



2023/0226(COD)

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# COMPROMISE AMENDMENT

## 1- 20

**Draft report**

**Jessica Polfjärd**

(PE755.986v01-00)(PE756.242v01-00)(PE756.243v01-00)(PE756.244v01-00)

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

Proposal for a regulation

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

Agence Europe

**Compromise Amendment 1 - Subject matter and scope**  
**Supported by EPP, Renew, ECR**

Compromise amendment replacing Amendments 364-384, ACA 1

**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.***

Or. en

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

*Text proposed by the Commission*

(1) NGT plants;

*Amendment*

(1) NGT plants;

**Proposal for a regulation**  
**Article 2 – paragraph 1 - point 4**

*Text proposed by the Commission*

(4) products, other than food and feed containing or consisting of NGT plants.

*Amendment*

(4) products, other than food and feed containing or consisting of NGT plants.

## **Alternative Compromise Amendment 1 - Subject matter and scope**

**Supported by S&D, Greens/EFA, The Left**

Compromise amendment replacing Amendments 364-384

### **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 annual **arable crop** 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.*

### **Proposal for a regulation**

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

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

(1) NGT plants;

##### *Amendment*

(1) NGT plants *in their use as annual arable crops*;

### **Compromise Amendment 2 - Definitions** **Supported by EPP, Renew, ECR**

Compromise amendment replacing Amendments 10-12, 386-393, 396-457, AGRI 22-AGRI 28, ACA2

### **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

##### *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;

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;

Or. en

### **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;

### **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 or cross-bred, using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;

### **Proposal for a regulation** **Article 3 – paragraph 1 – point 15a (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. It recognises that the health of humans, domestic and wild animals, plants, and the wider environment including ecosystems are closely interlinked and inter-dependent;***

**Alternative Compromise Amendment 2 - Definitions**

**Supported by S&D, Greens/EFA, The LEFT**

Compromise amendment replacing Amendments 10-12, 386-393, 396-457, AGRI 22-AGRI 28

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 6**

*Text proposed by the Commission*

*Amendment*

(6) ‘***breeders’*** gene pool’ means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy ***and bridge crosses***;

(6) ‘gene pool ***for conventional 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 embryo rescue ***or*** induced polyploidy. ***Transgenes shall not be part of the plant’s gene pool;***

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 15a (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. It recognises that the health of humans, domestic and wild animals, plants, and the wider environment***

*including ecosystems are closely interlinked and inter-dependent;*

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

*(15b) 'polluter pays principle' means a principle according to which polluters should bear the costs of their pollution or environmental damage, including the cost of measures taken to prevent, control and remedy pollution, as well as the costs the polluters impose on society.*

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

*(15c) 'extended producer responsibility (EPR)' means an environmental policy approach in which a producer's responsibility, physical and/or financial, for a product is extended to the post-consumer stage of a product's life-cycle.*

**Compromise Amendment 3 - Deliberate release of NGT plants**  
**Supported by EPP, S&D, Renew, ECR**

Compromise amendment replacing Amendments 13, 458- 479, AGRI 29

**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

(b) is progeny of plant(s) referred to in

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point (a); or

point (a) *on the condition that the criteria of equivalence set out in Annex 1 are still satisfied* ; or

## Proposal for a regulation

### Article 4 – paragraph 1 – 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.

### Compromise Amendment Category 1 NGT

#### 4 - Verification procedure, System of exchange

### Supported by EPP, Renew, ECR

Compromise amendment replacing Amendments 18-20, 509- 654, 954-977, AGRI 37 - AGRI 46, ACA4

## Proposal for a regulation

### Article 6 – paragraph 1

#### *Text proposed by the Commission*

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)*.

#### *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 *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 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)**.

