Draft CAs on NGTs draft opinion - ahead of 2nd Shadow meeting

CA 1

Replacing AM 4

Title

Text proposed by the Commission	*Amendment*
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain ***new genomic*** techniques and their food and feed, and amending Regulation (EU) 2017/625 (Text with EEA relevance)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain ***precision breeding*** techniques and their food and feed, and amending Regulation (EU) 2017/625 and Directive 98/44/EC (Text with EEA relevance)

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

CA 2

Replacing AMs 196 to 204

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 ([1])*** 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*** ~~breeders' gene pool~~ that temporarily may have been inserted during the development of the NGT plant; ***([1])*** Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants

CA 3
Replacing AMs 205 to 212

Article 3 – point 4

Text proposed by the Commission	*Amendment*
(4) 'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at ***precise*** locations in the genome of an organism;	(4) 'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at ***targeted*** locations in the genome of an organism;

CA 4
Replacing AMs 216 to 220

Article 3 – 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 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;

CA 5
Replacing AMs 236 to 239

Article 3 – point 12

Text proposed by the Commission	*Amendment*
(12) 'NGT product' means ***a product, other than*** food and feed***, containing or consisting of a NGT plant and*** food and feed containing, consisting of or produced from ***such a plant***;	(12) 'NGT product' means food and feed containing, consisting of or produced from ***NGT plants, and other products containing or consisting of such plants***;

CA 6
Replacing AMs 249 to 253

Article 4 – 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.

CA 7
Replacing AMs 256 to 265

Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The rules which apply to ***GMOs in Union legislation*** shall ***not*** apply to category 1 NGT plants.	**1.** The rules which apply to ***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**.**

CA 7A and CA G
Replacing AMs 267 to 275 and 103 to 113

Article 5 - paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of Regulation (EU) 2018/848, the rules set out in its Articles 5 (f) (iii) and 11 shall apply to category 1 NGT plants and to products produced from or by such plants.	***deleted***

Commented [MV1]: This is a new CA to delete the ban on NGTs in organic production.
CA G on recital 23 is moved here.

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([47]) 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***.	(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([47]) 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 ***for the purposes of organic production*** should ***be clarified in Regulation (EU) 2018/848***.

CA 8 (patentability)

Replacing AMs 231, 276, 281, 282, 289, 290, 481, 493, 491, 494 and AMs 188, 65, 190, 175, 179, 231, 276, 281 (recital 45a (new)

Commented [MV2]: CA 8 on patentability is expanded to also cover CA L (see below)

Article 5 – paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	2a. ~~[Category 1]~~ NGT plants, plant material and parts thereof shall not be patentable.

Commented [MV3]: Both NGT categories are excluded from patentability.

This Article 5(2a) will be renumbered, so as to be moved into the chapter on General Provisions that covers both NGT categories.
It will thus be renumbered as:
Article 4a (new), titled 'Exclusion from patentability'

Corresponding technical alignments will be made in other parts of the text.

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) ~~[category 1]~~ NGT plants, plant material and parts thereof, as defined in Regulation (EU) .../... [insert reference to this Regulation];
	(d) plant material that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B to that directive.'

Commented [MV4]: Technical alignment ensuring all parts of the plant and its material are excluded from patentability.

Justification

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

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 SME. The report shall assess whether further legal provisions are necessary in addition to those provided for in Article 5(2a) 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 SME, the report shall be accompanied by a roadmap to address further necessary adjustments in the intellectual property framework.

Article 34 – paragraph 2

Text proposed by the Commission	*Amendment*
2. It shall apply from [*24 months from the date of entry into force of this Regulation*].	2. It shall apply from [*24 months from the date of entry into force of this Regulation*]. ***However, Article 5(2a) and Article 33a shall apply from the date of entry into force.***

CA L
Recital 45a (new)

(45a) ~~The issue of patents on NGTs was raised by many stakeholders during the consultation.~~ 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 may also occur in nature and~~ which 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. ~~Category 1~~ NGT plants, their derived seed, their plant material,

Commented [MV5]: CA 8 on patentability also covers CA L.

Commented [MV6]: Deletion to keep text more concise (on request of RE)

Commented [MV7]: Deletion after last technical meeting. This part is not needed here.

	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, ~~to after the study that the Commission intends to do~~ 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.

Commented [MV8]: Deletion to keep text more concise.

CA 9

Replacing AMs 291 to 303 (on Art. 6) and AMs 365 to 377 (on Art. 7)

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
Article 7	***Deleted***

[...]

