



EUROPEAN  
COMMISSION

Brussels, 5.7.2023  
COM(2023) 411 final

2023/0226 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on plants obtained by certain new genomic techniques and their food and feed, and  
amending Regulation (EU) 2017/625**

(Text with EEA relevance)

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

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### • Reasons for and objectives of the proposal

New genomic techniques (NGTs)<sup>1</sup> 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 modifications to the genome than conventional breeding or established genomic techniques<sup>2</sup> and these modifications could or could not be produced in nature or obtained by conventional breeding techniques.

Targeted mutagenesis<sup>3</sup> and cisgenesis<sup>4</sup> (including intragenesis) are considered NGTs. They are different from established genomic techniques because they have novel features, for example, higher precision and speed in introducing the desired genetic modifications and the insertion of genetic material only from a crossable<sup>5</sup> species. Targeted mutagenesis and cisgenesis do not introduce genetic material from non-crossable species -transgenesis- whereas this is the case with established genomic techniques. In addition, in some cases, products containing or consisting of plants with genetic modifications introduced by NGTs cannot be differentiated from products containing or consisting of plants bred with conventional breeding methods by analytical methods, whereas this is always possible for established genomic techniques.

The scope of this initiative are plants produced by targeted mutagenesis and cisgenesis (including intragenesis), products containing or consisting of these plants and food and feed containing, consisting or produced from these plants. The choice of the scope is based on several reasons. Numerous advanced and early 'research & development' applications concern plants, and several plant products are already on or very close to the market. In certain cases, substantially equivalent plants can be obtained with conventional breeding methods and with 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 specific hazards linked to

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<sup>1</sup> 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 Union legislation on genetically modified organisms (GMOs) was adopted.

<sup>2</sup> Genetic modification techniques developed prior to 2001, when the Union GMO legislation was adopted.

<sup>3</sup> 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

<sup>4</sup> 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).

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

targeted mutagenesis or cisgenesis<sup>6</sup>. 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. Therefore, due to how these novel techniques work, and compared to transgenesis, a lesser amount of data might be needed for the risk assessment of these plants and products made from them.

There is significant demand in the Union and globally for NGT plants, because of their potential to contribute to addressing current challenges in the agri-food system. Climate change and biodiversity loss have put the focus on long-term resilience of the food chain and the need to transition to more sustainable agriculture and food systems. The European Green Deal's Farm to Fork Strategy<sup>7</sup> specifically identifies new techniques, including biotechnology, that are safe for consumers and the environment and bring benefits to society as a whole, as a possible tool to increase sustainability of agri-food systems and contribute to guaranteeing food security<sup>8</sup>.

The Covid-19 pandemic and Russia's war of aggression against Ukraine have also revealed the Union's external dependencies. In its Trade Policy Review Communication<sup>9</sup>, the Commission 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 genomic techniques and can contribute, for example, to decreasing the Union's dependence on imports of plant proteins. They can also support the special needs in the Outermost Regions. NGTs are more technically accessible than established genomic techniques as they have low entry and operating costs. This could mean that the developers and users of these techniques are more diversified if access to and affordability of the technologies is maintained. NGTs could be also relevant in low- and middle income countries, which would benefit from adapting traditional, local crop species so that

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<sup>6</sup> EFSA Panel on Genetically Modified Organisms, Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. *EFSA Journal* 2012;10(10):2943. doi:10.2903/j.efsa.2012.2943.

EFSA Panel on Genetically Modified Organisms, 'Applicability of the EFSA Opinion on SDNs type 3 for the safety assessment of plants developed using SDNs type 1 and 2 and oligonucleotide-directed mutagenesis', *EFSA Journal* 2020;18(11):6299. <https://doi.org/10.2903/j.efsa.2020.6299>

EFSA Panel on Genetically Modified Organisms, 2012. Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. *EFSA Journal* 2012;10(2):2561.

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>.

EFSA Panel on Genetically Modified Organisms, 2021. Scientific Opinion on the evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology. *EFSA Journal* 2021;19(2):6301, 21 pp. <https://doi.org/10.2903/j.efsa.2021.6301>

EFSA Panel on Genetically Modified Organisms, 2022. Scientific Opinion on the evaluation of existing guidelines for their adequacy for the food and feed risk assessment of genetically modified plants obtained through synthetic biology. *EFSA Journal* 2022;20 (7):7410, 25 pp. <https://doi.org/10.2903/j.efsa.2022.7410>

<sup>7</sup> A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system. COM (2020) 381 final

<sup>8</sup> Safeguarding food security and reinforcing the resilience of food systems. COM (2022) 133 final.

<sup>9</sup> Trade Policy Review - An Open, Sustainable and Assertive Trade Policy. COM (2021) 66 final

they can withstand changing conditions. An enabling framework in the EU could also support use in those countries.

In its judgment of 25 July 2018, in case C-528/16<sup>10</sup> the Court of Justice of the European Union held that Directive 2001/18 cannot be interpreted as excluding from its scope Genetically Modified Organisms ('GMOs') obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since that Directive was adopted.

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 that judgment 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 study<sup>11</sup> on 29 April 2021 (the 'Commission NGT study'). It concluded that there are strong indications that the current Union GMO legislation is not fit to regulate NGT plants obtained by targeted mutagenesis or cisgenesis, and products (including food and feed) derived from them and that that legislation needs to be adapted to scientific and technical progress in this area. The study identified the following problems:

- the risk assessment requirements and authorisation procedure 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 will be difficult to implement and enforce for certain plants produced by targeted mutagenesis or cisgenesis, in particular those for which a specific detection method cannot be provided;
- the application of the current GMO legislation to NGTs is not conducive to the development of innovative products that are potentially beneficial for breeders, farmers, food business operators, consumers and the environment.

These problems affect numerous operators across the agri-food system, especially breeders, the agricultural biotechnology innovation and research sector, farmers, bio-based industry and consumers, traders, and Union and national authorities. In addition, outside the Union, various third countries have already taken measures on NGTs, adapting the degree of regulatory oversight to the specific nature of NGT plants and products made from them. The Union risks being excluded to a significant extent from the technological developments and economic, social and environmental benefits that these new technologies can potentially generate, if its GMO framework is not adapted to NGTs. In turn, this would lead to less strategic autonomy for the Union.

Therefore, the Union's regulatory framework should be adapted to make NGTs subject to the appropriate level of regulatory oversight. The objectives of the proposal are the following:

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<sup>10</sup> 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.

<sup>11</sup> SWD(2021) 92

## 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<sup>12</sup>;
- ensure the effective functioning of the internal market in NGT plants and products and food and feed containing, consisting or produced from NGT plants, and enhance the competitiveness of the Union agri-food sector at the Union and global levels, including a level-playing field for 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 Union legislation on GMOs (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC). This proposal sets new requirements specifically for NGT plants obtained by targeted mutagenesis and cisgenesis and products containing or consisting in these plants and food and feed containing, consisting or produced from these plants. This proposal 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 and Biodiversity strategies, the Union's Strategy on Adaptation to Climate Change and the planned initiative on a legislative framework for a sustainable food system. It is consistent with these strategies' objectives.

For example, through the development of pest-resistant plants, 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 products<sup>13</sup>.

The placing on the market and cultivation of NGT plant and forest reproductive material will also have to comply with Union legislation on the marketing of seeds

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<sup>12</sup> EU Biodiversity Strategy for 2030 Bringing nature back into our lives, COM/2020/380 final

<sup>13</sup> COM (2022)305 final, 2022/0196 (COD), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0305&qid=1674645473396>

and other Plant and Forest Reproductive Material ('PRM', 'FRM') which is also undergoing a revision. The aim of that revision is to ensure availability and choice within the Union of PRM and FRM of high quality, adaptable to the current and foreseeable climatic changes, and that contributes to food security, sustainable production and protection of biodiversity. The objectives of the NGT initiative, on the one hand and the PRM/FRM revision on the other are therefore fully compatible.

This proposal shares objectives related to sustainable agriculture and food production with the Union legislation on organic production (Regulation (EU) 2018/848<sup>14</sup>) ('Organic Products Regulation'). The Organic Products Regulation bans the use of GMOs and GM food and feed in organic production. Under this proposal the ban continues to apply to all NGT plants and food and feed falling within its scope. This is consistent with the Organic Products Regulation because the use of new genomic techniques is incompatible with the current concept of organic production in the Regulation (EC) 2018/848 and current consumers' perception of organic products.

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

- **Subsidiarity (for non-exclusive competence)<sup>15</sup>**

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 and cross national borders. The requirements for the deliberate release and the placing on the market of NGT plants and food and feed derived from them are already harmonised at Union level under the existing legal framework applicable to GMOs. In order to ensure that these plants, products and food and feed can circulate freely within the internal market, while ensuring a high level of protection of human and animal health and the environment, the regulatory framework needs to be adapted to the specificities of plants obtained by these techniques. In addition, the EU Farm to Fork Strategy recognises the potential of new techniques, including biotechnology, to increase sustainability of the food system and bring benefits to society as a whole.