### **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(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 including disclosure of the sequence of genetic modification;***

### **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)***;

### **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;***

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

(da) *the denomination of the variety*

**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 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.

**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 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. **These reasoned objections must solely refer to the criteria as set out in Annex I and Annex III and shall include a scientific justification.**

**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.

**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.

**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*

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

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

*Text proposed by the Commission*

*Amendment*

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

- (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.**

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

*Text proposed by the Commission*

*Amendment*

- (b a) the denomination of the variety;**

**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 including disclosure of the sequence of genetic modification;**

**Proposal for a regulation**  
**Article 7 – paragraph 7**

*Text proposed by the Commission*

*Amendment*

- 7. The Commission shall publish **a**

- 7. The Commission shall publish **the**

*summary of the decision in the Official Journal of the European Union.*

*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.*

### **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 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.

### **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

*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.

*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

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.

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.

**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.

**Proposal for a regulation**  
**Article 27 -paragraph 1 - point a**

*Text proposed by the Commission*

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

*Amendment*

*Deleted*

**Proposal for a regulation**

**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*

**Alternative Compromise Amendment 4 - Verification procedure, System of exchange**  
**Category 1 NGT**

**Supported by S&D, Greens/EFA**

Compromise amendment replacing: 18-20, 509- 654, AGRI 37 - AGRI 46

**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 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 26.

**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(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 including disclosure of the sequence of genetic modification;***

**Proposal for a regulation**

**Article 6 – paragraph 3 – point c b (new)**

*Text proposed by the Commission*

**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*

***(cb) any granted patent or pending application for patent covering the whole Cat.1 NGT plant or part of it;***

*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 26;

**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;***

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

*Text proposed by the Commission*

*Amendment*

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

**Article 6 – paragraph 3 – point db (new)**

*Text proposed by the Commission*

*Amendment*

**(db) a declaration on the non-applicability of Regulation (EU) 2015/2283 on Novel Foods, or on the correct application of possible obligations arising from this Regulation;**

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

*Text proposed by the Commission*

*Amendment*

**(ea) an environmental risk assessment carried out in accordance with the delegated act adopted in accordance with Article 26;**

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

*Text proposed by the Commission*

*Amendment*

**(eb) a monitoring plan for environmental effects;**

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

*Text proposed by the Commission*

*Amendment*

**(fa) samples of the category 1 NGT plant and their control samples, and information as to the place where the**

*reference material can be accessed;*

**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 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.

**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 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. **These reasoned objections shall notably refer to the criteria as set out in Annex I and Annex III and include a scientific justification.**

**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 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.

**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*

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.

**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

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

28(2).

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

*Text proposed by the Commission*

*Amendment*

**(b a) the denomination of the variety;**

**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 including disclosure of the sequence of genetic modification;***

**Proposal for a regulation**  
**Article 7 – paragraph 2 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

**(ca) any granted patent or pending application for patent covering the whole Cat.1 NGT plant or part of it;**

**Proposal for a regulation**  
**Article 7 – paragraph 2 – point d a (new)**

*Text proposed by the Commission*

*Amendment*

**(da) an environmental risk assessment carried out in accordance with the delegated act adopted in accordance with Article 26;**

Or. en

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

*Text proposed by the Commission*

*Amendment*

**(db) a monitoring plan for environmental effects;**

**Proposal for a regulation**

**Article 7 – paragraph 2 – point d c (new)**

*Text proposed by the Commission*

*Amendment*

**(dc) samples of the category 1 NGT plant and their control samples, and information as to the place where the reference material can be accessed;**

**Proposal for a regulation**

**Article 7 – paragraph 2 – point d d (new)**

*Text proposed by the Commission*

*Amendment*

**(dd) a declaration on the non-applicability of Regulation (EU) 2015/2283 of 25 November 2015 on novel foods, or on the correct application of possible obligations arising from this Regulation;**

