/EC and Regulation (EU) 2017/625

1.2. Policy area(s) concerned

1 - Single Market, Innovation and Digital
2 - Cohesion, Resilience and Values

1.3. The proposal/initiative relates to:

- a new action
- a new action following a pilot project/preparatory action¹
- the extension of an existing action
- a merger or redirection of one or more actions towards another/a new action

1.4. Objective(s)

1.4.1. General objective(s)

The general objectives of the new legislation are:

- I) Maintain a high level of protection of human and animal health and of the environment, in accordance with the precautionary principle.
- II) Enable 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.
- III) Ensure the effective functioning of the internal market and enhance the competitiveness of the EU agri-food sector at the EU and global level, providing a level-playing field for its operators.

1.4.2. Specific objective(s)

Specific objective No

- 1. Procedures for the deliberate release and placing on the market that ensure NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden.
- 2. Deliberate release and placing on the market of NGT plants and derived food/feed products that feature a wide range of plant species and traits by various developers
- 3. NGT plants released or placed on the market feature traits that can contribute to a sustainable agri-food system.

¹ As referred to in Article 58(2)(a) or (b) of the Financial Regulation.

1.4.3. *Expected result(s) and impact*

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The authorisation procedures and risk assessment requirements of plants obtained by certain new genomic techniques would be fit to the diversity of products. Regulatory costs and administrative burden would be reduced, which would also reduce the entry barriers to SMEs and public institutions in plant breeding.

Breeders' global competitiveness and innovative power would be supported by simplification and future-proofing through a framework that is adaptable to scientific and technological development. Breeders, operators, especially SMEs, would see reduced burden and costs as well as a more predictable timeline to develop new products.

Farmers would have more varieties adapted to current needs, in particular more plant traits that contribute to a sustainable agri-food system.

Consumers would benefit from products that are designed to meet their expectations and needs (e.g. improved taste, improved nutrient profile or reduced allergen content).

Academic/research institutions would see more (funding) opportunities in the EU for their research in the area.

1.4.4. *Indicators of performance*

Specify the indicators for monitoring progress and achievements.

For NGT plants as safe as their conventional counterparts:

- Number of products authorised or notified to be placed on the market
- Reported cases demonstrating risk to human and animal health and the environment due to the genetic modification in authorised/notified product and any regulatory action taken

For NGT plants featuring a wide range of plant species and traits by various developers:

- Number of crop-trait combinations in notification/authorisation applications
- Number and proportion of SMEs/public institutions applying for field trial/notification/authorisation applications

For NGT plants featuring traits that can contribute to a sustainable agri-food system

- Impact of NGT plants in the EU on economic, environmental and social sustainability e.g., through pesticide use, fertiliser user, biodiversity, greenhouse gas emissions, yield, yield stability, health benefits.

1.5. **Grounds for the proposal/initiative**

1.5.1. *Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative*

The NGT plants/products can be placed on the market either if they fulfill the notification criteria or if they are risk assessed to be safe and consequently authorised. Verification of the notification criteria and the risk assessment will be carried out, in certain cases, by a EU regulatory body (in other cases, the procedures will be handled by the Member States).

The European Food Safety Authority (EFSA) is already a key actor in the application of the GMO legislative framework, whose tasks need to be extended in order to properly implement the notification and authorisation requirements for the new plants/products in terms of data analysis and risk assessment.

The tasks of EFSA would need to be implemented from 2025 onwards.

New IT tools would also be needed for the NGT plants/products by integrating them in the already running FIP/ESFC system, which will limit the costs of IT needs.

This should be included in the budget for IT needs of DG SANTE for 2025.

- 1.5.2. *Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention, which is additional to the value that would have been otherwise created by Member States alone.*

Reasons for action at European level (ex-ante):

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 the high level of safety for humans, animals and for the protection of environment throughout the EU, a level playing field for operators within the single market and a more predictable and efficient regulatory oversight.

There is a 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 reduction, which have been further aggravated by the present geopolitical and energy crisis in Europe, and to secure food security in the future.

- 1.5.3. *Lessons learned from similar experiences in the past*

The Regulation is based on experiences from the legislations for deliberate release of GMO (Directive 2001/18/EC) and for the placing on the market of GMO for food and feed uses (Regulation (EC) 1829/2003).

The proposal takes into account the diversity of products that can be obtained by new genomic techniques based on latest scientific knowledge and provides requirements that are better tailored for the different types of products.

- 1.5.4. *Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments*

The Regulation is to be part of the Single Market Programme Food Strand and will work in synergy with the Common Agriculture Policy. While this proposal will tend to promote the use of NGT plants, and products derived from NGT plants, with traits that can contribute to sustainability, the CAP includes various instruments to tackle climate change through investments and advice on new methods and technology.

