



**2023/0226(COD)**

14.11.2023

# **AMENDMENTS**

## **1 - 292**

**Draft opinion**

**Veronika Vrecionová**

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

Proposal for a regulation

(COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))



**Amendment 1**  
**Maria Noichl**

**Proposal for a regulation**

—

*Proposal for rejection*

*The Committee on Agriculture and Rural Development calls on the Committee on Environment, Public Health and Food Safety, as the committee responsible, to propose the rejection of 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.*

Or. en

**Amendment 2**  
**Sandra Pereira**

**Proposal for a regulation**

—

*Proposal for rejection*

*The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to propose rejection of the Commission proposal.*

Or. pt

**Amendment 3**  
**Benoît Biteau, Sarah Wiener, Claude Gruffat, Francisco Guerreiro, Pär Holmgren, Thomas Waitz, Rosa D'Amato**

**Proposal for a regulation**

—

*Proposal for rejection*

***The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to propose rejection of Commission proposal.***

Or. en

*Justification*

*By creating a category of NGTs to which apply neither impact assessment, nor monitoring or traceability, the Commission proposal does not respect the precautionary principle. This is made even more problematic by the unlimited length of the authorizations and the absence of safeguard clause for that category (See Georg Buchholz, 2023, Kommissionsvorschlag einer Verordnung über neue genomische Techniken (NGT): zur Verletzung des Vorsorgeprinzips, as well as the 2018 Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law).*

*Furthermore, there is no scientific basis provided by the Commission to support the allegation that the list of conditions to determine if a NGT fulfils the criteria of equivalence to conventional plants guarantee a lower level of risks.*

*The Commission proposal also contradicts the Cartagena Protocol on Biosafety, which notably obligates its signatories to clearly identify living modified organisms (including NGT grains) when exporting them to another signatory country, and to carry out risk assessments in a “scientifically sound manner”.*

*The Commission proposal completely ignores the specific issues linked to the diffusion of patented material without proper traceability, or the potential issues linked to coexistence with non NGT productions.*

*Finally, this proposal decreases drastically the information available to consumers and citizens by exempting NGTs from labelling on products, a rule that is still extremely popular among EU citizens.*

*The extent of the exemptions given to NGTs are not only barely supported by scientific arguments, they are also disproportionate when compared to the alleged benefits of NGTs, the extent of which are extremely difficult to evaluate.*

**Amendment 4**  
**Veronika Vrecionová**

**Proposal for a regulation**  
**Title 1**

*Text proposed by the Commission*

*Amendment*

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)

Proposal for a  
REGULATION OF THE EUROPEAN  
PARLIAMENT AND OF THE COUNCIL  
on plants obtained by certain ***precision  
breeding*** techniques and their food and  
feed, and amending Regulation (EU)  
2017/625  
(Text with EEA relevance)

Or. en

*Justification*

*This change will have to be reflected in the entire text, including changes of abbreviations from NGT to PBT (or similar).*

**Amendment 5**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Citation -1 (new)**

*Text proposed by the Commission*

*Amendment*

– ***The European Parliament rejects  
the Commission proposal.***

Or. en

**Amendment 6**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital -1 (new)**

*Text proposed by the Commission*

*Amendment*

***(-1) Biotechnology is one of the most  
important technologies for the future and  
should be supported by a suitable policy  
framework, with ethical, environmental  
and health aspects also being taken into  
account. However, life should under no  
circumstances be patented, either in the  
form of reproductive techniques or by***

*privatising genome sequences, because knowledge is of benefit to all.*

Or. pt

**Amendment 7**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital -1 a (new)**

*Text proposed by the Commission*

*Amendment*

*(-1a) Ethical questions relating to the use and practice of science in the field of genetic engineering are a fundamental issue. First and foremost, the short-, medium- and long-term consequences of using such technologies must be examined. It will be undeniably important to gain further knowledge about the impact on the environment, climate, farming, biodiversity and food security. It will also be important to build bridges between science and the advances it produces and the development of agriculture and production in general avoiding sacrificing the future and ensuring that such choices follow the precautionary principle.*

Or. pt

**Amendment 8**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 1**

*Text proposed by the Commission*

*Amendment*

(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council <sup>(32)</sup>, on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted,

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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.

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, ***however, the results cannot be fully foreseen and may be equivalent to or different from plants obtained using conventional selection.***

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<sup>32</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).

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<sup>32</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).

Or. pt

## **Amendment 9** **Annie Schreijer-Pierik**

### **Proposal for a regulation** **Recital 1**

#### *Text proposed by the Commission*

(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council (<sup>32</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.

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<sup>32</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).

#### *Amendment*

(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council (<sup>32</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*** locations.

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<sup>32</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).

**Amendment 10**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***(1a) Trade in genetically modified organism varieties cannot directly or indirectly rely solely on monopolistic private multinational companies, which benefit the most from the mass use of those patented varieties, a situation that leaves farmers more dependent on seed producers and, therefore, reduces the Member States' food and production sovereignty.***

Or. pt

**Amendment 11**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 1 b (new)**

*Text proposed by the Commission*

*Amendment*

***(1b) Since knowledge about the properties of each gene is incomplete and the number of variables is considerable, the impact of using such genetic techniques and their subsequent large-scale roll-out is not yet fully understood. Natural or organic crops, i.e. crops that have not been genetically modified by humans, existing alongside genetically modified crops poses the issue of gene flow, since pollination is often anemophilous, by way of the wind.***

Or. pt



**Amendment 12**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 1 d (new)**

*Text proposed by the Commission*

*Amendment*

***(1d) The use of genetically modified organisms has led to an excessive use of pesticides and persistent fertilisers, which can lead to reduced soil fertility, aridity and low water holding capacity. Defending the genetic integrity of natural crops is therefore fundamental, given that the impact of large-scale agriculture on soil properties affects the hydrosphere, biosphere, atmosphere and climate and, over time, contributes to desertification, which poses a threat to long-term food security. The precautionary principle should therefore be followed with the introduction of new NGT varieties.***

Or. pt

**Amendment 13**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 1 e (new)**

*Text proposed by the Commission*

*Amendment*

***(1e) The impact that consumption of GMOs and NGTs may have on animal feed and human food has not been sufficiently weighed up, particularly in the long term. There are no studies in the European Union that assess with any certainty the true impact on farming and food of introducing such plant varieties.***

Or. pt

**Amendment 14**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Recital 2**

*Text proposed by the Commission*

*Amendment*

**(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.** *deleted*

Or. en

*Justification*

*The nature of the modifications should not be the focus of this regulation, but the risks that intended and unintended alterations of the genomes or the cell functioning might have on health and the environment.*

**Amendment 15**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 2**

*Text proposed by the Commission*

(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.

*Amendment*

(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 *theoretically* 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. *However, the processes used in cisgenesis (and in intragenesis) are the same as those used to carry out transgenesis (insertion of additional gene sequences). Moreover, the gene pool used by conventional breeders in practical conditions may include variations not present in a gene pool that can be harnessed through the direct (and potentially reproducible) transfer of genes through all types of genetic backgrounds and can therefore produce plants that are difficult to obtain through conventional breeding methods.* Targeted mutagenesis techniques result in modification(s) of the DNA sequence at precise locations in the genome of an organism. Cisgenesis techniques result in insertion in the genome of an organism. *However, the results in terms of intentional and unintentional genetic alterations and biological effects cannot be predicted.* 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. ***However, the processes used in cisgenesis (and in intragenesis) are the same as those used to achieve transgenesis (insertion of additional gene sequences). Moreover, the gene pool used by conventional breeders, when taking practical decisions, may include restrictions absent from a gene pool that can be harnessed through the direct (and potentially repeated) transfer of genes through all genetic backgrounds and can therefore produce plants that will be difficult to obtain through conventional breeding methods.***

Or. pt

**Amendment 16**  
**Annie Schreijer-Pierik**

**Proposal for a regulation**  
**Recital 2**

*Text proposed by the Commission*

(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

*Amendment*

(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.

modification(s) of the DNA sequence at **targeted** 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.

Or. en

**Amendment 17**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***(2a) The introduction of plant varieties into the environment and/or into foodstuffs or feed for animals that may be different in their intended or unintended genotypes and phenotypes from those obtained by conventional breeding processes poses challenges to the regulatory authority, which must ensure safety for health and the environment. Such differences may not always be obvious or predictable and suitable data therefore is needed before conclusions about their safety can be drawn.***

Or. pt

**Amendment 18**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 2 b (new)**

*Text proposed by the Commission*

*Amendment*

***(2b) A risk assessment must be carried out on all NGT plants in order to produce adequate data on their intended and unintended genetic alterations and the effects that may arise from those alterations. This first stage of the risk assessment, which simply requires experiments under contained use conditions, should be used to take decisions about their status and the amount of data that will be needed for an overall risk assessment.***

Or. pt

**Amendment 19**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 3**

*Text proposed by the Commission*

(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>(33)</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>(34)</sup> and of the ‘Farm to Fork’ <sup>(35)</sup>, ***Biodiversity*** <sup>(36)</sup> and Adaptation to Climate Change<sup>(37)</sup> Strategies, ***to global food security*** <sup>(38)</sup>, the Bioeconomy Strategy <sup>(39)</sup> and to the Union’s strategic

*Amendment*

(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>(33)</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>(34)</sup> and of the ‘Farm to Fork’ <sup>(35)</sup> and Adaptation to Climate Change<sup>(37)</sup> Strategies, the Bioeconomy Strategy <sup>(39)</sup> and to the Union’s strategic autonomy <sup>(40)</sup>.

autonomy <sup>(40)</sup>.

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<sup>33</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>34</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>35</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>36</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>37</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>38</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social**

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<sup>33</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>34</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>35</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>37</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

*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>39</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>40</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>39</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>40</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.

Or. pt

**Amendment 20**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***(3a) Given that sustainability comprises many degrees of complexity, clear and transparent criteria are needed for a suitable technological assessment before conclusions can be drawn on the potential benefits of NGTs' specific characteristics.***

Or. pt

**Amendment 21**  
**Benoît Biteau**



on behalf of the Verts/ALE Group

## Proposal for a regulation

### Recital 4

#### *Text proposed by the Commission*

(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>(41)</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>(42)</sup>, while the contained use of plant cells is subject to Directive 2009/1/EC, and transboundary movements of NGT plants to third countries are regulated by Regulation (EC) No 1946/2003 ('the Union GMO legislation').

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<sup>41</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>42</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).

#### *Amendment*

(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>(41)</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>(42)</sup>, while the contained use of plant cells is subject to Directive 2009/1/EC, and transboundary movements of NGT plants to third countries are regulated by Regulation (EC) No 1946/2003 ('the Union GMO legislation'), ***in line with the Cartagena Protocol on Biosafety.***

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<sup>41</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>42</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).

Or. en

#### *Justification*

*The EU is a signatory of the Cartagena Protocol on Biosafety, which applies to the transboundary movement, transit, handling and use of living modified organisms, and obliges its signatories to clearly identify such organisms. NGT seeds and grains, as defined in this proposal, fall under the Cartagena Protocol's definition of "Living modified organism", which*

*means any living organism that possesses a novel combination of genetic material obtained through modern biotechnology. According to Art. 15 para 1 CP, risk assessments must be carried out in a “scientifically sound manner”.*

## **Amendment 22**

**Theresa Bielowski, Maria Noichl**

### **Proposal for a regulation**

#### **Recital 5**

##### *Text proposed by the Commission*

(5) In its judgment in case C-528/16 Confédération paysanne and Others<sup>43</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.

##### *Amendment*

(5) In its judgment in case C-528/16 Confédération paysanne and Others 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, ***as the new mutagenesis techniques/methods have a comparable risk potential to the production of transgenic plants, in which foreign genetic material is introduced into the genome of organisms. In accordance with the precautionary principle, the regulations of the Genetic Engineering Law would therefore have to be applied (Art.2 No.2 of Directive 2001/18; fourth, eighth and 25th recitals). These organisms and all products derived from them must therefore be subjected to a comprehensive safety assessment for humans, animals and the environment before being placed on the market. Likewise, they must be traceable and labelled.***

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<sup>43</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.

Or. en

## *Justification*

*According to the ruling of the European Court of Justice (ECJ) of July 25, 2018, organisms obtained by mutagenesis are in principle to be classified as genetically modified organisms (GMOs) and are therefore subject to the regulations of the Genetic Engineering Act (Directive 2001/18/EC). The reason given for this is that mutagenesis processes lead to a change in the genetic material of an organism that is not possible in a natural way.*

### **Amendment 23** **Anja Hazekamp**

#### **Proposal for a regulation** **Recital 6 a (new)**

*Text proposed by the Commission*

*Amendment*

***(6 a) The European Parliament, in its reaction to the Farm to Fork strategy for a fair, healthy and environmentally-friendly food system, highlighted the precautionary principle and the need to ensure transparency and freedom of choice to farmers, processors and consumers, and stressed that any policy action on NGTs should include risk assessments and a comprehensive overview and assessment of options for traceability and labelling with a view to achieving proper regulatory oversight and should provide consumers with relevant information, including for products from third countries in order to ensure a level playing field;***

Or. en

### **Amendment 24** **Anja Hazekamp**

#### **Proposal for a regulation** **Recital 6 b (new)**

*Text proposed by the Commission*

*Amendment*

***(6 b) The European Parliament has called<sup>1a</sup> for a comprehensive analysis of the socioeconomic and environmental***

*effects on the food system of patents on breeding processes, plant propagation material and parts thereof, including their potential to increase market concentration and monopolisation in the food chain, as well as their impact on the affordability and availability of food, and called for the EU and its Member States not to grant patents on biological material and to safeguard the freedom to operate and breeders' exemption for varieties. It is therefore appropriate to ensure that patented plants are not subject to any exemptions of the Union GMO legislation.*

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*<sup>1a</sup> European Parliament resolution of 14 June 2023 on ensuring food security and long-term resilience of the EU agriculture (2022/2183(INI)) P9\_TA(2023)0238*

Or. en

**Amendment 25**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 7**

*Text proposed by the Commission*

*Amendment*

*(7) The Commission's study on new genomic techniques <sup>(45)</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*

*deleted*

*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.*

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*<sup>45</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.*

Or. pt

**Amendment 26**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 7**

*Text proposed by the Commission*

*Amendment*

*(7) The Commission's study on new genomic techniques (<sup>45</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.*

*deleted*

*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.*

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<sup>45</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.*

Or. en

**Amendment 27**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Recital 7**

**(7) The Commission’s study on new genomic techniques <sup>(45)</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.**

**deleted**

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<sup>45</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.

