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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Regulation on New Genomic Techniques (NGT)- Four-column table

Delegations will find attached a table containing, in the first column, the Commission proposal and, in the second and third columns, the European Parliament's and the Council's negotiating positions.

This four-column table serves as the basis for negotiations in the trilogue to be held on 6 May 2025.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Formula				
1	2023/0226 (COD)	2023/0226 (COD)	2023/0226 (COD)	
Proposal Title				
2	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (Text with EEA relevance)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 ***and Directive 98/44/EC*** (Text with EEA relevance)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their ~~food and feed~~**products**, and amending Regulation (EU) 2017/625 (Text with EEA relevance)	
Formula				
3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Citation 1				
4	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 Treaty on the Functioning of the European Union, and in particular Articles 43, 114 and 168(4) (b) thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114 and 168(4) (b) thereof,	
Citation 2				
5	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	

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Citation 3				
6	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	
Citation 4				
7	Having regard to the opinion of the European Economic and Social Committee,	Having regard to the opinion of the European Economic and Social Committee,	Having regard to the opinion of the European Economic and Social Committee,	
Citation 5				
8	Having regard to the opinion of the Committee of the Regions,	Having regard to the opinion of the Committee of the Regions,	Having regard to the opinion of the Committee of the Regions,	
Citation 6				
9	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	
Formula				
10	Whereas:	Whereas:	Whereas:	
Recital 1				
11	(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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	techniques that enable changes to be made to the genome at precise locations. _____ 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).	techniques that enable changes to be made to the genome at precise locations. ***Major advances in genetic engineering have already contributed to the widespread use of marker-assisted selection, which makes it possible to identify and mobilise interesting genes that are present in biodiversity.*** _____ 1. 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).	techniques that enable changes to be made to the genome at ~~precise~~**targeted** locations. _____ 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).	
Recital 1a				
11a		***(1a) Allowing for new genomic techniques and their results to be patented risks giving multinational seed companies even more power over farmers' access to seeds. In a context where large companies already have a monopoly on seeds and increasingly control natural resources, this would deprive farmers of all freedom of action by making them dependent on private companies. For this reason, patents on these products must be banned.***		
Recital 2				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
12	(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications. Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis). They rely only on the breeders' gene pool, i.e. the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced breeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at precise locations in the genome of an organism. Cisgenesis techniques result in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool. Intragenesis is a subset	(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications. Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis). They rely only on the breeders' gene pool, i.e. the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced breeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at ~~*precise*~~***targeted*** locations in the genome of an organism. Cisgenesis techniques result in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool. Intragenesis	(2) NGTs constitute a diverse group of genomic techniques, and each of them can be used in various ways to achieve different results and products. They can result in organisms with modifications equivalent to what can be obtained by conventional breeding methods or in organisms with more complex modifications. Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis). They rely only on the breeders' gene pool, i.e. the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced **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[1] and the**	

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	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.	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.	**High Level Group of the Commission´s Scientific Advice Mechanism in its Explanatory note on New techniques in agricultural biotechnology[2] provide an overview of the state of these conventional** breeding techniques. Targeted mutagenesis techniques result in modification(s) of the DNA sequence at ~~precise~~**targeted** locations in the genome of an organism. Cisgenesis techniques result in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool. ~~Intragenesis is a subset of cisgenesis resulting in the insertion in the genome of a rearranged copy of~~**The** genetic material ~~composed of two or more DNA~~**may be incorporated as a continuos (exact) copy (cisgenesis in the strict sense) or a re-arranged copy of** sequences already present in the **breeder´s gene pool (intragenesis, also considered a subset of cisgenesis in a broader sense). Intragenic plants result from the use of intragenesis techniques, but can be also obtained by cisgenesis techniques in the strict sense. In**	

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			the latter case, new developments of site-directed modification also offer the possibility to target the insertion of continuous DNA sequences other than complete genes (for example promoters or regulatory sequences), from the breeders' gene pool **at specific loci in the genome. When the insertion of such fragments occurs within an endogenous gene, interrupting it, this leads to the formation of a rearranged gene in the recipient plant and, as such, the plant should also be considered intragenic, except in those particular cases in which the resulting DNA sequences in the recipient plant already occur in species from the breeder´s gene pool.** _____ **1. 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.** **2. European Commission, Directorate-General for Research and**	

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			Innovation, New techniques in agricultural biotechnology, Publications Office, 2017, https://data.europa.eu/doi/10.2777/574498	
Recital 3				
13	(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([1]). This includes plants with improved tolerance or resistance to plant diseases and pests, plants with improved tolerance or resistance to climate change effects and environmental stresses, improved nutrient and water-use efficiency, plants with higher yields and resilience and improved quality characteristics. These types of new plants, coupled with the fairly easy and speedy applicability of those new techniques, could deliver benefits to farmers, consumers and to the environment. Thus, NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal ([2]) and of the 'Farm to Fork' ([3]), Biodiversity ([4]) and Adaptation to	(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([1]). This includes plants with improved tolerance or resistance to plant diseases and pests***, plants with tolerance to herbicides***, plants with improved tolerance or resistance to climate change effects and environmental stresses, improved nutrient and water-use efficiency, plants with higher yields and resilience and improved quality characteristics. These types of new plants, coupled with the fairly easy and speedy applicability of those new techniques, could deliver benefits to farmers, consumers and to the environment. Thus, NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal ([2]) and of the 'Farm to Fork' ([3]),	(3) There is ongoing public and private research using NGTs on a wider variety of crops and traits compared to those obtained ~~through~~**by** transgenic techniques authorised in the Union or globally([1]). This includes plants with improved tolerance or resistance to plant diseases and pests, plants with improved tolerance or resistance to climate change effects and environmental stresses, improved nutrient and water-use efficiency, plants with higher yields and resilience and improved quality characteristics. These types of new plants, coupled with the fairly easy and speedy applicability of those new techniques, could deliver benefits to farmers, consumers and to the environment. Thus, NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal ([2]) and of the 'Farm to Fork' ([3]), Biodiversity ([4]) and Adaptation to	

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	Climate Change([5]) Strategies, to global food security ([6]), the Bioeconomy Strategy ([7]) and to the Union's strategic autonomy ([8]). _____ 1. 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. 2. 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. 3. 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. 4. 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	Biodiversity ([4]) and Adaptation to Climate Change([5]) Strategies, to global food security ([6]), the Bioeconomy Strategy ([7]) and to the Union's strategic autonomy ([8]). _____ 1. 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. 2. 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. 3. 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. 4. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the	Climate Change([5]) Strategies, to global food security ([6]), the Bioeconomy Strategy ([7]) and to the Union's strategic autonomy ([8]). _____ 1. 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. 2. 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. 3. 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. 4. 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	

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	2030: Bringing nature back into our lives, COM/2020/380 final. 5. 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 6. 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. 7. 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 . 8. 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.	Regions, EU Biodiversity Strategy for 2030: Bringing nature back into our lives, COM/2020/380 final. 5. 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. 6. 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. 7. 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 . 8. 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.	2030: Bringing nature back into our lives, COM/2020/380 final. 5. 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 6. 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. 7. 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 . 8. 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.	
Recital 4				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
14	(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 ([1]) of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003 ([2]), 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'). _____ 1. 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). 2. 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).	(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 ([1]) of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003 ([2]), 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'). _____ 1. 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). 2. 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).	(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 ([1]) of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003 ([2]), while the contained use of plant cells is subject to Directive ~~2009/1/EC~~**2009/41/EC ([3])**, and transboundary movements of ~~NGT plants~~**these organisms** to third countries are regulated by Regulation (EC) No 1946/2003 (**[4]**) **(taken together,** 'the Union GMO legislation'). _____ 1. 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). 2. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically	

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			modified food and feed (OJ L 268, 18.10.2003, p. 1). 3. **Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).** 4. **Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movement of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).**	
Recital 5				
15	(5) In its judgment in case C-528/16 Confédération paysanne and Others[1] 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. __________ 1. 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.	(5) In its judgment in case C-528/16 Confédération paysanne and Others[1] 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. __________ 1. 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.	(5) In its judgment in case C-528/16 Confédération paysanne and Others[1] 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. __________ 1. 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.	
Recital 6				
16	(6) The Council, in Decision (EU) 2019/1904[1], requested the Commission to submit, by 30	(6) The Council, in Decision (EU) 2019/1904[1], requested the Commission to submit, by 30	(6) The Council, in Decision (EU) 2019/1904[1], requested the Commission to submit, by 30	

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	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. __________ 1. 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. __________ 1. 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. __________ 1. 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).	
Recital 7				
17	(7) The Commission's study on new genomic techniques ([1]) 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	(7) The Commission's study on new genomic techniques ([1]) 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	(7) The Commission's study on new genomic techniques ([1]) 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	

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	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 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	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 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	products that can be obtained ~~with~~**by** 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 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 **European Union Reference Laboratory for GM Food and Feed (EURL), in collaboration with the European Network of GM Laboratories (ENGL) stressed that products**	

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	security and resilience of the agri-food chain. _____ 1. 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.	security and resilience of the agri-food chain. _____ 1. 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.	**that have identical DNA sequence but have been developed either naturally or by conventional breeding or by using certain new genomic techniques cannot be distinguished by analytical methods ([2]). 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. _____ 1. 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. **2. European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289); 13 June 2023 (JRC133689; EUR 31521 EN).**	
Recital 8				
18	(8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.	(8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.	(8) 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.	
Recital 9				

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

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	transgenesis need adaptation at the present time.	~~*indication that current requirements in the Union GMO legislation for GMOs obtained by transgenesis need adaptation at the present time.*~~	transgenesis need adaptation at the present time.	
Recital 10				
20	(10) The legal framework for NGT plants should share the objectives of the Union GMO legislation to ensure a high level of protection of human and animal health and of the environment and the good functioning of the internal market for the concerned plants and products, while addressing the specificity of NGT plants. This legal framework should enable the development and placing on the market of plants, food and feed containing, consisting of or produced from NGT plants and other products containing or consisting of NGT plants ('NGT products') so as to contribute to the innovation and sustainability objectives of the European Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and to enhance the competitiveness of the Union agri-food sector at Union and world level.	(10) ***With full regard to the precautionary principle,*** the legal framework for NGT plants should share the objectives of the Union GMO legislation to ensure a high level of protection of human and animal health and of the environment and the good functioning of the internal market for the concerned plants and products, while addressing the specificity of NGT plants. This legal framework should enable the development and placing on the market of plants, food and feed containing, consisting of or produced from NGT plants and other products containing or consisting of NGT plants ('NGT products') so as to contribute to the innovation and sustainability objectives of the European Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and to enhance the competitiveness of the	(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 **their** products, while addressing the specificity of NGT plants. This legal framework should enable the development and placing on the market of plants~~,~~ **and their products (including** food and feed**) obtained by 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Union agri-food sector at Union and world level.	the Union agri-food sector at Union and world level.	
Recital 11				
21	(11) This Regulation constitutes lex specialis with regard to the Union GMO legislation. It introduces specific provisions for NGT plants and NGT products. However, where there are no specific rules in this Regulation, NGT plants and products (including food and feed) obtained from them should remain subject to the requirements of the Union GMO legislation and the rules on GMOs in sectoral legislation, such as Regulation (EU) 2017/625 on official controls or the legislation on certain products like plant and forest reproductive material.	(11) This Regulation constitutes lex specialis with regard to the Union GMO legislation. It introduces specific provisions for NGT plants and NGT products. However, where there are no specific rules in this Regulation, NGT plants and products ~~*(including food and feed)*~~ obtained from them should remain subject to the requirements of the Union GMO legislation and the rules on GMOs in sectoral legislation, such as Regulation (EU) 2017/625 on official controls or the legislation on certain products like plant and forest reproductive material.	(11) This Regulation constitutes lex specialis with regard to the Union GMO legislation. It introduces specific provisions for NGT plants and ~~NGT~~**their** products. However, where there are no specific rules in this Regulation, NGT plants and **their** products ~~(including food and feed)~~ obtained from them should remain subject to the requirements of the Union GMO legislation and the rules on GMOs in sectoral legislation, such as Regulation (EU) 2017/625 on official controls or the legislation on certain products like plant and forest reproductive material.	
Recital 11a				
21a			**(11a) In keeping with the Union GMO legislation, this Regulation should include under its scope NGT plants and their products (food and feed containing, consisting of or produced from such NGT plants, and products, other than food and feed, containing or consisting of such NGT plants,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			hereinafter ‘NGT products’). Plant reproductive material, including forest reproductive material, falls under the scope of this Regulation both under the term ‘plant’ (when it is deliberately relased into the environment) and under the term ‘product’ (when it is placed on the market, including for the purpose of cultivation).	
Recital 12				
22	(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.	(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.	(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.	
Recital 13				
23	(13) This Regulation should distinguish between two categories of NGT plants.	(13) This Regulation should distinguish between two categories of NGT plants.	(13) This Regulation should distinguish between two categories of NGT plants.	
Recital 13a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
23a		***(13a) NGT plants with the potential to persist, reproduce or spread in the environment, within or beyond fields, should be evaluated with the highest level of scrutiny in respect of such plants' impact on nature and the environment.***		
Recital 14				
24	(14) NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny obtained by conventional breeding techniques ('category 1 NGT plants') should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable, thereby derogating in full from the Union GMO legislation and GMO related requirements in sectoral legislation. In order to ensure legal certainty, this Regulation should set out the criteria to ascertain if a NGT plant is equivalent to naturally occurring or conventionally bred plants and lay down a procedure for competent authorities to verify and take a decision on the fulfillment of those	(14) NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny ~~*obtained by conventional breeding techniques*~~ ('category 1 NGT plants') should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable, thereby derogating in full from the Union GMO legislation and GMO related requirements in sectoral legislation. In order to ensure legal certainty, this Regulation should set out the criteria to ascertain if a NGT plant is equivalent to naturally occurring or conventionally bred plants and lay down a procedure for competent authorities to verify and take a decision on the	(14) **"Category 1 NGT plants" are** ~~NGT~~ plants that could also occur naturally or be produced by conventional breeding techniques ~~and their progeny obtained by conventional breeding techniques ('~~**. This** category ~~1 NGT plants')~~ should be treated **in the same way** 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 **(criteria of equivalence)** and lay	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	criteria, prior to the release or placing on the market of NGT plants or NGT products. Those criteria should be objective and based on science. They should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained with conventional breeding techniques and should include thresholds for both size and number of genetic modifications to the genome of NGT plants. Since scientific and technical knowledge evolves rapidly in this area, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to update these criteria in light of scientific and technical progress as regards the type and extent of genetic modifications that can occur in nature or through conventional breeding.	~~*fulfillment*~~***fulfilment*** of those criteria, prior to the release or placing on the market of NGT plants or NGT products. Those criteria should be objective and based on science. They should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained with conventional breeding techniques and should include thresholds for both size and number of genetic modifications to the genome of NGT plants. Since scientific and technical knowledge evolves rapidly in this area, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to update these criteria in light of scientific and technical progress as regards the type and extent of genetic modifications that can occur in nature or through conventional breeding.	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~~**up-to-date scientific knowledge**. They should cover the type and extent of genetic modifications that can be observed in nature or in organisms obtained ~~with~~**by** conventional breeding techniques and should include thresholds for both size and number of genetic modifications to the genome of NGT plants. ~~Since scientific and technical knowledge evolves rapidly in this area, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to update these criteria in light of scientific and technical progress as regards the type and extent of genetic modifications that can occur in nature or through conventional breeding.~~	
Recital 14a				
24a			**(14a) Current scientific knowledge indicates that**	

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			targeted mutagenesis and cisgenesis techniques can lead to genetic modifications that are similar to mutations occurring spontaneously in nature or as a result of conventional breeding techniques. These mutations include substitutions, insertions (including duplications, translocations and inversions) and deletions of nucleotides in the DNA. Furthermore, insertion of genetic material from the breeders´ gene pool is also possible through crossing or conventional breeding. The scientific literature also shows differences in the size of these invidual genetic modifications and in the number of genetic modifications per plant, considering also for the latter the ploidy level of the plant. On this basis, targeted substitutions and insertions of limited size, deletions and targeted inversions of any size as well as larger targeted substitutions with, and insertions of, continuous sequences of genetic material from the breeders´ gene pool should be included in the criteria of equivalence. In	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			addition, those criteria should include certain conditions in order to exclude intragenic plants from category 1 NGT plants since novel hazards can be associated with intragenic plants compared with cisgenic and conventionally bred plants[21]. **_____** **2. 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.** **1. 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.**	
Recital 14a				
24b		***(14a) Taking into account the high complexity of plant genomes, the criteria for considering that a NGT plant is equivalent to a naturally occurring or conventionally bred plant should reflect the diversity of plants genomic size and their***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		characteristics. Polyploid plants contain more than two homologous chromosomes. Within that category of polyploid plants, tetraploid, hexaploid, and octoploid have 4, 6 and 8 sets of chromosomes respectively. Polyploid plants tend to exhibit greater numbers of genetic modifications compared to monoploid plants. For those reasons, any limit to the total number of individual modifications per plant should reflect the number of chromosomes set in a plant ("ploidy").		
Recital 14b				
24c			**(14b) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the breeding technique, with the risk of a negative impact on human and animal health and**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the environment In addition, the Farm to Fork Strategy proposes specific targets to reduce the use of pesticides by 2030. This Regulation should also contribute to these objectives. Therefore, the development and use of NGT plants that include tolerance to herbicides among the intended traits conveyed by the genetic modification should be followed up and these plants should remain subject to authorization, traceability, and monitoring requirements. Therefore, NGT plants that include tolerance to herbicides among the intended traits conveyed by the genetic modification should be subject to the provisions for category 2 NGT plants.	
Recital 14c				
24d			**(14c) Since category 1 NGT plants encompass plants that are equivalent to plants occurring naturally or obtained by conventional breeding and that should be treated in the same way as those plants, their progeny obtained by conventional breeding techniques should also be**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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 of equivalence, 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.	
Recital 14d				
24e			**(14d) Since scientific and technical knowledge evolves**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 the criteria of equivalence 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. This empowerment should only apply to the extent justified by available evidence of advances in scientific knowledge and technical progress following the adoption of this Regulation.	
Recital 14e				
24f			**(14e) The balance between effective protection of invention and stimulation of research and development on the one hand and wide access to varieties serving the development of new varieties on the other hand should be maintained. Making patents on category 1 NGT plants available to breeders on equitable conditions and providing information on the applicable licensing conditions, should contribute to the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			development of new varieties, and to further encourage the development and placing on the market of NGT plants and their products obtained by NGTs. To that end, it should be possible for the patent holder (irrespective of whether it is the requester) to announce their willingness to license their patent under certain terms and conditions, such as those referred to in licensing platforms, among others. This information should be provided by the requester, on a voluntary basis, in the context of category 1 NGT verification procedure.	
Recital 15				
25	(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.	(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.	(15) All NGT plants that are not category 1 **NGT plants** ('category 2 NGT plants**') and their products (hereinafter 'category 2 NGT products**') should remain subject to the requirements of the Union GMO legislation because they feature more complex sets of modifications to the genome.	
Recital 16				
26	(16) Category 1 NGT plants and products should not be subject	(16) Category 1 NGT plants and products should not be subject	(16) Category 1 NGT plants and **their** products **(hereinafter**	

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	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.	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.	**'category 1 NGT 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. **For the same reason, in order to improve transparency for breeding activities prior to deliberate release, including placing on the market, requesters should submit declarations describing the extent to which a plant for which the verification of NGT 1 status has been requested benefits from any type of patent protection. Requesters should make such declarations to the best of their knowledge, providing any relevant information of which they are aware. At the same time, the existence of patent protection does not determine the eligibility of the plant for category 1 NGT status, which is based solely on scientific equivalence criteria.**	

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Recital 17				
27	(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.	(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.	(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.	
Recital 17a				
27a			**(17a) The fact that a notification for consent or an application for authorisation has been submitted under Union GMO legislation does not preclude the subsequent submission of a request to obtain a declaration of category 1 NGT plant status for the same plant or product under the present regulation.**	
Recital 18				

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

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	conducted at Union level in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.	***reasoned objections by other Member States,*** the procedure should be conducted ~~*at Union level*~~***in consultation with the Commission and the European Food Safety Authority ('the Authority')*** in order to ensure effectiveness of the verification procedure and consistency of the category 1 NGT plant status declarations.	~~other national~~ competent authorities **of other Member States**. Where the verification request is submitted prior to the placing on the market of **category 1** 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.	
Recital 18a				
28a		***(18a) In order to effectively select new varieties that help the agricultural sector increase food security, as well as sustainability, adaptation and resilience in relation to the consequences of climate change, it is necessary to consider the specificity of polyploid plants, which are plants that contain more than two genomes. For such plants, the maximum number of genetic modifications allowed for inclusion in category 1 NGT should be proportionate to the number of genomes they contain.***		
Recital 19				
29	(19) The competent authorities of the Member States, the	(19) The competent authorities of the Member States, the	(19) The competent authorities of the Member States, the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	Commission and the ~~*European Food Safety*~~ Authority ~~*('the Authority')*~~ should be subject to ~~*strict*~~***appropriate*** deadlines to ensure that category 1 NGT plant status declarations are made within a reasonable time.	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.	
Recital 20				
30	(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.	(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.	(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.	
Recital 21				
31	(21) Decisions declaring the category 1 NGT plant status should assign an identification number to the NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database and for the purpose of labelling of plant reproductive material derived from them.	(21) Decisions declaring the category 1 NGT plant status should assign an identification number to the NGT plant concerned in order to ensure transparency and traceability of such plants when they are listed in the database ~~*and for the purpose of labelling of plant reproductive material derived from them*~~***. The***	(21) Decisions declaring the category 1 NGT plant status should assign an identification number to the **category 1** 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. **For**	