For these reasons, action needs to be taken by the Union. Carving out NGT plants from the current Union legal framework and leaving it to Member States to regulate them would likely lead to different regulatory requirements and levels of protection in the Union. Differing national requirements for NGT plants and products derived from them would hinder the free movement of these plants and products, fragment the internal market and lead to uneven competition between economic operators.

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<sup>14</sup> OJ L 150, 14.6.2018, p. 1–92.

<sup>15</sup> SWD(2023) 411

- **Proportionality**

The principle of proportionality has been taken into account in the comparison of the 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 of NGT plants and products (including food and feed) derived from them have been designed to cater for the diversity of risk profiles of these plants and products. The proposal provides for a verification procedure for those NGT plants and products derived from them that could also occur naturally or be produced by conventional breeding and an authorisation procedure with a risk assessment adapted to the risk profile for all other NGT plants and derived products. These different procedures enable competent authorities to verify that NGT plants and products derived from them are as safe as their conventional counterparts, and are no stricter than necessary to ensure that the potential risks to human or animal health or the environment are properly identified and evaluated.

- **Choice of the instrument**

The chosen policy instrument is a Regulation. The authorisation procedure as well as the verification procedure are based on fully harmonised criteria, requirements and procedures that should lead to a decision for the whole Union, ensuring the same high level of protection of health and the environment and the availability of the products concerned across the Union. 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 Union GMO legislation were carried out on behalf of the Commission in 2010 (on GM food and feed)<sup>16</sup> and 2011 (GMO cultivation and placing of GMOs on the market)<sup>17</sup>. They noted concerns that the legislative framework was only focused on risks and not suited for the Union 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. These 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 confirmed that the findings of those prior studies remain relevant and that the challenges have increased, especially as regards plants produced by targeted mutagenesis and cisgenesis.

- **Stakeholder consultations**

A consultation strategy<sup>18</sup> was prepared 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

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<sup>16</sup> Food Chain Evaluation Consortium (2010)

<sup>17</sup> GHK Consulting (2011)

<sup>18</sup> [https://food.ec.europa.eu/system/files/2022-09/sc\\_modif-genet\\_consultation-strategy-ngts.pdf](https://food.ec.europa.eu/system/files/2022-09/sc_modif-genet_consultation-strategy-ngts.pdf)

agri-food sector; academic and research stakeholders active in the field of biotechnology in general and agricultural/plant biotechnology; civil society/non-governmental organisations with interest in the topic; Union Member States' and third country public authorities; union 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 Assessment<sup>19</sup> (24 September 2021 – 22 October 2021);
- Commission's public consultation (29 April 2022 – 22 July 2022)<sup>20</sup>;
- 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 in organic agriculture and GM-free production), 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, while the majority of citizens' contributions in the public consultation and the non-campaign replies in the inception impact assessment favoured the adaptation of legislation).

Some respondents (majority of academia/research institutions, biotechnology/bio-based industry, farming, feed, food processing/manufacturing, plant breeding/seeds, plants protection products/fertilisers, ornamental plants sector, 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. Various stakeholders (biotechnology/biotech industry, plant breeding/seeds, plant protection products/fertilisers, feed, ornamental plants sector 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 NGOs, and consumer 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 the inclusion of sustainability provisions in the 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

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<sup>19</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en)

<sup>20</sup> [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](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)



single trait. On the other side, such provisions are supported by a majority of respondent 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 considered as the most relevant, 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 NGOs, the organic and GM-free sectors call for physical labels on the final product, while the 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 those in organic agriculture and GM-free production), 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 was raised by many stakeholders. Concerns have been expressed by breeders and farmers' organisations on the need to ensure breeders' access to patented genetic material and access by of farmers to PRM from NGT plants bearing in mind that certain NGT plants are undistinguishable from plants obtained by conventional breeding techniques.

- **Collection and use of expertise**

The following studies were conducted to support the impact assessment:

- Technopolis Group, Arcadia International and Wageningen University & Research. Study to support the impact assessment of legislation for plants produced by certain new genomic techniques<sup>21</sup>;
- Commission's Joint Research Centre (JRC) case studies to analyse the potential economic, environmental and social (health) impacts of selected NGT plants in the development pipeline<sup>22</sup>. The impact assessment also relies on the

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<sup>21</sup> <https://doi.org/10.2875/282347>

<sup>22</sup> 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.

two JRC reports (on market applications<sup>23</sup> and latest scientific developments relating to NGTs<sup>24</sup>) supporting the Commission NGT study;

- two mandates were given to EFSA to support this impact assessment (statement on criteria for risk assessment<sup>25</sup> and update of EFSA's 2012 opinion on cisgenesis<sup>26</sup>). Other, previous relevant EFSA opinions (referenced above) 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 2023<sup>27</sup>.

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.

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<sup>23</sup> 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.

<sup>24</sup> Broothaerts, 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>

<sup>25</sup> 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>

<sup>26</sup> 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>

<sup>27</sup> SWD(2023) 412

5. **Option 4:** verification procedure<sup>28</sup> 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 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 NGT plants not fulfilling the criteria of equivalence to conventional plants).

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

The verification procedure for plants obtained by targeted mutagenesis or cisgenesis that could also occur naturally or be produced by conventional breeding achieves a high level of protection of human and animal health and the environment while ensuring that requirements are proportionate to risks. These plants are not subject to traceability and labelling as GMOs. This regime is expected to have by far the strongest positive impact on the development and placing on the market of NGT plants and products (including food and feed), as it results in a higher degree of simplification and reduction of administrative burden for applicants and authorities. The savings for breeders per verification procedure are estimated to range from EUR 9.95 million to EUR 11.2 million. For administrations, the total savings for verification procedures are estimated to be up to EUR 1.4 million per year. In light of the traits under development, this option also shows the highest potential to facilitate the contribution of NGTs to sustainability of the agri-food system. It is the most advantageous for SMEs, as administrative and compliance costs will substantially decrease, has the strongest impact on competitiveness and would be the least disruptive of trade.

The authorisation procedure with adapted risk assessment for NGT plants and products not covered by the verification procedure ensures a high level of protection of human and animal health and the environment, while being proportionate as the data requirements for the risk assessment are adapted to the risk profile. The savings for breeders per authorisation are estimated to range from EUR 0 to EUR 10 365 000 (from negligible reduction if similar data requirements apply as today to a maximum reduction of 85% in cases with minimum data requirements). For administrations, total savings for authorisation are estimated to range from EUR 0 to 700 000 per year. These savings will increase attractiveness to develop such NGT plants in the

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In the impact assessment, this verification procedure is referred to as 'notification procedure'. That terminology is not used in the legislative proposal to avoid confusion with the notification procedure in Directive 2001/18/EC.

Union. Regulatory incentives would help steer the development of NGTs towards traits with the potential to contribute to the sustainability of the agri-food chain and would support the competitiveness of SMEs. The waiving of fees for the validation of the detection methods adds an extra saving of EUR 105 000 (EUR 52 500 for SMEs) for breeders in the authorisation procedure.

NGT plants subject to authorisation would also remain subject to traceability and labelling as GMOs. The existing GM label would be complemented with the possibility to inform purchasers 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 trait will be determined in the authorisation, and 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 would remain mandatory.

As regards the treatment in organic production of NGT plants and derived products that meet the criteria to be considered equivalent to conventional breeding, two possible sub-options were considered in the Impact Assessment: to treat them as GMOs or as conventional products. The use of new genomic techniques is currently incompatible with the concept of organic production in the Regulation (EC) 2018/848 and current consumers' perception of organic products. This was reflected in the concerns of the majority of the organic sector in the impact assessment. Therefore, 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.

In full alignment with the 'do no significant 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.

The European Climate Law<sup>29</sup> requires relevant Union institutions and the Member States to ensure continuous progress in enhancing adaptive capacity, strengthening resilience and reducing vulnerability to climate change. Against this background, the EU Strategy on Adaptation to Climate Change<sup>30</sup> considers 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 adaptation and resilience and, by doing so, also to land-based climate mitigation in support of the Unions's 2050 climate neutrality target.

The proposal has the potential to contribute towards the implementation of several of the United Nations' Sustainable Development Goals ('SDG'): SDG2 (End hunger), SDG3 (Good Health and Well-being), SDG9 (Industry, Innovation and Infrastructure); SDG12 (Responsible consumption and production), SDG13 (Take

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<sup>29</sup> Regulation (EU) 2021/1119

<sup>30</sup> COM (2021) 82 final

urgent action to combat climate change and its impacts) (see section 1.1 of the impact assessment).

A first version of the Impact Assessment Report was submitted to the Regulatory Scrutiny Board (RSB) on 15 February 2023. The Board's overall opinion was negative because of a lack of a clear, consistent, and hierarchical set of general and specific objectives, insufficient detail with regard to the main elements of the options and the key policy choices, an insufficient assessment of the impact on consumer trust, the organic sector, the environment and health, a lack of a comprehensive overview of the costs and benefits and the lack of a comprehensive assessment of all relevant (combinations of) options in terms of effectiveness, efficiency and coherence. These points were all addressed in a revised version (see Annex 1 of the impact assessment).