*Justification*

*The conclusions of the study are actually much more prudent than what is stated there, and several other studies have shown identification could be possible under certain conditions - these conditions are just considered too inconvenient by some stakeholders. See notably Yves Bertheau (2019), *New Breeding Techniques: Detection and Identification of the Techniques and Derived Products*, and Ribarits, A. et al. (2021): *Genome-Edited Plants: Opportunities and Challenges for an Anticipatory Detection and Identification Framework*.*

**Amendment 28**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 8**

*Text proposed by the Commission*

*Amendment*

**(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.*** ***deleted***

Or. pt

**Amendment 29**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 8**

*Text proposed by the Commission*

*Amendment*

**(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.*** ***deleted***

Or. en



### Amendment 30

**Asger Christensen**

on behalf of the Renew Group

**Emma Wiesner, Jan Huitema, Erik Poulsen**

#### Proposal for a regulation

##### Recital 8

*Text proposed by the Commission*

(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.*

*Amendment*

(8) Therefore, *category 1 NGT plants and products* obtained by targeted mutagenesis and cisgenesis and related products *shall not be subject to the rules and requirements of the Union GMO legislation and to provisions in other Union legislation that apply to GMOs. Targeted mutagenesis Category 1 NGT plants and products shall be exempted in Directive 2001/18/EC Annex 1 B like other mutagenecis methods.*

Or. en

*Justification*

*As the GMO legislation is not fit for purpose and NGT of category 1 should not be considered GMO it is important that they are exempted as such. The wording from the Commission muddies the distinction between GMOs and NGTs.*

### Amendment 31

**Daniel Buda, Dan-Ştefan Motreanu**

#### Proposal for a regulation

##### Recital 8

*Text proposed by the Commission*

(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.

*Amendment*

(8) It is therefore necessary to adopt a specific legal framework for **plants** obtained by **NGTs such as** targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market. *A periodic review of the approach to establishing equivalence to conventional breeding methods is mandated in order to reflect scientific and technological*

*progress.*

Or. en

*Justification*

*Plant breeding techniques are rapidly evolving and it is important for the new Regulation to enable scientific and technological progress well into the future.*

**Amendment 32**

**Maria Noichl**

**Proposal for a regulation**

**Recital 8**

*Text proposed by the Commission*

(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.

*Amendment*

(8) It is therefore **not** 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, **as the current legal framework 2001/18 is appropriate.**

Or. en

**Amendment 33**

**Maria Noichl**

**Proposal for a regulation**

**Recital 9**

*Text proposed by the Commission*

(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**

*Amendment*

(9) Based on the current scientific and technical knowledge in particular on safety aspects, **all GMOs, and therefore also** NGT plants, should remain **regulated under the existing Directive 2001/18.**

*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.*

Or. en

#### **Amendment 34 Sandra Pereira**

#### **Proposal for a regulation Recital 9**

*Text proposed by the Commission*

(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

*Amendment*

(9) Based on the current scientific and technical knowledge in particular on safety aspects, this Regulation should be limited to GMOs that are *annual agricultural crops with no potential to persist, reproduce and spread in the environment, excluding other organisms* for which the available knowledge is more limited. For the same reason, this Regulation should only cover plants obtained by certain NGTs: targeted mutagenesis (hereinafter ‘NGT plants’), but not by other new genomic techniques. Such NGT plants do not carry genetic material from non-crossable species *or insertions of additional genetic material prepared outside cells*. GMOs produced by other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) *or that*

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.

***contain additional genetic material prepared outside cells*** should remain subject only to the Union GMO legislation, given that the resulting plants might bear specific risks associated to the transgene ***or the inserted additional genetic material***. Moreover, there is no indication that current requirements in the Union GMO legislation for GMOs obtained by transgenesis need adaptation at the present time.

Or. pt

### **Amendment 35**

**Asger Christensen**

on behalf of the Renew Group

**Emma Wiesner, Elsi Katainen, Ulrike Müller, Erik Poulsen**

### **Proposal for a regulation**

#### **Recital 9**

*Text proposed by the Commission*

(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

*Amendment*

(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. ***For other organisms, such as*** microorganisms, the available knowledge ***will be reviewed in view of a future proposal***. 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, ***the wider*** GMO legislation

legislation for GMOs obtained by transgenesis need adaptation at the present time.

*should be examined in view of the Commission conclusion that it is no longer fit purpose to ensure that requirements are science-based and proportional to the risk.*

Or. en

#### *Justification*

*The Explanatory Memorandum notes that “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.” it is therefore relevant to make similar legislation on microorganisms.*

### **Amendment 36** **Sandra Pereira**

#### **Proposal for a regulation** **Recital 10**

##### *Text proposed by the Commission*

(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.***

##### *Amendment*

(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 ***but without undermining the precautionary principle.***

**Amendment 37**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 10**

*Text proposed by the Commission*

(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.**

*Amendment*

(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, **in line with the precautionary principle** and the **One Health principle**, for the concerned plants and products, so as to contribute to the sustainability objectives of the European Green Deal and the Farm to Fork, Biodiversity, **Zero Pollution** and Climate Adaptation strategies.

Or. en

**Amendment 38**  
**Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton**

**Proposal for a regulation**  
**Recital 10**

*Text proposed by the Commission*

(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

*Amendment*

(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.

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 **allow for flexibility and adaptation to ensure the continued yet monitored** 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 **and profitability of companies especially small and medium-sized enterprises in** the Union agri-food sector at Union and world level.

Or. en

### **Amendment 39**

**Benoît Biteau**

on behalf of the Verts/ALE Group

### **Proposal for a regulation**

#### **Recital 10**

#### *Text proposed by the Commission*

(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

#### *Amendment*

(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, **and while fully respecting the precautionary principle**. 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

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.

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.

Or. en

#### *Justification*

*The Precautionary Principle is one of the fundamental elements of the EU Treaties, and it applies to the release in nature and the use in food of organisms that have been genetically modified, notably NGTs. As highlighted by the 2018 ECJ ruling, the precautionary principle requires that products developed with such gene editing should not be released into the environment without an extensive risk assessment, especially in situations where too little is known about the risks of a technology (ECJ, 2018).*

#### **Amendment 40**

**Maria Noichl**

#### **Proposal for a regulation**

#### **Recital 11**

*Text proposed by the Commission*

*Amendment*

***(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.***

***deleted***

Or. en

#### **Amendment 41**

**Sandra Pereira**



## Proposal for a regulation

### Recital 11

*Text proposed by the Commission*

(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.

*Amendment*

(11) This Regulation constitutes *lex specialis* with regard to the Union GMO legislation, ***based on the precautionary principle***. 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.

Or. pt

## Amendment 42

**Benoît Biteau**

on behalf of the Verts/ALE Group

## Proposal for a regulation

### Recital 12

*Text proposed by the Commission*

***(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.***

*Amendment*

***deleted***

Or. en

*Justification*

*There is no way of knowing if some of these plants present risks which are similar to conventionally-bred plants without an impact assessment. None of the criteria proposed in this regulation to define the different categories of NGT plants are linked to an increased or decreased risk profile.*

**Amendment 43**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 13**

*Text proposed by the Commission*

*Amendment*

**(13) This Regulation should distinguish between two categories of NGT plants.** *deleted*

Or. en

*Justification*

*NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT plants has no link to actual risk factors as they are usually considered by risk assessors.*

**Amendment 44**

**Anja Hazekamp**

**Proposal for a regulation**

**Recital 13**

*Text proposed by the Commission*

*Amendment*

**(13) This Regulation should distinguish between two categories of NGT plants.** *deleted*

Or. en

**Amendment 45**

**Maria Noichl**

**Proposal for a regulation**  
**Recital 13**

*Text proposed by the Commission*

*Amendment*

**(13) This Regulation should distinguish between two categories of NGT plants.**

*deleted*

Or. en

**Amendment 46**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 13 a (new)**

*Text proposed by the Commission*

*Amendment*

**(13a) To evaluate the status of NGT plants, it is necessary to know the 'indoor risk assessment' data (which requires experiments under contained conditions involving molecular characterisation and greenhouse experiments) to check the two categories of NGT plants. Given that field trials or food consumption trials are not required for the 'indoor risk assessment' (which requires experiments in contained conditions), such data can be supplied and evaluated without excessive costs in a shorter period of time.**

Or. pt

**Amendment 47**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 13 b (new)**

*Text proposed by the Commission*

*Amendment*

**(13b) Given that many NGT plants with different characteristics and from a variety of species may be released into the same environment, clear criteria and**

*methods should be established to assess potential interactions and avoid overloading ecosystems with organisms that have not adapted through evolutionary processes. NGT plants that have the potential to persist, reproduce or spread in the environment (within or outside fields) must have their impact on nature and the environment assessed with greater scrutiny. In the event of any doubts, their release into the environment should be banned.*

Or. pt

**Amendment 48**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 13 c (new)**

*Text proposed by the Commission*

*Amendment*

*(13c) The status of each NGT plant should be checked by clearly establishing what makes it considerably different from plants derived from conventional reproductive methods.*

Or. pt

**Amendment 49**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

*Amendment*

*(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*

*deleted*

*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.*

Or. en

#### **Amendment 50**

**Benoît Biteau**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

##### **Recital 14**

*Text proposed by the Commission*

*Amendment*

**(14) NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny**

*deleted*

*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.*

Or. en

#### *Justification*

*NGT plants, by definition, could not also occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. This is why we propose to delete the specific rules dedicated to category 1 NGTs.*

**Amendment 51**  
**Theresa Bielowski, Maria Noichl**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

*Amendment*

***(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.*** *deleted*

*Justification*

*The latest science in the field of molecular genetics suggests that the law governing genetic modification including NGT should be re-appraised and strengthened rather than weakened. The Commission proposal is not in accordance with science- and evidence-based risk assessment, because there is as yet little experience regarding the safety of new genetic engineering techniques. Instead, the proposal provides a list of non-scientific “equivalence criteria” that simply redefine the vast majority of new GMOs as “equivalent to conventional plants” (Category 1, Annex I).*

**Amendment 52**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

*Amendment*

**(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** **deleted**



*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.*

Or. en

**Amendment 53**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

(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*

*Amendment*

(14) *In order to ensure legal certainty and safety for health and the environment, this Regulation should set out the criteria and establish suitable methods to ascertain the impact that a NGT plant has on the reproduction of 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. Decision-making should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained with conventional breeding techniques and the site of the intended or unintended genetic alterations and associated biological effects. The methods needed for the 'indoor risk assessment' (for example for whole genome sequencing and to carry out omics, greenhouse and environmental chamber experiments) must be proposed*

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.

**by the European Food Safety Authority (EFSA) and established by an implementing regulation. They should cover** the type and extent of genetic modifications that can **be observed** in nature or **in organisms obtained with** conventional breeding **techniques**.

Or. pt

**Amendment 54**  
**Herbert Dorfmann**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

(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 **fulfilment** of those criteria, prior to the release or placing on the market of NGT plants or NGT products. Those criteria should be objective and

*Amendment*

(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 **fulfilment** 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.

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, **extent, dimensions and number** of genetic modifications that can occur in nature or through conventional breeding.

Or. it

**Amendment 55**  
**Daniela Rondinelli**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

(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 **fulfilment** of those criteria, prior to the release or placing on the

*Amendment*

(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 **fulfilment** 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.

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, **extent, dimensions and number** of genetic modifications that can occur in nature or through conventional breeding.

Or. it

## **Amendment 56**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

### **Proposal for a regulation**

#### **Recital 14**

##### *Text proposed by the Commission*

(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

##### *Amendment*

(14) NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny ('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,

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.

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.

Or. en

#### *Justification*

*Progeny of Category 1 NGT plants should remain category 1 if additional modifications fulfil the equivalence criteria set out in annex I, without considering the previous modifications. Breeders constantly improve on commercial varieties, in order to reach incremental productivity gains over time. This is not future-proof and will greatly limit the range of what could be achieved when combining complex traits, like drought tolerance with disease resistance.*

#### **Amendment 57**

**Asger Christensen**

on behalf of the Renew Group

**Emma Wiesner, Elsi Katainen, Ulrike Müller, Jan Huitema, Erik Poulsen**

#### **Proposal for a regulation**

**Recital 14 a (new)**

*Text proposed by the Commission*

*Amendment*

***(14 a) In view of the high complexity of plant genomes, the criteria for considering that a NGT plant is equivalent to naturally occurring or conventionally bred plants should reflect***

*the diversity of plants genomic size and their characteristics. Polyploid plants contain more than two homologous chromosomes. Within this, tetraploid, hexaploid, and octoploid have 4, 6 and 8 sets of chromosomes respectively. Polyploid plants tend to exhibit greater numbers of genetic modifications compared to monoploid plants. Based on this any limit to the total number of individual modifications per plant should reflect the plants “ploidy”, meaning the number of chromosomes set in a plant.*

Or. en

*Justification*

*The recital provides an explanation to how the limitations set out in Annex 1 should be understood and a general explanation of the complexity of plant genomes.*

**Amendment 58**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 15**

*Text proposed by the Commission*

*Amendment*

*(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.*

*deleted*

Or. en

**Amendment 59**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 15**

*Text proposed by the Commission*

*Amendment*

(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.

