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*Plenary sitting*

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**A9-0014/2024**

29.1.2024

**\*\*\*I**  
**REPORT**

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

Committee on the Environment, Public Health and Food Safety

Rapporteur: Jessica Polfjård

### ***Symbols for procedures***

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

### ***Amendments to a draft act***

#### **Amendments by Parliament set out in two columns**

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

#### **Amendments by Parliament in the form of a consolidated text**

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▬ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0411),
  - having regard to Article 294(2), Article 43(2), Article 114 and Article 168(4)(b) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0238/2023),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Cypriot Parliament and the Hungarian Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,
  - having regard to the opinion of the European Economic and Social Committee of 26 April 2023<sup>1</sup>,
  - after consulting the Committee of the Regions,
  - having regard to Rules 59 of its Rules of Procedure,
  - having regard to the opinion of the Committee on Agriculture and Rural Development,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0014/2024),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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<sup>1</sup> Not yet published in the Official Journal.

## Amendment 1

### 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 2

### 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

*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 precise locations. ***Major advances in genetic engineering have already contributed to the widespread use of marker-assisted selection, which makes it possible to identify and mobilise interesting genes that are present in biodiversity.***

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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*

(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.

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 *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.

### Amendment 3

#### 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

###### *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 tolerance to herbicides***, 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,

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 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

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

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<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 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.

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 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.

## Amendment 4

### 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) ***Category 1 NGT plants and products obtained by targeted mutagenesis and cisgenesis and related 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.***

***Targeted mutagenesis Category 1 NGT plants and products should be exempted from Annex 1 B to Directive 2001/18/EC as other mutagenesis methods have been.***

## Amendment 5

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

## Amendment 6

### Proposal for a regulation

#### Recital 10

*Text proposed by the Commission*

*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. ***Available knowledge on other organisms, such as*** microorganisms, fungi and animals, ***should be reviewed with a view to future legislative initiatives on them***. 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.

(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.

(10) ***With full regard to the precautionary principle***, 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 7**

### **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. It introduces specific provisions for NGT plants and NGT products. However, where there are no specific rules in this Regulation, NGT plants and products 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 8**

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

*Text proposed by the Commission*

*Amendment*

***(13a) NGT plants with the potential to persist, reproduce or spread in the environment, within or beyond fields, should be evaluated with the highest level of scrutiny in respect of such plants' impact on nature and the environment.***

**Amendment 9**

**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 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

(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 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

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.

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.

## Amendment 10

### Proposal for a regulation Recital 14 a (new)

*Text proposed by the Commission*

*Amendment*

***(14a) Taking into account the high complexity of plant genomes, the criteria for considering that a NGT plant is equivalent to a naturally occurring or conventionally bred plant should reflect the diversity of plants genomic size and their characteristics. Polyploid plants contain more than two homologous chromosomes. Within that category of polyploid plants, 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. For those reasons, any limit to the total number of individual modifications per plant should reflect the number of chromosomes set in a plant (“ploidy”).***

## Amendment 11

### 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

(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.

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

## Amendment 12

### Proposal for a regulation

#### Recital 18 a (new)

*Text proposed by the Commission*

*Amendment*

***(18a) In order to effectively select new varieties that help the agricultural sector increase food security, as well as sustainability, adaptation and resilience in relation to the consequences of climate change, it is necessary to consider the specificity of polyploid plants, which are plants that contain more than two***

*genomes. For such plants, the maximum number of genetic modifications allowed for inclusion in category 1 NGT should be proportionate to the number of genomes they contain.*

## Amendment 13

### 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 Authority should be subject to **appropriate** deadlines to ensure that category 1 NGT plant status declarations are made within a reasonable time.

## Amendment 14

### 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 should include information on the technique or techniques used to obtain the trait or traits.**

## Amendment 15

### 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).

## Amendment 16

### 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

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. ***Currently, the compatibility of*** the use of new genomic techniques with the ***principles*** of organic production ***requires further consideration***. The use of category 1 NGT plants should therefore be prohibited in organic production, ***until such further consideration takes place***.

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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).

##### *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 or techniques used to obtain the trait or traits.*** 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 17

### 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 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

##### *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, 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. ***In view of the precautionary principle***, a monitoring plan for environmental effects should ***always*** be required ***when consent is first given***. ***It should only be possible to waive the requirement for monitoring upon the renewal of consent, provided that it has***

on the environment.

*been demonstrated that* the category 2 NGT plant *does not* pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.

## Amendment 18

### 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 [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].*

*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 *fall within the scope of the category 1 NGT plants.*

## Amendment 19

### 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

*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.

facilitated. This requires predictability for breeders and farmers as regards the possibility to cultivate such plants in the Union. Therefore, ***it should not be possible*** 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, ***as this*** would undermine those goals.

## Amendment 20

### 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 and NGT products across the Union, the deliberate release of NGT plants and placing on the market of NGT products should be based on the harmonised 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 NGT products within the territory of the*** Union.

## Amendment 21

### 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***

#### *Amendment*

(40) Given the ***ongoing*** development of ***new genomic techniques, the Commission should carry out an evaluation*** within five years after the adoption of the first decision

***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.

allowing the deliberate release or the marketing of NGT plants or NGT products in the Union. ***That*** evaluation ***should*** measure the progress made towards the availability of NGT plants ***or NGT products*** containing such characteristics or properties on the EU market, ***with the aim of further improving this Regulation.***

## Amendment 22

### Proposal for a regulation Recital 43

*Text proposed by the Commission*

(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.’

*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, ***fully taking into account the precautionary principle,*** 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.’

## Amendment 23

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

*Text proposed by the Commission*

*Amendment*

***(45a) The European Parliament has called for the Union and its Member States not to grant patents on biological***

*material and to safeguard the freedom to operate and the breeders' exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT plants, which by definition are not transgenic plants. 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). As current provisions in patent law do not provide for a full breeder's exemption, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Hence, NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption. NGT plants, their derived seeds, their plant material, associated genetic material such as genes and gene sequences, and plant traits should therefore be excluded from patentability. The exclusion from patentability should be applied in a consistent manner across legislation. Furthermore, in order to avoid patents being granted or patent applications being submitted between the date of the entry into force of this Regulation and the application of its provisions, it should be ensured that plant material is excluded from patentability from the day of entry into force of this Regulation. For patents already granted or pending patent applications covering plant material, the effects of patents should be further limited. In addition, the Commission should assess and address, in the forthcoming study, how the broader problem of patents being granted, directly or indirectly, on plant material despite previous efforts to close loopholes, should be further addressed. The assessment should address in particular 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 in particular on opportunities for SMEs. The report of the Commission should be accompanied by the appropriate legislative proposals in order to ensure further necessary adjustments are made to the intellectual property rights framework.*

**Amendment 24**  
**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, ***in accordance with the precautionary principle*** 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, ***ensuring a high level of protection of human and animal health and the environment.***

**Amendment 25**  
**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 condition that it does not contain any genetic material originating from outside the gene pool ***for conventional breeding purposes*** that temporarily may have been inserted during the development of the NGT plant;

**Amendment 26**  
**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;

**Amendment 27**  
**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 conventional breeding purposes**’ means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;

**Amendment 28**  
**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 15 a (new)**

*Text proposed by the Commission*

*Amendment*

**(15a) ‘One Health Approach’ means an integrated, unifying approach that aims to sustainably balance and optimise the health of people, animals, plants and ecosystems and recognises that the health of humans, domestic and wild animals, plants, and the wider environment including ecosystems are closely interlinked and inter-dependent;**