**Proposal for a regulation**

**Article 7 – paragraph 7**

*Text proposed by the Commission*

*Amendment*

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

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.**

**Compromise Amendment  
Supported by EPP, Renew, ECR**

**4A - Freedom of Movement**

Compromise amendment replacing Amendments: 723, 655, 662, 661, AGRI 47

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

*Text proposed by the Commission*

*Amendment*

**Article 7a**

***Freedom of movement***

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

**Compromise Amendment            5 - Patentability**  
**Supported by EPP, S&D, Renew, Greens/EFA, ECR, The Left**

Compromise amendment replacing Amendments 73, 85, 331, 353, 362, 363, 424, 433, 479, 491, 492, 493, 508, 530, 542, 938, 993-995, 1004, 1007, 1014, 1015, 1035- 1037, AGRI 20, AGRI 31, AGRI 33, AGRI 57, AGRI 58, AGRI 59

**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 process features they contain shall not be patentable.***

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

*Text proposed by the Commission*

*Amendment*

***5 a.    The Commission shall by June 2025 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, the report shall be accompanied by a legislative proposal to address further necessary adjustments in the intellectual property framework.*

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

*Amendment*

*Present Text*

**Article 33a**

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

***1. 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, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) .../... [insert reference to 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.'***

***Paragraph 4 is added:***

***'4. Paragraph 2 and 3 shall be without***

*prejudice to the exclusions from patentability covered in paragraph 1.'*

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

*Text proposed by the Commission*

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

*Amendment*

2. 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.**

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

*Text proposed by the Commission*

*Amendment*

**(45a) 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 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 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 could be granted or patent applications could be submitted between the date of the entry into force of this Regulation and the application of its provisions, it should be ensured that the 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 announced 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 changes to the intellectual property rights framework.*

**Compromise Amendment**            **6 - Status of category - 1 NGT Plants (organic)**  
**Supported by EPP, Renew, ECR**

Compromise amendment replacing Amendments 4, 16, 217- 230, 480-497, 1009, AGRI 10, AGRI 32, AGRI 33, AGRI 34, AGRI 35

**Proposal for a Regulation**

**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), point (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 European Commission shall present a report on the evolution of the consumers' and producers' perception, accompanied, where appropriate, by a legislative proposal.**

### **Proposal for a regulation Article 5 – paragraph 3a (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 authorized in organic production in accordance with Article 24 and 25 Regulation (EU) 2018/848, shall not constitute a non-compliance of that Regulation.**

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

*Text proposed by the Commission*

*Amendment*

(23) Regulation (EU) 2018/848 of the European Parliament and the Council on organic production and labelling of organic products and repealing Council Regulation (EC) 834/2007<sup>(20)</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

(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>(20)</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**

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.

*production requires further consideration.* The use of category 1 NGT plants should therefore be prohibited in organic production, *until further consideration.*

**Compromise Amendment 6A - Article 9**  
**Supported by EPP, S&D, Renew, Greens/EFA, ECR**

Compromise amendment replacing Amendments : 664- 697  
**Article 9 – paragraph 1 – subparagraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

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

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

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

*Text proposed by the Commission*

*Amendment*

*(b a) the denomination of the variety ;*

**Proposal for a regulation**

**Article 9 – paragraph 1 – subparagraph 2 – point d**

*Text proposed by the Commission*

*Amendment*

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

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

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

*Text proposed by the Commission*

*Amendment*

*(e a) If provided, the opinion or statement of EFSA, as referred to in Article 6 (10) and Article 7(5), and*

**Article 9 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. The database shall be publicly available.

2. The database shall be publicly available, *and in on line format.*

**Compromise Amendment 7 - Labelling and traceability**  
**Supported by EPP, Renew, ECR**

Compromise amendment replacing Amendments: 21, 698-719, AGRI 49, AGRI 50, ACA 7

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

**Alternative Compromise Amendment 7 - Labelling and Traceability**

Compromise amendment replacing Amendments: 5, 21, 235-246, 698-719, AGRI 11, AGRI 49, AGRI 50

**Supported by S&D, Greens/EFA**

**Proposal for a regulation**  
**Article 10 – title**

*Text proposed by the Commission*

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

*Amendment*

**Traceability and labelling requirements for category 1 NGT plants, category 1** NGT plant reproductive material, including breeding material **and category 1 NGT products**

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

*Text proposed by the Commission*

Plant reproductive material, including for

*Amendment*

**Category 1 NGT plants, products**

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.