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		information listed should include information on the technique or techniques used to obtain the trait or traits.	**transparency reasons, the patent information and the licence declaration as provided by the requester should also be included in the database and be kept up-to-date, without any responsibility on the part of the Commission for the accuracy of that information and subject to the caveat that this information is only limited to what the requester was aware of.**	
Recital 22				
32	(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	(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	(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 **their** products, those **category 1** NGT plants and their **category 1 NGT** products will be subject to the applicable sectoral legislation on **food, feed and products other than food and feed, such as** 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	

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	considered as novel food and thus fall into the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council ([1]) and will be risk assessed in that context. __________ 1. 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).	considered as novel food and thus fall into the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council ([1]) and will be risk assessed in that context. __________ 1. 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).	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 ([1]) and will be risk assessed in that context. __________ 1. 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).	
Recital 23				
33	(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([1]) 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	(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([1]) 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	(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([1]) 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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. _____ 1. 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).	techniques of genetic modification listed in Annex 1.B of Directive 2001/18/EC. As a result, category 2 NGT plants will be banned in organic production. However, it is necessary to clarify the status of category 1 NGT plants for the purposes of organic production. ***Currently, the compatibility of*** the use of new genomic techniques ~~*is currently incompatible*~~ with the ~~*concept*~~***principles*** of organic production ~~*in the Regulation (EC) 2018/848 and with consumers' perception of organic products*~~***requires further consideration***. The use of category 1 NGT plants should therefore be ~~*also*~~ prohibited in organic production***, until such further consideration takes place***. _____ 1. 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).	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. _____ 1. 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).	
Recital 24				
34	(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	(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	(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	

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	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.	from NGTs can do so and thereby safeguard consumer trust. NGT plants that have obtained a category 1 NGT plant status declaration should be listed in a publicly available database ***including information on the technique or techniques used to obtain the trait or traits***. To ensure traceability, transparency and choice for operators, during research and plant breeding, when selling seed to farmers or making plant reproductive material available to third parties in any other way, plant reproductive material of category 1 NGT plants should be labelled as category 1 NGT.	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. **Moreover, in certain circumstances it may be necessary for Member States to adopt appropriate measures on their territory to avoid the unintended presence of category 1 NGT plants in organic agriculture, in particular in areas with specific geographical conditions, such as certain Mediterranean island Member States and insular regions, in accordance with Article 29(7) of Regulation (EU) 2018/848.**	
Recital 25				
35	(25) Category 2 NGT plants should remain subject to the requirements of the Union GMO	(25) Category 2 NGT plants should remain subject to the requirements of the Union GMO	(25) Category 2 NGT plants **and their products** should remain subject to the requirements of the	

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	legislation given that on the basis of current scientific and technical knowledge, their risks need to be assessed. Special rules should be provided in order to adapt the procedures and certain other rules laid down in Directive 2001/18/EC and Regulation (EC) No 1829/2003 to the specific nature of category 2 NGT plants and the differing levels of risk that they may pose.	legislation given that on the basis of current scientific and technical knowledge, their risks need to be assessed. Special rules should be provided in order to adapt the procedures and certain other rules laid down in Directive 2001/18/EC and Regulation (EC) No 1829/2003 to the specific nature of category 2 NGT plants and the differing levels of risk that they may pose.	Union GMO legislation given that on the basis of current scientific and technical knowledge, their risks need to be assessed. Special rules should be provided in order to adapt the procedures and certain other rules laid down in Directive 2001/18/EC and Regulation (EC) No 1829/2003 to the specific nature of category 2 NGT plants and the differing levels of risk that they may pose.	
Recital 26				
36	(26) Category 2 NGT plants and products, in order to be released into the environment or placed on the market, should remain subject to a consent or authorisation in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003. However, given the wide variety of those NGT plants, the amount of information necessary for the risk assessment will vary on a case-by-case basis. The Authority, in its scientific opinions on plants developed through cisgenesis and intragenesis[1] and on plants developed through targeted mutagenesis[2] recommended flexibility in data requirements for the risk assessment of these plants.	(26) Category 2 NGT plants and products, in order to be released into the environment or placed on the market, should remain subject to a consent or authorisation in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003. However, given the wide variety of those NGT plants, the amount of information necessary for the risk assessment will vary on a case-by-case basis. The Authority, in its scientific opinions on plants developed through cisgenesis and intragenesis[1] and on plants developed through targeted mutagenesis[2] recommended flexibility in data requirements for the risk assessment of these plants.	(26) Category 2 NGT plants and **their** products, in order to be released into the environment or placed on the market, should remain subject to a consent or authorisation in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003. However, given the wide variety of those **category 2** NGT plants, the amount of information necessary for the risk assessment will vary on a case-by-case basis. The Authority, in its scientific opinions on plants developed through cisgenesis and intragenesis[1] and on plants developed through targeted mutagenesis[2] recommended flexibility in data requirements for	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Based on the Authority's 'Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis' ([3]), considerations on the history of safe use, familiarity for the environment and the function and structure of the modified/inserted sequence(s) should assist in determining the type and amount of data required to perform the risk assessment of those NGT plants. It is therefore necessary to establish general principles and criteria for the risk assessment of these plants, while providing for flexibility and possibility to adapt risk assessment methodologies to scientific and technical progress. _____ 1. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta, J, Fernandez Dumont A, Gennaro A, Lenzi, P, Lewandowska A, Munoz Guajardo IP, Papadopoulou N and Rostoks N, 2022. 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. 2. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli	Based on the Authority's 'Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis' ([3]), considerations on the history of safe use, familiarity for the environment and the function and structure of the modified/inserted sequence(s) should assist in determining the type and amount of data required to perform the risk assessment of those NGT plants. It is therefore necessary to establish general principles and criteria for the risk assessment of these plants, while providing for flexibility and possibility to adapt risk assessment methodologies to scientific and technical progress. _____ 1. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta, J, Fernandez Dumont A, Gennaro A, Lenzi, P, Lewandowska A, Munoz Guajardo IP, Papadopoulou N and Rostoks N, 2022. 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. 2. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli	the risk assessment of these plants. Based on the Authority's 'Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis' ([3]), considerations on the history of safe use, familiarity for the environment and the function and structure of the modified/inserted sequence(s) should assist in determining the type and amount of data required to perform the risk assessment of those **category 2** NGT plants. It is therefore necessary to establish general principles and ~~criteria~~**information requirements** for the risk assessment of these plants, while providing for flexibility and possibility to adapt risk assessment methodologies to scientific and technical progress. _____ 1. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta, J, Fernandez Dumont A, Gennaro A, Lenzi, P, Lewandowska A, Munoz Guajardo IP, Papadopoulou N and Rostoks N, 2022. Updated scientific opinion on plants developed through cisgenesis and intragenesis. EFSA Journal	

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	H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta J, Gennaro A, Paraskevopoulos K, Raffaello T and Rostoks N, 2020. Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA Journal 2020;18(11):6299, 14 pp. https://doi. org/10.2903/j.efsa.2020.6299. 3. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Fernandez A, Gennaro A, Papadopoulou N, Raffaello T and Schoonjans R, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. https://doi.org/10.2903/j.efsa.2022.7618.	H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta J, Gennaro A, Paraskevopoulos K, Raffaello T and Rostoks N, 2020. Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA Journal 2020;18(11):6299, 14 pp. https://doi. org/10.2903/j.efsa.2020.6299. 3. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Fernandez A, Gennaro A, Papadopoulou N, Raffaello T and Schoonjans R, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. https://doi.org/10.2903/j.efsa.2022.7618.	2022;20(10):7621, 33 pp. https://doi.org/10.2903/j.efsa.2022.7621. 2. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Casacuberta J, Gennaro A, Paraskevopoulos K, Raffaello T and Rostoks N, 2020. Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA Journal 2020;18(11):6299, 14 pp. https://doi. org/10.2903/j.efsa.2020.6299. 3. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Fernandez A, Gennaro A, Papadopoulou N, Raffaello T and Schoonjans R, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. https://doi.org/10.2903/j.efsa.2022.7618.	
Recital 27				
37	(27) Requirements on the content of notifications for consent for the placing on the market of products containing or consisting of GMOs other than food or feed	(27) Requirements on the content of notifications for consent for the placing on the market of products containing or consisting of GMOs other than food or feed	(27) Requirements on the content of notifications for consent for the placing on the market of products**, other than food or feed,** containing or consisting of GMOs	

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	and on the content of applications for authorisation for the placing on the market of genetically modified food and feed are laid down in different pieces of legislation. To ensure consistency between the notifications for consent and applications for authorisation for category 2 NGT products, the content of such notifications and applications should be the same, except those concerning the assessment of food and feed safety assessment as these are only relevant to category 2 NGT food and feed.	and on the content of applications for authorisation for the placing on the market of genetically modified food and feed are laid down in different pieces of legislation. To ensure consistency between the notifications for consent and applications for authorisation for category 2 NGT products, the content of such notifications and applications should be the same, except those concerning the assessment of food and feed safety assessment as these are only relevant to category 2 NGT food and feed.	~~other than food or feed~~**,** and on the content of applications for authorisation for the placing on the market of genetically modified food and feed are laid down in different pieces of legislation. To ensure consistency between the notifications for consent and applications for authorisation for category 2 NGT products, the content of such notifications and applications should be the same, except those concerning the assessment of food and feed safety assessment as these are only relevant to category 2 NGT food and feed.	
Recital 28				
38	(28) The European Union Reference Laboratory for GM Food and Feed (EURL), in collaboration with the European Network of GM Laboratories (ENGL), concluded that analytical testing is not considered feasible for all products obtained by targeted mutagenesis and cisgenesis ([1]). When the introduced modifications of the genetic material are not specific to the NGT plant in question, they do not allow the differentiation of the NGT plant from conventional	(28) The European Union Reference Laboratory for GM Food and Feed (EURL), in collaboration with the European Network of GM Laboratories (ENGL), concluded that analytical testing is not considered feasible for all products obtained by targeted mutagenesis and cisgenesis ([1]). When the introduced modifications of the genetic material are not specific to the NGT plant in question, they do not allow the differentiation of the NGT plant from conventional	(28) The European Union Reference Laboratory for GM Food and Feed (EURL), in collaboration with the European Network of GM Laboratories (ENGL), ~~concluded that~~**has identified** analytical ~~testing is not considered feasible for all~~**challenges and limitations associated with the identification and quantification of certain plants and** products obtained by targeted mutagenesis and cisgenesis ([1]). **For example,** when the introduced modifications of the	

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	plants. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier or the applicant, the modalities to comply with analytical method requirements should be adapted. This should be done in the implementing acts adopted pursuant to this Regulation. Provision should also be made for the EURL, assisted by the ENGL, to adopt guidance for applicants on the minimum performance requirements for analytical methods. Modalities for performing method validation may also be adapted. _____ 1. European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289); 13 June 2023 (JRC133689; EUR 31521 EN)	plants. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier or the applicant, the modalities to comply with analytical method requirements should be adapted. This should be done in the implementing acts adopted pursuant to this Regulation. Provision should also be made for the EURL, assisted by the ENGL, to adopt guidance for applicants on the minimum performance requirements for analytical methods. Modalities for performing method validation may also be adapted. _____ 1. European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289); 13 June 2023 (JRC133689; EUR 31521 EN)	genetic material are not specific to the NGT plant in question, they do not allow the differentiation of the NGT plant from conventional plants. In **such** cases ~~where it is not feasible to provide~~**,** an analytical method ~~that detects, identifies and quantifies, if duly justified~~**should still be provided** by the notifier or ~~the~~ applicant**, but, if duly justified**, the modalities to comply with analytical method **performance** requirements should be adapted. This should be done in the implementing acts adopted pursuant to this Regulation. Provision should also be made for the EURL, assisted by the ENGL, to adopt guidance for applicants on the minimum performance requirements for analytical methods. Modalities for performing method validation may also be adapted. _____ 1. European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289); 13 June 2023 (JRC133689; EUR 31521 EN)	
Recital 29				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
39	(29) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market but provides for flexibility as to the design of the plan taking into account the environmental risk assessment, the characteristics of the GMO, of its expected use and of the receiving environment. Genetic modifications in category 2 NGT plants may range from changes only needing a limited risk assessment to complex alterations requiring a more thorough analysis of potential risks. Therefore, post-market monitoring requirements for environmental effects of category 2 NGT plants should be adapted in the light of the environmental risk assessment and the experience in field trials, the characteristics of the NGT plant concerned, the characteristics and scale of its expected use, in particular any history of safe use of the plant and the characteristics of the receiving environment. Therefore, a monitoring plan for environmental effects should not be required if the category 2 NGT plant is unlikely to pose risks that	(29) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market but provides for flexibility as to the design of the plan taking into account the environmental risk assessment, the characteristics of the GMO, of its expected use and of the receiving environment. Genetic modifications in category 2 NGT plants may range from changes only needing a limited risk assessment to complex alterations requiring a more thorough analysis of potential risks. Therefore, post-market monitoring requirements for environmental effects of category 2 NGT plants should be adapted in the light of the environmental risk assessment and the experience in field trials, the characteristics of the NGT plant concerned, the characteristics and scale of its expected use, in particular any history of safe use of the plant and the characteristics of the receiving environment. ~~*Therefore*~~***In view of the precautionary principle***, a monitoring plan for environmental effects should ~~*not*~~***always*** be	(29) Directive 2001/18/EC requires a monitoring plan for environmental effects of GMOs after their deliberate release or placing on the market but provides for flexibility as to the design of the plan taking into account the environmental risk assessment, the characteristics of the GMO, of its expected use and of the receiving environment. **This requirement for a monitoring plan should apply as a rule to category 2 NGT plants. However,** genetic modifications in category 2 NGT plants may range from changes only needing a limited risk assessment to complex alterations requiring a more thorough analysis of potential risks. Therefore, **it should be possible for the competent authority not to require** post-market monitoring ~~requirements~~ for environmental effects of category 2 NGT plants ~~should be adapted in the light~~**where duly justified, based on the results of any previous release of the category 2 NGT plant, the findings** of the environmental risk assessment~~ and the experience in field trials~~, the characteristics of the **category 2**	

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	need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.	required ~~if~~***when consent is first given. It should only be possible to waive the requirement for monitoring upon the renewal of consent, provided that it has been demonstrated that*** the category 2 NGT plant ~~is unlikely to~~***does not*** pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.	NGT plant ~~concerned~~, the characteristics and scale of its expected use~~, in particular any history of safe use of the plant~~ and the characteristics of the receiving environment. ~~Therefore, a monitoring plan for environmental effects should not be required if the category 2 NGT plant is unlikely to pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.~~	
Recital 29a				
39a			**(29a) Provision should be made for the Authority to adopt guidance to assist the notifier or the applicant in the preparation and the presentation of the notification and the application, including as regards the monitoring plan for environmental effects.**	
Recital 30				
40	(30) For reasons of proportionality, after a first renewal of the authorisation, the authorisation should be valid for an unlimited period, unless decided differently at the time of that renewal based on the risk	(30) For reasons of proportionality, after a first renewal of the authorisation, the authorisation should be valid for an unlimited period, unless decided differently at the time of that renewal based on the risk	(30) For reasons of proportionality, ~~after~~**upon** a first renewal of the authorisation, the authorisation should be valid for an unlimited period, unless decided differently at the time of that renewal based on the risk	

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	assessment and the available information on the NGT plant concerned, subject to reassessment when new information has become available.	assessment and the available information on the NGT plant concerned, subject to reassessment when new information has become available.	assessment and the available information on the **category 2** NGT plant concerned, subject to reassessment when new information has become available.	
Recital 31				
41	(31) For reasons of legal certainty and good administration, the timeline for the Authority to deliver its opinion on an application for authorisation should only be extended when additional information is necessary to carry out the assessment of the application, and the extension should not be longer than the originally foreseen time limit unless it is justified by the nature of the data or exceptional circumstances.	(31) For reasons of legal certainty and good administration, the timeline for the Authority to deliver its opinion on an application for authorisation should only be extended when additional information is necessary to carry out the assessment of the application, and the extension should not be longer than the originally foreseen time limit unless it is justified by the nature of the data or exceptional circumstances.	(31) For reasons of legal certainty and good administration, the timeline for the Authority to deliver its opinion on an application for authorisation should only be extended when additional information is necessary to carry out the assessment of the application, and the extension should not be longer than the originally foreseen time limit unless it is justified by the nature of the data or exceptional circumstances.	
Recital 32				
42	(32) To increase transparency and consumers' information, operators should be allowed to complement the labelling of category 2 NGT products as GMO with information on the trait conferred by the genetic modification. In order to avoid misleading or confusing indications, a proposal for such a labelling should be provided in the	(32) To increase transparency and consumers' information, operators should be allowed to complement the labelling of category 2 NGT products as GMO with information on the trait conferred by the genetic modification. In order to avoid misleading or confusing indications, a proposal for such a labelling should be provided in the	(32) To increase transparency and consumers' information, operators should be allowed to complement the labelling of category 2 NGT products as GMO with information on the trait**(s)** conferred by the genetic modification. In order to avoid misleading or confusing indications, a proposal for such a labelling should be provided in the	

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	notification for consent or in the application for authorisation and should be specified in the consent or in the authorisation decision.	notification for consent or in the application for authorisation and should be specified in the consent or in the authorisation decision.	notification for consent or in the application for authorisation and should be specified in the consent or in the authorisation decision.	
Recital 33				
43	(33) Regulatory incentives should be offered to potential notifiers or applicants for category 2 NGT plants and products containing traits with the potential to contribute to a sustainable agri-food system, in order to steer the development of category 2 NGT plants towards such traits. The criteria to trigger these incentives should focus on broad trait categories with the potential to contribute to sustainability (such as those linked to tolerance or resistance to biotic and abiotic stresses, improved nutritional characteristics or increased yield) and should be based on the contribution to the value for sustainable cultivation and use as defined in [Article 52(1) of 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[1]]. The applicability of the criteria across the EU does not	(33) Regulatory incentives should be offered to potential notifiers or applicants for category 2 NGT plants and products containing traits with the potential to contribute to a sustainable agri-food system, in order to steer the development of category 2 NGT plants towards such traits. The criteria to trigger these incentives should focus on broad trait categories with the potential to contribute to sustainability (such as those linked to tolerance or resistance to biotic and abiotic stresses, improved nutritional characteristics or increased yield) and should be based on the contribution to the value for sustainable cultivation and use as defined in [Article 52(1) of 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[1]]. The applicability of the criteria across the EU does not	(33) Regulatory incentives should be offered to potential notifiers or applicants for category 2 NGT plants and **their** products containing traits with the potential to contribute to a sustainable agri-food system, in order to steer the development of category 2 NGT plants towards such traits. The criteria to trigger these incentives should focus on broad trait categories with the potential to contribute to sustainability (such as those linked to tolerance or resistance to biotic and abiotic stresses, improved nutritional characteristics or increased yield) and should be based on the contribution to the value for sustainable cultivation and use as defined in [Article 52(1) of 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[1]]. The applicability of the criteria across the EU does not	

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	allow a narrower definition of traits to focus on specific issues or address local and regional specificities. _____ 1. COM(2023) 414 final	allow a narrower definition of traits to focus on specific issues or address local and regional specificities. _____ 1. COM(2023) 414 final	allow a narrower definition of traits to focus on specific issues or address local and regional specificities. _____ 1. ~~-~~COM(2023) 414 final	
Recital 34				
44	(34) Incentives should consist in an accelerated procedure for risk assessment as regards applications handled by a fully centralised procedure (food and feed products) and enhanced pre-submission advice to help developers prepare the dossier for the purpose of the environmental and food and feed safety assessments, without affecting the general provisions on pre-submission advice, notification of studies and consultation of third parties pursuant to Articles 32a, 32b and 32c of Regulation (EC) No 178/2002([1]). _____ 1. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031 1.2.2002, p. 1).	(34) Incentives should consist in an accelerated procedure for risk assessment as regards applications handled by a fully centralised procedure (food and feed products) and enhanced pre-submission advice to help developers prepare the dossier for the purpose of the environmental and food and feed safety assessments, without affecting the general provisions on pre-submission advice, notification of studies and consultation of third parties pursuant to Articles 32a, 32b and 32c of Regulation (EC) No 178/2002([1]). _____ 1. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031 1.2.2002, p. 1).	(34) Incentives should consist in an accelerated procedure for risk assessment as regards applications handled by a fully centralised procedure (**category 2 NGT plants for food or feed use and category 2 NGT** food and feed ~~products~~) and enhanced pre-submission advice to help developers prepare the dossier for the purpose of the environmental and food and feed safety assessments, without affecting the general provisions on pre-submission advice, notification of studies and consultation of third parties pursuant to Articles 32a, 32b and 32c of Regulation (EC) No 178/2002([1]). **The submission of evidence demonstrating compliance with regulatory requirements in the context of a notification or an application for authorisation remains the notifier's or applicant's responsibility.**	

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			_____ 1. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031 1.2.2002, p. 1).	
Recital 35				
45	(35) Additional incentives should be afforded when the notifier or applicant is a small or medium-sized enterprise (SME), to promote access to the regulatory procedures by these enterprises, support diversification of developers of NGT plants and encourage the development by small breeders of crop species and traits by means of NGTs, by granting fee waivers for the validation of detection methods to SMEs and more extensive pre-submission advice covering also the design of studies to be carried out for the purpose of risk assessment.	(35) Additional incentives should be afforded when the notifier or applicant is a small or medium-sized enterprise (SME), to promote access to the regulatory procedures by these enterprises, support diversification of developers of NGT plants and encourage the development by small breeders of crop species and traits by means of NGTs, by granting fee waivers for the validation of detection methods to SMEs and more extensive pre-submission advice covering also the design of studies to be carried out for the purpose of risk assessment.	(35) Additional incentives should be afforded when the notifier or applicant is a small or medium-sized enterprise (SME), to promote access to the regulatory procedures by these enterprises, support diversification of developers of **category 2** NGT plants and encourage the development by small breeders of crop species and traits by means of NGTs, by granting fee waivers for the validation of detection methods to SMEs and more extensive pre-submission advice covering also the design of studies to be carried out for the purpose of risk assessment.	
Recital 36				
46	(36) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with	(36) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with	(36) Herbicide tolerant plants are bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with	

