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COVER NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	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 Proposal for a Regulation of the Parliament and of the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material) - Opinion of the European Committee of the Regions

Delegations will find attached the opinion[1] of the European Committee of the Regions on the above.

[1] This opinion is also available in other language versions on CoR's website: https://dmsearch.cor.europa.eu/search/opinion

European Committee of the Regions

NAT-VII/038

160th CoR Plenary session, 17-18 April 2024

OPINION

New genomic techniques and plant reproductive materials

THE EUROPEAN COMMITTEE OF THE REGIONS

- calls for mandatory risk assessment and authorisation procedures for all NGTs;asks for full transparency and traceability, including labelling, throughout the entire value chain from the seed to the plate to ensure the freedom of choice of NGT-free products for consumers and organic and/or GMO-free agriculture actors;
- asks for the modification of the EU law on intellectual property rights, to forbid patents on NGTs before the two regulations enter into force;
- asks for the principle of subsidiarity to be guaranteed in general and, in particular, for EU Member States to be empowered to define NGT-free territories;
- welcomes and strongly supports the Commission's current proposal to exclude the use of NGT in organic farming;
- asks for measures, including financial compensation, to ensure lasting and effective protection against unintended contamination and further disadvantages for organic and GMO-free agriculture, as well as high-quality food production protected by geographical indications;
- asks for EU-level measures to be defined for the coexistence of GMO and GMO-free production before the release of NGT 1 and NGT 2 crops, as this cannot be delegated to the Member States;
- welcomes the recognition of the diversity of operators' profiles and the possibility to sell and exchange seeds outside the legislation;
- highlights that the new regulation of Plant Reproductive Material might unnecessarily increase the administrative burden on our farmers and their dependency on big seed companies;
- asks to enable Plant Genetic Resource (PGR) access to farmers to promote sustainable use and on farm research, as motor of place-based innovation.

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Rapporteur

Erik Konczer (HU/PES), Member of Komárom-Esztergom County Government

Reference document

Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625
COM(2023) 411 final
Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material)
COM(2023) 414 final

Opinion of the European Committee of the Regions –
New genomic techniques and plant reproductive materials

I. RECOMMENDATIONS FOR AMENDMENTS

Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (COM(2023) 411 final)

Amendment 1

Recital 3

Text proposed by the European Commission	*CoR amendment*
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(2). 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(3) and of the 'Farm to Fork'(4), Biodiversity(5) and Adaptation to Climate	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(2). This includes plants with ***potentially*** improved tolerance or resistance to plant diseases and pests ***or tolerance to herbicides***, plants with ***potentially*** 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. Thus, NGTs ***might*** have the potential to contribute to the innovation and sustainability goals of the European Green Deal(3) and of the 'Farm to Fork'(4), Biodiversity(5) and Adaptation to Climate Change(6) Strategies, to global food security(7), the Bioeconomy Strategy(8) and to the Union's strategic autonomy(9). ***However, a***

Change[6] Strategies, to global food security[7], the Bioeconomy Strategy[8] and to the Union's strategic autonomy[9].	***significant number of NGTs in the pre-commercial stage relate to pesticide tolerance. Increased herbicide use resulting from NGT cultivation in the European Union must be avoided. Additionally, the different action pathways to fulfil the objectives of the European Green Deal[3] and of the 'Farm to Fork'[4], Biodiversity[5] and Adaptation to Climate Change[6] Strategies, global food security[7], the Bioeconomy Strategy[8] and the Union's strategic autonomy[9], must not undermine one another.***

Reason
We want to highlight to the decisionmakers and to the citizens that the sustainability potential of NGTs remains largely theoretical due to limited global practical experience with NGT cultivation. A 2021 JRC study indicates that 6 out of 16 NGT products in the pre-commercial stage focus on herbicide tolerance. Statements about sustainability need to be nuanced, reflecting theoretical assumptions. Moreover, the speed, ease, and efficacy of these breeding techniques are still largely hypothetical, and the Regulation should avoid overstating their potential to prevent misinformation.

Amendment 2

Recital 3a (new)

Text proposed by the European Commission	***CoR amendment***
	The development of NGTs will lead to increased control over plant reproductive material by a few multinationals which will exercise the patents they have been granted on genetic processes and extend them to the plants obtained. This development is not

	without risk for the sustainability of the plant breeding system operating in the European Union, which has allowed joint management of plant genetic resources that ensures that innovation is spread among a number of breeders of different sizes. The Commission has acknowledged the importance of this issue, into which there will need to be an additional investigation in order to assess the impact of patents on NGTs in terms of strategic autonomy for the European Union, concentration on the seed sector and preservation of cultivated biodiversity, but also the cost of food for consumers. Insofar as all plant reproductive material that has been genetically modified may be the subject of one or more patents, traceability and labelling measures should be made compulsory for category 1 and 2 NGT plants and products in order, on the one hand, to enforce the rights of patent holders and, on the other, to ensure that other breeders, farmers and other economic agents are fully informed, since they might otherwise be led to make use of patented plants or products without their knowledge and risk being required by patent holders to pay royalties.

Amendment 3

Recital 3b (new)

Text proposed by the European Commission	*CoR amendment*

	In this connection, it is necessary to step up support for public research at Member State level concerning control over NGT plants, assessment of risks and effects on health and the environment and the discovery of solutions that reconcile an eco-friendly transition with food sovereignty.

Amendment 4

Recital 3c (new)

Text proposed by the European Commission	***CoR amendment***
	Given that sustainability comprises many degrees of complexity, clear and transparent criteria are needed for a suitable technological assessment before conclusions can be drawn on the potential benefits of NGTs' specific characteristics.

Amendment 5

Recital 3d (new)

Text proposed by the European Commission	***CoR amendment***
	The European Green Deal and the 'Farm to Fork' and EU Biodiversity Strategies put organic farming at the core of a transition to sustainable food systems, with a target of expanding 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.

Reason
The European Green Deal includes various goals and policy approaches, NGTs being just one part of the overall strategy. It is crucial for the legislative proposal not to create conflicts among these policy choices. Specifically, any new regulations for NGTs should not compromise the development of GMO-free organic cultivation, which also includes GMOs derived from NGTs.

Amendment 6

Recital 4

Text proposed by the European Commission	***CoR amendment***
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[10] of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003[11], 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'). _____	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[10] of the European Parliament and of the Council and, in the case of food and feed, also to Regulation (EC) No 1829/2003[11], 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')***, in line with the Cartagena Protocol on Biosafety***.

[10] 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). [11] 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).	_____ [10] 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). [11] 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).

Reason
The EU is a signatory of the Cartagena Protocol on Biosafety, which applies to the transboundary movement, handling and use of living modified organisms, and obliges its signatories to clearly identify such organisms. NGT seeds and crops, as defined in the proposal, fall under the Cartagena Protocol's definition of "Living modified organism". According to Article 15(1) CP, risk assessments must be carried out in a "scientifically sound manner".

Amendment 7

Recital 5

Text proposed by the European Commission	***CoR amendment***
In its judgment in case C-528/16 *Confédération paysanne and Others*(12) the Court of Justice of the European Union held that GMOs obtained by means of new techniques/methods of mutagenesis that had	In its judgment in case C-528/16 *Confédération paysanne and Others*(12) 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.	appeared or had been mostly developed since Directive 2001/18/EC was adopted could not be considered excluded from the scope of that Directive***, as the new mutagenesis techniques/methods have a comparable risk potential to the production of transgenic plants. In accordance with the precautionary principle, the regulations of the Genetic Engineering Law would therefore have to be applied (Article 2(2) of Directive 2001/18; recitals 4, 8 and 25). These organisms and all products derived from them must therefore be subject to a comprehensive safety assessment for humans, animals and the environment before being placed on the market. Likewise, they must be traceable and labelled.***

Reason
According to the ruling of the European Court of Justice (ECJ) of 25 July 2018, organisms obtained by new mutagenesis techniques/methods which have appeared or have been mainly developed since the adoption of Directive 2001/18/EC, are in principle to be classified as genetically modified organisms (GMOs) and are therefore subject to the regulations of the Genetic Engineering Act (Directive 2001/18/EC); therefore traceability and labelling is a must to inform all the stakeholders and customers along the value chain.

Amendment 8

Recital 6a (new recital)

Text proposed by the European Commission	***CoR amendment***
	The European Committee of the Regions, in its opinion NAT-VII/033 "Legislative framework for sustainable food systems"

	expressed its concern about a possible re-introduction of genetically modified organisms (GMOs) in our European food with the future European regulation proposal on plants produced by new genomic techniques (NGTs). This should be based on a robust assessment and sound scientific evidence from the European Food Safety Authority (EFSA). In any case, every food product containing GMOs should show a front-of-the-pack label indicating the presence of GMOs.

Amendment 9

Recital 6b (new)

Text proposed by the European Commission	*CoR amendment*
	The European Parliament, in its reaction to the Farm to Fork strategy for a fair, healthy and environmentally-friendly food system, highlighted the precautionary principle and the need to ensure transparency and freedom of choice to farmers, processors and consumers, and stressed that any policy action on NGTs should include risk assessments and a comprehensive overview and assessment of options for traceability and labelling with a view to achieving proper regulatory oversight and should provide consumers with relevant information, including for products from third countries in order to ensure a level playing field.