## 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**.

**containing or consisting of** category 1 **NGT plant(s)** and 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 '**New Genomic Techniques**'. **In the case of plant reproductive material, it shall be** followed by the identification number of the NGT plant(s) it has been derived from.

*Amendment*

(24) Provision should be made to ensure transparency **and traceability** as regards the use of NGT plant varieties, to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard consumer trust. **All** NGT plants **approved in the EU** should be listed in a publicly available database **including information on the technique(s) used to obtain the trait(s)**. To ensure traceability, transparency and **freedom of choice for consumers, food producers, farmers and other operators**, plant reproductive material, **plants, food and feed and products** of category 1 NGT plants should be labelled as NGT. **NGT plants should be traceable at all stages between production and consumption of the final products. Traceability measures should make it easier to withdraw products in the event of unforeseen effects on human health, animal health or the environment, and monitor the environmental effects, in line with the precautionary principle.**

### **Alternative Compromise Amendment 7A - Duration of validity of consent and authorisation of category NGT plants**

Compromise amendment replacing Amendments: 739, 740, 814 -824, 867-876

**Supported by S&D, Greens/EFA**

**Proposal for a regulation  
Article 11 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 11a**

***Duration of the validity of the declaration***

***If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports this hypothesis, the competent authority may withdraw its decision referred to in Article 6 (8) or statement referred to in Article 7 (5).***

***The withdrawal decision must be sent by registered mail to the beneficiary of the decision, who has 15 days in which to make observations. In that case, the marketing of the NGT plant or product is prohibited from the day following the date of receipt of the registered letter.***

**Proposal for a regulation  
Article 17 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. The consent granted under Part C of Directive 2001/18/EC shall, after ***the first*** renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for ***an unlimited period, unless the decision referred to in Article 17(6) or (8) provides that the renewal is for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the consent.***

1. The consent granted under Part C of Directive 2001/18/EC shall, after ***each*** renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for ***10 years.***

**Proposal for a regulation  
Article 17 – paragraph 2 a (new)**

**2a.** *If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports this hypothesis, the competent authority may withdraw its decision.*

*The withdrawal decision must be sent by registered mail to the beneficiary of the decision, who has 15 days in which to make observations. In that case, the marketing of the NGT plant or product is prohibited from the day following the date of receipt of the registered letter.*

**Proposal for a regulation**  
**Article 21 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

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

The authorisation shall be valid for a period of 10 years.

**Proposal for a regulation**  
**Article 21 – paragraph 1 b (new)**

*Text proposed by the Commission*

*Amendment*

**1b.** *If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports this hypothesis or if the competent authority may withdraw its decision.*

*The withdrawal decision must be sent by registered mail to the beneficiary of the*

*decision, who has 15 days in which to make observations. In that case, the marketing of the NGT plant or product is prohibited from the day following the date of receipt of the registered letter.*

**Compromise Amendment 8 - Annex I**  
**Supported by EPP, Renew, ECR**

Compromise amendment replacing Amendments: 22-23, 498-507, AGRI 36, 1012, 1039-1077, 1079-1085, 1087-1099, 1101, 1102, AGRI 60, AGRI 61, AGRI 62, AGRI 63, AGRI 64, AGRI 65, AGRI 66, ACA 8

**Proposal for a regulation**  
**Article 2 – point 15b (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.*

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

*Text proposed by the Commission*

*Amendment*

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.*

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

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

*Amendment*

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

*(1) The number of the following genetic modifications, 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;

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

*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 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.***

Or. en

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

*Text proposed by the Commission*

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

*Amendment*

***deleted***

**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:*
- (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;*
- deleted*

**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*

**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*

Or. en

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

*Text proposed by the Commission*

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.