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	the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the breeding technique. For this reason, NGT plants featuring herbicide-tolerant traits should not be eligible for incentives under this framework. However, this Regulation should not take other specific measures on herbicide tolerant NGT plants, because such measures are taken horizontally in [the Commission's Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union].	the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the breeding technique. For this reason, NGT plants featuring herbicide-tolerant traits should not ~~*be eligible for incentives under this framework. However, this Regulation should not take other specific measures on herbicide tolerant*~~***fall within the scope of the category 1*** NGT plants~~,~~ ~~*because such measures are taken horizontally in [the Commission's Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union]*~~.	the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need to increase of quantities of herbicides applied, regardless of the breeding technique. For this reason, **category 2** NGT plants featuring herbicide-tolerant traits should not be eligible for incentives under this framework. However, this Regulation should not take other specific measures on herbicide tolerant NGT plants, because such measures are taken horizontally in [the Commission's Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union].	
Recital 37				
47	(37) In order to enable NGT plants to contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity Strategies, cultivation of NGT plants in the Union should be facilitated. This requires predictability for breeders and farmers as regards the	*deleted*	(37) ~~In order to enable NGT plants to contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity Strategies, cultivation of NGT plants in the Union should be facilitated. This requires predictability for breeders and farmers as regards the~~	

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	possibility to cultivate such plants in the Union. Therefore, the possibility for Member States to adopt measures restricting or prohibiting the cultivation of category 2 NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals.		~~possibility to cultivate such plants in the Union. Therefore,~~**Directive 2001/18/EC provides** the possibility for Member States to ~~adopt measures restricting or prohibiting~~**restrict or prohibit** the cultivation of **GMOs on their territory and to take appropriate measures to avoid the unintended presence of GMOs in other products, taking into account *inter alia* the diversity of farming systems and natural and economic conditions, such as those pertaining to islands. Those provisions continue to apply to** category 2 NGT plants~~ in all or part of their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals~~**, given that experience has shown that cultivation of genetically modified plants is an issue with strong national, regional and local dimensions. In this context, the Commission will continue gathering and coordinating relevant information to complement and update, as necessary, the guidelines on coexistence**.	
Recital 38				

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48	(38) The special rules laid down in this Regulation concerning the authorisation procedure for category 2 NGT plants are expected to result in more cultivation in the Union of category 2 NGT plants compared to the situation so far under the current Union GMO legislation. That renders necessary for Member States' public authorities to define coexistence measures to balance the interests of producers of conventional, organic and GM plants and thereby allow producers a choice between different types of production, in line with the Farm to Fork Strategy's target of 25 % of agricultural land under organic farming by 2030.	(38) The special rules laid down in this Regulation concerning the authorisation procedure for category 2 NGT plants are expected to result in more cultivation in the Union of category 2 NGT plants compared to the situation so far under the current Union GMO legislation. That renders necessary for Member States' public authorities to define coexistence measures to balance the interests of producers of conventional, organic and GM plants and thereby allow producers a choice between different types of production, in line with the Farm to Fork Strategy's target of 25 % of agricultural land under organic farming by 2030.	*deleted*	
Recital 39				
49	*(39)* To achieve the goal of ensuring the effective functioning of the internal market, NGT plants and related products should benefit from the free movement of goods, provided they comply with the requirements of other Union law.	(39) To achieve the goal of ensuring the effective functioning of the internal market~~, NGT plants and related products should benefit from~~ ***and*** the free movement of ~~*goods, provided they comply with the*~~***NGT plant and NGT products across the Union, the deliberate release of NGT plants and placing on the market of NGT products should be based on the harmonised*** requirements	(39) To achieve the goal of ensuring the effective functioning of the internal market, NGT plants and ~~related~~**their** products should benefit from the free movement of goods, provided they comply with the requirements of other Union law.	

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		and procedures laid down in this Regulation, leading to the adoption of a decision uniformly applicable to all Member States ~~*of other Union law*~~.		
Recital 40				
50	(40) Given the novelty of the NGTs, it will be important to monitor closely the development and presence on the market of NGT plants and products and evaluate any accompanying impact on human and animal health, the environment and environmental, economic and social sustainability. Information should be collected regularly and within five years after the adoption of the first decision allowing the deliberate release or the marketing of NGT plants or NGT products in the Union, the Commission should carry out an evaluation of this Regulation to measure the progress made towards the availability of NGT plants containing such characteristics or properties on the EU market.	(40) Given the ~~*novelty of the NGTs, it will be important to monitor closely the*~~***ongoing*** development ~~*and presence on the market of NGT plants and products and evaluate any accompanying impact on human and animal health, the environment and environmental, economic and social sustainability. Information*~~***of new genomic techniques, the Commission*** should ~~*be collected regularly and*~~***carry out an evaluation*** within five years after the adoption of the first decision allowing the deliberate release or the marketing of NGT plants or NGT products in the Union~~*, the Commission should carry out an*~~***.*** ***That*** evaluation ~~*of this Regulation to*~~***should*** measure the progress made towards the availability of NGT plants ***or NGT products*** containing such characteristics or properties on the EU market***, with***	(40) Given the novelty of the NGTs, it will be important to monitor closely the development and presence on the market of NGT plants and **their** products and evaluate any accompanying impact on human and animal health, the environment and environmental, economic and social sustainability. Information should be collected regularly and within five years after the adoption of the first decision allowing the deliberate release or the marketing of NGT plants or ~~NGT~~**their** products in the Union, the Commission should carry out an evaluation of this Regulation to measure the progress made towards the availability of NGT plants containing such characteristics or properties on the EU market.	

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		the aim of further improving this Regulation.		
Recital 41				
51	(41) In order to provide a high level of protection of health and environmental protection in relation to NGT plants and NGT products, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Union and imported from third countries.	(41) In order to provide a high level of protection of health and environmental protection in relation to NGT plants and NGT products, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Union and imported from third countries.	(41) In order to provide a high level of protection of health and environmental protection in relation to NGT plants and ~~NGT~~**their** products, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Union and imported from third countries.	
Recital 41a				
51a			**(41a) This Regulation is without prejudice to the application of relevant provisions of Union and national law on public access to documents.**	
Recital 42				
52	(42) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can be better achieved at Union level, so that NGT plants and NGT products may circulate freely within the internal market, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5	(42) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can be better achieved at Union level, so that NGT plants and NGT products may circulate freely within the internal market, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5	(42) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can be better achieved at Union level, so that NGT plants and ~~NGT~~**their** products may circulate freely within the internal market, the Union may adopt measures, in accordance with the principle of subsidiarity as set out	

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	of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	
Recital 43				
53	(43) The types of NGT plants developed and the impact of certain traits on environmental, social and economic sustainability are continuously evolving. Therefore, based on the available evidence of such developments and impacts, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to adapt the list of traits that should be incentivized or discouraged to achieve the goals of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies.'	(43) The types of NGT plants developed and the impact of certain traits on environmental, social and economic sustainability are continuously evolving. Therefore, based on the available evidence of such developments and impacts***, fully taking into account the precautionary principle***, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to adapt the list of traits that should be incentivized or discouraged to achieve the goals of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies.'	(43) The types of NGT plants developed and the impact of certain traits on environmental, social and economic sustainability are continuously evolving. Therefore, based on the available evidence of such developments and impacts, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union to adapt the list of traits that should be incentivized or discouraged to achieve the goals of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies.[2]	
Recital 44				
54	(44) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work,	(44) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work,	(44) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([1]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1	including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([1]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1	including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([1]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. **It is of particular importance that the consultations be carried out also on the basis of relevant reports which the Commission may be required to publish prior to adopting delegated acts.** _____ 1. OJ L 123, 12.5.2016, p. 1	
Recital 45				
55	(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the information required to demonstrate that a NGT plant is a category 1 NGT plant, as regards	(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the information required to demonstrate that a NGT plant is a category 1 NGT plant, as regards	(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the information required to demonstrate that a NGT plant is a category 1 NGT plant, as regards	

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	the preparation and the presentation of the notification for that determination, and as regards the methodology and information requirements for the environmental risk assessments of category 2 NGT plants and of NGT food and NGT feed, in accordance with the principles and criteria laid down in this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council([1]). _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	the preparation and the presentation of the notification for that determination, and as regards the methodology and information requirements for the environmental risk assessments of category 2 NGT plants and of NGT food and NGT feed, in accordance with the principles and criteria laid down in this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council([1]). _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	the preparation and the presentation of the notification for that determination, **as regards the content of the verification reports and of the decision,** and as regards the methodology and information requirements for the environmental risk assessments of category 2 NGT plants ~~and of~~ **and the safety assessment of category 2** NGT food and ~~NGT~~ feed, in accordance with the principles and ~~criteria~~**factors** laid down in this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council([1]). _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	
Recital 45a				
55a		***(45a) The European Parliament has called for the Union and its Member States not to grant patents on biological material and to safeguard the freedom to operate and the***		

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		breeders' exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT plants, which by definition are not transgenic plants. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (breeder's exemption). As current provisions in patent law do not provide for a full breeder's exemption, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Hence, NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption. NGT plants, their derived seeds, their plant material, associated genetic material such as genes and gene sequences, and plant traits should therefore be excluded from patentability. The exclusion from patentability should be applied in a consistent manner across		

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		legislation. Furthermore, in order to avoid patents being granted or patent applications being submitted between the date of the entry into force of this Regulation and the application of its provisions, it should be ensured that plant material is excluded from patentability from the day of entry into force of this Regulation. For patents already granted or pending patent applications covering plant material, the effects of patents should be further limited. In addition, the Commission should assess and address, in the forthcoming study, how the broader problem of patents being granted, directly or indirectly, on plant material despite previous efforts to close loopholes, should be further addressed. The assessment should address in particular the role and impact of patents on breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, as well as on innovation and in particular on opportunities for SMEs. The report of the Commission should be accompanied by the		

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		appropriate legislative proposals in order to ensure further necessary adjustments are made to the intellectual property rights framework.		
Recital 46				
56	(46) The Commission should regularly collect information in order to assess the performance of the legislation in achieving the development and availability of NGT plants and NGT products in the market that can contribute to the objectives of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and in order to inform an evaluation of the legislation. A broad set of indicators have been identified[1] and should be periodically reviewed by the Commission. The indicators should support monitoring of potential risks to health or the environment of category 2 NGT plants and related NGT products, impact of NGT plants on environmental, economic and social sustainability as well as impact on organic agriculture and on consumers acceptance of NGT products. A first monitoring report should be presented three years	(46) The Commission should regularly collect information in order to assess the performance of the legislation in achieving the development and availability of NGT plants and NGT products in the market that can contribute to the objectives of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and in order to inform an evaluation of the legislation. A broad set of indicators have been identified[1] and should be periodically reviewed by the Commission. The indicators should support monitoring of potential risks to health or the environment of category 2 NGT plants and related NGT products, impact of NGT plants on environmental, economic and social sustainability as well as impact on organic agriculture and on consumers acceptance of NGT products. A first monitoring report should be presented three years	(46) The Commission should regularly collect information in order to assess the performance of the legislation in achieving the development and availability of NGT plants and ~~NGT~~**their** products in the market that can contribute to the objectives of the Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation strategies and in order to inform an evaluation of the legislation. A broad set of indicators have been identified[1] and should be periodically reviewed by the Commission. The indicators should support monitoring of potential risks to health or the environment of category 2 NGT plants and ~~related NGT~~**their** products, impact of NGT plants on environmental, economic and social sustainability as well as impact on organic agriculture and on consumers acceptance of NGT products. A first monitoring report should be	

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	after the first products have been notified/authorised, to ensure that enough data is available after full implementation of the new legislation, and at regular intervals thereafter. The Commission should carry out an evaluation of this Regulation two years after the first monitoring report has been published, in order to allow for the impact of the first products going through the verification or authorisation to fully materialise. 1. SWD(2023) 412	after the first products have been notified/authorised, to ensure that enough data is available after full implementation of the new legislation, and at regular intervals thereafter. The Commission should carry out an evaluation of this Regulation two years after the first monitoring report has been published, in order to allow for the impact of the first products going through the verification or authorisation to fully materialise. 1. SWD(2023) 412	presented three years after the first **NGT plants or their** products have been notified/authorised, to ensure that enough data is available after full implementation of the new legislation, and at regular intervals thereafter. The Commission should carry out an evaluation of this Regulation two years after the first monitoring report has been published, in order to allow for the impact of the first products going through the verification or authorisation to fully materialise. 1. **Impact assessment report accompanying the Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625,** SWD(2023) 412	
Recital 46a				
56a			**(46a) Directive 98/44/EC on the legal protection of biotechnological inventions sets out principles regarding the patentability of biological material including plants. In order to be able to take possible action in case of adverse impacts of patented NGT plants, the**	

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			Commission should conduct a study on the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders' access to plant genetic material and techniques and on the availability of plant reproductive material to farmers as well as the overall competitiveness of the EU plant breeding industry. For the same reason, the Commission should establish an expert group on the effect of the patenting of NGT plants. It is important to ensure that farmers and breeders have access to techniques and material to promote the diversity of plant reproductive material, such as seeds, at affordable prices, while also strongly supporting innovation in both conventional and organic plant breeding by preserving investment incentives.	
Recital 46b				
56b			**(46b) Stakeholders raised concerns that patents on NGT plants may limit the access of breeders to those plants. Article 27(c) of the Agreement on a**	

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			Unified Patent Court[1] already provides that rights conferred by a patent shall not extend to the use of biological material for the purpose of breeding or discovering and developing other plant varieties. **1. Agreement on a Unified Patent Court (OJ C 175, 20.6.2013, p. 1).**	
Recital 46c				
56c			**(46c) Breeders can benefit from guidelines to help them navigate the plant intellectual property landscape. The Commission should therefore publish guidelines to assist operators, in particular breeders, in navigating the plant intellectual property landscape.**	
Recital 46d				
56d			**(46d) Breeders should have a broad understanding of, and opportunities to benefit from, the various projects, mechanisms and policies designed to support research and development in the area of new genomic techniques. The Commission should therefore publish information for operators about the**	

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			opportunities to benefit from the various projects, financial mechanisms and policies designed to support research and development in the area of new genomic techniques.	
Recital 47				
57	(47) Certain references to provisions of the Union GMO legislation in Regulation (EU) 2017/625 of the European Parliament and of the Council ([1]) need to be amended to include the specific provisions in this legislation applicable to NGT plants. __________ 1. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European	(47) Certain references to provisions of the Union GMO legislation in Regulation (EU) 2017/625 of the European Parliament and of the Council ([1]) need to be amended to include the specific provisions in this legislation applicable to NGT plants. __________ 1. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European	(47) Certain references to provisions of the Union GMO legislation in Regulation (EU) 2017/625 of the European Parliament and of the Council ([1]) need to be amended to include the specific provisions in this legislation applicable to NGT plants. __________ 1. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).	Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).	Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).	
Recital 47a				
57a		***(47a) The European Green Deal, the 'Farm to Fork', and the EU Biodiversity Strategies put organic farming at the core of a transition to sustainable food systems, with a target to expand European agricultural land under organic production to 25 % by 2030. This is a clear recognition of the environmental benefits of organic farming, for less dependency on inputs for farmers, and a resilient food supply and food sovereignty. This Regulation must not adversely undermine the pathway to a transition of European food systems to organic farming to 25 % by 2030.***		
Recital 47b				
57b		***(47b) Traceability requirements for food and feed produced from NGTs should be established to facilitate the accurate labelling of such products, in accordance with the requirements of***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner, as well as to enable control and verification of labelling claims. Requirements for food and feed produced from NGTs should be similar in order to avoid discontinuity of information in cases of change in end use.		
Recital 48				
58	(48) Since the application of this Regulation requires the adoption of implementing acts, it should be deferred in time to allow for the adoption of such measures,	(48) Since the application of this Regulation requires the adoption of implementing acts, it should be deferred in time to allow for the adoption of such measures,	(48) Since the application of this Regulation requires the adoption of implementing acts, it should be deferred in time to allow for the adoption of such measures,	
Formula				
59	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	
CHAPTER I				
60	CHAPTER I GENERAL PROVISIONS	CHAPTER I GENERAL PROVISIONS	CHAPTER I GENERAL PROVISIONS	
Article 1				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
61	Article 1 Subject matter	Article 1 Subject matter	Article 1 Subject matter	
Article 1, first paragraph				
62	This Regulation lays down specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by certain new genomic techniques ('NGT plants') and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants.	This Regulation***, in accordance with the precautionary principle*** lays down specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by certain new genomic techniques ('NGT plants') and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants***, ensuring a high level of protection of human and animal health and the environment***.	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~~**and** feed, containing or consisting of such plants **('NGT products')**.	
Article 2				
63	Article 2 Scope	Article 2 Scope	Article 2 Scope	
Article 2, first paragraph				
64	This Regulation shall apply to:	This Regulation shall apply to:	This Regulation shall apply to:	
Article 2, first paragraph, point (1)				
65	(1) NGT plants;	(1) NGT plants;	(1) NGT plants;	
Article 2, first paragraph, point (2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
66	(2) food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;	(2) food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;	(2) food containing, consisting of or produced from NGT plants, or containing ingredients produced from NGT plants;	
Article 2, first paragraph, point (3)				
67	(3) feed containing, consisting or produced from NGT plants;	(3) feed containing, consisting or produced from NGT plants;	(3) feed containing, consisting or produced from NGT plants;	
Article 2, first paragraph, point (4)				
68	(4) products, other than food and feed, containing or consisting of NGT plants.	(4) products, other than food and feed, containing or consisting of NGT plants.	(4) products, other than food and feed, containing or consisting of NGT plants.	
Article 3				
69	Article 3 Definitions	Article 3 Definitions	Article 3 Definitions	
Article 3, first paragraph				
70	For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:	
Article 3, first paragraph, point (1)				
71	(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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(EU) 2016/2031 of the European Parliament and of the Council([1]) 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[2]]; _____ 1. 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). 2. COM(2023) 414 final	(EU) 2016/2031 of the European Parliament and of the Council([1]) 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[2]]; _____ 1. 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). 2. COM(2023) 414 final	(EU) 2016/2031 of the European Parliament and of the Council([1]) 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[2]]; _____ 1. 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). 2. -COM(2023) 414 final	
Article 3, first paragraph, point (1a)				
71a			**(1a) '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;**	
Article 3, first paragraph, point (2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
72	(2) 'NGT plant' means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant;	(2) 'NGT plant' means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the ~~*breeders'*~~ gene pool ***for conventional breeding purposes*** that temporarily may have been inserted during the development of the NGT plant;	(2) 'NGT plant' means a ~~genetically modified~~ plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant;	
Article 3, first paragraph, point (3)				
73	(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;	(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;	*deleted*	
Article 3, first paragraph, point (4)				
74	*(4)* 'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at precise locations in the genome of an organism;	(4) 'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at ~~*precise*~~***targeted*** locations in the genome of an organism;	(4) 'targeted mutagenesis' means mutagenesis techniques resulting in modification(s) of the DNA sequence at ~~precise~~**targeted** locations in the genome of an organism;	
Article 3, first paragraph, point (5)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
75	(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) '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) '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**. The genetic material may be incorporated as a continuous (exact) copy (cisgenesis in the strict sense) or a re-arranged copy of sequences already present in the breeder´s gene pool (intragenesis, also considered a subset of cisgenesis in a broader sense)**;	
Article 3, first paragraph, point (6)				
76	(6) 'breeders' gene pool' means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;	(6) '~~*breeders'*~~ gene pool ***for conventional breeding purposes***' means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, ~~*including by*~~ using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;	(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;	
Article 3, first paragraph, point (7)				
77	(7) 'category 1 NGT plant' means a NGT plant that:	(7) 'category 1 NGT plant' means a NGT plant that:	(7) 'category 1 NGT plant' means a NGT plant that:	
Article 3, first paragraph, point (7)(a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
78	(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, or	(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, or	(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, **and does not include tolerance to herbicides among the intended traits conveyed by the genetic modification,** or	
Article 3, first paragraph, point (7)(b)				
79	(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 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~~**obtained** 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;	
Article 3, first paragraph, point (8)				
80	(8) 'category 2 NGT plant' means a NGT plant other than a category 1 NGT plant;	(8) 'category 2 NGT plant' means a NGT plant other than a category 1 NGT plant;	(8) 'category 2 NGT plant' means a NGT plant other than a category 1 NGT plant;	
Article 3, first paragraph, point (9)				
81	(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;	(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;	(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;	
Article 3, first paragraph, point (10)				
82	(10) 'NGT plant for feed use' means a NGT plant that may be	(10) 'NGT plant for feed use' means a NGT plant that may be	(10) 'NGT plant for feed use' means a NGT plant that may be	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	used as feed or as a source material for the production of feed;	used as feed or as a source material for the production of feed;	used as feed or as a source material for the production of feed;	
Article 3, first paragraph, point (11)				
83	(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;	(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;	(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;	
Article 3, first paragraph, point (12)				
84	(12) 'NGT product' means a product, other than food and feed, containing or consisting of a NGT plant and food and feed containing, consisting of or produced from such a plant;	(12) 'NGT product' means a product, other than food and feed, containing or consisting of a NGT plant and food and feed containing, consisting of or produced from such a plant;	(12) 'NGT product' means ~~a product, other than food and feed, containing or consisting of a NGT plant and~~ food and feed containing, consisting of or produced from **NGT plants, and products other than food and feed containing or consisting of such plants** ~~such a plant~~;	
Article 3, first paragraph, point (13)				
85	(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;	(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;	(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;	
Article 3, first paragraph, point (14)				
86	(14) 'category 2 NGT product' means a NGT product where the NGT plant it contains, consists of	(14) 'category 2 NGT product' means a NGT product where the NGT plant it contains, consists of	(14) 'category 2 NGT product' means a NGT product where the NGT plant it contains, consists of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	or, in the cases of food or feed, is produced from, is a category 2 NGT plant;	or, in the cases of food or feed, is produced from, is a category 2 NGT plant;	or, in the cases of food or feed, is produced from, is a category 2 NGT plant;	
Article 3, first paragraph, point (15)				
87	(15) 'small or medium sized enterprise (SME)' means a SME within the meaning of Commission Recommendation 2003/361/EC[2].	(15) 'small or medium sized enterprise (SME)' means a SME within the meaning of Commission Recommendation 2003/361/EC[2].	(15) 'small or medium sized enterprise (SME)' means a SME within the meaning of Commission Recommendation 2003/361/EC[2].	
Article 3, first paragraph, point (15a)				
87a		***(15a) 'One Health Approach' means an integrated, unifying approach that aims to sustainably balance and optimise the health of people, animals, plants and ecosystems and recognises that the health of humans, domestic and wild animals, plants, and the wider environment including ecosystems are closely interlinked and inter-dependent;***		
Article 3, first paragraph, point (15b)				
87b		***(15b) "Chimeric protein" means proteins created through the joining of two or more genes or parts of genes that originally coded for separate proteins.***		
Article 4				
88	Article 4	Article 4	Article 4	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products	Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products	Deliberate release of NGT plants for any other purpose than placing on the market and placing on the market of NGT products	
Article 4, first paragraph				
89	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:	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:	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:	
Article 4, first paragraph, point (1)				
90	(1) the plant is a category 1 NGT plant and	(1) the plant is a category 1 NGT plant and	(1) the plant is a category 1 NGT plant and	
Article 4, first paragraph, point (1)(a)				
91	(a) has obtained a decision declaring that status in accordance with Article 6 or 7; or	(a) has obtained a decision declaring that status in accordance with Article 6 or 7; or	(a) has obtained a decision declaring that status in accordance with Article 6 or 7; or	
Article 4, first paragraph, point (1)(b)				
92	(b) is progeny of plant(s) referred to in point (a); or	(b) is progeny of plant (s) referred to in point (a) ***on condition that the criteria of equivalence set out in Annex I are still satisfied*** ; or	(b) is progeny of plant(s) referred to in point (a); or	
Article 4, first paragraph, point (2)				
93	(2) the plant is a category 2 NGT plant and has been	(2) the plant is a category 2 NGT plant***, and has been granted***	(2) the plant is a category 2 NGT plant**, and has been granted**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorised in accordance with Chapter III.	***consent or*** ~~*and*~~ has been authorised in accordance with Chapter III.	**consent or** ~~and~~ has been authorised**,** in accordance with Chapter III.	
Article 4, first paragraph a				
93a		***The implementation, enforcement and application of this Regulation shall not have the object or effect of preventing or impeding imports from third countries of NGT plants and products that meet the same standards as those laid down in this Regulation***		
Article 4a				
93b		***Article 4a*** ***Exclusion from patentability***		
Article 4a, first paragraph				
93c		***NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable.***		
CHAPTER II				
94	CHAPTER II Category 1 NGT plants and category 1 NGT products	CHAPTER II Category 1 NGT plants and category 1 NGT products	CHAPTER II Category 1 NGT plants and category 1 NGT products	
Article 5				
95	Article 5 Status of category 1 NGT plants	Article 5 Status of category 1 NGT plants	Article 5 Status of category 1 NGT plants **and category 1 NGT products**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 5(1)				
96	1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants.	1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants.	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**.	
Article 5(2)				
97	2. For the purposes of Regulation (EU) 2018/848, the rules set out in its Articles 5 (f) (iii) and 11 shall apply to category 1 NGT plants and to products produced from or by such plants.	2. For the purposes of Regulation (EU) 2018/848, the rules set out in its ~~*Articles 5 (f) (iii) and*~~***Article 5 (f), (iii), and Article*** 11 shall apply to category 1 NGT plants and to products produced from or by such plants. ***[7 years after the entry into force of this Regulation], the Commission shall present a report on the evolution of the consumers' and producers' perception, accompanied, where appropriate, by a legislative proposal.***	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.	
Article 5(3)				
98	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	3. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I***, taking into account***	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	scientific and technological progress as regards the types and extent of modifications which can occur naturally or through conventional breeding.	***potential associated risks and functional consequences in the verification procedure*** in order to adapt ~~*them to*~~***those criteria to the latest*** scientific and technological ~~*progress*~~***developments*** as regards the types and extent of modifications which can occur naturally or through conventional breeding.	scientific and technological progress**, to the extent justified by advances in scientific knowledge,** as regards the types and extent of modifications which can occur naturally or through conventional breeding. **This empowerment shall be subject to the following conditions:**	
Article 5(3), point (a)				
98a			**(a) The Commission shall publish a report to justify that, on the basis of scientific evidence, the criteria of equivalence laid down in Annex I no longer reflect what can occur naturally or through conventional breeding. The report shall include an up-to-date scientific literature review as regards the types and extent of modification that can occur naturally or through conventional breeding.**	
Article 5(3), point (b)				
98b			**(b) Where applicable, the Commission shall take into account any relevant new or updated scientific opinions from the Authority.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 5(3a)				
98c		***3a. The adventitious or technically unavoidable presence of category 1 NGT plants, reproductive material or parts thereof in organic production, or in non-organic products authorised in organic production in accordance with Articles 24 and 25 of Regulation (EU) 2018/848, shall not constitute non-compliance with that Regulation.***		
Article 6				
99	Article 6 Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market	Article 6 Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market	Article 6 Verification procedure of category 1 NGT plant status **for requests submitted** prior to the deliberate release for any other purpose than placing on the market	
Article 6(1)				
100	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	criteria set out in Annex I ***at least one of the traits referred to in Annex III, Part 1, and the exclusion criteria in Annex III, Part 2,*** are met ('verification request'). ***That verification request shall be submitted*** to the competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the ~~*implementing*~~***delegated*** act adopted in accordance with Article ~~*27*~~***6(11a)***, point (b).	~~criteria~~**conditions** set out in ~~Annex I~~**Article 3(7)(a)** 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).	
Article 6(2)				
101	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.	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.	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.	
Article 6(3)				
102	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	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	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	

