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Plants obtained by certain new genomic techniques and their food and feed

Amendments adopted by the European Parliament on 7 February 2024 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)) [1]

(Ordinary legislative procedure: first reading)

(C/2024/6358)

Amendment 292

Proposal for a regulation

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 new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 ***and Directive 98/44/EC*** (Text with EEA relevance)

Amendment 1

Proposal for a regulation

Recital 1

Text proposed by the Commission	*Amendment*
(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council [32], on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted, significant progress in biotechnology has led to the development of new genomic techniques (NGTs), most prominently genome editing techniques that enable changes to be made to the genome at precise locations.	(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council [32], on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted, significant progress in biotechnology has led to the development of new genomic techniques (NGTs), most prominently genome editing techniques that enable changes to be made to the genome at precise locations. ***Major advances in genetic engineering have already contributed to the widespread use of marker-assisted selection, which makes it possible to identify and mobilise interesting genes that are present in biodiversity.***

[1] The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 59(4), fourth subparagraph (A9-0014/2024).

Text proposed by the Commission	*Amendment*
([32]) Directive 2001/18/EC of the European Parliament and of the Council of 12.3.2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).	([32]) Directive 2001/18/EC of the European Parliament and of the Council of 12.3.2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

Amendment 167

Proposal for a regulation

Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Allowing for new genomic techniques and their results to be patented risks giving multinational seed companies even more power over farmers' access to seeds. In a context where large companies already have a monopoly on seeds and increasingly control natural resources, this would deprive farmers of all freedom of action by making them dependent on private companies. For this reason, patents on these products must be banned.

Amendment 2

Proposal for a regulation

Recital 2

Text proposed by the Commission	*Amendment*
(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications. Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis). They rely only on the breeders' gene pool, i.e. the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced breeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at ***precise*** locations in the genome of an organism. Cisgenesis techniques result in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool. Intragenesis is a subset of cisgenesis resulting in the insertion in the genome of a rearranged copy of genetic material composed of two or more DNA sequences already present in the breeders' gene pool.	(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications. Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis). They rely only on the breeders' gene pool, i.e. the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced breeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at ***targeted*** locations in the genome of an organism. Cisgenesis techniques result in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool. Intragenesis is a subset of cisgenesis resulting in the insertion in the genome of a rearranged copy of genetic material composed of two or more DNA sequences already present in the breeders' gene pool.

Amendment 3

Proposal for a regulation

Recital 3

Text proposed by the Commission	*Amendment*
(3) There is ongoing public and private research using NGTs on a wider variety of crops and traits compared to those obtained through transgenic techniques authorised in the Union or globally ([33]). This includes plants with improved tolerance or resistance to plant diseases and pests, plants with improved tolerance or resistance to climate change effects and environmental stresses, improved nutrient and water-use efficiency, plants with higher yields and resilience and improved quality characteristics. These types of new plants, coupled with the fairly easy and speedy applicability of those new techniques, could deliver benefits to farmers, consumers and to the environment. Thus, NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal ([34]) and of the 'Farm to Fork' ([35]), Biodiversity ([36]) and Adaptation to Climate Change ([37])Strategies, to global food security ([38]), the Bioeconomy Strategy ([39]) and to the Union's strategic autonomy ([40]).	(3) There is ongoing public and private research using NGTs on a wider variety of crops and traits compared to those obtained through transgenic techniques authorised in the Union or globally ([33]). This includes plants with improved tolerance or resistance to plant diseases and pests***, plants with tolerance to herbicides***, plants with improved tolerance or resistance to climate change effects and environmental stresses, improved nutrient and water-use efficiency, plants with higher yields and resilience and improved quality characteristics. These types of new plants, coupled with the fairly easy and speedy applicability of those new techniques, could deliver benefits to farmers, consumers and to the environment. Thus, NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal ([34]) and of the 'Farm to Fork' ([35]), Biodiversity ([36]) and Adaptation to Climate Change ([37]) Strategies, to global food security ([38]), the Bioeconomy Strategy ([39]) and to the Union's strategic autonomy ([40]).
([33]) Insights and solutions stemming from EU-funded research and innovation projects on plant breeding strategies may contribute to address detection challenges, ensure traceability and authenticity, and promote innovation in the area of new genomic techniques. More than 1,000 projects were funded under the Seventh Framework Programme and successor Horizon 2020 programme with an investment of over 3 billion Euros. Horizon Europe support to new collaborative research projects on plant breeding strategies is also ongoing, SWD(2021) 92.	([33]) Insights and solutions stemming from EU-funded research and innovation projects on plant breeding strategies may contribute to address detection challenges, ensure traceability and authenticity, and promote innovation in the area of new genomic techniques. More than 1,000 projects were funded under the Seventh Framework Programme and successor Horizon 2020 programme with an investment of over 3 billion Euros. Horizon Europe support to new collaborative research projects on plant breeding strategies is also ongoing, SWD(2021) 92.
([34]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM/2019/640 final.	([34]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM/2019/640 final.
([35]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Farm to Fork Strategy for a fair, healthy and environmentally friendly food system, COM/2020/381 final.	([35]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Farm to Fork Strategy for a fair, healthy and environmentally friendly food system, COM/2020/381 final.
([36]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, EU Biodiversity Strategy for 2030: Bringing nature back into our lives, COM/2020/380 final.	([36]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, EU Biodiversity Strategy for 2030: Bringing nature back into our lives, COM/2020/380 final.