**Amendment 29**  
**Proposal for a regulation**

**Article 3 – paragraph 1 – point 15 b (new)**

*Text proposed by the Commission*

*Amendment*

**(15b) “Chimeric protein” means proteins created through the joining of two or more genes or parts of genes that originally coded for separate proteins.**

**Amendment 30**

**Proposal for a regulation**

**Article 4 – paragraph 1 – point 1 – point b**

*Text proposed by the Commission*

*Amendment*

(b) is progeny of plant(s) referred to in point (a); or

(b) is progeny of plant(s) referred to in point (a) **on condition that the criteria of equivalence set out in Annex I are still satisfied** ; or

**Amendment 31**

**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.

**Amendment 32**

**Proposal for a regulation**

**Article 4 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

**1a. 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.**



**Amendment 33**  
**Proposal for a regulation**  
**Article 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 4a**

***Exclusion from patentability***

***NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable.***

**Amendment 34**  
**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 **Article 5 (f), (iii), and Article 11** shall apply to category 1 NGT plants and to products produced from or by such plants. ***[7 years after the entry into force of this Regulation], the Commission shall present a report on the evolution of the consumers' and producers' perception, accompanied, where appropriate, by a legislative proposal.***

**Amendment 35**  
**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, ***taking into account potential associated risks and functional consequences in the verification procedure*** in order to adapt those criteria to ***the latest*** scientific and

technological *developments* as regards the types and extent of modifications which can occur naturally or through conventional breeding.

**Amendment 36**  
**Proposal for a regulation**  
**Article 5 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3a. The adventitious or technically unavoidable presence of category 1 NGT plants, reproductive material or parts thereof in organic production, or in non-organic products authorised in organic production in accordance with Articles 24 and 25 of Regulation (EU) 2018/848, shall not constitute non-compliance with that Regulation.**

**Amendment 37**  
**Proposal for a regulation**  
**Article 6 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I are met ('verification request') to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the *implementing* act adopted in accordance with Article 27, point (b).

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I **at least one of the traits referred to in Annex III, Part 1, and the exclusion criteria in Annex III, Part 2**, are met ('verification request'). **That verification request shall be submitted** to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the *delegated* act adopted in accordance

with Article **6(11a)**, point (b).

**Amendment 38**  
**Proposal for a regulation**  
**Article 6 – paragraph 3 – point c**

*Text proposed by the Commission*

(c) a description of the trait(s) and characteristics which have been introduced or modified;

*Amendment*

(c) a description of the trait or traits and characteristics which have been introduced or modified, ***including information on the technique or techniques used to obtain the trait or the traits and including disclosure of the sequence of genetic modification;***

**Amendment 39**  
**Proposal for a regulation**  
**Article 6 – paragraph 3 – point d – point i**

*Text proposed by the Commission*

(i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the ***breeders'*** gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the ***implementing*** act adopted in accordance with Article **27**, point (a);

*Amendment*

(i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the gene pool ***for conventional breeding purposes*** where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the ***delegated*** act adopted in accordance with Article **6(11a)**, point (a);

**Amendment 40**  
**Proposal for a regulation**  
**Article 6 – paragraph 3 – point d – point ii**

*Text proposed by the Commission*

(ii) the NGT plant meets the criteria set out in Annex I;

*Amendment*

(ii) the NGT plant meets the criteria set out in Annex I, ***at least one of the traits in Annex III, Part 1, and the exclusion criteria of Annex III, Part 2;***

**Amendment 41**  
**Proposal for a regulation**  
**Article 6 – paragraph 3 – point d a (new)**

*Text proposed by the Commission*

*Amendment*

**(da) the denomination of the variety**

**Amendment 42**  
**Proposal for a regulation**  
**Article 6 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority **may, where appropriate, consult with the European Food Safety Authority ('EFSA') while preparing the verification report.** The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.

**Amendment 43**  
**Proposal for a regulation**  
**Article 6 – paragraph 7**

*Text proposed by the Commission*

*Amendment*

7. The other Member States and the Commission may make **comments** to the verification report within 20 days from the date of receipt of that report.

7. The other Member States and the Commission may make **reasoned objections** to the verification report, **as regards the fulfilment of the criteria set out in Annex I**, within 20 days from the date of receipt of that report. **Such reasoned objections shall solely refer to the criteria as set out in Annex I and Annex III and shall include a scientific justification.**

**Amendment 44**  
**Proposal for a regulation**  
**Article 6 – paragraph 8**

*Text proposed by the Commission*

8. In the absence of any **comments** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

**Amendment 45**  
**Proposal for a regulation**  
**Article 6 – paragraph 9**

*Text proposed by the Commission*

9. In cases where a **comment** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall **forward the comment(s) to the Commission** without undue delay.

**Amendment 46**  
**Proposal for a regulation**  
**Article 6 – paragraph 10**

*Text proposed by the Commission*

10. The Commission, after having consulted the **European Food Safety Authority ('the Authority')**, shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment(s)**, taking the latter into

*Amendment*

8. In the absence of any **reasoned objections** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

*Amendment*

9. In cases where a **reasoned objection** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall **make the reasoned objections publicly available** without undue delay.

*Amendment*

10. The Commission, after having consulted the Authority, shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **reasoned objections**, taking the latter into account. The decision shall be adopted

account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

in accordance with the procedure referred to in Article 28(2).

**Amendment 47**  
**Proposal for a regulation**  
**Article 6 – paragraph 11 a (new)**

*Text proposed by the Commission*

*Amendment*

**11a. The Commission is empowered to adopt delegated acts in accordance with Article 26 supplementing this Regulation concerning:**

- (a) the information required to demonstrate that a plant is a NGT plant;**
- (b) the preparation and the presentation of the verification requests referred to in Articles 6 and 7.**

**Amendment 48**  
**Proposal for a regulation**  
**Article 7 – paragraph 2 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

- (ba) the denomination of the variety;**

**Amendment 49**  
**Proposal for a regulation**  
**Article 7 – paragraph 2 – point c**

*Text proposed by the Commission*

*Amendment*

(c) a description of the trait(s) and characteristics which have been introduced or modified;

(c) a description of the trait(s) and characteristics which have been introduced or modified ***including information on the technique or techniques used to obtain the trait or the traits and on disclosure of the sequence of genetic modification;***

**Amendment 50**  
**Proposal for a regulation**

## Article 7 – paragraph 7

*Text proposed by the Commission*

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

*Amendment*

7. The Commission shall publish the **final** decision in the Official Journal of the European Union **and shall publish, in a dedicated and publicly available webpage, its draft decision and the reasoned objections referred to in Article 6.**

## Amendment 51

### Proposal for a regulation

#### Article 9 – paragraph 1 – subparagraph 2 – point b

*Text proposed by the Commission*

(b) the designation of the category 1 NGT plant;

*Amendment*

(b) the designation **and specification** of the category 1 NGT plant;

## Amendment 52

### Proposal for a regulation

#### Article 9 – paragraph 1 – subparagraph 2 – point b a (new)

*Text proposed by the Commission*

*Amendment*

**(ba) the denomination of the variety;**

## Amendment 53

### Proposal for a regulation

#### Article 9 – paragraph 1 – subparagraph 2 – point e a (new)

*Text proposed by the Commission*

*Amendment*

**(ea) if provided, the opinion or statement of EFSA, as referred to in Article 6 (10) and Article 7(5); and**

## Amendment 54

### Proposal for a regulation

#### Article 9 – paragraph 2

*Text proposed by the Commission*

*Amendment*

2. The database shall be publicly

2. The database shall be publicly

available.

available, *and in an online format*.

**Amendment 55**  
**Proposal for a regulation**  
**Article 10 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

Plant reproductive material, including for breeding and scientific purposes that contains or consists of category 1 NGT plant or plants and is made available to third parties, whether in return for payment or free of charge, shall bear a label ***and a reference to a variety register automatically transmitted to the EU common register*** indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant or plants it has been derived from.

