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From:	General Secretariat of the Council
To:	Delegations
Subject:	Regulation on new genomic techniques (NGT) – comments from Finland, France, Greece and Hungary

Delegations will find in annex submissions from delegations on the above subject, concerning drafting suggestions and comments on the Presidency compromise text for a Regulation on new genomic techniques (NGT) put forward after the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 5-6 October 2023.

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Presidency compromise text (NGT) **ST 13725/23 INIT**	**MS Drafting Suggestions**	**MS Comments**
Proposal for a **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** **on plants obtained by certain new genomic techniques and their <u>products</u> ~~food and feed~~, and amending Regulation (EU) 2017/625** (Text with EEA relevance)		

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114 and 168(4) (b) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council ([1]), 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.		
(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and		

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1 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

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 conventional breeding techniques (excluding genetic modification techniques other than those listed in Annex I B of Directive 2001/18/EC). The European Food Safety Authority ('the Authority'), in its scientific opinion on plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases[2] and the High Level Group of the Commission´s Scientific Advise Mechanism in its Explanatory note on New techniques in agricultural biotechnology[3] provide an overview of the current state of these conventional breeeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA		

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[2] EFSA Panel on Genetically modified organisms (GMO); Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 2012;10(10):2943. [31 pp.] doi:10.2903/j.efsa.2012.2943. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2943.

[3] European Commission, Directorate-General for Research and Innovation, *New techniques in agricultural biotechnology*, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498

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.~~ This can lead to the presence, in the recipient plant, of a continuous DNA sequence existing in the breeder´s gene pool, but also to the presence of a rearranged copy of genetic material composed of two or more DNA sequences from the breeder´s gene pool. The term intragenesis, a subset of cisgenesis, refers to the latter, therefore resulting in an intragenic plant.		
(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([4]). 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		

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[4] 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.

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 ([5]) and of the 'Farm to Fork' ([6]), Biodiversity ([7]) and Adaptation to Climate Change([8]) Strategies, to global food security ([9]), the Bioeconomy Strategy ([10]) and to the Union's strategic autonomy ([11]).		

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5 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.

6 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.

7 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.

8 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

9 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.

10 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.

11 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.

(4) The deliberate release into the environment of organisms obtained by NGTs, including products containing or consisting of such organisms, as well as the placing on the market of food and feed produced from these organisms, are subject to Directive 2001/18/EC and, Regulation (EC) No 1830/2003 ([12]) of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003 ([13]), while the contained use of plant cells is subject to Directive 2009/1/EC, and transboundary movements of NGT plants to third countries are regulated by Regulation (EC) No 1946/2003 ('the Union GMO legislation').		
(5) In its judgment in case C-528/16 *Confédération paysanne and Others*[14] the Court of Justice of the European Union held that GMOs obtained by means of new techniques/methods of mutagenesis that had appeared or had been mostly developed since Directive 2001/18/EC was adopted could not be considered excluded from the scope of that Directive.		

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12 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

13 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

14 Judgement of the Court of Justice of 25 July 2018, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, C-528/16, ECLI:EU:C:2018:583.

(6) The Council, in Decision (EU) 2019/190415, requested the Commission to submit, by 30 April 2021, a study in light of that judgment regarding the status of novel genomic techniques under Union law, and a proposal (accompanied by an impact assessment), if appropriate, depending on the conclusions of the study.		
(7) The Commission's study on new genomic techniques ([16]) concluded that the Union GMO legislation is not fit for the purpose of regulating the deliberate release of plants obtained by certain NGTs and the placing on the market of related products including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained with some NGTs, namely targeted mutagenesis and cisgenesis (including intragenesis), and these requirements can be disproportionate or inadequate. The study showed that this is particularly the case for plants obtained by these techniques, given the		

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15 Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study (OJ L 293, 14.11.2019, p. 103).

16 Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) 92 final.

amount of scientific evidence that is already available, in particular on their safety. Furthermore, the Union GMO legislation is difficult to implement and enforce for plants obtained by targeted mutagenesis and cisgenesis and related products. In certain cases, genetic modifications introduced by these techniques are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques, whereas the distinction is generally possible for genetic modifications introduced by transgenesis. The Union GMO legislation is also not conducive to developing innovative and beneficial products that could contribute to sustainability, food security and resilience of the agri-food chain.		
(8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.		
(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		

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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.		
(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~~,~~ and products (including food and feed) obtained with NGTs ~~containing, consisting of or produced from NGT plants and other products containing or consisting of NGT plants ('NGT products')~~ so as to contribute to		

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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.		
(11a) In keeping with the Union GMO legislation, this Regulation should include under its scope NGT plants, food and feed containing, consisting of or produced from NGT plants, and other products containing or consisting of NGT plants ('NGT products'). Plant reproductive material, including forest reproductive material, falls under the scope of this Regulation both as a plant (when it is deliberately relased for any purpose other than the placing on the market) and as a product (when it is placed on the market, including for the purpose of commercial cultivation).		
(12) The potential risks of NGT plants vary, ranging from risk profiles similar to conventionally-bred plants to various types and degrees of hazards and risks that might be similar to those of plants obtained by transgenesis. This Regulation should therefore lay down special rules to adjust the risk assessment and risk management requirements according to the potential risks or lack thereof posed by NGT plants and NGT products.		
(13) This Regulation should distinguish between		

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two categories of NGT plants.		
(14) ~~NGT~~ "Category 1 NGT plants" includes 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')~~ This category 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. Novel hazards can be associated with		We thank for clarifying the status of intragenic plants.

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intragenic plants compared with cisgenic and conventionally bred plants[17][18], therefore intragenic plants should remain subject to the Union GMO legislation and be excluded from the criteria for category 1 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.~~		
(14a) Since category 1 NGT plants encompasses plants that are equivalent to plants occurring naturally or produced by conventional breeding and that should be treated as those plants, also their progeny obtained by conventional breeding techniques should be treated accordingly and be included under category 1 NGT plants. Therefore, the progeny deriving from the application of conventional breeding techniques to a category 1 NGT plant, including		1. We are of the opinion, that the progeny of NGT 1 plants should be classified according to the criteria of Annex I. 2. However, the issue of null-segregants cannot be ignored in sexually reproducing plants. When outcrossed with wild-type plants or conventional cultivars, not all progeny inherit the modification in the parental NGT plant genome because of chromosome segregation. Thus, with the exception of total inbreeding, the

[17] EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561, 33 pp. doi:10.2903/j.efsa.2012.2561. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2561.

[18] EFSA Panel on Genetically Modified Organisms ; Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 2022;20(10):7621, 33 pp. https://doi.org/10.2903/j.efsa.2022.7621.

the result of the crossing of a category 1 NGT plant with a conventionally bred plant, or of the crossing of two category 1 NGT plants, should remain subject to the provisions of category 1 NGT plants without the need to go through the verification procedure, prior to their release or placing on the market. Conversely, the progeny deriving from the application of targeted mutagenesis or cisgenesis to a category 1 NGT plant shall be subject to the procedure to verify the fulfillment of the criteria for category 1 NGT plants, prior to its release or placing on the market as category 1 NGT plant. If those criteria are not met, the progeny can be released or placed on the market only as category 2 NGT plant.		NGT-modification of the parental plant may become completely lost in subsequent generations. This applies to both category 1 and 2 NGT plants, with the exemption of vegetative propagation. Hence, to ensure that the proposal is scientifically sound and provides the necessary legal certainty, the status of null-segregants should be clarified in different situations. Moreover, the last sentence would indicate that null-segregants from category 1 NGT plants would be classified as category 2 NGT plants. 3.
(14b) 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.		
(15) All NGT plants that are not category 1 ('category 2 NGT plants') should remain subject to the requirements of the Union GMO legislation because they feature more complex sets of modifications to the genome.		

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(16) Category 1 NGT plants and products should not be subject to the rules and requirements of the Union GMO legislation and to provisions in other Union legislation that apply to GMOs. For legal certainty for operators and transparency, a declaration of the category 1 NGT plant status should be obtained prior to deliberate release, including the placing on the market.		
(17) This declaration should be obtained prior to any deliberate release of any category 1 NGT plants for any other purpose than placing on the market, such as for field trials that are to take place in the territory of the Union, since the criteria are based on data that is available before the field trials and does not depend on these field trials. When no field trials are to take place in the territory of the Union, operators should obtain that declaration before placing the category 1 NGT product on the market.		
(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		We welcome the new wording.

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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~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I, 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.		
(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.		
(20) The verification of category 1 NGT plant status is of technical nature and does not involve any risk assessment or risk management considerations and the decision on the status is only declaratory. Therefore, when the procedure is conducted at Union level, such implementing		

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decisions should be adopted by the advisory procedure, supported by scientific and technical assistance by the Authority.		
(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.		
(22) Category 1 NGT plants should remain subject to any regulatory framework that applies to conventionally bred plants. As is the case for conventional plants and products, those NGT plants and their products will be subject to the applicable sectoral legislation on seed and other plant reproductive material, food, feed and other products, and horizontal frameworks, such as the nature conservation legislation and environmental liability. In this regard, category 1 NGT food featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances of the food will be considered as novel food and thus fall into the		

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scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council ([19]) and will be risk assessed in that context.		
(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		

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19 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

20 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).

production.		
(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.		
[Recitals 25-48 were not amended in the Presidency compromise text in ST 13725/23 INIT, nor are they directly corresponding to Articles 1-11. They are omitted here to reduce the length of this document.]		
CHAPTER I **GENERAL PROVISIONS**		
Article 1 **Subject matter**		
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		

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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 (‘NGT products’).		
Article 2 **Scope** This Regulation shall apply to:		
(1) NGT plants;		
(2) food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;		
(3) feed containing, consisting or produced from NGT plants;		
(4) products, other than food and feed, containing or consisting of NGT plants.		
Article 3 **Definitions** For the purposes of this Regulation, the following definitions shall apply:		
(1) the definitions of ‘organism’, ‘deliberate release’ and ‘placing on the market’ set out in Directive 2001/18/EC, those of ‘food’ and ‘feed’ set out in Regulation (EC) No 178/2002, that of ‘traceability’ set out in Regulation (EC) No 1830/2003, that		

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	of 'plant' set out in Regulation (EU) 2016/2031 of the European Parliament and of the Council([21]) and that of 'plant reproductive material' set out 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*[22]];		
(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 that is genetically modified ~~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;	It is clear that all NGT-plants are genetically modified. (See recitals 7, 8, 9 and 14). The proposal suggests that NGT plants are divided into two categories, out of which category NGT 1 plants are exempted from the GMO-legislation. Both categories are a result of genetic modification using targeted mutagenesis or cisgenesis. We suggest a wording accordingly.
(3)	'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive	(3) 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms specified in Article 3 (1) of ~~obtained through the techniques of genetic modification listed in Annex I B to~~ Directive 2001/18/EC;	We suggest removing the text after the comma. It is not necessary and may cause confusion. If considered necessary, a reference to Article 3(1) of the Directive could be added instead of reference to Annex I B.