Text proposed by the Commission	*Amendment*
([37]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions forging a Climate-Resilient Europe - The New EU Strategy on Adaptation to Climate Change, COM(2021) 82 final	([37]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions forging a Climate-Resilient Europe - The New EU Strategy on Adaptation to Climate Change, COM(2021) 82 final
([38]) Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Safeguarding food security and reinforcing the resilience of food systems, COM (2022) 133 final; Food and Agriculture Organisation of the United Nations (FAO), 2022, Gene editing and agrifood systems, Rome, ISBN 978-92-5-137417-7.	([38]) Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Safeguarding food security and reinforcing the resilience of food systems, COM (2022) 133 final; Food and Agriculture Organisation of the United Nations (FAO), 2022, Gene editing and agrifood systems, Rome, ISBN 978-92-5-137417-7.
([39]) European Commission, Directorate-General for Research and Innovation, A sustainable bioeconomy for Europe – Strengthening the connection between economy, society and the environment: updated bioeconomy strategy, Publications Office, 2018, https://data.europa.eu/doi/10.2777/792130.	([39]) European Commission, Directorate-General for Research and Innovation, A sustainable bioeconomy for Europe – Strengthening the connection between economy, society and the environment: updated bioeconomy strategy, Publications Office, 2018, https://data.europa.eu/doi/10.2777/792130.
([40]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Trade Policy Review - An Open, Sustainable and Assertive Trade Policy, COM(2021)66 final.	([40]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Trade Policy Review - An Open, Sustainable and Assertive Trade Policy, COM(2021)66 final.

Amendment 5

Proposal for a regulation

Recital 9

Text proposed by the Commission	*Amendment*
(9) Based on the current scientific and technical knowledge in particular on safety aspects, this Regulation should be limited to GMOs that are plants, i.e. organisms in the taxonomic groups Archaeplastida or Phaeophyceae***, excluding*** microorganisms, fungi and animals ***for which the available knowledge is more limited***. For the same reason, this Regulation should only cover plants obtained by certain NGTs: targeted mutagenesis and cisgenesis (including intragenesis) (hereinafter 'NGT plants'), but not by other new genomic techniques. Such NGT plants do not carry genetic material from non-crossable species. GMOs produced by other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) should remain subject only to the Union GMO legislation, given that the resulting plants might bear specific risks associated to the transgene. ***Moreover, there is no indication that current requirements in the Union GMO legislation for GMOs obtained by transgenesis need adaptation at the present time.***	(9) Based on the current scientific and technical knowledge in particular on safety aspects, this Regulation should be limited to GMOs that are plants, i.e. organisms in the taxonomic groups Archaeplastida or Phaeophyceae***. Available knowledge on other organisms, such as*** microorganisms, fungi and animals***, should be reviewed with a view to future legislative initiatives on them***. For the same reason, this Regulation should only cover plants obtained by certain NGTs: targeted mutagenesis and cisgenesis (including intragenesis) (hereinafter 'NGT plants'), but not by other new genomic techniques. Such NGT plants do not carry genetic material from non-crossable species. GMOs produced by other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) should remain subject only to the Union GMO legislation, given that the resulting plants might bear specific risks associated to the transgene.