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	shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:	shall include, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002:	shall include~~, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002~~:	
Article 6(3), point (a)				
103	(a) the name and the address of the requester;	(a) the name and the address of the requester;	(a) the name and the address of the requester;	
Article 6(3), point (b)				
104	(b) the designation and specification of the NGT plant;	(b) the designation and specification of the NGT plant;	(b) the designation and specification of the NGT plant;	
Article 6(3), point (c)				
105	(c) a description of the trait(s) and characteristics which have been introduced or modified;	(c) a description of the trait~~(s)~~ ***or traits*** and characteristics which have been introduced or modified, ***including information on the technique or techniques used to obtain the trait or the traits and including disclosure of the sequence of genetic modification***;	(c) a description of the trait(s) and characteristics which have been introduced or modified;	
Article 6(3), point (ca)				
105a		***(ca) any patent or pending application for a patent that covers the whole or part of Cat.1 NGT plant;***		
Article 6(3), point (d)				
106	(d) a copy of the studies, which have been carried out and	(d) a copy of the studies, which have been carried out and	(d) a copy of the studies, which have been carried out and	

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	any other available material to demonstrate that:	any other available material to demonstrate that:	any other available material to demonstrate that:	
Article 6(3), point (d)(i)				
107	(i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);	(i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the ~~*breeders'*~~ gene pool ***for conventional breeding purposes*** where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the ~~*implementing*~~***delegated*** act adopted in accordance with Article ~~*27*~~***6(11a)***, point (a);	(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);	
Article 6(3), point (d)(ii)				
108	(ii) the NGT plant meets the criteria set out in Annex I;	(ii) the NGT plant meets the criteria set out in Annex I***, at least one of the traits in Annex III, Part 1, and the exclusion criteria of Annex III, Part 2***;	(ii) the NGT plant meets the criteria set out in Annex I;	
Article 6(3), point (da)				
108a		***(da) the denomination of the variety***		
Article 6(3), point (e)				
109	(e) in the cases referred to in paragraph 2, an indication of the Member States in which the	(e) in the cases referred to in paragraph 2, an indication of the Member States in which the	(e) in the cases referred to in paragraph 2, an indication of the Member States in which the	

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	requester intends to undertake the deliberate release;	requester intends to undertake the deliberate release;	requester intends to undertake the deliberate release;	
Article 6(3), point (f)				
110	(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.	(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.	(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.	
Article 6(3a)				
110a			**3a. The requester shall, acting to the best of their knowledge, submit a written statement identifying patents claiming modifications of biological material of the NGT plant resulting in particular traits, or published applications for granting such patents, or declaring the absence of such patents or published applications for granting such patents (patent information).**	
Article 6(3b)				
110b			**3b. The requester may submit a written declaration of the holder of a patent identified**	

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			under paragraph 3a confirming their willingness to licence the protected subject under equitable conditions in all Member States where the patent holder is entitled to grant such a licence (licence declaration).	
Article 6(3c)				
110c			**3c. The patent information and the licence declaration shall not be subject to verification and shall only have declaratory value.**	
Article 6(3d)				
110d			**3d. Articles 32b and 32c(2) of Regulation (EC) No 178/2002 shall not apply.**	
Article 6(4)				
111	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.	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.	4. The competent authority shall acknowledge receipt of the verification request**, the patent information and the licence declaration, as appropriate,** to the requester without undue delay, stating the date of receipt. It shall make available the request**, the patent information and the licence declaration, as appropriate,** to the other Member States and to the Commission without undue delay.	

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Article 6(5)				
112	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.	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.	5. If the verification request does not contain all the necessary information**, including the information referred to in paragraph 3a**, 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.	
Article 6(6)				
113	6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.	6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority ***may, where appropriate, consult with the European Food Safety Authority ('EFSA') while preparing the verification report.***	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~~**meets the conditions** set out in ~~Annex I~~**Article 3(7)(a)** 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	

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		The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.	and to the Commission without undue delay.	
Article 6(7)				
114	7. The other Member States and the Commission may make comments to the verification report within 20 days from the date of receipt of that report.	7. The other Member States and the Commission may make ~~comments~~***reasoned objections*** to the verification report***, as regards the fulfilment of the criteria set out in Annex I,*** within 20 days from the date of receipt of that report. ***Such reasoned objections shall solely refer to the criteria as set out in Annex I and Annex III and shall include a scientific justification.***	7. The other Member States and the Commission may make ~~comments~~**reasoned objections** to the verification report**, as regards the fulfillment of the conditions set out in Article 3(7)(a),** within 20 days from the date of receipt of that report.	
Article 6(8)				
115	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	8. In the absence of any ~~comments~~***reasoned scientific objections*** from a Member State or the Commission, within ~~*10 working days from the expiry of*~~ the deadline referred to in paragraph 7, the ***national*** competent authority that prepared the verification report shall adopt a decision~~–~~ declaring whether the NGT plant is a category 1 NGT plant. ~~*It*~~***The national competent authority*** shall transmit the	8. In the absence of any ~~comments~~**reasoned objection** 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	

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	requester, the other Member States and to the Commission.	decision ~~*without undue delay*~~***within 10 working days*** to the requester, the other Member States and ~~*to*~~ the Commission.	other Member States and to the Commission.	
Article 6(9)				
116	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.	9. In cases where a ~~*comment*~~***reasoned objection*** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall ~~*forward the the comment(s) to the Commission*~~***make the reasoned objections publicly available*** without undue delay.	9. In cases where a ~~comment~~**reasoned objection** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the the ~~comment(s)~~**reasoned objection to the other Member States and** to the Commission without undue delay.	
Article 6(10)				
117	10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the comment(s), taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).	10. The Commission, after having consulted the ~~*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).	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 objection**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).	

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Article 6(11)				
118	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.	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.	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				
119	Article 7 Verification procedure of category 1 NGT plant status prior to the placing on the market of NGT products	Article 7 Verification procedure of category 1 NGT plant status prior to the placing on the market of NGT products	Article 7 Verification procedure of category 1 NGT plant status **for requests submitted** prior to the placing on the market of NGT products	
Article 7(1)				
120	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).	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).	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).	
Article 7(2)				
121	2. The verification request referred to in paragraph 1 shall be	2. The verification request referred to in paragraph 1 shall be	2. The verification request referred to in paragraph 1 shall be	

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	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:	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:	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~~:	
Article 7(2), point (a)				
122	(a) the name and the address of the requester;	(a) the name and the address of the requester;	(a) the name and the address of the requester;	
Article 7(2), point (b)				
123	(b) the designation and specification of the NGT plant;	(b) the designation and specification of the NGT plant;	(b) the designation and specification of the NGT plant;	
Article 7(2), point (ba)				
123a		***(ba) the denomination of the variety;***		
Article 7(2), point (c)				
124	(c) a description of the trait(s) and characteristics which have been introduced or modified;	(c) a description of the trait(s) and characteristics which have been introduced or modified ***including information on the technique or techniques used to obtain the trait or the traits and on disclosure of the sequence of genetic modification***;	(c) a description of the trait(s) and characteristics which have been introduced or modified;	
Article 7(2), point (d)				

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125	(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:	(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:	(d) a copy of the studies, which have been carried out and any other available material to demonstrate that:	
Article 7(2), point (d)(i)				
126	(i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);	(i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the breeders' gene pool where such genetic material has been temporarily inserted during the development of the plant, in accordance with the information requirements specified in the implementing act adopted in accordance with Article 27, point (a);	(i) the plant is a NGT plant, including that it does not contain any genetic material originating from outside the 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);	
Article 7(2), point (d)(ii)				
127	(ii) the NGT plant meets the criteria set out in Annex I;	(ii) the NGT plant meets the criteria set out in Annex I;	(ii) the NGT plant meets the criteria set out in Annex I;	
Article 7(2), point (da)				
127a		***(da) a monitoring plan for environmental effects;***		
Article 7(2), point (e)				
128	(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	(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	(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	

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	verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.	verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.	verifiable justification, pursuant to Article 11 of this Regulation and Article 39 of Regulation (EC) No 178/2002.	
Article 7(2a)				
128a			**2a. The requester shall submit, acting to the best of their knowledge, a written statement identifying patents claiming modifications of biological material of the NGT plant resulting in particular traits, or published applications for granting such patents, or declaring the absence of such patents or published applications for granting such patents (patent information).**	
Article 7(2b)				
128b			**2b. The requester may submit a written declaration of the holder of a patent identified under paragraph 2a confirming their willingness to licence the protected subject under equitable conditions in all Member States where the patent holder is entitled to grant such a licence (licence declaration).**	
Article 7(2c)				

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128c			**2c. The patent information and the licence declaration shall not be subject to verification and shall only have declaratory value.**	
Article 7(2d)				
128d			**2d. Articles 32b and 32c(2) of Regulation (EC) No 178/2002 shall not apply.**	
Article 7(3)				
129	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.	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.	3. The Authority shall acknowledge receipt of the verification request**, the patent information and the licence declaration, as appropriate,** to the requester without **undue** delay, stating the date of receipt. It shall make available the verification request**, the patent information and the licence declaration, as appropriate,** 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	

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			Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.	
Article 7(4)				
130	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.	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.	4. If the verification request does not contain all the necessary information**, including the information referred to in paragraph 2a**, 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.	
Article 7(5)				
131	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	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	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~~**meets the conditions** set out in ~~Annex I~~**Article 3(7)(a)** 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	

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	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.	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.	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.	
Article 7(6)				
132	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).	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).	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).	
Article 7(7)				
133	7. The Commission shall publish a summary of the decision in the Official Journal of the European Union.	7. The Commission shall publish ~~a summary of~~ the ***final*** decision in the Official Journal of the European Union ***and shall publish, in a dedicated and publicly available webpage, its draft decision and the reasoned objections referred to in Article 6***.	7. The Commission shall publish a summary of the decision in the Official Journal of the European Union.	
Article 8				

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134	Article 8 System of exchange of information between Member States, the Commission and the Authority	Article 8 System of exchange of information between Member States, the Commission and the Authority	Article 8 System of exchange of information between Member States, the Commission and the Authority	
Article 8, first paragraph				
135	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.	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.	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				
136	Article 9 Database of decisions declaring the category 1 NGT plant status	Article 9 Database of decisions declaring the category 1 NGT plant status	Article 9 Database of decisions declaring the category 1 NGT plant status	
Article 9(1), first subparagraph				
137	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).	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).	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).	
Article 9(1), second subparagraph				
138	The database shall contain the following information:	The database shall contain the following information:	The database shall contain the following information:	
Article 9(1), second subparagraph, point (a)				

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139	(a) name and the address of the requester;	(a) name and the address of the requester;	(a) name and the address of the requester;	
Article 9(1), second subparagraph, point (b)				
140	(b) the designation of the category 1 NGT plant;	(b) the designation ***and specification*** of the category 1 NGT plant;	(b) the designation of the category 1 NGT plant;	
Article 9(1), second subparagraph, point (ba)				
140a		***(ba) the denomination of the variety;***		
Article 9(1), second subparagraph, point (c)				
141	(c) a summarised description of the technique(s) used to obtain the genetic modification;	(c) a summarised description of the technique(s) used to obtain the genetic modification;	(c) a summarised description of the technique(s) used to obtain the genetic modification;	
Article 9(1), second subparagraph, point (d)				
142	(d) a description of the trait(s) and characteristics which have been introduced or modified;	(d) a description of the trait(s) and characteristics which have been introduced or modified;	(d) a description of the trait(s) and characteristics which have been introduced or modified;	
Article 9(1), second subparagraph, point (e)				
143	(e) an identification number, and	(e) an identification number, and	(e) an identification number~~,~~ ~~and~~**;**	
Article 9(1), second subparagraph, point (ea)				
143a		***(ea) if provided, the opinion or statement of EFSA, as referred to in Article 6 (10) and Article 7(5); and***		
Article 9(1), second subparagraph, point (f)				