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21 Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

22 COM(2023) 414 final

	2001/18/EC;		
(4)	'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at ~~precise~~ targeted locations in the genome of an organism;		
(5)	'cisgenesis' means techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool;	(5 a) 'intragenesis', a subset of cisgenesis, refers to insertion of a rearranged copy of genetic material composed of two or more DNA sequences from the breeder´s gene pool;	We suggest adding the text from recital 2 on intragenesis as article 3, point 5 a.
(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;		
(7)	'category 1 NGT plant' means a NGT plant that:		
	(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, or		

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	(b) is progeny of the NGT plant(s) referred to in point (a), including progeny derived by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003;	(b) is progeny of the NGT plant(s) referred to in point (a), including progeny derived by crossing of such plants, on the condition that criteria listed in Annex I are fulfilled and that there are no further modifications that would make it subject to	See our comments in Recital 14 a.
(8)	'category 2 NGT plant' means a NGT plant other than a category 1 NGT plant;		
(9)	'NGT plant for food use' means a NGT plant that may be used as food or as a source material for the production of food;		
(10)	'NGT plant for feed use' means a NGT plant that may be used as feed or as a source material for the production of feed;		
(11)	'produced from a NGT plant' means derived, in whole or in part, from a NGT plant, but not containing or consisting of a NGT plant;		
(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		

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	produced from ~~such a plant~~ NGT plants, and other products containing or consisting of such plants;		
(13)	'category 1 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 1 NGT plant;		
(14)	'category 2 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 2 NGT plant;		
(15)	'small or medium sized enterprise (SME)' means a SME within the meaning of Commission Recommendation 2003/361/EC[2].		
Article 4 **Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products**			
Without prejudice to other requirements of Union law, a NGT plant may only be deliberately released into the environment for any other purpose than placing on the market, and a NGT product may only be placed on the market, if:			

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(1) the plant is a category 1 NGT plant and		
(a) has obtained a decision declaring that status in accordance with Article 6 or 7; or		
(b) is progeny of plant(s) referred to in point (a); or		
(2) the plant is a category 2 NGT plant, and has been granted consent or has been authorised, in accordance with Chapter III.		
CHAPTER II **Category 1 NGT plants and category 1 NGT products**		
Article 5 **Status of category 1 NGT plants and category 1 NGT products**		
1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants that fulfill the condition of article 4(1) and their NGT products.		
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		

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	produced from or by such plants.		
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.		For Finand the written legal opinion from the Council Legal Service on the delegated act is not essential.

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Article 6 **Verification procedure of category 1 NGT plant status <u>for requests submitted</u> prior to the deliberate release for any other purpose than placing on the market**		Administrative procedures should be put in place regarding situations where: • a verification request for NGT1 plant status and a Part B GMO notification are made in parellel before commencing the field trial (in an attempt to speed up the administrative process); • a field trial is already going on according to Part B of the Directive, but a verification request for a NGT1 plant status is made during the field trial; • a field trial has already been performed according to Part B of the Directive, but later the plant receives a NGT1 status in the verification procedure. If the NGT1 status is confirmed, should the MS CA annul its authorisation under Part B of the Directive? If so, should the information on the Part B-trial be removed from the MS and EU GMO-registers and BCH? Should other MS and the public be informed about the changed status of the plant? Are there other procedural issues regarding Part B of the Directive in such situations?
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		We welcome the proposed new wording. But we are still worried about how the verification process would negatively affect academic basic research for other than commercial purposes. We consider that the procedure for verifying the status of category 1 NGT plants should be legally secure, predictable, cost-effective and

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	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).		sufficiently light so that basic academic research and SMEs can also make effective use of it. We would welcome a leaner procedure for NGT1 plants which are not going to enter the market (i.e. the field trial is purely for scientific purposes and performed in one MS only). The verification procedure for field trials of NGT1 plants should work in such a way that the administrative burden, costs for operators and authorities and the time required for the authorisation procedure will not increase significantly from the current GMO legislation.
2.	Where a person intends to undertake such a deliberate release simultaneously in more than one Member State, that person shall submit the verification request to the competent authority of one of those Member States.		
3.	The verification request referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:		
	(a) the name and the address of the		

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requester;		
(b) the designation and specification of the NGT plant;		
(c) a description of the trait(s) and characteristics which have been introduced or modified;		
(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:		
(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);		
(ii) the NGT plant meets the criteria set out in Annex I;		

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	(e) in the cases referred to in paragraph 2, an indication of the Member States in which the requester intends to undertake the deliberate release;		
	(f) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.		
4.	The competent authority shall acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt. It shall make available the request to the other Member States and to the Commission without undue delay.		
5.	If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the		

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	other Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.		
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.		
7.	The other Member States and the Commission may make ~~comments~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I, within 20 days from the date of receipt of that report.		We welcome the new wording.
8.	In the absence of any ~~comments~~ reasoned objections from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the		

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	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.		
9.	In cases where ~~a comment is~~ reasoned objections are made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the ~~the comment(s)~~ reasoned objections to the other Member States and to the Commission without undue delay.		
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)~~ reasoned objections, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).		
11.	The Commission shall publish a summary of the decisions referred to in paragraphs 8 and 10 in the *Official*		

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Journal of the European Union.		
Article 7 **Verification procedure of category 1 NGT plant status <u>for requests submitted</u> prior to the placing on the market of NGT products**		
1. Where a declaration of category 1 NGT plant status referred to in Article 4(1), point (a), has not already been made in accordance with Article 6, to obtain such a declaration before placing on the market a NGT product, the person intending to place the product on the market shall submit a verification request to the Authority in accordance with paragraph 2 and the implementing act adopted in accordance with Article 27, point (b).		
2. The verification request referred to in paragraph 1 shall be submitted to the Authority in accordance with standard data formats, where they exist, pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:		
(a) the name and the address of the		

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requester;		
(b) the designation and specification of the NGT plant;		
(c) a description of the trait(s) and characteristics which have been introduced or modified;		
(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:		
(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);		
(ii) the NGT plant meets the criteria set out in Annex I;		

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	(e) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.		
3.	The Authority shall acknowledge receipt of the verification request to the requester without delay, stating the date of receipt. It shall make available the verification request to the Member States and to the Commission without undue delay and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article 38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.		
4.	If the verification request does not contain all the necessary information, it shall be declared inadmissible by the		

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	Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.		
5.	If the verification request is not deemed inadmissible in accordance with paragraph 4, the Authority shall deliver its statement on whether the NGT plant fulfils the criteria set out in Annex I within 30 working days from the date of receipt of a verification request. The Authority shall make available the statement to the Commission and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its statement public, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.		
6.	The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 30 working days from the date of receipt of the statement of the		

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Authority, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).		
7. The Commission shall publish a summary of the decision in the *Official Journal of the European Union*.		
Article 8 **System of exchange of information between Member States, the Commission and the Authority**		
The Commission shall set up and maintain an electronic system for the submission of verification requests in accordance with Articles 6 and 7 and the exchange of the information under this ~~Title~~ Chapter.		
Article 9 **Database of decisions declaring the category 1 NGT plant status**		
1. The Commission shall establish and maintain a database listing the decisions declaring the category 1 NGT plant status adopted in accordance with Article 6(8) and (10) and Article 7(6). The database shall contain the following information:		

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(a) name and the address of the requester;		
(b) the designation of the category 1 NGT plant;		
(c) a summarised description of the technique(s) used to obtain the genetic modification;		
(d) a description of the trait(s) and characteristics which have been introduced or modified;		
(e) an identification number, and		
(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.		
2. The database shall be publicly available.		
Article 10 **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		We support the COM proposal, i.e. labelling of NGT1 propagating material, but not extending the labelling obligation to products (food and feed).

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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.		
Article 11 **Confidentiality**		
1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this ~~Title~~ Chapter as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.		
2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.		
3. The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:		

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	(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;		
	(b) DNA sequence information; and		
	(c) breeding patterns and strategies.		
4.	The competent authority or the Authority, as appropriate, shall, after consultation with the requester, decide which information is to be treated as confidential and shall inform the requester of its decision.		
5.	Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged under this Chapter is not made public.		
6.	The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.		
7.	In the event of a withdrawal of the verification request by the requester, Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the		

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withdrawal of the verification request takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.		

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FRANCE

Dans le tableau ci-dessous, la France indique ses positions sur les propositions d'amendements de compromis et rappelle ses commentaires et propositions d'amendements du 06/10 avec, le cas échéant, des précisions complémentaires.

Translation
In the table below, France indicates its positions on the proposed compromise amendments and recalls its comments and proposed amendments of 06/10 with, where appropriate, additional elements.

Presidency compromise text (NGT) **ST 13725/23 INIT**	**MS Drafting Suggestions**	**MS Comments**
Proposal for a **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** **on plants obtained by certain new genomic techniques and their <u>products</u> ~~food and feed~~, and amending Regulation (EU) 2017/625** (Text with EEA relevance)		Accord de la France sur cet amendement. Translation Agreement of France on this amendment.

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114 and 168(4) (b) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council ([23]), 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.		
(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and		

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[23] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

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 conventional breeding techniques (excluding genetic modification techniques other than those listed in Annex I B of Directive 2001/18/EC). The European Food Safety Authority ('the Authority'), in its scientific opinion on plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases[24] and the High Level Group of the Commission´s Scientific Advise Mechanism in its Explanatory note on New techniques in agricultural biotechnology[25] provide an overview of the current state of these conventional breeeding techniques. Targeted mutagenesis techniques result in modification(s)		La France soutient l'ajout de références relatives aux méthodes de sélection conventionnelle. Translation France supports the addition of references relating to conventional breeding methods.

[24] EFSA Panel on Genetically modified organisms (GMO); Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 2012;10(10):2943. [31 pp.] doi:10.2903/j.efsa.2012.2943. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2943.