Amendment 6

Proposal for a regulation

Recital 10

Text proposed by the Commission	*Amendment*
(10) The legal framework for NGT plants should share the objectives of the Union GMO legislation to ensure a high level of protection of human and animal health and of the environment and the good functioning of the internal market for the concerned plants and products, while addressing the specificity of NGT plants. This legal framework should enable the development and placing on the market of plants, food and feed containing, consisting of or produced from NGT plants and other products containing or consisting of NGT plants ('NGT products') so as to contribute to the innovation and sustainability objectives of the European Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and to enhance the competitiveness of the Union agri-food sector at Union and world level.	(10) ***With full regard to the precautionary principle,*** the legal framework for NGT plants should share the objectives of the Union GMO legislation to ensure a high level of protection of human and animal health and of the environment and the good functioning of the internal market for the concerned plants and products, while addressing the specificity of NGT plants. This legal framework should enable the development and placing on the market of plants, food and feed containing, consisting of or produced from NGT plants and other products containing or consisting of NGT plants ('NGT products') so as to contribute to the innovation and sustainability objectives of the European Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and to enhance the competitiveness of the Union agri-food sector at Union and world level.

Amendment 7

Proposal for a regulation

Recital 11

Text proposed by the Commission	*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.

Amendment 8

Proposal for a regulation

Recital 13 a (new)

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

Amendment 9

Proposal for a regulation

Recital 14

Text proposed by the Commission	*Amendment*
(14) NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny ***obtained by conventional breeding techniques*** ('category 1 NGT plants') should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable, thereby derogating in full from the Union GMO legislation and GMO related requirements in sectoral legislation. In order to ensure legal certainty, this Regulation should set out the criteria to ascertain if a NGT plant is equivalent to naturally occurring or conventionally bred plants and lay down a procedure for competent authorities to verify and take a decision on the fulfillment of those criteria, prior to the release or placing on the market of NGT plants or NGT products. Those criteria should be objective and based on science. They should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained with conventional breeding techniques and should include thresholds for both size and number of genetic modifications to the genome of NGT plants. Since scientific and technical knowledge evolves rapidly in this area, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to update these criteria in light of scientific and technical progress as regards the type and extent of genetic modifications that can occur in nature or through conventional breeding.	(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 in light of scientific and technical progress as regards the type and extent of genetic modifications that can occur in nature or through conventional breeding.

Amendment 10

Proposal for a regulation

Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Taking into account the high complexity of plant genomes, the criteria for considering that a NGT plant is equivalent to a naturally occurring or conventionally bred plant should reflect the diversity of plants genomic size and their characteristics. Polyploid plants contain more than two homologous chromosomes. Within that category of polyploid plants, tetraploid, hexaploid, and octoploid have 4, 6 and 8 sets of chromosomes respectively. Polyploid plants tend to exhibit greater numbers of genetic modifications compared to monoploid plants. For those reasons, any limit to the total number of individual modifications per plant should reflect the number of chromosomes set in a plant ("ploidy").

Amendment 11

Proposal for a regulation

Recital 18

Text proposed by the Commission	*Amendment*
(18) Since the criteria for considering that a NGT plant is equivalent to naturally 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***	(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 verification request is submitted prior to the placing on the market of NGT products, ***and if there are reasoned objections by other Member***

Text proposed by the Commission	*Amendment*
level in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.	***States,*** the procedure should be conducted ***in consultation with the Commission and the European Food Safety Authority ("the Authority")*** in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.