(15) All NGT plants should remain subject to the requirements of the Union GMO legislation *and the overall risk assessment* because they feature more complex sets of modifications to the genome *or have a genotype and/or phenotype that is unlikely to be obtained through conventional or natural reproductive processes. The amount of additional data needed to draw a conclusion about the safety of those plants can be decided based on data in their 'indoor risk assessment' as the first step in the approval process.*

Or. pt

## **Amendment 60**

**Benoît Biteau**

on behalf of the Verts/ALE Group

### **Proposal for a regulation**

#### **Recital 15**

*Text proposed by the Commission*

(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.

*Amendment*

(15) All NGT plants should remain subject to the requirements of the Union GMO legislation because they feature complex sets of modifications to the genome.

Or. en

## **Amendment 61**

**Anja Hazekamp**

### **Proposal for a regulation**

#### **Recital 15**

*Text proposed by the Commission*

(15) All NGT plants *that are not category 1 ('category 2 NGT plants')* should remain subject to the requirements

*Amendment*

(15) All NGT plants should remain subject to the requirements of the Union GMO legislation because they feature

of the Union GMO legislation because they feature *more* complex sets of modifications to the genome.

complex sets of modifications to the genome.

Or. en

## **Amendment 62**

**Sandra Pereira**

### **Proposal for a regulation**

#### **Recital 16**

*Text proposed by the Commission*

*Amendment*

***(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.***

***deleted***

Or. pt

## **Amendment 63**

**Benoît Biteau**

on behalf of the Verts/ALE Group

### **Proposal for a regulation**

#### **Recital 16**

*Text proposed by the Commission*

*Amendment*

***(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.***

***deleted***



**Amendment 64**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

*Amendment*

**(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.**

**deleted**

Or. en

**Amendment 65**  
**Peter Jahr, Lena Düpont, Christine Schneider, Marlene Mortler**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

*Amendment*

(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*.

(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*. **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. The biological material of plant breeding, which may also occur in nature, must be widely available for plant breeding. Category 1 plants, their derived seed, their plant material, associated genetic material such as genes and gene sequences, and plant traits should be excluded from patentability.*

Or. en

**Amendment 66**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

(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.

*Amendment*

(16) Category 1 NGT plants and products should 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 comprehensive risk assessment and evaluation within an authorisation procedure, including the provision of a specific detection method, as well as reference and control material** should be obtained. **Without authorisation, zero tolerance applies. After authorisation, NGT-1 products are subject to mandatory labelling along the entire value chain and at legal level, coexistence regulations (such as a parcel-specific site register, distance and liability regulations in accordance with the polluter principle) that reliably prevent contamination need to be implemented. NGT plants should be subject to monitoring. Member states should be given the option of opt-out in order to protect people from health hazards,** prior to deliberate release, including the placing on the market.

**Amendment 67**

**Veronika Vrecionová**

**Proposal for a regulation**

**Recital 16**

*Text proposed by the Commission*

(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.

*Amendment*

(16) Category 1 NGT plants and products **must** 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.

Or. en

**Amendment 68**

**Juozas Olekas, Carmen Avram**

**Proposal for a regulation**

**Recital 16**

*Text proposed by the Commission*

(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.

*Amendment*

(16) Category 1 NGT plants and products **must** 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.

Or. en

Clarification

**Amendment 69**

**Anne Sander**

**Proposal for a regulation**

**Recital 16**

*Text proposed by the Commission*

(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.

*Amendment*

(16) Category 1 NGT plants and products **must** 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.

Or. fr

**Amendment 70**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 17**

*Text proposed by the Commission*

***(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***

*Amendment*

***deleted***

*NGT product on the market.*

Or. en

**Amendment 71**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 17**

*Text proposed by the Commission*

*Amendment*

*(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.*

*deleted*

Or. en

**Amendment 72**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 17**

*Text proposed by the Commission*

*Amendment*

*(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*

*deleted*

*Union, operators should obtain that declaration before placing the category 1 NGT product on the market.*

Or. pt

**Amendment 73**

**Sandra Pereira**

**Proposal for a regulation**

**Recital 18**

*Text proposed by the Commission*

*Amendment*

*(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.*

*deleted*

Or. pt

**Amendment 74**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

*Amendment*

*(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.*

*deleted*

Or. en

**Amendment 75**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

*Amendment*

**(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.*

*deleted*

Or. en

**Amendment 76**  
**Theresa Bielowski, Maria Noichl**

**Proposal for a regulation**  
**Recital 18**



**(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.*** **deleted**

Or. en

*Justification*

*The latest science in the field of molecular genetics suggests that the law governing genetic modification including NGT should be re-appraised and strengthened rather than weakened. The Commission proposal is not in accordance with science- and evidence-based risk assessment, because there is as yet little experience regarding the safety of new genetic engineering techniques. Instead, the proposal provides a list of non-scientific “equivalence criteria” that simply redefine the vast majority of new GMOs as “equivalent to conventional plants” (Category 1, Annex I).*

**Amendment 77**

**Herbert Dorfmann**

**Proposal for a regulation**

**Recital 18**

*Text proposed by the Commission*

(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.

*Amendment*

(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 *in consultation with the Commission and the European Food Safety Authority ('the Authority') only if there are reasoned objections by other Member States* in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.

Or. it

**Amendment 78**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(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.

*Amendment*

(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 *reasoned scientific objections* 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.

Or. en

*Justification*

*The verification procedure should be science based. Any intervention should be scientifically justified and based on correct application of the equivalence criteria set in Annex I, to make the verification process effective and predictable (within a reasonable timeframe) based on clear criteria and the scientific expertise of competent authorities.*

**Amendment 79**

**Daniela Rondinelli**

**Proposal for a regulation**

**Recital 18**

*Text proposed by the Commission*

(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.

*Amendment*

(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. **Where the verification request is submitted prior to the placing on the market of NGT products, the procedure should be conducted in consultation with the Commission and the European Food Safety Authority ('the Authority') only if there are reasoned scientific objections by other Member States** in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.

Or. it

**Amendment 80**

**Herbert Dorfmann**

**Proposal for a regulation**

**Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) With a view to effectively selecting new varieties that help the agricultural sector to increase food security and sustainability as well as to adopt to and ensure resilience to the consequences of climate change, the specific characteristics of polyploid plants – those containing more than two genomes – need to be considered. This is the case, for instance, with wheat, potato, sugar beet, banana, kiwi, peanut, rapeseed, etc. For polyploid plants, the maximum number of genetic modifications allowed for inclusion in category 1 NGT should be proportionate to the number of genomes they contain.***

Or. it

**Amendment 81  
Daniela Rondinelli**

**Proposal for a regulation  
Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) With a view to effectively selecting new varieties that help the agricultural sector to increase food security and sustainability as well as to adopt to and ensure resilience to the consequences of climate change, the specific characteristics of polyploid plants – those containing more than two genomes – need to be considered. For polyploid plants, the maximum number of genetic modifications allowed for inclusion in category 1 NGT should be proportionate to the number of genomes they contain.***

Or. it

**Amendment 82**

**Sandra Pereira**

**Proposal for a regulation  
Recital 19**

*Text proposed by the Commission*

*Amendment*

**(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.**

**deleted**

Or. pt

**Amendment 83  
Anja Hazekamp**

**Proposal for a regulation  
Recital 19**

*Text proposed by the Commission*

*Amendment*

**(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.**

**deleted**

Or. en

**Amendment 84  
Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation  
Recital 19**

*Text proposed by the Commission*

*Amendment*

**(19) The competent authorities of the Member States, the Commission and the**

**deleted**

***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.***

Or. en

**Amendment 85**  
**Theresa Bielowski, Maria Noichl**

**Proposal for a regulation**  
**Recital 19**

*Text proposed by the Commission*

(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.

*Amendment*

(19) The competent authorities of the Member States, the Commission and the European Food Safety Authority ('the Authority') should be subject to ***feasible*** deadlines to ensure that category 1 NGT plant status declarations are made within a reasonable time.

Or. en

*Justification*

*Authorities shall have sufficient time to inspect NGT plants to ensure that they are safe. Current proposals are far from realistic planning for the authorities.*

**Amendment 86**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

(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***

*Amendment*

***deleted***

*implementing decisions should be adopted by the advisory procedure, supported by scientific and technical assistance by the Authority.*

Or. pt

**Amendment 87**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 20**

*Text proposed by the Commission*

*Amendment*

**(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.* **deleted**

Or. en

**Amendment 88**

**Anja Hazekamp**

**Proposal for a regulation**

**Recital 20**

*Text proposed by the Commission*

*Amendment*

**(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* **deleted**



*by the advisory procedure, supported by scientific and technical assistance by the Authority.*

Or. en

## **Amendment 89**

**Maria Noichl**

### **Proposal for a regulation**

#### **Recital 20**

*Text proposed by the Commission*

(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.*

*Amendment*

(20) *All NGT plants should be tested and assessed for their risks before being put on the market and prior to authorisation for cultivation.*

Or. en

## **Amendment 90**

**Theresa Bielowski, Maria Noichl**

### **Proposal for a regulation**

#### **Recital 20**

*Text proposed by the Commission*

(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

*Amendment*

(20) The verification of category 1 NGT plant status *needs a* risk assessment or risk management considerations. 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.

Authority.

Or. en

### *Justification*

*There are no good reasons for weakening the existing GMO legislation, let alone abolishing it for the majority of new GM plants. The advancing knowledge of molecular genetics shows that the genome functions as a delicately balanced, integrated network. That genes function as networks, implies that any modification can have major consequences with respect to patterns of gene expression and an organism's biochemistry. Thus, the latest science suggests that the law governing genetic modification including NGT should be re-appraised and strengthened rather than weakened.*

#### **Amendment 91 Sandra Pereira**

##### **Proposal for a regulation Recital 21**

*Text proposed by the Commission*

*Amendment*

**(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.** **deleted**

Or. pt

#### **Amendment 92 Anja Hazekamp**

##### **Proposal for a regulation Recital 21**

*Text proposed by the Commission*

*Amendment*

**(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** **deleted**

*plants when they are listed in the database and for the purpose of labelling of plant reproductive material derived from them.*

Or. en

**Amendment 93**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 21**

*Text proposed by the Commission*

*Amendment*

**(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.** *deleted*

Or. en

**Amendment 94**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

**Proposal for a regulation**

**Recital 21**

*Text proposed by the Commission*

*Amendment*

**(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.***

**(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.**

Or. en

## *Justification*

*Information related to the use of NGTs in breeding Category 1 NGT plants is already foreseen in the Common Catalogue and a public registry. Physically labelling the seed bags does not provide any additional value to farmers or consumers, and results in additional costs and administrative burden.*

### **Amendment 95 Herbert Dorfmann**

#### **Proposal for a regulation Recital 21**

##### *Text proposed by the Commission*

(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.***

##### *Amendment*

(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.

Or. en

### **Amendment 96 Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero**

#### **Proposal for a regulation Recital 21**

##### *Text proposed by the Commission*

(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.***

##### *Amendment*

(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.

Or. en

**Amendment 97**  
**Daniel Buda, Dan-Ştefan Motreanu**

**Proposal for a regulation**  
**Recital 21**

*Text proposed by the Commission*

(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.***

*Amendment*

(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.

Or. en

*Justification*

*Category 1 NGT plants are considered equivalent to conventional plants and this extra requirement is discriminatory, creating unjustified distinctions and administrative burden. Transparency can be ensured by making the database public. Furthermore, creating labelling requirements for a third category of plant reproductive material, between conventional and GMOs, would have a negative impact on trade.*

**Amendment 98**  
**Asger Christensen**  
on behalf of the Renew Group  
**Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Ulrike Müller, Jan Huitema, Erik Poulsen**

**Proposal for a regulation**  
**Recital 21**

*Text proposed by the Commission*

(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.***

*Amendment*

(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. ***The information listed shall include information on the technique(s) used to obtain the trait(s).***

Or. en

## Justification

*Listing the specific techniques is relevant because it gives organic farmers (as well as conventional) the option to choose seeds made with techniques they deem compatible with their farming methods.*

### Amendment 99

**Maria Noichl**

#### Proposal for a regulation

##### Recital 21

*Text proposed by the Commission*

(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.*

*Amendment*

(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, ***they must undergo an authorisation procedure in accordance with Directive 2001/18.***

Or. en

### Amendment 100

**Sandra Pereira**

#### Proposal for a regulation

##### Recital 22

*Text proposed by the Commission*

(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*

*Amendment*

*deleted*

*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>(46)</sup> and will be risk assessed in that context.*

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*<sup>46</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).*

Or. pt

**Amendment 101**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

*Amendment*

*(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*

*deleted*

*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>(46)</sup> and will be risk assessed in that context.*

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*<sup>46</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).*

Or. en

## **Amendment 102**

**Benoît Biteau**

on behalf of the Verts/ALE Group

### **Proposal for a regulation**

#### **Recital 22**

*Text proposed by the Commission*

(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

*Amendment*

(22) 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, 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



the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council <sup>(46)</sup> ) and will be risk assessed in that context.

European Parliament and of the Council <sup>(46)</sup> ) and will be risk assessed in that context.

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<sup>46</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).

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<sup>46</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).