[25] European Commission, Directorate-General for Research and Innovation, *New techniques in agricultural biotechnology*, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498

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.~~ This can lead to the presence, in the recipient plant, of a continuous DNA sequence existing in the breeder´s gene pool, but also to the presence of a rearranged copy of genetic material composed of two or more DNA sequences from the breeder´s gene pool. The term intragenesis, a subset of cisgenesis, refers to the latter, therefore resulting in an intragenic plant.	Cisgenesis techniques result in the insertion, in the genome of an organism, of ~~genetic material~~ an exact copy of continuous DNA sequences already present already present in the breeders' gene pool. This can lead to the presence, in the recipient plant, of an exact copy of a ~~continuous DNA sequence~~ gene existing in the breeder´s gene pool, ~~but also~~ or, where the inserted DNA sequences are gene fragments, to the presence of a rearranged~~copy of genetic material~~ gene composed of two or more DNA sequences from the breeder´s gene pool. ~~The term intragenesis, a subset of cisgenesis, refers to the latter, therefore resulting in an intragenic plant.~~ A cisgenic plant is a plant in which the result of cisgenesis is the presence of an exact copy of a gene existing in the breeder´s gene pool. An intragenic plant is a plant in which the result of cisgenesis is the presence of a rearranged gene composed of two or more DNA sequences from the breeder´s gene pool.	La rédaction proposée par la Présidence sur la cisgénèse et l'intragénèse ne distingue pas clairement les techniques et les produits qui en résultent. De plus, la notion de plante cisgénique n'est pas expliquée alors qu'elle est utilisée dans le considérant 14. Une rédaction alternative est proposée afin de distinguer les techniques et les produits qui en résultent. De plus, cette proposition d'amendement aligne la définition de la cisgénèse à celle donnée par l'EFSA, conformément au commentaire de la France transmis le 06/10 sur la définition de la cisgénèse à l'article 3(5). La rédaction des considérants 7 et 9 devrait également être adaptée en cohérence. Translation The wording proposed by the Presidency on cisgenesis and intragenesis does not clearly distinguish between the techniques and the resulting products. Furthermore, the notion of cisgenic plant is not explained, although it is used in the recital 14. An alternative wording is proposed in order to

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		distinguish between techniques and the resulting products. In addition, this proposed amendment aligns the definition of cisgenesis into line with that given by EFSA, in accordance with France's comment sent on 06/10 on the definition of cisgenesis in Article 3(5). The wording of recitals 7 and 9 should also be adapted consistently.
(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([26]). 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		

[26] 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.

to contribute to the innovation and sustainability goals of the European Green Deal ([27]) and of the 'Farm to Fork' ([28]), Biodiversity ([29]) and Adaptation to Climate Change([30]) Strategies, to global food security ([31]), the Bioeconomy Strategy ([32]) and to the Union's strategic autonomy ([33]).		
(4) The deliberate release into the environment of organisms obtained by NGTs, including products containing or consisting of such organisms, as well as the placing on the market of food and feed produced from these		

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27 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.

28 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.

29 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.

30 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

31 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.

32 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.

33 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.

organisms, are subject to Directive 2001/18/EC and, Regulation (EC) No 1830/2003 ([34]) of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003 ([35]), while the contained use of plant cells is subject to Directive 2009/1/EC, and transboundary movements of NGT plants to third countries are regulated by Regulation (EC) No 1946/2003 ('the Union GMO legislation').		
(5) In its judgment in case C-528/16 *Confédération paysanne and Others*[36] the Court of Justice of the European Union held that GMOs obtained by means of new techniques/methods of mutagenesis that had appeared or had been mostly developed since Directive 2001/18/EC was adopted could not be considered excluded from the scope of that Directive.		
(6) The Council, in Decision (EU) 2019/190437, requested the Commission to submit, by 30		

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34 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

35 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

36 Judgement of the Court of Justice of 25 July 2018, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, C-528/16, ECLI:EU:C:2018:583.

37 Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study (OJ L 293, 14.11.2019, p. 103).

April 2021, a study in light of that judgment regarding the status of novel genomic techniques under Union law, and a proposal (accompanied by an impact assessment), if appropriate, depending on the conclusions of the study.		
(7) The Commission's study on new genomic techniques ([38]) concluded that the Union GMO legislation is not fit for the purpose of regulating the deliberate release of plants obtained by certain NGTs and the placing on the market of related products including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained with some NGTs, namely targeted mutagenesis and cisgenesis (including intragenesis), and these requirements can be disproportionate or inadequate. The study showed that this is particularly the case for plants obtained by these techniques, given the amount of scientific evidence that is already available, in particular on their safety. Furthermore, the Union GMO legislation is difficult to implement and enforce for plants obtained by targeted mutagenesis and cisgenesis and related products. In certain cases, genetic		

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[38] Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) 92 final.

modifications introduced by these techniques are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques, whereas the distinction is generally possible for genetic modifications introduced by transgenesis. The Union GMO legislation is also not conducive to developing innovative and beneficial products that could contribute to sustainability, food security and resilience of the agri-food chain.		
(8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.		
(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		

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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.		
(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~~,~~ and products (including food and feed) obtained with NGTs ~~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.		Accord de la France sur ces amendements. Translation Agreement of France on these amendments.

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(11a) In keeping with the Union GMO legislation, this Regulation should include under its scope NGT plants, food and feed containing, consisting of or produced from NGT plants, and other products containing or consisting of NGT plants ('NGT products'). Plant reproductive material, including forest reproductive material, falls under the scope of this Regulation both as a plant (when it is deliberately relased for any purpose other than the placing on the market) and as a product (when it is placed on the market, including for the purpose of commercial cultivation).		Accord de la France sur cet amendement. Translation Agreement of France on this amendment.
(12) The potential risks of NGT plants vary, ranging from risk profiles similar to conventionally-bred plants to various types and degrees of hazards and risks that might be similar to those of plants obtained by transgenesis. This Regulation should therefore lay down special rules to adjust the risk assessment and risk management requirements according to the potential risks or lack thereof posed by NGT plants and NGT products.		
(13) This Regulation should distinguish between two categories of NGT plants.		
(14) ~~NGT~~ "Category 1 NGT plants" includes plants that could also occur naturally or be produced by conventional breeding techniques ~~and their progeny obtained by conventional~~		Voir les commentaires et propositions d'amendements sur le chapitre II et les articles 6, 7 et 10, concernant le cadre applicable à la catégorie 1.

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~~breeding techniques ('category 1 NGT plants')~~ This category 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. Novel hazards can be associated with intragenic plants compared with cisgenic and conventionally bred plants[3940], therefore		Translation See comments and proposed amendments on Chapter II and Articles 6, 7 and 10, concerning the framework applicable to Category 1.

[39] EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561, 33 pp. doi:10.2903/j.efsa.2012.2561. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2561.

intragenic plants should remain subject to the Union GMO legislation and be excluded from the criteria for category 1 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.~~		La France soutient l'ajout d'explications sur l'exclusion des plantes intragéniques de la catégorie 1, sous réserve de précisions sur les notions de plante intragénique et de plante cisgénique (cf commentaires et propositions d'amendements au considérant 2) Translation France supports the addition of explanations on the exclusion of intragenic plants from category 1, subject to clarifications on the notions of intragenic plant and cisgenic plant (see comments and proposed amendments to recital 2).
(14a) Since category 1 NGT plants encompasses plants that are equivalent to plants occurring naturally or produced by conventional breeding and that should be treated as those plants, also their progeny obtained by conventional breeding techniques should be treated accordingly and be included under category 1 NGT plants. Therefore, the progeny deriving from the application of conventional breeding techniques to a category 1 NGT plant, including the result of the crossing of a category 1 NGT plant with a conventionally bred plant, or of the crossing of two category 1 NGT plants, should		La France soutient l'ajout d'explications sur le statut de la descendance des végétaux de catégorie 1. Translation France supports the addition of explanations on the status of the progeny of category 1 plants.

[40] EFSA Panel on Genetically Modified Organisms ; Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 2022;20(10):7621, 33 pp. https://doi.org/10.2903/j.efsa.2022.7621.

remain subject to the provisions of category 1 NGT plants without the need to go through the verification procedure, prior to their release or placing on the market. Conversely, the progeny deriving from the application of targeted mutagenesis or cisgenesis to a category 1 NGT plant shall be subject to the procedure to verify the fulfillment of the criteria for category 1 NGT plants, prior to its release or placing on the market as category 1 NGT plant. If those criteria are not met, the progeny can be released or placed on the market only as category 2 NGT plant.		
(14b) 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.		Voir les commentaires sur l'article 5(2). Translation See comments on Article 5(2).
(15) All NGT plants that are not category 1 ('category 2 NGT plants') should remain subject to the requirements of the Union GMO legislation because they feature more complex sets of modifications to the genome.		
(16) Category 1 NGT plants and products should not be subject to the rules and requirements of the Union GMO legislation and		

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to provisions in other Union legislation that apply to GMOs. For legal certainty for operators and transparency, a declaration of the category 1 NGT plant status should be obtained prior to deliberate release, including the placing on the market.		
(17) This declaration should be obtained prior to any deliberate release of any category 1 NGT plants for any other purpose than placing on the market, such as for field trials that are to take place in the territory of the Union, since the criteria are based on data that is available before the field trials and does not depend on these field trials. When no field trials are to take place in the territory of the Union, operators should obtain that declaration before placing the category 1 NGT product on the market.		
(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		Voir les commentaires et propositions d'amendements sur les articles 6 et 7, incluant la proposition de supprimer la procédure nationale prévue à l'article 6. Translation See comments and proposed amendments on Articles 6 and 7, including the proposal to delete the national procedure provided for in Article 6.

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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~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I, 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.		
(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.		
(20) The verification of category 1 NGT plant status is of technical nature and does not involve any risk assessment or risk management considerations and the decision on the status is only declaratory. Therefore, when the procedure is conducted at Union level, such implementing decisions should be adopted by the advisory procedure, supported by scientific and technical assistance by the Authority.		

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(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.		
(22) Category 1 NGT plants should remain subject to any regulatory framework that applies to conventionally bred plants. As is the case for conventional plants and products, those NGT plants and their products will be subject to the applicable sectoral legislation on seed and other plant reproductive material, food, feed and other products, and horizontal frameworks, such as the nature conservation legislation and environmental liability. In this regard, category 1 NGT food featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances of the food will be considered as novel food and thus fall into the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council ([41]) and will be risk assessed in that context.		
(23) Regulation (EU) 2018/848 of the European Parliament and the Council on organic		

[41] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

production and labelling of organic products and repealing Council Regulation (EC) 834/2007([42]) 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.		
(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		

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[42] 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).

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.		
[Recitals 25-48 were not amended in the Presidency compromise text in ST 13725/23 INIT, nor are they directly corresponding to Articles 1-11. They are omitted here to reduce the length of this document.]		
CHAPTER I **GENERAL PROVISIONS**		
Article 1 **Subject matter**		
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 (‘NGT products’).		Accord de la France sur cet amendement. Translation Agreement of France on this amendment.

