



Council of the  
European Union

Brussels, 20 June 2024  
(OR. en)

11318/24

---

---

**Interinstitutional File:  
2023/0226(COD)**

---

---

**LIMITE**

**AGRI 527  
AGRILEG 324  
ENV 673  
CODEC 1571  
PI 96  
IA 148**

**NOTE**

---

From:	General Secretariat of the Council
To:	Committee of Permanent Representatives (part 1)
No. Cion doc.:	11592/23 + ADD1
Subject:	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 <i>- Mandate for negotiations with the European Parliament</i>

---

**I. INTRODUCTION**

1. On 6 July 2023, the Commission submitted to the Council and the European Parliament a 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 products<sup>1</sup>, which aims to enable the EU agri-food sector to contribute to the innovation and sustainability objectives of the European Green Deal and Farm to Fork and Biodiversity strategies, and to enhance the sector's competitiveness, while maintaining a high level of protection of health and of the environment.

---

<sup>1</sup> 11592/23 + ADD 1

2. The proposal is based on Articles 43, 114 and 168(4)(b) of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).
3. In the European Parliament, the Committee on Environment, Public Health and Food Safety (ENVI) has the lead responsibility, while the Committee on Agriculture and Rural Development (AGRI) is associated. The Parliament adopted its first reading position at the plenary session on 24 April 2024<sup>2</sup>.
4. Both the European Economic and Social Committee (EESC) and the European Committee of the Regions (CoR) were consulted. The EESC delivered its opinion on 26 October 2023<sup>3</sup>. The CoR delivered its opinion on 17 April 2024<sup>4</sup>.

## **II. WORK WITHIN THE COUNCIL AND ITS PREPARATORY BODIES**

5. The Council (Agriculture and Fisheries), at its meeting on 25 July 2023, heard a presentation from the Commission and exchanged views on the proposal. At its meeting on 20 November 2023, the Council took note of the information provided by the Presidency on the state of play of the examination of the proposal in Council preparatory bodies, and of the information provided by the Croatian delegation on their position. The Council further took note of the reactions of other delegations and of the Commission.

---

<sup>2</sup> [https://www.europarl.europa.eu/doceo/document/TA-9-2024-0325\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-9-2024-0325_EN.html)

<sup>3</sup> 14926/23

<sup>4</sup> 9226/24

6. The Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) (hereafter the Working Party) started examining the proposal and the accompanying impact assessment on 10 July 2023. Delegations did not raise any specific issues regarding the impact assessment. The Working Party held eight more meetings (on 26-27 July, 11-12 September, 25-26 September, 5-6 October, 30-31 October, 14 November, 27-28 November 2023 and 11-12 January 2024). That last meeting, as well as an informal videoconference of the members of the Working Party on 1 December 2023, was dedicated to questions and concerns raised by delegations on biotechnology patents in plant breeding. A meeting of the Working Party of Agricultural Counsellors/Attachés was held on 4 December 2023.
7. During the examination at technical and Attachés levels, the Spanish Presidency suggested several amendments to the Commission proposal that were supported by a majority of delegations. Some delegations requested additional changes that could not be taken on board as they would have jeopardised the overall balance of the latest compromise text presented by the Presidency and put into question the principles underpinning the categorisation of NGT products as proposed by the Commission and agreed by a majority of delegations.
8. On 6 December 2023, the Permanent Representatives Committee examined the latest compromise text of the Spanish Presidency<sup>5</sup>. In light of the views expressed by delegations, the Presidency concluded that while many delegations supported the text, there was insufficient support to ensure a qualified majority at that stage. The Presidency decided to submit the latest compromise text to the Council without further modifications.

---

<sup>5</sup> 16151/1/23 REV 1

9. The Council (Agriculture and Fisheries), at its meeting on 11 December 2023, discussed the compromise text as proposed by the Spanish Presidency<sup>6</sup>. Further to the request of a few delegations insisting on the needs of areas with specific geographical conditions, such as certain Mediterranean island Member States and insular regions, the Presidency tabled a room document with a text suggestion referring to existing provisions in Union legislation on organic production<sup>7</sup>, which was supported by many delegations. The Presidency, while regretting the absence of sufficient support to reach a General Approach at that stage, noted the broad support on its suggestions regarding areas with specific geographical conditions. The Presidency further recalled the importance of the file and informed delegations about its intention to continue working towards reaching agreement on a Council position as soon as possible.
10. On 7 February 2024, the Permanent Representatives Committee examined the compromise text of the Belgian Presidency<sup>8</sup>. That text introduced additional changes with a view to addressing concerns on the impact of patenting practices. Notably, it added a provision to establish an expert group on the effect of patents on NGT plants; an evaluation by the Commission of the conditions necessary to ensure that breeding companies that are small- or medium sized enterprises have access to patented modified genetic resources in fair, transparent and predictable terms; and a reference to the limited breeders' exemption that already exists in the Agreement on a Unified Patent Court<sup>9</sup>. In light of the views expressed by delegations, the Presidency concluded that while many delegations supported the text, there was still insufficient support to ensure a qualified majority at that stage, and that it would consider the best way forward to make further progress on this file.