**Amendment 56**

**Proposal for a regulation**  
**Article 16**

*Text proposed by the Commission*

***Article 16***

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

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

*Amendment*

***deleted***

**Amendment 57**

**Proposal for a regulation**  
**Article 22 – paragraph 1**

*Text proposed by the Commission*

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least

*Amendment*

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least



one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **Part 1 of Annex III** and it does not have any traits referred to in Part 2 of that Annex.

one of the intended traits of the NGT plant conveyed by the genetic modification is contained in **Article 51(1) of Regulation (EU/...)\*** and it does not have any traits referred to in Part 2 of that Annex.

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**\* Commission proposal for a Regulation on plant reproductive material (COM/2023/414), (2023/0227(COD)).**

## **Amendment 58**

### **Proposal for a regulation Article 24**

#### *Text proposed by the Commission*

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

#### *Amendment*

Member States **may** take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003, **only in the event that the category 2 NGT plants are able to be detected, identified and quantified by analytical methods. These provisions shall not apply to category 1 NGT plants and category 1 NGT products.**

## **Amendment 59**

### **Proposal for a regulation Article 26 – paragraph 2**

#### *Text proposed by the Commission*

2. The power to adopt the delegated acts referred to in Article 5(3) and Article 22(8) shall be conferred on the Commission for a period of 5 years from [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods

#### *Amendment*

2. The power to adopt the delegated acts referred to in Article 5(3), **Article 6(11a)** and Article 22(8) shall be conferred on the Commission for a period of 5 years from [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods

of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.

of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.

**Amendment 60**  
**Proposal for a regulation**  
**Article 26 – paragraph 3**

*Text proposed by the Commission*

3. The delegations of power referred to in Article 5(3) and Article 22(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

*Amendment*

3. The delegations of power referred to in Article 5(3), **Article 6(11a)** and Article 22(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

**Amendment 61**  
**Proposal for a regulation**  
**Article 26 – paragraph 6**

*Text proposed by the Commission*

6. A delegated act adopted pursuant to Articles Article 5(3) and Article 22(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.

*Amendment*

6. A delegated act adopted pursuant to Articles Article 5(3), **Article 6(11a)** and Article 22(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.

**Amendment 62**  
**Proposal for a regulation**  
**Article 27 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

**(a) the information required to demonstrate that a plant is a NGT plant;**

**deleted**

**Amendment 63**  
**Proposal for a regulation**  
**Article 27 – paragraph 1 – point b**

*Text proposed by the Commission*

*Amendment*

**(b) the preparation and the presentation of the verification requests referred to in Articles 6 and 7;**

**deleted**

**Amendment 64**

**Proposal for a regulation**  
**Article 30 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. The report shall also address any ethical issues that have arisen with the application of this Regulation.

2. The report shall also **identify and** address any issues regarding **biodiversity and environmental, human and animal health, changes to agronomic practices as well as socio-economic and** ethical issues that **may** have arisen with the application of this Regulation.

**Amendment 65**

**Proposal for a regulation**  
**Article 30 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

3. For the purpose of the reporting referred to in paragraph 1, the Commission, by [24 months after the date of entry into force of this Regulation] at the latest, shall establish, after consulting the

3. For the purpose of the reporting referred to in paragraph 1, the Commission, by [24 months after the date of entry into force of this Regulation] at the latest, shall establish, after consulting the

competent authorities of the Member States in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact of this Regulation. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.

competent authorities of the Member States in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact of this Regulation, ***including the intended and unintended effects and systematic effects on the environment, biodiversity and ecosystems***. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.

**Amendment 66**  
**Proposal for a regulation**  
**Article 30 – paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

***5a. By June 2025 the Commission shall submit a report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the role and impact of patents on breeders' and farmers' access to varied plant reproductive material, as well as on innovation and, in particular, on opportunities for SMEs. The report shall assess whether further legal provisions are necessary in addition to those provided for in Article 4a and Article 33a of this Regulation. Where appropriate to ensure breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, the report shall be accompanied by a legislative proposal to address further necessary adjustments in the intellectual property rights framework.***

**Amendment 67**  
**Proposal for a regulation**  
**Article 30 – paragraph 5 b (new)**

*Text proposed by the Commission*

*Amendment*

**5b. By 2024, the Commission shall submit a report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions evaluating the specificities of and needs for other sectors not covered in this legislation, such as microorganisms, including a proposal for further policy actions.**

**Amendment 68**  
**Proposal for a regulation**  
**Article 30 – paragraph 5 c (new)**

*Text proposed by the Commission*

*Amendment*

**5c. Every four years, the Commission shall assess the criteria of equivalence established in Annex I and, if necessary, update them through a delegated act as referred to in Article 5, (3).**

**Amendment 69**  
**Proposal for a regulation**  
**Article 33 a (new)**  
Directive 98/44/EC  
Article 4

*Text proposed by the Commission*

*Amendment*

**Article 33a**

**Amendments to Directive 98/44/EC<sup>1a</sup>**

**1. Article 4 of Directive 98/44/EC on the legal protection of biotechnological inventions is amended as follows:**

**(a) In paragraph 1, the following points are added:**

**'(c) NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) .../... [O.J. please insert the number of this Regulation];**

**(d) plants, plant material, parts thereof, genetic information and process**

*features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B to that directive.'*

*(b) the following paragraph 4 is added:*

*'4. Paragraph 2 and 3 shall be without prejudice to the exclusions from patentability covered in paragraph 1.'*

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*<sup>1a</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13).*

**Amendment 70**  
**Proposal for a regulation**  
**Article 34 – paragraph 2 – subparagraph 1**

*Text proposed by the Commission*

It shall apply from [24 months from the date of entry into force of this Regulation].

*Amendment*

It shall apply from [24 months from the date of entry into force of this Regulation].  
*Article 4a and Article 33a shall apply from the date of entry into force.*

**Amendment 71**  
**Proposal for a regulation**  
**Annex I – paragraph 1**

*Text proposed by the Commission*

A NGT plant is considered equivalent to conventional plants *when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types* referred to in points 1 *to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.*

*Amendment*

A NGT plant is considered equivalent to conventional plants *if the following conditions* referred to in points 1 *and 1a are met:*

**Amendment 72**  
**Proposal for a regulation**

## **Annex I – point 1**

*Text proposed by the Commission*

(1) substitution or insertion of no more than 20 nucleotides;

*Amendment*

(1) ***The number of the following genetic modifications, which can be combined with each other, does not exceed 3 per any protein-coding sequence taking into account that mutations in introns and regulatory sequences are excluded from this limit:***

(a) substitution or insertion of no more than 20 nucleotides;

(b) ***deletion of any number of nucleotides;***

## **Amendment 73 Proposal for a regulation Annex I – point 1 a (new)**

*Text proposed by the Commission*

*Amendment*

(1a) ***The following genetic modifications, which can be combined with each other, do not create a chimeric protein that is not present in species from the gene pool for breeding purposes or does not interrupt an endogenous gene;***

(a) ***insertion of continuous DNA sequences existing in the gene pool for breeding purposes;***

(b) ***substitution of endogenous DNA sequences with continuous DNA sequences existing in the gene pool for breeding purposes;***

(c) ***inversion or translocation of continuous endogenous DNA sequences existing in the gene pool for breeding purposes.***