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Article 2 **Scope** This Regulation shall apply to:		
(1) NGT plants;		
(2) food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;		
(3) feed containing, consisting or produced from NGT plants;		
(4) products, other than food and feed, containing or consisting of NGT plants.		
Article 3 **Definitions** For the purposes of this Regulation, the following definitions shall apply:		
(1) the definitions of 'organism', 'deliberate release' and 'placing on the market' set out in Directive 2001/18/EC, those of 'food' and 'feed' set out in Regulation (EC) No 178/2002, that of 'traceability' set out in Regulation (EC) No 1830/2003, that of 'plant' set out in Regulation (EU)		

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	2016/2031 of the European Parliament and of the Council([43]) and that of 'plant reproductive material' set out 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*[44]];		
(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;	'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;	La France souhaite le maintien de la formulation originale, dans la mesure où les plantes NGT de catégorie 1 comme de catégorie 2 restent légalement considérées comme des OGM Translation France wishes to maintain the current wording, as category 1 and category 2 NGT plants are still legally considered as GMOs.
(3)	'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the		

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[43] Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

[44] COM(2023) 414 final

	techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;		
(4)	'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at ~~precise~~ targeted locations in the genome of an organism;		La France soutient l'amendement proposé. Cet amendement devrait également être répercuté aux considérants 1 et 2. Translation France supports the proposed amendment. This amendment should also be reflected in recitals 1 and 2.
(5)	'cisgenesis' means techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool;	*Amendment proposal of 06/10:* 'cisgenesis' means techniques of genetic modification resulting in the insertion, in the genome of an organism, of ~~genetic material already present in the breeders' gene pool;~~ an exact copy of sequences already present in the species or in a sexually compatible species	*Commentaires du 06/10 :* La France propose d'utiliser la définition de la cisgenèse retenue par l'EFSA dans ses avis. Translation *Comments of 06/10:* France proposes to use EFSA's definition of cisgenesis.
(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;		

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(7) ‘category 1 NGT plant’ means a NGT plant that:		
(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, or	*Amendment proposal of 06/10:* (a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, have at least one of the intended trait(s) conveyed by the genetic modification that is contained in Part 1 of Annex III and does not have any traits referred to in Part 2 of Annex III, or	En complément des commentaires et de la proposition d’amendement du 06/10, la France confirme sa demande d’exclusion les variétés rendues tolérantes aux herbicides de la catégorie 1 et précise que, pour la condition que la plante soit également durable, la France pourrait considérer des solutions alternatives visant à assurer la durabilité, en lien avec le projet de règlement PRM. *Commentaires du 06/10 :* La France souhaite que la plus-value en matière de durabilité soit un critère d’accès à la catégorie 1 et que les variétés rendues tolérantes aux herbicides en soient exclues. Translation : In addition to the comments and proposed amendment of 06/10, France confirms its request for exclusion of varieties made tolerant to herbicides from category 1 and specifies that, for the condition that the plant must also be sustainable, France could consider alternative solutions to ensure sustainability, in connection with the draft PRM regulation. *Comments of 06/10:* France wants added value in terms of

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		sustainability to be a criterion for access to category 1 and herbicide-tolerant varieties to be excluded.
(b) is progeny of the NGT plant(s) referred to in point (a), including progeny derived by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003;		
(8) ‘category 2 NGT plant’ means a NGT plant other than a category 1 NGT plant;		
(9) ‘NGT plant for food use’ means a NGT plant that may be used as food or as a source material for the production of food;		
(10) ‘NGT plant for feed use’ means a NGT plant that may be used as feed or as a source material for the production of feed;		
(11) ‘produced from a NGT plant’ means derived, in whole or in part, from a NGT plant, but not containing or consisting of a NGT plant;		
(12) ‘NGT product’ means ~~a product, other~~		Accord de la France sur cet amendement.

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	~~than food and feed, containing or consisting of a NGT plant and~~ food and feed containing, consisting of or produced from ~~such a plant~~ NGT plants, and other products containing or consisting of such plants;		Translation Agreement of France on this amendment.
(13)	'category 1 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 1 NGT plant;		
(14)	'category 2 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 2 NGT plant;		
(15)	'small or medium sized enterprise (SME)' means a SME within the meaning of Commission Recommendation 2003/361/EC[2].		
Article 4 **Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products**			
Without prejudice to other requirements of Union law, a NGT plant may only be deliberately released into the environment for any other purpose than placing on the market,			

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and a NGT product may only be placed on the market, if:		
(1) the plant is a category 1 NGT plant and		
(a) has obtained a decision declaring that status in accordance with Article 6 or 7; or		
(b) is progeny of plant(s) referred to in point (a); or		
(2) the plant is a category 2 NGT plant, and has been granted consent or has been authorised, in accordance with Chapter III.		

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CHAPTER II **Category 1 NGT plants and category 1 NGT products**		Comme indiqué dans les commentaires du 06/10, la France soutient le principe d'une catégorie 1 de végétaux NGT sur la base d'une reconnaissance d'équivalence avec les végétaux issus de méthodes de sélection conventionnelle. Cependant, elle souhaite encore vérifier la robustesse des critères proposés et s'interroge sur l'opportunité d'une forme d'évaluation des risques simplifiée pour les végétaux NGT de catégorie 1. Les informations scientifiques qu'a apporté la Commission sous forme écrite (non-papier) explicitant les sous-jacents scientifiques sur lesquels repose sa propositon intiale seront précieuses pour apprécier la robustesse des critères. Translation As indicated in the comments of 06/10, France supports the principle of a category 1 of NGT plants on the basis of recognition of equivalence with plants derived from conventional breeding methods. However, France still wishes to check the robustness of the proposed criteria and is considering whether a simplified form of risk assessment is appropriate for category 1 NGT plants. The scientific information provided by the Commission in written form (non-paper) explaining the scientific underlyings on which

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		its initial proposal is based will be valuable in assessing the robustness of the criteria.
Article 5 **Status of category 1 NGT plants <u>and category 1 NGT products</u>**		Accord de la France sur cet amendement. Translation Agreement of France on this amendment.
1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants <u>that fulfill the condition of article 4(1) and their NGT products</u>.		Accord de la France sur cet amendement. Translation Agreement of France on this 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.		
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		*Commentaires du 06/10 :* La France souhaite une analyse juridique sur les actes délégués relatifs aux critères d'équivalence et sur les solutions alternatives possibles, concernant la forme juridique de l'acte et son périmètre, pour permettre d'adapter la réglementation à l'évolution des techniques et des connaissances (notamment dans le sens de retraits ou d'ajouts de critères).

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breeding.		Translation: *Comments of 06/10:* France is asking for a legal analysis on the delegated acts relating to the equivalence criteria and on possible alternative solutions, concerning the legal form of the act and its scope, to enable the regulations to be adapted to developments in technology and knowledge (for exemple for adding or withdrawing criteria).

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Article 6 **Verification procedure of category 1 NGT plant status <u>for requests submitted</u> prior to the deliberate release for any other purpose than placing on the market**	*Amendment proposal of 06/10:* ~~***4. Article 6***~~ ~~***Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market***~~	En complément des commentaires du 06/10, la France s'interroge sur les moyens que les autorités compétentes auraient pour faire respecter les conditions d'accès à la procédure nationale (intention réelle de réaliser un essai au champ dans l'Etat membre où la demande est déposée). Comme indiqué dans les commentaires du 06/10, la France souhaite une approche harmonisée au niveau de l'UE sous la responsabilité de l'EFSA et des États membres, plutôt qu'une procédure au niveau national, en termes de robustesse et de fiabilité. C'est pourquoi il est proposé de supprimer l'article 6 et d'étendre l'application de l'article 7 à la vérification du statut avant la dissémination volontaire à toute autre fin que la mise sur le marché. La France souhaite encore vérifier la robustesse des critères proposés et s'interroge sur l'opportunité d'une forme d'évaluation des risques simplifiée pour les végétaux NGT de catégorie 1. Les informations scientifiques qu'a apporté la Commission sous forme écrite (non-papier) explicitant les sous-jacents scientifiques sur lesquels repose sa propositon intiale seront précieuses pour apprécier la robustesse des

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		critères. Translation: Translation In addition to the comments of 06/10, France wonders about the means that the competent authorities would have to enforce the conditions of access to the national procedure (real intention to carry out a field trial in the Member State where the request is submitted). As indicated in the comments of 06/10, France wants a harmonised approach to the EU level under the responsibility of EFSA and Member States, rather than a procedure at the national level, in terms of robustness and reliability. It is therefore proposed to delete Article 6 and to extend the application of Article 7 to verification of status prior deliberate release for any purpose other than placing on the market. France still wishes to check the robustness of the proposed criteria and is considering whether a simplified form of risk assessment is appropriate for category 1 NGT plants. The scientific information provided by the Commission in written form (non-paper) explaining the scientific underlyings on which its initial proposal is based will be valuable in assessing the robustness of the criteria

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1.	To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I are met ('verification request') to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the implementing act adopted in accordance with Article 27, point (b).	*Amendment proposal of 06/10:* ~~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).~~	
2.	Where a person intends to undertake such a deliberate release simultaneously in more than one Member State, that person shall submit the verification request to the competent authority of one of those Member States.	*Amendment proposal of 06/10:* ~~2. Where a person intends to undertake such a deliberate release simultaneously in more than one Member State, that person shall submit the verification request to the competent authority of one of those Member States. Please comment on definitions linked to Article 15-17 and 20-23~~ ~~Please insert rows below for the relevant definitions you want to comment on, and indicate clearly in this column which definition you are commenting on~~	

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3. The verification request referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:	*Amendment proposal of 06/10:* ~~3. The verification request referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:~~	
(a) the name and the address of the requester;	*Amendment proposal of 06/10:* ~~(a) the name and the address of the requester;~~	
(b) the designation and specification of the NGT plant;	*Amendment proposal of 06/10:* ~~(b) the designation and specification of the NGT plant;~~	
(c) a description of the trait(s) and characteristics which have been introduced or modified;	*Amendment proposal of 06/10:* ~~(c) a description of the trait(s) and characteristics which have been introduced or modified;~~	
(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:	*Amendment proposal of 06/10:* ~~(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:~~	
(i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene	*Amendment proposal of 06/10:* ~~(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~~	

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);	~~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);~~	
(ii) the NGT plant meets the criteria set out in Annex I;	*Amendment proposal of 06/10:* ~~(ii) the NGT plant meets the criteria set out in Annex I;~~	
(e) in the cases referred to in paragraph 2, an indication of the Member States in which the requester intends to undertake the deliberate release;	*Amendment proposal of 06/10:* ~~(e) in the cases referred to in paragraph 2, an indication of the Member States in which the requester intends to undertake the deliberate release;~~	
(f) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.	*Amendment proposal of 06/10:* ~~(f) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.~~	
4. The competent authority shall	*Amendment proposal of 06/10:*	

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	acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt. It shall make available the request to the other Member States and to the Commission without undue delay.	~~4. The competent authority shall acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt. It shall make available the request to the other Member States and to the Commission without undue delay.~~	
5.	If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.	*Amendment proposal of 06/10:* ~~5. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.~~	
6.	If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.	*Amendment proposal of 06/10:* ~~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.~~	

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7.	The other Member States and the Commission may make ~~comments~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I, within 20 days from the date of receipt of that report.	*Amendment proposal of 06/10:* ~~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.~~	
8.	In the absence of any ~~comments~~ reasoned objections from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.	*Amendment proposal of 06/10:* ~~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.~~	
9.	In cases where ~~a comment is~~ reasoned objections are made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the ~~the comment(s)~~ reasoned objections to the other Member States and to the Commission without undue delay.	*Amendment proposal of 06/10:* ~~9. In cases where a comment is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the the comment(s) to the Commission without undue delay.~~	

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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)~~ reasoned objections, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).	*Amendment proposal of 06/10:* ~~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).~~	
11.	The Commission shall publish a summary of the decisions referred to in paragraphs 8 and 10 in the *Official Journal of the European Union*.	*Amendment proposal of 06/10:* ~~11. The Commission shall publish a summary of the decisions referred to in paragraphs 8 and 10 in the Official Journal of the European Union.~~	

Article 7 **Verification procedure of category 1 NGT plant status <u>for requests submitted</u> prior to the placing on the market of NGT products**	*Amendment proposal of 06/10:* ***5. Article 7*** ***Verification procedure of category 1 NGT plant status ~~prior to the placing on the market of NGT products~~***	Accord de la France sur cet amendement, sans préjudice des commentaires et propositions d'amendements du 06/10 sur l'article 7. Comme indiqué dans les commentaires du 06/10, la France souhaite une approche harmonisée au niveau de l'UE sous la responsabilité de l'EFSA et des États membres, plutôt qu'une procédure au niveau national, en termes de robustesse et de fiabilité. Les modifications proposées à l'article 7 visent à étendre l'application de cet article à la vérification du statut d'un végétal NGT de catégorie 1 avant la dissémination volontaire à toute autre fin que la mise sur le marché, afin de mettre en place une approche harmonisée au niveau de l'UE pour toutes les procédures de vérification. La France souhaite encore vérifier la robustesse des critères proposés et s'interroge sur l'opportunité d'une forme d'évaluation des risques simplifiée pour les végétaux NGT de catégorie 1. Les informations scientifiques qu'a apporté la Commission sous forme écrite (non-papier) explicitant les sous-jacents scientifiques sur lesquels repose sa propositon intiale seront précieuses pour apprécier la robustesse des critères.