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144	(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.	(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.	(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate**-;**	
Article 9(1), second subparagraph, point (fa)				
144a			**(fa) the patent information referred to in Article 6(3x) and Article 7(2x);**	
Article 9(1), second subparagraph, point (fb)				
144b			**(fb) the licence declaration referred to in Article 6(3xx) and Article 7(2xx), as appropriate.**	
Article 9(2)				
145	2. The database shall be publicly available.	2. The database shall be publicly available***, and in an online format***.	2. The database shall be publicly available.	
Article 9(2a)				
145a			**2a. Should there be any change in the information referred to in paragraph 1 letter (g) and/or letter (h), the requester, acting to the best of their knowledge, shall expeditiously inform the Commission of such a change, in writing. The Commission shall update the database accordingly.**	
Article 10				
146	Article 10	Article 10	Article 10	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Labelling of category 1 NGT plant reproductive material, including breeding material	Labelling of category 1 NGT plant reproductive material, including breeding material	Labelling of category 1 NGT plant reproductive material, including breeding material**, and the transparency of information**	
Article 10, first paragraph				
147	Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words 'cat 1 NGT', followed by the identification number of the NGT plant(s) it has been derived from.	***Category 1 NGT plants, products containing or consisting of category 1 NGT plant(s) and*** plant reproductive material, including for breeding and scientific purposes~~,~~ that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words '~~*cat 1 NGT'*~~***New Genomic Techniques'. In the case of plant reproductive material, it shall be*** followed by the identification number of the NGT plant(s) it has been derived from.	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 10, first paragraph a				
147a		***Appropriate document-based traceability for NGTs shall be provided by the transmission and holding of information that products contain or consist of NGT plants and product, and the unique codes for those NGTs, at each stage of their placing on the market.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 10, first paragraph b				
147b			**1. The words 'cat 1 NGT', followed by the identification number of the NGT plant(s), shall be included into catalogues of varieties referred to in Articles 44 and 45 of [*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, COM/2023/414 final*], any data bases and marketing documentation where the plant reproductive material is offerred.**	
Article 11				
148	Article 11 Confidentiality	Article 11 Confidentiality	Article 11 Confidentiality	
Article 11(1)				
149	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 as confidential, accompanied by verifiable justification, in	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 as confidential, accompanied by verifiable justification, in	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	accordance with paragraphs 3 and 6.	accordance with paragraphs 3 and 6.	accordance with paragraphs 3 and 6.	
Article 11(2)				
150	2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.	2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.	2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.	
Article 11(3)				
151	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:	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:	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:	
Article 11(3), point (a)				
152	(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;	(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;	(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;	
Article 11(3), point (b)				
153	(b) DNA sequence information; and	(b) DNA sequence information; and	(b) DNA sequence information; and	
Article 11(3), point (c)				
154	(c) breeding patterns and strategies.	(c) breeding patterns and strategies.	(c) breeding patterns and strategies.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 11(4)				
155	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.	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.	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.	
Article 11(5)				
156	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.	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.	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.	
Article 11(6)				
157	6. The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.	6. The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.	6. The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.	
Article 11(7)				
158	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 11a				
158a		***Article 11a*** ***Withdrawal of the decision***		
Article 11a, first paragraph				
158b		***If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports this hypothesis, the competent authority may withdraw its decision referred to in Article 6(8) or statement referred to in Article 7(5). The withdrawal decision must be sent by registered mail to the beneficiary of the decision, who shall have 15 days in which to make observations. In that case, the marketing of the NGT plant or product shall be prohibited from the day following the date of receipt of the registered letter.***		
CHAPTER III				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
159	CHAPTER III Category 2 NGT plants and category 2 NGT products	CHAPTER III Category 2 NGT plants and category 2 NGT products	CHAPTER III Category 2 NGT plants and category 2 NGT products	
Article 12				
160	Article 12 Status of Category 2 NGT plants and category 2 NGT products	Article 12 Status of Category 2 NGT plants and category 2 NGT products	Article 12 Status of Category 2 NGT plants and category 2 NGT products	
Article 12, first paragraph				
161	The rules which apply to GMOs in Union legislation in so far as they are not derogated from by this Regulation, shall apply to category 2 NGT plants and category 2 NGT products.	The rules which apply to GMOs in Union legislation in so far as they are not derogated from by this Regulation, shall apply to category 2 NGT plants and category 2 NGT products.	The rules which apply to GMOs in Union legislation in so far as they are not derogated from by this Regulation, shall apply to category 2 NGT plants and category 2 NGT products.	
SECTION 1				
162	SECTION 1 Deliberate release of category 2 NGT plants for any other purpose than for placing on the market	SECTION 1 Deliberate release of category 2 NGT plants for any other purpose than for placing on the market	SECTION 1 Deliberate release of category 2 NGT plants for any other purpose than for placing on the market	
Article 13				
163	Article 13 Content of the notification referred in Article 6 of Directive 2001/18/EC	Article 13 Content of the notification referred in Article 6 of Directive 2001/18/EC	Article 13 Content of the notification referred in Article 6 of Directive 2001/18/EC	
Article 13, first paragraph				
164	As regards the deliberate release of a category 2 NGT plant for any other purpose than placing on the market, the notification referred to	As regards the deliberate release of a category 2 NGT plant for any other purpose than placing on the market, the notification referred to	As regards the deliberate release of a category 2 NGT plant for any other purpose than placing on the market, the notification referred to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	in Article 6(1) of Directive 2001/18/EC shall include:	in Article 6(1) of Directive 2001/18/EC shall include:	in Article ~~6(1)~~**6(2)** of Directive 2001/18/EC shall include:	
Article 13, first paragraph, point (a)				
165	(a) the name and the address of the notifier;	(a) the name and the address of the notifier;	(a) the name and the address of the notifier;	
Article 13, first paragraph, point (b)				
166	(b) a copy of the studies, which have been carried out and any other available material to demonstrate that 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);	(b) a copy of the studies, which have been carried out and any other available material to demonstrate that 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);	(b) a copy of the studies, which have been carried out and any other available material to demonstrate that 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);	
Article 13, first paragraph, point (c)				
167	(c) a technical dossier supplying the information specified in Annex II necessary to carry out the environmental risk assessment of the deliberate release of a NGT plant or combination of NGT plants:	(c) a technical dossier supplying the information specified in Annex II necessary to carry out the environmental risk assessment of the deliberate release of a NGT plant or combination of NGT plants:	(c) a technical dossier supplying the information specified in Annex II necessary to carry out the environmental risk assessment of the deliberate release of a NGT plant or combination of NGT plants:	
Article 13, first paragraph, point (c)(i)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
168	(i) general information including information on personnel and training;	(i) general information including information on personnel and training;	(i) general information including information on personnel and training;	
Article 13, first paragraph, point (c)(ii)				
169	(ii) information relating to the category 2 NGT plant(s);	(ii) information relating to the category 2 NGT plant(s);	(ii) information relating to the category 2 NGT plant(s);	
Article 13, first paragraph, point (c)(iii)				
170	(iii) information relating to the conditions of release and the potential receiving environment;	(iii) information relating to the conditions of release and the potential receiving environment;	(iii) information relating to the conditions of release and the potential receiving environment;	
Article 13, first paragraph, point (c)(iv)				
171	(iv) information on the interactions between the category 2 NGT plant(s) and the environment;	(iv) information on the interactions between the category 2 NGT plant(s) and the environment;	(iv) information on the interactions between the category 2 NGT plant(s) and the environment;	
Article 13, first paragraph, point (c)(v)				
172	(v) a plan for monitoring in order to identify effects of the category 2 NGT plant(s) on human health or the environment;	(v) a plan for monitoring in order to identify effects of the category 2 NGT plant(s) on human health or the environment;	(v) a plan for monitoring in order to identify effects of the category 2 NGT plant(s) on human health or the environment;	
Article 13, first paragraph, point (c)(vi)				
173	(vi) where relevant, information on control, remediation methods, waste treatment and emergency response plans;	(vi) where relevant, information on control, remediation methods, waste treatment and emergency response plans;	(vi) where relevant, information on control, remediation methods, waste treatment and emergency response plans;	
Article 13, first paragraph, point (c)(vii)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
174	(vii) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18;	(vii) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18;	(vii) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive ~~2001/18~~**2001/18/EC**;	
Article 13, first paragraph, point (c)(viii)				
175	(viii) a summary of the dossier;	(viii) a summary of the dossier;	(viii) a summary of the dossier;	
Article 13, first paragraph, point (d)				
176	(d) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c).	(d) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c).	(d) the environmental risk assessment carried out in accordance with the principles and ~~criteria~~**information** set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c).	
SECTION 2				
177	SECTION 2 Placing on the market of category 2 NGT products other than food or feed	SECTION 2 Placing on the market of category 2 NGT products other than food or feed	SECTION 2 Placing on the market of category 2 NGT products **for** other **uses** than food or feed	
Article 14				
178	Article 14 Content of the notification referred to in Article 13 of Directive 2001/18/EC	Article 14 Content of the notification referred to in Article 13 of Directive 2001/18/EC	Article 14 Content of the notification referred to in Article 13 of Directive 2001/18/EC	
Article 14(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
179	1. As regards the placing on the market of category 2 NGT products other than food and feed, the notification referred to in Article 13(2) of Directive 2001/18/EC, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, shall contain:	1. As regards the placing on the market of category 2 NGT products other than food and feed, the notification referred to in Article 13(2) of Directive 2001/18/EC, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, shall contain:	1. As regards the placing on the market of category 2 NGT products other than food and feed, the notification referred to in Article 13(2) of Directive 2001/18/EC, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, shall contain:	
Article 14(1), point (a)				
180	(a) name and address of the notifier and of its representative established in the Union (if the notifier is not established in the Union);	(a) name and address of the notifier and of its representative established in the Union (if the notifier is not established in the Union);	(a) name and address of the notifier and of its representative established in the Union (if the notifier is not established in the Union);	
Article 14(1), point (b)				
181	(b) designation and specification of the category 2 NGT plant;	(b) designation and specification of the category 2 NGT plant;	(b) designation and specification of the category 2 NGT plant;	
Article 14(1), point (c)				
182	(c) scope of the notification:	(c) scope of the notification:	(c) scope of the notification:	
Article 14(1), point (c)(i)				
183	(i) cultivation;	(i) cultivation;	(i) cultivation;	
Article 14(1), point (c)(ii)				
184	(ii) other uses (to be specified in the notification);	(ii) other uses (to be specified in the notification);	(ii) other uses (to be specified in the notification);	
Article 14(1), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
185	(d) a copy of the studies, which have been carried out and any other available material to demonstrate that 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);	(d) a copy of the studies, which have been carried out and any other available material to demonstrate that 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);	(d) a copy of the studies, which have been carried out and any other available material to demonstrate that 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);	
Article 14(1), point (e)				
186	(e) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);	(e) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);	(e) the environmental risk assessment carried out in accordance with the principles and ~~criteria~~**information** set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);	
Article 14(1), point (f)				
187	(f) the conditions for the placing on the market of the product, including specific conditions of use and handling;	(f) the conditions for the placing on the market of the product, including specific conditions of use and handling;	(f) the conditions for the placing on the market of the product, including specific conditions of use and handling;	
Article 14(1), point (g)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
188	(g) with reference to Article 15(4) of Directive 2001/18/EC, a proposed period for the consent, which should not exceed 10 years;	(g) with reference to Article 15(4) of Directive 2001/18/EC, a proposed period for the consent, which should not exceed 10 years;	(g) with reference to Article 15(4) of Directive 2001/18/EC, a proposed period for the consent, which should not exceed 10 years;	
Article 14(1), point (h)				
189	(h) where appropriate, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent. If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the notifier considers that the NGT plant does not need a monitoring plan, the notifier may propose not to submit a monitoring plan;	(h) where appropriate, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent. If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the notifier considers that the NGT plant does not need a monitoring plan, the notifier may propose not to submit a monitoring plan;	(h) ~~where appropriate,~~ a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent. ~~If~~**By way of derogation from the first sentence, a monitoring plan shall not be required where the notifier duly justifies that it is not needed**, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the **category 2** NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted ~~in accordance with~~**pursuant to** Article 27, point (d), ~~the notifier considers that the NGT plant does not need a monitoring plan, the notifier may propose not to submit~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~a monitoring plan~~**and the guidance referred to in Article 29(1)**;	
Article 14(1), point (i)				
190	(i) a proposal for labelling which shall comply with the requirements laid down in point A.8. of Annex IV to Directive 2001/18/EC, Article 4(6) of Regulation (EC) No 1830/2003 and Article 23 of this Regulation;	(i) a proposal for labelling which shall comply with the requirements laid down in point A.8. of Annex IV to Directive 2001/18/EC, Article 4(6) of Regulation (EC) No 1830/2003 and Article 23 of this Regulation;	(i) a proposal for labelling which shall comply with the requirements laid down in point A.8. of Annex IV to Directive 2001/18/EC, Article 4(6) of Regulation (EC) No 1830/2003 and Article 23 of this Regulation;	
Article 14(1), point (j)				
191	(j) proposed commercial names of the products and names of category 2 NGT plants contained therein, and a proposal for a unique identifier for the category 2 NGT plant, developed in accordance with Commission Regulation (EC) No 65/2004 ([1]). After the consent any new commercial names should be provided to the competent authority; _____ 1. Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).	(j) proposed commercial names of the products and names of category 2 NGT plants contained therein, and a proposal for a unique identifier for the category 2 NGT plant, developed in accordance with Commission Regulation (EC) No 65/2004 ([1]). After the consent any new commercial names should be provided to the competent authority; _____ 1. Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).	(j) proposed commercial names of the products and names of category 2 NGT plants contained therein, and a proposal for a unique identifier for the category 2 NGT plant, developed in accordance with Commission Regulation (EC) No 65/2004 ([1]). After the consent any new commercial names should be provided to the competent authority **of the Member State**; _____ 1. Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).	
Article 14(1), point (k)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
192	(k) description of how the product is intended to be used. Differences in use or management of that product compared to similar non-genetically modified products shall be highlighted;	(k) description of how the product is intended to be used. Differences in use or management of that product compared to similar non-genetically modified products shall be highlighted;	(k) description of how the product is intended to be used. Differences in use or management of that product compared to similar non-genetically modified products shall be highlighted;	
Article 14(1), point (l)				
193	(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);	(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);	(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the **category 2** NGT plant. ~~In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies~~**As regards identification and quantification**, if duly justified by the notifier, the modalities to comply with analytical method **performance** requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);	
Article 14(1), point (m)				
194	(m) samples of the category 2 NGT plant and their control samples, and information as to the place where the reference material can be accessed;	(m) samples of the category 2 NGT plant and their control samples, and information as to the place where the reference material can be accessed;	(m) samples of the category 2 NGT plant and their control samples, and information as to the place where the reference material can be accessed;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 14(1), point (n)				
195	(n) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;	(n) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;	(n) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;	
Article 14(1), point (o)				
196	(o) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18/EC and Articles 39 to 39e of Regulation (EC) No 178/2002;	(o) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18/EC and Articles 39 to 39e of Regulation (EC) No 178/2002;	(o) an identification of the parts of the notification and any other supplementary information that the notifier requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 25 of Directive 2001/18/EC and Articles 39 to 39e of Regulation (EC) No 178/2002;	
Article 14(1), point (p)				
197	(p) a summary of the dossier in a standardised form.	(p) a summary of the dossier in a standardised form.	(p) a summary of the dossier in a standardised form.	
Article 14(2)				
198	2. The notifier shall include in this notification information on data or results from releases of the same category 2 NGT plant or the same combination of category 2 NGT plants previously or currently notified and/or carried out by the notifier either inside or outside the Union.	2. The notifier shall include in this notification information on data or results from releases of the same category 2 NGT plant or the same combination of category 2 NGT plants previously or currently notified and/or carried out by the notifier either inside or outside the Union.	2. The notifier shall include in this notification information on data or results from releases of the same category 2 NGT plant or the same combination of category 2 NGT plants previously or currently notified and/or carried out by the notifier either inside or outside the Union.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 14(3)				
199	3. The competent authority that prepares the assessment report referred to in Article 14 of Directive 2001/18/EC shall examine the notification for compliance with paragraphs 1 and 2.	3. The competent authority that prepares the assessment report referred to in Article 14 of Directive 2001/18/EC shall examine the notification for compliance with paragraphs 1 and 2.	3. The competent authority **of the Member State** that prepares the assessment report referred to in Article 14 of Directive 2001/18/EC shall examine the notification for compliance with paragraphs 1 and 2.	
Article 15				
200	Article 15 Specific provisions on monitoring	Article 15 Specific provisions on monitoring	Article 15 Specific provisions on monitoring	
Article 15, first paragraph				
201	The written consent referred to in Article 19 of Directive 2001/18/EC shall either specify monitoring requirements, as described in Article 19(3) point (f) or state that monitoring is not required. Article 17(2), point (b), of Directive 2001/18/EC shall not apply if monitoring is not required by the consent.	The written consent referred to in Article 19 of Directive 2001/18/EC shall either specify monitoring requirements, as described in Article 19(3) point (f) or state that monitoring is not required. Article 17(2), point (b), of Directive 2001/18/EC shall not apply if monitoring is not required by the consent.	The written consent referred to in Article 19 of Directive 2001/18/EC shall either specify monitoring requirements, as described in Article 19(3) point (f) or state that monitoring is not required. Article 17(2), point (b), of Directive 2001/18/EC shall not apply if monitoring is not required by the consent.	
Article 15a				
201a			**Article 15a** **Specific provision on analytical method requirements**	
Article 15a(1)				
201b			**1. Where appropriate, the competent authority of the**	

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			Member State that prepares the assesment report may request expert assistance from the relevant national reference laboratories referred to in Regulation (EU) 2017/625 to assess whether the information provided by the applicant according to Article 14(1), point (l), justifies the application of adapted modalities to comply with analytical method performance requirements.	
Article 15a(2)				
201c			**2. The national reference laboratory may request expert assistance from the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003.**	
Article 16				
202	Article 16 Labelling in accordance with Article 23	~~*Article 16*~~ *deleted*	Article 16 Labelling in accordance with Article 23	
Article 16, first paragraph				
203	In addition to Article 19(3) of Directive 2001/18/EC, the written consent shall specify the labelling in accordance with Article 23 of this Regulation.	*deleted*	In addition to Article 19(3)**, point (e),** of Directive 2001/18/EC, the written consent shall specify the labelling in accordance with Article 23 of this Regulation.	

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Article 17				
204	Article 17 Duration of the validity of the consent after renewal	Article 17 Duration of the validity of the consent after renewal	Article 17 Duration of the validity of the consent ~~after~~**upon** renewal	
Article 17(1)				
205	1. The consent granted under Part C of Directive 2001/18/EC shall, after the first renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for an unlimited period, unless the decision referred to in Article 17(6) or (8) provides that the renewal is for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the consent.	1. The consent granted under Part C of Directive 2001/18/EC shall, after the first renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for an unlimited period, unless the decision referred to in Article 17(6) or (8) provides that the renewal is for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the consent.	1. The consent granted under Part C of Directive 2001/18/EC shall, ~~after~~**upon** the first renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for an unlimited period, unless the decision referred to in ~~Article~~**Articles** 17(6) or (8) **or 18(2)** provides that the renewal is for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the consent.	
Article 17(2)				
206	2. The last sentence in Article 17(6) and (8) of Directive 2001/18/EC shall not apply.	2. The last sentence in Article 17(6) and (8) of Directive 2001/18/EC shall not apply.	2. The last sentence in Article 17(6) and (8) of Directive 2001/18/EC shall not apply.	
Article 17(2a)				
206a		***2a. If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports this hypothesis, the competent***		

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		authority may withdraw its decision. The withdrawal decision must be sent by registered mail to the beneficiary of the decision, who shall have 15 days in which to make observations. In that case, the marketing of the NGT plant or product shall be prohibited from the day following the date of receipt of the registered letter.		
SECTION 3				
207	SECTION 3 Placing on the market of category 2 NGT plants for food or feed use and of category 2 NGT food and feed	SECTION 3 Placing on the market of category 2 NGT plants for food or feed use and of category 2 NGT food and feed	SECTION 3 Placing on the market of category 2 NGT plants for food or feed use and of category 2 NGT food and feed	
Article 18				
208	Article 18 Scope	Article 18 Scope	Article 18 Scope	
Article 18, first paragraph				
209	This Section shall apply to:	This Section shall apply to:	This Section shall apply to:	
Article 18, first paragraph, point (a)				
210	(a) category 2 NGT plants for food use or for feed use;	(a) category 2 NGT plants for food use or for feed use;	(a) category 2 NGT plants for food use or for feed use;	
Article 18, first paragraph, point (b)				
211	(b) food containing, consisting or produced from category 2 NGT plants or containing ingredients produced	(b) food containing, consisting or produced from category 2 NGT plants or containing ingredients produced	(b) food containing, consisting **of** or produced from category 2 NGT plants or containing ingredients produced	

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	from category 2 NGT plants ('category 2 NGT food');	from category 2 NGT plants ('category 2 NGT food');	from category 2 NGT plants ('category 2 NGT food');	
Article 18, first paragraph, point (c)				
212	(c) feed containing, consisting or produced from category 2 NGT plants ('category 2 NGT feed').	(c) feed containing, consisting or produced from category 2 NGT plants ('category 2 NGT feed').	(c) feed containing, consisting **of** or produced from category 2 NGT plants ('category 2 NGT feed').	
Article 19				
213	Article 19 Specific provisions on the application for authorisation referred to in Articles 5 and 17 of Regulation (EC) No 1829/2003	Article 19 Specific provisions on the application for authorisation referred to in Articles 5 and 17 of Regulation (EC) No 1829/2003	Article 19 Specific provisions on the application for authorisation referred to in Articles 5 and 17 of Regulation (EC) No 1829/2003	
Article 19(1)				
214	1. By way of derogation from Articles 5(3), point (e), and 17(3), point (e), of Regulation (EC) No 1829/2003, and without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, an application for authorisation of a category 2 NGT plant for food or feed use, or category 2 NGT food or feed shall be accompanied by a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other	1. By way of derogation from Articles 5(3), point (e), and 17(3), point (e), of Regulation (EC) No 1829/2003, and without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, an application for authorisation of a category 2 NGT plant for food or feed use, or category 2 NGT food or feed shall be accompanied by a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other	1. By way of derogation from Articles 5(3), point (e), and 17(3), point (e), of Regulation (EC) No 1829/2003, and without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, an application for authorisation of a category 2 NGT plant for food or feed use, or category 2 NGT food or feed shall be accompanied by a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	available material to demonstrate that:	available material to demonstrate that:	available material to demonstrate that:	
Article 19(1), point (a)				
215	(a) 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);	(a) 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);	(a) 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);	
Article 19(1), point (b)				
216	(b) the food or the feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003, respectively, based on a safety assessment of the food or feed carried out in accordance with the principles and criteria laid down in Parts 1 and 3 of Annex II to this Regulation and with the implementing act adopted in accordance with Article 27, point (c).	(b) the food or the feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003, respectively, based on a safety assessment of the food or feed carried out in accordance with the principles and criteria laid down in Parts 1 and 3 of Annex II to this Regulation and with the implementing act adopted in accordance with Article 27, point (c).	(b) the food or the feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003, respectively, based on a safety assessment of the food or feed carried out in accordance with the principles and ~~criteria~~**information** laid down in Parts 1 and 3 of Annex II to this Regulation and with the implementing act adopted in accordance with Article 27, point (c).	
Article 19(2), first subparagraph				

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217	2. By way of derogation from Articles 5(3), point (i), and 17(3), point (i), of Regulation (EC) No 1829/2003, an application for authorisation shall be accompanied by methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant and, where applicable, for the detection and identification of the NGT plant in the NGT food or feed.	2. By way of derogation from Articles 5(3), point (i), and 17(3), point (i), of Regulation (EC) No 1829/2003, an application for authorisation shall be accompanied by methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant and, where applicable, for the detection and identification of the NGT plant in the NGT food or feed.	2. By way of derogation from Articles 5(3), point (i), and 17(3), point (i), of Regulation (EC) No 1829/2003, an application for authorisation shall be accompanied by methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the **category 2** NGT plant and, where applicable, for the detection ~~and~~**,** identification **and quantification** of the **category 2** NGT plant in the NGT food or feed **produced from it**.	
Article 19(2), second subparagraph				
218	In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);	In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);	~~In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies~~**As regards identification and quantification**, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method **performance** requirements shall be adapted as specified in the implementing act adopted in accordance with Article	