Amendment 10

Recital 6c (new)

Text proposed by the European Commission	*CoR amendment*
	The European Parliament has called[13a] for a comprehensive analysis of the socioeconomic and environmental effects on the food system of patents on breeding processes, plant propagation material and parts thereof, including their potential to increase market concentration and monopolisation in the food chain, as well as their impact on the affordability and availability of food, and called for the EU and its Member States not to grant patents on biological material and to safeguard the freedom to operate and breeders' exemption for varieties. It is therefore appropriate to ensure that patented plants are not subject to any exemptions of the Union GMO legislation. ***[13a] European Parliament resolution of 14 June 2023 on ensuring food security and the long-term resilience of EU agriculture (2022/2183(INI)) P9_TA(2023)0238***

Amendment 11

Recital 7

Text proposed by the European Commission	*CoR amendment*
The Commission's study on new genomic	The Commission's study on new genomic

techniques[14] concluded that the Union GMO legislation is not fit for the purpose of regulating the deliberate release of plants obtained by certain NGTs and the placing on the market of related products including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained with some NGTs, namely targeted mutagenesis and cisgenesis (including intragenesis), and these requirements can be ***disproportionate or inadequate***. The study showed that this is particularly the case for plants obtained by these techniques, given the amount of scientific evidence that is already available, in particular on their safety. Furthermore, the Union GMO legislation is difficult to implement and enforce for plants obtained by targeted mutagenesis and cisgenesis and related products. In certain cases, genetic 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***	techniques[14] concluded that the Union GMO legislation is not fit for the purpose of regulating the deliberate release of plants obtained by certain NGTs and the placing on the market of related products including food and feed. In particular, the study concluded that the authorisation procedure and risk assessment requirements for GMOs under the Union GMO legislation are not adapted to the variety of potential organisms and products that can be obtained with some NGTs, namely targeted mutagenesis and cisgenesis (including intragenesis), and these requirements can be ***inconducive to the cultivation and release of GMOs into the environment and their placing on the market***. 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, ***until the present day,*** genetic modifications introduced by these techniques ***can be considered*** 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.

sustainability, food security and resilience of the agri-food chain.	***The development of detection methods in the foreseeable future is considered highly probable by scientists and experts. Research and scientific knowledge in the field of genetic engineering and detection technologies are consistently expanding. Further research is necessary to accelerate the development of analytical detection methods. The existence of detection methods is not a prerequisite for traceability. Several existing quality schemes and labels rely on documentary traceability, for which no detection methods are presently available or required.***

Reason
Regarding detection methods, it is important to support the development of such analytical methods and acknowledge that the lack of detection methods for certain NGTs is merely an analytical research gap at the moment – in fact, scientists, for example from the Norwegian Research Centre (NORCE), are confident that such detection methods will be developed in the coming years.

Amendment 12

Recital 7a (new)

Text proposed by the European Commission	***CoR amendment***
	Currently, the debate on using NGTs in plant breeding is held almost exclusively among scientists, scientific and industry organisations, and companies in the agri-food field, as well as a small number of NGOs. However, in shaping a new policy on NGTs, it is important to include the voice of

	citizens, not only because biotechnologies have the power to redesign life, but also because they offer the potential to reshape the practice of agriculture and the future of our food (system). The way we produce food involves questions of how we want to live on this planet and how we want to relate to other species. For the purposes of democracy, citizens need to have a say on which public values are incorporated in a new policy for NGTs.

Amendment 13

Recital 7b (new)

Text proposed by the European Commission	*CoR amendment*
	One of the few studies that have been performed to investigate the attitude of the public, concluded[(15a)] that in general, citizens' views converged towards reservation and hesitation about the use of NGTs and genetic modification in crops. Citizens raised doubts mainly about the plausibility that these crops will contribute meaningfully to the solving of our current societal challenges in the food system, and whether they are indeed the right approach for dealing with these challenges. They wondered if alternative solutions may be better, and how these may come with fewer unforeseen, long-term risks for human health and ecosystems. Moreover, the citizens in this study questioned whether

	companies will in practice develop valuable varieties for society, as the logics of the corporate world tend to be focused on capital accumulation and on making profits. Citizens were unanimous in their view that regulation of NGT crops is necessary for diverse reasons: to prevent harms to the environment and human health, to give consumers freedom of choice, to guard against the potential of the technology to increase inequalities, and to ensure that the technology is directed towards contributing to solutions to societal problems. The latter is viewed as an important pre-condition for the introduction of NGT products onto the marketplace. According to citizens, NGTs should not be developed purely for commercial motives driven by the logic of the market. There needs to be a clear societal purpose for their introduction. In terms of policy, this would necessitate a case-by-case assessment of NGT crops for broader considerations such as purpose, and value to society. **_____** ***[15a] Rathenau Instituut (2023). Editing under provision – Dutch citizens' views on new genomic techniques in food crops. Den Haag. Habets M., Pirson I, Macnaghten P and Verhoef P.***

Amendment 14

Recital 7c (new)

Text proposed by the European Commission	*CoR amendment*
	This regulation must align with Article 169 of the Treaty on the Functioning of the European Union, which lays down the principle of consumer protection, in seeking to protect consumers' health, safety and economic interests, and promote their right to information.

Amendment 15

Recital 7c (new)

Text proposed by the European Commission	*CoR amendment*
	The precautionary principle, as enshrined in Article 191 of the Treaty on the Functioning of the European Union, seeks to ensure a higher level of environmental protection and consumer health in the context of food, as well as human, animal, and plant health, through preventative decision-making in the case of risks. This Regulation must align with the precautionary principle, particularly as NGT plants are intended to be released and cultivated in the environment.

Amendment 16

Recital 8

Text proposed by the European Commission	*CoR amendment*

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.	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***, while maintaining the central principles of GMO legislation that has been in place for over 20 years: sound information and freedom of choice for consumers and farmers, risk assessment and monitoring by health authorities, precautionary principle and reversibility, and coexistence of sectors. A periodic review of the approach to establishing equivalence to conventional breeding methods is required in order to reflect scientific and technological progress.***

Amendment 17

Recital 10

Text proposed by the European Commission	***CoR amendment***
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	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***, based on the precautionary principle detailed in Article 191 of the Treaty on the Functioning of the European Union,*** and the good functioning of the internal market for the concerned plants and products, while addressing the specificity of NGT plants. ***The precautionary principle should be fully implemented to ensure***

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.	***adequate risk assessment and monitoring frameworks for the release of NGT plants into the environment.*** 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.

Reason
It is essential to incorporate the precautionary principle into this Regulation, given that the release and cultivation of genetically engineered plants in the environment may have significant impacts on human, animal, and environmental health. Robust standards of precaution and preventative decision-making must be adhered to in the new regulatory framework to ensure the vitality and resilience of food production in Europe, which relies on healthy and thriving ecosystems.

Amendment 18

Recital 10a (new)

Text proposed by the European Commission	***CoR amendment***
	The issue of patents on genetic material, plant traits, and characteristics associated with genetic engineering, extending to conventionally bred varieties, must not be disconnected from the new regulatory

	framework on NGTs. This Regulation aims to facilitate field trials, cultivation, and market placement in the European Union for NGT plants and products, a development anticipated to exacerbate existing challenges impeding the unfettered circulation of genetic material and breeding innovation in Europe. Considering the economic potential of the European SME breeding sector and the importance of reversing genetic erosion in plant breeding for biodiverse and resilient outcomes, innovation in the European breeding sector must be safeguarded. Given that all plant reproductive material modified with genetic engineering (including NGTs) can be assumed to be subject to patents, mandatory traceability provisions for both category 1 and 2 NGT plants and products serve as crucial temporary safeguards. These provisions assist in identifying whether such genetically engineered plants or products have been utilised or introduced throughout the entire supply chain.

Reason
We need to empower breeders and farmers to avoid using such material, thereby protecting them from potential legal threats related to unintended patent infringements or the obligation to pay royalties to patent owners.

Amendment 19

Recital 10b (new)

Text proposed by the European Commission	***CoR amendment***

	All European quality schemes and geographical indicators (GIs) should have the possibility to choose not to use NGTs in their standards.

Reason
Quality schemes and geographical indicators constitute a vital economic sector in Europe. This sector should have the right to establish its own standards, tailored to consumer expectations, among other considerations.

Amendment 20

Recital 10c (new)

Text proposed by the European Commission	***CoR amendment***
	Organic and conventional operators should be entitled to the right and freedom to abstain from using NGTs in their production processes and throughout their supply chain. This Regulation must provide adequate provisions to ensure operators have the freedom to choose not to use both category 1 and 2 NGT plants and seeds in their production processes. Any additional financial and legal burdens to maintain the GMO and NGT-free status of production should not be imposed on farmers and operators who choose not to use NGTs. Economic losses resulting from the inadvertent presence of GMOs should not be borne by NGT-free conventional and organic operators. Given the challenges in establishing causes, faults, and responsibilities in most cases of adventitious

	presence, this Regulation should establish coexistence measures, forming the foundation for national liability provisions and compensation funds.