Or. en

### *Justification*

*All NGT plants are subjected to any regulatory framework that applies to conventionally bred plants. There is no sense singling specific NGT plants and products in this recital.*

## **Amendment 103**

**Veronika Vrecionová**

### **Proposal for a regulation**

#### **Recital 23**

*Text proposed by the Commission*

*Amendment*

***(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>(47)</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***

***deleted***

***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.***

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***<sup>47</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).***

Or. en

#### *Justification*

*Provisions related to organic farming shall not be dealt with in this Regulation.*

#### **Amendment 104**

**Ulrike Müller, Atidzhe Alieva-Veli**

#### **Proposal for a regulation**

#### **Recital 23**

##### *Text proposed by the Commission*

(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>(47)</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

##### *Amendment*

(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>(47)</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.

is necessary to clarify the status of category 1 NGT plants for the purposes of organic production. ***While category 1 NGT plants are indistinguishable from plants obtained from conventional breeding including chemical and radiation induced mutagenesis which are accepted in organic production, and while relevant science bodies point out the particular potential of NGT plants in organic farming<sup>47a</sup>, it should be respected that the use of new genomic techniques is currently considered incompatible with the concept of organic production in the Regulation (EC) 2018/848 by a large majority of the organic farming and food sector and with consumers' perception of organic products. The use of category 1 NGT plants should therefore be also prohibited in organic production. The prohibition of category 1 NGT plants in organic production further will ensure freedom of choice for consumers who wish to opt for products free from NGT plants.***

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<sup>47</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).

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<sup>47</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>47a</sup>

***[https://www.dfg.de/download/pdf/dfg\\_im\\_profil/geschaeftsstelle/publikationen/stellungsnahmen\\_papiere/2023/statement\\_genomic\\_techniques.pdf](https://www.dfg.de/download/pdf/dfg_im_profil/geschaeftsstelle/publikationen/stellungsnahmen_papiere/2023/statement_genomic_techniques.pdf)***

Or. en

## **Amendment 105**

**Anne Sander**

### **Proposal for a regulation**

#### **Recital 23**

*Text proposed by the Commission*

*Amendment*

(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>(47)</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.***

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<sup>47</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).

(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>(47)</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.

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<sup>47</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).

Or. fr

## **Amendment 106**

**Irène Tolleret**

### **Proposal for a regulation**

#### **Recital 23**

*Text proposed by the Commission*

(23) Regulation (EU) 2018/848 of the European Parliament and the Council on organic production and labelling of organic products and repealing Council Regulation

*Amendment*

(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>(47)</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.

(EC) 834/2007(20) 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 *the current consumers' and producers'* perception of organic products. The use of category 1 NGT plants should therefore be also prohibited in organic production. ***The Commission should present a report on the evolution of consumers' and organic producers' perception 7 years after the entry into force of this Regulation in order to reconsider, if appropriate, the ban on the use of NGT1 in organic production.***

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<sup>47</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).

Or. en

**Amendment 107**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 23**

*Text proposed by the Commission*

(23) Regulation (EU) 2018/848 of the

*Amendment*

(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>(47)</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.***

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<sup>47</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).

European Parliament and the Council on organic production and labelling of organic products and repealing Council Regulation (EC) 834/2007<sup>(47)</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.

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<sup>47</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).

Or. pt

## **Amendment 108**

### **Anja Hazekamp**

#### **Proposal for a regulation**

#### **Recital 23**

##### *Text proposed by the Commission*

(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>(47)</sup> prohibits the use of

##### *Amendment*

(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>(47)</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.**

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<sup>47</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).

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, NGT plants **are** banned in organic production.

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<sup>47</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).

Or. en

## **Amendment 109**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

### **Proposal for a regulation**

#### **Recital 23**

*Text proposed by the Commission*

(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>(47)</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,

*Amendment*

(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>(47)</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.***

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.

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<sup>47</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).

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<sup>47</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).

Or. en

### *Justification*

*The exclusion of category 1 NGT plants from the organic sector has no scientific basis. All farmers should have the freedom of choice to use NGT plants. As category 1 NGT plants are considered equivalent to conventional plants in other parts of the legislation, they should not be considered separately regarding organic farming. Currently certain private standards in the organic sector exclude seeds derived from conventional breeding methods based on transparent information from the breeding sector. It should therefore be left to the organic operators to decide which seeds to use.*

### **Amendment 110**

**Michaela Šojdrová, Daniel Buda, Dan-Ștefan Motreanu, Peter Jahr, Herbert Dorfmann, Asim Ademov, Christine Schneider, Anne Sander**

### **Proposal for a regulation**

#### **Recital 23**

*Text proposed by the Commission*

(23) Regulation (EU) 2018/848 of the European Parliament and the Council on

*Amendment*

(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>(47)</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.***

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<sup>47</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).

organic production and labelling of organic products and repealing Council Regulation (EC) 834/2007<sup>(47)</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, ***apart from*** category 1 NGT plants.

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<sup>47</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).

Or. en

## **Amendment 111**

**Jérémy Decerle, Elsi Katainen**

### **Proposal for a regulation**

#### **Recital 23**

#### *Text proposed by the Commission*

(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>(47)</sup> ) prohibits the use of GMOs and products from and by GMOs in

#### *Amendment*

(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>(47)</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.***

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<sup>47</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).

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. The use of category 1 NGT plants should ***be clarified in Regulation (EU) 2018/848.***

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<sup>47</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).

Or. en

## **Amendment 112**

**Asger Christensen**

on behalf of the Renew Group

**Emma Wiesner, Jan Huitema, Erik Poulsen**

### **Proposal for a regulation**

#### **Recital 23**

*Text proposed by the Commission*

(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>(47)</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

*Amendment*

(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>(47)</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.

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 techniques *used in* category 1 NGT plants *are by their definition comparable with conventional breeding techniques and* should therefore be *accessible for* organic production.

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<sup>47</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).

Or. en

#### *Justification*

*Organic agriculture should not be prohibited access to 1 NGT plants. Any limitations should instead be decided in Regulation (EU) 2018/848 on organic farming. Organic farming face the same challenges as conventional when it comes to climate change and more extreme weather conditions. The organics sector also benefits from the technological advancements made in the development of seeds made in conventional agriculture which will inevitably use NGTs to develop new seeds, excluding the organics sector will limit their opportunities and access to R&D made in conventional farming.*

#### **Amendment 113**

**Benoît Biteau**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Recital 23**

*Text proposed by the Commission*

(23) Regulation (EU) 2018/848 of the

*Amendment*

(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>(47)</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.

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<sup>47</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).

European Parliament and the Council on organic production and labelling of organic products and repealing Council Regulation (EC) 834/2007<sup>(47)</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. It is necessary to clarify the status of 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 NGT plants should therefore be also prohibited in organic production.

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<sup>47</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).

Or. en

#### *Justification*

*All NGTs should be clearly banned in organic production, as repeatedly and clearly requested by the organic sector these last 15 years.*

#### **Amendment 114**

**Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero**

#### **Proposal for a regulation**

#### **Recital 24**

*Text proposed by the Commission*

*Amendment*

(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.***

(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.

Or. en

**Amendment 115**  
**Daniel Buda, Dan-Ştefan Motreanu**

**Proposal for a regulation**  
**Recital 24**

*Text proposed by the Commission*

(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.***

*Amendment*

(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.

Or. en

### *Justification*

*Category 1 NGT plants are considered equivalent to conventional plants and this extra requirement is discriminatory, creating unjustified distinctions and administrative burden. Transparency can be ensured by making the database public. Furthermore, creating labelling requirements for a third category of plant reproductive material, between conventional and GMOs, would have a negative impact on trade.*

#### **Amendment 116**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

#### **Proposal for a regulation**

##### **Recital 24**

###### *Text proposed by the Commission*

(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.***

###### *Amendment*

(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 indicated by a mention in the national and EU variety registers.***

Or. en

### *Justification*

*Information related to the use of NGTs in breeding Category 1 NGT plants is already foreseen in the Common Catalogue and a public registry. Physically labelling the seed bags does not provide any additional value to farmers or consumers, and results in additional costs and administrative burden.*

#### **Amendment 117**

**Theresa Bielowski, Maria Noichl**

#### **Proposal for a regulation**

## Recital 24

*Text proposed by the Commission*

(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.

*Amendment*

(24) Provision **should** be made to ensure transparency as regards the use of **all in EU approved** NGT plant varieties, to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard consumer trust. **All** NGT plant **varieties approved in the EU** should be listed in a publicly available database. To ensure traceability, transparency and choice for operators, **consumers and farmers, all NGT verified and authorised in the EU** should be labelled **according to existing EU law, namely Directive 2001/18 and Regulation (EC) No 1830/2003**.

Or. en

*Justification*

*All plants that fall under the definition of Article 3 paragraph 7 are recognisable for consumers to have the possibility to take a free choice when buying food.*

## Amendment 118

**Asger Christensen**

on behalf of the Renew Group

**Emma Wiesner, Elsi Katainen, Ulrike Müller, Jan Huitema, Erik Poulsen**

## Proposal for a regulation

### Recital 24

*Text proposed by the Commission*

(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

*Amendment*

(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, **including**

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.***

***information on the technique(s) used to obtain the trait(s)***, to ensure traceability, transparency and choice for operators.

Or. en

#### *Justification*

*Listing the specific techniques is relevant because it gives particularly organic farmers (as well as conventional) the option to only use seeds which have been made with specific techniques, and to avoid other techniques that they do not see as compatible with their farming methods. It shall therefore be clear in the database which technique has been used.*

#### **Amendment 119** **Sandra Pereira**

#### **Proposal for a regulation** **Recital 24**

##### *Text proposed by the Commission*

(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.

##### *Amendment*

(24) Provision should be made to ensure transparency as regards the use of 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 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 NGT plants should be labelled as NGT.

Or. pt



**Amendment 120**  
**Veronika Vrecionová**

**Proposal for a regulation**  
**Recital 24**

*Text proposed by the Commission*

(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**.

*Amendment*

(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 indicated by a mention in the national and EU variety registers**.

Or. en

**Amendment 121**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 24**

*Text proposed by the Commission*

(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

*Amendment*

(24) Provision should be made to ensure transparency as regards the use of 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 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

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.

available to third parties in any other way, plant reproductive material of NGT plants should be labelled as NGT.

Or. en

#### **Amendment 122**

**Benoît Biteau**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

##### **Recital 24**

*Text proposed by the Commission*

(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.

*Amendment*

(24) Provision should be made to ensure transparency as regards the use of 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 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 NGT plants should be labelled as **GMO**.

Or. en

#### **Amendment 123**

**Sandra Pereira**

#### **Proposal for a regulation**

##### **Recital 24 a (new)**

*Text proposed by the Commission*

*Amendment*

***(24a) Labelling must be used on NGT plants, their progeny and derived products in order to guarantee transparency and traceability throughout the food production chain right up to the consumer.***

Or. pt

**Amendment 124**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

(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.***

*Amendment*

(25) 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.

Or. en

**Amendment 125**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

(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***

*Amendment*

(25) ***All*** NGT plants should remain subject to the requirements of the Union GMO legislation given that on the basis of current scientific and technical knowledge ***as well as possible expected and unexpected outcomes***, their risks need to

*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.*

be assessed. *The* rules laid down in Directive 2001/18/EC *should serve in order to assess risks that* NGT plants may pose.

Or. en

**Amendment 126**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

(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.

*Amendment*

(25) 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 NGT plants and the differing levels of risk that they may pose.

Or. pt

**Amendment 127**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

(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.

*Amendment*

(25) 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

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.

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 NGT plants and the differing levels of risk that they may pose.

Or. en

**Amendment 128**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 25 a (new)**

*Text proposed by the Commission*

*Amendment*

***(25a) The Member States cannot be restricted or prevented from establishing themselves as countries free from GMO and NGT varieties.***

Or. pt

**Amendment 129**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 25 b (new)**

*Text proposed by the Commission*

*Amendment*

***(25b) The release of GMOs or organisms obtained by way of NGTs into the environment is irreversible/uncontrollable, has incalculable effects on ecosystems and biodiversity and poses a serious risk of polluting organic/conventional crops, thus making it impossible for those farmers to have freedom of choice.***

Or. pt

## Amendment 130

**Benoît Biteau**

on behalf of the Verts/ALE Group

### Proposal for a regulation

#### Recital 26

*Text proposed by the Commission*

(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>48</sup> and on plants developed through targeted mutagenesis<sup>49</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>50</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 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.***

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<sup>48</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

*Amendment*

(26) 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.

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>49</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>50</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>.

Or. en

**Amendment 131**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 26**

(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>48</sup> and on plants developed through targeted mutagenesis<sup>49</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>50</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 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.

(26) 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. 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.

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<sup>48</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>49</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>50</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>.*

Or. pt

**Amendment 132**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 26**

*Text proposed by the Commission*

(26) **Category 2** NGT plants and products, in order to be released into the environment or placed on the market,

*Amendment*

(26) **All** NGT plants and products, in order to be released into the environment or placed on the market, should remain

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>48</sup> *and on plants developed through targeted mutagenesis*<sup>49</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>(50)</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 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.

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 in data requirements for the risk assessment of these plants should *increase respectively*.

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<sup>48</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>49</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>50</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>.

Or. en

### **Amendment 133** **Maria Noichl**

#### **Proposal for a regulation** **Recital 27**

##### *Text proposed by the Commission*

(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.

##### *Amendment*

(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.*

To ensure consistency *these pieces of legislation* should *apply to NGT plants as well.*

Or. en

#### **Amendment 134**

**Sandra Pereira**

#### **Proposal for a regulation**

##### **Recital 27**

*Text proposed by the Commission*

(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.*

*Amendment*

(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 NGT products, the content of such notifications and applications should be the same

Or. pt

#### **Amendment 135**

**Benoît Biteau**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

##### **Recital 27**

*Text proposed by the Commission*

*Amendment*

(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.

(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 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 NGT food and feed.