---

<sup>6</sup> 16443/23

<sup>7</sup> Now reflected in Recital 24, see Annex to this note.

<sup>8</sup> 16714/23

<sup>9</sup> OJ C 175, 20.6.2013, p. 1.

11. On 22 and 23 May 2024, a revised compromise text of the Belgian Presidency<sup>10</sup> was examined at technical and Attachés levels. That text introduced provisions to exclude patented NGT plants from the category 1 NGT status, with a view to limiting the extent to which NGT plants can be protected by patents and hence increasing the accessibility of NGT plants to plant breeders and their availability to farmers. Taking into account the views expressed by delegations, the Presidency decided to continue refining the text, to ensure that the new provisions are effective in achieving their aim, while avoiding unnecessary burden for requesters and competent authorities.

### III. KEY POLITICAL OUTSTANDING ISSUES

12. The impact of patenting practices for NGT plants remains the main outstanding issue. Therefore the Belgian Presidency focused on further adjustments that could be introduced to the text to gain additional support without jeopardising the existing support. On this basis and following additional bilateral consultations, the Belgian Presidency proposes the additional changes set out below.

Building on the earlier proposal of May 2024, and in order to address the concerns of some delegations that the impacts of patenting practices may already materialise before the completion of a study on such impacts, the Presidency proposes to exclude patented NGT plants and their products from being placed on the market as category 1 NGT plants or products.

To this end, the Presidency introduced a provisional category 1 NGT status that allows for the deliberate release into the environment of a category 1 NGT plant (e.g. for conducting field trials), but not for its placing on the market. Such provisional category 1 NGT status is based on a verification that the plant meets the equivalence criteria to conventional plants and does not carry herbicide tolerance among the intended traits. That verification does not extend to product patents and product patent applications at that stage, to avoid unnecessary burden for requesters and competent authorities,

---

<sup>10</sup> 9904/24

To obtain full (non-provisional) category 1 NGT status that allows for the placing on the market of the plant and its products, an additional verification is required that the plant or its products are not protected by one or more product patents or published product patent applications in one or more Member States of the European Union.

According to this proposal, patented NGT plants and their products can only be placed on the market as category 2 NGT plants or products, following a risk assessment and under the stricter regulatory conditions proposed for NGT-2 plants and products.

In addition, the Presidency introduced a provision that allows the Commission to revoke category 1 NGT status where it is shown that the necessary conditions as regards patents and patent applications are not, or no longer, fulfilled. It also introduced a provision for the Commission to publish guidelines to assist operators, in particular breeders, in navigating the plant intellectual property landscape.

13. The above-mentioned additional changes to the previous compromise text are included in the text set out in the Annex to this note.

#### **IV. CONCLUSION**

14. The Permanent Representatives Committee is therefore invited to examine the additional Presidency suggestions referred to in point 12 and to agree on the text set out in the Annex to this note, to be used as the mandate for the negotiations with the European Parliament.
15. In accordance with the approach to legislative transparency endorsed by Coreper on 14 July 2020<sup>11</sup>, and in full consistency with Regulation (EC) No 1049/2001 and the Council's Rules of Procedure, the text of the mandate thus agreed will be made public unless the Permanent Representatives Committee objects.

---

<sup>11</sup> 9493/20

Draft

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

**on plants obtained by certain new genomic techniques and their products ~~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 targeted precise locations.

---

<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).