## **Amendment 74 Proposal for a regulation Annex I – point 2**

*Text proposed by the Commission*

*Amendment*

**(2) deletion of any number of nucleotides;** **deleted**

**Amendment 75**  
**Proposal for a regulation**  
**Annex I – point 3**

*Text proposed by the Commission*

*Amendment*

**(3) on the condition that the genetic modification does not interrupt an endogenous gene:** **deleted**

**(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;**

**(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;**

**Amendment 76**  
**Proposal for a regulation**  
**Annex I – point 4**

*Text proposed by the Commission*

*Amendment*

**(4) targeted inversion of a sequence of any number of nucleotides;** **deleted**

**Amendment 77**  
**Proposal for a regulation**  
**Annex I – point 5**

*Text proposed by the Commission*

*Amendment*

**(5) any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool.** **deleted**



## **Amendment 78**

### **Proposal for a regulation**

#### **Annex II – Part 1 – paragraph 2 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

**(aa) the characteristics of the recipient plant like allergenicity, potential for gene flow, weed potential, ecological function;**

## **Amendment 79**

### **Proposal for a regulation**

#### **Annex II – Part 2 – point 6 a (new)**

*Text proposed by the Commission*

*Amendment*

**(6a) Impacts on organic cultivation**

## **Amendment 80**

### **Proposal for a regulation**

#### **Annex II – Part 2 – point 8 a (new)**

*Text proposed by the Commission*

*Amendment*

**(8a) Effects on protecting and conserving biodiversity**

## **Amendment 81**

### **Proposal for a regulation**

#### **Annex III – title 1**

*Text proposed by the Commission*

*Amendment*

Traits referred to in Article 22

Traits referred to in Article **6 and Article 22**

## **Amendment 82**

### **Proposal for a regulation**

#### **Annex III – Part 1 – paragraph 1 – point 1**

*Text proposed by the Commission*

*Amendment*

(1) yield, including yield stability and yield under low-input conditions;

(1) yield, including yield stability and yield under low-input conditions, ***provided that those traits also contribute to either point (2), (3) or (4) of this Annex;***

### **Amendment 83**

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

#### **Annex III – Part 1 – paragraph 1 – point 7**

*Text proposed by the Commission*

*Amendment*

(7) reduced need for external inputs, such as ***plant protection products and*** fertilisers.

(7) reduced need for external inputs, such as fertilisers, ***if it does not contradict with Annex III, part 2.***

### **Amendment 84**

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

#### **Annex III a (new)**

*Text proposed by the Commission*

*Amendment*

#### **ANNEX IIIa**

##### ***In-door safety assessment***

***A Cat.1 NGT plant is considered safe if, when compared to the non modified parent of the same species, through confined experiments evidence is provided that:***

***(1) the whole genome sequencing and profiling shows that the intended and unintended genetic modifications have not adversely modified the function of one or more genes; and***

***(2) the whole transcriptome sequencing carried out on the relevant part of the plant shows that the intended and unintended genetic modifications have not adversely modified biochemical pathways, leading in particular to adverse compositional consequences, verified for instance through gene ontology analysis;***

*and*

*(3) biochemical metabolite (metabolomics) and protein (proteomics) profiling realised on the relevant part of the plant shows that the intended and unintended genetic modifications have not induced an increase in the levels of known toxins or allergens or the production by the plant of toxic or allergenic novel biochemicals or proteins other than those sought after and tested .*

## EXPLANATORY STATEMENT

New genomic techniques (NGTs) provide unprecedented opportunities for European agriculture and food production. These techniques enable us to alter the genetic materials of a certain organism providing swift development of different plant varieties with certain characteristics. NGTs are not limited to one specific technique but rather represent a diverse group of techniques that can contribute to a more tailored modification of the genome in comparison to conventional plant breeding. The achieved modification of the genome could or could not be produced in nature or obtained by conventional breeding techniques.

Innovative technologies such as CRISPR/Cas9, which was awarded the Nobel Prize in Chemistry in 2020, have the ability to improve plant breeding by strengthening various crops through more targeted changes and without the need to add anything new in the genetic composition of a crop.

NGTs therefore have the ability to enhance agriculture by making crops and harvests more resilient and sustainable. Given their low operating and entry costs, these techniques could also contribute to improving the Union's trade policy and competitiveness.

Unfortunately, the European Union currently cannot utilize this potential.

In its judgment of 25 July 2018, the Court of Justice of the European Union held that Directive 2001/18 cannot be interpreted as excluding from its scope genetically modified organisms (GMOs) obtained by certain new techniques.

The practical implication of this has been significant, as NGTs have still not been introduced within the Union.

As the European Commission concluded in a 30 April 2021 study delivered at the request of the Council on 8 November 2019, EU legislation should be adapted in line with scientific and technical progress in this area.

A new, adapted, legislation is essential to enable the use of these new techniques. It is essential to have adequate risk assessment requirements and authorisation procedures to ensure that a variety of potential plant products can be introduced within the EU. The current requirements and processes for genetically modified crops are not enabling the new techniques or a variety of plant products.

Without an enabling framework in line with the scientific and technical progress, these problems continue to affect operators affected by the current regulations across the agri-food system. Consumers, farmers and the innovative sector cannot currently benefit from NGTs.

In the absence of a modern regulatory framework in the EU, other countries in the world have already undertaken measures to enable the usage of NGTs. The EU therefore risks falling behind in both competitiveness and scientific and technological research. This would negatively impact European food safety as well as resilience in European food production.

### **Objectives and ambitions of the draft proposal**

The rapporteur supports the overall approach of the European Commission and welcomes its proposal to introduce a new regulation on plants obtained by certain new genomic techniques and their food and feed. Taking into account that the current regulatory framework is not in line with the latest scientific and technological development, the rapporteur welcomes this proposal with its objectives set out in the food safety-strategy Farm to fork. The proposal goes in line with the Farm to fork-strategy and its aim to transform European agriculture and food production towards sustainability and strengthen European competitiveness.

The COVID-19 pandemic and Russia's war of aggression against Ukraine have both aggravated the situation for European agriculture and food production by showing the Union's external dependencies on critical inputs for agriculture.

While the rapporteur believes that the Commission proposal is a solid starting point, she believes that some further improvements and additions are required to ensure the best possible usage of the techniques.

### **Clarification and improvement of the criteria for NGT 1-plants**

The rapporteur is of the opinion that the provisions related to category 1 (NGT 1) should be further improved. She believes that the criteria in annex I that defines an NGT 1 plant should be further clarified and improved. The Commission proposes a threshold of 20 genetically modified changes that cannot be exceeded if a plant were to be defined as an NGT 1.

Concerning the criteria set out in annex I to fall under NGT 1: **the threshold of 20 genetically modified changes should be specified by ensuring that each change in a plant and/or a crop must be relative to the ploidy status in the crop.** If, for example, a plant has a duplication of chromosomes and one modification de facto makes two changes, 10 modifications can already make up to 20 potential changes. This would risk going beyond its purpose. The particular change in a crop or a plant must be based on a single copy of a gene.

### **Organic farming**

The rapporteur also believes that NGTs should be allowed and enabled in organic farming. The purpose of this draft report is to ensure that any operators without discrimination can use the techniques. **Thus, the proposed ban by the Commission for the techniques to be used in organic farming is lifted to ensure a fair playing field without imposing the technique on any operator.**

The proposal should ensure that every operator could have access to these new technologies. The freedom of choice is essential for operators and the technique should remain available.

### **Ensuring science-based verification processes**

The proposed regulation also introduces verification procedures for NGT 1 prior to the deliberate release of plants for this category. The rapporteur believes that is important to ensure full compliance with the regulation. **However, she believes that the verification process should be for the competent authority in a Member State where the application**

**is submitted and without additional Member States able to challenge a certain decision of approval without a reasoned objection.**

The verification process should be based on the scientifically approved criteria set out in the annex defining a category 1 plant and, where appropriate, in close consultation with the European Commission and the European Food Safety Authority.