Or. en

**Amendment 136**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 28**

*Text proposed by the Commission*

*Amendment*

***(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 <sup>(51)</sup>. 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***

***deleted***

*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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<sup>51</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)*

Or. en

#### *Justification*

*Several studies have outlined the conditions under which analytical testing could be feasible for all products obtained by targeted mutagenesis and cisgenesis. See notably Yves Bertheau (2019), *New Breeding Techniques: Detection and Identification of the Techniques and Derived Products*, and Ribarits, A. et al. (2021): *Genome-Edited Plants: Opportunities and Challenges for an Anticipatory Detection and Identification Framework*.*

#### **Amendment 137**

**Maria Noichl**

#### **Proposal for a regulation**

#### **Recital 28**

*Text proposed by the Commission*

(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 (<sup>51</sup>). 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*

*Amendment*

(28) *In order to ensure the necessary traceability and to at least enable retrievability, specific verification procedures are a basic requirement. As the DNA changes are known when the product is known, it is not a problem for the applicants to submit detection methods as well as reference and control material. If the distributors do not submit modalities to fulfil the requirements for the analytical method, authorisation shall*

***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.***

***be refused. In addition, financial support for investments in the development of general detection methods in order to be able to detect NGTs in imports, should be provided on EU level.***

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<sup>51</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)

Or. en

**Amendment 138  
Sandra Pereira**

**Proposal for a regulation  
Recital 29**

*Text proposed by the Commission*

*Amendment*

***(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,***

***deleted***

*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.*

Or. pt

#### Amendment 139

Maria Noichl

#### Proposal for a regulation

##### Recital 29

*Text proposed by the Commission*

(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***

*Amendment*

(29) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market, ***which should be valid for all*** NGT plants.



*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.*

Or. en

#### **Amendment 140**

**Benoît Biteau**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

##### **Recital 29**

*Text proposed by the Commission*

(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***

*Amendment*

(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.

***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.***

Or. en

*Justification*

*NGT plants will cover a far wider range of species than transgenic plants do. This will multiply the risks of unintended impacts on the ecosystems, notably through crossing with wild plants. It is therefore necessary to maintain a monitoring, as currently outlined in the GMO legislation.*

**Amendment 141  
Daniela Rondinelli**

**Proposal for a regulation  
Recital 29 a (new)**

*Text proposed by the Commission*

*Amendment*

***(29a) After the successful authorisation of a category 1 NGT plant based on scientific criteria, the authorisation should be valid for an unlimited period.***

Or. it

**Amendment 142  
Herbert Dorfmann**

**Proposal for a regulation  
Recital 29 a (new)**

*Text proposed by the Commission*

*Amendment*

***(29a) After the successful authorisation of a category 1 NGT plant based on scientific criteria, the authorisation should be valid for an unlimited period.***

Or. it

**Amendment 143**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 30**

*Text proposed by the Commission*

*Amendment*

**(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.**

*deleted*

Or. pt

**Amendment 144**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Recital 30**

*Text proposed by the Commission*

*Amendment*

**(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.**

*deleted*

Or. en

*Justification*

*It is not in line with the Precautionary principle, or with plain good sense, to deliver authorizations forever for products which can reproduce and interact with wild plants and the ecosystems. It is all the more problematic as the proposal does not contain any safeguard*

*clause that would allow the Commission to withdraw an authorization in case a problem is detected.*

#### **Amendment 145**

**Peter Jahr, Lena Düpont, Christine Schneider, Marlene Mortler**

#### **Proposal for a regulation**

##### **Recital 30**

*Text proposed by the Commission*

(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.*

*Amendment*

(30) After *successful* authorisation *of a NGT-plant based on scientific criteria*, the authorisation should be valid for an unlimited period.

Or. en

#### **Amendment 146**

**Herbert Dorfmann**

#### **Proposal for a regulation**

##### **Recital 30**

*Text proposed by the Commission*

(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.

*Amendment*

(30) For reasons of proportionality, after a first renewal of the authorisation *of a category 2 NGT plant*, 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.

Or. it

**Amendment 147**  
**Daniela Rondinelli**

**Proposal for a regulation**  
**Recital 30**

*Text proposed by the Commission*

(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.

*Amendment*

(30) For reasons of proportionality, after a first renewal of the authorisation *of a category 2 NGT plant*, 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.

Or. it

**Amendment 148**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Recital 32**

*Text proposed by the Commission*

*(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.*

*Amendment*

*deleted*

Or. en

**Amendment 149**

Maria Noichl

**Proposal for a regulation**

**Recital 32**

*Text proposed by the Commission*

(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.***

*Amendment*

(32) To increase transparency and consumers' information, ***there needs to be clear labelling of all NGTs in accordance with Directive 2001/18 up to the end product.***

Or. en

**Amendment 150**

Theresa Bielowski, Maria Noichl

**Proposal for a regulation**

**Recital 32**

*Text proposed by the Commission*

(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.***

*Amendment*

(32) To increase transparency and consumers' information, operators ***should label all NGT products which comply with the requirements laid down in existing EU law, namely Directive 2001/18 and Regulation (EC) No 1830/2003.***

Or. en

*Justification*

*In order to enable freedom of choice for consumers along the entire value chain, all food and*

*feed produced using new genetic engineering methods has to be labelled as genetically modified products to enable consumers and all users along the value chain to make an informed choice. Consumer's right to information is enshrined in EU food law (EU (VO) 178/2002) and the EU Treaties (Article 169).*

## **Amendment 151**

**Colm Markey**

### **Proposal for a regulation**

#### **Recital 32**

*Text proposed by the Commission*

(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.

*Amendment*

(32) To increase transparency and consumers' information, operators should be allowed to complement the labelling of category 2 NGT products with information on the trait conferred. 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.

Or. en

*Justification*

*NGTs should not be labelled as GMOs, but as NGTs.*

## **Amendment 152**

**Sandra Pereira**

### **Proposal for a regulation**

#### **Recital 32**

*Text proposed by the Commission*

(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

*Amendment*

(32) To increase transparency and consumers' information, operators should be allowed to complement the labelling of 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

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.

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.

Or. pt

**Amendment 153**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 33**

*Text proposed by the Commission*

(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>52</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.***

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<sup>52</sup> COM(2023) 414 final

*Amendment*

(33) Regulatory incentives should be offered to potential notifiers or applicants for NGT plants and products containing traits with the potential to contribute to a sustainable agri-food system, in order to steer the development of 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>52</sup>].

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<sup>52</sup> COM(2023) 414 final

Or. pt



**Amendment 154**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 34**

*Text proposed by the Commission*

*Amendment*

**(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 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>(53)</sup>.**

*deleted*

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<sup>53</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).*

Or. en

**Amendment 155**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 34**

*Text proposed by the Commission*

*Amendment*

**(34) Incentives should consist in *an accelerated procedure for risk assessment as regards applications handled by a fully***

**(34) Incentives should consist in enhanced pre-submission advice to help developers prepare the dossier for the**

**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 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>(53)</sup>.

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>(53)</sup>.

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<sup>53</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).

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<sup>53</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).

Or. pt

## **Amendment 156**

**Anne Sander**

### **Proposal for a regulation**

#### **Recital 36**

*Text proposed by the Commission*

***(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***

*Amendment*

***deleted***

*[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].*

Or. fr

**Amendment 157**  
**Veronika Vrecionová**

**Proposal for a regulation**  
**Recital 36**

*Text proposed by the Commission*

*Amendment*

**(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].***

***deleted***

Or. en

**Amendment 158**  
**Herbert Dorfmann**

**Proposal for a regulation**  
**Recital 36**

**(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].***

***deleted***

Or. en

**Amendment 159**

**Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero**

**Proposal for a regulation**

**Recital 36**

*Text proposed by the Commission*

*Amendment*

**(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***

**(36) 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].**

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].

Or. en

**Amendment 160**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 37**

*Text proposed by the Commission*

*Amendment*

**(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.**

**deleted**

Or. pt

**Amendment 161**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 37**

*Text proposed by the Commission*

*Amendment*

**(37) In order to enable NGT plants to contribute to the sustainability objectives**

**(37) In order to ensure the sovereignty of the Member States and regions, the**

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*.

possibility for Member States to adopt measures restricting or prohibiting the cultivation of NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC *needs to be kept*.

Or. en

#### **Amendment 162**

**Anna Zalewska, Krzysztof Jurgiel**

#### **Proposal for a regulation**

##### **Recital 37**

*Text proposed by the Commission*

(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*.

*Amendment*

(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. *However, the Regulation should respect the right of* Member States to *apply* measures restricting or prohibiting the cultivation of category 2 NGT plants in all or part of their territory, *in accordance with* Article 26b of Directive 2001/18/EC.

Or. pl

#### **Amendment 163**

**Benoît Biteau**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

## Recital 37

*Text proposed by the Commission*

(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**.

*Amendment*

(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 **regulated under existing EU law, in particular Directive 2001/18 and Regulation (EC) No 1830/2003**. 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 NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC **should remain**.

Or. en

*Justification*

*The so-called opt-out clause (article 26b of Directive 2001/18/EC) was adopted to allow Member states to adapt the cultivation of specific GM plants to their local conditions, notably: specific environmental challenges, % of organic farmers on the territory, specific economic interests, etc... This clause was widely used by Member states and will also be useful for NGTs. Member states should be able to decide for each NGTs if the potential benefits outweigh the social and economic risks.*

## Amendment 164

**Theresa Bielowski, Maria Noichl**

### Proposal for a regulation

#### Recital 37

*Text proposed by the Commission*

(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

*Amendment*

(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 **regulated under existing EU law, in Directive 2001/18 and Regulation (EC)**

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**.

**No 1830/2003**. 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 NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC **should remain**.

Or. en

### *Justification*

*The Commission's plan to ease market access for genetically modified plants also undermines its own Farm to Fork Strategy, which seeks to reduce pesticide use by 50 percent by 2030 and reverse biodiversity loss in the EU. The cultivation of genetically modified plants that are resistant to pesticides is rising worldwide. To date, the commercial distribution of plants is dominated by pesticide-resistant plants together with the large amounts of pesticides designed for them. The proportion of genetically modified plants with tolerance to herbicides was already 43 % in 2020.*

## **Amendment 165**

**Veronika Vrecionová**

### **Proposal for a regulation**

#### **Recital 37**

#### *Text proposed by the Commission*

(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.

#### *Amendment*

(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 **both categories of** NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals.

Or. en



## **Amendment 166**

**Anne Sander**

### **Proposal for a regulation**

#### **Recital 37**

*Text proposed by the Commission*

(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.

*Amendment*

(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 NGT plants **in the two categories** in all or part of their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals.

Or. fr

## **Amendment 167**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

### **Proposal for a regulation**

#### **Recital 37**

*Text proposed by the Commission*

(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

*Amendment*

(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 NGT plants in all or part of their territory,

their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals.

set out in Article 26b of Directive 2001/18/EC would undermine those goals.

Or. en

### *Justification*

### *Clarification*

#### **Amendment 168**

**Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos Ros Sempere**

#### **Proposal for a regulation Recital 38**

##### *Text proposed by the Commission*

(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.

##### *Amendment*

(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 **for category 2NGT plants** 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.

Or. en

#### **Amendment 169**

**Theresa Bielowski, Maria Noichl**

#### **Proposal for a regulation Recital 39**

##### *Text proposed by the Commission*

##### *Amendment*

**(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.**

*deleted*

Or. en

*Justification*

*Article 26b of Directive 2001/18 allows the total or partial exclusion of the cultivation of genetic engineering on the territory of the respective member state. In the sense of subsidiarity of the member states, this possibility is also to be maintained extensively for NGT plants.*

**Amendment 170**  
**Veronika Vrecionová**

**Proposal for a regulation**  
**Recital 39**

*Text proposed by the Commission*

(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.

*Amendment*

(39) To achieve the goal of ensuring the effective functioning of the internal market ***and*** the free movement of ***NGT plant products across the EU, the deliberate release of NGT plants and placing on the market of NGT products should be based on the harmonized requirements and procedures laid down in this Regulation, leading to the adoption of a decision uniformly applicable to all Member States. Member States should not unilaterally derogate from the provisions set out in this Regulation in a way that would restrict, prohibit or hinder the free movement, placing on the market and deliberate release of NGT plants or related products within the territory of the*** Union.

Or. en

**Amendment 171**

**Proposal for a regulation**

**Recital 39**

*Text proposed by the Commission*

(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.

*Amendment*

(39) To achieve the goal of ensuring the effective functioning of the internal market ***and the free movement of NGT plant products across the EU, the deliberate release of NGT plants and placing on the market of NGT products should be based on the harmonized requirements and procedures laid down in this Regulation, leading to the adoption of a decision uniformly applicable to all Member States. Member States shall not unilaterally derogate from the provisions set out in this Regulation in a way that would restrict, prohibit or hinder the free movement, placing on the market and deliberate release of NGT plants or related products within the territory of the*** Union.

Or. en

**Amendment 172**

**Daniel Buda, Dan-Ştefan Motreanu**

**Proposal for a regulation**

**Recital 39**

*Text proposed by the Commission*

(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.

*Amendment*

(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. ***Member States should adhere to this.***

Or. en

## Amendment 173

Maria Noichl

### Proposal for a regulation

#### Recital 39

*Text proposed by the Commission*

(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.***

*Amendment*

(39) To achieve the goal of ensuring the effective functioning of the internal market, ***the EU-wide rules for the regulation of*** NGT plants and related products should ***be maintained.*** ***Accordingly, EU-wide strict coexistence rules should be introduced across the EU.***

Or. en

## Amendment 174

Theresa Bielowski, Maria Noichl

### Proposal for a regulation

#### Recital 39 a (new)

*Text proposed by the Commission*

*Amendment*

***(39 a) To achieve the goal of ensuring the effective functioning of the internal market, EU-wide legally binding coexistence measures for category 1 and category 2 NGTs have to be adopted.***

Or. en

*Justification*

*For the internal market for organic farming to continue to function well also in the future, it is not enough to leave coexistence measures at national level. EU-wide regulations are needed. Therefore the Commission should offer such rules*

## Amendment 175

Ulrike Müller, Elsi Katainen

### Proposal for a regulation

#### Recital 40

(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 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.