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		Translation Agreement of France on this amendment, without prejudice to the comments and proposed amendments of 06/10 on article 7. As indicated in the comments of 06/10, France wants a harmonised approach to the EU level under the responsibility of EFSA and Member States, rather than a procedure at the national level, in terms of robustness and reliability. The proposed amendments to Article 7 aim to extend the application of this article to the verification of the status of a category 1 NGT plant prior to deliberate release for any purpose other than placing on the market, in order to establish a harmonised approach at EU level for all verification procedures. France still wishes to check the robustness of the proposed criteria and is examining the opportunity of a specific, simplified form of risk assessment for category 1 NGTs. The scientific information provided by the Commission in written form (non-paper) explaining the scientific underlyings on which its initial proposal is based will be valuable in assessing the robustness of the criteria
1. Where a declaration of category 1 NGT	*Amendment proposal of 06/10:*	

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	plant status referred to in Article 4(1), point (a), has not already been made in accordance with Article 6, to obtain such a declaration before placing on the market a NGT product, the person intending to place the product on the market shall submit a verification request to the Authority in accordance with paragraph 2 and the implementing act adopted in accordance with Article 27, point (b).	1. ~~Where a declaration of category 1 NGT plant status referred to in Article 4(1), point (a), has not already been made in accordance with Article 6,~~To obtain ~~such a~~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 or where a declaration of category 1 NGT plant status referred to in Article 4(1), point (a), has not already been made before placing on the market a NGT product, the person intending to undertake the deliberate release or to place the product on the market shall submit a ~~verification~~ request to verify whether the criteria set out in Annex I are met ('verification request') to the Authority in accordance with paragraph 2 and the implementing act adopted in accordance with Article 27, point (b).	
2.	The verification request referred to in paragraph 1 shall be submitted to the Authority in accordance with standard data formats, where they exist, pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:		
	(a) the name and the address of the		

requester;		
(b) the designation and specification of the NGT plant;		
(c) a description of the trait(s) and characteristics which have been introduced or modified;		
(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:		
(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);		
(ii) the NGT plant meets the criteria set out in Annex I;		

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	(e) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.	*Amendment proposal of 06/10:* 6. (e) in the cases where the verification request is submitted before a deliberate release of a NGT plant for any other purpose than placing on the market, an indication of the Member State(s) in which the requester intends to undertake the deliberate release; ~~(e)~~ (f) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.	
3.	The Authority shall acknowledge receipt of the verification request to the requester without delay, stating the date of receipt. It shall make available the verification request to the Member States and to the Commission without undue delay and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article 38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of		

	this Regulation.		
4.	If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.		
5.	If the verification request is not deemed inadmissible in accordance with paragraph 4, the Authority shall deliver its statement on whether the NGT plant fulfils the criteria set out in Annex I within 30 working days from the date of receipt of a verification request. The Authority shall make available the statement to the Commission and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its statement public, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.		

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6. The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 30 working days from the date of receipt of the statement of the Authority, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).		
7. The Commission shall publish a summary of the decision in the *Official Journal of the European Union*.		
Article 8 **System of exchange of information between Member States, the Commission and the Authority**		
The Commission shall set up and maintain an electronic system for the submission of verification requests in accordance with Articles 6 and 7 and the exchange of the information under this ~~Title~~ Chapter.		
Article 9 **Database of decisions declaring the category 1 NGT plant status**		
1. The Commission shall establish and maintain a database listing the decisions declaring the category 1 NGT		

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	plant status adopted in accordance with Article 6(8) and (10) and Article 7(6). The database shall contain the following information:		
	(a) name and the address of the requester;		
	(b) the designation of the category 1 NGT plant;		
	(c) a summarised description of the technique(s) used to obtain the genetic modification;		
	(d) a description of the trait(s) and characteristics which have been introduced or modified;		
	(e) an identification number, and		
	(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.		
2.	The database shall be publicly available.		

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Article 10 **Labelling of category 1 NGT plant reproductive material, including breeding material**		En complément des commentaires du 06/10, la France ajoute qu'un étiquetage obligatoire de la catégorie 1 jusqu'au consommateur final ferait peser une charge disproportionnée sur les opérateurs compte tenu de l'équivalence entre des variétés de catégorie 1 et des variétés conventionnelles. Par ailleurs, la difficulté, voire l'impossibilité, de différencier par des analyses les variétés de catégorie 1 des variétés conventionnelles obligerait les opérateurs à mettre en place des filières dédiées. *Commentaires du 06/10 :* La France soutient le niveau d'étiquetage et de tracabilité proposé par le texte sur la categorie 1. Cependant, la France souhaite que l'étiquetage reste possible, de manière volontaire, pour tous les acteurs qui le souhaitent, notamment le bio, mais aussi les autres filières spécifiques qui voudraient revendiquer l'absence de NGT dans leur chaine de valeur. Translation: In addition to the comments of 06/10, France adds that compulsory labelling from category 1 to the final consumer would place a disproportionate burden on operators, given the equivalence between category 1 and conventional varieties. In addition, the

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		difficulty, if not the impossibility, of differentiating category 1 varieties from conventional varieties by analysis would force operators to set up dedicated sectors. *Comments of 06/10* France supports the level of labelling and traceability proposed in the text for category 1. However, France whises that labelling should continue to be possible, on a voluntary basis, for all players wishing to do so, in particular organic producers, but also specific sectors wishing to claim the absence of NGT in their value chain.
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.		
Article 11 **Confidentiality**		
1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information		

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	submitted under this ~~Title~~ Chapter as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.		
2.	The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.		
3.	The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:		
	(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;		
	(b) DNA sequence information; and		
	(c) breeding patterns and strategies.		
4.	The competent authority or the Authority, as appropriate, shall, after consultation with the requester, decide which information is to be treated as		

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	confidential and shall inform the requester of its decision.		
5.	Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged under this Chapter is not made public.		
6.	The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.		
7.	In the event of a withdrawal of the verification request by the requester, Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the withdrawal of the verification request takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.		

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Presidency compromise text (NGT) **ST 13725/23 INIT**	**MS Drafting Suggestions**	**MS Comments**
Proposal for a **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** **on plants obtained by certain new genomic techniques and their products ~~food and feed~~, and amending Regulation (EU) 2017/625** (Text with EEA relevance)		

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114 and 168(4) (b) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council ([45]), 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.		Since with these techniques are enabled changes to be made to the genome at precise locations, we are of the opinion that these changes can be detected. In this sense, we believe that the applicant shall provide the relevant information for the detection of these changes (method, primer sequences, etc.).
(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in		

[45] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

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 conventional breeding techniques (excluding genetic modification techniques other than those listed in Annex I B of Directive 2001/18/EC). The European Food Safety Authority ('the Authority'), in its scientific opinion on plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases[46] and the High Level Group of the Commission´s Scientific Advise Mechanism in its Explanatory note on New techniques in agricultural biotechnology[47] provide an overview of the current state of these conventional breeeding techniques. Targeted		

[46] EFSA Panel on Genetically modified organisms (GMO); Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 2012;10(10):2943. [31 pp.] doi:10.2903/j.efsa.2012.2943. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2943.

[47] European Commission, Directorate-General for Research and Innovation, *New techniques in agricultural biotechnology*, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498

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.~~ This can lead to the presence, in the recipient plant, of a continuous DNA sequence existing in the breeder´s gene pool, but also to the presence of a rearranged copy of genetic material composed of two or more DNA sequences from the breeder´s gene pool. The term intragenesis, a subset of cisgenesis, refers to the latter, therefore resulting in an intragenic plant.		
(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([48]). This includes plants with improved tolerance or resistance to plant diseases and pests, plants with improved tolerance or resistance to climate change effects and		

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[48] 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.

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 ([49]) and of the 'Farm to Fork' ([50]), Biodiversity ([51]) and Adaptation to Climate Change([52]) Strategies, to global food security ([53]), the Bioeconomy Strategy ([54]) and to the Union's strategic autonomy ([55]).		

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49 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.

50 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.

51 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.

52 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

53 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.

54 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.

(4) The deliberate release into the environment of organisms obtained by NGTs, including products containing or consisting of such organisms, as well as the placing on the market of food and feed produced from these organisms, are subject to Directive 2001/18/EC and, Regulation (EC) No 1830/2003 ([56]) of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003 ([57]), while the contained use of plant cells is subject to Directive 2009/1/EC, and transboundary movements of NGT plants to third countries are regulated by Regulation (EC) No 1946/2003 ('the Union GMO legislation').		
(5) In its judgment in case C-528/16 *Confédération paysanne and Others*[58] the Court of Justice of the European Union held that GMOs obtained by means of new techniques/methods of mutagenesis that had appeared or had been mostly developed since Directive 2001/18/EC was adopted could not be		

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55 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.

56 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

57 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

58 Judgement of the Court of Justice of 25 July 2018, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, C-528/16, ECLI:EU:C:2018:583.

considered excluded from the scope of that Directive.		
(6) The Council, in Decision (EU) 2019/190459, requested the Commission to submit, by 30 April 2021, a study in light of that judgment regarding the status of novel genomic techniques under Union law, and a proposal (accompanied by an impact assessment), if appropriate, depending on the conclusions of the study.		
(7) The Commission's study on new genomic techniques ([60]) concluded that the Union GMO legislation is not fit for the purpose of regulating the deliberate release of plants obtained by certain NGTs and the placing on the market of related products including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained with some NGTs, namely targeted mutagenesis and cisgenesis (including intragenesis), and these requirements can be disproportionate or inadequate. The study		

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[59] Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study (OJ L 293, 14.11.2019, p. 103).