The revised impact assessment received a positive opinion with reservations on 26 May 2023<sup>31</sup>. The comments of the Board concerned the need for further information on the verification procedure and criteria, further clarity in the preferred option regarding the use in organic production of NGT plants/products fulfilling the criteria of equivalence to conventional plants, and a comprehensive overview of benefits and costs. They have all been addressed (see Annex 1 of the impact assessment).

- **Regulatory fitness and simplification**

The proposal represents an important simplification of the current authorisation procedure as regards NGTs, notably through the adapted risk assessment and the new verification procedure for products that fulfil the criteria for equivalence to conventional breeding, and is expected to lead to a considerable reduction in costs for developers 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 into the plant breeding sector, benefitting SMEs in particular.

**Verification procedure:** Breeders are expected to experience a considerable reduction in administrative burden and in compliance costs, primarily due to reduced data requirements for the verification procedure compared to the current situation (only data to show compliance with the criteria for equivalence to conventional breeding instead of data for risk assessment and on the 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 requirements for the adapted risk assessment. The savings may vary but they may be as high as 85% of the current costs.

The proposal is expected to support competitiveness of the Union plant breeding and farming sectors. In major trading partners of the Union, NGT plants, , that could also result from conventional breeding and food and feed derived from them are not subject to GMO regimes. The Union seed sector is the largest exporter of seeds in the world and the ability to use innovative technologies is a prerequisite to maintain

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<sup>31</sup> SEC(2023) 411

competitiveness on the global market. This proposal is also expected to have an impact on strategic autonomy and resilience of the Union 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 in line with 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 Union. Regulatory oversight procedures apply to ensure that only NGT plants and derived products 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).

As for the NGT products that could occur naturally or be produced by conventional breeding, these would not be subject to GMO traceability and labelling but would be entered into a public register. This would increase transparency compared to the treatment today, of GMOs exempted from the requirements of the GMO legislation (e.g., the products of random mutagenesis) for operators (organic, GM-free) and consumers and allow operators at the beginning of the food chain – from breeding to seed production – to identify products obtained from NGTs and to avoid them if so wanted.

Adapting data requirements to the risk profile of NGT plants and product will reduce the complexity, duration and costs of the application for authorisation, where such authorization is required, and the verification procedure will significantly reduce administrative and compliance costs for operators.

#### **4. BUDGETARY IMPLICATIONS**

The budgetary implications are set out in the legislative financial statement attached to the proposal. Overall, the proposal will be budget neutral. Indeed, the costs of this proposal, estimated at EUR 2,434 million will be fully covered by redeployments within existing financial envelopes of the current MFF.

The budgetary implications are mainly related to additional tasks to be carried out by EFSA in terms of new scientific and administrative tasks as regards the adapted risk assessment, the verification procedure for certain NGT plants and pre-submission advice. The Commission proposes to reinforce the budgetary envelope of EFSA by EUR 2,334 million from the unallocated margin of Heading 2b, which will be compensated through a reduction of the Single Market Programme, whose objectives are directly linked to those of this initiative, resulting in an increase of the unallocated margin of Heading 1.

In addition, new IT tools and database are also needed to implement the legislation. An amount of EUR 100 000 is foreseen under the Single Market Programme to integrate the NGT plants/products 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 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. An evaluation should be carried out no sooner than two years after the first monitoring report has been published.

- **Explanatory documents (for directives)**

n/a

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

**Chapter 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 and products (including food and feed) derived from them subject to one of two procedures: verification procedure to establish equivalence with conventional plants/products (Chapter II) or authorisation in accordance with Directive 2001/18 for products or Regulation (EC) No 1829/2003 (Chapter III) for food and feed.

**Chapter II** (Arts. 5-11) provides for a verification procedure and criteria to verify whether NGT plants obtained by targeted mutagenesis or cisgenesis could also have been obtained naturally or by conventional breeding techniques, based on the criteria of Annex I ('category 1 NGT plants'). Category 1 NGT plants are exempted from the requirements of the GMO legislation and are subject to the provisions applicable to conventional plants. However, they remain prohibited in organic production (Art. 5).

In case of verification prior to field trials, compliance with the criteria is done by the Member State that receives the verification request, as it is currently the case for field trials which are subject to the notification procedure in part B of Directive 2001/18. However, in the case of NGT plants, verification of compliance with the criteria of Annex I by the Member State that received the request will be in the form of a decision, valid for the whole of the Union and which will cover the subsequent placing on the market of the NGT plant, of products containing or consisting of such plant and of food and feed containing, consisting or produced from such plant (Art. 6). When no field trials have been carried out in the Union, including in the case of imported food or feed, the verification request will be submitted to EFSA, who will provide scientific advice on compliance with the criteria and the decision will be taken by the Commission (Art. 7).

Transparency about category 1 NGT plants is ensured through the setting up of a public database, through the labelling of seeds (Arts. 9-10) and through the inclusion of a mention in the catalogues provided for in the PRM/FRM legislation, that the variety is a category 1 NGT plant.

**Chapter III** (Arts. 12-25) applies to NGT plants which do not meet the criteria to consider that they could also be obtained naturally or by conventional breeding and, therefore, do not fall under the procedure laid down in Chapter II ('category 2 NGT plants'). In this case, the procedures of the GMO legislation apply with some adaptations: (i) section 1 (Art. 13) adapts the procedure in part B of Directive

2001/18 for the deliberate release for purposes other than placing on the market; (ii) section 2 (Arts. 14-17) adapts the procedure in part C of Directive 2001/18 for the placing on the market of products other than food and feed; and (iii) section 3 (Arts. 18-21) adapts the procedure of Regulation (EC) No 1829/2003 for the placing on the market of GM food and feed.

The main adaptations are a risk assessment based on Annex II to the present Regulation; the modalities to comply with detection method requirements in cases where it is not feasible to provide a method that detects, identifies and quantifies; and the possibility to tailor to the risk profile monitoring requirements and the need for regular renewal.

Regulatory incentives (section 4 Art. 22) apply for category 2 NGT plants containing the traits listed in Part 1 of Annex III. These are traits that could contribute to the overall performance of varieties as regards sustainability and provided they do not contain traits listed in Part 2 of Annex III (herbicide-tolerant).

Category 2 NGT plants and products remain subject to traceability and labelling requirements in the Union's GMO legislation with the possibility to add a factual statement on the intended purpose of the genetic modification (section 4 Art. 23). The possibility for Member States to restrict or prohibit cultivation in their territory of GMOs pursuant to Directive 2001/18 will not apply to such NGT plants. Member States will be required to adopt coexistence measures to avoid the unintended presence of such NGT plants in organic and conventional crops (section 4 Art. 24).

**Chapter IV** (Arts. 26-34) contains the provisions on delegated and implementing acts (Arts. 16-28), guidance (Art. 29), monitoring, reporting and evaluation (Art. 30), references in other Union legislation (Art. 31), administrative review (32) and amendments of other legislation (Art. 33).



Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625**

(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 Articles 43, 114 and 168(4) (b) 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 Committee,

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council <sup>(1)</sup>, on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted, significant progress in biotechnology has led to the development of new genomic techniques (NGTs), most prominently genome editing techniques that enable changes to be made to the genome at precise locations.
- (2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications. Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis). They rely only on the breeders' gene pool, i.e. the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced breeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at precise locations in the genome of an organism. Cisgenesis techniques result in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool. Intragenesis is a subset of cisgenesis resulting in the insertion in the genome of a rearranged copy of genetic material composed of two or more DNA sequences already present in the breeders' gene pool.

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<sup>1</sup> 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).

- (3) There is ongoing public and private research using NGTs on a wider variety of crops and traits compared to those obtained through transgenic techniques authorised in the Union or globally<sup>(2)</sup>. 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, plants with higher yields and resilience and improved quality characteristics. These types of new plants, coupled with the fairly easy and speedy applicability of those new techniques, could deliver benefits to farmers, consumers and to the environment. Thus, NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal<sup>(3)</sup> and of the ‘Farm to Fork’<sup>(4)</sup>, Biodiversity<sup>(5)</sup> and Adaptation to Climate Change<sup>(6)</sup> Strategies, to global food security<sup>(7)</sup>, the Bioeconomy Strategy<sup>(8)</sup> and to the Union’s strategic autonomy<sup>(9)</sup>.
- (4) The deliberate release into the environment of organisms obtained by NGTs, including products containing or consisting of such organisms, as well as the placing on the market of food and feed produced from these organisms, are subject to Directive 2001/18/EC and, Regulation (EC) No 1830/2003<sup>(10)</sup> of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003<sup>(11)</sup>, while the contained use of plant cells is subject to Directive

<sup>2</sup> Insights and solutions stemming from EU-funded research and innovation projects on plant breeding strategies may contribute to address detection challenges, ensure traceability and authenticity, and promote innovation in the area of new genomic techniques. More than 1,000 projects were funded under the Seventh Framework Programme and successor Horizon 2020 programme with an investment of over 3 billion Euros. Horizon Europe support to new collaborative research projects on plant breeding strategies is also ongoing, SWD(2021) 92.