(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, ***including the role and impact of patents on breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, as well as on innovation and particularly on the opportunities for SME. While a balance must be struck to ensure that patents do not unduly hinder the opportunities of SME in the market for NGT plants and products, it must be noted that patents play an important role for SME to facilitate access to finance, particularly in biotechnology.*** 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 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. ***With regard to the impacts of patents, the Commission should present a first assessment by 2026 in order to ensure that where necessary, changes to the framework for intellectual property rights can be discussed in due time before a significant number of NGT plants can be expected to be placed on the market. The assessment should include an analysis of the functioning of licensing platforms.***

Or. en

**Amendment 176**  
**Theresa Bielowski, Maria Noichl**

**Proposal for a regulation**  
**Recital 40**

*Text proposed by the Commission*

(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 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.

*Amendment*

(40) ***In its judgment of 25 July 2018, in case C-528/1610 the Court of Justice of the European Union held that organisms obtained by means of techniques/methods of mutagenesis which have not conventionally been used in a number of applications and do not have a long safety record come within the scope of Directive 2001/18 and are, therefore, subject to the obligations arising from that directive.*** 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 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.

Or. en

*Justification*

*Article 114 § 3 TFEU states that the Commission will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Already, many problems have been documented for NGTs. For example, CRISPR applications have turned out to cause toxicity and mosaicism, whereas the impact and adverse effects on non-target and unintentionally exposed organisms are yet unknown. Such knowledge is only generated when risk assessments are required and in place, and both the impact and the uncertainties are estimated and acknowledged.*

**Amendment 177**  
**Daniela Rondinelli**

**Proposal for a regulation**  
**Recital 40**

*Text proposed by the Commission*

(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 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.

*Amendment*

(40) Given the novelty of the NGTs, it will be important to monitor closely the development and presence on the market of **category 2** 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 deliberate release or the marketing of **category 2** NGT plants or **category 2** NGT products in the Union, the Commission should carry out an evaluation of this Regulation to measure the progress made towards the availability of **category 2** NGT plants containing such characteristics or properties on the EU market.

Or. it

**Amendment 178**  
**Daniel Buda, Dan-Ştefan Motreanu**

**Proposal for a regulation**  
**Recital 40**

*Text proposed by the Commission*

(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 deliberate release or the marketing of NGT plants or NGT products

*Amendment*

(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 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.

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 ***with the aim of further improving the Regulation.***

Or. en

**Amendment 179**  
**Anne Sander**

**Proposal for a regulation**  
**Recital 40 a (new)**

*Text proposed by the Commission*

*Amendment*

***(40a) In order to encourage scientific research on NGTs, in particular by small and medium-sized enterprises, universities and research institutes, and to ensure effective access for farmers to varietal innovations, the Commission should undertake to carry out a study by 2025 on the impact of patents on the NGT market and on innovation in breeding, and to present any appropriate legislative proposals.***

Or. fr

**Amendment 180**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 42**

*Text proposed by the Commission*

*Amendment*

***(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***

***deleted***

*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.*

Or. pt

**Amendment 181**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 42**

*Text proposed by the Commission*

*Amendment*

*(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.*

*deleted*

Or. en

**Amendment 182**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 43**

*Text proposed by the Commission*

*Amendment*

**(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.*** *deleted*

Or. pt

**Amendment 183**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 43**

*Text proposed by the Commission*

*Amendment*

**(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.*** *deleted*

Or. en

**Amendment 184**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 44**

*Text proposed by the Commission*

*Amendment*

**(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>(54)</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.**

*deleted*

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<sup>54</sup> OJ L 123, 12.5.2016, p. 1

Or. en

**Amendment 185**  
**Sandra Pereira**

**Proposal for a regulation**  
**Recital 45**

*Text proposed by the Commission*

*Amendment*

**(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**

*deleted*

*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>(55)</sup>.*

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<sup>55</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).*

Or. pt

**Amendment 186**  
**Maria Noichl**

**Proposal for a regulation**  
**Recital 45**

*Text proposed by the Commission*

*Amendment*

*(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>(55)</sup>.*

*deleted*

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*<sup>55</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).*

Or. en

#### **Amendment 187**

**Benoît Biteau**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

##### **Recital 45**

*Text proposed by the Commission*

*Amendment*

*(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>(55)</sup>.*

*deleted*

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*<sup>55</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).*

Or. en

**Amendment 188**  
**Bert-Jan Ruissen**

**Proposal for a regulation**  
**Recital 45 a (new)**

*Text proposed by the Commission*

*Amendment*

***(45 a) The issue of patents on NGTs was raised by many stakeholders during the consultation. It should be ensured that breeders have full access to the genetic material of NGT plants. As current provisions do not provide for a full breeders exemption in patent law, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (Breeder's exemption). It should furthermore be avoided that patents are being granted or patent applications can be submitted while further legal provisions on the issue would be postponed following the study that the Commission intends to do. It should therefore be ensured that NGT plant material is excluded from patentability from the day of entry into force of this Regulation. In addition, the Commission in the announced forthcoming study should assess how the broader problem of patents being granted, directly or indirectly, on plant material despite previous efforts to close loopholes, should be further addressed.***

Or. en

**Amendment 189**

Daniel Buda, Dan-Ştefan Motreanu

**Proposal for a regulation**  
**Recital 46 a (new)**

*Text proposed by the Commission*

*Amendment*

***(46 a) Member States should organise factual public information campaigns regarding the safety and the benefits of plants obtained thorough new genomic techniques, with a particular emphasis on category 1 NGT plants. Member States should aim to dispel myths and misconceptions about new genomic techniques as well as to counteract disinformation and misinformation on this subject via these public information campaigns or by other means. The European Commission should provide assistance and guidelines to Member States in this respect, upon request.***

Or. en

**Amendment 190**  
**Ivan David**

**Proposal for a regulation**  
**Recital 48 a (new)**

*Text proposed by the Commission*

*Amendment*

***(48 a) NGT category 1 plants, as well as plants and varieties that may arise and occur naturally or may arise through conventional breeding or are considered to be conventional plants, should not be the subject of a patent but of a plant variety right that allows the use of the so-called breeder's exemption, thereby supporting innovation and creation of new varieties. It should still be possible to use the so-called farmer's exemption for these plants. Protection of the intellectual property of the breeders of these plants should continue to be governed by COUNCIL DECISION of 30 May 2005***



*approving the accession of the European Community to the International Convention for the Protection of New Varieties of Plants, as revised in Geneva on 19 March 1991, and Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, as amended.*

Or. cs

**Amendment 191**  
**Theresa Bielowski, Maria Noichl**

**Proposal for a regulation**  
**Article 1 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

*This Regulation corresponds to the provisions of Directive 2001/18 and extends these provisions to the deliberate release of plants obtained by certain new genomic techniques (hereinafter "NGT plants"). In accordance with the precautionary principle, and with the primary objective of ensuring a high level of protection of human and animal health and the environment, 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.*

Or. en

*Justification*

*Article 114 § 3 TFEU states that the Commission will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Already, many problems have been documented for NGTs. For example, CRISPR applications have turned out to cause toxicity and mosaicism, whereas the impact and adverse effects on*

*non-target and unintentionally exposed organisms are yet unknown. Such knowledge is only generated when risk assessments are required and in place, and both the impact and the uncertainties are estimated and acknowledged.*

## **Amendment 192**

**Maria Noichl**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

This Regulation ***contains derogations from the provisions of Directive 2001/18*** for the deliberate release of plants obtained by certain new genomic techniques (***hereinafter "NGT plants"***) ***into the environment for purposes other than*** 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. ***The derogations apply insofar as at least equivalent requirements to those laid down in Directive 2001/18 in accordance with the precautionary principle for the protection of human and animal health and the environment are fulfilled.***

Or. en

## **Amendment 193**

**Sandra Pereira**

### **Proposal for a regulation**

#### **Article 2.º – paragraph 1 – point 1**

*Text proposed by the Commission*

(1) NGT plants;

*Amendment*

(1) NGT ***agricultural*** plants;

Or. pt

**Amendment 194**

**Sandra Pereira**

**Proposal for a regulation**

**Article 2.º – paragraph 1 – point 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**(4a) Wild plants, trees and algae fall outside the scope of this Regulation.**

Or. pt

**Amendment 195**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 2 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***This regulation shall not apply to:***

***(1) patented material or material for which a patent application is being processed;***

***(2) herbicide-tolerant plants;***

***(3) wild plants, trees and algae.***

Or. en

*Justification*

*Patentability of plants is not linked to the GMO legislation, but to the European Patent Convention, and secondarily, to Directive 98/44/EC (so-called Biotech directive), which is not modified by this proposal. Therefore, most or all NGT plants will be patentable if their promoters choose to apply for a patent. Patented material should be subject to the most thorough rules available concerning traceability and labelling, in order to allow farmers, breeders and consumers to make informed choices in full knowledge of the rules and liability linked to this form of Intellectual Property.*

**Amendment 196**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 2**

*Text proposed by the Commission*

(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;

*Amendment*

(2) ‘NGT plant’ means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the **conditions that:**

**(i)** 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 **and;**

**(ii) there are no patents or exclusive rights covering the process used to develop the plant,**

**and there are no patents or exclusive rights covering the plant or parts thereof,**

**and no application has been tabled for such patents or exclusive rights to be granted;**

Or. en

*Justification*

*Patentability of plants is not linked to the GMO legislation, but to the European Patent Convention, and secondarily, to Directive 98/44/EC (so-called Biotech directive), which is not modified by this proposal. Therefore, most or all NGT plants will be patentable if their promoters choose to apply for a patent. Patented material should be subject to the most thorough rules available concerning traceability and labelling, in order to allow farmers, breeders and consumers to make informed choices in full knowledge of the rules and liability linked to this form of Intellectual Property.*

**Amendment 197**  
**Sandra Pereira**

**Proposal for a regulation**  
**Article 3.º – paragraph 1 – point 2**

*Text proposed by the Commission*

*Amendment*

(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;

(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 ***or prepared outside cells*** that temporarily may have been inserted during the development of the NGT plant, ***and there is no type of intellectual property associated with the plant, its properties or the technique used to create it;***

Or. pt

**Amendment 198**

**Veronika Vrecionová**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 2**

*Text proposed by the Commission*

*Amendment*

(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;

(2) ‘NGT plant’ means a plant ***as set out in Regulation (EU) 2016/2031 of the European Parliament and of the Council(?)***, 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;

Or. en

*Justification*

*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).*

## Amendment 199

Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 2

*Text proposed by the Commission*

(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;

*Amendment*

(2) ‘NGT plant’ means a 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;

Or. en

## Amendment 200

Michaela Šojdrová, Daniel Buda, Dan-Ștefan Motreanu, Peter Jahr, Herbert Dorfmann, Asim Ademov, Christine Schneider, Anne Sander

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 2

*Text proposed by the Commission*

(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;

*Amendment*

(2) ‘NGT plant’ means a 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;

Or. en

## Amendment 201

Colm Markey

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 2

*Text proposed by the Commission*

(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;

*Amendment*

(2) ‘NGT plant’ means a 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;

Or. en

*Justification*

*NGTs should not be defined as GMOs.*

**Amendment 202**

**Anja Hazekamp**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 2**

*Text proposed by the Commission*

(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;

*Amendment*

(2) ‘NGT plant’ means a genetically modified plant obtained by targeted mutagenesis, on the condition that it does not contain any genetic material **prepared** outside the **cell, and there is no intellectual property right of any kind attached to** the plant, **its properties or the technique used to create it**;

Or. en

**Amendment 203**

**Tom Vandenkendelaere**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 2**

*Text proposed by the Commission*

*Amendment*

(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;

(2) ‘NGT plant’ means a 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;

Or. en

#### **Amendment 204**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 2**

##### *Text proposed by the Commission*

(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;

##### *Amendment*

(2) ‘NGT plant’ means a 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;

Or. en

##### *Justification*

##### *Clarification*

#### **Amendment 205**

**Tom Vandenkendelaere**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 4**

##### *Text proposed by the Commission*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in

##### *Amendment*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in



modification(s) of the DNA sequence at **precise** locations in the genome of an organism;

modification(s) of the DNA sequence at **predetermined** locations in the genome of an organism;

Or. en

#### **Amendment 206**

**Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos Ros Sempere**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 4**

##### *Text proposed by the Commission*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **precise** locations in the genome of an organism;

##### *Amendment*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **targeted** locations in the genome of an organism;

Or. en

#### **Amendment 207**

**Annie Schreijer-Pierik**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 4**

##### *Text proposed by the Commission*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **precise** locations in the genome of an organism;

##### *Amendment*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **targeted** locations in the genome of an organism;

Or. en

#### **Amendment 208**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 4**

*Text proposed by the Commission*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **precise** locations in the genome of an organism;

*Amendment*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **targeted** locations in the genome of an organism;

Or. en

*Justification*

*Clarity and coherence*

**Amendment 209**  
**Veronika Vrecionová**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 4**

*Text proposed by the Commission*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **precise** locations in the genome of an organism;

*Amendment*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **targeted** locations in the genome of an organism;

Or. en

*Justification*

*Clarification to the EC text*

**Amendment 210**  
**Bert-Jan Ruissen**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 4**

*Text proposed by the Commission*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **precise** locations in the genome of an

*Amendment*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at **targeted** locations in the genome of an

organism;

organism;

Or. en

**Amendment 211**  
**Herbert Dorfmann**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 4**

*Text proposed by the Commission*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at ***precise*** locations in the genome of an organism;