(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 conventional breeding techniques (excluding genetic modification techniques other than those listed in Annex I B of Directive 2001/18/EC). The European Food Safety Authority ('the Authority'), in its scientific opinion on plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases<sup>2</sup> and the High Level Group of the Commission's Scientific Advice Mechanism in its Explanatory note on New techniques in agricultural biotechnology<sup>3</sup> provide an overview of the ~~current~~ state of these conventional breeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at targeted 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.~~ The genetic material may be incorporated as a continuous (exact) copy (cisgenesis in the strict sense) or a re-arranged copy of sequences already present in the breeder's gene pool (intragenesis, also considered a subset of cisgenesis in a broader sense). Intragenic plants result from the use of intragenesis techniques, but can be also obtained by through cisgenesis techniques in the strict sense. In the latter case, new developments of site-directed modification also offer the possibility to target the insertion of continuous DNA sequences other than complete genes (for example promoters or regulatory sequences), from the breeders' gene pool at specific loci in the genome. When the insertion of such fragments

---

<sup>2</sup> EFSA Panel on Genetically modified organisms (GMO); 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. [31 pp.] doi:10.2903/j.efsa.2012.2943. Available online: <https://www.efsa.europa.eu/en/efsajournal/pub/2943>.

<sup>3</sup> European Commission, Directorate-General for Research and Innovation, *New techniques in agricultural biotechnology*, Publications Office, 2017, <https://data.europa.eu/doi/10.2777/574498>

occurs within an endogenous gene, interrupting it, this leads to the formation of a rearranged gene in the recipient plant and, as such, the plant should also be considered intragenic, except in those particular cases in which the resulting DNA sequences in the recipient plant already occur in species from the breeder's gene pool.

- (3) There is ongoing public and private research using NGTs on a wider variety of crops and traits compared to those obtained ~~by~~ through transgenic techniques authorised in the Union or globally<sup>(4)</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>(5)</sup> and of the 'Farm to Fork' <sup>(6)</sup>, Biodiversity <sup>(7)</sup> and Adaptation to Climate Change<sup>(8)</sup> Strategies, to global food security <sup>(9)</sup>, the Bioeconomy Strategy <sup>(10)</sup> and to the Union's strategic autonomy <sup>(11)</sup>.

---

<sup>4</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>5</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>6</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>7</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>8</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>9</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

- (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>(12)</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>(13)</sup>, while the contained use of plant cells is subject to Directive 2009/41/EC <sup>(14)</sup>, and transboundary movements of these organisms ~~NGT plants~~ to third countries are regulated by Regulation (EC) No 1946/2003 <sup>(15)</sup> (taken together, ‘the Union GMO legislation’).
- (5) In its judgment in case C-528/16 *Confédération paysanne and Others*<sup>16</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.

---

(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>10</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>11</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>12</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>13</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).

<sup>14</sup> Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).

<sup>15</sup> Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movement of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

<sup>16</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.

- (6) The Council, in Decision (EU) 2019/1904<sup>17</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>18</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 by ~~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 European Union Reference Laboratory for GM Food and Feed (EURL), in collaboration with the European Network of GM Laboratories (ENGL) stressed that products that have identical DNA sequence but have been developed either naturally or by conventional breeding or by using certain new genomic techniques cannot be distinguished by analytical methods (<sup>19</sup>). 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.

---

<sup>17</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>18</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.

<sup>19</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).

- (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 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 their products, while addressing the specificity of NGT plants. This legal framework should enable the development and placing on the market of plants; and their products (including food and feed) obtained by with NGTs 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 their NGT products. However, where there are no specific rules in this Regulation, NGT plants and their 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.
- (11a) In keeping with the Union GMO legislation, this Regulation should include under its scope NGT plants, and their products (food and feed containing, consisting of or produced from such NGT plants, and other products, other than food and feed, containing or consisting of such NGT plants, ( hereinafter ‘NGT products’). Plant reproductive material, including forest reproductive material, falls under the scope of this Regulation both as-a under the term ‘plant’ (when it is deliberately released into the environment for any purpose other than the placing on the market) and as-a under the term ‘product’ (when it is placed on the market, including for the purpose of commercial cultivation). In keeping with Union legislation, the definition of the term ‘plant’ in this regulation should be the same as that in Regulation (EU) 2016/2031<sup>20</sup>. That definition includes living plants and certain living parts of plants. Since a plant does not exist without its genetic material, that material is also considered a part of the plant.
- (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.

---

<sup>20</sup> Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, p. 4–104).