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

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions forging a Climate-Resilient Europe - The New EU Strategy on Adaptation to Climate Change, COM(2021) 82 final

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

<sup>8</sup> European Commission, Directorate-General for Research and Innovation, A sustainable bioeconomy for Europe – Strengthening the connection between economy, society and the environment: updated bioeconomy strategy, Publications Office, 2018, <https://data.europa.eu/doi/10.2777/792130>.

<sup>9</sup> 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.

<sup>10</sup> 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).

<sup>11</sup> 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).

2009/1/EC, and transboundary movements of NGT plants to third countries are regulated by Regulation (EC) No 1946/2003 ('the Union GMO legislation').

- (5) In its judgment in case C-528/16 *Confédération paysanne and Others*<sup>12</sup> the Court of Justice of the European Union held that GMOs obtained by means of new techniques/methods of mutagenesis that had appeared or had been mostly developed since Directive 2001/18/EC was adopted could not be considered excluded from the scope of that Directive.
- (6) The Council, in Decision (EU) 2019/1904<sup>13</sup>, requested the Commission to submit, by 30 April 2021, a study in light of that judgment regarding the status of novel genomic techniques under Union law, and a proposal (accompanied by an impact assessment), if appropriate, depending on the conclusions of the study.
- (7) The Commission's study on new genomic techniques (<sup>14</sup>) concluded that the Union GMO legislation is not fit for the purpose of regulating the deliberate release of plants obtained by certain NGTs and the placing on the market of related products including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained with some NGTs, namely targeted mutagenesis and cisgenesis (including intragenesis), and these requirements can be disproportionate or inadequate. The study showed that this is particularly the case for plants obtained by these techniques, given the amount of scientific evidence that is already available, in particular on their safety. Furthermore, the Union GMO legislation is difficult to implement and enforce for plants obtained by targeted mutagenesis and cisgenesis and related products. In certain cases, genetic modifications introduced by these techniques are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques, whereas the distinction is generally possible for genetic modifications introduced by transgenesis. The Union GMO legislation is also not conducive to developing innovative and beneficial products that could contribute to sustainability, food security and resilience of the agri-food chain.
- (8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.
- (9) Based on the current scientific and technical knowledge in particular on safety aspects, this Regulation should be limited to GMOs that are plants, i.e. organisms in the taxonomic groups Archaeplastida or Phaeophyceae, excluding microorganisms, fungi and animals for which the available knowledge is more limited. For the same reason, this Regulation should only cover plants obtained by certain NGTs: targeted mutagenesis and cisgenesis (including intragenesis) (hereinafter 'NGT plants'), but not by other new genomic techniques. Such NGT plants do not carry genetic material from

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<sup>12</sup> 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.

<sup>13</sup> Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study ([OJ L 293, 14.11.2019, p. 103](#)).

<sup>14</sup> 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.

non-crossable species. GMOs produced by other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) should remain subject only to the Union GMO legislation, given that the resulting plants might bear specific risks associated to the transgene. Moreover, there is no indication that current requirements in the Union GMO legislation for GMOs obtained by transgenesis need adaptation at the present time.

- (10) The legal framework for NGT plants should share the objectives of the Union GMO legislation to ensure a high level of protection of human and animal health and of the environment and the good functioning of the internal market for the concerned plants and products, while addressing the specificity of NGT plants. This legal framework should enable the development and placing on the market of plants, food and feed containing, consisting of or produced from NGT plants and other products containing or consisting of NGT plants ('NGT products') so as to contribute to the innovation and sustainability objectives of the European Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and to enhance the competitiveness of the Union agri-food sector at Union and world level.
- (11) This Regulation constitutes *lex specialis* with regard to the Union GMO legislation. It introduces specific provisions for NGT plants and NGT products. However, where there are no specific rules in this Regulation, NGT plants and products (including food and feed) obtained from them should remain subject to the requirements of the Union GMO legislation and the rules on GMOs in sectoral legislation, such as Regulation (EU) 2017/625 on official controls or the legislation on certain products like plant and forest reproductive material.
- (12) The potential risks of NGT plants vary, ranging from risk profiles similar to conventionally-bred plants to various types and degrees of hazards and risks that might be similar to those of plants obtained by transgenesis. This Regulation should therefore lay down special rules to adjust the risk assessment and risk management requirements according to the potential risks or lack thereof posed by NGT plants and NGT products.
- (13) This Regulation should distinguish between two categories of NGT plants.
- (14) NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny obtained by conventional breeding techniques ('category 1 NGT plants') should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable, thereby derogating in full from the Union GMO legislation and GMO related requirements in sectoral legislation. In order to ensure legal certainty, this Regulation should set out the criteria to ascertain if a NGT plant is equivalent to naturally occurring or conventionally bred plants and lay down a procedure for competent authorities to verify and take a decision on the fulfillment of those criteria, prior to the release or placing on the market of NGT plants or NGT products. Those criteria should be objective and based on science. They should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained with conventional breeding techniques and should include thresholds for both size and number of genetic modifications to the genome of NGT plants. Since scientific and technical knowledge evolves rapidly in this area, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to update these criteria in light of scientific and

technical progress as regards the type and extent of genetic modifications that can occur in nature or through conventional breeding.

- (15) All NGT plants that are not category 1 ('category 2 NGT plants') should remain subject to the requirements of the Union GMO legislation because they feature more complex sets of modifications to the genome.
- (16) Category 1 NGT plants and products should not be subject to the rules and requirements of the Union GMO legislation and to provisions in other Union legislation that apply to GMOs. For legal certainty for operators and transparency, a declaration of the category 1 NGT plant status should be obtained prior to deliberate release, including the placing on the market.
- (17) This declaration should be obtained prior to any deliberate release of any category 1 NGT plants for any other purpose than placing on the market, such as for field trials that are to take place in the territory of the Union, since the criteria are based on data that is available before the field trials and does not depend on these field trials. When no field trials are to take place in the territory of the Union, operators should obtain that declaration before placing the category 1 NGT product on the market.
- (18) Since the criteria for considering that a NGT plant is equivalent to naturally occurring or conventionally bred plants are unrelated to the type of activity that requires the deliberate release of the NGT plant, a declaration of the category 1 NGT plant status made prior to its deliberate release for any other purpose than placing on the market in the territory of the Union should also be valid for the placing on the market of related NGT products. 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 verification procedure of category 1 NGT plant status prior to field trials should be conducted by national competent authorities as this would be less administratively burdensome for operators, and a decision should be taken at Union level only in case there are comments to the verification report by other national competent authorities. Where the verification request is submitted prior to the placing on the market of NGT products, the procedure should be conducted at Union level in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.
- (19) The competent authorities of the Member States, the Commission and the European Food Safety Authority ('the Authority') should be subject to strict deadlines to ensure that category 1 NGT plant status declarations are made within a reasonable time.
- (20) The verification of category 1 NGT plant status is of technical nature and does not involve any risk assessment or risk management considerations and the decision on the status is only declaratory. Therefore, when the procedure is conducted at Union level, such implementing decisions should be adopted by the advisory procedure, supported by scientific and technical assistance by the Authority.
- (21) Decisions declaring the category 1 NGT plant status should assign an identification number to the NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database and for the purpose of labelling of plant reproductive material derived from them.
- (22) Category 1 NGT plants should remain subject to any regulatory framework that applies to conventionally bred plants. As is the case for conventional plants and products, those NGT plants and their 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, category 1 NGT food featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances of the food will be considered as novel food and thus fall into the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council<sup>(15)</sup> and will be risk assessed in that context.

- (23) Regulation (EU) 2018/848 of the European Parliament and the Council on organic production and labelling of organic products and repealing Council Regulation (EC) 834/2007<sup>(16)</sup> prohibits the use of GMOs and products from and by GMOs in organic production. It defines GMOs for the purposes of that Regulation by reference to Directive 2001/18/EC, excluding from the prohibition GMOs which have been obtained through the techniques of genetic modification listed in Annex 1.B of Directive 2001/18/EC. As a result, category 2 NGT plants will be banned in organic production. However, it is necessary to clarify the status of category 1 NGT plants for the purposes of organic production. The use of new genomic techniques is currently incompatible with the concept of organic production in the Regulation (EC) 2018/848 and with consumers' perception of organic products. The use of category 1 NGT plants should therefore be also prohibited in organic production.
- (24) Provision should be made to ensure transparency as regards the use of category 1 NGT plant varieties, to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard consumer trust. NGT plants that have obtained a category 1 NGT plant status declaration should be listed in a publicly available database. To ensure traceability, transparency and choice for operators, during research and plant breeding, when selling seed to farmers or making plant reproductive material available to third parties in any other way, plant reproductive material of category 1 NGT plants should be labelled as category 1 NGT.
- (25) Category 2 NGT plants should remain subject to the requirements of the Union GMO legislation given that on the basis of current scientific and technical knowledge, their risks need to be assessed. Special rules should be provided in order to adapt the procedures and certain other rules laid down in Directive 2001/18/EC and Regulation (EC) No 1829/2003 to the specific nature of category 2 NGT plants and the differing levels of risk that they may pose.
- (26) Category 2 NGT plants and products, in order to be released into the environment or placed on the market, should remain subject to a consent or authorisation in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003. However, given the wide variety of those NGT plants, the amount of information necessary for the risk assessment will vary on a case-by-case basis. The Authority, in its scientific opinions on plants developed through cisgenesis and intragenesis<sup>17</sup> and on plants

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<sup>15</sup> 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).