Amendment 12

Proposal for a regulation

Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18a) In order to effectively select new varieties that help the agricultural sector increase food security, as well as sustainability, adaptation and resilience in relation to the consequences of climate change, it is necessary to consider the specificity of polyploid plants, which are plants that contain more than two genomes. For such plants, the maximum number of genetic modifications allowed for inclusion in category 1 NGT should be proportionate to the number of genomes they contain.

Amendment 13

Proposal for a regulation

Recital 19

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

Amendment 14

Proposal for a regulation

Recital 21

Text proposed by the Commission	*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 should include information on the technique or techniques used to obtain the trait or traits***.

Amendment 15

Proposal for a regulation

Recital 23

Text proposed by the Commission	*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. However, it is necessary to clarify the status of category 1 NGT plants for the purposes of organic production. ***Currently, the compatibility of*** the use of new genomic techniques with the ***principles*** of organic production ***requires further consideration***. The use of category 1 NGT plants should therefore be prohibited in organic production***, until such further consideration takes place***.
([47]) Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).	([47]) Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

Amendment 16

Proposal for a regulation

Recital 24

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

Amendment 17

Proposal for a regulation

Recital 29

Text proposed by the Commission	*Amendment*
(29) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market but provides for flexibility as to the design of the plan taking into account the environmental risk assessment, the characteristics of the GMO, of its expected use and of the receiving environment. Genetic modifications in category 2 NGT plants may range from changes only needing a limited risk assessment to complex alterations requiring a more thorough analysis of potential risks. Therefore, post-market monitoring requirements for environmental effects of category 2 NGT plants should be adapted in the light of the environmental risk assessment and the experience in field trials, the characteristics of the NGT plant concerned, the characteristics and scale of its expected use, in particular any history of safe use of the plant and the characteristics of the receiving environment. ***Therefore***, a monitoring plan for environmental effects should ***not*** be required ***if*** the category 2 NGT plant ***is unlikely to*** pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.	(29) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market but provides for flexibility as to the design of the plan taking into account the environmental risk assessment, the characteristics of the GMO, of its expected use and of the receiving environment. Genetic modifications in category 2 NGT plants may range from changes only needing a limited risk assessment to complex alterations requiring a more thorough analysis of potential risks. Therefore, post-market monitoring requirements for environmental effects of category 2 NGT plants should be adapted in the light of the environmental risk assessment and the experience in field trials, the characteristics of the NGT plant concerned, the characteristics and scale of its expected use, in particular any history of safe use of the plant and the characteristics of the receiving environment. ***In view of the precautionary principle***, a monitoring plan for environmental effects should ***always*** be required ***when consent is first given. It should only be possible to waive the requirement for monitoring upon the renewal of consent, provided that it has been demonstrated that*** the category 2 NGT plant ***does not*** pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.

Amendment 18

Proposal for a regulation

Recital 36

Text proposed by the Commission	*Amendment*
(36) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the breeding technique. For this reason, NGT plants featuring herbicide-tolerant traits should not ***be eligible for incentives under this framework. However, this Regulation should not take other specific measures on herbicide tolerant NGT plants, because such measures are taken horizontally in [the Commission's Proposal for a Regulation*** of the ***European Parliament and of the Council on the production and marketing of plant reproductive material in the Union]***.	(36) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the breeding technique. For this reason, NGT plants featuring herbicide-tolerant traits should not ***fall within the scope*** of the ***category 1 NGT plants***.