Amendment 21

Recital 12

Text proposed by the European Commission	***CoR amendment***
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.	

Reason
There is no way of knowing if some of these plants present risks which are similar to conventionally-bred plants without an impact assessment. None of the criteria proposed in this regulation to define the different categories of NGT plants are linked to an increased or decreased risk profile.

Amendment 22

Recital 16

Text proposed by the European Commission	***CoR amendment***
Category 1 NGT plants and products ***should not*** be subject to the rules and requirements	Category 1 NGT plants and products ***must not*** be subject to the rules and requirements

of the Union GMO legislation and to provisions in other Union legislation that apply to GMOs. For legal certainty for operators and transparency, a declaration of the category 1 NGT plant status should be obtained prior to deliberate release, including the placing on the market	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.

Amendment 23

Recital 19

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

Reason
Authorities must have sufficient time to inspect NGT plants to ensure that they are safe. Current proposals are far from realistic planning for the authorities.

Amendment 24

Recital 20

Text proposed by the European Commission	*CoR amendment*
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.	***All NGT plants should be tested and assessed for their risks before being put on the market and prior to authorisation for cultivation on a case-by-case basis, as unexpected effects on the phenotype and***

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**.**	***agronomic characteristics of the modified plants are always possible, and that unexpected changes in the composition of the plants or the foods derived from them could also be observed, regardless of the modified trait.*** When the ***evaluation*** 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.

Amendment to the reason given in the opinion
. ***ANSES (Opinion of the Anses Referral no. 2021-SA-0019) recommends a case-by-case assessment of the health and environmental risks resulting from NGTs, taking into account the characteristics of the genetic modification carried out and of the resulting product, and analysing the consequences of the genetic modification in terms of agronomic, phenotypic and compositional characteristics, as well as immunological, toxicological and nutritional aspects.***

Amendment 25

Recital 24

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

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***.	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 indicated by a mention in the national and EU variety registers.***

Reason
The freedom of choice of whether to use NGTs or not is an essential right of farmers and food producers, both conventional and organic, which can only be ensured through the implementation of a traceability. NGTs cat. 1 should also be indicated by a mention in the national and EU variety registers.

Amendment 26

Recital 25

Text proposed by the European Commission	***CoR amendment***
Category 2 NGT plants should remain subject to the requirements of the 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.	NGT plants should remain subject to the requirements of the 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 levels of risk that they may pose.

Amendment 27

Recital 26

Text proposed by the European Commission	*CoR amendment*
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[(17)] and on plants developed through targeted mutagenesis[(18)] recommended flexibility in data requirements for the risk assessment of these plants. Based on the Authority's 'Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis'[(19)], 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***	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 NGT plants, the amount of information necessary for the risk assessment will vary on a case-by-case basis.

adapt risk assessment methodologies to scientific and technical progress.	

[17] 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.

[18] 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.

[19] 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.	

Amendment 28

Recital 29

Text proposed by the European Commission	*CoR amendment*
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***	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 ***lead to complex alterations requiring a thorough analysis of potential risks. Therefore, post-market monitoring requirements for environmental effects of category 2 NGT plants should be adapted in***

environmental effects of category 2 NGT plants should be adapted in the light of the environmental risk assessment and the experience in field trials, the characteristics of the NGT plant concerned, the characteristics and scale of its expected use, in particular any history of safe use of the plant and the characteristics of the receiving environment. Therefore, a monitoring plan for environmental effects should not be required if the category 2 NGT plant is unlikely to pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.	***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.***

Reason
NGT plants will cover a far wider range of species than transgenic plants do. This will multiply the risks of unintended impacts on ecosystems, notably through crossing with wild plants. It is therefore necessary to maintain monitoring, as currently outlined in the GMO legislation.

Amendment 29

Recital 30

Text proposed by the European Commission	***CoR amendment***
For reasons of proportionality, after a first renewal of the authorisation, the authorisation should be valid for an unlimited period, unless decided differently at the time of that renewal based on the risk assessment and the available information on the NGT plant concerned, subject to	

reassessment when new information has become available.	

Reason
It is not in line with the precautionary principle to grant authorisations indefinitely for products capable of reproduction and interaction with wild plants and ecosystems. This is particularly concerning as the proposal lacks a safeguard clause, preventing the Commission from withdrawing an authorisation if a problem is detected.

Amendment 30

Recital 32

Text proposed by the European Commission	***CoR amendment***
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 notification for consent or in the application for authorisation and should be specified in the consent or in the authorisation decision***.	To increase transparency and consumers' information, operators should ***label all*** NGT products ***indicating the words 'New Genomic Techniques'. If operators would like to complete the labelling with information on the trait conferred by the genetic modification, in order to avoid misleading, a proposal for such a labelling should be provided in the notification for consent or in the application for authorisation and should be specified in the consent or in the authorisation decision..***

Amendment to the reason given in the opinion
The high level of consumer protection, and particularly consumers' right to information, are clearly recognised in Article 169 of the TFEU: 'In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.'

Amendment 31

Recital 37

Text proposed by the European Commission	***CoR amendment***
In order to enable NGT plants to contribute to the sustainability objectives of the Green Deal and the Farm to Fork and Biodiversity Strategies, cultivation of NGT plants in the Union should be ***facilitated***. ***This requires predictability for breeders and farmers as regards the possibility to cultivate such plants in the Union***. ***Therefore,*** the possibility for Member States to adopt measures restricting or prohibiting the cultivation of ***category 2*** NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC would undermine those goals.	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 ***monitored***. ***If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports such risks,*** the possibility for Member States to adopt measures restricting or prohibiting the cultivation of ***both categories of*** NGT plants in all or part of their territory, set out in Article 26b of Directive 2001/18/EC should be enabled .

Reason given in the opinion	**Amendment to the reason given in the opinion**
	Based on scientific articles and case studies ANSES (Opinion of the Anses Referral No 2021-SA-0019) concludes that there are potential new health and environmental

	risks associated with plants derived from NGTs. They also recommend that a post-authorisation monitoring plan for environmental risks must be put in place for the entire duration of the authorisation for plants derived from NGTs.

Amendment 32

Recital 38

Text proposed by the European Commission	***CoR amendment***
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.	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. ***In order to ensure that the coexistence measures are consistent, the Commission should draw up an implementing act to cover, in particular, the size of buffer strips between conventional and organic plants and NGT plants, for each type of crop.***

Amendment 33

Recital 39a (new)

Text proposed by the European Commission	*CoR amendment*
	To achieve the goal of ensuring the effective functioning of the internal market, EU-wide legally binding coexistence measures for category 1 and category 2 NGTs have to be adopted.

Reason
For the internal market for organic farming to continue to function well in the future, it is not enough to leave coexistence measures at national level. EU-wide regulations are needed. Therefore, the Commission should offer such rules.

Amendment 34

Recital 40

Text proposed by the European Commission	*CoR amendment*
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	***In its judgment of 25 July 2018 in case C-528/1610, the Court of Justice of the European Union held that organisms obtained by means of techniques/methods of mutagenesis which have not conventionally been used in a number of applications and do not have a long safety record come within the scope of Directive 2001/18 and are, therefore, subject to the obligations arising from that directive.*** 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

NGT plants containing such characteristics or properties on the EU market.	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.

Reason
Article 114(3) TFEU states that the Commission will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Already, many problems have been documented for NGTs. For example, CRISPR applications have turned out to cause toxicity and mosaicism, while the impact and adverse effects on non-target and unintentionally exposed organisms are yet unknown. Such knowledge is only generated when risk assessments are required and in place, and both the impact and the uncertainties are estimated and acknowledged.

Amendment 35

Recital 42

Text proposed by the European Commission	***CoR amendment***
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 of the	In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union, ***Member States must be authorised to opt-out of this regulation.*** 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

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.	objectives.

Amendment 36

Recital 45

Text proposed by the European Commission	*CoR amendment*
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 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[24]. ***[24] 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).	

Amendment 37

Recital 45a (new)

Text proposed by the European Commission	*CoR amendment*
	The issue of patents on NGTs was raised by many stakeholders during the consultation. It should be ensured that breeders have full access to the genetic material of NGT plants. As current provisions do not provide for a full breeders' exemption in patent law, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (breeders' exemption). It should furthermore be avoided that patents are granted or patent applications can be submitted while further legal provisions on the issue would be postponed following the study that the Commission intends to do. It should therefore be ensured that NGT plant material and material resulting from a patented NGT process are excluded from patentability from the day of entry into force of this Regulation. In addition, the Commission should assess in the announced 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.

Amendment 38

Article 1

Text proposed by the European Commission	***CoR amendment***
This Regulation lays down specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by certain new genomic techniques ('NGT plants') and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants.	This Regulation ***corresponds to the provisions of Directive 2001/18 and extends those provisions to the deliberate release of plants obtained by certain new genomic techniques ('NGT plants'). In accordance with the precautionary principle, and with the primary objective of 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 feed, containing or consisting of such plants.