- (13) This Regulation should distinguish between two categories of NGT plants.
- (14) NGT “Category 1 NGT plants” are ~~includes~~ 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’~~). This category should be treated in the same way 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 (criteria of equivalence for category 1 NGT plant) 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 up-to-date scientific knowledge science. They should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained ~~by~~ with conventional breeding techniques and should include thresholds for both size and number of genetic modifications to the genome of NGT plants. ~~Targeted substitutions and insertions of limited size, deletions and targeted inversions of any size as well as larger targeted substitutions with, and insertions of, continuous sequences of genetic material from the breeder’s gene pool should be included in the criteria for category 1 NGT plants, under certain conditions to exclude intragenic plants. Novel hazards can be associated with intragenic plants compared with cisgenic and conventionally bred plants<sup>21,22</sup>; therefore intragenic plants should remain subject to the Union GMO legislation and be excluded from the criteria for category 1 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.~~

---

<sup>21</sup> — ~~EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561, 33 pp. doi:10.2903/j.efsa.2012.2561. Available online: <https://www.efsa.europa.eu/en/efsajournal/pub/2561>.~~

<sup>22</sup> — ~~EFSA Panel on Genetically Modified Organisms ; 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>.~~

(14 bis) Current scientific knowledge indicates that targeted mutagenesis and cisgenesis techniques can lead to genetic modifications that are similar to mutations occurring spontaneously in nature or as a result of conventional breeding techniques. These mutations include substitutions, insertions (including duplications, translocations and inversions) and deletions of nucleotides in the DNA. Furthermore, insertion of genetic material from the breeders' gene pool is also possible through crossing or conventional breeding. The scientific literature also shows differences in the size of these individual genetic modifications and in the number of genetic modifications per plant, considering also for the latter the ploidy level of the plant. In addition, the efficiency varies between breeding techniques. On this basis, targeted substitutions and insertions of limited size, deletions and targeted inversions of any size as well as larger targeted substitutions with, and insertions of, continuous sequences of genetic material from the breeders' gene pool should be included in the criteria of equivalence for category 1 NGT plant. In addition, those criteria should include certain conditions in order to exclude intragenic plants from category 1 NGT plants since novel hazards can be associated with intragenic plants compared with cisgenic and conventionally bred plants<sup>2324</sup>.

---

<sup>23</sup> EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561, 33 pp. doi:10.2903/j.efsa.2012.2561. Available online: <https://www.efsa.europa.eu/en/efsajournal/pub/2561>.

<sup>24</sup> EFSA Panel on Genetically Modified Organisms ; 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>.

(14 ter) 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, with the risk of a negative impact on human and animal health and the environment In addition, the Farm to Fork Strategy proposes specific targets to reduce the use of pesticides by 2030. This Regulation should also contribute to these objectives. Therefore, the development and use of NGT plants that include tolerance to herbicides among the intended traits conveyed by the genetic modification should be followed up and these plants should remain subject to authorization, traceability, and monitoring requirements. Therefore, NGT plants that include tolerance to herbicides among the intended traits conveyed by the genetic modification should be subject to the provisions for category 2 NGT plants.

(14 quater) In Member States of the European Union, inventions can be protected by national patents granted by national patent offices under national law and/or European patents granted by the European Patent Office under the Convention on the Grant of European Patents for one or more Member States or other Contracting Parties to the Convention. Applicants of European patents indicate the countries in which they seek protection in the European patent application. For European patents, a unitary effect can be registered under the framework of Regulations (EU) No 1257/2012<sup>25</sup> and No 1260/2012<sup>26</sup>. Even before grant, European patent applications provide protection after publication, as do national patent applications if provided for in national law. Concerns Different views exist about the impact that patents on NGT plants may have on access to breeding material and breeding techniques and the availability of propagating material. In order to increase the accessibility of NGT plants to plant breeders and their availability to farmers, it is appropriate to limit the extent to which NGT plants can be protected by patents. Such a limitation would facilitate the placing on the market of plants and their products (including food and feed) obtained by NGTs. Therefore, for a NGT plant to obtain a declaration of category I NGT plant status, that plant should neither be protected by one or more national patents or patent applications for products in one or more Member States, nor by one or more European patents (with or without unitary effect) or patent applications for products designating one or more Member States.

---

<sup>25</sup> Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, p. 1–8).

<sup>26</sup> Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements (OJ L 361, p. 89–92).

(14 quinquies) Subject to exclusions, patents shall be available for any inventions, whether products or processes, in accordance with Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, to which the Union and its Member States are Parties. Whereas, in accordance with Article 28 of that Agreement, a patent where its subject matter is a product shall confer on its owner exclusive rights on that product, a patent where its subject matter is a process shall confer on its owner both exclusive rights on that process as well as on the product directly obtained by that process.