*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, **taking into account potential associated risks and functional consequences in the verification procedure** in order to adapt them to **the latest** scientific and technological **development** as regards the types and extent of modifications which can occur naturally or through conventional breeding.

**Prpoosal for a regulation**  
**Article 30 – paragraph 5b (new)**

*Text proposed by the Commission*

*Amendment*

**5b. Every 4 years, the Commission shall assess the equivalence criteria established in Annex I and, if necessary, update them through a delegated act as referred to in Article 5, paragraph 3.**

**Alternative Compromise Amendment 8 - Annex I**

**Supported by S&D, Greens/EFA**

Compromise amendment replacing Amendments: 22-23, 1012,498-507, AGRI 36, 1012, 1039-1077, 1079-1085, 1087-1099, 1101, 1102, AGRI 60, AGRI 61, AGRI 62, AGRI 63, AGRI 64, AGRI 65, AGRI 66

**Proposal for a regulation**  
**Article 2 – point 15b (new)**

*Text proposed by the Commission*

*Amendment*

**(15b) “Chimeric RNA or protein” means a new RNA or protein that did not exist previously in nature.**

**Proposal for a regulation**  
**Article 2 – point 15c (new)**

*Text proposed by the Commission*

*Amendment*

***(15c) “Novel RNA or protein” means an RNA or protein that does not exist within the gene pool for conventional breeding purposes.***

**Proposal for a regulation**  
**Annex I**

*Text proposed by the Commission*

*Amendment*

***Criteria of equivalence of NGT plants to conventional plants***

***Classification of category 1 NGT plants***

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.

A NGT plant ***may be classified as category 1 if the following conditions*** referred to in points 1, 2 and 3 are met:

- (1) substitution or insertion of no more than 20 nucleotides;***
- (2) deletion of any number of nucleotides;***
- (3) on the condition that the genetic modification does not interrupt an endogenous gene:***
  - (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;***
- (4) targeted inversion of a sequence of any number of nucleotides;***
- (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***

***(1) The following genetic modifications, which can be combined with each other, consist in:***

- (a) substitution or insertion of nucleotides, if the resulting gene sequence does not give rise to a novel or chimeric RNA or protein;***
- (b) deletion of nucleotides, if the resulting gene sequence does not give rise to a novel or chimeric RNA or protein;***

***(2) The following genetic modifications, which can be combined with each other, on the conditions that they do not interrupt one or more endogenous gene and do not create a novel or chimeric protein:***

- (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***

*from the breeders' gene pool.*

sequences existing in the gene pool for breeding purposes ***and if that sequence is not the result of a previous targeted or untargeted genetic modification;***

(c) targeted inversion of a sequence of any number of nucleotides;

***(3) The respect of paragraph 1 and 2 shall be verified through an assessment of the results of the genetic modifications on the modified plant. When compared to the non modified parent of the same species grown under the same conditions, the following result-based criteria shall fulfilled:***

***(a) the whole genome sequencing and profiling shows the genetic modifications have not modified the sequence and function of one or more genes or regulatory sequences, other than the one or those specifically targeted; and***

***(b) the whole transcriptome sequencing realized on the relevant part of the plant shows the genetic modifications have not modified other biochemical pathways than those specifically targeted; and***

***(c) biochemical metabolite (metabolomics) and protein (proteomics) profiling realized on the relevant part of the plant shows the genetic modifications have not induced an increase in the levels of known toxins, allergens or antinutrients, or the production by the plant of novel biochemicals or proteins other than those specifically desired and tested;***

## **Proposal for a regulation**

## Article 5 – paragraph 3

*Text proposed by the Commission*

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.

