European Parliament
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Committee on the Environment, Public Health and Food Safety

2023/0226(COD)

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***I
DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625
(COM(2023)0411 – C9-0238/2023 – (2023)0226(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Jessica Polfjärd

Symbols for procedures

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

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

Amendments to a draft act

Amendments by Parliament set out in two columns

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

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

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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on the proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625
(COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0411),

– having regard to Article 43(2), Article 114 and Article 168(4)(b)of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0238/2023),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of (…)[1],

– having regard to the opinion of the Committee of the Regions of (...)[2],

– having regard to Rules 59 of its Rules of Procedure,

– having regard to the opinion of the Committee on Agriculture and Rural Development,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0000/2023),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.
[2] OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.

Amendment 1

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) This Regulation constitutes lex specialis with regard to the Union GMO legislation. It introduces specific provisions for NGT plants and NGT products. However, where there are no specific rules in this Regulation, NGT plants and products ***(including food and feed)*** obtained from them should remain subject to the requirements of the Union GMO legislation and the rules on GMOs in sectoral legislation, such as Regulation (EU) 2017/625 on official controls or the legislation on certain products like plant and forest reproductive material.	(11) This Regulation constitutes lex specialis with regard to the Union GMO legislation. It introduces specific provisions for NGT plants and NGT products. However, where there are no specific rules in this Regulation, NGT plants and products obtained from them should remain subject to the requirements of the Union GMO legislation and the rules on GMOs in sectoral legislation, such as Regulation (EU) 2017/625 on official controls or the legislation on certain products like plant and forest reproductive material.

Or. en

Amendment 2

Proposal for a regulation
Recital 18

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

competent authorities as this would be less administratively burdensome for operators***, and a decision should be taken at Union level only in case there are comments to the verification report by other national competent authorities***. Where the verification request is submitted prior to the placing on the market of NGT products, the procedure should be conducted ***at Union level*** in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.	competent authorities as this would be less administratively burdensome for operators. Where the verification request is submitted prior to the placing on the market of NGT products, the procedure should be conducted ***in consultation with the Commission and the European Food Safety Authority ('the Authority') only if there are reasoned objections by other Member States*** in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.

Or. en

Justification

The criteria set out in this proposal for considering that a NGT plant is equivalent to naturally occurring or conventionally bred plants should be a subject for the national competent authority where the application takes place. This it to ensure that category 1 NGT plants status declarations are made without further delay.

Amendment 3

Proposal for a regulation
Recital 21

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

Or. en

Amendment 4

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(20) prohibits the use of GMOs and products from and by GMOs in organic production. It defines GMOs for the purposes of that Regulation by reference to Directive 2001/18/EC, excluding from the prohibition GMOs which have been obtained through the techniques of genetic modification listed in Annex 1.B of Directive 2001/18/EC. As a result, category 2 NGT plants will be banned in organic production. ***However, it is necessary to clarify the status of category 1 NGT plants for the purposes of organic production. The use of new genomic techniques is currently incompatible with the concept of organic production in the Regulation (EC) 2018/848 and with 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(20) prohibits the use of GMOs and products from and by GMOs in organic production. It defines GMOs for the purposes of that Regulation by reference to Directive 2001/18/EC, excluding from the prohibition GMOs which have been obtained through the techniques of genetic modification listed in Annex 1.B of Directive 2001/18/EC. As a result, category 2 NGT plants will be banned in organic production. ***Conversely, the use of category 1 NGT plants should be allowed in organic production.***

Or. en

Amendment 5

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) Provision should be made to ensure transparency as regards the use of category 1 NGT plant varieties, to ensure that production chains that wish to remain free from NGTs can do so and thereby safeguard consumer trust. NGT plants that have obtained a category 1 NGT plant status	(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.***	declaration should be listed in a publicly available database.

Or. en

Justification

Seed bag labelling for verified conventional-like NGT plants is discriminatory. Conventional-like NGT plants should be treated conventionally, this extra requirement is creating unjustified distinctions and administrative burden. Transparency and consumer choice can be fully ensured by making information about the use of NGTs publicly available (public databases). The additional seed bag labelling provisions create a third category of plant products between conventional and GMOs. This is not in line with the approaches taken in other countries and will create trade issues.

Amendment 6

Proposal for a regulation
Recital 30

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

Or. en

Amendment 7

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) In order to enable NGT plants to contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity Strategies, cultivation of NGT plants in the Union should be facilitated. This requires predictability for breeders and farmers as regards the possibility to cultivate such plants in the Union. Therefore, the possibility for Member States to adopt measures restricting or prohibiting the cultivation of category 2 NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals.	(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 should therefore not be provided for***.