*Amendment*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at ***targeted*** locations in the genome of an organism;

Or. it

**Amendment 212**  
**Daniela Rondinelli**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 4**

*Text proposed by the Commission*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at ***precise*** locations in the genome of an organism;

*Amendment*

(4) ‘targeted mutagenesis’ means mutagenesis techniques resulting in modification(s) of the DNA sequence at ***targeted*** locations in the genome of an organism;

Or. it

**Amendment 213**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 5**

*Text proposed by the Commission*

*Amendment*

(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;*

*deleted*

Or. en

#### **Amendment 214**

**Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 5**

*Text proposed by the Commission*

(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;*

*Amendment*

(5) *'cisgenesis' means a genetic modification involving genetic material obtained from the breeders' gene pool and transferred to the host using various delivery strategies; the incorporated sequences contain an exact copy of a sequence already present in the breeders' gene pool;*

Or. en

#### **Amendment 215**

**Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 5 a (new)**

*Text proposed by the Commission*

*(5 a) 'Intragenesis': a genetic modification involving genetic material obtained from the breeders' gene pool and transferred to the host using various delivery strategies; the incorporated sequences contain a re-arranged copy of a sequence already present in the breeders' gene pool (adopted from EFSA GMO Panel, 2022).*

*Amendment*

Or. en

**Amendment 216**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 6**

*Text proposed by the Commission*

*Amendment*

(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;**

*deleted*

Or. en

**Amendment 217**  
**Anne Sander**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 6**

*Text proposed by the Commission*

*Amendment*

(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;**

(6) **‘gene pool *for reproductive purposes*’ 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;**

Or. fr

**Amendment 218**  
**Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 6**

*Text proposed by the Commission*

*Amendment*

(6) **‘breeders’ gene pool’ means the**

(6) **‘gene pool *for breeding purposes*’**

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;

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;

Or. en

**Amendment 219**  
**Veronika Vrecionová**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 6**

*Text proposed by the Commission*

(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;

*Amendment*

(6) ‘gene pool *for breeding purposes*’ 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;

Or. en

**Amendment 220**  
**Juozas Olekas, Carmen Avram, Paolo De Castro**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 6**

*Text proposed by the Commission*

(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;

*Amendment*

(6) ‘gene pool *for breeding purposes*’ 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;

Or. en

*Justification*

*As the PVR/UPOV system must be preserved, the proliferation of a variety, growing, harvesting and further breeding of the variety should be free of charge, which stimulates maximum innovation and development for the benefit of society, farmers and breeders*

**Amendment 221**  
**Herbert Dorfmann**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 6 – point a (new)**

*Text proposed by the Commission*

*Amendment*

**(a) 'Polyploidy' means the presence of more than two genomes in a single cell;**

Or. it

**Amendment 222**  
**Daniela Rondinelli**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**(6a) 'Polyploidy' means the presence of more than two genomes in a single cell;**

Or. it

**Amendment 223**  
**Sandra Pereira**

**Proposal for a regulation**  
**Article 3.º – paragraph 1 – point 7**

*Text proposed by the Commission*

*Amendment*

**(7) 'category 1 NGT plant' means a NGT plant that:** *deleted*

**(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;*

Or. pt

**Amendment 224**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 7**

*Text proposed by the Commission*

*Amendment*

**(7) ‘category 1 NGT plant’ means a NGT plant that:** **deleted**

*(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;*

Or. en

**Amendment 225**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 7**

*Text proposed by the Commission*

*Amendment*

**(7) ‘category 1 NGT plant’ means a NGT plant that:** **deleted**

*(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;*

Or. en

*Justification*

*NGT plants, by definition, could not occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why we propose to delete the specific rules dedicated to category 1 NGTs.*

**Amendment 226**

**Juozas Olekas, Paolo De Castro**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 7 – point b**

*Text proposed by the Commission*

*(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;***

*Amendment*

*(b) is progeny of the NGT plant(s)  
referred to in point (a), including progeny  
derived by crossing of such plants, **or  
progeny that has undergone** further  
modifications **and fulfils the criteria of  
equivalence to conventional plants, set out  
in Annex I;***

Or. en

*Justification*

*Breeders constantly improve on commercial varieties, in order to reach incremental productivity gains over time. This is not future-proof and will greatly limit the range of what could be achieved when combining complex traits, like drought tolerance with disease*

resistance.

#### **Amendment 227**

**Benoît Biteau**

on behalf of the Verts/ALE Group

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 7 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(b a) is not covered by patents or exclusive rights and for which no application has been tabled for such patents or exclusive rights to be granted;***

Or. en

#### *Justification*

*Patentability of plants is not linked to the GMO legislation, but to the European Patent Convention, and secondarily, to Directive 98/44/EC (so-called Biotech directive), which is not modified by this proposal. Therefore, most or all NGT plants will be patentable if their promoters choose to apply for a patent. Patented material should be subject to the most thorough rules available concerning traceability and labelling, in order to allow farmers, breeders and consumers to make informed choices in full knowledge of the rules and liability linked to this form of Intellectual Property.*

#### **Amendment 228**

**Annie Schreijer-Pierik**

#### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 7 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(b a) for which it is not feasible to provide an analytical method that detects, identifies and quantifies.***

Or. en

#### *Justification*

*The proposal suggests that for certain Category 2 NGT plants no, or only an adapted, identification method can be developed. However, as they are regulated GMOs, these plants will not be fully identifiable or distinguishable from conventional plants, which makes it a*

*specific challenge for imports where it is not possible to identify unauthorised NGTs with Category 2 changes. It is therefore discriminatory to require GM traceability and labelling of such products. Consequently, such Category 2 NGT plants should logically be treated as Category 1 NGT plants (conventional-like).*

#### **Amendment 229**

**Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos Ros Sempere**

#### **Proposal for a regulation**

**Article 3 – paragraph 1 – point 7 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(b a) for which it is not feasible to provide an analytical method that detects, identifies and quantifies;***

Or. en

*Justification*

*Cat 2 plants for which no or only an adapted identification method can be developed –should logically be treated as Cat 1 NGT plants (conventional-like).*

#### **Amendment 230**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

#### **Proposal for a regulation**

**Article 3 – paragraph 1 – point 7 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(b a) for which it is not feasible to provide an analytical method that detects, identifies and quantifies.***

Or. en

*Justification*

*NGT plants for which no unique identification method can be developed, should be regulated as Category 1 NGT plants, as they will be indistinguishable from conventionally-bred plants.*

#### **Amendment 231**

**Veronika Vrecionová**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 7 a (new)**

*Text proposed by the Commission*

*Amendment*

**(7 a) This plant shall be subject to  
Community Plant Variety Rights (CPVR).**

Or. en

**Amendment 232**

**Veronika Vrecionová**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 7 b (new)**

*Text proposed by the Commission*

*Amendment*

**(7 b) for which it is not feasible to  
provide an analytical method that detects,  
identifies and quantifies.**

Or. en

**Amendment 233**

**Sandra Pereira**

**Proposal for a regulation**

**Article 3.<sup>o</sup> – paragraph 1 – point 8**

*Text proposed by the Commission*

*Amendment*

**(8) ‘category 2 NGT plant’ means a  
NGT plant other than a category 1 NGT  
plant;**

**deleted**

Or. pt

**Amendment 234**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 8**

*Text proposed by the Commission*

*Amendment*

**(8) ‘category 2 NGT plant’ means a NGT plant other than a category 1 NGT plant;**

*deleted*

Or. en

**Amendment 235**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 8**

*Text proposed by the Commission*

*Amendment*

**(8) ‘category 2 NGT plant’ means a NGT plant other than a category 1 NGT plant;**

*deleted*

Or. en

**Amendment 236**  
**Annie Schreijer-Pierik**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 12**

*Text proposed by the Commission*

*Amendment*

**(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;**

**(12) ‘NGT product’ means a food and feed *product* containing, consisting of *or produced from* a NGT plant and *other products* containing, consisting of or produced from such a plant;**

Or. en

**Amendment 237**  
**Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos Ros Sempere**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 12**

*Text proposed by the Commission*

(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***;

*Amendment*

(12) ‘NGT product’ means food and feed containing, consisting of or produced from ***NGT plants and other products containing or consisting of such plants***;

Or. en

*Justification*

*Clarification of the proposal text.*

**Amendment 238**  
**Bert-Jan Ruissen**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 12**

*Text proposed by the Commission*

(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***;

*Amendment*

(12) ‘NGT product’ means food and feed containing, consisting of or produced from ***NGT plants, and other products containing or consisting of such plants***;

Or. en

**Amendment 239**  
**Juozas Olekas, Carmen Avram, Paolo De Castro**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 12**

*Text proposed by the Commission*

(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

*Amendment*

(12) ‘NGT product’ means food and feed containing, consisting of or produced from ***such a plant, and other products containing or consisting of such plants***;

from such a plant;

Or. en

*Justification*

*Clarification*

**Amendment 240**

**Sandra Pereira**

**Proposal for a regulation**

**Article 3.<sup>o</sup> – paragraph 1 – point 13**

*Text proposed by the Commission*

*Amendment*

**(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;** **deleted**

Or. pt

**Amendment 241**

**Anja Hazekamp**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 13**

*Text proposed by the Commission*

*Amendment*

**(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;** **deleted**

Or. en

**Amendment 242**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 13**

*Text proposed by the Commission*

*Amendment*

**(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;** **deleted**

Or. en

*Justification*

*NGT plants, by definition, could not occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice’s judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why we propose to delete the specific rules dedicated to category 1 NGTs.*

**Amendment 243**  
**Sandra Pereira**

**Proposal for a regulation**  
**Article 3.º – paragraph 1 – point 14**

*Text proposed by the Commission*

*Amendment*

**(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;** **deleted**

Or. pt

**Amendment 244**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group



**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 14**

*Text proposed by the Commission*

*Amendment*

**(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;** **deleted**

Or. en

**Amendment 245**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 14**

*Text proposed by the Commission*

*Amendment*

**(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;** **deleted**

Or. en

**Amendment 246**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 4 – paragraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

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:

Without prejudice to other requirements of Union law, **and with strict regard to the precautionary principle**, 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 **the**

***plant is a NGT plant and has been authorised in accordance with Chapter III.***

Or. en

**Amendment 247**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 4 – paragraph 1 – point 1**

*Text proposed by the Commission*

*Amendment*

***(1) the plant is a category 1 NGT plant and*** ***deleted***

***(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***

Or. en

*Justification*

*NGT plants, by definition, could not occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why we propose to delete the specific rules dedicated to category 1 NGTs.*

**Amendment 248**

**Maria Noichl**

**Proposal for a regulation**

**Article 4 – paragraph 1 – point 1 – point a**

*Text proposed by the Commission*

*Amendment*

(a) ***has obtained a decision declaring that status in accordance with Article 6 or 7; or***

(a) ***the requirements of Article 6 of Directive 2001/18 are fulfilled.***

Or. en

**Amendment 249**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 4 – paragraph 1 – point 2**

*Text proposed by the Commission*

*Amendment*

(2) ***the plant is a category 2 NGT plant and has been authorised in accordance with Chapter III.***

***deleted***

Or. en

**Amendment 250**

**Annie Schreijer-Pierik**

**Proposal for a regulation**

**Article 4 – paragraph 1 – point 2**

*Text proposed by the Commission*

*Amendment*

(2) the plant is a category 2 NGT plant and has been authorised in accordance with Chapter III.

(2) the plant is a category 2 NGT plant and ***has been granted consent or*** has been authorised in accordance with Chapter III.

Or. en

**Amendment 251**

**Veronika Vrecionová**

**Proposal for a regulation**

**Article 4 – paragraph 1 – point 2**

*Text proposed by the Commission*

*Amendment*

(2) the plant is a category 2 NGT plant and has been authorised in accordance with Chapter III.

(2) the plant is a category 2 NGT plant and ***has been granted consent or*** has been authorised in accordance with Chapter III.

Or. en

**Amendment 252**

**Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos Ros Sempere**

**Proposal for a regulation**

**Article 4 – paragraph 1 – point 2**

*Text proposed by the Commission*

*Amendment*

(2) the plant is a category 2 NGT plant and has been authorised in accordance with Chapter III.

(2) the plant is a category 2 NGT plant and ***has been granted consent or*** has been authorised in accordance with Chapter III.

Or. en

*Justification*

*Clarification to the proposal text.*

**Amendment 253**

**Bert-Jan Ruissen**

**Proposal for a regulation**

**Article 4 – paragraph 1 – point 2**

*Text proposed by the Commission*

*Amendment*

(2) the plant is a category 2 NGT plant and has been authorised in accordance with Chapter III.

(2) the plant is a category 2 NGT plant and ***has been granted consent or*** has been authorised in accordance with Chapter III.