<sup>16</sup> Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

<sup>17</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta, J, Fernandez Dumont A, Gennaro A, Lenzi, P, Lewandowska A, Munoz Guajardo IP, Papadopoulou N and Rostoks N, 2022.

developed through targeted mutagenesis<sup>18</sup> recommended flexibility in data requirements for the risk assessment of these plants. Based on the Authority's 'Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis' (19), considerations on the history of safe use, familiarity for the environment and the function and structure of the modified/inserted sequence(s) should assist in determining the type and amount of data required to perform the risk assessment of those NGT plants. It is therefore necessary to establish general principles and criteria for the risk assessment of these plants, while providing for flexibility and possibility to adapt risk assessment methodologies to scientific and technical progress.

- (27) Requirements on the content of notifications for consent for the placing on the market of products containing or consisting of GMOs other than food or feed and on the content of applications for authorisation for the placing on the market of genetically modified food and feed are laid down in different pieces of legislation. To ensure consistency between the notifications for consent and applications for authorisation for category 2 NGT products, the content of such notifications and applications should be the same, except those concerning the assessment of food and feed safety assessment as these are only relevant to category 2 NGT food and feed.
- (28) The European Union Reference Laboratory for GM Food and Feed (EURL), in collaboration with the European Network of GM Laboratories (ENGL), concluded that analytical testing is not considered feasible for all products obtained by targeted mutagenesis and cisgenesis (20). When the introduced modifications of the genetic material are not specific to the NGT plant in question, they do not allow the differentiation of the NGT plant from conventional plants. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier or the applicant, the modalities to comply with analytical method requirements should be adapted. This should be done in the implementing acts adopted pursuant to this Regulation. Provision should also be made for the EURL, assisted by the ENGL, to adopt guidance for applicants on the minimum performance requirements for analytical methods. Modalities for performing method validation may also be adapted.

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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>.

<sup>18</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta J, Gennaro A, Paraskevopoulos K, Raffaello T and Rostoks N, 2020. Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA Journal 2020;18(11):6299, 14 pp. <https://doi.org/10.2903/j.efsa.2020.6299>.

<sup>19</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank 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>.

<sup>20</sup> European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289); 13 June 2023 (JRC133689; EUR 31521 EN)

- (29) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market but provides for flexibility as to the design of the plan taking into account the environmental risk assessment, the characteristics of the GMO, of its expected use and of the receiving environment. Genetic modifications in category 2 NGT plants may range from changes only needing a limited risk assessment to complex alterations requiring a more thorough analysis of potential risks. Therefore, post-market monitoring requirements for environmental effects of category 2 NGT plants should be adapted in the light of the environmental risk assessment and the experience in field trials, the characteristics of the NGT plant concerned, the characteristics and scale of its expected use, in particular any history of safe use of the plant and the characteristics of the receiving environment. Therefore, a monitoring plan for environmental effects should not be required if the category 2 NGT plant is unlikely to pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.
- (30) For reasons of proportionality, after a first renewal of the authorisation, 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.
- (31) For reasons of legal certainty and good administration, the timeline for the Authority to deliver its opinion on an application for authorisation should only be extended when additional information is necessary to carry out the assessment of the application, and the extension should not be longer than the originally foreseen time limit unless it is justified by the nature of the data or exceptional circumstances.
- (32) To increase transparency and consumers' information, operators should be allowed to complement the labelling of category 2 NGT products as GMO with information on the trait conferred by the genetic modification. In order to avoid misleading or confusing indications, a proposal for such a labelling should be provided in the notification for consent or in the application for authorisation and should be specified in the consent or in the authorisation decision.
- (33) Regulatory incentives should be offered to potential notifiers or applicants for category 2 NGT plants and products containing traits with the potential to contribute to a sustainable agri-food system, in order to steer the development of category 2 NGT plants towards such traits. 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) and should be based on the contribution to the value for sustainable cultivation and use as defined in [Article 52(1) of the Commission's Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union<sup>21</sup>]. The applicability of the criteria across the EU does not allow a narrower definition of traits to focus on specific issues or address local and regional specificities.
- (34) Incentives should consist in an accelerated procedure for risk assessment as regards applications handled by a fully centralised procedure (food and feed products) and enhanced pre-submission advice to help developers prepare the dossier for the purpose of the environmental and food and feed safety assessments, without affecting the

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general provisions on pre-submission advice, notification of studies and consultation of third parties pursuant to Articles 32a, 32b and 32c of Regulation (EC) No 178/2002<sup>(22)</sup>.

- (35) Additional incentives should be afforded when the notifier or applicant is a small or medium-sized enterprise (SME), to promote access to the regulatory procedures by these enterprises, support diversification of developers of NGT plants and encourage the development by small breeders of crop species and traits by means of 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.
- (36) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the breeding technique. For this reason, NGT plants featuring herbicide-tolerant traits should not be eligible for incentives under this framework. However, this Regulation should not take other specific measures on herbicide tolerant NGT plants, because such measures are taken horizontally in [the Commission's Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union].
- (37) In order to enable NGT plants to contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity Strategies, cultivation of NGT plants in the Union should be facilitated. This requires predictability for breeders and farmers as regards the possibility to cultivate such plants in the Union. Therefore, the possibility for Member States to adopt measures restricting or prohibiting the cultivation of category 2 NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals.
- (38) The special rules laid down in this Regulation concerning the authorisation procedure for category 2 NGT plants are expected to result in more cultivation in the Union of category 2 NGT plants compared to the situation so far under the current Union GMO legislation. That renders necessary for Member States' public authorities to define coexistence measures to balance the interests of producers of conventional, organic and GM plants and thereby allow producers a choice between different types of production, in line with the Farm to Fork Strategy's target of 25 % of agricultural land under organic farming by 2030.
- (39) To achieve the goal of ensuring the effective functioning of the internal market, NGT plants and related products should benefit from the free movement of goods, provided they comply with the requirements of other Union law.
- (40) Given the novelty of the NGTs, it will be important to monitor closely the development and presence on the market of NGT plants and products and evaluate any accompanying impact on human and animal health, the environment and environmental, economic and social sustainability. Information should be collected regularly and within five years after the adoption of the first decision allowing the

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<sup>22</sup> 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).

deliberate release or the marketing of NGT plants or NGT products in the Union, the Commission should carry out an evaluation of this Regulation to measure the progress made towards the availability of NGT plants containing such characteristics or properties on the EU market.

- (41) In order to provide a high level of protection of health and environmental protection in relation to NGT plants and NGT products, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Union and imported from third countries.
- (42) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can be better achieved at Union level, so that NGT plants and NGT products may circulate freely within the internal market, 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.
- (43) The types of NGT plants developed and the impact of certain traits on environmental, social and economic sustainability are continuously evolving. Therefore, based on the available evidence of such developments and impacts, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to adapt the list of traits that should be incentivized or discouraged to achieve the goals of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies.<sup>7</sup>
- (44) 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<sup>(23)</sup>. 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.
- (45) 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 NGT plant is a category 1 NGT plant, as regards the preparation and the presentation of the notification for that determination, and as regards the methodology and information requirements for the environmental risk assessments of category 2 NGT plants and of NGT food and NGT feed, in accordance with the principles and criteria laid down in this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>(24)</sup>.
- (46) The Commission should regularly collect information in order to assess the performance of the legislation in achieving the development and availability of NGT plants and NGT products in the market that can contribute to the objectives of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and

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<sup>23</sup> OJ L 123, 12.5.2016, p. 1

<sup>24</sup> 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).

in order to inform an evaluation of the legislation. A broad set of indicators have been identified<sup>25</sup> and should be periodically reviewed by the Commission. The indicators should support monitoring of potential risks to health or the environment of category 2 NGT plants and related NGT products, impact of NGT plants on environmental, economic and social sustainability as well as impact on organic agriculture and on consumers acceptance of NGT products. A first monitoring report should be presented 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. The Commission should carry out an evaluation of this Regulation two years after the first monitoring report has been published, in order to allow for the impact of the first products going through the verification or authorisation to fully materialise.

- (47) Certain references to provisions of the Union GMO legislation in Regulation (EU) 2017/625 of the European Parliament and of the Council (<sup>26</sup>) need to be amended to include the specific provisions in this legislation applicable to NGT plants.
- (48) Since the application of this Regulation requires the adoption of implementing acts, it should be deferred in time to allow for the adoption of such measures,

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

### GENERAL PROVISIONS

#### *Article 1*

##### **Subject matter**

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

#### *Article 2*

##### **Scope**

This Regulation shall apply to:

- (1) NGT plants;

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<sup>25</sup> SWD(2023) 412

<sup>26</sup> 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).

- (2) food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;
- (3) feed containing, consisting or produced from NGT plants;
- (4) products, other than food and feed, containing or consisting of NGT plants.