[60] Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) 92 final.

showed that this is particularly the case for plants obtained by these techniques, given the amount of scientific evidence that is already available, in particular on their safety. Furthermore, the Union GMO legislation is difficult to implement and enforce for plants obtained by targeted mutagenesis and cisgenesis and related products. In certain cases, genetic modifications introduced by these techniques are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques, whereas the distinction is generally possible for genetic modifications introduced by transgenesis. The Union GMO legislation is also not conducive to developing innovative and beneficial products that could contribute to sustainability, food security and resilience of the agri-food chain.		We do not agree with the highlighetd text. It is impossible to be indistinguishable genetic modifications by NGTs from natural mutations or from genetic modifications by conventional breeding techniques, since the latters are random while the NGTs are targeted.
(8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.		
(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		

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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.		
(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~~,~~ and products (including food and feed) obtained with NGTs ~~containing, consisting of or produced from NGT plants and~~		

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~~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.		
(11a) In keeping with the Union GMO legislation, this Regulation should include under its scope NGT plants, food and feed containing, consisting of or produced from NGT plants, and other products containing or consisting of NGT plants ('NGT products'). Plant reproductive material, including forest reproductive material, falls under the scope of this Regulation both as a plant (when it is deliberately relased for any purpose other than the placing on the market) and as a product (when it is placed on the market, including for the purpose of commercial cultivation).		We agree with the clarification regarding that plant reproductive material falls under the scope of this regulation but we think that it should also be mentioned in main text of the proposal.
(12) The potential risks of NGT plants vary, ranging from risk profiles similar to conventionally-bred plants to various types and degrees of hazards and risks that might be similar to those of plants obtained by transgenesis. This Regulation should therefore lay down special rules to adjust the risk assessment and risk management requirements according to the potential risks or lack thereof posed by NGT plants and NGT products.		

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(13) This Regulation should distinguish between two categories of NGT plants.		
(14) ~~NGT~~ "Category 1 NGT plants" includes 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')~~ This category 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. Novel hazards can be associated with intragenic plants compared with cisgenic and		We doubt if the naturally occured or produced by conventional breeding techniques plants have in the same position the genetic modification(s) introduced by NGTs.

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conventionally bred plants[6162], therefore intragenic plants should remain subject to the Union GMO legislation and be excluded from the criteria for category 1 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.~~		We believe that thresholds for size and number of genetic modifications as they are provided in Annex I are not on scientific basis.
(14a) Since category 1 NGT plants encompasses plants that are equivalent to plants occurring naturally or produced by conventional breeding and that should be treated as those plants, also their progeny obtained by conventional breeding techniques should be treated accordingly and be included under category 1 NGT plants. Therefore, the progeny deriving from the application of conventional breeding techniques to a category 1 NGT plant, including		

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[61] EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561, 33 pp. doi:10.2903/j.efsa.2012.2561. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2561.

[62] EFSA Panel on Genetically Modified Organisms ; Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 2022;20(10):7621, 33 pp. https://doi.org/10.2903/j.efsa.2022.7621.

the result of the crossing of a category 1 NGT plant with a conventionally bred plant, or of the crossing of two category 1 NGT plants, should remain subject to the provisions of category 1 NGT plants without the need to go through the verification procedure, prior to their release or placing on the market. Conversely, the progeny deriving from the application of targeted mutagenesis or cisgenesis to a category 1 NGT plant shall be subject to the procedure to verify the fulfillment of the criteria for category 1 NGT plants, prior to its release or placing on the market as category 1 NGT plant. If those criteria are not met, the progeny can be released or placed on the market only as category 2 NGT plant.		
(14b) 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.		
(15) All NGT plants that are not category 1 ('category 2 NGT plants') should remain subject to the requirements of the Union GMO legislation because they feature more complex sets of modifications to the genome.		

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(16) Category 1 NGT plants and products should not be subject to the rules and requirements of the Union GMO legislation and to provisions in other Union legislation that apply to GMOs. For legal certainty for operators and transparency, a declaration of the category 1 NGT plant status should be obtained prior to deliberate release, including the placing on the market.		
(17) This declaration should be obtained prior to any deliberate release of any category 1 NGT plants for any other purpose than placing on the market, such as for field trials that are to take place in the territory of the Union, since the criteria are based on data that is available before the field trials and does not depend on these field trials. When no field trials are to take place in the territory of the Union, operators should obtain that declaration before placing the category 1 NGT product on the market.		
(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		

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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~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I, 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.		
(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.		
(20) The verification of category 1 NGT plant status is of technical nature and does not involve any risk assessment or risk management considerations and the decision on the status is only declaratory. Therefore, when the procedure is conducted at Union level, such implementing		

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decisions should be adopted by the advisory procedure, supported by scientific and technical assistance by the Authority.		
(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.		This is not in full agreement with the farm to fork strategy. We believe that labelling should be applied in the whole food and feed chain.
(22) Category 1 NGT plants should remain subject to any regulatory framework that applies to conventionally bred plants. As is the case for conventional plants and products, those NGT plants and their products will be subject to the applicable sectoral legislation on seed and other plant reproductive material, food, feed and other products, and horizontal frameworks, such as the nature conservation legislation and environmental liability. In this regard, category 1 NGT food featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances of the food will be considered as novel food and thus fall into the		

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scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council ([63]) and will be risk assessed in that context.		
(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([64]) 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		

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63 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

64 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).

production.		
(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.		
[Recitals 25-48 were not amended in the Presidency compromise text in ST 13725/23 INIT, nor are they directly corresponding to Articles 1-11. They are omitted here to reduce the length of this document.]		
CHAPTER I **GENERAL PROVISIONS**		
Article 1 **Subject matter**		
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	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'~~)~~ (plants obtained by	In order to be clear to everyone the subject matter.

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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 (‘NGT products’).	certain new genomic techniques) 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~~ (‘NGT products’)~~)~~ (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).	
Article 2 **Scope** This Regulation shall apply to:		
(1) NGT plants;	NGT plants, including plant reproductive material and forest reproductive material;	
(2) food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;		
(3) feed containing, consisting or produced from NGT plants;		
(4) products, other than food and feed, containing or consisting of NGT plants.	products, other than food and feed, containing or consisting of NGT plants, including plant reproductive material and forest reproductive material.	

Article 3 **Definitions** For the purposes of this Regulation, the following definitions shall apply:		
(1) the definitions of 'organism', 'deliberate release' and 'placing on the market' set out in Directive 2001/18/EC, those of 'food' and 'feed' set out in Regulation (EC) No 178/2002, that of 'traceability' set out in Regulation (EC) No 1830/2003, that of 'plant' set out in Regulation (EU) 2016/2031 of the European Parliament and of the Council([65]) and that of 'plant reproductive material' set out 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*[66]];		
(2) 'NGT plant' means a ~~genetically modified~~ plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition		

[65] Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

[66] COM(2023) 414 final

	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;		
(3)	'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;		
(4)	'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at ~~precise~~ targeted locations in the genome of an organism;		
(5)	'cisgenesis' means techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool;		
(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,		

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	induced polyploidy and bridge crosses;		
(7)	'category 1 NGT plant' means a NGT plant that:		
	(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, or		
	(b) is progeny of the NGT plant(s) referred to in point (a), including progeny derived by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003;		
(8)	'category 2 NGT plant' means a NGT plant other than a category 1 NGT plant;		
(9)	'NGT plant for food use' means a NGT plant that may be used as food or as a source material for the production of food;		
(10)	'NGT plant for feed use' means a NGT plant that may be used as feed or as a source material for the production of feed;		
(11)	'produced from a NGT plant' means		

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	derived, in whole or in part, from a NGT plant, but not containing or consisting of a NGT plant;		
(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~~ NGT plants, and other products containing or consisting of such plants;	'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~~ NGT plants, plant reproductive material and forest reproductive material and other products containing or consisting of such plants;	
(13)	'category 1 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 1 NGT plant;		
(14)	'category 2 NGT product' means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 2 NGT plant;		
(15)	'small or medium sized enterprise (SME)' means a SME within the meaning of Commission Recommendation 2003/361/EC[2].		

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Article 4 **Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products**		
Without prejudice to other requirements of Union law, a NGT plant may only be deliberately released into the environment for any other purpose than placing on the market, and a NGT product may only be placed on the market, if:		
(1) the plant is a category 1 NGT plant and		
(a) has obtained a decision declaring that status in accordance with Article 6 or 7; or		
(b) is progeny of plant(s) referred to in point (a); or		
(2) the plant is a category 2 NGT plant, and has been granted consent or has been authorised, in accordance with Chapter III.		

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CHAPTER II **Category 1 NGT plants and category 1 NGT products**		
Article 5 **Status of category 1 NGT plants <u>and category 1 NGT products</u>**		
1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants <u>that fulfill the condition of article 4(1) and their NGT products</u>.		
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.		
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.		

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Article 6 **Verification procedure of category 1 NGT plant status <u>for requests submitted</u> prior to the deliberate release for any other purpose than placing on the market**		
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).		
2. Where a person intends to undertake such a deliberate release simultaneously in more than one Member State, that person shall submit the verification request to the competent authority of one of those Member States.		

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3. The verification request referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:		
(a) the name and the address of the requester;		
(b) the designation and specification of the NGT plant;		
(c) a description of the trait(s) and characteristics which have been introduced or modified;	a description of the trait(s) and characteristics which have been introduced or modified, including the detection method of those trait(s);	
(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:		
(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		

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	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);		
	(ii) the NGT plant meets the criteria set out in Annex I;		
	(e) in the cases referred to in paragraph 2, an indication of the Member States in which the requester intends to undertake the deliberate release;		
	(f) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.		
4.	The competent authority shall acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt. It		

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

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	report, as regards the fulfillment of the criteria set out in Annex I, within 20 days from the date of receipt of that report.		
8.	In the absence of any ~~comments~~ reasoned objections from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.		
9.	In cases where ~~a comment is~~ reasoned objections are made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the ~~the comment(s)~~ reasoned objections to the other Member States and to the Commission without undue delay.		
10.	The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring		

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	whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the ~~comment(s)~~ reasoned objections, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).		
11.	The Commission shall publish a summary of the decisions referred to in paragraphs 8 and 10 in the *Official Journal of the European Union*.		
Article 7 **Verification procedure of category 1 NGT plant status for requests submitted prior to the placing on the market of NGT products**			
1.	Where a declaration of category 1 NGT plant status referred to in Article 4(1), point (a), has not already been made in accordance with Article 6, to obtain such a declaration before placing on the market a NGT product, the person intending to place the product on the market shall submit a verification request to the Authority in accordance with paragraph 2 and the implementing act adopted in accordance with Article 27, point (b).		
2.	The verification request referred to in		

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paragraph 1 shall be submitted to the Authority in accordance with standard data formats, where they exist, pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:		
(a) the name and the address of the requester;		
(b) the designation and specification of the NGT plant;		
(c) a description of the trait(s) and characteristics which have been introduced or modified;	a description of the trait(s) and characteristics which have been introduced or modified, including the detection method of those trait(s);	
(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:		
(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		

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	the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);		
	(ii) the NGT plant meets the criteria set out in Annex I;		
	(e) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.		
3.	The Authority shall acknowledge receipt of the verification request to the requester without delay, stating the date of receipt. It shall make available the verification request to the Member States and to the Commission without undue delay and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article		

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	38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.		
4.	If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.		
5.	If the verification request is not deemed inadmissible in accordance with paragraph 4, the Authority shall deliver its statement on whether the NGT plant fulfils the criteria set out in Annex I within 30 working days from the date of receipt of a verification request. The Authority shall make available the statement to the Commission and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its statement public, after omission of any information identified		

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as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.		
6. The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 30 working days from the date of receipt of the statement of the Authority, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).		
7. The Commission shall publish a summary of the decision in the *Official Journal of the European Union*.		
Article 8 **System of exchange of information between Member States, the Commission and the Authority**		
The Commission shall set up and maintain an electronic system for the submission of verification requests in accordance with Articles 6 and 7 and the exchange of the information under this ~~Title~~ Chapter.		