### **Traceability and labelling**

As regards the traceability and labelling of NGT 1 plants, the rapporteur supports the proposal by the commission by making information about the use of NGTs publicly available in the proposed public database. This ensures transparency and consumer choice. **However, the rapporteur does not support seed bag labelling for verified conventional-like NGT plants as that would be discriminatory.** Conventional-like NGT plants should be treated conventionally; this extra requirement is creating unjustified distinctions and administrative burden

### **Patents and patentability**

The rapporteur also takes note of the concerns expressed with regard to the patent on NGTs by breeders and farmers. The rapporteur believes that this should be regulated in existing separate regulations where they are currently regulated to avoid having this proposal go beyond its scope. The rapporteur therefore supports the proposed approach by the commission to assess on a regular basis and submit a report on how to address this after the legislation has worked in practice in order to assess if a technique is subject to be patentable.

The Committee on Agriculture and Rural Development (AGRI) also has shared competencies on some provisions pursuant to Rule 57 with the Committee on the Environment, Public Health and Food Safety (ENVI). The rapporteur is therefore committed to working constructively with the rapporteur from the AGRI committee to find a good and balanced proposal for these techniques.

**ANNEX: LIST OF ENTITIES OR PERSONS  
FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT**

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur declares that she has received input from the following entities or persons in the preparation of the report, until the adoption thereof in committee:

<b>Entity and/or person</b>
Euroseeds
KRAV Ekonomisk Förening
KWS SAAT SE & Co. KGaA
European Commission: DG Sante

The list above is drawn up under the exclusive responsibility of the rapporteur.

## MINORITY POSITION

pursuant to Rule 55(4) of the Rules of Procedure  
Christophe Clergeau, Martin Häusling and Anja Hazekamp

By exempting category 1 NGTs, which will be the vast majority of NGTs, from GMO risk assessment, monitoring, traceability and consumer labelling, the Commission fails to respect consumer rights as well as the precautionary principle, laid down in the TFEU. Furthermore, there is no scientific basis underlying the criteria in Annex I, which defines if a NGT fulfils the criteria of ‘equivalence’ to conventional plants. The criteria have no bearing on safety therefore there is no guarantee that GM plants meeting the criteria have a lower level of risk to human health and the environment. The Commission proposal ignores aspects linked to coexistence with organic and conventional production. Finally, the alleged benefits of NGTs do not justify excluding NGT products from existing GMO rules and will not contribute to the necessary just transition in agriculture.

Unfortunately, the compromise amendments presented by the rapporteur further exacerbate these issues. We would like to record our disapproval regarding the extremely tight timeline that was applied to this dossier, which made it impossible to adequately consider and discuss different scientific opinions, notably when it came to what could constitute proper criteria for NGT category 1.



13.12.2023

## OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on the Environment, Public Health and Food Safety  
on 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  
(COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Rapporteur for opinion: Veronika Vrecionová

### AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on Agriculture and Rural Development, as the committee responsible, to take the following into account:

#### Amendment 1

##### Proposal for a regulation Title 1

*Text proposed by the Commission*

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)

*Amendment*

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 **and Directive 98/44/EC** (Text with EEA relevance)

#### Amendment 2

##### 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, 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).

(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 3

#### 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

###### *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.

**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.

#### Amendment 4

##### 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 ***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. Targeted mutagenesis and cisgenesis to obtain Category 1 NGT plants and products should be exempted in Directive 2001/18/EC Annex 1 B like mutagenesis and cell fusion. A periodic review of the approach to establishing equivalence to conventional breeding methods is required in order to reflect scientific and technological progress.***

#### Amendment 5

##### 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

*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, **excluding** microorganisms, **fungi and animals for which** the available knowledge **is more limited**. For the same reason, this Regulation should only cover plants obtained by certain NGTs: targeted mutagenesis and cisgenesis (including intragenesis) (hereinafter ‘NGT plants’), but not by other new genomic techniques. Such NGT plants do not carry genetic material from non-crossable species. GMOs produced by other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) should remain subject only to the Union GMO legislation, given that the resulting plants might bear specific risks associated to the transgene. Moreover, **there is no indication that current requirements in the Union GMO legislation for GMOs obtained by transgenesis need adaptation at the present time**.

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

#### *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 6**

### **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’)

##### *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

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.

## Amendment 7

### 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

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

*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.

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 ('category 1 NGT plants') should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques.***

## Amendment 8

### 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***

##### *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 ***and prior to the placing on the market of NGT products*** should be conducted by national competent authorities as this would be less administratively burdensome for operators. The verification procedure ***of category 1 NGT plant status*** should be conducted at ***national level based on the scientific opinion of 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.

plant status declarations.

## Amendment 9

### 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).***

## Amendment 10

### 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 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***

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

***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).

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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).

## **Amendment 11**

### **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 catalogues and/or common catalogue of varieties of agricultural plant species , including information on the technique(s) used to obtain the trait(s).***

## **Amendment 12**

### **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.*

## **Amendment 13**

### **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.

## **Amendment 14**

### **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.

*Justification*

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

## **Amendment 15**

**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 [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].***

*Amendment*

***deleted***

**Amendment 16**

**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

*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, set out in Article 26b of Directive

those goals.

2001/18/EC would undermine those goals.

## Amendment 17

### 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.

## Amendment 18

### 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 Union, 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.*

## Amendment 19

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

## Amendment 20

### Proposal for a regulation

#### Recital 45 a (new)

*Text proposed by the Commission*

*Amendment*

**(45 a) The European Parliament has called for the EU and its Member States not to grant patents on biological material and to safeguard the freedom to operate and the breeder's exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT**

*plants, which by definition are not transgenic plants. 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). As current provisions do not provide for a full breeder's exemption in patent law, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Hence, these plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption. NGT plants, their derived seed, their plant material, associated genetic material such as genes and gene sequences, and plant traits should therefore be excluded from patentability. The exclusion from patentability should be applied in a consistent manner across legislation. Furthermore, in order to avoid that patents are being granted or patent applications can be submitted while further legal provisions on the issue would be postponed, it should be ensured that the 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. The assessment should address in particular 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 SMEs. The Commission should present its report no later than 2026, accompanied by the appropriate legislative proposals in order to ensure further necessary changes to the framework for intellectual property*

*rights.*

## Amendment 21

### 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 through 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 Commission should provide assistance and guidelines to Member States in this respect, upon request.*

## Amendment 22

### Proposal for a regulation Article 3 – 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 defined in Article 2 point (1) of Regulation (EU) 2016/2031 (1a)** 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 gene pool **for breeding purposes** that temporarily may have been inserted during the development of the NGT plant;

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***1a Regulation (EU) 2016/2031 of the European Parliament and of the Council***

### **Amendment 23**

#### **Proposal for a regulation Article 3– 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;

### **Amendment 24**

#### **Proposal for a regulation Article 3– 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;

### **Amendment 25**

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

*Text proposed by the Commission*

*Amendment*

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

### **Amendment 26**

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

### Article 3– 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;***

*Justification*

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

### Amendment 27

#### Proposal for a regulation

#### Article 3 – 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;***

*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 28

#### Proposal for a regulation

#### Article 3 – 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***;

## **Amendment 29**

### **Proposal for a regulation Article 4 – point 2**

*Text proposed by the Commission*

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

*Amendment*

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

## **Amendment 30**

### **Proposal for a regulation Article 4 - paragraph 1a (new)**

*Text proposed by the Commission*

*Amendment*

***(1 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.***

## **Amendment 31**

### **Proposal for a regulation Article 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***Article 4a  
Exclusion from patentability***

***NGT plants, plant material and parts thereof shall not be patentable.***

## **Amendment 32**

### **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 ***organisms that result from the application of techniques of genetic modification listed in Annex I B to Directive 2001/18/EC*** shall ***also*** apply to category 1 NGT plants.