- 1.5.5. *Assessment of the different available financing options, including scope for redeployment*

The amount required for EFSA to conduct the new tasks (2.8 million EUR in the current MFF period) will result in an increase of the EFSA annual subsidy by 2,7

million EUR and in an increase of the DG SANTE operational expense by 0,1 million EUR will be redeployed internally within Heading 1 (Single Market Programme – Food Strand), by a corresponding reduction of the budgetary envelope of the aforementioned programme in years 2025 to 2027². The mandate of EFSA contributes to the objectives of the food strand of the SMP to contribute to a high level of health and safety for humans, animals and plants in plant, animal, food and feed areas.

² The first year of implementation might be updated during the draft budgetary procedure 2025 in case of a delay in the adoption process of this proposal

1.6. Duration and financial impact of the proposal/initiative

limited duration

- in effect from [DD/MM]YYYY to [DD/MM]YYYY
- Financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

unlimited duration

- Implementation with a start-up period from YYYY to YYYY,
- followed by full-scale operation.

1.7. Method(s) of budget implementation planned³

Direct management by the Commission

- by its departments, including by its staff in the Union delegations;
- by the executive agencies

Shared management with the Member States

Indirect management by entrusting budget implementation tasks to:

- third countries or the bodies they have designated;
- international organisations and their agencies (to be specified);
- the EIB and the European Investment Fund;
- bodies referred to in Articles 70 and 71 of the Financial Regulation;
- public law bodies;
- bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees;
- bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees;
- bodies or persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.
- *If more than one management mode is indicated, please provide details in the 'Comments' section.*

Comments

³ Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: <https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx>

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

All Union agencies work under a strict monitoring system involving an internal control coordinator, the Internal Audit Service of the Commission, the Management Board, the Commission, the Court of Auditors and the Budgetary Authority. This system is reflected and laid down in the European Food Safety Authority's (EFSA) founding regulation. In accordance with the Joint Statement on the EU decentralised agencies (the 'Common Approach'), the framework financial regulation (2019/715) and related Commission Communication C(2020)2297, the annual work programme and Single Programming Document of the Authority comprise detailed objectives and expected results, including a set of performance indicators.

The Single Programming Document combines multiannual and annual programming as well as "strategy documents", e.g. on independence. DG SANTE comments through the Authority's Management Board and prepares a formal Commission Opinion on the Single Programming Document. The activities of the Authority will be measured against these indicators in the Consolidated Annual Activity Report.

The European Food Safety Authority will monitor periodically the performance of its internal control system to ensure that data is collected efficiently, effectively and timely and to identify internal control deficiencies, register and assess the results of controls, control deviations and exceptions. The results of the internal control assessments, including significant weaknesses identified and any differences as compared to internal and external audit findings will be disclosed in the Consolidated Annual Activity report.

2.2. Management and control system(s)

2.2.1. *Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed*

The annual EU subsidy will be transferred to the Authority in accordance with its payment needs and upon its request. The Authority will be subject to administrative controls including budgetary control, internal audit, annual reports by the European Court of Auditors, the annual discharge for the execution of the EU budget and possible investigations conducted by OLAF to ensure, in particular, that the resources allocated to the Authority are put to proper use. Through its representation in the Authority's Management Board and Audit Committee, the Commission will receive audit reports and ensures that adequate actions are defined and timely implemented by the Authority to address the issues identified. All payments will remain pre-financing payments until the Authority's accounts have been audited by the European Court of Auditors and the Authority has submitted its final accounts. If necessary, the Commission will recover unspent amounts of the instalments paid to the Authority.

The activities of the Agency will also be subject to the supervision of the Ombudsman in accordance with Article 228 of the Treaty. These administrative controls provide a number of procedural safeguards to ensure that account is taken of the interests of the stakeholders.

EFSA's Internal Control Framework is designed to provide reasonable assurance regarding the achievement of five objectives set out in Article 30¹ of the EFSA Financial Regulation.

2.2.2. *Information concerning the risks identified and the internal control system(s) set up to mitigate them*

The main risks relate to the Authority's performance and independence in implementing the tasks entrusted to it. Underperformance or impaired independence could hamper the achievement of the objectives of this initiative and also reflect negatively on the Commission's reputation.

The Commission and the Agency have put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations. First and foremost, sufficient resources should be made available to the Authority in both financial and staffing terms to achieve the objectives of this initiative.