Reason
Article 114(3) TFEU states that the Commission will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Already, many problems have been documented for NGTs. For example, CRISPR applications have turned out to cause toxicity and mosaicism, whereas the impact and adverse effects on non-target and unintentionally exposed organisms are yet unknown. Such knowledge is only generated when risk assessments are required and in place, and both the impact and the uncertainties are

estimated and acknowledged.

Amendment 39

Article 2(1) (new)

Text proposed by the European Commission	*CoR amendment*
	This Regulation shall not apply to: ***(1) material resulting from a patented NGT process or material for which a patent application is being processed;*** ***(2) herbicide-tolerant plants;*** ***(3) wild plants, trees and algae.***

Reason
Patentability of plants is not linked to GMO legislation, but to the European Patent Convention, and secondarily to Directive 98/44/EC (the Biotech Directive), which is not modified by this proposal. Therefore, most or all NGT plants will be patentable if their promoters choose to apply for a patent. Patented material should be subject to the most thorough rules available concerning traceability and labelling, in order to allow farmers, breeders and consumers to make informed choices in full knowledge of the rules and liability linked to this form of Intellectual Property.

Amendment 40

Article 3 point (7)(ba) (new)

Text proposed by the European Commission	*CoR amendment*
	is not covered by patents or exclusive rights and for which no application has been tabled for such patents or exclusive rights to be granted;

Amendment 41

Article 4, first paragraph

Text proposed by the European Commission	*CoR amendment*
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***, and with strict regard to the precautionary principle***, 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 ***the plant is a NGT plant and has been authorised in accordance with Chapter III, and if***:

Amendment 42

Article 4, point (2a) (new)

Text proposed by the European Commission	*CoR amendment*
	an extended producer responsibility (EPR) scheme has been settled at European or national level to ensure the financing of risks and possible future damages of human health, animal health or the environment or cross-contamination of organic food and non-GMO food are financed in line with the polluter pays principle.

Amendment 43

Article 5(1) and (2)

Text proposed by the European Commission	*CoR amendment*
1. The rules which apply to GMOs in	1. The rules which apply to GMOs in

Union legislation shall not apply to category 1 NGT plants. 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.	Union legislation shall not apply to category 1 NGT plants ***except when category 1 are suspected to have potential health and environmental risks until proven otherwise.*** 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.

Reason
The content of Annex I is of central importance to this legislative proposal, as it can have significant practical implications on which NGTs would fall under each category. Therefore, it must not be listed in the Annex making it amendable through a simple delegated act. Instead, it must follow an ordinary legislative procedure to ensure thorough and democratic decision-making.

Amendment 44

Article 5(3)

Text proposed by the European Commission	***CoR amendment***
The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I in order to adapt them to scientific and technological progress as regards the types and extent of modifications which can occur naturally or through conventional breeding.	

Amendment 45

Article 6(2)

Text proposed by the European Commission	*CoR amendment*
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***.	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 ***each*** Member ***State***.

Amendment 46

Article 6(3), point (e)

Text proposed by the European Commission	*CoR amendment*
in the cases referred to in paragraph 2, an indication of the Member States in which the requester intends to undertake the deliberate release;	

Amendment 47

Article 6(3), point (ea) (new)

Text proposed by the European Commission	*CoR amendment*
	an 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);

Amendment 48

Article 6(3), point (eb) (new)

Text proposed by the European Commission	*CoR amendment*
	a monitoring plan for environmental effects as mentioned in Parts 1 and 2 of Annex II;

Amendment 49

Article 6(5)

Text proposed by the European Commission	*CoR amendment*
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.	If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within ***two months*** within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission without undue delay of the inadmissibility of the verification request and shall provide the reasons of its decision.

Amendment 50

Article 6(6)

Text proposed by the European Commission	*CoR amendment*
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	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 ***Annex IV. For that purpose, the competent authority shall forward the request to the European Food Safety***

competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.	***Authority ('The Authority') without undue delay. Within six months, the Authority shall make a statement on whether the plant is a NGT plant fulfilling the criteria set out in Annex I, including whether it contains any genetic material originating from outside the breeders' gene pool. The statement shall be forwarded to all Member States and to the Commission, and shall be made public. After receiving this statement, the competent authority shall*** prepare a verification report within ***three months*** from the date of receipt of ***the*** verification request. The competent authority shall make available the verification report to the other Member States and to the Commission without undue delay.

Amendment 51

Article 6(7)

Text proposed by the European Commission	***CoR amendment***
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.	The other Member States and the Commission may make ***reasoned objections*** to the verification report within 20 days from the date of receipt of that report. ***Those reasoned objections shall solely refer to the criteria set out in Annex I and shall include a scientific justification.***

Reason
Self-evident

Amendment 52

Article 6(8)

Text proposed by the European Commission	*CoR amendment*
In the absence of any comments from a Member State or the Commission, within ***10 working days*** from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.	In the absence of any comments from a Member State or the Commission, within ***one month*** from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Amendment 53

Article 6(9)

Text proposed by the European Commission	*CoR amendment*
In cases where a comment is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the comment(s) to the Commission without undue delay.	In cases where a comment is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the comment(s) to the Commission ***and to the other Member States,*** without undue delay.

Amendment 54

Article 6(10)

Text proposed by the European Commission	*CoR amendment*
The Commission, after having consulted the European Food Safety Authority ('the	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).	Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within ***three months*** 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).

Amendment 55

Article 6(11)

Text proposed by the European Commission	***CoR amendment***
The Commission shall ***publish a summary of*** the decisions referred to in paragraphs 8 and 10 ***in the Official Journal of the European Union***.	***Within 15 days following their full submission , the competent authority of the Member State to which the verification request was submitted and, where relevant, the*** Commission shall ***make public the verification request, the verification report referred to in paragraph 6, the comments referred to in paragraph 7 and*** the decisions referred to in paragraphs 8 and 10.

Amendment 56

Article 7(2), point (da) (new)

Text proposed by the European Commission	***CoR amendment***
	an 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);

Amendment 57

Article 7(2), point (db) (new)

Text proposed by the European Commission	*CoR amendment*
	a monitoring plan for environmental effects as mentioned in Parts 1 and 2 of Annex II;

Amendment 58

Article 7(2), point (dc) (new)

Text proposed by the European Commission	*CoR amendment*
	a declaration from the applicant that there are: ***(i) no patents or exclusive rights covering the process used to develop the plant,*** ***(ii) no patents or exclusive rights covering the plant or parts thereof, or genetic information it contains, and*** ***(iii) no application has been tabled for such patents or exclusive rights to be granted;***

Reason
The Commission proposal aims to facilitate the commercialisation of NGT plants in Europe. In the absence of specific safeguards, this could lead to an increased number of patented seeds in the EU. As a result, breeders and farmers could find themselves at heightened risk of legal action from NGT developers if they inadvertently use their patented genetic sequences.

Amendment 59

Article 7(2), point (dd) (new)

Text proposed by the European Commission	*CoR amendment*
	a declaration that the placing on the market would not be in breach of the Cartagena Protocol on biosafety under the UN convention on biological diversity, and a description of how the protocol's requirements are fulfilled;

Amendment 60

Article 7(2), point (de) (new)

Text proposed by the European Commission	*CoR amendment*
	a declaration that the placing on the market is in conformity with the Regulation on food information to consumers, as well as legislation on nutrition and health claims made on food, and a description of how the relevant provisions are fulfilled;

Amendment 61

Article 7(2), point (ea) (new)

Text proposed by the European Commission	*CoR amendment*
	a declaration on the non-applicability of Regulation (EU) 2015/2283 of 25 November 2015 on novel foods, or on the correct application of possible obligations arising from this Regulation.

Amendment 62

Article 7(2), point (eb) (new)

Text proposed by the European Commission	*CoR amendment*
	any other relevant information relating to the file, including possible refusal, withdrawal or acceptance of previous requests or national or European decisions.

Amendment 63

Article 7(4)

Text proposed by the European Commission	*CoR amendment*
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.	If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Authority within ***60*** 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.

Amendment 64

Article 7(5)

Text proposed by the European Commission	*CoR amendment*
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.	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 ***six months*** from the date of receipt of a verification request. The

The Authority shall make available the statement to the Commission and the Member States. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its statement public, after omission of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 11 of this Regulation.	Authority shall make available the statement to the Commission and the Member States ***without undue delay. Member States may make comments on the statement within two months from the date of receipt of that statement***. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its statement***, and where relevant, comments made by Member States,*** 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.

Amendment 65

Article 7(6)

Text proposed by the European Commission	***CoR amendment***
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).	The Commission shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within ***three months*** from the date of receipt of the statement of the Authority, taking the latter into account. ***Member States may make comments on the draft decision within two months from the date of receipt of that draft decision.*** The decision shall be adopted ***within the three following months,*** in accordance with the procedure referred to in Article 28(2).