## **Amendment 33**

### **Proposal for a regulation Article 5 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

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

## **Amendment 34**

### **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 category 1 NGT plants and to products produced from or by such plants. ***Seven years after the entry into force of this Regulation, the 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 NGTs in organic production.***

**Amendment 35**

**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 established under Article 24 of this Regulation or Regulation 1829/2003.***

*Justification*

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

**Amendment 36**

**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.

**Amendment 37**

**Proposal for a regulation**

**Article 6 – title**

*Text proposed by the Commission*

*Amendment*

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

Verification procedure of category 1 NGT plant status.

### **Amendment 38**

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

#### **Article 6 – paragraph 3 – point c**

*Text proposed by the Commission*

*Amendment*

(c) a description of the trait(s) and characteristics which have been introduced or modified;

(c) a description of the trait(s) and characteristics which have been introduced or modified ***including information on the technique(s) used to obtain the trait(s)***;

*Justification*

*To align with previous amendments on information in the database - see recital 23.*

### **Amendment 39**

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

#### **Article 6 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

4. The competent authority shall acknowledge receipt of the verification request to the requester ***without undue delay***, stating the date of receipt. It shall make available the request to the other Member States and to the Commission ***without undue delay***.

4. The competent authority shall acknowledge receipt of the verification request to the requester ***within 10 working days***, stating the date of receipt. It shall make available the request to the other Member States and to the Commission ***within 10 working days***.

*Justification*

*The timeline should be more predictable with firm number of days to make it easier for particularly SMEs to know the length of the process.*

## Amendment 40

### Proposal for a regulation Article 6 – paragraph 5

*Text proposed by the Commission*

5. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission ***without undue delay*** of the inadmissibility of the verification request and shall provide the reasons of its decision.

*Amendment*

5. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission ***within 10 working days*** of the inadmissibility of the verification request and shall provide the reasons of its decision.

## Amendment 41

### Proposal for a regulation Article 6 – paragraph 6

*Text proposed by the Commission*

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.

*Amendment*

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the ***national*** competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The ***national*** competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.

## Amendment 42

### Proposal for a regulation Article 6 – paragraph 7

*Text proposed by the Commission*

7. The other Member States and the Commission may make **comments** to the verification report within 20 days from the date of receipt of that report.

*Amendment*

7. The other Member States and the Commission may make **reasoned scientific objections** to the verification report within 20 days from the date of receipt of that report. **Those reasoned scientific objections shall solely refer to the criteria set out in Annex I and shall include a scientific justification.**

**Amendment 43**

**Proposal for a regulation  
Article 6 – paragraph 8**

*Text proposed by the Commission*

8. In the absence of any **comments** from a Member State or the Commission, within **10 working days from the expiry of** the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. **It** shall transmit the decision **without undue delay** to the requester, the other Member States and **to** the Commission.

*Amendment*

8. In the absence of any **reasoned scientific objections** from a Member State or the Commission, within the deadline referred to in paragraph 7, the **national** competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. **The national competent authority** shall transmit the decision **within 10 working days** to the requester, the other Member States and the Commission.

**Amendment 44**

**Proposal for a regulation  
Article 6 – paragraph 9**

*Text proposed by the Commission*

9. **In cases where a comment is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the the comment(s) to the Commission without undue delay.**

*Amendment*

**deleted**

## Amendment 45

### Proposal for a regulation Article 6 – paragraph 10

*Text proposed by the Commission*

10. ***The Commission, after having consulted*** the European Food Safety Authority ('the Authority'), shall ***prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant*** within 45 working days from the date of receipt of ***the comment(s), taking the latter into account***. The decision ***shall be adopted in accordance with the procedure referred to in Article 28(2)***.

*Amendment*

10. ***Where reasoned scientific objections have been made, the national competent authority shall ask*** the European Food Safety Authority ('the Authority') ***for a scientific opinion on the verification report***. ***The Authority shall issue its scientific opinion on the verification report within 30 days from the date of receipt of that report***. ***The competent authority shall adopt a decision based on the Authority's scientific opinion within 20 working days from the date of receipt of that opinion***. ***The competent authority shall transmit the decision without undue delay to the requester, the other Member States and the Commission***.

## Amendment 46

### Proposal for a regulation Article 7

*Text proposed by the Commission*

***[...]***

*Amendment*

***deleted***

## Amendment 47

### Proposal for a regulation Article 7 a (new)

*Text proposed by the Commission*

*Amendment*

#### ***Article 7a***

***Free movement of category 1 NGT plants and category 1 NGT products***

***Member States shall not prohibit, restrict or impede the deliberate release or the placing on the EU single market of category 1 NGT plants and category 1 NGT products, which comply with the requirements of this Regulation.***

## **Amendment 48**

### **Proposal for a regulation Article 7 b (new)**

*Text proposed by the Commission*

*Amendment*

#### ***Article 7b***

***Plants resulting from a conventional cross between two category 1 NGT plants***

***A plant that is the result of a conventional cross between two verified category 1 NGT plants and in which the introduced modifications are maintained is not considered a new NGT plant and automatically maintains category 1 NGT status.***

#### *Justification*

*It is very useful to clarify the category 1 NGT status of plants that are the result of a conventional cross between two verified category 1 NGT plants.*

## **Amendment 49**

### **Proposal for a regulation Article 10**

*Text proposed by the Commission*

*Amendment*

#### ***Article 10***

***deleted***

***Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’,***



*followed by the identification number of the NGT plant(s) it has been derived from.*

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

## **Amendment 50**

### **Proposal for a regulation**

#### **Article 10 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***It shall be prohibited to label consumer products as containing NGT products or having been developed using NGT. It shall furthermore be prohibited to use ‘negative labelling’ by labelling products as not containing or not having been developed using NGT.***

*Justification*

*It is important to ensure that there will not be any labelling on consumer products - also ‘negative labelling’ as described. Such labelling is discriminatory and misleading towards consumers as the knowledge of plant breeding techniques is not widespread and is traditionally never labelled.*

## **Amendment 51**

### **Proposal for a regulation**

#### **Article 14 – paragraph 1 – point 1**

*Text proposed by the Commission*

*Amendment*

(1) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible

(1) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible

to provide an analytical method that detects, identifies and quantifies, *if duly justified by the notifier, the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);*

to provide an analytical method that detects, identifies and quantifies, *the NGT plant shall fall under category 1 in accordance with Article 3(7)(ba).*

#### *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. Any other outcome will result in enforcement issues and create challenges for imports.*

### **Amendment 52**

#### **Proposal for a regulation Article 16**

*Text proposed by the Commission*

*Amendment*

#### *Article 16*

*deleted*

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

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

### **Amendment 53**

#### **Proposal for a regulation Article 22 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **Part 1 of Annex III** and it does not have any traits referred to in Part 2 of *that* Annex.