Amendment 239

Proposal for a regulation

Recital 37

Text proposed by the Commission	*Amendment*
(37) In order to enable NGT plants to contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity Strategies, cultivation of NGT plants in the Union should be facilitated. This requires predictability for breeders and farmers as regards the possibility to cultivate such plants in the Union. Therefore, the possibility for Member States to adopt measures restricting or prohibiting the cultivation of category 2 NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals.	***deleted***

Amendment 20

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 ***and*** the free movement of ***NGT plant and NGT products across the Union, the deliberate release of NGT plants and placing on the market of NGT products should be based on the harmonised*** requirements ***and procedures laid down in this Regulation, leading to the adoption of a decision uniformly applicable to all Member States.***

Amendment 21

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) Given the ***ongoing*** development ***of new genomic techniques, the Commission*** should ***carry out an evaluation*** within five years after the adoption of the first decision allowing the deliberate release or the marketing of NGT plants or NGT products in the Union***. That*** evaluation ***should*** measure the progress made towards the availability of NGT plants ***or NGT products*** containing such characteristics or properties on the EU market***, with the aim of further improving this Regulation***.

Amendment 22

Proposal for a regulation

Recital 43

Text proposed by the Commission	*Amendment*
(43) The types of NGT plants developed and the impact of certain traits on environmental, social and economic sustainability are continuously evolving. Therefore, based on the available evidence of such developments and impacts, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to adapt the list of traits that should be incentivized or discouraged to achieve the goals of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies.'	(43) The types of NGT plants developed and the impact of certain traits on environmental, social and economic sustainability are continuously evolving. Therefore, based on the available evidence of such developments and impacts, ***fully taking into account the precautionary principle,*** the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to adapt the list of traits that should be incentivized or discouraged to achieve the goals of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies.'

Amendment 23

Proposal for a regulation

Recital 45 a (new)

Text proposed by the Commission	*Amendment*
	(45a) The European Parliament has called for the Union and its Member States not to grant patents on biological material and to safeguard the freedom to operate and the breeders' exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT plants, which by definition are not transgenic plants. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (breeder's exemption). As current provisions in patent law do not provide for a full breeder's exemption, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Hence, NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption. NGT plants, their derived seeds, their plant material, associated genetic material such as genes and gene sequences, and plant traits should therefore be excluded from patentability. The exclusion from patentability should be applied in a consistent manner across legislation. Furthermore, in order to avoid patents being granted or patent applications being submitted between the date of the entry into force of this Regulation and the application of its provisions, it should be ensured that plant material is excluded from patentability from the day of entry into force of this Regulation. For patents already granted or pending patent appli-

Text proposed by the Commission	*Amendment*
	cations covering plant material, the effects of patents should be further limited. In addition, the Commission should assess and address, in the forthcoming study, how the broader problem of patents being granted, directly or indirectly, on plant material despite previous efforts to close loopholes, should be further addressed. The assessment should address in particular the role and impact of patents on breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, as well as on innovation and in particular on opportunities for SMEs. The report of the Commission should be accompanied by the appropriate legislative proposals in order to ensure further necessary adjustments are made to the intellectual property rights framework.

Amendment 241

Proposal for a regulation

Recital 47 a (new)

Text proposed by the Commission	*Amendment*
	(47a) The European Green Deal, the 'Farm to Fork', and the EU Biodiversity Strategies put organic farming at the core of a transition to sustainable food systems, with a target to expand European agricultural land under organic production to 25 % by 2030. This is a clear recognition of the environmental benefits of organic farming, for less dependency on inputs for farmers, and a resilient food supply and food sovereignty. This Regulation must not adversely undermine the pathway to a transition of European food systems to organic farming to 25 % by 2030.

Amendment 243

Proposal for a regulation

Recital 47 b (new)

Text proposed by the Commission	*Amendment*
	(47b) Traceability requirements for food and feed produced from NGTs should be established to facilitate the accurate labelling of such products, in accordance with the requirements of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner, as well as to enable control and verification of labelling claims. Requirements for food and feed produced from NGTs should be similar in order to avoid discontinuity of information in cases of change in end use.

Amendment 24

Proposal for a regulation

Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	This Regulation***, in accordance with the precautionary principle*** lays down specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by certain new genomic techniques ('NGT plants') and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants***, ensuring a high level of protection of human and animal health and the environment***.