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			27, point (e) and the guidance referred to in Article 29(2);	
Article 19(3)				
219	3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of category 2 NGT plants or food or feed containing or consisting of category 2 NGT plants, the application shall also be accompanied by:	3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of category 2 NGT plants or food or feed containing or consisting of category 2 NGT plants, the application shall also be accompanied by:	3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of category 2 NGT plants or food or feed containing or consisting of category 2 NGT plants, the application shall also be accompanied by:	
Article 19(3), point (a)				
220	(a) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);	(a) the environmental risk assessment carried out in accordance with the principles and criteria set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);	(a) the environmental risk assessment carried out in accordance with the principles and ~~criteria~~**information** set out in Parts 1 and 2 of Annex II and with the implementing act adopted in accordance with Article 27, point (c);	
Article 19(3), point (b)				
221	(b) where appropriate, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan. This duration may be different from the duration of the authorisation. If, based on the results of any release notified in	(b) where appropriate, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan. This duration may be different from the duration of the authorisation. If, based on the results of any release notified in	(b) ~~where appropriate,~~ a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan. This duration may be different from the duration of the authorisation. ~~If~~**By way of derogation from the first**	

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	accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the applicant considers that the NGT plant does need a monitoring plan, the applicant may propose not to submit a monitoring plan.	accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the applicant considers that the NGT plant does need a monitoring plan, the applicant may propose not to submit a monitoring plan.	**sentence, a monitoring plan shall not be required where the applicant duly justifies that it is not needed**, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the **category 2** NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted ~~in accordance with~~**pursuant to** Article 27, point (d), ~~the applicant considers that the NGT plant does need a monitoring plan, the applicant may propose not to submit a monitoring plan~~**and the guidance referred to in Article 29(1)**.	
Article 19(4)				
222	4. The application shall also contain a proposal for labelling in accordance with Article 23.	4. The application shall also contain a proposal for labelling in accordance with Article 23.	4. The application shall also contain a proposal for labelling in accordance with Article 23.	
Article 20				
223	Article 20 Specific provisions on the opinion of the Authority	Article 20 Specific provisions on the opinion of the Authority	Article 20 Specific provisions on the opinion of the Authority	
Article 20(1), first subparagraph				

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224	1. By way of derogation from Article 6(1) and (2) and Article 18(1) and (2) of Regulation (EC) No 1829/2003, the Authority shall deliver an opinion on the application for authorisation referred to in Article 19 of this Regulation within six months as from the receipt of a valid application.	1. By way of derogation from Article 6(1) and (2) and Article 18(1) and (2) of Regulation (EC) No 1829/2003, the Authority shall deliver an opinion on the application for authorisation referred to in Article 19 of this Regulation within six months as from the receipt of a valid application.	1. By way of derogation from Article 6(1) and (2) and Article 18(1) and (2) of Regulation (EC) No 1829/2003, the Authority shall deliver an opinion on the application for authorisation referred to in Article 19 of this Regulation within six months as from the receipt of a valid application.	
Article 20(1), second subparagraph				
225	Where the Authority or the competent authority of the Member State carrying out the environmental risk assessment or the safety assessment of the food or feed pursuant to Article 6(3), points (b) and (c) and Article 18(3), points (b) and (c) of Regulation (EC) No 1829/2003 considers that additional information is necessary, the Authority, or the national competent authority through the Authority, shall ask the applicant to submit that information within a specified time limit. In that case, the six months period shall be extended by that additional period. The extension shall not exceed six months unless it is justified by the nature of the data requested or by exceptional circumstances.	Where the Authority or the competent authority of the Member State carrying out the environmental risk assessment or the safety assessment of the food or feed pursuant to Article 6(3), points (b) and (c) and Article 18(3), points (b) and (c) of Regulation (EC) No 1829/2003 considers that additional information is necessary, the Authority, or the national competent authority through the Authority, shall ask the applicant to submit that information within a specified time limit. In that case, the six months period shall be extended by that additional period. The extension shall not exceed six months unless it is justified by the nature of the data requested or by exceptional circumstances.	Where the Authority or the competent authority of the Member State carrying out the environmental risk assessment or the safety assessment of the food or feed pursuant to Article 6(3), points (b) and (c) and Article 18(3), points (b) and (c) of Regulation (EC) No 1829/2003 considers that additional information is necessary, the Authority, or the ~~national~~ competent authority **of the Member State** through the Authority, shall ask the applicant to submit that information within a specified time limit. In that case, the six months period shall be extended by that additional period. The extension shall not exceed six months unless it is justified by the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			nature of the data requested or by exceptional circumstances.	
Article 20(2)				
226	2. In addition to the tasks referred to in Article 6(3) and Article 18(3) of Regulation (EC) No 1829/2003, the Authority shall verify whether all the particulars and documents submitted by the applicant are in conformity with Article 19 of this Regulation.	2. In addition to the tasks referred to in Article 6(3) and Article 18(3) of Regulation (EC) No 1829/2003, the Authority shall verify whether all the particulars and documents submitted by the applicant are in conformity with Article 19 of this Regulation.	2. In addition to the tasks referred to in Article 6(3) and Article 18(3) of Regulation (EC) No 1829/2003, the Authority shall verify whether all the particulars and documents submitted by the applicant are in conformity with Article 19 of this Regulation.	
Article 20(3)				
227	3. By way of derogation from Article 6(3), point (d), and Article 18(3), point (d), of Regulation (EC) No 1829/2003, the Authority shall forward to the Union reference laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 the particulars referred to in Article 19(2) of this Regulation and in Article 5(3), point (j), and Article 17(3), point (j), of Regulation (EC) No 1829/2003.	3. By way of derogation from Article 6(3), point (d), and Article 18(3), point (d), of Regulation (EC) No 1829/2003, the Authority shall forward to the Union reference laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 the particulars referred to in Article 19(2) of this Regulation and in Article 5(3), point (j), and Article 17(3), point (j), of Regulation (EC) No 1829/2003.	3. By way of derogation from Article 6(3), point (d), and Article 18(3), point (d), of Regulation (EC) No 1829/2003, the Authority shall forward to the **European** Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 the particulars referred to in Article 19(2) of this Regulation and in Article 5(3), point (j), and Article 17(3), point (j), of Regulation (EC) No 1829/2003.	
Article 20(4)				
228	4. The Union reference laboratory shall test and validate the method of detection, identification and quantification	4. The Union reference laboratory shall test and validate the method of detection, identification and quantification	4. The **European** Union Reference Laboratory shall test and validate the method of detection, identification and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	proposed by the applicant in accordance with Article 19(2) or assess whether the information provided by the applicant justifies the application of adapted modalities to comply with detection method requirements referred to in that paragraph.	proposed by the applicant in accordance with Article 19(2) ~~*or assess whether the information provided by*~~. ***If*** the applicant justifies the application of adapted modalities to comply with detection method requirements, ***the Union reference laboratory shall carry out its own research and analyses to confirm the claimed unfeasibility.*** ~~*referred to*~~ In that ~~*paragraph*~~***case, the decision of the Union reference laboratory shall be motivated and be made public***.	quantification proposed by the applicant in accordance with Article 19(2) or assess whether the information provided by the applicant justifies the application of adapted modalities to comply with detection method requirements referred to in that paragraph.	
Article 20(5)				
229	5. By way of derogation from Article 6(5), point (f), and Article 18(5), point (f), of Regulation (EC) No 1829/2003, in the event of an opinion in favour of authorising the food or the feed, the opinion shall also include:	5. By way of derogation from Article 6(5), point (f), and Article 18(5), point (f), of Regulation (EC) No 1829/2003, in the event of an opinion in favour of authorising the food or the feed, the opinion shall also include:	5. By way of derogation from Article 6(5), point (f), and Article 18(5), point (f), of Regulation (EC) No 1829/2003, in the event of an opinion in favour of authorising the food or the feed, the opinion shall also include:	
Article 20(5), point (a)				
230	(a) the method, validated by the Union reference laboratory, for detection, including sampling, and, where applicable, identification and quantification of the NGT plant and detection and identification of the NGT plant in the NGT food or feed, and a	(a) the method, validated by the Union reference laboratory, for detection, including sampling, and, where applicable, identification and quantification of the NGT plant and detection and identification of the NGT plant in the NGT food or feed, and a	(a) the method, validated by the **European** Union Reference Laboratory, for detection, including sampling, **identification and quantification of the category 2 NGT plant** and, where applicable**, for the detection**, identification and quantification of	

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	justification of any adaptation of the method in the cases referred to in Article 19(2), subparagraph 2;	justification of any adaptation of the method in the cases referred to in Article 19(2), subparagraph 2;	the ~~NGT plant and detection and identification of the~~**category 2** NGT plant in the NGT food or feed **produced from it**, and a justification of any adaptation of the **analytical** method **performance requirements** in the cases referred to in Article 19(2), subparagraph 2;	
Article 20(5), point (b)				
231	(b) an indication of where appropriate reference material can be accessed.	(b) an indication of where appropriate reference material can be accessed.	(b) an indication of where appropriate reference material can be accessed.	
Article 20(6)				
232	6. In addition to the particulars mentioned in Article 6(5), point (d) and Article 18(5), point (d) of Regulation (EC) No 1829/2003, the opinion shall also include a proposal for labelling in accordance with Article 23 of this Regulation.	6. In addition to the particulars mentioned in Article 6(5), point (d) and Article 18(5), point (d) of Regulation (EC) No 1829/2003, the opinion shall also include a proposal for labelling in accordance with Article 23 of this Regulation.	6. In addition to the particulars mentioned in Article 6(5), point (d) and Article 18(5), point (d) of Regulation (EC) No 1829/2003, the opinion shall also include a proposal for labelling in accordance with Article 23 of this Regulation.	
Article 21				
233	Article 21 Duration of the validity of the authorisation after renewal	Article 21 Duration of the validity of the authorisation after renewal	Article 21 Duration of the validity of the authorisation ~~after~~**upon** renewal	
Article 21, first paragraph				
234	By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003,	By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003,	By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003,	

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	after the first renewal, the authorisation shall be valid for an unlimited period, unless the Commission decides to renew the authorisation for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the authorisation.	after the first renewal, the authorisation shall be valid for an unlimited period, unless the Commission decides to renew the authorisation for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the authorisation.	~~after~~**upon** the first renewal, the authorisation shall be valid for an unlimited period, unless the Commission decides to renew the authorisation for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the authorisation.	
Article 21, first paragraph a				
234a		***If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports this hypothesis or if the competent authority may withdraw its decision. The withdrawal decision must be sent by registered mail to the beneficiary of the decision, who shall have 15 days in which to make observations. In that case, the marketing of the NGT plant or product shall be prohibited from the day following the date of receipt of the registered letter.***		
SECTION 4				
235	SECTION 4 Common provisions for category 2 NGT	SECTION 4 Common provisions for category 2 NGT	SECTION 4 Common provisions for category 2 NGT	

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	plants and category 2 NGT products	plants and category 2 NGT products	plants and category 2 NGT products	
Article 22				
236	Article 22 Incentives for category 2 NGT plants and category 2 NGT products containing traits relevant for sustainability	Article 22 Incentives for category 2 NGT plants and category 2 NGT products containing traits relevant for sustainability	Article 22 Incentives for category 2 NGT plants and category 2 NGT products containing traits relevant for sustainability	
Article 22(1)				
237	1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in Part 1 of Annex III and it does not have any traits referred to in Part 2 of that Annex.	1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended ~~*trait(s)*~~***traits*** of the NGT plant conveyed by the genetic modification is contained in ~~*Part 1 of Annex III*~~***Article 51(1) of Regulation (EU/…)**** and it does not have any traits referred to in Part 2 of that Annex. ***. Commission proposal for a Regulation on plant reproductive material (COM/2023/414), (2023/0227(COD)).***	1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the **category 2** NGT plant conveyed by the genetic modification is contained in Part 1 of Annex III and it does not have any traits referred to in Part 2 of that Annex.	
Article 22(2)				
238	2. The following incentives shall apply to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:	2. The following incentives shall apply to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:	2. The following incentives shall apply to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:	

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Article 22(2), point (a)				
239	(a) by way of derogation from Article 20(1), subsection (1) of this Regulation, the Authority shall deliver its opinion on the application within 4 months from the receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 20(1). The time limit shall be extendable under the conditions set out in Article 20(1), subsection (2);	(a) by way of derogation from Article 20(1), subsection (1) of this Regulation, the Authority shall deliver its opinion on the application within 4 months from the receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 20(1). The time limit shall be extendable under the conditions set out in Article 20(1), subsection (2);	(a) by way of derogation from Article 20(1), subsection (1) of this Regulation, the Authority shall deliver its opinion on the application within 4 months from the receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 20(1). The time limit shall be extendable under the conditions set out in Article 20(1), subsection (2);	
Article 22(2), point (b)				
240	(b) where the applicant is a SME, it shall be exempted from the payment of the financial contributions to the Union Reference Laboratory and to the European Network of GMO Laboratories referred to in Article 32 of Regulation (EC) No 1829/2003.	(b) where the applicant is a SME, it shall be exempted from the payment of the financial contributions to the Union Reference Laboratory and to the European Network of GMO Laboratories referred to in Article 32 of Regulation (EC) No 1829/2003.	(b) where the applicant is a SME, it shall be exempted from the payment of the financial contributions to the **European** Union Reference Laboratory and to the European Network of GMO Laboratories referred to in Article 32 of Regulation (EC) No 1829/2003.	
Article 22(3)				
241	3. The following pre-submission advice for the purposes of the risk assessment conducted in accordance with Annex II shall, in addition to Article 32a of Regulation (EC) No 178/2002,	3. The following pre-submission advice for the purposes of the risk assessment conducted in accordance with Annex II shall, in addition to Article 32a of Regulation (EC) No 178/2002,	3. The following pre-submission advice for the purposes of the risk assessment conducted in accordance with Annex II shall, in addition to Article 32a of Regulation (EC) No 178/2002,	

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	apply prior to notifications submitted in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:	apply prior to notifications submitted in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:	apply prior to notifications submitted in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and to applications for authorisation submitted in accordance with Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19:	
Article 22(3), point (a)				
242	(a) the staff of the Authority shall, at the request of a potential applicant or notifier, provide advice on plausible risk hypotheses that the potential applicant or notifier has identified based on the properties of a plant, product or hypothetical plant or product, that need to be addressed by providing the information under Parts 2 and 3 of Annex II. The advice shall not, however, cover the design of studies to address the risk hypotheses;	(a) the staff of the Authority shall, at the request of a potential applicant or notifier, provide advice on plausible risk hypotheses that the potential applicant or notifier has identified based on the properties of a plant, product or hypothetical plant or product, that need to be addressed by providing the information under Parts 2 and 3 of Annex II. The advice shall not, however, cover the design of studies to address the risk hypotheses;	(a) the staff of the Authority shall, at the request of a potential applicant or notifier, provide advice on ~~plausible~~**the** risk hypotheses that the potential applicant or notifier has identified ~~based on the properties of a plant, product or hypothetical plant or product, that need~~ to be ~~addressed~~**tested in the risk assesment** by providing the information under Parts 2 and 3 of Annex II~~. The advice shall not, however, cover the design of studies to address the risk hypotheses~~;	
Article 22(3), point (b)				
243	(b) where the potential applicant or notifier is a SME, it may notify the Authority of how it intends to address the plausible risk hypotheses referred to in point	(b) where the potential applicant or notifier is a SME, it may notify the Authority of how it intends to address the plausible risk hypotheses referred to in point	(b) **the advice referred to in point (a) shall not cover the design of studies to address the risk hypotheses unless the advice concerns guidance documents**	

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	(a) that it has identified based on the properties of a plant, product or hypothetical plant or product, including the design of the studies it intends to perform in accordance with the requirements laid down Parts 2 and 3 of Annex II. The Authority shall provide advice on the notified information, including on the design of the studies.	(a) that it has identified based on the properties of a plant, product or hypothetical plant or product, including the design of the studies it intends to perform in accordance with the requirements laid down Parts 2 and 3 of Annex II. The Authority shall provide advice on the notified information, including on the design of the studies.	**developed by the Authority in which study design is addressed. By way of derogation from the first sentence,** where the potential applicant or notifier is a SME, it may notify the Authority of how it intends to address the ~~plausible~~ risk hypotheses referred to in point (a) that it has identified ~~based on the properties of a plant, product or hypothetical plant or product~~**to be tested in the risk assesment**, including the design of the studies it intends to perform in accordance with the requirements laid down Parts 2 and 3 of Annex II. The Authority shall provide advice on the notified information, including on the design of the studies.	
Article 22(4)				
244	4. The pre-submission advice referred to in paragraph 3 shall comply with the following requirements:	4. The pre-submission advice referred to in paragraph 3 shall comply with the following requirements:	4. The pre-submission advice referred to in paragraph 3 shall comply with the following requirements:	
Article 22(4), point (a)				
245	(a) it shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Panel on Genetically Modified Organisms of the Authority. The staff of the Authority providing	(a) it shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Panel on Genetically Modified Organisms of the Authority. The staff of the Authority providing	(a) it shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Panel on Genetically Modified Organisms of the Authority. The staff of the Authority providing	

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	the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice;	the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice;	the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice;	
Article 22(4), point (b)				
246	(b) for potential notifications in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and for potential applications under Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19 concerning a category 2 NGT plant to be used as seeds or other plant reproductive material, the pre-submission advice shall be provided by the Authority together, or in close collaboration with the competent authority of the Member State to which the notification or application is going to be submitted;	(b) for potential notifications in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and for potential applications under Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19 concerning a category 2 NGT plant to be used as seeds or other plant reproductive material, the pre-submission advice shall be provided by the Authority together, or in close collaboration with the competent authority of the Member State to which the notification or application is going to be submitted;	(b) for potential notifications in accordance with Article 13 of Directive 2001/18/EC in conjunction with Article 14 and for potential applications under Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19 concerning a category 2 NGT plant to be used as seeds or other plant reproductive material, the pre-submission advice shall be provided by the Authority together, or in close collaboration with the competent authority of the Member State to which the notification or application is going to be submitted;	
Article 22(4), point (c)				
247	(c) the Authority shall make public without delay a summary of the pre-submission advice once an application or notification has been considered valid. Articles	(c) the Authority shall make public without delay a summary of the pre-submission advice once an application or notification has been considered valid. Articles	(c) the Authority shall make public without delay a summary of the pre-submission advice once an application or notification has been considered valid. ~~Articles 38(1a)~~**Article 38(1a) of**	

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	38(1a) shall apply mutatis mutandis;	38(1a) shall apply mutatis mutandis;	**Regulation (EC) No 178/2002** shall apply mutatis mutandis;	
Article 22(4), point (d)				
248	(d) potential applicants or notifiers demonstrating that they are a SME can request the pre-submission advice referred to in paragraph 3, point (a), at different points in time.	(d) potential applicants or notifiers demonstrating that they are a SME can request the pre-submission advice referred to in paragraph 3, point (a), at different points in time.	(d) potential applicants or notifiers demonstrating that they are a SME can request the pre-submission advice referred to in paragraph 3, point (a), at different points in time.	
Article 22(5)				
249	5. Any request for the incentives shall be submitted to the Authority at the time of request of advice referred to in paragraph 3 or the application referred to in Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19, and accompanied by the following information:	5. Any request for the incentives shall be submitted to the Authority at the time of request of advice referred to in paragraph 3 or the application referred to in Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19, and accompanied by the following information:	5. Any request for the incentives shall be submitted to the Authority at the time of request of advice referred to in paragraph 3 or the application referred to in Articles 5 or 17 of Regulation (EC) No 1829/2003 in conjunction with Article 19, and accompanied by the following information:	
Article 22(5), point (a)				
250	(a) the information necessary to establish that the intended trait(s) conveyed by the genetic modification of the category 2 NGT plant meet the conditions referred to in paragraph 1;	(a) the information necessary to establish that the intended trait(s) conveyed by the genetic modification of the category 2 NGT plant meet the conditions referred to in paragraph 1;	(a) the information necessary to establish that the intended trait(s) conveyed by the genetic modification of the category 2 NGT plant meet the conditions referred to in paragraph 1;	
Article 22(5), point (b)				
251	(b) where applicable, the information necessary to	(b) where applicable, the information necessary to	(b) where applicable, the information necessary to	

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	demonstrate the (potential) applicant or notifier is a SME;	demonstrate the (potential) applicant or notifier is a SME;	demonstrate the (potential) applicant or notifier is a SME;	
Article 22(5), point (c)				
252	(c) for the purpose of paragraph 3, information on the aspects listed in Part 1 of Annex II as far as it can already be provided and any other relevant information.	(c) for the purpose of paragraph 3, information on the aspects listed in Part 1 of Annex II as far as it can already be provided and any other relevant information.	(c) for the purpose of paragraph 3, information on the aspects listed in Part 1 of Annex II as far as it can already be provided and any other relevant information.	
Article 22(6)				
253	6. Article 26 of Directive 2001/18/EC and Article 30 of Regulation (EC) No 1829/2003 shall apply to information submitted under this article to the Authority, as appropriate.	6. Article 26 of Directive 2001/18/EC and Article 30 of Regulation (EC) No 1829/2003 shall apply to information submitted under this article to the Authority, as appropriate.	6. Article ~~26~~**25** of Directive 2001/18/EC and Article 30 of Regulation (EC) No 1829/2003 shall apply to information submitted under this article to the Authority, as appropriate.	
Article 22(7)				
254	7. The Authority shall lay down the practical arrangements to implement paragraphs (3) to (6).	7. The Authority shall lay down the practical arrangements to implement paragraphs (3) to (6).	7. The Authority shall lay down the practical arrangements to implement paragraphs (3) to (6)**, including the verification that the category 2 NGT plant meets the conditions referred to in paragraph 1**.	
Article 22(8)				
255	8. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the lists of traits of NGT plants laid down in Annex III in	8. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the lists of traits of NGT plants laid down in Annex III in	8. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the lists of traits of NGT plants laid down in Annex III in	