Or. en

**Amendment 254**

**Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**(2 a) The implementation, enforcement and application of this Regulation shall not have the object or effect of preventing or impeding imports from third countries of NGT plants and products that meet the same standards as those laid down in this regulation.**

Or. en

**Amendment 255**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Chapter II – title**

*Text proposed by the Commission*

*Amendment*

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

**II Deleted.**

Or. en

**Amendment 256**  
**Sandra Pereira**

**Proposal for a regulation**  
**Article 5.º**

*Text proposed by the Commission*

*Amendment*

**Article 5**

**deleted**

**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.***

Or. pt

**Amendment 257**  
**Anja Hazekamp**

**Proposal for a regulation**  
**Article 5**

*Text proposed by the Commission*

*Amendment*

***Article 5***

***deleted***

***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.***

Or. en

**Amendment 258**

**Theresa Bielowski, Maria Noichl**

**Proposal for a regulation**

**Article 5**

*Text proposed by the Commission*

*Amendment*

**Article 5**

**deleted**

**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.**

Or. en

*Justification*

*A distinction of NGTs into category 1 and 2 is not scientifically tenable. Therefore, all NGTs are to be included in one group. The advancing knowledge of molecular genetics shows that the genome functions as a delicately balanced, integrated network. That genes function as networks, implies that any modification can have major consequences with respect to patterns of gene expression and an organism's biochemistry. Thus, the latest science suggests that the law governing genetic modification including NGT should be re-appraised and strengthened rather than weakened.*

**Amendment 259**

**Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton**

**Proposal for a regulation**

**Article 5 – title**

*Text proposed by the Commission*

*Amendment*

Status of category 1 NGT plants

Status of category 1 NGT plants *and category 1 NGT products*

Or. en

### **Amendment 260**

**Benoît Biteau**

on behalf of the Verts/ALE Group

### **Proposal for a regulation**

#### **Article 5 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. *The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants.* **deleted**

Or. en

#### *Justification*

*NGT plants, by definition, could not occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why we propose to delete the specific rules dedicated to category 1 NGTs.*

### **Amendment 261**

**Daniel Buda, Dan-Ștefan Motreanu**

### **Proposal for a regulation**

#### **Article 5 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants.

1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants, ***with the exception of the techniques referred to in Annex IB***



*to Directive 2001/18, which shall also apply to category 1 NGT plants.*

Or. en

*Justification*

*Category 1 NGT plants should be subject to the same regulatory framework as products resulted from conventional plant breeding.*

**Amendment 262**

**Asger Christensen**

on behalf of the Renew Group

**Emma Wiesner, Jan Huitema, Erik Poulsen**

**Proposal for a regulation**

**Article 5 – paragraph 1**

*Text proposed by the Commission*

1. The rules which apply to **GMOs in Union legislation** shall **not** apply to category 1 NGT plants.

*Amendment*

1. The rules which apply to **the techniques referred to in Annex 1B to Directive 2001/18** shall **also** apply to category 1 NGT plants.

Or. en

*Justification*

*Category 1 (conventional-like) NGT plants should be subject to the same regulatory framework as conventional breeding products. This also allows The Organics sector to be able to make their own choice on whether or not they want to use NGTs. By including 1 NGT among the techniques in Annex 1B of Directive 2001/18, it will be possible to use these plants in organic agriculture unless the organic farming regulation specifies otherwise.*

**Amendment 263**

**Annie Schreijer-Pierik**

**Proposal for a regulation**

**Article 5 – paragraph 1**

*Text proposed by the Commission*

1. The rules which apply to **GMOs in Union legislation** shall **not** apply to category 1 NGT plants.

*Amendment*

1. The rules which apply to **GMOs listed in Annex 1 B to Directive 2001/18/EC** shall **also** apply to category 1

NGT plants.

Or. en

*Justification*

*The proposal establishes a verification process to verify if an NGT plant meets the equivalence criteria to be grouped as category 1 NGT plant. Consequently, those category 1 NGT plants should also be subject to the same regulatory framework as conventional breeding products. Instead, the Commission proposal creates a distinct category and foresees specific requirements for verified conventional-like NGT plants different from conventional plants. It would be much more consistent to include verified conventional-like category 1 NGT plants under Annex I B of Directive 2001/18/EC..*

**Amendment 264**

**Juozas Olekas, Carmen Avram, Paolo De Castro**

**Proposal for a regulation**

**Article 5 – paragraph 1**

*Text proposed by the Commission*

1. The rules which apply to GMOs in Union legislation shall **not** apply to category 1 NGT plants.

*Amendment*

1. The rules which apply to **Annex IB** GMOs in Union legislation shall **also** apply to category 1 NGT plants.

Or. en

*Justification*

*The proposal describes a verification process to confirm if an NGT plant meets the equivalence criteria in Annex I to be regulated as Category 1 NGT plants. Therefore, Category 1 NGT plants should be regulated as conventionally-bred plants. Any additional requirements would be discriminatory and would create a third category, in addition to conventional plants and GMOs. To avoid confusion, it would be more consistent to include verified Category 1 NGT plants under Annex IB of Dir. 2001/18.*

**Amendment 265**

**Maria Noichl**

**Proposal for a regulation**

**Article 5 – paragraph 1**

*Text proposed by the Commission*

1. The rules which apply to GMOs in Union legislation shall **not** apply to

*Amendment*

1. The rules which apply to GMOs in Union legislation shall apply to **all** NGT

*category 1* NGT plants.

plants.

Or. en

**Amendment 266**

**Peter Jahr, Lena Düpont, Christine Schneider, Marlene Mortler**

**Proposal for a regulation**

**Article 5 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***(1a) Category 1 NGT plants are subject to the same legal framework as conventionally bred plants, in particular with regard to plant breeders' rights and to self-propagation;***

Or. de

**Amendment 267**

**Michaela Šojdrová, Daniel Buda, Dan-Ștefan Motreanu, Peter Jahr, Herbert Dorfmann, Asim Ademov, Christine Schneider, Anne Sander**

**Proposal for a regulation**

**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

***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.***

***deleted***

Or. en

**Amendment 268**

**Tom Vandenkendelaere**

**Proposal for a regulation**

**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**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.** **deleted**

Or. en

*Justification*

*Even without this Article, category 1 NGT plants are, given the 2018 CJEU ruling and the interpretation given to it by the European Commission, not allowed to be used in organic agriculture. What is allowed to be used in organic agriculture should be determined by what is laid down in Regulation (EU) 2018/848 and not by other pieces of legislation.*

#### **Amendment 269**

**Asger Christensen**

on behalf of the Renew Group

**Emma Wiesner, Elsi Katainen, Jérémy Decerle, Jan Huitema, Erik Poulsen**

#### **Proposal for a regulation**

**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**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.** **deleted**

Or. en

*Justification*

*Any regulation made on organics should be done via the organic farming regulation.*

#### **Amendment 270**

**Juozas Olekas, Carmen Avram**

#### **Proposal for a regulation**

**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**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.** *deleted*

Or. en

*Justification*

*The exclusion of category 1 NGT plants from the organic sector has no scientific basis. All farmers should have the freedom of choice to use NGT plants. As category 1 NGT plants are considered equivalent to conventional plants in other parts of the legislation, they should not be considered separately regarding organic farming. Currently certain private standards in the organic sector exclude seeds derived from conventional breeding methods based on transparent information from the breeding sector. It should therefore be left to the organic operators to decide which seeds to use.*

**Amendment 271**  
**Annie Schreijer-Pierik**

**Proposal for a regulation**  
**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**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.** *deleted*

Or. en

*Justification*

*The prohibition for organic farmers to use conventional-like NGTs (Category 1) in their production is neither science-based nor justifiable. Already today, certain private standards in the organic sector exclude seeds derived from certain conventional breeding methods (e.g. CMS) based on transparent information from the breeding sector. It should therefore be left to the organic operators to decide which seeds to use in their production (private certification standards) and all references to organics should be deleted from the NGT proposal).*

**Amendment 272**  
**Veronika Vrecionová**

**Proposal for a regulation**  
**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**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.**

**deleted**

Or. en

*Justification*

*This Regulation is not a place to regulate bans in organic farming.*

**Amendment 273**  
**Martin Hlaváček**

**Proposal for a regulation**  
**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**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.**

**deleted**

Or. en

**Amendment 274**  
**Irène Tolleret**

**Proposal for a regulation**  
**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

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.

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. **Seven years after the entry into force of this**

***Regulation, the European Commission shall present a report on the evolution of the consumers' and producers' perception, accompanied, if appropriate, by a legislative proposal to lift the ban on the use of NGT in organic production.***

Or. en

**Amendment 275**

**Benoît Biteau**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 5 – paragraph 2**

*Text proposed by the Commission*

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.

*Amendment*

2. For the purposes of Regulation (EU) 2018/848, the rules set out in its Articles 5 (f) (iii) and 11 shall apply to NGT plants and to products produced from or by such plants.

Or. en

**Amendment 276**

**Martin Hlaváček**

**Proposal for a regulation**

**Article 5 – paragraph 2 – point 1 (new)**

*Text proposed by the Commission*

*Amendment*

***(1) Plant varieties that may arise and occur naturally or may be produced by conventional breeding or are considered to be conventional plants (such NGT plants) shall not be subject to Patent legislation but to Plant Variety Rights legislation, which allows the use of the so-called Plant breeders 'exemption and Farm saved Seeds exemption'.***

Or. en

**Amendment 277**

**Annie Schreijer-Pierik**

**Proposal for a regulation**

**Article 5 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. For the purposes of Regulation (EU) 2018/848, the rules set out in its Articles 5 (f) (iii) and 11 shall only apply to category 2 NGT plants and to products produced from or by such plants.**

Or. en

*Justification*

*The prohibition for organic farmers to use conventional-like NGTs (Category 1) in their production is neither science-based nor justifiable. Already today, certain private standards in the organic sector exclude seeds derived from certain conventional breeding methods (e.g. CMS) based on transparent information from the breeding sector. It should therefore be left to the organic operators to decide which seeds to use in their production (private certification standards) and all references to organics should be deleted from the NGT proposal).*

**Amendment 278**

**Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero**

**Proposal for a regulation**

**Article 5 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. NGT CAT 1 (conventional-like) plants and to products produced from or by such plants, are not subject to provisions established in Article 26b of Directive 2001/18/EC.**

Or. en

*Justification*

*Given the fact that NGT CAT 1 are conventional-like, and in line with the current situation, no pot-out from cultivation of these products should be allowed.*



**Amendment 279**  
**Juozas Olekas, Carmen Avram, Paolo De Castro**

**Proposal for a regulation**  
**Article 5 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. 2a. Category 1 NGT plants and the products from such plants, are not subject to provisions established in Article 24 of this Regulation or Regulation 1829/2003.**

Or. en

*Justification*

*As no specific coexistence measures exist between conventional and organic production systems, and as Cat1 NGT plants are conventional-like, no coexistence measures should be needed.*

**Amendment 280**  
**Daniel Buda, Dan-Ştefan Motreanu**

**Proposal for a regulation**  
**Article 5 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Category 1 NGT plants and products obtained from or by such plants, shall not be subject to coexistence measures with Regulation (EC) No 1829/2003 1829/2003.**

Or. en

*Justification*

*Considering that category 1 NGT plants are conventional-like plants no coexistence measures should be imposed*

**Amendment 281**  
**Jérémy Decerle**

**Proposal for a regulation**  
**Article 5 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Regulation 2100/94 on Community plant variety rights shall always apply to Category 1 NGT plants. Category 1 NGT plants shall not be patentable.**

Or. en

**Amendment 282  
Martin Hlaváček**

**Proposal for a regulation  
Article 5 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2 a. Category 1 NGT plants shall not be patentable.**

Or. en

**Amendment 283  
Annie Schreijer-Pierik**

**Proposal for a regulation  
Article 5 – paragraph 2 b (new)**

*Text proposed by the Commission*

*Amendment*

**2 b. Category 1 NGT plants and category 1 NGT products (conventional-like) shall not be subject to provisions like as established in Article 24 of this Regulation or Regulation (EC) 1829/2003.**

Or. en

*Justification*

*Given the fact that NGT CAT 1 are conventional-like, and in line with the current situation between conventional and organic farming, no coexistence measures are needed.*

**Amendment 284**  
**Juozas Olekas, Carmen Avram, Paolo De Castro**

**Proposal for a regulation**  
**Article 5 – paragraph 2 b (new)**

*Text proposed by the Commission*

*Amendment*

**2 b. Category 1 NGT plants and products from such plants are not subject to provisions established in Article 26b of Directive 2001/18/EC.**

Or. en

*Justification*

*Since Category 1 NGT plants are equivalent to conventionally bred plants, no opt-out from cultivation of these products should be needed.*

**Amendment 285**  
**Annie Schreijer-Pierik**

**Proposal for a regulation**  
**Article 5 – paragraph 2 c (new)**

*Text proposed by the Commission*

*Amendment*

**2 c. Category 1 NGT plants and category 1 NGT products (conventional-like) are not subject to provisions established in Article 26b of Directive 2001/18/EC.**

Or. en

*Justification*

*Given the fact that NGT CAT 1 are conventional-like, and in line with the current situation, no opt-out from cultivation of these products should be allowed.*

**Amendment 286**  
**Benoît Biteau**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 5 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

**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.**

**deleted**

Or. en

**Amendment 287  
Herbert Dorfmann**

**Proposal for a regulation  
Article 5 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

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.

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, **extent, dimensions and number** of modifications which can occur naturally or through conventional breeding.

Or. it

**Amendment 288  
Daniela Rondinelli**

**Proposal for a regulation  
Article 5 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

3. The Commission is empowered to

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.

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, *extent, dimensions and number of genetic* modifications which can occur naturally or through conventional breeding.

Or. it

#### **Amendment 289**

**Peter Jahr, Lena Düpont, Christine Schneider, Marlene Mortler**

#### **Proposal for a regulation**

#### **Article 5 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3 a. By way of derogation, category 1 plants and their derived seeds cannot be patented.**

Or. en

#### **Amendment 290**

**Michaela Šojdrová, Daniel Buda, Dan-Ștefan Motreanu, Peter Jahr, Herbert Dorfmann, Asim Ademov, Christine Schneider**

#### **Proposal for a regulation**

#### **Article 5 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3 a. Category 1 NGT plants shall not be patentable.**

Or. en

#### **Amendment 291**

**Sandra Pereira**

#### **Proposal for a regulation**

**Article 6.º**

*Text proposed by the Commission*

*Amendment*

*[...]*

*deleted*

Or. pt

**Amendment 292**

**Anja Hazekamp**

**Proposal for a regulation**

**Article 6**

*Text proposed by the Commission*

*Amendment*

*[...]*

*deleted*

Or. en