Amendment 25

Proposal for a regulation

Article 3 – paragraph 1 – point 2

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

Amendment 26

Proposal for a regulation

Article 3 – paragraph 1 – point 4

Text proposed by the Commission	*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;

Amendment 27

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, using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;

Amendment 28

Proposal for a regulation

Article 3 – paragraph 1 – point 15 a (new)

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

Amendment 29

Proposal for a regulation

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

Text proposed by the Commission	*Amendment*
	(15b) "Chimeric protein" means proteins created through the joining of two or more genes or parts of genes that originally coded for separate proteins.

Amendment 30

Proposal for a regulation

Article 4 – paragraph 1 – point 1 – point b

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

Amendment 31

Proposal for a regulation

Article 4 – paragraph 1 – point 2

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

Amendment 32

Proposal for a regulation

Article 4 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The implementation, enforcement and application of this Regulation shall not have the object or effect of preventing or impeding imports from third countries of NGT plants and products that meet the same standards as those laid down in this Regulation.

Amendment 33

Proposal for a regulation

Article 4 a (new)

Text proposed by the Commission	*Amendment*
	Article 4a
	Exclusion from patentability
	NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable.

Amendment 34

Proposal for a regulation

Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of Regulation (EU) 2018/848, the rules set out in its ***Articles 5 (f) (iii) and*** 11 shall apply to category 1 NGT plants and to products produced from or by such plants.	2. For the purposes of Regulation (EU) 2018/848, the rules set out in its ***Article 5 (f), (iii), and Article*** 11 shall apply to category 1 NGT plants and to products produced from or by such plants. ***[7 years after the entry into force of this Regulation], the Commission shall present a report on the evolution of the consumers' and producers' perception, accompanied, where appropriate, by a legislative proposal.***

Amendment 35

Proposal for a regulation

Article 5 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I in order to adapt them to scientific and technological ***progress*** as regards the types and extent of modifications which can occur naturally or through conventional breeding.	3. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I***, taking into account potential associated risks and functional consequences in the verification procedure*** in order to adapt those criteria to ***the latest*** scientific and technological ***developments*** as regards the types and extent of modifications which can occur naturally or through conventional breeding.

Amendment 36

Proposal for a regulation

Article 5 – paragraph 3 a (new)

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

Amendment 37

Proposal for a regulation

Article 6 – paragraph 1

Text proposed by the Commission	*Amendment*
1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I are met ("verification request") to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the ***implementing*** act adopted in accordance with Article ***27***, point (b).	1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I ***at least one of the traits referred to in Annex III, Part 1, and the exclusion criteria in Annex III, Part 2,*** are met ("verification request")***. That verification request shall be submitted*** to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the ***delegated*** act adopted in accordance with Article ***6(11a)***, point (b).

Amendment 38

Proposal for a regulation

Article 6 – paragraph 3 – point c

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

Amendment 253

Proposal for a regulation

Article 6 – paragraph 3 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) any patent or pending application for a patent that covers the whole or part of Cat.1 NGT plant;

Amendment 39

Proposal for a regulation

Article 6 – paragraph 3 – point d – point i

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

Amendment 40

Proposal for a regulation

Article 6 – paragraph 3 – point d – point ii

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

Amendment 41

Proposal for a regulation

Article 6 – paragraph 3 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the denomination of the variety

Amendment 42

Proposal for a regulation

Article 6 – paragraph 6

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

Amendment 43

Proposal for a regulation

Article 6 – paragraph 7

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

Amendment 311

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 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. ***The national competent authority*** shall transmit the decision ***within 10 working days*** to the requester, the other Member States and the Commission.

Amendment 45

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 ***make the reasoned objections publicly available*** without undue delay.

Amendment 46

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).

Amendment 48

Proposal for a regulation

Article 7 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the denomination of the variety;

Amendment 49

Proposal for a regulation

Article 7 – paragraph 2 – point c

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

Amendment 260

Proposal for a regulation

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

Text proposed by the Commission	*Amendment*
	(da) a monitoring plan for environmental effects;

Amendment 50

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***.