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **Article 52(1) of Regulation (EU) .../... (on Plant Reproductive Material)** and it does not have any traits referred to in Part 2 of Annex **III to this**

**Regulation.**

**Amendment 54**

**Proposal for a regulation**

**Article 23**

*Text proposed by the Commission*

*Amendment*

**Article 23**

**deleted**

**Labelling of authorised category 2 NGT products**

***In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s) conveyed by the genetic modification, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation.***

**Amendment 55**

**Proposal for a regulation**

**Article 24**

*Text proposed by the Commission*

*Amendment*

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

Member States ***may*** take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003, ***only in the event that the category 2 NGT plants are able to be detected, identified and quantified by analytical method. These provisions shall not apply to category 1 NGT plants and category 1 NGT products.***

## Amendment 56

### Proposal for a regulation Article 25

*Text proposed by the Commission*

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

*Amendment*

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

*Justification*

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

## Amendment 57

### Proposal for a regulation Article 30 – paragraph 5 a (new)

*Text proposed by the Commission*

*Amendment*

**5 a. No later than 2026, the Commission shall present a report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the role and impact of patents on breeders' and farmers' access to varied plant reproductive material, as well as on innovation and particularly on the opportunities for SMEs. The report shall assess whether further legal provisions are necessary in addition to those provided for in Article 4a and Article 33a of this Regulation. Where appropriate to ensure breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, as well as the ongoing promotion of innovation, particularly with a view to opportunities for SMEs, the report shall be accompanied by a roadmap to address further necessary adjustments in the intellectual property framework.**

## **Amendment 58**

### **Proposal for a regulation Article 33 a (new)**

*Text proposed by the Commission*

*Amendment*

#### *Article 33a*

##### *Amendments to Directive 98/44/EC*

*Article 4 of Directive 98/44/EC on the legal protection of biotechnological inventions is amended as follows:*

*In paragraph 1, points (c) and (d) are added:*

*'(c) NGT plants, plant material and parts thereof, as defined in Regulation (EU) .../... [insert reference to this Regulation];*

*(d) plants, plant material and parts thereof that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B to that directive.'*

#### *Justification*

*Technical alignment in relation to the exclusion of the plant material from patentability.*

## **Amendment 59**

### **Proposal for a regulation Article 34 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

It shall apply from [24 months from the date of entry into force of this Regulation].

It shall apply from [24 months from the date of entry into force of this Regulation].  
***However, Article 4a and Article 33a shall apply from the date of entry into force.***

## **Amendment 60**

### **Proposal for a regulation Annex I – paragraph 1**

*Text proposed by the Commission*

A NGT plant is considered equivalent to conventional plants ***when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.***

*Amendment*

A NGT plant is considered equivalent to conventional plants ***if the following conditions*** referred to in points 1 ***and 1a*** are met:

## **Amendment 61**

### **Proposal for a regulation Annex I – point 1**

*Text proposed by the Commission*

(1) substitution or insertion of no more than 20 nucleotides;

*Amendment*

(1) ***The number of the following mutation events, which can be combined with each other, does not exceed 3 per any protein-coding sequence (mutations in introns and regulatory sequences are excluded from this limit):***

(a) substitution or insertion of no more than 20 nucleotides;

(b) ***deletion of any number of nucleotides;***

## **Amendment 62**

### **Proposal for a regulation Annex I – point 1 a (new)**

*Text proposed by the Commission*

*Amendment*

(1 a) ***The following genetic modifications, which can be combined with each other, do not create a chimeric protein that is not present in species from the gene pool for breeding purposes:***

(a) ***targeted insertion of continuous DNA sequences existing in the gene pool for breeding purposes;***

*(b) targeted substitution of endogenous DNA sequences with continuous DNA sequences existing in the gene pool for breeding purposes;*

*(c) inversion or translocation of continuous endogenous DNA sequences existing in the gene pool for breeding purposes.*

## **Amendment 63**

### **Proposal for a regulation Annex I – point 2**

*Text proposed by the Commission*

*Amendment*

*(2) deletion of any number of nucleotides;* **deleted**

## **Amendment 64**

### **Proposal for a regulation Annex I – point 3**

*Text proposed by the Commission*

*Amendment*

*(3) on the condition that the genetic modification does not interrupt an endogenous gene:* **deleted**

*(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;*

*(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;*

## **Amendment 65**

### **Proposal for a regulation Annex I – point 4**

*Text proposed by the Commission*

*Amendment*

**(4) targeted inversion of a sequence of any number of nucleotides;** **deleted**

#### **Amendment 66**

##### **Proposal for a regulation Annex I – point 5**

*Text proposed by the Commission*

*Amendment*

**(5) any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool.** **deleted**

#### **Amendment 67**

##### **Proposal for a regulation Annex III – Part 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

Traits justifying the incentives referred to in Article 22:

Traits justifying the incentives referred to in Article 22 **are listed in Article 52(1) of Regulation (EU) .../... ( on Plant Reproductive Material).**

#### *Justification*

*The sustainability assessment should be in line with Regulation on Plant Reproductive Material, which establishes the sustainability requirements for all types of Plant Reproductive Material. The following points (1 to 7 ) are deleted.*

#### **Amendment 68**

##### **Proposal for a regulation Annex III – Part 1– point 1**

*Text proposed by the Commission*

*Amendment*



**(1) yield, including yield stability and yield under low-input conditions;** *deleted*

#### **Amendment 69**

##### **Proposal for a regulation Annex III – Part 1– point 2**

*Text proposed by the Commission*

*Amendment*

**(2) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses and other pests;** *deleted*

#### **Amendment 70**

##### **Proposal for a regulation Annex III – Part 1 – point 3**

*Text proposed by the Commission*

*Amendment*

**(3) tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;** *deleted*

#### **Amendment 71**

##### **Proposal for a regulation Annex III – Part 1– point 4**

*Text proposed by the Commission*

*Amendment*

**(4) more efficient use of resources, such as water and nutrients;** *deleted*

#### **Amendment 72**

##### **Proposal for a regulation Annex III – Part 1– point 5**

*Text proposed by the Commission*

*Amendment*

**(5) characteristics that enhance the sustainability of storage, processing and** *deleted*

*distribution;*

#### **Amendment 73**

##### **Proposal for a regulation Annex III – Part 1– point 6**

*Text proposed by the Commission*

*Amendment*

**(6) improved quality or nutritional characteristics;** **deleted**

#### **Amendment 74**

##### **Proposal for a regulation Annex III – Part 1– point 7**

*Text proposed by the Commission*

*Amendment*

**(7) reduced need for external inputs, such as plant protection products and fertilisers.** **deleted**

#### **Amendment 75**

##### **Proposal for a regulation Annex III – Part 2**

*Text proposed by the Commission*

*Amendment*

**2 Traits excluding the application of the incentives referred to in Article 22: tolerance to herbicides.** **deleted**

#### *Justification*

*Annex III, Part 2 excludes NGT plants featuring herbicide-tolerant traits from the regulatory incentives. Such an exclusion is further not consistent with recital 36 which clarifies that the proposed Regulation is not intended to take specific measures on herbicide tolerant NGT plants.*

**ANNEX: ENTITIES OR PERSONS  
FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT**

The rapporteur declares under her exclusive responsibility that she did not receive input from any entity or person to be mentioned in this Annex pursuant to Article 8 of Annex I to the Rules of Procedure.