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Article 9 **Database of decisions declaring the category 1 NGT plant status**		
1. The Commission shall establish and maintain a database listing the decisions declaring the category 1 NGT plant status adopted in accordance with Article 6(8) and (10) and Article 7(6). The database shall contain the following information:		
(a) name and the address of the requester;		
(b) the designation of the category 1 NGT plant;		
(c) a summarised description of the technique(s) used to obtain the genetic modification;		
(d) a description of the trait(s) and characteristics which have been introduced or modified;		
(e) an identification number, and		
(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.		

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2. The database shall be publicly available.		
Article 10 **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.		We fully agree with this article but this is not in full agreement with the farm to fork strategy. We believe that labelling should be applied in the whole food and feed chain.
Article 11 **Confidentiality**		
1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this ~~Title~~ Chapter as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.		
2. The competent authority or the Authority, as appropriate, shall assess		

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	the confidentiality request referred to in paragraph 1.		
3.	The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:		
	(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;		
	(b) DNA sequence information; and		
	(c) breeding patterns and strategies.		
4.	The competent authority or the Authority, as appropriate, shall, after consultation with the requester, decide which information is to be treated as confidential and shall inform the requester of its decision.		
5.	Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged		

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	under this Chapter is not made public.		
6.	The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.		
7.	In the event of a withdrawal of the verification request by the requester, Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the withdrawal of the verification request takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.		

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Presidency compromise text (NGT) **ST 13725/23 INIT**	**MS Drafting Suggestions**	**MS Comments**
Proposal for a **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** **on plants obtained by certain new genomic techniques and their <u>products</u> ~~food and feed~~, and amending Regulation (EU) 2017/625** (Text with EEA relevance)		Hungary thanks the Presidency for the modification and supports the proposed amendment.

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114 and 168(4) (b) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
(1) Since 2001, when Directive 2001/18/EC of the European Parliament and of the Council ([67]), 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.		
(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and		Hungary thanks the Presidency for the modification and can support the proposed amendment regarding the clarification on the list

[67] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

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 conventional breeding techniques (excluding genetic modification techniques other than those listed in Annex I B of Directive 2001/18/EC). The European Food Safety Authority ('the Authority'), in its scientific opinion on plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases[68] and the High Level Group of the Commission´s Scientific Advise Mechanism in its Explanatory note on New techniques in agricultural biotechnology[69] provide an overview of the current state of these conventional breeeding techniques. Targeted mutagenesis techniques result in modification(s)		of the advanced teecniques.

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[68] EFSA Panel on Genetically modified organisms (GMO); Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 2012;10(10):2943. [31 pp.] doi:10.2903/j.efsa.2012.2943. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2943.

[69] European Commission, Directorate-General for Research and Innovation, *New techniques in agricultural biotechnology*, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498

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.~~ This can lead to the presence, in the recipient plant, of a continuous DNA sequence existing in the breeder´s gene pool, but also to the presence of a rearranged copy of genetic material composed of two or more DNA sequences from the breeder´s gene pool. The term intragenesis, a subset of cisgenesis, refers to the latter, therefore resulting in an intragenic plant.		
(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([70]). 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		

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[70] 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.

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 ([71]) and of the 'Farm to Fork' ([72]), Biodiversity ([73]) and Adaptation to Climate Change([74]) Strategies, to global food security ([75]), the Bioeconomy Strategy ([76]) and to the Union's strategic autonomy ([77]).		

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71 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.

72 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.

73 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.

74 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

75 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.

76 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.

77 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.

(4) The deliberate release into the environment of organisms obtained by NGTs, including products containing or consisting of such organisms, as well as the placing on the market of food and feed produced from these organisms, are subject to Directive 2001/18/EC and, Regulation (EC) No 1830/2003 ([78]) of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003 ([79]), while the contained use of plant cells is subject to Directive 2009/1/EC, and transboundary movements of NGT plants to third countries are regulated by Regulation (EC) No 1946/2003 ('the Union GMO legislation').		
(5) In its judgment in case C-528/16 *Confédération paysanne and Others*[80] the Court of Justice of the European Union held that GMOs obtained by means of new techniques/methods of mutagenesis that had appeared or had been mostly developed since Directive 2001/18/EC was adopted could not be considered excluded from the scope of that Directive.		

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78 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

79 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

80 Judgement of the Court of Justice of 25 July 2018, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, C-528/16, ECLI:EU:C:2018:583.

(6) The Council, in Decision (EU) 2019/190481, requested the Commission to submit, by 30 April 2021, a study in light of that judgment regarding the status of novel genomic techniques under Union law, and a proposal (accompanied by an impact assessment), if appropriate, depending on the conclusions of the study.		
(7) The Commission's study on new genomic techniques ([82]) concluded that the Union GMO legislation is not fit for the purpose of regulating the deliberate release of plants obtained by certain NGTs and the placing on the market of related products including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained with some NGTs, namely targeted mutagenesis and cisgenesis (including intragenesis), and these requirements can be disproportionate or inadequate. The study showed that this is particularly the case for plants obtained by these techniques, given the		

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81 Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study (OJ L 293, 14.11.2019, p. 103).

82 Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) 92 final.

amount of scientific evidence that is already available, in particular on their safety. Furthermore, the Union GMO legislation is difficult to implement and enforce for plants obtained by targeted mutagenesis and cisgenesis and related products. In certain cases, genetic modifications introduced by these techniques are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques, whereas the distinction is generally possible for genetic modifications introduced by transgenesis. The Union GMO legislation is also not conducive to developing innovative and beneficial products that could contribute to sustainability, food security and resilience of the agri-food chain.		
(8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.		
(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		

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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.		
(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~~,~~ and products (including food and feed) obtained with NGTs ~~containing, consisting of or produced from NGT plants and other products containing or consisting of NGT plants ('NGT products')~~ so as to contribute to		Hungary thanks the Presidency for the modification and supports the proposed amendment.

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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.		
(11a) In keeping with the Union GMO legislation, this Regulation should include under its scope NGT plants, food and feed containing, consisting of or produced from NGT plants, and other products containing or consisting of NGT plants ('NGT products'). Plant reproductive material, including forest reproductive material, falls under the scope of this Regulation both as a plant (when it is deliberately relased for any purpose other than the placing on the market) and as a product (when it is placed on the market, including for the purpose of commercial cultivation).	(11a) In keeping with the Union GMO legislation, this Regulation should include under its scope NGT plants, food and feed containing, consisting of or produced from NGT plants, and other products containing or consisting of NGT plants ('NGT products'). Plant reproductive material, including forest reproductive material, falls under the scope of this Regulation both as a plant (when it is deliberately relased for any purpose other than the placing on the market) and as a product (when it is placed on the market, including for the purpose of ~~commercial~~ cultivation).	Hungary thanks the Presidency for the modification and in general supports the proposed amendment with one exception. As we have already expressed cultivation is not only for commercial purposes but also for small scale cultivation purposes.
(12) The potential risks of NGT plants vary, ranging from risk profiles similar to conventionally-bred plants to various types and degrees of hazards and risks that might be similar to those of plants obtained by transgenesis. This Regulation should therefore lay down special rules to adjust the risk assessment and risk management requirements according to the potential risks or lack thereof posed by NGT plants and NGT products.		
(13) This Regulation should distinguish between		

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two categories of NGT plants.		
(14) ~~NGT~~ "Category 1 NGT plants" includes 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')~~ This category 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. Novel hazards can be associated with		

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intragenic plants compared with cisgenic and conventionally bred plants[8384], therefore intragenic plants should remain subject to the Union GMO legislation and be excluded from the criteria for category 1 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.~~		
(14a) Since category 1 NGT plants encompasses plants that are equivalent to plants occurring naturally or produced by conventional breeding and that should be treated as those plants, also their progeny obtained by conventional breeding techniques should be treated accordingly and be included under category 1 NGT plants. Therefore, the progeny deriving from the application of conventional breeding techniques to a category 1 NGT plant, including		

[83] EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 2012;10(2):2561, 33 pp. doi:10.2903/j.efsa.2012.2561. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/2561.

[84] EFSA Panel on Genetically Modified Organisms ; Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal 2022;20(10):7621, 33 pp. https://doi.org/10.2903/j.efsa.2022.7621.

the result of the crossing of a category 1 NGT plant with a conventionally bred plant, or of the crossing of two category 1 NGT plants, should remain subject to the provisions of category 1 NGT plants without the need to go through the verification procedure, prior to their release or placing on the market. Conversely, the progeny deriving from the application of targeted mutagenesis or cisgenesis to a category 1 NGT plant shall be subject to the procedure to verify the fulfillment of the criteria for category 1 NGT plants, prior to its release or placing on the market as category 1 NGT plant. If those criteria are not met, the progeny can be released or placed on the market only as category 2 NGT plant.		
(14b) 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.		
(15) All NGT plants that are not category 1 ('category 2 NGT plants') should remain subject to the requirements of the Union GMO legislation because they feature more complex sets of modifications to the genome.		

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(16) Category 1 NGT plants and products should not be subject to the rules and requirements of the Union GMO legislation and to provisions in other Union legislation that apply to GMOs. For legal certainty for operators and transparency, a declaration of the category 1 NGT plant status should be obtained prior to deliberate release, including the placing on the market.		
(17) This declaration should be obtained prior to any deliberate release of any category 1 NGT plants for any other purpose than placing on the market, such as for field trials that are to take place in the territory of the Union, since the criteria are based on data that is available before the field trials and does not depend on these field trials. When no field trials are to take place in the territory of the Union, operators should obtain that declaration before placing the category 1 NGT product on the market.		
(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		Clarification is needed what should be considered as *reasoned objection*.