CA 10

Replacing AMs 308 to 310 and AM 324

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 ***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. ~~***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.***~~

Commented [MV9]: For consistency (technical change), this part is moved into CA 12-13, paragraph 10

CA 11

Replacing AMs 311 to 323 and AM 325

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 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.***

CA 12 - CA 13

Replacing AMs 326 to 337 (on Art. 6 par. 8), AMs 338 to 350 (on Article 9) and AMs 351 to 363 (on Art. 6 par. 10)

Commented [MV10]: CA 12 - CA 13 is reorganised for consistency of the verification procedure.

Article 6 – paragraph 8

Text proposed by the Commission	*Amendment*
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.	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. ~~***based on the Authority's opinion within 20 working days from the date of receipt of that opinion***~~ ***The national*** competent authority shall transmit the decision ~~***without undue delay within 10 working days***~~ to the requester, the other Member States and the Commission.

Commented [MV11]: Deletion for consistency (technical change).
This part is covered in paragraph 10 below.

Article 6 – paragraph 9

Commented [MV12]: For consistency (technical change), Art. 6 par. 9 is deleted. It is covered in par. 10 below.

Text proposed by the Commission	*Amendment*
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.	***deleted***

Article 6 – paragraph 10

Text proposed by the Commission	*Amendment*
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***	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***

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

Commented [MV13]: For consistency (technical change), this part was moved here from CA 10, Art. 6 par. 6.

CA 14

Replacing AMs 378, 379, 381, 382, 386

Article 7 a (new)

Text proposed by the Commission	*Amendment*
	Article7a
	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.

CA 15

Article 22 paragraph 1 and Annex III Part 1

Replacing AMs 463 to 467

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.***

Annex III – Part 1

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].***
	[Deletion of points 1 to 7]

CA 16
Replacing AMs 477 to 480

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*** (477 SD). ***These provisions shall not apply to category 1 NGT plants and category 1 NGT products.***

CA 17
Replacing AMs from 495 to 556

Annex I

Criteria of equivalence of NGT plants to conventional plants

A NGT plant is considered equivalent to conventional plants ***if the following conditions referred to in points 1 and 2 are met:***

~~A NGT plant ***prepared by new genomic techniques*** is considered equivalent to ***a*** conventional plants when if it differs from the recipient/parental plant ***only*** by no more than 20 genetic modifications of the types referred to in points 1 ***and*** 5 ***2, which can be combined which each other.*** in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.~~

(1) ~~***Criteria specific for the use of targeted mutagenesis on the condition that the***~~ ***The number of the following mutation~~s~~ events, which can be combined with each other, ~~per any protein~~***

Commented [MV14]: More clear and more scientifically sound wording.

Commented [MV15]: More clear and more scientifically sound wording.

~~coding sequence~~ 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;

(2) ~~Criteria specific for the use of cisgenesis on the condition that the~~ The genetic modification does not create a chimeric protein that is not ~~already~~ present in ~~a~~ species from the gene pool for breeding purposes~~breeders' gene pool~~:

(a) targeted insertion of a continuous DNA sequence existing in the ***gene pool for breeding purposes***~~breeders' gene pool~~;

(b) targeted substitution of an endogenous DNA sequence with a continuous DNA sequence existing in the ***gene pool for breeding purposes***~~breeders' gene pool~~;

(c) inversion or translocation of a continuous endogenous DNA sequence existing in the gene pool for breeding purposes~~the breeders' 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 from the breeders' gene pool.~~

Commented [MV16]: More clear and more scientifically sound wording.

CAs on Recitals

CA A
Recital 8

Replacing AMs 28 to 32

Text proposed by the Commission	*Amendment*
(8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.	(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 ~~other~~***

mutagenesis methods and cell fusion (RE 30). A periodic review of the approach to establishing equivalence to conventional breeding methods is required in order to reflect scientific and technological progress.

CA B
Recital 14

Replacing AMs 49 to 56

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 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***	(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 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

extent of genetic modifications that can occur in nature or through conventional breeding.	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.

CA C
Recital 14 a (new)

Commented [MV17]: Depends on CA 17 on Annex I. (Recital 14a might be obsolete if no maximum number of genetic modifications is foreseen in Annex I)

Replacing AMs 57, 80, 81

Text proposed by the Commission	*Amendment*
	(14a) In view of the high complexity of plant genomes, the criteria for considering that a NGT plant is equivalent to naturally occurring or conventionally bred plants should reflect the diversity of plants' genomic size and their characteristics. Polyploid plants contain more than two homologous chromosomes. Within this, tetraploid, hexaploid, and octoploid have 4, 6 and 8 sets of chromosomes respectively. Polyploid plants tend to exhibit greater numbers of genetic modifications compared to monoploid plants. This is the case, for instance, with wheat, potato, sugar beet, banana, kiwi, peanut, rapeseed, etc. For polyploid plants, the maximum number of genetic modifications allowed for inclusion in category 1 NGT should be proportionate to the number of genomes they contain.