Furthermore, quality management will include both the integrated quality-management activities and risk-management activities within the Authority. A risk review is a continuous, proactive and systematic process, conducted annually, with risks being assessed at a residual level, i.e. taking into account controls and mitigations already in place. Conducting self-assessments (as part of the EU Agencies benchmarking programme), annual reviews of sensitive functions and ex-post controls also fall within this area, as does maintain a register of exceptions.

To preserve impartiality and objectivity in every aspect of the Authority's work, a number of policies and rules on management of competing interests have been put in place and will be regularly updated, describing specific arrangements, requirements and processes applying to the Authority's Management Board, scientific committee members and experts, the Authority's staff and candidates, as well as consultants and contractors.

EFSA's risk-based internal control and auditing scheme under the new integrated management system framework, and with the cohesive planning and reporting of respective Assurance Management activities in EFSA. The Commission will be informed timely of relevant management and independence issues encountered by the Authority and will react upon notified issues timely and adequately.

2.2.3. *Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)*

The Commission's and the Agency's internal control strategies take into consideration the main cost drivers, and the efforts already taken over several years to reduce the cost of controls, without compromising the effectiveness of controls. The existing control systems proved to be able to prevent and/or to detect errors and/or irregularities, and in case of errors or irregularities, to correct them.

¹ Objectives emphasised under Art. 30 of EFSA's Financial Regulation: (i) effectiveness, efficiency and economy of operations; (ii) reliability of reporting; (iii) safeguarding of assets and information; (iv) prevention, detection, correction and follow-up of fraud and irregularities; and (v) adequate management of risks relating to the legality and regularity of the underlying transactions.

In the past five years, the Commission's yearly costs of controls under indirect management represented less than 1% of the annual budget spent on subsidies paid to the Authority. The Authority allocated 5% of its total annual budget on control activities centering around integrated quality management, audit, anti-fraud measures, finance and verification processes, corporate risk management, risk assessment and self-assessment activities.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.

As for its activities in indirect management, the Commission shall take appropriate measures ensuring that the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportional and deterrent penalties.

To this effect, the Commission adopted an anti-fraud strategy, latest update of April 2019 (COM(2019)176), covering preventive, detective and corrective measures.

The Commission or its representatives and the European Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds. OLAF shall be authorised to carry out on-the-spot checks and inspections on economic operators concerned indirectly by such funding.

As regards the European Food Safety Authority, the anti-fraud measures are provided for in Article 25 point 9 of Regulation (EC) No 178/2002 and the framework financial Regulation (2019/715). The Management Board shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the Financial Regulation of 21 December 1977 applicable to the general budget of the European Communities(26) and with the legislative requirements concerning investigations conducted by the European Anti-Fraud Office. In line with the Common Approach and Article 42 of the framework financial Regulation, an anti-fraud strategy has been developed, in accordance with the European Anti-Fraud Office methodology and guidance, and is followed by the Authority.

EFSA set up and implemented measures to counter fraud and any illegal activities affecting the interests of the EFSA by putting in place a sound anti-fraud strategy and implementing rules to improve the prevention, detection and conditions for investigating fraud, and to set out reparation and deterrence actions, with proportionate and dissuasive measures. The validity of the EFSA's Anti-Fraud Strategy is aligned with EFSA Strategy. The Authority's Anti-fraud strategy is accompanied by a corresponding action plan, outlining both specific focus areas and actions for the next years, and several continuous actions that are carried out every year, such as a specific standalone fraud risk assessment, with the identified fraud risks included in the overall Agency risk register. Mandatory anti-fraud trainings are organised as part of the awareness anti-fraud sessions. Tailored training sessions to selected Process Owners /Managers are developed in order to address the risks associated to the areas that resulted potentially more exposed to fraud . Staff are made aware of how to report any suspects of wrongdoings and disciplinary procedures are in place as per the rules of the Staff Regulations.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff. ¹	from EFTA countries ²	from candidate countries and potential candidates ³	from other third countries	other assigned revenue
	03 02 06 Contributing to a high level of health and welfare for humans, animals and plants	Diff.	NO	NO	NO	NO
	06 10 02 European Food Safety Authority	Diff.	YES	NO	NO	NO

¹ Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

² EFTA: European Free Trade Association.

³ Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	1 - Single Market, Innovation and Digital
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DG: SANTE			Year 2025	Year 2026	Year 2027 et seqq	TOTAL
• Operational appropriations						
03 02 06 Contributing to a high level of health and welfare for humans, animals and plants	Commitments	(1a)	0,100	0,000	0,000	0,100
	Payments	(2a)	0,050	0,050	0,000	0,100
<u>Appropriations of an administrative nature financed from the envelope of specific programmes</u>						
Budget line		-3	0	0	0	0
TOTAL appropriations for DG SANTE	Commitments	=1a+1b +3	0,100	0,000	0,000	0,100
	Payments	.=2a+2b +3	0,050	0,050	0,000	0,100

• TOTAL operational appropriations	Commitments	-4	0,100	0,000	0,000	0,100
	Payments	-5	0,050	0,050	0,000	0,100
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		-6	0,000	0,000	0,000	0,000
TOTAL appropriations under HEADING 1- Single Market, Innovation and Digital of the multiannual financial framework	Commitments	=4+6	0,100	0,000	0,000	0,100
	Payments	=5+6	0,050	0,050	0,000	0,100

Heading of multiannual financial framework	2	2b - Cohesion, Resilience and Values
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DG: SANTE			Year 2025	Year 2026	Year 2027 et seqq	TOTAL
• Operational appropriations						
06 10 02 European Food Safety Authority	Commitments	(1a)	0,565	1,055	1,056	2,676
	Payments	(2a)	0,113	0,380	2,182	2,676
<u>Appropriations of an administrative nature financed from the envelope of specific programmes</u>						
Budget line		-3	0	0	0	0
TOTAL appropriations for DG SANTE	Commitments	.=1a +3	0,565	1,055	1,056	2,676
	Payments	.=2a+3	0,113	0,380	2,182	2,676

• TOTAL operational appropriations	Commitments	(4)	0,565	1,055	1,056	2,676
	Payments	(5)	0,113	0,380	2,182	2,676
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0,000	0,000	0,000	0,000
TOTAL appropriations under HEADING 2 -Cohesion, Resilience and Values of the multiannual financial framework	Commitments	=4+6	0,565	1,055	1,056	2,676
	Payments	=5+6	0,113	0,380	2,182	2,676

Heading of multiannual financial framework	7	‘Administrative expenditure’
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This section should be filled in using the 'budget data of an administrative nature' to be firstly introduced in the [Annex to the Legislative Financial Statement](#) (Annex 5 to the Commission decision on the internal rules for the implementation of the Commission section of the general budget of the European Union), which is uploaded to DECIDE for interservice consultation purposes.

EUR million (to three decimal places)

		Year 2025	Year 2026	Year 2027	Year 2027 et seqq	TOTAL
DG: SANTE						
• Human resources		0,000	0,000	0,000	0,000	0,000
• Other administrative expenditure		0,000	0,000	0,000	0,000	0,000
TOTAL DG SANTE	Appropriations	0,000	0,000	0,000	0,000	0,000
TOTAL appropriations under HEADING 7 of the multiannual financial framework		(Total commitments = Total payments)	0,000	0,000	0,000	0,000

EUR million (to three decimal places)

		Year 2025	Year 2026	Year 2027 et seqq	TOTAL
TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework	Commitments	0,665	1,055	1,056	2,776
	Payments	0,163	0,430	2,182	2,776

3.2.2. Estimated output funded with operational appropriations

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs			Year		Year		Year		TOTAL	
			2025		2026		2027 et seqq			
OUTPUTS										
	Type[1]	Average cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1 : Procedures for the deliberate release and placing on the market ensure that NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden.										
Verification on equivalence of NGT plants to conventional plants : New EFSA task to determine before placing on the market or before filed trials whether the notified NGT plant meets pre-defined equivalence criteria (Preparatory work, Assessment of equivalence to predefined criteria)				0,081		0,231		0,232		0,544
Placing on the market of NGT plants and food/feed - related tasks- Extension of the EFSA capacity to risk assess new applications for the placing on the market of NGT plants and food/feed and to provide scientific/technical advice before the authorisation procedure in pre-determined cases (Preparatory work and Risk Assessment of NGT applications)				0,223		0,489		0,490		1,201
Verification on equivalence of NGT plants to conventional plants - Outsourcing for molecular data verification (18 notifications)				0,090		0,090		0,090		0,270
Expansion of the E-Submission Food Chain (ESFC) to include exchange of information and maintenance and development and maintenance of a public register for:A new domain in the FIP/ESFC system				0,100		0,000		0,000		0,100
Placing on the market of NGT plants and food/feed - related tasks - Preparatory work (Cost of indemnities and expert meetings and Cost of contracts supporting RA)				0,150		0,150		0,150		0,450