Amendment 66

Article 7(7)

Text proposed by the European Commission	*CoR amendment*
The Commission shall ***publish a summary of the*** decision ***in the Official Journal of the European Union***.	The Commission shall ***make public its draft*** decision***, the comments referred to in paragraph 6, and its decision***.

Amendment 67

Article 10 - Title

Text proposed by the European Commission	*CoR amendment*
Labelling of category 1 NGT plant reproductive material, including breeding material.	***Transparency, traceability and labelling of*** category 1 NGT plant reproductive material, including breeding material.

Reason
Self-evident.

Amendment 68

Article 10

Text proposed by the European Commission	*CoR amendment*
Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words 'cat 1 NGT', followed by the identification number of the NGT plant(s) it has been derived from.	Plant reproductive material, including for breeding and scientific purposes, ***as well as food, feed and other products*** 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 ***mention in national variety register automatically transmitted in the EU common register provided for in PRM / FRM*** indicating the words 'cat 1 NGT' ***and***

	shall be traceable, including for final consumers, followed by the identification number of the NGT plant(s) it has been derived from.

Reason
Self-evident.

Amendment 69

Article 10a (new)

Text proposed by the European Commission	***CoR amendment***
	Traceability of NGT category 1 ***1. When placing products produced from category 1 NGT plants and products on the market, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:*** ***(a) an indication of each of the food ingredients which is produced from category 1 NGT plants and products;*** ***(b) an indication of each of the feed materials or additives which is produced from category 1 NGT plants and products;*** ***(c) in the case of products for which no list of ingredients exists, an indication that the product is produced from category 1 NGT plants and products.*** ***2. Without prejudice to Article 6 of Regulation (EC) No 1830/2003, operators shall have in place systems and***

	standardised procedures to allow the holding of the information specified in paragraph 1 and the identification, for a period of five years from each transaction, of the operator by whom and to whom the products referred to in paragraph 1 have been made available. ***3. Paragraphs 1 and 2 shall be without prejudice to other specific requirements in Community legislation.*** ***4. Paragraphs 1, 2 and 3 shall not apply to traces of category 1 NGT plants and products in products for food and feed produced from category 1 NGT plants and products in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of category 1 NGT plants and products are adventitious or technically unavoidable.***

Reason
Traceability measures are needed throughout the whole supply chain to enable food processors and operators to avoid the accidental or unavoidable adventitious presence of NGTs in their production process. The absence of a traceability system would amount to imposing the entry of NGTs into the production stream to all food production systems, including organic operators. The freedom to choose whether to use NGTs or not is an essential right of farmers and food producers, both conventional and organic, across Europe

Amendment 70

Article 10b (new)

Text proposed by the European Commission	*CoR amendment*
	Opt-out possibility for Member States ***During the authorisation procedure of a given category 1 NGT or during the renewal of authorisation, a Member State may demand that the geographical scope of the written consent or authorisation be adjusted to the effect that all or part of the territory of that Member State is to be excluded from cultivation, according to Article 26b of Directive 2001/18/EC.*** ***Member States shall take appropriate measures to avoid the unintended presence of category 1 NGTs, including the possibility of applying the opt-out. Member States shall develop crop-specific and adapted measures, based on the latest scientific knowledge and independent science, in order to avoid the unintended presence of category 1 NGTs. Member States shall instate a strict liability system and a compensation fund to compensate operators in the event of contamination. Member States shall take the necessary measures to prevent plants subject to the opt-out being imported from third countries.***

Amendment 71

Article 11

Text proposed by the European Commission	*CoR amendment*
Confidentiality ***1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this Title as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.*** ***2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.*** ***3. The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:*** ***(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;*** ***(b) DNA sequence information; and*** ***(c) breeding patterns and strategies.*** ***4. The competent authority or the Authority, as appropriate, shall, after consultation with the requester, decide which information is to***	

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

Amendment 72

Article 11(7a) (new)

Text proposed by the European Commission	*CoR amendment*
	Third parties may access confidential information on substantiated grounds based on significant damage to the environment, human or animal health. To that end, they should address a request to the national

	competent authority, the Commission or the Authority.

Amendment 73

Article 11a (new)

Text proposed by the European Commission	***CoR amendment***
	Measures to avoid the unintended presence of category 1 NGT plants ***1. Member States shall take appropriate measures to avoid the unintended presence of category 1 NGT plants in other products on the basis of a delegated act proposed by Commission in accordance with Article 26 to define notably the size of the buffer strip for each sort of crops and the obligation of NGT growers to inform organic and certified non-GMO growers with field plots next to those where NGT plants are grown.*** ***2. Member States shall develop the definition of crop-specific and adapted measures as a matter of subsidiarity, based on the latest scientific and experimental knowledge, to avoid the unintended presence of category 1 NGT plants.*** ***3. Member States shall instate a strict liability system and a compensation fund to compensate operators in the event of contamination in accordance with the principle of the extended producer responsibility.*** ***4. The Commission shall gather and coordinate information based on the studies***

	at EU and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of NGT, conventional and organic crops.

Amendment 74

Article 13(1), point (da) (new)

Text proposed by the European Commission	***CoR amendment***
	a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC;

Amendment 75

Article 17 (1)

Text proposed by the European Commission	***CoR amendment***
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.	The consent granted under Part C of Directive 2001/18/EC shall, after ***each*** renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for ***10 years***, unless ***after three renewal rounds*** the decision referred to in Article 17(6) or (8) provides that the renewal is for ***an unlimited*** 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.

Reason
Considering there is no history of safe use for new genomic techniques yet, it is important to review the validity of the consent every 10 years to take into account latest scientific evidence and market trends.

Amendment 76

Article 17(2a) (new)

Text proposed by the European Commission	*CoR amendment*
	If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports this hypothesis, the competent authority may withdraw its decision. ***The withdrawal decision must be sent by registered mail to the beneficiary of the decision, who has 15 days in which to make observations. In that case, the marketing of the NGT plant or product is prohibited from the day following the date of receipt of the registered letter.***

Amendment 77

Article 21

Text proposed by the European Commission	*CoR amendment*
By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003, 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	By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003, after the first renewal, the authorisation shall be valid for ***a*** period ***of 10 years***, 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.	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.

Amendment 78

Article 22

Text proposed by the European Commission	*CoR amendment*
1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in Part 1 of Annex III and it does not have any traits referred to in Part 2 of that Annex. ***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:*** ***(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);*** ***(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. ***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, 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:*** ***(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;*** ***(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 (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. ***4. The pre-submission advice referred to in paragraph 3 shall comply with the following requirements:*** ***(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 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;*** ***(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; ***(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) shall apply mutatis mutandis;*** ***(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.*** ***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:*** ***(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;*** ***(b)where applicable, the information***	

necessary to demonstrate the (potential) applicant or notifier is a SME; ***(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.*** ***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.*** ***7. The Authority shall lay down the practical arrangements to implement paragraphs (3) to (6).*** ***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 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:*** ***(a) the Commission shall take into account the monitoring of the impacts of this Regulation in accordance with Article 30(3);*** ***(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;***	

(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.	

Reason
The arguable sustainability potential of NGT remains a hypothetical promise since there is extremely limited practical experience with NGT cultivation globally. On the contrary, the 2021 JRC study shows that 6 out of 16 NGT products currently in the pre-commercial stage, so, those most likely to enter the market soon, relate to herbicide tolerance.

Amendment 79

Article 23

Text proposed by the European Commission	***CoR amendment***
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, the labelling of authorised category 2 NGT products ***shall*** 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. ***However, if that mention falls under the qualification of an environmental claim as defined in Article 2 point (o) of Directive 2005/29/EC concerning unfair business-to-consumer***

	commercial practices in the internal market, then it must comply with the requirements of Directive 2023/85/EC on substantiation and communication of explicit environmental claims.

Reason
In line with the current Union objectives to prevent traders adding environmental claims along with the traits, this labelling should be in accordance with the various upcoming consumer rights and environmental claims legislations: if producers want to claim that the trait conveyed by the genetic modification is better for the environment, they have to substantiate it like any other environmental claim.

Amendment 80

Article 24

Text proposed by the European Commission	***CoR amendment***
Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants ***in products not subject to Directive 2001/18 or Regulation 1829/2003***.	Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants. ***Member States shall develop the definition of crop-specific and adapted measures as a matter of subsidiarity, based on the latest scientific and experiential knowledge, to avoid the unintended presence of category 2 NGTs.*** ***Member States shall instate a strict liability system and a compensation fund to compensate operators in the event of contamination. The category 2 NGT plants should be detected, identified and quantified by analytical method.***

Reason
The responsibility and liability for the GMO sector to produce without using NGTs must not fall on the operators alone. Member States shall adopt robust coexistence measures and establish compensation funds, based on guidelines provided by the European Union, to prevent additional economic and administrative burden on the operators. This is of particular importance as in most cases the origin of the contamination might be difficult to establish.

Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material) (COM(2023) 414 final)

Amendment 81

Recital 64

Text proposed by the European Commission	*CoR amendment*
Regulation (EU) 2018/848 should be amended to align the definitions of 'plant reproductive material' and 'heterogeneous material' with the definitions provided for by this Regulation. Moreover, the empowerment for the Commission to adopt specific provisions for the marketing of PRM of organic heterogeneous material should be excluded from Regulation (EU) 2018/848, as all rules concerning the production and marketing of PRM should be set out in this Regulation for reasons of legal clarity.	

Reason

There should be no amendment of Regulation (EU) 2018/848 as for example organic heterogeneous material (OHM) is not only organic seed of HM but also developed under organic conditions, thus organic seed of OHM. Therefore, the definition of HM is not compatible with the original definition of OHM. Moreover, there is a risk of more restrictive use of OHM due to secondary regulation (Article 27(3)). Thus, the rules in Regulation (EU) 2018/848 should be untouched. Furthermore, there are already seeds on the market of OHM; any changes can negatively affect stakeholders.

Amendment 82

CHAPTER I, Article 2(2)

Text proposed by the European Commission	***CoR amendment***
The objectives of this Regulation are the following: (a) to ensure quality and diversity of choice for PRM, and its availability for professional operators and final users; (b) to ensure a equal conditions for the competition of the professional operators across the Union and the functioning of the internal market in PRM; (c) to support innovation and competitiveness of the PRM sector in the Union; (d) to contribute to conservation and sustainable use of plant genetic resources and agro-biodiversity; (e) to contribute to sustainable agricultural production, adapted to current and future projected climatic conditions; (f) to contribute to food security	The objectives of this Regulation are the following: (a) to ensure adequate and proportionate quality and diversity of choice for PRM, and its availability for professional operators and final users; (b) to ensure a equal conditions for the competition of the professional operators across the Union and the functioning of the internal market in PRM; (c) to support innovation and competitiveness of the PRM sector in the Union; (d) to contribute to conservation and sustainable use of plant genetic resources and agro-biodiversity; (e) to contribute to sustainable agricultural production, adapted to current and future projected climatic conditions, ***and diversity of climatic and soil***

	conditions; (f) to contribute to food security ***and sovereignty***.

Amendment 83

CHAPTER I, Article 2(4)

Text proposed by the European Commission	***CoR amendment***
This Regulation does not apply to: (a) propagating material of ornamental plants as defined in Article 2 of Directive 98/56/EC; (b) forest reproductive material as defined in Article 3 of Regulation (EU) .../… of the European Parliament and of the Council; (c) PRM produced for export to third countries; (d) PRM sold or transferred in any way, whether free of charge or not, between final users ***for their own private use and outside their commercial activities***; (e) PRM ***used solely*** for official testing, breeding, inspections, exhibitions or scientific purposes**.**	This Regulation does not apply to: (a) propagating material of ornamental plants as defined in Article 2 of Directive 98/56/EC; (b) forest reproductive material as defined in Article 3 of Regulation (EU) .../… of the European Parliament and of the Council; (c) PRM produced for export to third countries; (d) PRM sold or transferred in any way, whether free of charge or not, between final users; (e) PRM ***sold or transferred in any way, whether free of charge or not,*** for official testing, breeding, inspections, exhibitions or scientific purposes, ***including on-farm participatory research, conservation of and access to plant genetic resources for food and agriculture;*** ***(f) PRM produced by farmers for their own use.***

Reason

In light of the biodiversity and climate crises, and in order to fulfil the obligations under international agreements such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which aims to ensure farmers' freedom and rights to use, reuse, select, and exchange their seeds, as guaranteed by Article 9, the Second Global Plan of Action for Plant Genetic Resources, and the United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas (UNDROP), PRM transferred for the purpose of the conservation and sustainable use of plant genetic resources and agro-biodiversity needs to be exempted from this regulation.

Amendment 84

CHAPTER I, Article 3(2)

Text proposed by the European Commission	***CoR amendment***
'professional operator' means any natural or legal person, involved professionally in one or more of the following activities in the Union concerning PRM: (a) production; (b) marketing; (c) maintenance of varieties; (d) provision of services for identity and quality; (e) preservation, storage, drying, processing, treating, packaging, sealing, labelling, sampling or testing*;*	'professional operator' means any natural or legal person, involved professionally in one or more of the following activities in the Union concerning PRM, ***intended for commercial exploitation of the PRM by the professional operator:*** (a) production; (b) marketing; (c) maintenance of varieties ***for commercial seed production***; (d) provision of services for identity and quality; (e) preservation, storage, drying, processing, treating, packaging, sealing, labelling, sampling or testing*;*

Reason
The proposal should explicitly exclude in situ and ex situ maintenance, as well as Plant Reproductive Material (PRM) produced by farmers for personal use on their holdings, as amended in Article 2(4).

Amendment 85

CHAPTER I Article 3 (3)

Text proposed by the European Commission	*CoR amendment*
'marketing' means the following actions conducted by a professional operator: sale, holding, ***transfer for free***, or offering for sale or any other way of transferring or distribution within, or import into, the Union	'marketing' means the following actions conducted by a professional operator: sale, holding, or offering for sale or any other way of transferring or distribution ***of PRM*** within, or import into, the Union ***aimed at the commercial exploitation of the PRM;***

Reason
The current seed marketing laws should continue targeting situations where there is an intention for commercial gain from PRM. The proposed regulation should exclude seed exchange among farmers, community seed banks, and civil society networks. Selling seeds for food or feed, and production under commercial contracts, should not fall under seed marketing legislation.

Amendment 86

CHAPTER I, Article 3(27)

Text proposed by the European Commission	*CoR amendment*
'heterogeneous material' means a plant grouping within a single botanical taxon of the lowest known rank which: (a) presents common phenotypic characteristics; (b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that plant grouping is represented by the material as a whole, and not by a small number of units;	'heterogeneous material' means a plant grouping within a single botanical taxon of the lowest known rank which: (a) presents common phenotypic characteristics; (b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that plant grouping is represented by the material as a whole, and not by a small number of units;

(c) is not a variety; and (d) is not a mixture of varieties;	(c) is not a variety ***according to Article 5(2) of Regulation (EC) 2100/94***; and (d) is not a mixture of varieties ***according to Article 21 of this Regulation;*** ***(e) does not consist of a GMO or a category 1 NGT plant as defined in Article 3(7) of Regulation (EU) …/… or of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation ...).***

Reason
The aim of heterogeneous material is to encourage the local adaptation of plants, reducing their reliance on pesticides. GMOs and NGTs are inconsistent with the concept of heterogeneous material, as it is created through a dynamic field process, not in a laboratory. Organic heterogeneous material (OHM) should adhere to the definition in Regulation (EU) 2018/848. Its breeding, selection, and production under organic conditions are crucial for these propagating materials to adapt and thrive under organic and low-input conditions.

Amendment 87

CHAPTER I, Article 3(29)

Text proposed by the European Commission	***CoR amendment***
'***conservation*** variety' means a variety that is: (a) traditionally grown or locally newly bred under specific local conditions ***in the Union***, and adapted to those conditions; and (b) characterised by a ***high*** level of genetic and phenotypical diversity between individual reproductive units;	'***niche*** variety' means a variety that is: (a) traditionally grown or locally newly bred, ***or developed*** under specific local conditions, and adapted to those conditions ***or the utilisation in a marginal environment or production system***; and (b) ***not an F1 hybrid;*** ***(c) can be*** characterised by a ***certain*** level

	of genetic and phenotypical diversity between individual reproductive units; ***(d) developed in line with the natural reproduction modes of the species;*** ***(e) not consisting of a GMO or a category 1 NGT plant as defined in Article 3(7) of Regulation (EU) …/… or of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation ...);***

Reason
Hybrids, GMO and NGT plants are incompatible with the definition of a 'conservation variety', which is produced through artisanal methods; therefore they should be excluded. The term "conservation" typically refers to maintaining something in a static state. As the new proposal rightfully extends to locally newly bred varieties, the term "conservation" is no longer suitable. We suggest using the term "niche variety" instead. Achieving a high level of genetic diversity is not always possible, such as in the case of certain old landraces developed under intense selection pressure to meet market demands. Additionally, for vegetatively propagated plants like fruit trees or potatoes, ensuring high genetic diversity is biologically impossible.

Amendment 88

CHAPTER I, Article 7

Text proposed by the European Commission	***CoR amendment***
Requirements for the production and marketing of pre-basic, basic and certified seed and material	Requirements for the production and marketing of pre-basic, basic and certified seed and material
1. Pre-basic, basic and certified seed may only be produced and marketed within the Union, if all the following conditions are	1. Pre-basic, basic and certified seed may only be produced and marketed within the Union, if all the following conditions are

fulfilled: (a) the pre-basic, basic or certified seed is practically free from quality pests; (b) it is produced and marketed: (i) following official certification by the competent authorities, or certification by the professional operator under official supervision; (ii) in accordance with the requirements set out in Part A of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1). 2. Pre-basic, basic and certified material may only be produced and marketed within the Union, if all the following conditions are fulfilled: (a) the pre-basic, basic or certified material is practically free from quality pests; (b) it is produced and marketed: (i) following official certification by the competent authorities, or certification by the professional operator under official supervision; (ii) in accordance with the requirements set out in Part B of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1). ***3. The Commission is empowered to adopt delegated acts in accordance with***	fulfilled: (a) the pre-basic, basic or certified seed is practically free from quality pests; (b) it is produced and marketed: (i) following official certification by the competent authorities, or certification by the professional operator under official supervision; (ii) in accordance with the requirements set out in Part A of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1). 2. Pre-basic, basic and certified material may only be produced and marketed within the Union, if all the following conditions are fulfilled: (a) the pre-basic, basic or certified material is practically free from quality pests; (b) it is produced and marketed: (i) following official certification by the competent authorities, or certification by the professional operator under official supervision; (ii) in accordance with the requirements set out in Part B of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1).