Or. en

Amendment 8

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) To achieve the goal of ensuring the effective functioning of the internal market, NGT plants and related products should benefit from the free movement of goods, provided they comply with the requirements of other Union law.	(39) To achieve the goal of ensuring the effective functioning of the internal market, NGT plants and related products should benefit from the free movement of goods, provided they comply with the requirements of other Union law. ***Member States should adhere to this.***

Or. en

Amendment 9

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) ***Given the novelty of the NGTs, it will be important to monitor closely the development and presence on the market of NGT plants and products and evaluate any accompanying impact on human and animal health, the environment and environmental, economic and social sustainability. Information should be collected regularly and within five years after the adoption of the first decision allowing the deliberate release or the marketing of NGT plants or NGT products in the Union,*** the Commission should carry out an evaluation of this Regulation to measure the progress made towards the availability of NGT plants containing such characteristics or properties on the EU market.	(40) ***Where appropriate, every five years*** the Commission should carry out an evaluation of this Regulation to measure the progress made towards the availability of NGT plants containing such characteristics or properties on the EU market ***with the aim of further improving the Regulation***.

Or. en

Amendment 10

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

Text proposed by the Commission	*Amendment*
(2) 'NGT plant' means a ***genetically modified*** plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant;	(2) 'NGT plant' means a plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant;

Or. en

Justification

The wording "genetically modified" would indicate that the process of using NGT techniques would change the DNA of an organism by introducing elements of DNA from a different organism. It should therefore be deleted.

Amendment 11

Proposal for a regulation
Article 3 – paragraph 1 – 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;

Or. en

Justification

"Targeted" would give a more appropriate wording since the aim of the techniques resulting in modifications of the DNA sequence could be a specific part in the genome of an organism, but not necessary an exact part in that specific part in the genome.

Amendment 12

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

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

Or. en

Justification

A product as such can be described as "food" and/or "feed" hence it gives more clarity to state that 'NGT product' means anything that might contain elements from NGT plants.

Amendment 13

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

Text proposed by the Commission	*Amendment*
(2) the plant is a category 2 NGT plant and has been authorised in accordance with Chapter III.	(2) the plant is a category 2 NGT plant, and has been ***granted consent or has been*** authorised, in accordance with Chapter III.

Or. en

Justification

Further clarification to the text proposed by the European Commission.

Amendment 14

Proposal for a regulation
Article 5 – title

Text proposed by the Commission	*Amendment*
Status of category 1 NGT plants	Status of category 1 NGT plants ***and category 1 NGT products***

Or. en

Justification

Adding on "category 1 NGT products" provides clarity for the meaning of the article.

Amendment 15

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The rules which apply to ***GMOs in Union legislation*** shall ***not*** apply to category 1 NGT plants.	1. The rules which apply ***to the techniques referred to in Annex IB to Directive 2001/18*** shall ***also apply to category 1 NGT plants.***

Or. en

Justification

The proposal establishes a verification process to verify if an NGT plant is meeting the equivalence criteria to be grouped as Category 1 (conventional-like). Consequently, those Cat 1 plants should also be subject to the same regulatory framework as conventional breeding products. Any additional requirements would be discriminatory and unjustified. Instead, the Commission proposal creates a distinct category and foresees specific requirements for verified conventional-like NGT plants different from conventional plants and from exempted GMOs like random mutagenesis. This creates confusion and legal complexity. It would be much more consistent to include verified conventional like Cat 1 NGT plants under Annex IB of Dir. 2001/18.

Amendment 16

Proposal for a regulation
Article 5 – paragraph 2

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

Or. en

Justification

The proposal establishes a verification process to verify if an NGT plant is meeting the equivalence criteria to be The prohibition for organic farmers to use conventional-like NGTs (Category 1) in their production is neither science-based nor politically justifiable. Moreover, the prohibition of GMOs is part of the organic farming regulation, but not the GMO Directive 2001/18. Already today certain private standards in the organic sector exclude seeds derived from certain conventional breeding methods based on transparent information from the breeding sector. It should therefore be left to the organic operators to decide which seeds to use in their production and all references to organics should be deleted from the NGT proposal.

Amendment 17

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The ***other Member States and the*** Commission may make **comments** to the verification report within 20 days from the date of receipt of that report.	7. The Commission may make, ***after having consulted the European Food Safety Authority ('the Authority') and other Member States, reasoned objections*** to the verification report, ***as regards the fulfilment of the criteria set out in Annex I,*** within 20 days from the date of receipt of that report. ***Such reasoned objections shall solely refer to the criteria as set out in Annex I and shall include a scientific justification.***

Or. en

Justification

The verification process should, without prejudice, be based and focused on fulfilling the science-based criteria set out in Annex I defining a category NGT 1 plant and assessed by the competent authority in the Member State subject for the verification request. Allowing other Member States to make comments without any further specifications risk undermining the process and make it go beyond its scope. Any intervention of the Commission should be scientifically justified and based on correct application of the equivalence criteria (Annex I).