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	order to adapt them to scientific and technological progress and to new evidence relating to the impact on sustainability of those traits, subject to the following conditions:	order to adapt them to scientific and technological progress and to new evidence relating to the impact on sustainability of those traits, subject to the following conditions:	order to adapt them to **advances in** scientific and technological progress ~~and~~**or** to new evidence relating to the impact on sustainability of those traits, subject to the following conditions:	
Article 22(8), point (a)				
256	(a) the Commission shall take into account the monitoring of the impacts of this Regulation in accordance with Article 30(3);	(a) the Commission shall take into account the monitoring of the impacts of this Regulation in accordance with Article 30(3);	(a) the Commission shall take into account the monitoring of the impacts of this Regulation in accordance with Article 30(3);	
Article 22(8), point (b)				
257	(b) the Commission shall conduct an up-to-date scientific literature review of the impact on environmental, social and economic sustainability of the trait(s) it intends to add to or delete from the list in Annex III;	(b) the Commission shall conduct an up-to-date scientific literature review of the impact on environmental, social and economic sustainability of the trait(s) it intends to add to or delete from the list in Annex III;	(b) the Commission shall conduct **and publish** an up-to-date scientific literature review of the impact on environmental, social and economic sustainability of the trait(s) it intends to add to or delete from the list in Annex III;	
Article 22(8), point (c)				
258	(c) where applicable, the Commission shall take into account the results of monitoring which was carried out in accordance with Article 14, point (h), or Article 19(3), of NGT plants harbouring the trait(s) conveyed by their genetic modification.	(c) where applicable, the Commission shall take into account the results of monitoring which was carried out in accordance with Article 14, point (h), or Article 19(3), of NGT plants harbouring the trait(s) conveyed by their genetic modification.	(c) where applicable, the Commission shall take into account the results of monitoring which was carried out in accordance with Article 14, point (h), or Article 19(3), of **category 2** NGT plants harbouring the trait(s) conveyed by their genetic modification.	
Article 23				

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259	Article 23 Labelling of authorised category 2 NGT products	Article 23 Labelling of authorised category 2 NGT products	Article 23 Labelling of authorised category 2 NGT products	
Article 23, first paragraph				
260	In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s) conveyed by the genetic modification, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation.	In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s) conveyed by the genetic modification, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation.	In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s) conveyed by the genetic modification, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation. **Where use is made of this provision, the label shall mention all the traits of the category 2 NGT plant conveyed by the genetic modification.**	
Article 24				
261	Article 24 Measures to avoid the unintended presence of category 2 NGT plants	Article 24 Measures to avoid the unintended presence of category 2 NGT plants	~~Article 24~~ *deleted*	

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Article 24, first paragraph				
262	Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.	Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.	*deleted*	
Article 25				
263	Article 25 Cultivation	Article 25 Cultivation	~~Article 25~~ *deleted*	
Article 25, first paragraph				
264	Article 26b of Directive 2001/18/EC shall not apply to category 2 NGT plants.	Article 26b of Directive 2001/18/EC shall not apply to category 2 NGT plants.	*deleted*	
CHAPTER IV				
265	CHAPTER IV FINAL PROVISIONS	CHAPTER IV FINAL PROVISIONS	CHAPTER IV FINAL PROVISIONS	
Article 26				
266	Article 26 Exercise of the delegation	Article 26 Exercise of the delegation	Article 26 Exercise of the delegation	
Article 26(1)				
267	1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	
Article 26(2)				

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268	2. The power to adopt the delegated acts referred to in Article 5(3) and Article 22(8) shall be conferred on the Commission for a period of 5 years from [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.	2. The power to adopt the delegated acts referred to in Article 5(3)***, Article 6(11a)*** and Article 22(8) shall be conferred on the Commission for a period of 5 years from [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.	2. The power to adopt the delegated acts referred to in Article 5(3) and Article 22(8) shall be conferred on the Commission for a period of 5 years from [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.	
Article 26(3)				
269	3. The delegations of power referred to in Article 5(3) and Article 22(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the	3. The delegations of power referred to in Article 5(3)***, Article 6(11a)*** and Article 22(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not	3. The delegations of power referred to in Article 5(3) and Article 22(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the	

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	validity of any delegated acts already in force.	affect the validity of any delegated acts already in force.	validity of any delegated acts already in force.	
Article 26(4)				
270	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making([1]). __________ 1. OJ L 123, 12.5.2016, p. 1.	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making([1]). __________ 1. OJ L 123, 12.5.2016, p. 1.	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making([1]). __________ 1. OJ L 123, 12.5.2016, p. 1.	
Article 26(5)				
271	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	
Article 26(6)				
272	6. A delegated act adopted pursuant to Articles Article 5(3) and Article 22(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European	6. A delegated act adopted pursuant to Articles Article 5(3)***,*** ***Article 6(11a)*** and Article 22(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period,	6. A delegated act adopted pursuant to ~~Articles~~ Article 5(3) and Article 22(8) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European	

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	Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.	the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.	Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.	
Article 27				
273	Article 27 Implementing acts	Article 27 Implementing acts	Article 27 Implementing acts	
Article 27, first paragraph				
274	The Commission shall adopt implementing acts concerning:	The Commission shall adopt implementing acts concerning:	The Commission shall adopt implementing acts concerning:	
Article 27, first paragraph, point (a)				
275	(a) the information required to demonstrate that a plant is a NGT plant;	*deleted*	*(a)* the information required to demonstrate that a plant is a NGT plant;	
Article 27, first paragraph, point (b)				
276	(b) the preparation and the presentation of the verification requests referred to in Articles 6 and 7;	*deleted*	(b) the preparation and the presentation of the verification requests **and of the content of the patent information, and the content of the verification reports and of the decisions** referred to in Articles 6 and 7;	
Article 27, first paragraph, point (c)				
277	(c) the methodology and information requirements for the environmental risk assessment of	(c) the methodology and information requirements for the environmental risk assessment of	(c) the methodology and information requirements for the environmental risk assessment of	

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	category 2 NGT plants and the safety assessments of category 2 NGT food and feed, in accordance with the principles and criteria laid down in Annex II;	category 2 NGT plants and the safety assessments of category 2 NGT food and feed, in accordance with the principles and criteria laid down in Annex II;	category 2 NGT plants and the safety assessments of category 2 NGT food and feed, in accordance with the principles and ~~criteria~~**factors** laid down in Annex II;	
Article 27, first paragraph, point (d)				
278	(d) the application of Articles 14 and 19, including rules concerning the preparation and the presentation of the notification or application;	(d) the application of Articles 14 and 19, including rules concerning the preparation and the presentation of the notification or application;	(d) the application of Articles 14 and 19, including rules concerning the preparation and the presentation of the notification or application;	
Article 27, first paragraph, point (e)				
279	(e) adapted modalities to comply with analytical method requirements referred to in Article 14(1), point (l), and Article 19(2).	(e) adapted modalities to comply with analytical method requirements referred to in Article 14(1), point (l), and Article 19(2).	(e) adapted modalities to comply with analytical method **performance** requirements referred to in Article 14(1), point (l), and Article 19(2).	
Article 27, second paragraph				
280	Before adopting the implementing acts referred to in points (a) to (d), the Commission shall consult the Authority. The implementing acts shall be adopted in accordance with the procedure referred to in Article 28(3).	Before adopting the implementing acts referred to in points (a) to (d), the Commission shall consult the Authority. The implementing acts shall be adopted in accordance with the procedure referred to in Article 28(3).	Before adopting the implementing acts referred to in points (a) to (d), the Commission shall consult the Authority. The implementing acts shall be adopted in accordance with the procedure referred to in Article 28(3).	
Article 28				
281	Article 28 Committee procedure	Article 28 Committee procedure	Article 28 Committee procedure	
Article 28(1)				

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282	1. The Commission shall be assisted by the committee set up by Article 58 of Regulation (EC) No 178/2002.	1. The Commission shall be assisted by the committee set up by Article 58 of Regulation (EC) No 178/2002.	1. The Commission shall be assisted by the committee set up by Article 58 of Regulation (EC) No 178/2002.	
Article 28(2)				
283	2. Where reference is made to this paragraph, Article 4 of Regulation (EC) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 4 of Regulation (EC) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 4 of Regulation (EC) No 182/2011 shall apply.	
Article 28(3)				
284	3. Where reference is made to this paragraph, Article 5 of Regulation (EC) No 182/2011 shall apply.	3. Where reference is made to this paragraph, Article 5 of Regulation (EC) No 182/2011 shall apply.	3. Where reference is made to this paragraph, Article 5 of Regulation (EC) No 182/2011 shall apply.	
Article 29				
285	Article 29 Guidance	Article 29 Guidance	Article 29 Guidance	
Article 29(1)				
286	1. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the notifier or the applicant in the preparation and the presentation of the notifications and the application referred to in Chapters II and III and for the implementation of Annex II.	1. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the notifier or the applicant in the preparation and the presentation of the notifications and the application referred to in Chapters II and III and for the implementation of Annex II.	1. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the notifier or the applicant in the preparation and the presentation of the notifications and the application referred to in Chapters II and III and for the implementation of Annex II.	
Article 29(2)				

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287	2. Before the date of application of this Regulation, the European Union Reference Laboratory for Genetically Modified Food and Feed established pursuant to Article 32 of Regulation (EC) No 1829/2003, assisted by the European Network of GMO Laboratories, shall publish detailed guidance to assist the notifier or the applicant for the application of Article 14(1), point (l), and Article 19(2).	2. Before the date of application of this Regulation, the European Union Reference Laboratory for Genetically Modified Food and Feed established pursuant to Article 32 of Regulation (EC) No 1829/2003, assisted by the European Network of GMO Laboratories, shall publish detailed guidance to assist the notifier or the applicant for the application of Article 14(1), point (l), and Article 19(2).	2. Before the date of application of this Regulation, the European Union Reference Laboratory for Genetically Modified Food and Feed established pursuant to Article 32 of Regulation (EC) No 1829/2003, assisted by the European Network of GMO Laboratories, shall publish detailed guidance to assist the notifier or the applicant for the application of Article 14(1), point (l), and Article 19(2).	
Article 29(2a)				
287a			**2a. Before the date of application of this Regulation, the Commission shall publish, and thereafter review and update if needed, guidelines for the purpose of assisting operators, in particular breeders, in navigating the plant intellectual property landscape. The Commission shall consult the competent intellectual property offices of the Member States when drafting the guidelines. The guidelines shall at least specify:**	
Article 29(2a), point (a)				
287b			**(a) existing plant licencing platforms and their members;**	

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Article 29(2a), point (b)				
287c			**(b) existing public organisations that have the purpose of assisting plant breeders with intellectual property-related questions;**	
Article 29(2a), point (c)				
287d			**(c) existing databases allowing operators to identify the intellectual property rights which apply to a given plant;**	
Article 29(2a), point (d)				
287e			**(d) basic information on the forms and conditions of protection of intellectual property in plants, including information on compulsory licencing and exemptions.**	
Article 29(2b)				
287f			**2b. Before the date of application of this Regulation, the Commission shall publish information for operators, with particular emphasis on breeders, about the opportunities to benefit from the various projects, financial mechanisms and policies designed to support research and development in the area of new genomic techniques.**	

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Article 30				
288	Article 30 Monitoring, reporting and evaluation	Article 30 Monitoring, reporting and evaluation	Article 30 Monitoring, reporting and evaluation	
Article 30(1)				
289	1. No sooner than three years after the first decision is adopted in accordance with Article 6(8) or (10) or Article 7(6) or in accordance with Sections 2 or 3 of Chapter III, whichever is the earliest, and thereafter every five years, the Commission shall forward to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the implementation of this Regulation.	1. No sooner than three years after the first decision is adopted in accordance with Article 6(8) or (10) or Article 7(6) or in accordance with Sections 2 or 3 of Chapter III, whichever is the earliest, and thereafter every five years, the Commission shall forward to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the implementation of this Regulation.	1. No sooner than three **years and no later than five** years after the first decision is adopted in accordance with Article 6(8) or (10) or Article 7(6) or in accordance with Sections 2 or 3 of Chapter III, whichever is the earliest, and thereafter every five years, the Commission shall forward to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the implementation of this Regulation.	
Article 30(2)				
290	2. The report shall also address any ethical issues that have arisen with the application of this Regulation.	2. The report shall also ***identify and*** address any ***issues regarding biodiversity and environmental, human and animal health, changes to agronomic practices as well as socio-economic and*** ethical issues that ***may*** have arisen with the application of this Regulation.	2. The report shall also address any ethical issues that have arisen with the application of this Regulation.	
Article 30(3)				

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291	3. For the purpose of the reporting referred to in paragraph 1, the Commission, by [24 months after the date of entry into force of this Regulation] at the latest, shall establish, after consulting the competent authorities of the Member States in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact of this Regulation. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.	3. For the purpose of the reporting referred to in paragraph 1, the Commission, by [24 months after the date of entry into force of this Regulation] at the latest, shall establish, after consulting the competent authorities of the Member States in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact of this Regulation***, including the intended and unintended effects and systematic effects on the environment, biodiversity and ecosystems***. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.	3. For the purpose of the reporting referred to in paragraph 1, the Commission, by [24 months after the date of entry into force of this Regulation] at the latest, shall establish, after consulting the competent authorities of the Member States in accordance with Directive 2001/18/EC and Regulation (EC) No 1829/2003, a detailed programme for monitoring, based on indicators, the impact of this Regulation. It shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.	
Article 30(4)				
292	4. No sooner than two years after the publication of the first report referred to in paragraph 1 the Commission shall carry out an evaluation of the implementation of this Regulation and its impact on human and animal health, the environment, consumer information, the functioning of the internal market, and economic,	4. No sooner than two years after the publication of the first report referred to in paragraph 1 the Commission shall carry out an evaluation of the implementation of this Regulation and its impact on human and animal health, the environment, consumer information, the functioning of the internal market, and economic,	4. No sooner than two **years and no later than three** years after the publication of the first report referred to in paragraph 1 the Commission shall carry out an evaluation of the implementation of this Regulation and its impact on human and animal health, the environment, consumer information, the functioning of the	

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	environmental and social sustainability.	environmental and social sustainability.	internal market, **small or medium-sized enterprises (SMEs), the breeding sector, the organic sector,** and economic, environmental and social sustainability.	
Article 30(5)				
293	5. The Commission shall present a report on the main findings of the evaluation referred to in paragraph 4 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.	5. The Commission shall present a report on the main findings of the evaluation referred to in paragraph 4 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.	5. The Commission shall present a report on the main findings of the evaluation referred to in paragraph 4 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.	
Article 30(5a)				
293a		***5a. By June 2025 the Commission shall submit a report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the role and impact of patents on breeders' and farmers' access to varied plant reproductive material, as well as on innovation and, in particular, on opportunities for SMEs. The report shall assess whether further legal provisions are necessary in addition to those provided for in Article 4a and***		

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		Article 33a of this Regulation. Where appropriate to ensure breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, the report shall be accompanied by a legislative proposal to address further necessary adjustments in the intellectual property rights framework.		
Article 30(5b)				
293b		***5b. By 2024, the Commission shall submit a report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions evaluating the specificities of and needs for other sectors not covered in this legislation, such as microorganisms, including a proposal for further policy actions.***		
Article 30(5c)				
293c		***5c. Every four years, the Commission shall assess the criteria of equivalence established in Annex I and, if necessary, update them through a delegated act as referred to in Article 5(3).***		
Article 30a				

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293d			**Article 30a** **NGT patent expert group and the study on the impact of patenting practices**	
Article 30a(1)				
293e			**1. As from the date of entry into force of this regulation, the Commission shall establish an expert group on the effect of patents on NGT plants (the 'NGT patent expert group').**	
Article 30a(2)				
293f			**2. The NGT patent expert group shall survey and exchange information on a regular basis as regards the effect of patent law and the implementation practice on access to modified genetic resources, transparency of the patent landscape and innovation in the field of NGT plants. The NGT patent expert group shall in particular survey the patent licensing practices for the breeding and marketing of NGT plants protected by a patent, ongoing patent application procedures on NGT plants and patent enforcement practices vis à vis farmers and, if available, case-examples thereof.**	

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Article 30a(3)				
293g			**3. The NGT patent expert group shall be constituted in accordance with Commission Decision C(2016) 3301 final of 30 May 2016 establishing the horizontal rules on the creation and operation of Commission expert groups. Each Member State may appoint a delegation of maximum two experts to the NGT patent expert group. The experts shall have knowledge and experience in the areas covered by this Regulation and in the area of intellectual property rights, including their impact on the market. The European Patent Office may also appoint one expert to the NGT patent expert group.**	
Article 30a(4)				
293h			**4. The Commission shall conduct a study on the impact that the patenting of plants, as well as related licensing and transparency practices, may have on innovation in plant breeding, on breeders' access to plant genetic material and techniques and on the availability of plant**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			reproductive material to farmers as well as the overall competitiveness of the EU plant breeding industry. The study shall include, in particular, an evaluation of the conditions necessary to ensure the access of the Union breeding sector using new genomic techniques to patented modified genetic resources in equitable and predictable terms, including whether breeders should be granted commercial access to those resources free of cost. When carrying out the study and considering the appropriate follow-up actions, the Commission shall take into account the findings of the NGT patent expert group as well as the reporting from the Union breeding sector. To this end, the Commission shall invite the Union breeding sector to report on its experience with commercial access to patented modified genetic resources in plants. The Commission shall report on its findings one year after entry into force of this Regulation.	
Article 30a(5)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
293i			**5. The NGT patent expert group may continue working for as long as necessary after the completion of the study referred to in paragraph 4.**	
Article 30a(6)				
293j			**6. In view of the outcomes of the study referred to in paragraph 4, the Commission shall inform on measures to follow-up, and in particular, if appropriate, submit a legislative proposal addressing any identified issues such as negative impacts on breeders or farmers. If the Commission considers there is no need to submit a proposal, it shall inform the Parliament and the Council of the reasons.**	
Article 30a(7)				
293k			**7. If in view of the outcomes of the study referred to in paragraph 4, the Commission considers that no measures to follow-up are necessary, the Commisson shall conduct another study of the same scope, no sooner than four years and no later than six years after the publication of the first report referred to in paragraph**	

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			4. Paragraphs 5 and 6 shall apply accordingly.	
Article 31				
294	Article 31 References in other Union legislation	Article 31 References in other Union legislation	Article 31 References in other Union legislation	
Article 31, first paragraph				
295	With regard to category 2 NGT plants, references in other Union legislation to Annex II or Annex III to Directive 2001/18/EC shall be construed as references to Parts 1 and 2 of Annex II to this Regulation.	With regard to category 2 NGT plants, references in other Union legislation to Annex II or Annex III to Directive 2001/18/EC shall be construed as references to Parts 1 and 2 of Annex II to this Regulation.	With regard to category 2 NGT plants, references in other Union legislation to Annex II or Annex III to Directive 2001/18/EC shall be construed as references to Parts 1 and 2 of Annex II to this Regulation.	
Article 32				
296	Article 32 Administrative review	Article 32 Administrative review	Article 32 Administrative review	
Article 32, first paragraph				
297	Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.	Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.	Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.	
Article 32, second paragraph				

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298	To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.	To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.	To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.	
Article 32, third paragraph				
299	The Commission shall prepare a draft decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act.	The Commission shall prepare a draft decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act.	The Commission shall prepare a draft decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act.	
Article 33				
300	Article 33 Amendments to Regulation (EU) 2017/625	Article 33 Amendments to Regulation (EU) 2017/625	Article 33 Amendments to Regulation (EU) 2017/625	
Article 33, first paragraph				
301	Article 23 of Regulation (EU) 2017/625 is amended as follows:	Article 23 of Regulation (EU) 2017/625 is amended as follows:	Article 23 of Regulation (EU) 2017/625 is amended as follows:	
Article 33, first paragraph, point (1)				
302	(1) in paragraph 2, point (a)(ii) is replaced by the following:	(1) in paragraph 2, point (a)(ii) is replaced by the following:	(1) in paragraph 2, point (a)(ii) is replaced by the following:	
Article 33, first paragraph, point (1), amending provision, numbered paragraph (ii)				
303	‘ (ii) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of	‘ (ii) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of	‘ (ii) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of	

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	Directive 2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Articles 14(1), point (h) and 19(3), point (b) of Regulation [reference to this Regulation];; ’	Directive 2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Articles 14(1), point (h) and 19(3), point (b) of Regulation [reference to this Regulation];; ’	Directive 2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Articles 14(1), point (h) and 19(3), point (b) of Regulation [reference to this Regulation];; ’	
Article 33, first paragraph, point (2)				
304	(2) in paragraph 3, point (b) is replaced by the following:	(2) in paragraph 3, point (b) is replaced by the following:	(2) in paragraph 3, point (b) is replaced by the following:	
Article 33, first paragraph, point (2), amending provision, numbered paragraph (b)				
305	‘ (b) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of Directive 2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Articles 14(1), point (h) and 19(3), point (b) of Regulation [reference to this Regulation];. ’	‘ (b) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of Directive 2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Articles 14(1), point (h) and 19(3), point (b) of Regulation [reference to this Regulation];. ’	‘ (b) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in Article 13(2), point (e), of Directive 2001/18/EC, in Article 5(5), point (b), and Article 17(5), point (b), of Regulation (EC) No 1829/2003 and in Articles 14(1), point (h) and 19(3), point (b) of Regulation [reference to this Regulation];. ’	
Article 33a				
305a		***Article 33a***		

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		Amendments to Directive 98/44/EC[1]		
		1. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13).		
Article 33a, first paragraph				
305b				
Article 33a, first paragraph, point (1)				
305c		***1. Article 4 of Directive 98/44/EC on the legal protection of biotechnological inventions is amended as follows:***		
Article 33a, first paragraph, point (1)(a)				
305d		***(a) In paragraph 1, the following points are added:***		
Article 33a, first paragraph, point (1)(a), amending provision, point (a)				
305e		‘ ***(c) NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) .../... [O.J. please insert the number of this Regulation];***		
Article 33a, first paragraph, point (1)(a), amending provision, point (d)				
305f		***(d) plants, plant material, parts thereof, genetic information***		