(14 sexies) To ensure a balance between facilitating access to breeding material and the availability of propagating material on the one hand and fostering innovation through the protection of intellectual property, it is appropriate to differentiate between patents whose subject matter are products consisting of or containing biological material and patents whose subject matter are processes by means of which biological material is produced, processed or used.

(14a) Since category 1 NGT plants encompasses plants that are equivalent to plants occurring naturally or ~~produced~~ obtained by conventional breeding and that should be treated in the same way as those plants, ~~also~~ their progeny obtained by conventional breeding techniques should also be treated accordingly and be included under category 1 NGT plants. Therefore, the progeny deriving from the application of conventional breeding techniques to a category 1 NGT plant, including the result of the crossing of a category 1 NGT plant with a conventionally bred plant, or of the crossing of two category 1 NGT plants, should remain subject to the provisions of category 1 NGT plants without the need to go through the verification procedure, prior to their release or placing on the market. Conversely, the progeny deriving from the application of targeted mutagenesis or cisgenesis to a category 1 NGT plant shall be subject to the procedure to verify the fulfillment of the criteria of equivalence ~~for category 1 NGT plants~~, prior to its release or placing on the market as category 1 NGT plant. If those criteria are not met, the progeny can be released or placed on the market only as category 2 NGT plant.

- (14b) 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 of equivalence for category 1 NGT plants 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. This empowerment should only apply to the extent justified by available evidence of advances in scientific knowledge and technical progress following the adoption of this Regulation.
- (15) All NGT plants that are not category 1 NGT plants ('category 2 NGT plants') and their products (hereinafter 'category 2 NGT products') 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 their products (hereinafter 'category 1 NGT 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.
- (17a) The fact that a notification for consent or an application for authorisation has been submitted under Union GMO legislation does not preclude the subsequent submission of a request to obtain a declaration of category 1 NGT plant status for the same plant or product under the present regulation.

- (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 category 1 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 category 1 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 of Member States as this would be less administratively burdensome for operators, and a decision should be taken at Union level only in case there are ~~comments~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I conditions for category 1 NGT plants, by ~~other national~~ competent authorities of other Member States. Where the verification request is submitted prior to the placing on the market of category 1 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 category 1 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 their products, those category 1 NGT plants and their category 1 NGT products will be subject to the applicable sectoral legislation on ~~seed and other plant reproductive material~~, food, feed and ~~other~~ products other than food and feed, such as seed and other plant reproductive material, 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>(27)</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>(28)</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.

---

<sup>27</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>28</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).

- (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. Moreover, in certain circumstances it may be necessary for Member States to adopt appropriate measures on their territory to avoid the unintended presence of category 1 NGT plants in organic agriculture, in particular in areas with specific geographical conditions, such as certain Mediterranean island Member States and insular regions, in accordance with Article 29(7) of Regulation (EU) 2018/848.
- (25) Category 2 NGT plants and their products 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 their 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 category 2 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>29</sup> and on plants developed through targeted mutagenesis<sup>30</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' (<sup>31</sup>), 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 category 2 NGT plants. It is therefore necessary to establish general principles and information requirements criteria for the risk assessment of these plants, while providing for flexibility and possibility to adapt risk assessment methodologies to scientific and technical progress.

---

<sup>29</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. 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>30</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>31</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>.

- (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, containing or consisting of GMOs, 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~~ has identified analytical challenges and limitations associated with the identification and quantification of certain plants and products obtained by targeted mutagenesis and cisgenesis <sup>(32)</sup>. For example, wWhen 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 such cases, an analytical method should still be provided by the notifier or applicant, but, if duly justified, the modalities to comply with analytical method performance requirements should be adapted. ~~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.

---

<sup>32</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. This requirement for a monitoring plan should apply as a rule to category 2 NGT plants. However, gGenetic 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, it should be possible for the competent authority not to require post-market monitoring requirements for environmental effects of category 2 NGT plants where duly justified, based on the results of any previous release of the category 2 NGT plant, the findings of the environmental risk assessment, the characteristics of the category 2 NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act concerning the notifications and applications adopted pursuant this Regulation. 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.
- (29a) Provision should be made for the Authority to adopt guidance to assist the notifier or the applicant in the preparation and the presentation of the notification and the application, including as regards the monitoring plan for environmental effects.
- (30) For reasons of proportionality, ~~after~~ upon 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 category 2 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(s) 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 their 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>33</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.