## PROCEDURE – COMMITTEE ASKED FOR OPINION

<b>Title</b>	Plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625
<b>References</b>	COM(2023)0411 – C9-0238/2023 – 2023/0226(COD)
<b>Committee responsible</b> Date announced in plenary	ENVI 19.10.2023
<b>Opinion by</b> Date announced in plenary	AGRI 19.10.2023
<b>Associated committees - date announced in plenary</b>	19.10.2023
<b>Rapporteur for the opinion</b> Date appointed	Veronika Vrecionová 28.8.2023
<b>Discussed in committee</b>	26.10.2023
<b>Date adopted</b>	11.12.2023
<b>Result of final vote</b>	+: 34 –: 11 0: 1
<b>Members present for the final vote</b>	Mazaly Aguilar, Clara Aguilera, Daniel Buda, Isabel Carvalhais, Asger Christensen, Dacian Cioloș, Ivan David, Paolo De Castro, Jérémy Decerle, Salvatore De Meo, Herbert Dorfmann, José Manuel Fernandes, Paola Ghidoni, Martin Häusling, Martin Hlaváček, Krzysztof Jurgiel, Jarosław Kalinowski, Elsi Katainen, Camilla Laureti, Norbert Lins, Elena Lizzi, Colm Markey, Marlene Mortler, Ulrike Müller, Maria Noichl, Juozas Olekas, Eugenia Rodríguez Palop, Daniela Rondinelli, Katarína Roth Nevedálová, Bert-Jan Ruissen, Anne Sander, Veronika Vrecionová, Sarah Wiener, Juan Ignacio Zoido Álvarez
<b>Substitutes present for the final vote</b>	Anna Deparnay-Grunenberg, Dino Giarrusso, Charles Goerens, Claude Gruffat, Anja Hazekamp, Peter Jahr, Cristina Maestre Martín De Almagro, Sandra Pereira, Michaela Šojdrová, Tom Vandenkendelaere, Thomas Waitz
<b>Substitutes under Rule 209(7) present for the final vote</b>	Mercedes Bresso

## FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

34	+
ECR	Mazaly Aguilar, Bert-Jan Ruissen, Veronika Vrecionová
ID	Ivan David, Paola Ghidoni, Elena Lizzi
NI	Dino Giarrusso
PPE	Daniel Buda, Salvatore De Meo, Herbert Dorfmann, José Manuel Fernandes, Peter Jahr, Jarosław Kalinowski, Norbert Lins, Colm Markey, Marlene Mortler, Anne Sander, Michaela Šojdrová, Tom Vandenkendelaere, Juan Ignacio Zoido Álvarez
Renew	Asger Christensen, Dacian Cioloș, Jérémy Decerle, Charles Goerens, Martin Hlaváček, Elsi Katainen, Ulrike Müller
S&D	Clara Aguilera, Mercedes Bresso, Paolo De Castro, Camilla Laureti, Cristina Maestre Martín De Almagro, Juozas Olekas, Daniela Rondinelli

11	-
ECR	Krzysztof Jurgiel
NI	Katarína Roth Neveďalová
S&D	Maria Noichl
The Left	Anja Hazekamp, Sandra Pereira, Eugenia Rodríguez Palop
Verts/ALE	Anna Deparnay-Grunenberg, Claude Gruffat, Martin Häusling, Thomas Waitz, Sarah Wiener

1	0
S&D	Isabel Carvalhais

**Key to symbols:**

- + : in favour
- : against
- 0 : abstention

## PROCEDURE – COMMITTEE RESPONSIBLE

<b>Title</b>	Plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625
<b>References</b>	COM(2023)0411 – C9-0238/2023 – 2023/0226(COD)
<b>Date submitted to Parliament</b>	6.7.2023
<b>Committee responsible</b> Date announced in plenary	ENVI 19.10.2023
<b>Committees asked for opinions</b> Date announced in plenary	AGRI 19.10.2023
<b>Associated committees</b> Date announced in plenary	AGRI 19.10.2023
<b>Rapporteurs</b> Date appointed	Jessica Polfjård 28.8.2023
<b>Discussed in committee</b>	7.11.2023
<b>Date adopted</b>	24.1.2024
<b>Result of final vote</b>	+: 47 –: 31 0: 4
<b>Members present for the final vote</b>	Catherine Amalric, Maria Arena, Hildegard Bentele, Sergio Berlato, Michael Bloss, Delara Burkhardt, Pascal Canfin, Sara Cerdas, Mohammed Chahim, Nathalie Colin-Oesterlé, Maria Angela Danzi, Esther de Lange, Christian Doleschal, Bas Eickhout, Pietro Fiocchi, Helène Fritzson, Malte Gallée, Gianna Gancia, Catherine Griset, Teuvo Hakkarainen, Anja Hazekamp, Martin Hojsík, Jan Huitema, Karin Karlsbro, Petros Kokkalis, Peter Liese, Javi López, César Luena, Marian-Jean Marinescu, Lydie Massard, Liudas Mažylis, Marina Measure, Silvia Modig, Dolores Montserrat, Alessandra Moretti, Ville Niinistö, Nikos Papandreou, Francesca Peppucci, Stanislav Polčák, Jessica Polfjård, Erik Poulsen, Nicola Procaccini, Frédérique Ries, María Soraya Rodríguez Ramos, Maria Veronica Rossi, Silvia Sardone, Günther Sidl, Maria Spyraiki, Nils Torvalds, Edina Tóth, Achille Variati, Petar Vitanov, Alexandr Vondra, Mick Wallace, Pernille Weiss, Emma Wiesner, Michal Wiezik, Tiemo Wölken
<b>Substitutes present for the final vote</b>	Asger Christensen, Christophe Clergeau, Margarita de la Pisa Carrión, Martin Häusling, Ska Keller, Danilo Oscar Lancini, Sara Matthieu, Marlene Mortler, Manuela Ripa, Nicolae Ștefănuță, Idoia Villanueva Ruiz
<b>Substitutes under Rule 209(7) present for the final vote</b>	Mazaly Aguilar, Katarina Barley, Franc Bogovič, Daniel Buda, Ana Collado Jiménez, Paola Ghidoni, Peter Jahr, Thierry Mariani, Nora Mebarek, Sara Skytvedal, Michaela Šojdrová, Veronika Vrecionová, Stefania Zambelli
<b>Date tabled</b>	29.1.2024

## FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

47	+
ECR	Mazaly Aguilar, Sergio Berlato, Pietro Fiocchi, Teuvo Hakkarainen, Margarita de la Pisa Carrión, Nicola Procaccini, Alexandr Vondra, Veronika Vrecionová
ID	Gianna Gancia, Paola Ghidoni, Danilo Oscar Lancini, Maria Veronica Rossi, Silvia Sardone
PPE	Hildegard Bentele, Franc Bogovič, Daniel Buda, Nathalie Colin-Oesterlé, Ana Collado Jiménez, Christian Doleschal, Peter Jahr, Esther de Lange, Peter Liese, Marian-Jean Marinescu, Liudas Mažylis, Dolors Montserrat, Marlene Mortler, Francesca Peppucci, Stanislav Polčák, Jessica Polfjård, Sara Skytvedal, Michaela Šojdrová, Maria Spyraki, Pernille Weiss, Stefania Zambelli
Renew	Catherine Amalric, Pascal Canfin, Asger Christensen, Jan Huitema, Karin Karlsbro, Erik Poulsen, Frédérique Ries, Nils Torvalds, Emma Wiesner
S&D	Helène Fritzon, Javi López, César Luena, Achille Variati

31	-
NI	Maria Angela Danzi, Edina Tóth
Renew	Martin Hojsík, Michal Wiezik
S&D	Maria Arena, Katarina Barley, Delara Burkhardt, Sara Cerdas, Mohammed Chahim, Christophe Clergeau, Nora Mebarek, Nikos Papandreou, Günther Sidl, Petar Vitanov, Tiemo Wölken
The Left	Anja Hazekamp, Petros Kokkalis, Marina Measure, Silvia Modig, Idoia Villanueva Ruiz, Mick Wallace
Verts/ALE	Michael Bloss, Bas Eickhout, Malte Gallée, Martin Häusling, Ska Keller, Lydie Massard, Sara Matthieu, Ville Niinistö, Manuela Ripa, Nicolae Ștefănuță

4	0
ID	Catherine Griset, Thierry Mariani
Renew	María Soraya Rodríguez Ramos
S&D	Alessandra Moretti

Key to symbols:

+ : in favour

- : against

0 : abstention