### *Article 3*

#### **Definitions**

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

- (1) the definitions of ‘organism’, ‘deliberate release’ and ‘placing on the market’ 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) 2016/2031 of the European Parliament and of the Council<sup>(27)</sup> and that of ‘plant reproductive material’ set out in [the *Commission’s Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union*<sup>28</sup>];
- (2) ‘NGT plant’ means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it 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) ‘genetically modified organism’ or ‘GMO’ means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;
- (4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at precise locations in the genome of an organism;
- (5) ‘cisgenesis’ means techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders’ gene pool;
- (6) ‘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;
- (7) ‘category 1 NGT plant’ means a NGT plant that:
  - (a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, or
  - (b) is progeny of the NGT plant(s) 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 or Regulation 1829/2003;

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<sup>27</sup> Regulation (EU) 2016/2031 of the European Parliament and 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).

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- (8) ‘category 2 NGT plant’ means a NGT plant other than a category 1 NGT plant;
- (9) ‘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;
- (10) ‘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;
- (11) ‘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;
- (12) ‘NGT product’ means a product, other than food and feed, containing or consisting of a NGT plant and food and feed containing, consisting of or produced from such a plant;
- (13) ‘category 1 NGT product’ means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 1 NGT plant;
- (14) ‘category 2 NGT product’ means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 2 NGT plant;
- (15) ‘small or medium sized enterprise (SME)’ means a SME within the meaning of Commission Recommendation 2003/361/EC<sup>2</sup>.

#### *Article 4*

### **Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products**

Without prejudice to other requirements of Union law, a NGT plant may only be deliberately released into the environment for any other purpose than placing on the market, and a NGT product may only be placed on the market, if:

- (1) the plant is a category 1 NGT plant and
  - (a) has obtained a decision declaring that status in accordance with Article 6 or 7; or
  - (b) is progeny of plant(s) referred to in point (a); or
- (2) the plant is a category 2 NGT plant and has been authorised in accordance with Chapter III.

## **CHAPTER II**

### **Category 1 NGT plants and category 1 NGT products**

#### *Article 5*

#### **Status of category 1 NGT plants**

- 1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants.
- 2. For the purposes of Regulation (EU) 2018/848, the rules **set out in its Articles 5 (f) (iii) and 11 shall apply to** category 1 NGT plants and to products produced from or by such plants.

3. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I in order to adapt them to scientific and technological progress as regards the types and extent of modifications which can occur naturally or through conventional breeding.

#### *Article 6*

#### **Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market**

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I are met ('verification request') 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 in accordance with paragraphs 2 and 3 and the implementing act adopted in accordance with Article 27, point (b).
2. Where a person intends to undertake such a deliberate release simultaneously in more than one Member State, that person shall submit the verification request to the competent authority of one of those Member States.
3. The verification request 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, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:
  - (a) the name and the address of the requester;
  - (b) the designation and specification 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:
    - (i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
    - (ii) the NGT plant meets the criteria set out in Annex I;
  - (e) in the cases referred to in paragraph 2, an indication of the Member States in which the requester intends to undertake the deliberate release;
  - (f) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.

4. The competent authority shall acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt. It shall make available the request to the other Member States and to the Commission without undue delay.
5. If the verification request 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 verification request. The competent authority shall inform the requester, the other Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.
6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.
7. The other Member States and the Commission may make comments to the verification report within 20 days from the date of receipt of that report.
8. In the absence of any comments from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.
9. In cases where a comment is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the the comment(s) to the Commission without undue delay.
10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the comment(s), taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).
11. The Commission shall publish a summary of the decisions referred to in paragraphs 8 and 10 in the *Official Journal of the European Union*.

#### *Article 7*

#### **Verification procedure of category 1 NGT plant status prior to the placing on the market of NGT products**

1. Where a declaration of category 1 NGT plant status referred to in Article 4(1), point (a), has not already been made in accordance with Article 6, to obtain such a declaration before placing on the market a NGT product, the person intending to place the product on the market shall submit a verification request to the Authority in accordance with paragraph 2 and the implementing act adopted in accordance with Article 27, point (b).
2. The verification request referred to in paragraph 1 shall be submitted to the Authority in accordance with standard data formats, where they exist, pursuant to Article 39f of

Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:

- (a) the name and the address of the requester;
  - (b) the designation and specification 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:
    - (i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
    - (ii) the NGT plant meets the criteria set out in Annex I;
  - (e) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.
3. The Authority shall acknowledge receipt of the verification request to the requester without delay, stating the date of receipt. It shall make available the verification request to the Member States and to the Commission without undue delay and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article 38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.
4. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.
5. If the verification request is not deemed inadmissible in accordance with paragraph 4, the Authority shall deliver its statement on whether the NGT plant fulfils the criteria set out in Annex I within 30 working days from the date of receipt of a verification request. 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 omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.
6. The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant 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 referred to in Article 28(2).



7. The Commission shall publish a summary of the decision in the *Official Journal of the European Union*.

#### *Article 8*

### **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 verification requests in accordance with Articles 6 and 7 and the exchange of the information under this Title.

#### *Article 9*

### **Database of decisions declaring the category 1 NGT plant status**

1. The Commission shall establish and maintain a database listing the decisions declaring the category 1 NGT plant status adopted in accordance with Article 6(8) and (10) and Article 7(6).

The database shall contain the following information:

- (a) name and the address of the requester;
  - (b) the designation of the category 1 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 decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.
2. The database shall be publicly available.

#### *Article 10*

### **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 is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

#### *Article 11*

### **Confidentiality**

1. The requester referred to in Articles 6 and 7 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 referred to in paragraph 1.

3. 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 requester 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 requester, decide which information is to be treated as confidential and shall inform the requester 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 Chapter 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 verification request by the requester, 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 verification request 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.

## **CHAPTER III**

### **Category 2 NGT plants and category 2 NGT products**

#### *Article 12*

##### **Status of Category 2 NGT plants and category 2 NGT products**

The rules which apply to GMOs in Union legislation in so far as they are not derogated from by this Regulation, shall apply to category 2 NGT plants and category 2 NGT products.

#### **SECTION 1**

##### **DELIBERATE RELEASE OF CATEGORY 2 NGT PLANTS FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET**

#### *Article 13*

##### **Content of the notification referred in Article 6 of Directive 2001/18/EC**

As regards the deliberate release of a category 2 NGT plant for any other purpose than placing on the market, the notification referred to in Article 6(1) of Directive 2001/18/EC shall include:

- (a) the name and the address of the notifier;

- (b) 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 it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
- (c) a technical dossier supplying the information specified in Annex II necessary to carry out the environmental risk assessment of the deliberate release of a NGT plant or combination of NGT plants:
  - (i) general information including information on personnel and training;
  - (ii) information relating to the category 2 NGT plant(s);
  - (iii) information relating to the conditions of release and the potential receiving environment;
  - (iv) information on the interactions between the category 2 NGT plant(s) and the environment;
  - (v) a plan for monitoring in order to identify effects of the category 2 NGT plant(s) on human health or the environment;
  - (vi) where relevant, information on control, remediation methods, waste treatment and emergency response plans;
  - (vii) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18;
  - (viii) a summary of the dossier;
- (d) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c).

## **SECTION 2**

### **PLACING ON THE MARKET OF CATEGORY 2 NGT PRODUCTS OTHER THAN FOOD OR FEED**

#### *Article 14*

#### **Content of the notification referred to in Article 13 of Directive 2001/18/EC**

1. As regards the placing on the market of category 2 NGT products other than food and feed, the notification referred to in Article 13(2) of Directive 2001/18/EC, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, shall contain:
  - (a) name and address of the notifier and of its representative established in the Union (if the notifier is not established in the Union);
  - (b) designation and specification of the category 2 NGT plant;
  - (c) scope of the notification:
    - (i) cultivation;
    - (ii) other uses (to be specified in the notification);

- (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 it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
- (e) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);
- (f) the conditions for the placing on the market of the product, including specific conditions of use and handling;
- (g) with reference to Article 15(4) of Directive 2001/18/EC, a proposed period for the consent, which should not exceed 10 years;
- (h) where appropriate, a monitoring plan for environmental effects 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, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the notifier considers that the NGT plant does not need a monitoring plan, the notifier may propose not to submit a monitoring plan;
- (i) a proposal for labelling which shall comply with the requirements laid down in point A.8. of Annex IV to Directive 2001/18/EC, Article 4(6) of Regulation (EC) No 1830/2003 and Article 23 of this Regulation;
- (j) proposed commercial names of the products and names of category 2 NGT plants contained therein, and a proposal for a unique identifier for the category 2 NGT plant, developed in accordance with Commission Regulation (EC) No 65/2004<sup>(29)</sup>. After the consent any new commercial names should be provided to the competent authority;
- (k) description of how the product is intended to be used. Differences in use or management of that product compared to similar non-genetically modified products shall be highlighted;
- (l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);

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<sup>29</sup> 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).