Amendment 18

Proposal for a regulation
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	8. In the absence of any ***reasoned objections*** from the Commission ***or Member States***, 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.	Commission.

Or. en

Justification

Consistency with Art 6(7).

Amendment 19

Proposal for a regulation
Article 6 – paragraph 9

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 ***comment(s) to the Commission*** without undue delay.	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 ***upon request make*** the ***reasoned objections publicly available*** without undue delay.

Or. en

Justification

Consistency with Art 6(7).

Amendment 20

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

Or. en

Justification

The verification process should, without prejudice, be based and focused on fulfilling the science-based criteria set out in Annex I defining a category NGT 1 plant and assessed by the competent authority in the Member State subject for the verification request.

Amendment 21

Proposal for a regulation
Article 10

Text proposed by the Commission	*Amendment*
Article 10	***deleted***
Labelling of category 1 NGT plant reproductive material, including breeding material	
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.	

Or. en

Justification

Seed bag labelling for verified conventional-like NGT plants is discriminatory. Conventional-like NGT plants should be treated conventionally; this extra requirement is creating unjustified distinctions and administrative burden. Transparency and consumer choice can be fully ensured by making information about the use of NGTs publicly available (public databases). However, the additional seed bag labelling provisions create a third category of plant products between conventional and GMOs. This is not in line with the approaches taken in other countries and will create trade issues.

Amendment 22

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 when it ***contains only genetic modifications referred to in points 1 to 5 and when it*** differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to ***4***, in the targeted ***site or sites in the monoploid genome***.

Or. en

Justification

The Criteria to establish equivalence with conventional plants should allow crops with complex genomes (polyploids like e.g. wheat) to benefit from NGTs in the same way as diploid crops – the 20 genetic changes should be based on the haploid genome. In addition, EFSA[1] concluded that off-target changes would be the same types (and fewer) as those produced by conventional breeding techniques. There is a risk that a requirement for the identification of these off-targets might discriminate crops (specifically smaller crops) for which no whole genome sequence is available. Number 5 of Annex I refers to genetic changes existing in the breeders gene pool and therefore the changes as to number (5) should not be counted in the verification that the threshold of 20 genetic modifications is met.

There are multiple examples of cisgenesis being used to introduce beneficial traits. As long as the insertion does not result in the creation of an intragenic plant which would express a chimeric protein neither random introductions nor interruptions of endogenous genes by cisgenes should be excluded from Category 1. Excluding these applications from Annex I means less opportunities for developing beneficial traits by cisgene(s) in Category 1 (e.g. introduction of multiple disease resistant cisgenes to ensure durable resistance).

Amendment 23

Proposal for a regulation
Annex I – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
3) on the condition that the genetic modification does not ***interrupt an***	(3) on the condition that the genetic modification does not ***create an intragenic***

[1] doi: 10.2903/j.efsa.2020.6299

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

Or. en

Justification

The Criteria to establish equivalence with conventional plants should allow crops with complex genomes (polyploids like e.g. wheat) to benefit from NGTs in the same way as diploid crops – the 20 genetic changes should be based on the haploid genome. In addition, EFSA[1] concluded that off-target changes would be the same types (and fewer) as those produced by conventional breeding techniques. There is a risk that a requirement for the identification of these off-targets might discriminate crops (specifically smaller crops) for which no whole genome sequence is available. Number 5 of Annex I refers to genetic changes existing in the breeders gene pool and therefore the changes as to number (5) should not be counted in the verification that the threshold of 20 genetic modifications is met.

There are multiple examples of cisgenesis being used to introduce beneficial traits. As long as the insertion does not result in the creation of an intragenic plant which would express a chimeric protein neither random introductions nor interruptions of endogenous genes by cisgenes should be excluded from Category 1. Excluding these applications from Annex I means less opportunities for developing beneficial traits by cisgene(s) in Category 1 (e.g. introduction of multiple disease resistant cisgenes to ensure durable resistance).

[1] doi: 10.2903/j.efsa.2020.6299

EXPLANATORY STATEMENT

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

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

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

Unfortunately, the European Union currently cannot utilize this potential.

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

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

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

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

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

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

Objectives and ambitions of the draft proposal

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

The COVID-19 pandemic and Russia´s war of aggression against Ukraine have both aggravated the situation for European agriculture and food production by showing the Union´s external dependencies on critical inputs for agriculture.
While the rapporteur believes that the Commission proposal is a solid starting point, she believes that some further improvements and additions are required to ensure the best possible usage of the techniques.

Clarification and improvement of the criteria for NGT 1-plants

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

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

Organic farming

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

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

Ensuring science-based verification processes

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

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

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

Traceability and labelling

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

Patents and patentability

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

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

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

The following list is drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the draft report:

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