Amendment 51

Proposal for a regulation

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;

Amendment 52

Proposal for a regulation

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

Text proposed by the Commission	*Amendment*
	(ba) the denomination of the variety;

Amendment 53

Proposal for a regulation

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

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

Amendment 54

Proposal for a regulation

Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The database shall be publicly available.	2. The database shall be publicly available***, and in an on-line format***.

Amendment 264

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission	*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 indicating the words '***cat 1 NGT***', followed by the identification number of the NGT plant(s) it has been derived from.	***Category 1 NGT plants, products 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 265

Proposal for a regulation

Article 10 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Appropriate document-based traceability for NGTs shall be provided by the transmission and holding of information that products contain or consist of NGT plants and product, and the unique codes for those NGTs, at each stage of their placing on the market.

Amendment 266

Proposal for a regulation

Article 11 a (new)

Text proposed by the Commission	*Amendment*
	Article 11a
	Withdrawal of the decision
	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 shall have 15 days in which to make observations. In that case, the marketing of the NGT plant or product shall be prohibited from the day following the date of receipt of the registered letter.

Amendment 56

Proposal for a regulation

Article 16

Text proposed by the Commission	*Amendment*
Article 16	***deleted***
Labelling in accordance with Article 23	
In addition to Article 19(3) of Directive 2001/18/EC, the written consent shall specify the labelling in accordance with Article 23 of this Regulation.	

Amendment 268

Proposal for a regulation

Article 17 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	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 shall have 15 days in which to make observations. In that case, the marketing of the NGT plant or product shall be prohibited from the day following the date of receipt of the registered letter.

Amendment 228

Proposal for a regulation

Article 20 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Union reference laboratory shall test and validate the method of detection, identification and quantification proposed by the applicant in accordance with Article 19(2) ***or assess whether the information provided by*** the applicant justifies the application of adapted modalities to comply with detection method requirements ***referred to*** in that ***paragraph***.	4. The Union reference laboratory shall test and validate the method of detection, identification and quantification proposed by the applicant in accordance with Article 19(2)***. If*** the applicant justifies the application of adapted modalities to comply with detection method requirements***, the Union reference laboratory shall carry out its own research and analyses to confirm the claimed unfeasibility.*** In that ***case, the decision of the Union reference laboratory shall be motivated and be made public***.

Amendment 270

Proposal for a regulation

Article 21 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	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 shall have 15 days in which to make observations. In that case, the marketing of the NGT plant or product shall be prohibited from the day following the date of receipt of the registered letter.

Amendment 57

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in ***Part 1 of Annex III*** and it does not have any traits referred to in Part 2 of that Annex.	1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended traits of the NGT plant conveyed by the genetic modification is contained in ***Article 51(1) of Regulation (EU/…)*** (*) and it does not have any traits referred to in Part 2 of that Annex. (*) ***Commission proposal for a Regulation on plant reproductive material (COM/2023/414), (2023/0227(COD)).***

Amendment 59

Proposal for a regulation

Article 26 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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 60

Proposal for a regulation

Article 26 – paragraph 3

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

Amendment 61

Proposal for a regulation

Article 26 – paragraph 6

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

Amendment 62

Proposal for a regulation

Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the information required to demonstrate that a plant is a NGT plant;	***deleted***

Amendment 63

Proposal for a regulation

Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the preparation and the presentation of the verification requests referred to in Articles 6 and 7;	***deleted***

Amendment 64

Proposal for a regulation

Article 30 – paragraph 2

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

Amendment 65

Proposal for a regulation

Article 30 – paragraph 3

Text proposed by the Commission	*Amendment*
3. For the purpose of the reporting referred to in paragraph 1, the Commission, by [24 months after the date of entry into force of this Regulation] at the latest, shall establish, after consulting the competent authorities of the Member States in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact of this Regulation. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.	3. For the purpose of the reporting referred to in paragraph 1, the Commission, by [24 months after the date of entry into force of this Regulation] at the latest, shall establish, after consulting the competent authorities of the Member States in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact of this Regulation***, including the intended and unintended effects and systematic effects on the environment, biodiversity and ecosystems***. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.