*Amendment*

***Deleted***

### **Alternative Compromise Amendment 9 - Coexistence**

#### **Supported by S&D, Greens/EFA, The Left**

Compromise amendment replacing Amendments: 321- 323, 720, 722, 724, 737, 738, 740, 923- 932, 935, AGRI 17, AGRI 55

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

#### **Article 24**

*Text proposed by the Commission*

Article 24

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

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

*Amendment*

Article 24

Measures to avoid the unintended presence of NGT plants

***1. Member States shall take appropriate measures to avoid the unintended presence of NGT plants and parts or residues thereof in other crops and products.***

***To that effect, Member States shall develop crop specific and adapted mandatory measures, including buffer strips between NGT crops and non NGT crops, detailed binding measures to avoid cross contamination in the food chain, a system of information for organic and conventional growers with field plots next to those where NGT plants are grown, as well as an enforcement plan and appropriately dissuasive penalties. These measures must be based on the latest scientific and experimental knowledge.***

***2. Before the entry into force of the Regulation, the Commission shall adopt a delegated act in accordance with Article 26 to define minimum crop-specific rules to avoid the unintended presence of NGT***

*plants, including minimal width of buffer strips.*

*3. The Commission shall gather information and coordinate the exchange of information based on the studies at Union and national level, monitor the developments regarding coexistence in the Member States and, on the basis of this information and observations, develop further guidelines for the coexistence of NGT, conventional and organic crops, if needed.*

## **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 NGT plants are expected to result in more cultivation in the Union of 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 **protect** the interests of producers of conventional **and** organic 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.

***Organic and conventional operators should have the right and freedom not to use NGTs in their production process and throughout their supply chain. This Regulation should lay out adequate provisions to ensure the freedom of choice for operators not to use NGT plants and seeds in their production processes. Any additional financial or legal burden to ensure the GMO-free and NGT-free status of production should not fall on farmers and operators who do not wish to use NGTs. Economic losses incurred due to the adventitious presence of GMOs should not fall on NGT-free conventional and organic operators. In most cases of adventitious presence, it is impossible to***

*establish the causes, faults, and therefore responsibilities.*

*To achieve the goal of ensuring the effective functioning of the internal market, and in order to ensure that the coexistence measures are consistent, EU-wide legally binding coexistence measures for cultivation of NGTs should be adopted. Thus, this Regulation should establish coexistence measures, laying the basis for national liability provisions and compensation funds. The Commission should be empowered to draw up delegated acts to cover, in particular, the width of buffer strips between conventional plants and NGT plants, for each type of crop.*

**Alternative Compromise Amendment 10 - Transparency**

Compromise amendment replacing Amendments: 929, 934, 937

**Supported by Greens/EFA, The Left**

***Proposal for a regulation***

**Article 24a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 24a**

**Transparency**

***Member States shall set up public registers in which all locations where NGT plants are bred or cultivated need to be registered, described by means of latitude and longitude coordinates.***

**Alternative Compromise Amendment 11 - Liability Schemes**

Compromise amendment replacing Amendments: 724, 737, 926, 929, 935, 936

**Supported by S&D, Greens/EFA, The Left**

**Proposal for a regulation**  
**Article 24b (new)**

*Text proposed by the Commission*

*Amendment*

**Article 24b**

**Liability schemes**

***Member States shall instate a liability scheme and a compensation fund based on an Extended Producer Responsibility (EPR) scheme to compensate operators in the event of contamination in neighbouring fields as well as contamination caused by joint use of machineries, storages and processing entities in accordance with the polluter pays principle and the One Health approach.***

**Alternative Compromise Amendment 12 - *Opt-out for NGT***

Compromise amendment replacing Amendments: 7, 723, 310- 320, 939 - 947, AGRI 16, AGRI 56

**Supported by S&D, Greens/EFA, The Left**

**Proposal for a regulation**  
**Article 25 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

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

Article 26b of Directive 2001/18/EC shall apply to NGT plants.

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

*Text proposed by the Commission*

*Amendment*

***(37) In order to enable NGT plants to contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity Strategies, cultivation of NGT plants in the Union should be facilitated. This requires predictability for breeders and farmers as regards the***

***deleted***

*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.*

Agence Europe