Subtotal for specific objective No 1			0,644	0,960	0,962	2,566
SPECIFIC OBJECTIVE No 2 .Deliberate release and placing on the market of NGT plants and derived food/feed products that feature a wide range of plant species and traits by various developers						
Verification on equivalence of NGT plants to conventional plants - New EFSA task to determine before placing on the market or before filed trials whether the notified NGT plant meets pre-defined equivalence criteria : Intake steps			0,000	0,062	0,062	0,124
Placing on the market of NGT plants and food/feed - related tasks- Extension of the EFSA capacity to risk assess new applications for the placing on the market of NGT plants and food/feed and to provide scientific/technical advice before the authorisation procedure in pre-determined cases (Pre-submission advice and Intake steps)			0,021	0,033	0,033	0,086
Subtotal for specific objective No 2			0,021	0,094	0,095	0,210
TOTALS			0,665	1,055	1,056	2,776

i. *Summary of estimated impact on EFSA's Human Resources*

	2025	2026	2027 and et seqq	Total
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in EUR million (to three decimal places)

Temporary agents (AD Grades)	0,325	0,652	0,653	1,630
Temporary agents (AST grades)	0,000	0,163	0,163	0,326
Contract staff	0,000	0,000	0,000	0,000
Seconded National Experts	0,000	0,000	0,000	0,000
Total	0,325	0,815	0,816	1,956

Staff requirements (FTE): Total posts Union funded

Temporary agents (AD Grades)	2,0	4,0	4,0	4,0
Temporary agents (AST grades)	0,0	1,0	1,0	1,0
Contract staff	0,0	0,0	0,0	0,0
Seconded National Experts	0,0	0,0	0,0	0,0
Total	2,0	5,0	5,0	5,0

3.2.3. Summary of estimated impact on administrative appropriations

- The proposal/initiative does not require the use of appropriations of an administrative nature
- The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year N ¹	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)	TOTAL
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HEADING 7 of the multiannual financial framework							
Human resources							
Other administrative expenditure							
Subtotal HEADING 7 of the multiannual financial framework							

Outside HEADING 7² of the multiannual financial framework							
Human resources							
Other expenditure of an administrative nature							
Subtotal outside HEADING 7 of the multiannual financial framework							

TOTAL							
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The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

¹ Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

² Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

3.2.3.1. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources.
- The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

	Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
• Establishment plan posts (officials and temporary staff)							
20 01 02 01 (Headquarters and Commission's Representation Offices)							
20 01 02 03 (Delegations)							
01 01 01 01 (Indirect research)							
01 01 01 11 (Direct research)							
Other budget lines (specify)							
• External staff (in Full Time Equivalent unit: FTE)¹							
20 02 01 (AC, END, INT from the 'global envelope')							
20 02 03 (AC, AL, END, INT and JPD in the delegations)							
XX 01 xx yy zz ²	- at Headquarters						
	- in Delegations						
01 01 01 02 (AC, END, INT - Indirect research)							
01 01 01 12 (AC, END, INT - Direct research)							
Other budget lines (specify)							
TOTAL							

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	<ol style="list-style-type: none"> 1) managing (AD) and supporting (AST) the GMO panel in its risk assessment activities for NGT plants under the authorisation procedure 2) Assessing (AD) and supporting the assessment (AST) the equivalence to predefined criteria of NGT plants under the notification procedure 3) Supporting the applicants and performing the completeness check (AD) for NGT plants under the notification procedure 4) Giving scientific advice (AD) to the the applicant to NGT plants containing traits that contribute to sustainability under the authorisation procedure 5) Supporting the applicant and performing the completeness (AD) check for NGT plants under the authorisation procedure
External staff	

¹ AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JPD= Junior Professionals in Delegations.

² Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

3.2.4. *Compatibility with the current multiannual financial framework*

The proposal/initiative:

- can be fully financed through redeployment within the relevant heading of the Multiannual Financial Framework (MFF).

The increase of appropriations for EFSA budget line 06 10 02 European Food Safety Authority in years 2025 to 2027 by 2,7 million EUR, will be done via internal redeployment within heading 1, i.e. by an equal reduction of the SMP Food Strand budget line 03 02 06. For this period reprogramming is required, specifying the budget lines concerned and the corresponding amounts. The required financing of 0,100 million EUR under the line 03 02 06 - Contributing to a high level of health and welfare for humans, animals and plants will be covered by internal redeployment.

- requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation.

Explain what is required, specifying the headings and budget lines concerned, the corresponding amounts, and the instruments proposed to be used.

- requires a revision of the MFF.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. *Third-party contributions*

The proposal/initiative:

- does not provide for co-financing by third parties
- provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year N ¹	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

¹ Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

3.3. Estimated impact on revenue

- The proposal/initiative has no financial impact on revenue.
- The proposal/initiative has the following financial impact:
 - on own resources
 - on other revenue
 - please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative ²							
		Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			
Article									

For assigned revenue, specify the budget expenditure line(s) affected.

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

² As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20 % for collection costs.