---

<sup>33</sup> COM(2023) 414 final

- (34) Incentives should consist in an accelerated procedure for risk assessment as regards applications handled by a fully centralised procedure (category 2 NGT plants for food or feed use and category 2 NGT food and feed ~~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 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>(34)</sup>. The submission of evidence demonstrating compliance with regulatory requirements in the context of a notification or an application for authorisation remains the notifier's or applicant's responsibility.
- (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 category 2 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, category 2 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].

---

<sup>34</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).

- (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. Directive 2001/18/EC provides the possibility for Member States to restrict or prohibit the cultivation of GMOs on their territory and to take appropriate measures to avoid the unintended presence of GMOs in other products, taking into account *inter alia* the diversity of farming systems and natural and economic conditions, such as those pertaining to islands. Those provisions continue to apply to category 2 NGT plants, given that experience has shown that cultivation of genetically modified plants is an issue with strong national, regional and local dimensions. In this context, the Commission will continue gathering and coordinating relevant information to complement and update, as necessary, the guidelines on coexistence.
- (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 genetically modified 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. The diversity of farming systems and natural and economic conditions in the EU such as insularity, need to be taken into consideration when defining these measures, that need to be proportionate to the objective pursued. In some cases, depending on economic and natural conditions, it may be necessary to exclude the cultivation of these plants from large areas. This possibility should rest on a demonstration that, for those areas, other measures are not sufficient to prevent the unintended presence of genetically modified plants in conventional or organic crops. The Commission should continue gathering and coordinating relevant information to complement and update as necessary the guidelines on coexistence referred to in Article 26a(2) of Directive 2001/18/EC.

- (39) To achieve the goal of ensuring the effective functioning of the internal market, NGT plants and their 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 their 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 deliberate release or the marketing of NGT plants or ~~NGT~~ their 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~~ their products, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Union and imported from third countries.
- (41 bis) This Regulation is without prejudice to the application of relevant provisions of Union and national law on public access to documents.
- (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~~ their 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>2</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>(35)</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. It is of particular importance that the consultations be carried out also on the basis of relevant reports which the Commission may be required to publish prior to adopting 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, as regards the content of the verification reports and of the decision, and as regards the methodology and information requirements for the environmental risk assessments of category 2 NGT plants and the safety assessment of category 2 NGT food and NGT feed, in accordance with the principles and factors ~~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>(36)</sup>.

---

<sup>35</sup> OJ L 123, 12.5.2016, p. 1

<sup>36</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).

- (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~~ their 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 in order to inform an evaluation of the legislation. A broad set of indicators have been identified<sup>37</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 their ~~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 NGT plants or their 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.
- (46a) Directive 98/44/EC on the legal protection of biotechnological inventions sets out principles regarding the patentability of biological material including plants. In order to be able to take possible action in case of adverse impacts of patented NGT plants, the Commission should assess, as part of a broader market analysis, conduct a study on the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders' access to plant genetic material and techniques and on the availability of plant reproductive material to farmers as well as the overall competitiveness of the EU plant breeding industry. For the same reason, the Commission should establish an expert group on the effect of the patenting of NGT plants. It is important to ensure that farmers and breeders have access to techniques and material to promote the diversity of plant reproductive material, such as seeds, at affordable prices, while also strongly supporting innovation in both conventional and organic plant breeding by preserving investment incentives.

---

<sup>37</sup> Impact assessment report accompanying the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, SWD(2023) 412

- (46b) Stakeholders raised concerns that patents on NGT plants may limit the access of breeders to those plants. Article 27(c) of the Agreement on a Unified Patent Court<sup>38</sup> already provides that rights conferred by a patent shall not extend to the use of biological material for the purpose of breeding or discovering and developing other plant varieties.
- (46c) Breeders can benefit from guidelines to help them navigate the plant intellectual property landscape. The Commission should therefore publish guidelines to assist operators, in particular breeders, in navigating the plant intellectual property landscape.
- (47) Certain references to provisions of the Union GMO legislation in Regulation (EU) 2017/625 of the European Parliament and of the Council (<sup>39</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:

---

<sup>38</sup> Agreement on a Unified Patent Court (OJ C 175, 20.6.2013, p. 1).

<sup>39</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).

# 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 and ~~or~~ feed, containing or consisting of such plants ('NGT products').

### *Article 2*

#### **Scope**

This Regulation shall apply to:

- (1) NGT plants;
- (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.