Amendment 66

Proposal for a regulation

Article 30 – paragraph 5 a (new)

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

Amendment 67

Proposal for a regulation

Article 30 – paragraph 5 b (new)

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

Amendment 68

Proposal for a regulation

Article 30 – paragraph 5 c (new)

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

Amendments 69, 291cp1, 230/rev1 and 291cp3

Proposal for a regulation

Article 33 a (new)

Directive 98/44/EC

Article 4, Article 8 and Article 9

Text proposed by the Commission	*Amendment*
	Article 33a
	Amendments to Directive 98/44/EC [1a]
	1. Article 4 of Directive 98/44/EC on the legal protection of biotechnological inventions is amended as follows:
	(a) In paragraph 1, the following points are added:
	'(c) NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) .../... [O.J. please insert the number of this Regulation];
	(d) plants, plant material, parts thereof, genetic information and process features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B to that directive.'
	(b) the following paragraph 4 is added:
	'4. Paragraphs 2 and 3 shall be without prejudice to the exclusions from patentability covered in paragraph 1.'
	2. In Article 8, the following paragraph is added:
	'3. By way of derogation from paragraphs 1 and 2, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological material possessing the same characteristics that is obtained independently of the patented biological material and from essentially biological processes, or to biological material obtained from such material through propagation or multiplication.'
	3. In Article 9, the following paragraphs are added:
	'2. By way of derogation from paragraph 1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.

Text proposed by the Commission	*Amendment*
	3. By way of derogation from paragraph 1, the protection conferred by a patent on a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.
	4. The protection conferred by a patent on a technical process that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.'.
	([14]) Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13).

Amendment 70

Proposal for a regulation

Article 34 – paragraph 2 – subparagraph 1

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

Amendment 71

Proposal for a regulation

Annex I – paragraph 1

Text proposed by the Commission	*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***:

Amendment 72

Proposal for a regulation

Annex I – point 1

Text proposed by the Commission	*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 taking into account that mutations in introns and regulatory sequences are excluded from this limit:***
	(a) substitution or insertion of no more than 20 nucleotides;
	(b) deletion of any number of nucleotides;

Amendment 73

Proposal for a regulation

Annex I – point 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) The following genetic modifications, which can be combined with each other, do not create a chimeric protein that is not present in species from the gene pool for breeding purposes or does not interrupt an endogenous gene;
	(a) insertion of continuous DNA sequences existing in the gene pool for breeding purposes;
	(b) substitution of endogenous DNA sequences with continuous DNA sequences existing in the gene pool for breeding purposes;
	(c) inversion or translocation of continuous endogenous DNA sequences existing in the gene pool for breeding purposes.

Amendment 74

Proposal for a regulation

Annex I – point 2

Text proposed by the Commission	*Amendment*
(2) deletion of any number of nucleotides;	***deleted***

Amendment 75

Proposal for a regulation

Annex I – point 3

Text proposed by the Commission	*Amendment*
(3) on the condition that the genetic modification does not interrupt an endogenous gene:	***deleted***
(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;	
(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;	

Amendment 76

Proposal for a regulation

Annex I – point 4

Text proposed by the Commission	*Amendment*
(4) targeted inversion of a sequence of any number of nucleotides;	***deleted***

Amendment 77

Proposal for a regulation

Annex I – point 5

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

Amendment 78

Proposal for a regulation

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

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

Amendment 79

Proposal for a regulation

Annex II – Part 2 – point 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) Impacts on organic cultivation

Amendment 80

Proposal for a regulation

Annex II – Part 2 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) Effects on protecting and conserving biodiversity

Amendment 81

Proposal for a regulation

Annex III – title 1

Text proposed by the Commission	*Amendment*
Traits referred to in Article 22	Traits referred to in Article ***6 and Article*** 22

Amendment 82

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 1

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

Amendment 83

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 7

Text proposed by the Commission	*Amendment*
(7) reduced need for external inputs, such as ***plant protection products and*** fertilisers.	(7) reduced need for external inputs, such as fertilisers***, if it does not contradict with Annex III, part 2***.