Article 75, in order to amend Annex II. Those amendments shall adapt to the developments of international technical and scientific standards and may concern the requirements for the following: ***(a) sowing and planting, and production in the field, of pre-basic, basic and certified seed;*** ***(b) harvesting and post-harvesting of pre-basic, basic and certified seed;*** ***(c) marketing of seeds;*** ***(d) sowing and planting, and production in the field, of pre-basic, basic and certified material;*** ***(e) harvesting and post-harvesting of pre-basic, basic and certified material;*** ***(f) marketing of pre-basic, basic and certified material;*** ***(g) pre-basic, basic and certified material of clones, selected clones, multiclonal mixtures and polyclonal PRM;*** ***(h) production of pre-basic, basic and certified material produced by in vitro propagation;*** ***(i) marketing of pre-basic, basic and certified material produced by in vitro propagation.*** ***4. The Commission may adopt implementing acts specifying the production and marketing requirements referred to in Part A and Part B of Annex II for certain genera, species or categories of PRM, and, where appropriate, for certain grades,***	

classes, generations or other sub-divisions of the category concerned. Those requirements shall concern one or more of the following elements ***(a) specific uses of the genera, species or the types of the PRM concerned;*** ***(b) production methods of PRM, including sexual and asexual reproduction and in vitro propagation;*** ***(c) conditions for sowing or planting;*** ***(d) field cultivation;*** ***(e) harvesting and post-harvesting;*** ***(c) germination rates, purity and content of other PRM, moisture, vigour, presence of earth or extraneous matter;*** ***(c) certification methods of PRM, including the application of bio-molecular or other technical methods, as well as their approval and use, and the listing of approved methods in the Union;*** ***(d) the conditions for rootstocks and other parts of plants of genera or species other than those listed in Annex I, or their hybrids, if propagating material of the genus or species listed in Annex I or their hybrids is grafted onto them;*** ***(e) conditions for the production of seeds from fruit plants or vine;*** ***(f) conditions for the production of fruit plants, vine or seed potatoes from seeds.***	

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 76(2), in order to adapt to the developments of the relevant international technical and scientific standards.	

Reason
Taking into account the possible effects on the quality and variety of PRM in the market and the rights of different operators, the legislator should not authorise the Commission to define delegated and implementing acts without first specifying their scope.

Amendment 89

CHAPTER I, Article 8(3)

Text proposed by the European Commission	***CoR amendment***
Once a year, professional operators shall submit to the competent authority a declaration concerning the quantities per species of standard seed and material they produced.	***Professional operators shall keep data about*** the quantities per species of standard seed and material they produced ***for five years.***

Reason
It is too burdensome to require such administration; it should be sufficient to keep data for a number of years.

Amendment 90

CHAPTER II, Article 17

Text proposed by the European Commission	***CoR amendment***
1.The official label and the operator's label, shall be written in at least one of the official Union languages.	1. The official label and the operator's label, shall be written in at least one of the official Union languages.

2. The official label and the operator's label shall be legible, indelible, not modifiable if tampered with, printed on one side, not having been used previously, and easily visible. 3. Any space of the official label or the operator's label apart from the elements mentioned in paragraph 4, may be used for additional information by the competent authority. Such information shall be presented in letters not larger than those used for the content of the official label or the operator's label as referred to in paragraph 4. That additional information shall be strictly factual, it shall not represent advertising material, and shall be related only to the production and marketing requirements or to labelling requirements for genetically modified organisms or category 1 NGT plants as defined in Article 3(7) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation ...). .	2. The official label and the operator's label shall be legible, indelible, not modifiable if tampered with, printed on one side, not having been used previously, and easily visible. 3. Any space of the official label or the operator's label apart from the elements mentioned in paragraph 4, may be used for additional information by the competent authority. Such information shall be presented in letters not larger than those used for the content of the official label or the operator's label as referred to in paragraph 4. That additional information shall be strictly factual, it shall not represent advertising material, and shall be related only to the production and marketing requirements or to labelling requirements for genetically modified organisms or category 1 NGT plants as defined in Article 3(7) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation ...), ***or intellectual property rights related to the material.*** .

Reason
Information on restrictions on the use of marketed varieties resulting from a plant variety right or patent should be publicly available, indicated on seed packaging.

Amendment 91

CHAPTER II, Article 22(1)

Text proposed by the European Commission	***CoR amendment***

By way of derogation from Article 21(1), Member States may authorise the production and marketing of a mixture of seed of various genera or species listed in Part A of Annex I, and of different varieties of those genera or species, with seed of genera or species of other parts of that Annex, or of genera or species not listed in that Annex, if that mixture fulfils all of the following conditions: (a) it contributes to the conservation of genetic resources or the restoration of the natural environment; and (b) it is naturally associated with a particular area ("source area") contributing to the conservation of genetic resources or the restoration of the natural environment; (c) it meets the requirements of Annex V.	By way of derogation from Article 21(1), Member States may authorise the production and marketing of a mixture of seed of various genera or species listed in Part A of Annex I, and of different varieties of those genera or species, with seed of genera or species of other parts of that Annex, or of genera or species not listed in that Annex, if that mixture fulfils all of the following conditions: (a) it contributes to the conservation of genetic resources or the restoration of the natural environment; and (b) it is naturally associated with a particular area ("source area") contributing to the conservation of genetic resources or the restoration of the natural environment; (c) it meets the requirements of Annex V***;*** ***(d) a mixture for preservation, the parts and/or genetic components of PRM that constitute it cannot be covered by an intellectual property right limiting its use for conservation purposes;*** ***(e) it does not consist of a GMO or a category 1 NGT plant as defined in Article 3(7) of Regulation (EU) …/… or of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference***

	to NGT Regulation ...).

Reason
Marketing mixtures for preservation aim to conserve plant genetic resources. Intellectual property rights restricting their use for conservation, even on a farmer's own farm using seeds or plants from their crops, would contradict Article 12.3(d) of the International Treaty on Plant Genetic Resources for Food and Agriculture. Also, a preservation mixture is naturally linked to a specific area ("source zone") and should not result from laboratory genetic modifications for GMOs or other NGT plants.

Amendment 92

CHAPTER II, Article 26

Text proposed by the European Commission	***CoR amendment***
1. By way of derogation from Article 20, PRM belonging to a conservation variety registered in a national variety register referred to in Article 44(1), point (b), may be produced and marketed in the Union as standard seed or material, if it complies with all the requirements concerning standard seed and material for the respective species, as referred to in Article 8. 2. PRM referred to in paragraph 1 shall be accompanied by an operator's label with the indication 'Conservation variety'. 3. ***A professional operator who uses*** this derogation shall ***annually notify to the competent authority this activity,*** with regard to the species and quantities concerned***.***	1. By way of derogation from Article 20, PRM belonging to a conservation variety registered in a national variety register referred to in Article 44(1), point (b), may be produced and marketed in the Union as standard seed or material, if it complies with all the requirements concerning standard seed and material for the respective species, as referred to in Article 8. 2. PRM referred to in paragraph 1 shall be accompanied by an operator's label with the indication 'Conservation variety'. ***3. A variety of conservation, its parts and/or its genetic components may not be covered by an intellectual property right limiting its use for conservation, research, breeding and/or training, including on-farm participatory research and breeding.*** ***4. A conservation variety does not consist of***

	a GMO or a category 1 NGT plant as defined in Article 3(7) of Regulation (EU) …/… or of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation ...). ***5. Professional operators who use*** this derogation shall ***keep data*** with regard to the species and quantities concerned ***for five years.***

Amendment 93

CHAPTER II, Article 27(1)

Text proposed by the European Commission	***CoR amendment***
By way of derogation from Article 5, PRM of heterogeneous material may be produced and marketed within the Union without belonging to a variety. The heterogeneous material shall be notified to ***and register by*** the competent authority ***prior to its production and/or*** marketing, in accordance with the requirements set out in Annex VI.	By way of derogation from Article 5, PRM of heterogeneous material ***of all crop species*** may be produced and marketed within the Union without belonging to a variety. The heterogeneous material shall be notified to the competent authority ***three months before*** marketing, in accordance with the requirements set out in Annex VI ***and listing should be free of cost to the supplier***.

Reason
Commercialisation of PRM of heterogenous material should be possible for all crop species after notification as was laid out in the Organic Regulation 2018/848.