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		and process features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B to that directive. ’		
Article 33a, first paragraph, point (1)(b)				
305g		***(b) the following paragraph 4 is added:***		
Article 33a, first paragraph, point (1)(b), amending provision, numbered paragraph (1)				
305h		‘ ***4. Paragraphs 2 and 3 shall be without prejudice to the exclusions from patentability covered in paragraph 1.*** ’		
Article 33a, first paragraph, point (2)				
305i		***2. In Article 8, the following paragraph is added:***		
Article 33a, first paragraph, point (2), amending provision, numbered paragraph (1)				
305j		‘ ***3. By way of derogation from paragraphs 1 and 2, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological material***		

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		possessing the same characteristics that is obtained independently of the patented biological material and from essentially biological processes, or to biological material obtained from such material through propagation or multiplication. ,		
Article 33a, first paragraph, point (3)				
305k		***3. In Article 9, the following paragraphs are added:***		
Article 33a, first paragraph, point (3), amending provision, numbered paragraph (1)				
305l		‘ ***2. By way of derogation from paragraph 1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.***		
Article 33a, first paragraph, point (3), amending provision, numbered paragraph (2)				
305m		***3. By way of derogation from paragraph 1, the protection conferred by a patent on a product containing or consisting***		

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		of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.		
Article 33a, first paragraph, point (3), amending provision, numbered paragraph (3)				
305n		***4. The protection conferred by a patent on a technical process that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.*** ,		
Article 34				
306	Article 34 Entry into force and application	Article 34 Entry into force and application	Article 34 Entry into force and application	
Article 34(1)				

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307	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	
Article 34(2), first subparagraph				
308	2. It shall apply from [24 months from the date of entry into force of this Regulation].	2. It shall apply from [24 months from the date of entry into force of this Regulation]. ***Article 4a and Article 33a shall apply from the date of entry into force.***	2. It shall apply from [24 months from the date of entry into force of this Regulation].	
Article 34(2a), first subparagraph				
308a			**2a. Article 30 bis shall apply from the entry into force of this regulation.**	
Article 34(2), second subparagraph				
309	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Formula				
310	Done at Brussels,	Done at Brussels,	Done at Brussels,	
Formula				
311	For the European Parliament	For the European Parliament	For the European Parliament	
Formula				
312	The President	The President	The President	
Formula				
313	For the Council	For the Council	For the Council	

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Formula				
314	The President	The President	The President	
Annex I				
315	Annex I	Annex I	Annex I	
Annex I, first paragraph				
316	Criteria of equivalence of NGT plants to conventional plants	Criteria of equivalence of NGT plants to conventional plants	Criteria of equivalence of NGT plants to conventional plants	
Annex I, second paragraph				
317	A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.	A NGT plant is considered equivalent to conventional plants ~~*when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types*~~***if the following conditions*** referred to in points 1 ~~*to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.*~~***and 1a are met:***	A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications **per monoploid genome** of the types referred to in points 1 to ~~5~~**4**, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.	
Annex I, second paragraph a				
317a			**Criteria specific to the use of targeted mutagenesis:**	
Annex I, third paragraph				
318	(1) substitution or insertion of no more than 20 nucleotides;	(1) ~~*substitution or insertion of no more than 20 nucleotides;*~~***The number of the following genetic modifications, which can be***	(1) substitution or insertion of no more than 20 nucleotides;	

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		combined with each other, does not exceed 3 per any protein-coding sequence taking into account that mutations in introns and regulatory sequences are excluded from this limit:		
Annex I, third paragraph, point (a)				
318a		***(a) substitution or insertion of no more than 20 nucleotides;***		
Annex I, third paragraph, point (b)				
318b		***(b) deletion of any number of nucleotides;***		
Annex I, point 1.				
318c		***(1a) The following genetic modifications, which can be combined with each other, do not create a chimeric protein that is not present in species from the gene pool for breeding purposes or does not interrupt an endogenous gene;***		
Annex I, point 1.(a)				
318d		***(a) insertion of continuous DNA sequences existing in the gene pool for breeding purposes;***		
Annex I, point 1.(b)				
318e		***(b) substitution of endogenous DNA sequences with continuous DNA sequences***		

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		existing in the gene pool for breeding purposes;		
Annex I, point 1.(c)				
318f		***(c) inversion or translocation of continuous endogenous DNA sequences existing in the gene pool for breeding purposes.***		
Annex I, 2 paragraph				
319	(2) deletion of any number of nucleotides;	*deleted*	*(2)* deletion of any number of nucleotides;	
Annex I, 2 paragraph a				
319a			**Criteria specific to the use of cisgenesis:**	
Annex I, 3 paragraph				
320	(3) on the condition that the genetic modification does not interrupt an endogenous gene:	*deleted*	(3) on the condition that the genetic modification does not interrupt an endogenous gene **or that the resulting combination of DNA sequences in the recipient plant already occurs in a species from the breeders' gene pool**:	
Annex I, 3 paragraph, point (a)				
321	(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;	*deleted*	(a) ~~targeted~~ insertion of a ~~contiguous~~**continuous** DNA sequence existing in the ~~breeder's~~**breeders'** gene pool;	
Annex I, 3 paragraph, point (b)				

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322	(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;	*deleted*	(b) ~~targeted~~ substitution of an endogenous DNA sequence with a ~~contiguous~~**continuous** DNA sequence existing in the ~~breeder's~~**breeders'** gene pool;	
Annex I, 4 paragraph				
323	(4) targeted inversion of a sequence of any number of nucleotides;	*deleted*	(4) targeted inversion of a sequence of any number of nucleotides~~;~~**.**	
Annex I, 5 paragraph				
324	(5) any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool.	*deleted*	*deleted*	
Annex II				
325	*Annex II*	*Annex II*	*Annex II*	
Annex II, first paragraph				
326	Risk assessment of category 2 NGT plants and category 2 NGT food and feed	Risk assessment of category 2 NGT plants and category 2 NGT food and feed	Risk assessment of category 2 NGT plants and category 2 NGT food and feed	
Annex II, second paragraph				
327	Part 1 of this Annex describes the general principles to be followed to perform the environmental risk assessment of category 2 NGT	Part 1 of this Annex describes the general principles to be followed to perform the environmental risk assessment of category 2 NGT	Part 1 of this Annex describes the general principles to be followed to perform the environmental risk assessment of category 2 NGT	

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	plants referred to in Article 13, points (c) and (d), Article 14(1), point (e), and Article 19(3), point (a), and the safety assessment of category 2 NGT food and feed referred to in Article 19(1), point (b). Part 2 describes specific information for the environmental risk assessment of category 2 NGT plants and Part 3 describes specific information for the safety assessment of category 2 NGT food and feed.	plants referred to in Article 13, points (c) and (d), Article 14(1), point (e), and Article 19(3), point (a), and the safety assessment of category 2 NGT food and feed referred to in Article 19(1), point (b). Part 2 describes specific information for the environmental risk assessment of category 2 NGT plants and Part 3 describes specific information for the safety assessment of category 2 NGT food and feed.	plants referred to in Article 13, points (c) and (d), Article 14(1), point (e), and Article 19(3), point (a), and the safety assessment of category 2 NGT food and feed referred to in Article 19(1), point (b). Part 2 describes specific information for the environmental risk assessment of category 2 NGT plants and Part 3 describes specific information for the safety assessment of category 2 NGT food and feed.	
Annex II, Part I				
328	Part I Part 1- General principles and information	Part I Part 1- General principles and information	Part I Part 1- General principles and information	
Annex II, third paragraph				
329	The environmental risk assessment shall be carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC.	The environmental risk assessment shall be carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC.	The environmental risk assessment shall be carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC.	
Annex II, fourth paragraph				
330	The type and amount of information necessary for the environmental risk assessment of category 2 NGT plants laid down in Annex III of Directive 2001/18/EC and for the food and feed safety assessment of category 2 NGT food and feed shall be	The type and amount of information necessary for the environmental risk assessment of category 2 NGT plants laid down in Annex III of Directive 2001/18/EC and for the food and feed safety assessment of category 2 NGT food and feed shall be	The type and amount of information necessary for the environmental risk assessment of category 2 NGT plants laid down in Annex III of Directive 2001/18/EC and for the food and feed safety assessment of category 2 NGT food and feed shall be adapted ~~to their risk profile~~**on a**	

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	adapted to their risk profile. Factors to be considered include:	adapted to their risk profile. Factors to be considered include:	**case by case basis**. Factors to be considered include:	
Annex II, fourth paragraph, point (a)				
331	(a) the characteristics of the NGT plant, in particular the trait(s) introduced, the function of the modified or inserted genome sequence(s) and the function of any gene disrupted by the insertion of a cisgene or parts thereof;	(a) the characteristics of the NGT plant, in particular the trait(s) introduced, the function of the modified or inserted genome sequence(s) and the function of any gene disrupted by the insertion of a cisgene or parts thereof;	(a) the characteristics of the **category 2** NGT plant, in particular the trait(s) introduced, the function of the modified or inserted ~~genome~~**genomic** sequence(s) and the function of any gene disrupted by the ~~insertion of a cisgene or parts thereof~~**inserted genomic sequence(s)**;	
Annex II, fourth paragraph, point (aa)				
331a		***(aa) the characteristics of the recipient plant like allergenicity, potential for gene flow, weed potential, ecological function;***		
Annex II, fourth paragraph, point (b)				
332	(b) prior experience with the consumption of similar plants or their products;	(b) prior experience with the consumption of similar plants or their products;	(b) prior experience with the consumption of **the same plant species or plant species exhibiting** similar ~~plants~~**traits or in which similar genomic sequences have been modified, inserted or disrupted,** or their products;	
Annex II, fourth paragraph, point (c)				
333	(c) prior experience with the cultivation of the same plant	(c) prior experience with the cultivation of the same plant	(c) prior experience with the cultivation of the same plant	

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	species or plant species exhibiting similar traits or in which similar genome sequences have been modified, inserted or disrupted;	species or plant species exhibiting similar traits or in which similar genome sequences have been modified, inserted or disrupted;	species or plant species exhibiting similar traits or in which similar ~~genome~~**genomic** sequences have been modified, inserted or disrupted;	
Annex II, fourth paragraph, point (d)				
334	(d) the scale and conditions of the release;	(d) the scale and conditions of the release;	(d) the scale and conditions of the release;	
Annex II, fourth paragraph, point (e)				
335	(e) the intended conditions of use of the NGT plant.	(e) the intended conditions of use of the NGT plant.	(e) the intended conditions of use of the **category 2** NGT plant~~.~~**;**	
Annex II, fourth paragraph, point (ea)				
335a			**(ea) the potential receiving environment.**	
Annex II, fifth paragraph				
336	The environmental risk assessment of category 2 NGT plants and the risk assessment of category 2 NGT food and NGT feed shall consist of the following:	The environmental risk assessment of category 2 NGT plants and the risk assessment of category 2 NGT food and NGT feed shall consist of the following:	The environmental risk assessment of category 2 NGT plants and the risk assessment of category 2 NGT food and ~~NGT~~ feed shall consist of the following:	
Annex II, fifth paragraph, point (a)				
337	(a) hazard identification and characterisation;	(a) hazard identification and characterisation;	(a) **problem formulation including** hazard identification and **hazard** characterisation;	
Annex II, fifth paragraph, point (b)				
338	(b) exposure assessment;	(b) exposure assessment;	(b) exposure ~~assessment~~**characterisation**;	
Annex II, fifth paragraph, point (c)				

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339	(c) risk characterisation.	(c) risk characterisation.	(c) risk characterisation~~.~~**;**	
Annex II, fifth paragraph, point (ca)				
339a			**(ca) risk management strategies, as applicable;**	
Annex II, fifth paragraph, point (cb)				
339b			**(cb) overall risk evaluation and conclusion.**	
Annex II, sixth paragraph				
340	The following information shall always be required:	The following information shall always be required:	The following information shall always be required:	
Annex II, sixth paragraph, point (a), first subparagraph				
341	(a) hazard identification and characterisation	(a) hazard identification and characterisation	(a) hazard identification and **hazard** characterisation	
Annex II, sixth paragraph, point (a), first subparagraph, point (i)				
342	(i) information relating to the recipient plant or, where appropriate, to the parental plants;	(i) information relating to the recipient plant or, where appropriate, to the parental plants;	(i) information relating to the recipient plant or, where appropriate, to the parental plants;	
Annex II, sixth paragraph, point (a), first subparagraph, point (ii)				
343	(ii) molecular characterisation.	(ii) molecular characterisation.	(ii) molecular characterisation.	
Annex II, sixth paragraph, point (a), second subparagraph				
344	The information shall be provided by collating already available data from scientific literature or from other sources or generating scientific data where necessary by performing appropriate	The information shall be provided by collating already available data from scientific literature or from other sources or generating scientific data where necessary by performing appropriate	The information shall be provided by collating already available data from scientific literature or from other sources or generating scientific data where necessary by performing appropriate	

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	experimental or bioinformatic studies.	experimental or bioinformatic studies.	experimental or bioinformatic studies.	
Annex II, sixth paragraph, point (b), first subparagraph				
345	(b) exposure assessment	(b) exposure assessment	(b) exposure ~~assessment~~ **characterisation**	
Annex II, sixth paragraph, point (b), second subparagraph				
346	Information shall be provided on the likelihood of each identified potential adverse effect. This shall be evaluated taking into consideration, as relevant, the characteristics of the receiving environment(s), the intended function, the dietary role, the expected level of use of the food and feed in the EU and the scope of the application for authorisation.	Information shall be provided on the likelihood of each identified potential adverse effect. This shall be evaluated taking into consideration, as relevant, the characteristics of the receiving environment(s), the intended function, the dietary role, the expected level of use of the food and feed in the EU and the scope of the application for authorisation.	Information shall be provided on the likelihood of each identified potential adverse effect. This shall be evaluated taking into consideration, as relevant, the characteristics of the receiving environment(s), the **scale and conditions of release, the** intended function, the dietary role, the expected level of use of the food and feed in the EU and the scope of the application for authorisation.	
Annex II, sixth paragraph, point (c), first subparagraph				
347	(c) risk characterisation	(c) risk characterisation	(c) risk characterisation	
Annex II, sixth paragraph, point (c), second subparagraph				
348	The applicant shall base its risk characterisation of NGT plants and foods and feed on information from hazard identification, hazard characterisation and exposure assessment. The risk shall be characterised by combining, for each potential adverse effect, the	The applicant shall base its risk characterisation of NGT plants and foods and feed on information from hazard identification, hazard characterisation and exposure assessment. The risk shall be characterised by combining, for each potential adverse effect, the	The applicant shall base its risk characterisation of **category 2** NGT plants and foods and feed on information from hazard identification, hazard characterisation and exposure assessment. The risk shall be characterised by combining, for	

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	magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk. Where relevant, the uncertainty for each identified risk shall be described.	magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk. Where relevant, the uncertainty for each identified risk shall be described.	each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk. Where relevant, the uncertainty for each identified risk shall be described **and, where possible, expressed in quantitative terms**.	
Annex II, seventh paragraph				
349	Any information on hazard identification and characterisation specified under Parts 2 and 3 shall only be required if the specific characteristics and the intended use of the category 2 NGT plant or category 2 NGT food or feed give rise to a plausible risk hypothesis that can be addressed utilising the specified information.	Any information on hazard identification and characterisation specified under Parts 2 and 3 shall only be required if the specific characteristics and the intended use of the category 2 NGT plant or category 2 NGT food or feed give rise to a plausible risk hypothesis that can be addressed utilising the specified information.	~~Any~~ Information on hazard identification and **hazard** characterisation specified under Parts 2 and 3 shall only be required ~~if the specific characteristics and the intended use of~~**when necessary to address the risk hypothesis for** the category 2 NGT plant or category 2 NGT food or feed ~~give rise to a plausible risk hypothesis that can be addressed utilising the specified information~~.	
Annex II, Part II				
350	Part II Part 2 - Specific information for the environmental risk assessment of category 2 NGT plants concerning hazard identification and characterisation	Part II Part 2 - Specific information for the environmental risk assessment of category 2 NGT plants concerning hazard identification and characterisation	Part II Part 2 - Specific information for the environmental risk assessment of category 2 NGT plants concerning hazard identification and **hazard** characterisation	
Annex II, eighth paragraph				

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351	(1) Analysis of agronomic, phenotypic and compositional characteristics	(1) Analysis of agronomic, phenotypic and compositional characteristics	(1) Analysis of agronomic, phenotypic and compositional characteristics	
Annex II, 2 paragraph				
352	(2) Persistence and invasiveness	(2) Persistence and invasiveness	(2) Persistence and invasiveness**, including any selective advantage and disadvantage**	
Annex II, 3 paragraph				
353	(3) Potential gene transfer	(3) Potential gene transfer	(3) Potential gene transfer	
Annex II, 4 paragraph				
354	(4) Interactions of the NGT plant with target organisms	(4) Interactions of the NGT plant with target organisms	(4) Interactions of the **category 2** NGT plant with target organisms	
Annex II, 5 paragraph				
355	(5) Interactions of the NGT plant with non-target organisms	(5) Interactions of the NGT plant with non-target organisms	(5) Interactions of the **category 2** NGT plant with non-target organisms	
Annex II, 6 paragraph				
356	(6) Impacts of the specific cultivation, management and harvesting techniques	(6) Impacts of the specific cultivation, management and harvesting techniques	(6) Impacts of the specific cultivation, management and harvesting techniques	
Annex II, 6 paragraph a				
356a		***(6a) Impacts on organic cultivation***		
Annex II, 7 paragraph				

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357	(7) Effects on biogeochemical processes	(7) Effects on biogeochemical processes	(7) Effects on biogeochemical processes	
Annex II, 8 paragraph				
358	(8) Effects on human and animal health	(8) Effects on human and animal health	(8) Effects on human and animal health	
Annex II, 8 paragraph a				
358a		***(8a) Effects on protecting and conserving biodiversity***		
Annex II, Part III				
359	Part III Part 3–Specific information for the safety assessment of category 2 NGT food and feed concerning hazard identification and characterisation	Part III Part 3–Specific information for the safety assessment of category 2 NGT food and feed concerning hazard identification and characterisation	Part III Part 3–Specific information for the safety assessment of category 2 NGT food and feed concerning hazard identification and **hazard** characterisation	
Annex II, 9 paragraph				
360	(1) Analysis of agronomic, phenotypic and compositional characteristics	(1) Analysis of agronomic, phenotypic and compositional characteristics	(1) Analysis of agronomic, phenotypic and compositional characteristics	
Annex II, 2 paragraph				
361	(2) Toxicology	(2) Toxicology	(2) Toxicology	
Annex II, 3 paragraph				
362	(3) Allergenicity	(3) Allergenicity	(3) Allergenicity	
Annex II, 4 paragraph				
363	(4) Nutritional assessment	(4) Nutritional assessment	(4) Nutritional assessment	
Annex III				

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364	Annex III	Annex III	Annex III	
Annex III, first paragraph				
365	Traits referred to in Article 22	Traits referred to in Article ***6 and Article*** 22	Traits referred to in Article 22	
Annex III, Part I				
366	Part I Part 1	Part I Part 1	Part I Part 1	
Annex III, second paragraph				
367	Traits justifying the incentives referred to in Article 22:	Traits justifying the incentives referred to in Article 22:	Traits justifying the incentives referred to in Article 22:	
Annex III, third paragraph				
368	(1) yield, including yield stability and yield under low-input conditions;	(1) yield, including yield stability and yield under low-input conditions***, provided that those traits also contribute to either point (2), (3) or (4) of this Annex***;	(1) **improved** yield, including yield stability and yield under low-input conditions;	
Annex III, 2 paragraph				
369	(2) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses and other pests;	(2) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses and other pests;	(2) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses**, insects** and other pests;	
Annex III, 3 paragraph				
370	(3) tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;	(3) tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;	(3) tolerance/resistance to abiotic stresses, including ~~those created or exacerbated by~~**adaptation to** climate change **conditions**;	
Annex III, 4 paragraph				

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371	(4) more efficient use of resources, such as water and nutrients;	(4) more efficient use of resources, such as water and nutrients;	(4) more efficient use of **natural** resources, such as water and nutrients;	
Annex III, 4 paragraph a				
371a			**(4a) reduced need for external inputs, such as plant protection products and fertilisers;**	
Annex III, 5 paragraph				
372	(5) characteristics that enhance the sustainability of storage, processing and distribution;	(5) characteristics that enhance the sustainability of storage, processing and distribution;	(5) characteristics that enhance the sustainability of storage, processing and distribution;	
Annex III, 6 paragraph				
373	(6) improved quality or nutritional characteristics;	(6) improved quality or nutritional characteristics;	(6) improved quality or nutritional characteristics;	
Annex III, 7 paragraph				
374	(7) reduced need for external inputs, such as plant protection products and fertilisers.	(7) reduced need for external inputs, such as ~~*plant protection products and*~~ fertilisers***, if it does not contradict with Annex III, part 2***.	(7) ~~reduced need for external inputs, such as plant protection products and fertilisers~~**bioremediation**.	
Annex III, Part II				
375	Part II Part 2	Part II Part 2	Part II Part 2	
Annex III, 8 paragraph				
376	Traits excluding the application of the incentives referred to in Article 22: tolerance to herbicides.	Traits excluding the application of the incentives referred to in Article 22: tolerance to herbicides.	Traits excluding the application of the incentives referred to in Article 22: tolerance to herbicides.	