- (m) samples of the category 2 NGT plant and their control samples, and information as to the place where the reference material can be accessed;
  - (n) 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;
  - (o) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18/EC and Articles 39 to 39e of Regulation (EC) No 178/2002;
  - (p) a summary of the dossier in a standardised form.
2. The notifier shall include in this notification information on data or results from releases of the same category 2 NGT plant or the same combination of category 2 NGT plants previously or currently notified and/or carried out by the notifier either inside or outside the Union.
  3. The competent authority that prepares the assessment report referred to in Article 14 of Directive 2001/18/EC shall examine the notification for compliance with paragraphs 1 and 2.

#### *Article 15*

##### **Specific provisions on monitoring**

The written consent referred to in Article 19 of Directive 2001/18/EC shall either specify monitoring requirements, as described in Article 19(3) point (f) or state that monitoring is not required. Article 17(2), point (b), of Directive 2001/18/EC shall not apply if monitoring is not required by the consent.

#### *Article 16*

##### **Labelling in accordance with Article 23**

In addition to Article 19(3) of Directive 2001/18/EC, the written consent shall specify the labelling in accordance with Article 23 of this Regulation.

#### *Article 17*

##### **Duration of the validity of the consent after renewal**

1. The consent granted under Part C of Directive 2001/18/EC shall, after the first renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for an unlimited period, unless the decision referred to in Article 17(6) or (8) provides that the renewal is for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the consent.
2. The last sentence in Article 17(6) and (8) of Directive 2001/18/EC shall not apply.

**SECTION 3**  
**PLACING ON THE MARKET OF CATEGORY 2 NGT PLANTS FOR FOOD OR FEED**  
**USE AND OF CATEGORY 2 NGT FOOD AND FEED**

*Article 18*

**Scope**

This Section shall apply to:

- (a) category 2 NGT plants for food use or for feed use;
- (b) food containing, consisting or produced from category 2 NGT plants or containing ingredients produced from category 2 NGT plants ('category 2 NGT food');
- (c) feed containing, consisting or produced from category 2 NGT plants ('category 2 NGT feed').

*Article 19*

**Specific provisions on the application for authorisation referred to in Articles 5 and 17 of Regulation (EC) No 1829/2003**

1. By way of derogation from Articles 5(3), point (e), and 17(3), point (e), of Regulation (EC) No 1829/2003, and without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, an application for authorisation of a category 2 NGT plant for food or feed use, or category 2 NGT food or feed 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, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);
  - (b) the food or the feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003, respectively, based on a safety assessment of the food or feed carried out in accordance with the principles and criteria laid down in Parts 1 and 3 of Annex II to this Regulation and with the implementing act adopted in accordance with Article 27, point (c).
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 NGT food or feed.

In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method requirements shall be adapted as specified in the

implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);

3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of category 2 NGT plants or food or feed containing or consisting of category 2 NGT plants, the application shall also be accompanied by:
  - (a) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);
  - (b) where appropriate, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan. This duration may be different from the duration of the authorisation. If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the applicant considers that the NGT plant does need a monitoring plan, the applicant may propose not to submit a monitoring plan.
4. The application shall also contain a proposal for labelling in accordance with Article 23.

#### *Article 20*

##### **Specific provisions on the opinion of the Authority**

1. By way of derogation from Article 6(1) and (2) and Article 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 19 of this Regulation within six months as from the receipt of a valid application.

Where the Authority or the competent authority of the Member State carrying out the environmental risk assessment or the safety assessment of the food or feed pursuant to Article 6(3), points (b) and (c) and Article 18(3), points (b) and (c) of Regulation (EC) No 1829/2003 considers that additional information is necessary, the Authority, or the national competent authority through the Authority, shall ask the applicant to submit that information within a specified time limit. In that case, the six months period shall be extended by that additional period. The extension shall not exceed six months unless it is justified by the nature of the data requested or by exceptional circumstances.

2. In addition to the tasks referred to in Article 6(3) and Article 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 19 of this Regulation.
3. By way of derogation from Article 6(3), point (d), and Article 18(3), point (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 19(2) of this Regulation and in Article 5(3), point (j), and Article 17(3), point (j), of Regulation (EC) No 1829/2003.

4. The Union reference laboratory shall test and validate the method of detection, identification and quantification proposed by the applicant in accordance with Article 19(2) or assess whether the information provided by the applicant justifies the application of adapted modalities to comply with detection method requirements referred to in that paragraph.
5. By way of derogation from Article 6(5), point (f), and Article 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 NGT food or feed, and a justification of any adaptation of the method in the cases referred to in Article 19(2), subparagraph 2;
  - (b) an indication of where appropriate reference material can be accessed.
6. In addition to the particulars mentioned in Article 6(5), point (d) and Article 18(5), point (d) of Regulation (EC) No 1829/2003, the opinion shall also include a proposal for labelling in accordance with Article 23 of this Regulation.

#### *Article 21*

#### **Duration of the validity of the authorisation after renewal**

By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003, after the first renewal, the authorisation shall be valid for an unlimited period, unless the Commission decides to renew the authorisation for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the authorisation.

### **SECTION 4**

#### **COMMON PROVISIONS FOR CATEGORY 2 NGT PLANTS AND CATEGORY 2 NGT PRODUCTS**

#### *Article 22*

#### **Incentives for category 2 NGT plants and category 2 NGT products containing traits relevant for sustainability**

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in Part 1 of Annex III and it does not have any traits referred to in Part 2 of that Annex.
2. The following incentives shall apply to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:
  - (a) by way of derogation from Article 20(1), subsection (1) of this Regulation, the Authority shall deliver its opinion on the application within 4 months from the receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 20(1). The time limit shall be extendable under the conditions set out in Article 20(1), subsection (2);



- (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 (EC) No 178/2002, apply prior to notifications submitted in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:
  - (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 or notifier has identified based on the properties of a plant, product or hypothetical plant or product, that need to be addressed by providing the information under Parts 2 and 3 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 notify the Authority of how it intends to address the plausible risk hypotheses referred to in point (a) that it has identified based on the properties of a plant, product or hypothetical plant or product, including the design of the studies it intends to perform in accordance with the requirements laid down Parts 2 and 3 of Annex II. The Authority shall provide advice on the notified information, including on the design of the studies.
- 4. The pre-submission advice referred to in paragraph 3 shall comply with the following requirements:
  - (a) it shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Panel on Genetically Modified Organisms of the Authority. 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 in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and for potential applications under Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19 concerning a category 2 NGT plant to be used as seeds or other plant reproductive 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 or application is going to be submitted;
  - (c) the Authority shall make public without delay a summary of the pre-submission advice once an application or notification has been considered valid. Articles 38(1a) shall apply *mutatis mutandis*;
  - (d) potential applicants or notifiers demonstrating that they are a SME can request the pre-submission advice referred to in paragraph 3, point (a), at different points in time.
- 5. Any request for the incentives shall be submitted to the Authority at the time of request of advice referred to in paragraph 3 or the application referred to in Articles 5

or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19, and accompanied by the following information:

- (a) the information necessary to establish that the intended trait(s) conveyed by the genetic modification of the category 2 NGT plant meet the conditions referred to in paragraph 1;
  - (b) where applicable, 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 1 of Annex II as far as it can already be provided and any other relevant information.
6. Article 26 of Directive 2001/18/EC and Article 30 of Regulation (EC) No 1829/2003 shall apply to information submitted under this article to the Authority, as appropriate.
7. The Authority shall lay down the practical arrangements to implement paragraphs (3) to (6).
8. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the lists of traits of NGT plants laid down in Annex III in order to adapt them to scientific and technological progress and to new evidence relating to the impact on sustainability of those traits, subject to the following conditions:
- (a) the Commission shall take into account the monitoring of the impacts of this Regulation in accordance with Article 30(3);
  - (b) the Commission shall conduct an up-to-date scientific literature review of the impact on environmental, social and economic sustainability of the trait(s) 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 in accordance with Article 14, point (h), or Article 19(3), of NGT plants harbouring the trait(s) conveyed by their genetic modification.

#### *Article 23*

### **Labelling of authorised category 2 NGT products**

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 authorised category 2 NGT products may also mention the trait(s) conveyed by the genetic modification, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation.

#### *Article 24*

### **Measures to avoid the unintended presence of category 2 NGT plants**

Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.

## Article 25

### Cultivation

Article 26b of Directive 2001/18/EC shall not apply to category 2 NGT plants.

## CHAPTER IV

### FINAL PROVISIONS

## Article 26

### 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 5(3) and Article 22(8) 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 9 months before the end of the 5-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 5(3) and Article 22(8) 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<sup>(30)</sup>.
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 Articles Article 5(3) and Article 22(8) 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 2 months at the initiative of the European Parliament or of the Council.

## Article 27

### Implementing acts

The Commission shall adopt implementing acts concerning:

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<sup>30</sup> OJ L 123, 12.5.2016, p. 1.

- (a) the information required to demonstrate that a plant is a NGT plant;
- (b) the preparation and the presentation of the verification requests referred to in Articles 6 and 7;
- (c) the methodology and information requirements for the environmental risk assessment of category 2 NGT plants and the safety assessments of category 2 NGT food and feed, in accordance with the principles and criteria laid down in Annex II;
- (d) the application of Articles 14 and 19, including rules concerning the preparation and the presentation of the notification or application;
- (e) adapted modalities to comply with analytical method requirements referred to in Article 14(1), point (1), and Article 19(2).