CA D
Recital 16

Replacing AMs 62 to 69

Text proposed by the Commission	*Amendment*
(16) Category 1 NGT plants and products ***should*** not be subject to the rules and requirements of the Union GMO legislation and to provisions in other Union legislation that apply to GMOs. For legal	(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.	certainty for operators and transparency, a declaration of the category 1 NGT plant status should be obtained prior to deliberate release, including the placing on the market***. NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny ('category 1 NGT plants') should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques. ~~The biological material of plant breeding, which may also occur in nature, must be widely available for plant breeding. Category 1 NGT plants, their derived seed, their plant material, associated genetic material such as genes and gene sequences, and plant traits should be excluded from patentability within the meaning of Directive 98/44/EC.~~***

Commented [MV18]: The part on patentability is deleted because it is dealt with in CA L (patentability recital).

CA E
Recital 18

Replacing AMs 73 to 79

Text proposed by the Commission	*Amendment*
(18) Since the criteria for considering that a NGT plant is equivalent to naturally occurring or conventionally bred plants are unrelated to the type of activity that requires the deliberate release of the NGT plant, a declaration of the category 1 NGT plant status made prior to its deliberate release for any other purpose than placing on the market in the territory of the Union should also be valid for the placing on the market of related NGT products. In view of the high uncertainty existing at the field trial stage about the product reaching the market and the likely involvement of smaller operators in such releases, the verification procedure of category 1 NGT plant status prior to field trials should be conducted by national competent authorities as this would be less administratively burdensome for operators,	(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

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.	administratively burdensome for operators. ~~. and a decision should be taken at Union level only in case there are ***reasoned scientific objections*** to the verification report by other national competent authorities. Where the V~~ ***The verification procedure of category 1 NGT plant status*** ~~verification request is submitted prior to the placing on the market of NGT products, the procedure~~ should be conducted ~~***in consultation with the Commission and***~~ ***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.

CA F
Recital 21

Replacing AMs 91 to 99

Text proposed by the Commission	*Amendment*
(21) Decisions declaring the category 1 NGT plant status should assign an identification number to the NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database ***and for the purpose of labelling of plant reproductive material derived from them***.	(21) Decisions declaring the category 1 NGT plant status should assign an identification number to the NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database***. The information listed shall include information on the technique(s) used to obtain the trait(s)***.

~~**CA G**~~
~~**Recital 23**~~

Commented [MV19]: CA G on organic is moved to new CA 7A.

CA H
Recital 24

Replacing AMs 114 to 122

Text proposed by the Commission	*Amendment*
(24) Provision should be made to ensure transparency as regards the use of category 1 NGT plant varieties, to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard consumer trust. NGT plants that have obtained a category 1 NGT plant status declaration should be ***listed in a publicly available database. To ensure traceability, transparency and choice for operators, during research and plant breeding, when selling seed to farmers or making plant reproductive material available to third parties in any other way, plant reproductive material of category 1 NGT plants should be labelled as category 1 NGT***.	(24) Provision should be made to ensure transparency as regards the use of category 1 NGT plant varieties, to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard consumer trust. NGT plants that have obtained a category 1 NGT plant status declaration ***should be indicated by a mention in the national ~~and~~ catalogues and/or common catalogue of varieties of agricultural plant species ~~EU variety registers~~ , including information on the technique(s) used to obtain the trait(s)***.

CA I
Recital 30

Replacing AMs 143 to 147

Text proposed by the Commission	*Amendment*
(30) For reasons of proportionality, after a first renewal of the authorisation, the authorisation should be valid for an unlimited period, unless decided differently at the time of that renewal based on the risk assessment and the available information on the NGT plant concerned, subject to reassessment when new information has become available.	(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.

CA J
Recital 37

Replacing AMs 160 to 167

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	(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.	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 2001/18/EC would undermine those goals.

CA K
Recital 39

Replacing AMs 169 to 173

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

~~**CA L**~~
~~**Recital 45a (new)**~~

Commented [MV20]: CA L is moved to CA 8 (patentability)