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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~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I, 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.		
(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.		
(20) The verification of category 1 NGT plant status is of technical nature and does not involve any risk assessment or risk management considerations and the decision on the status is only declaratory. Therefore, when the procedure is conducted at Union level, such implementing		

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decisions should be adopted by the advisory procedure, supported by scientific and technical assistance by the Authority.		
(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.		
(22) Category 1 NGT plants should remain subject to any regulatory framework that applies to conventionally bred plants. As is the case for conventional plants and products, those NGT plants and their products will be subject to the applicable sectoral legislation on seed and other plant reproductive material, food, feed and other products, and horizontal frameworks, such as the nature conservation legislation and environmental liability. In this regard, category 1 NGT food featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances of the food will be considered as novel food and thus fall into the		

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scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council ([85]) and will be risk assessed in that context.		
(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([86]) 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		

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85 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

86 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).

production.		
(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.		
[Recitals 25-48 were not amended in the Presidency compromise text in ST 13725/23 INIT, nor are they directly corresponding to Articles 1-11. They are omitted here to reduce the length of this document.]		
CHAPTER I **GENERAL PROVISIONS**		
Article 1 **Subject matter**		
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		

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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 (‘NGT products’).		
Article 2 **Scope** This Regulation shall apply to:		
(1) NGT plants;		
(2) food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;		
(3) feed containing, consisting or produced from NGT plants;		
(4) products, other than food and feed, containing or consisting of NGT plants.		
Article 3 **Definitions** For the purposes of this Regulation, the following definitions shall apply:		
(1) the definitions of ‘organism’, ‘deliberate release’ and ‘placing on the market’ set out in Directive 2001/18/EC, those of ‘food’ and ‘feed’ set out in Regulation (EC) No 178/2002, that of ‘traceability’ set out in Regulation (EC) No 1830/2003, that		

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	of 'plant' set out in Regulation (EU) 2016/2031 of the European Parliament and of the Council([87]) and that of 'plant reproductive material' set out 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*[88]];		
(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;		
(3)	'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive		

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87 Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

88 COM(2023) 414 final

	2001/18/EC;		
(4)	'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at ~~precise~~ targeted locations in the genome of an organism;		
(5)	'cisgenesis' means techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool;		
(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;		
(7)	'category 1 NGT plant' means a NGT plant that:		
	(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, or		
	(b) is progeny of the NGT plant(s) referred to in point (a), including progeny derived by crossing of such plants, on the condition that		

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	there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003;		
(8)	'category 2 NGT plant' means a NGT plant other than a category 1 NGT plant;		
(9)	'NGT plant for food use' means a NGT plant that may be used as food or as a source material for the production of food;		
(10)	'NGT plant for feed use' means a NGT plant that may be used as feed or as a source material for the production of feed;		
(11)	'produced from a NGT plant' means derived, in whole or in part, from a NGT plant, but not containing or consisting of a NGT plant;		
(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~~ NGT plants, and other products containing or consisting of such plants;		
(13)	'category 1 NGT product' means a		

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NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 1 NGT plant;		
(14) ‘category 2 NGT product’ means a NGT product where the NGT plant it contains, consists of or, in the cases of food or feed, is produced from, is a category 2 NGT plant;		
(15) ‘small or medium sized enterprise (SME)’ means a SME within the meaning of Commission Recommendation 2003/361/EC[2].		
Article 4 **Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products**		
Without prejudice to other requirements of Union law, a NGT plant may only be deliberately released into the environment for any other purpose than placing on the market, and a NGT product may only be placed on the market, if:		
(1) the plant is a category 1 NGT plant and		
(a) has obtained a decision declaring that status in accordance with		

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Article 6 or 7; or		
(b) is progeny of plant(s) referred to in point (a); or		
(2) the plant is a category 2 NGT plant, and has been granted consent or has been authorised, in accordance with Chapter III.		
CHAPTER II **Category 1 NGT plants and category 1 NGT products**		Hungary reiterates the following: The opt-out possibility, risk assessment, labelling and monitoring should be ensured in this Chapter in case of category 1 NGT plants.
Article 5 **Status of category 1 NGT plants and category 1 NGT products**		
1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants that fulfill the condition of article 4(1) and their NGT products.		
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.		
3. The Commission is empowered to adopt delegated acts in accordance with		Hungary reiterates the following: The criteria included in Annex I, which - though

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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.		based on scientific literature - in fact is the result of a policy decision, therefore cannot be amended by means of a delegated act on the basis of scientific development. Hungary is concerned about this and believes that the criteria should not be included in an annex in this case, but in the body of the regulation itself and that, consequently, should only be amended through ordinary legislative procedure. Therefore Hungary supports the Austrian proposal in order to ask a written opinion of the Council Legal Service regarding this crucial issue.
Article 6 **Verification procedure of category 1 NGT plant status <u>for requests submitted</u> prior to the deliberate release for any other purpose than placing on the market**		
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		

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	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).		
2.	Where a person intends to undertake such a deliberate release simultaneously in more than one Member State, that person shall submit the verification request to the competent authority of one of those Member States.		
3.	The verification request referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:		
	(a) the name and the address of the requester;		
	(b) the designation and specification of the NGT plant;		
	(c) a description of the trait(s) and characteristics which have been		

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	introduced or modified;		
(d)	a copy of the studies, which have been carried out and any other available material to demonstrate that:		
	(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);		
	(ii) the NGT plant meets the criteria set out in Annex I;		
(e)	in the cases referred to in paragraph 2, an indication of the Member States in which the requester intends to undertake the deliberate release;		
(f)	an identification of the parts of		

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	the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.		
4.	The competent authority shall acknowledge receipt of the verification request to the requester without undue delay, stating the date of receipt. It shall make available the request to the other Member States and to the Commission without undue delay.		
5.	If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.		
6.	If the verification request is not deemed inadmissible in accordance with		

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	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.		
7.	The other Member States and the Commission may make ~~comments~~ reasoned objections to the verification report, as regards the fulfillment of the criteria set out in Annex I, within 20 days from the date of receipt of that report.		Clarification is needed what should be considered as *reasoned objection*.
8.	In the absence of any ~~comments~~ reasoned objections from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.		Clarification is needed what should be considered as *reasoned objection*.
9.	In cases where ~~a comment is~~ reasoned		Clarification is needed what should be

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	objections are made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the ~~the comment(s)~~ reasoned objections to the other Member States and to the Commission without undue delay.		considered as *reasoned objection*.
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)~~ reasoned objections, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).	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)~~ reasoned objections, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28~~(2)~~ (3).	Clarification is needed what should be considered as *reasoned objection*. Hungary reiterates the following: Hungary would like to emphasise the need for deciding in accordance with the examination procedure laid down in Article 5 of Regulation (EC) No 182/2001 (where the opinion shall be delivered by a "qualified" majority - the majority laid down in Article 16(4) and (5) of the Treaty on European Union) rather than in accordance with the advisory procedure laid down in Article 4 of Regulation (EC) No 182/2001 (where the opinion shall be delivered by a simple majority).
11.	The Commission shall publish a summary of the decisions referred to in paragraphs 8 and 10 in the *Official*		

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Journal of the European Union.		
Article 7 **Verification procedure of category 1 NGT plant status <u>for requests submitted</u> prior to the placing on the market of NGT products**		
1. Where a declaration of category 1 NGT plant status referred to in Article 4(1), point (a), has not already been made in accordance with Article 6, to obtain such a declaration before placing on the market a NGT product, the person intending to place the product on the market shall submit a verification request to the Authority in accordance with paragraph 2 and the implementing act adopted in accordance with Article 27, point (b).		
2. The verification request referred to in paragraph 1 shall be submitted to the Authority in accordance with standard data formats, where they exist, pursuant to Article 39f of Regulation (EC) No 178/2002, and shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:		
(a) the name and the address of the		

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requester;		
(b) the designation and specification of the NGT plant;		
(c) a description of the trait(s) and characteristics which have been introduced or modified;		
(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:		
(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);		
(ii) the NGT plant meets the criteria set out in Annex I;		

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	(e) an identification of the parts of the verification request and any other supplementary information that the requester demands to be treated as confidential, accompanied by verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.		
3.	The Authority shall acknowledge receipt of the verification request to the requester without delay, stating the date of receipt. It shall make available the verification request to the Member States and to the Commission without undue delay and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article 38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.		
4.	If the verification request does not contain all the necessary information, it shall be declared inadmissible by the		

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	Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.		
5.	If the verification request is not deemed inadmissible in accordance with paragraph 4, the Authority shall deliver its statement on whether the NGT plant fulfils the criteria set out in Annex I within 30 working days from the date of receipt of a verification request. The Authority shall make available the statement to the Commission and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its statement public, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.		
6.	The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 30 working days from the date of receipt of the statement of the	The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 30 working days from the date of receipt of the statement of the Authority, taking the latter into account. The decision shall	Hungary reiterates the following: Hungary would like to emphasise the need for deciding in accordance with the examination procedure laid down in Article 5 of Regulation

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Authority, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).	be adopted in accordance with the procedure referred to in Article 28~~(2)~~ (3).	(EC) No 182/2001 (where the opinion shall be delivered by a "qualified" majority - the majority laid down in Article 16(4) and (5) of the Treaty on European Union) rather than in accordance with the advisory procedure laid down in Article 4 of Regulation (EC) No 182/2001 (where the opinion shall be delivered by a simple majority).
7. The Commission shall publish a summary of the decision in the *Official Journal of the European Union*.		
Article 8 **System of exchange of information between Member States, the Commission and the Authority**		
The Commission shall set up and maintain an electronic system for the submission of verification requests in accordance with Articles 6 and 7 and the exchange of the information under this ~~Title~~ Chapter.		
Article 9 **Database of decisions declaring the category 1 NGT plant status**		
1. The Commission shall establish and maintain a database listing the decisions declaring the category 1 NGT plant status adopted in accordance with		

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Article 6(8) and (10) and Article 7(6). The database shall contain the following information:		
(a) name and the address of the requester;		
(b) the designation of the category 1 NGT plant;		
(c) a summarised description of the technique(s) used to obtain the genetic modification;		
(d) a description of the trait(s) and characteristics which have been introduced or modified;		
(e) an identification number, and		
(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.		
2. The database shall be publicly available.		

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Article 10 **Labelling of category 1 NGT plant reproductive material, including breeding material**		Hungary reiterates its earlier request that labelling should be extended to food and feed products as well.
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.		Hungary reiterates its earlier request that labelling should be extended to food and feed products as well.
Article 11 **Confidentiality**		
1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this ~~Title~~ Chapter as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.		
2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.		

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3.	The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:		
	(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;		
	(b) DNA sequence information; and		
	(c) breeding patterns and strategies.		
4.	The competent authority or the Authority, as appropriate, shall, after consultation with the requester, decide which information is to be treated as confidential and shall inform the requester of its decision.		
5.	Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged under this Chapter is not made public.		
6.	The relevant provisions of Articles 39e		

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	and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.		
7.	In the event of a withdrawal of the verification request by the requester, Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the withdrawal of the verification request takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.		

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