Before adopting the implementing acts referred to in points (a) to (d), the Commission shall consult the Authority. The implementing acts shall be adopted in accordance with the procedure referred to in Article 28(3).

#### *Article 28*

##### **Committee procedure**

1. The Commission shall be assisted by the committee set up by Article 58 of Regulation (EC) No 178/2002.
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 29*

##### **Guidance**

1. 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 notifications and the application referred to in Chapters II and III and for the implementation of Annex II.
2. Before the date of application of this Regulation, the European Union Reference Laboratory for Genetically Modified Food and Feed established pursuant to Article 32 of Regulation (EC) No 1829/2003, assisted by the European Network of GMO Laboratories, shall publish detailed guidance to assist the notifier or the applicant for the application of Article 14(1), point (1), and Article 19(2).

#### *Article 30*

##### **Monitoring, reporting and evaluation**

1. No sooner than three years after the first decision is adopted in accordance with Article 6(8) or (10) or Article 7(6) or in accordance with Sections 2 or 3 of Chapter 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 with the application of this Regulation.
3. For the purpose of the reporting referred to in paragraph 1, the Commission, by [24 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 in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact 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 and 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 4 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

#### *Article 31*

#### **References in other Union legislation**

With regard to category 2 NGT plants, references in other Union legislation to Annex II or Annex III to Directive 2001/18/EC shall be construed as references to Parts 1 and 2 of Annex II to this Regulation.

#### *Article 32*

#### **Administrative review**

Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.

The Commission shall prepare a draft decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act.

#### *Article 33*

#### **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 Articles 14(1), point (h) and 19(3), point (b) of Regulation [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 Articles 14(1), point (h) and 19(3), point (b) of Regulation [*reference to this Regulation*];’.

#### *Article 34*

##### **Entry into force and application**

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. It shall apply from [*24 months from the date of entry into force of this Regulation*].

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**

#### **2.1. Monitoring and reporting rules**

#### **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*

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

*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 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 action<sup>1</sup>
- 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.

### 1.4.3. Expected result(s) and impact

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

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

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.

- 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 (2.3 million EUR in the current MFF period) will be covered by an increase of the EFSA annual subsidy from the unallocated margin under Heading 2b, to be compensated by an equivalent decrease of the Food chain strand of the Single Market Programme, which will result in an increase of the unallocated margin under Heading 1. Furthermore, 0,1 million EUR will be redeployed internally within the Food strand of the Single Market

Programme to cover IT expenditure. 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.

## 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 planned<sup>2</sup>

### 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

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<sup>2</sup> 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 30<sup>1</sup> 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.

<sup>1</sup> 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. <sup>1</sup>	from EFTA countries <sup>2</sup>	from candidate countries and potential candidates <sup>3</sup>	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

<sup>1</sup> Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

<sup>2</sup> EFTA: European Free Trade Association.

<sup>3</sup> 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)

<b>Heading of multiannual financial framework</b>	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	<b>0,100</b>
	Payments	(2a)	0,050	0,050	0,000	<b>0,100</b>
<u>Appropriations of an administrative nature financed from the envelope of specific programmes</u>						
Budget line		-3	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>TOTAL appropriations for DG SANTE</b>	Commitments	=1a+1b +3	0,100	0,000	0,000	<b>0,100</b>
	Payments	.=2a+2b +3	0,050	0,050	0,000	<b>0,100</b>

• 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
<b>TOTAL appropriations under HEADING 1- Single Market, Innovation and Digital of the multiannual financial framework</b>	Commitments	=4+6	0,100	0,000	0,000	0,100
	Payments	=5+6	0,050	0,050	0,000	0,100

<b>Heading of multiannual financial framework</b>	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)	0,405	0,830	1,099	2,334
	Payments	(2a)	0,081	0,287	1,966	2,334
<u>Appropriations of an administrative nature financed from the envelope of specific programmes</u>						
Budget line		-3	0	0	0	0
<b>TOTAL appropriations for DG SANTE</b>	Commitments	.=1a +3	0,405	0,830	1,099	2,334
	Payments	.=2a+3	0,081	0,287	1,966	2,334

• TOTAL operational appropriations	Commitments	(4)	0,405	0,830	1,099	2,334
	Payments	(5)	0,081	0,287	1,966	2,334
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0,000	0,000	0,000	0,000
<b>TOTAL appropriations under HEADING 2 -Cohesion, Resilience and Values</b> of the multiannual financial framework	Commitments	=4+6	0,405	0,830	1,099	2,334
	Payments	=5+6	0,081	0,287	1,966	2,334

<b>Heading of multiannual financial framework</b>	<b>7</b>	‘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		<b>0,000</b>	<b>0,000</b>	<b>0,000</b>	<b>0,000</b>	<b>0,000</b>
<b>TOTAL DG SANTE</b>	Appropriations	0,000	0,000	0,000	0,000	0,000
<b>TOTAL appropriations under HEADING 7 of the multiannual financial framework</b>		(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	
<b>TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework</b>		Commitments	0,505	0,830	1,099	2,434
		Payments	0,131	0,337	1,966	2,434

For information, reduction of the SMP Food Chain line to increase Heading 1 unallocated margin to compensate for the increase of EFSA line from the Heading 2b unallocated margin.

EUR million (to three decimal places)

HEADING 1 - Single Market, Innovation and Digital			Year 2025	Year 2026	Year 2027	TOTAL
• Operational appropriations						
03 02 06 Contributing to a high level of health and welfare for humans, animals and plants	Commitments	(1a)	0,405	- 0,830	- 1,099	- 2,334

### 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			
<b>OUTPUTS</b>										
	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 field trials whether the notified NGT plant meets pre-defined equivalence criteria (Preparatory work, Assessment of equivalence to predefined criteria)				0,041		0,217		0,330		0,589

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)				0,113		0,286		0,412		0,812
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				0,494		0,744		0,982		2,221
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 field trials whether the notified NGT plant meets pre-defined equivalence criteria : Intake steps				0,000		0,048		0,065		0,113
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)				0,011		0,038		0,052		0,100
Subtotal for specific objective No 2				0,011		0,086		0,117		0,214



<b>TOTALS</b>		0,505		0,830	1,099	2,434
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*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)

<b>Temporary agents (AD Grades)</b>	0,165	0,505	0,687	1,358
<b>Temporary agents (AST grades)</b>	0,000	0,084	0,172	0,256
<b>Contract staff</b>	0,000	0,000	0,000	0,000
<b>Seconded National Experts</b>	0,000	0,000	0,000	0,000
<b>Total</b>	0,165	0,590	0,859	1,614

Staff requirements (FTE): Total posts Union funded

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

The staff costs have been adjusted in such a way that the newly recruited staff is accounted for 6 months during the year of recruitment.

### 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 <sup>1</sup>	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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<b>HEADING 7 of the multiannual financial framework</b>								
Human resources								
Other administrative expenditure								
<b>Subtotal HEADING 7 of the multiannual financial framework</b>								

<b>Outside HEADING 7<sup>2</sup> of the multiannual financial framework</b>								
Human resources								
Other expenditure of an administrative nature								
<b>Subtotal outside HEADING 7 of the multiannual financial framework</b>								

<b>TOTAL</b>								
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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.

<sup>1</sup> 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.

<sup>2</sup> 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)		
<b>• Establishment plan posts (officials and temporary staff)</b>							
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)							
<b>• External staff (in Full Time Equivalent unit: FTE)<sup>1</sup></b>							
20 02 01 (AC, END, INT from the 'global envelope')							
20 02 03 (AC, AL, END, INT and JPD in the delegations)							
<b>XX 01 xx yy zz <sup>2</sup></b>	- 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)							
<b>TOTAL</b>							

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"> <li>1) managing (AD) and supporting (AST) the GMO panel in its risk assessment activities for NGT plants under the authorisation procedure</li> <li>2) Assessing (AD) and supporting the assessment (AST) the equivalence to predefined criteria of NGT plants under the notification procedure</li> <li>3) Supporting the applicants and performing the completeness check (AD) for NGT plants under the notification procedure</li> <li>4) Giving scientific advice (AD) to the the applicant to NGT plants containing traits that contribute to sustainability under the authorisation procedure</li> <li>5) Supporting the applicant and performing the completeness (AD) check for NGT plants under the authorisation procedure</li> </ol>
External staff	

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

<sup>2</sup> 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 2,3 million EUR, will be covered from the unallocated margin under Heading 2b. To preserve the neutrality of this proposal towards the EU budget, an equal reduction of the SMP Food chain budget line 03 02 06 will be applied, resulting in an increase of the Heading 1 margin by the same amount. 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.
- As a consequence of the budgetary mechanism described above, the unallocated margin of Heading 2b will decrease by EUR 2,3 million over the years 2025-2027 while the unallocated margin of Heading 1 will increase by the same amount.  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 <sup>1</sup>	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								

<sup>1</sup> 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 <sup>2</sup>							
		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).

<sup>2</sup> 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.