Amendment 94

CHAPTER II, Article 27(3)

Text proposed by the European Commission	***CoR amendment***

The Commission is empowered to adopt a delegated act in accordance with Article 75, amending Annex VI. Those amendments may concern all, or particular genera or species only, and shall: (a) improve the provision of information in notifications, description and identification of heterogeneoys PRM, on the basis of experience gained by the application of the respective rules; (b) improve the rules concerning packaging and labelling of heterogeneous PRM, on the basis of the experience gained from the checks carried out by the competent authorities; (c) improve the rules on maintenance of heterogenous PRM, on the basis of the emergence of best practices. Those amendments shall be ***adopted*** in order to adapt to the development of the respective technical and scientific evidence, and the international standards, and to follow up on the experience gained by the application of this Article concerning all ***or certain genera or*** species ***only***.	The Commission is empowered to adopt a delegated act in accordance with Article 75, amending Annex VI. Those amendments may concern all, or particular genera or species only, and shall: (a) improve the provision of information in notifications, description and identification of heterogeneoys PRM, on the basis of experience gained by the application of the respective rules; (b) improve the rules concerning packaging and labelling of heterogeneous PRM, on the basis of the experience gained from the checks carried out by the competent authorities; (c) improve the rules on maintenance of heterogenous PRM, on the basis of the emergence of best practices. Those amendments shall be ***developed through a multi-actor stakeholder consultation involved in heterogeneous material,*** in order to adapt to the development of the respective technical and scientific evidence, and the international standards, and to follow up on the experience gained by the application of this Article concerning all species.

Reason
Multi-actor stakeholders (breeders, seed producers, farmers, examination offices, researchers etc.) of heterogeneous material should be involved in the development of secondary regulations to make sure that the delegated and implementing acts are precise, broad-based,

feasible and meeting the needs of the sector.

Amendment 95

CHAPTER II, Article 28(1)

Text proposed by the European Commission	*Amendment*
By way of derogation from Articles 5 - 12, 14, 15 and 20, PRM may be marketed to final users, if it complies with all of the following requirements: (a) to bear an operator's label with the denomination of the PRM and the indication 'Plant reproductive material for final users – not officially certified' or, in the case of seeds, 'Seeds for final users – not officially certified'; (b) in case not belonging to a variety registered in a national variety register referred to in Article 44, to have a description made publicly available, on the basis of a private documentation, in a commercial catalogue kept by the professional operator. This private documentation shall be made available by the professional operator upon request to the competent authority; (c) to be practically free from quality pests and any defects likely to impair its quality as reproductive material, and shall have satisfactory vigour and dimensions in respect of its usefulness as PRM, and, in the case of seeds, shall have satisfactory germination capacity; and	By way of derogation from Articles 5 - 12, 14, 15 and 20, PRM may be marketed to final users, if it complies with all of the following requirements: (a) to bear an operator's label with the denomination of the PRM and the indication 'Plant reproductive material for final users – not officially certified' or, in the case of seeds, 'Seeds for final users – not officially certified'; (b) in case not belonging to a variety registered in a national variety register referred to in Article 44, to have a description made publicly available, on the basis of a private documentation, in a commercial catalogue kept by the professional operator. This private documentation shall be made available by the professional operator upon request to the competent authority; (c) to be practically free from quality pests and any defects likely to impair its quality as reproductive material, and shall have satisfactory vigour and dimensions in respect of its usefulness as PRM, and, in the case of seeds, shall have satisfactory germination capacity; and

(d) to be marketed as individual plants, or, in the case of seeds and tubers, in small packages. A professional operator who uses this derogation shall ***annually notify this activity to the competent authority, with regard to*** the species and quantities concerned.	(d) to be marketed as individual plants, or, in the case of seeds and tubers, in small packages. A professional operator who uses this derogation shall ***keep the data on*** the species and quantities concerned ***for five years***.

Reason
The reporting obligation would impose too much of an administrative burden on both operators and competent authorities. Instead, there should be an obligation on traders to keep the relevant data for five years.

Amendment 96

CHAPTER I, Article 29

Text proposed by the European Commission	***CoR amendment***
PRM marketed to and between gene banks, organisations and networks ***1. By way of derogation from Articles 5 to 25, PRM may be marketed to, or between, gene banks, organisations and networks with a statutory objective, or an objective official notified to the competent authority, to conserve plant genetic resources, whereby any of the activities are carried out for non-profit purposes.*** ***It can be marketed as well from those gene banks, organisations and networks to persons who carry out conservation of that PRM as final consumers, for non-profit purposes.*** ***In the cases provided for in the first and the***	

second subparagraphs, PRM shall fulfil the following requirements: ***(a) be listed in a register kept by those gene banks, organisations and networks with an appropriate description of that PRM;*** ***(b) be conserved by those gene banks, organisations and networks, and samples of that PRM be made available by them to the competent authorities upon request; and*** ***(c) be practically free from quality pests and any defects likely to impair its quality as a reproductive material, and have satisfactory vigour and dimensions in respect of its usefulness as PRM, and, in the case of seeds, have satisfactory germination capacity.*** ***2. The gene banks, organisations and networks shall notify the competent authority of the use of the derogation referred to in paragraph 1 and the species concerned.***	

Reason
PRM exchange between gene banks and other organisations for the purpose of conservation cannot be considered as marketing. ITPGRF related activities (PGR conservation, including ex situ and in situ on farm conservation and sustainable management) should be out of the scope of the regulation.

Amendment 97

CHAPTER II, Article 30

Text proposed by the European Commission	*CoR amendment*
1. By way of derogation from Articles 5 - 25, farmers may exchange ***seeds*** in kind, if such ***seeds*** fulfil all of the following conditions: (a) are produced in the respective farmer's own premises; (b) are derived from the respective farmer's own harvest; (c) are not subject to a service contract conducted by the respective farmer with a professional operator performing seed production; and (d) ***the seed is*** used for dynamic management of farmer's own seed for the purpose of contributing to agro-diversity. 2. Such ***seeds*** shall fulfil all of the following requirements: (a) not ***to*** belong to a to variety for which plant variety rights have been granted in accordance with Regulation (EU) 2100/94; (b) ***to be limited to small quantities, defined by the competent authorities for specific species per year and per farmer,*** without ***using*** commercial intermediaries ***or public offer of marketing; and***	1. By way of derogation from Articles 5 - 25, farmers may exchange in kind, if such ***PRM*** fulfil all of the following conditions: (a) are produced in the respective farmer's own premises; (b) are derived from the respective farmer's own harvest; (c) are not subject to a service contract conducted by the respective farmer with a professional operator performing seed production; and (d) ***are*** used for ***mutual aid or for the*** dynamic management of farmer's own seed for the purpose of contributing to agro-diversity ***and for the selection adapted to local conditions.*** 2. Such ***PRM*** shall fulfil all of the following requirements: (a) not belong to a variety for which plant variety rights have been granted in accordance with Regulation (EU) 2100/94; (b) without ***the use of*** commercial intermediaries ***in quantities that correspond to the needs of agricultural parcels sized at least for the practices and equipment of a small farmer's holding as defined by Regulation 2100/94/EC and not to the needs of a user.*** (c) be practically free from quality pests**.**

(c) ***to*** be practically free from quality pests ***and any defects likely to impact their quality as seeds, and shall have satisfactory germination capacity.*** ***3. Member States shall annually notify to the Commission and the other Member States the amounts per species defined in accordance with paragraph 2, point (b).***	

Reason
According to Article 19 of UNDROP, peasants and other people living in rural areas have, among other things, 'the right to save, use, exchange and sell their farm-saved seed or propagating material.'

Amendment 98

CHAPTER II Article 36(1)

Text proposed by the European Commission	***CoR amendment***
The Commission, by means of implementing acts, may authorise the Member States to impose, with regards to production and marketing of PRM, more stringent production or marketing requirements than those referred to in Articles 7 and 8, in all or part of the territory of the Member State concerned, provided that those more stringent requirements correspond to specific production conditions in, and agro-climatic needs, of that Member State in regard to the respective PRM. Those implementing acts shall be adopted in accordance with the examination procedure	The Commission, by means of implementing acts, may authorise the Member States to impose, with regards to production and marketing of PRM, more stringent production or marketing requirements than those referred to in Articles 7 and 8, in all or part of the territory of the Member State concerned, provided that those more stringent requirements correspond to specific production conditions in, and agro-climatic needs, of that Member State in regard to the respective PRM. ***These requirements should be proportionate in light of the costs of PRM production and marketing and the foreseen impact of these more stringent requirements.***

referred to in Article 76(2).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Reason
The detailed requirements on production and marketing translate to additional costs and administrative burdens for operators on the ground. Additional requirements negatively impact the smallest actors most of all, especially those who strive to offer diversity of varieties and species, rather than focussing on the largest/mainstream crops. It is therefore important to include a safeguard so that any additional requirements are truly proportionate, especially given the lack of possibility for direct participation of affected stakeholders in the decision-making process on an implementing act.

Amendment 99

CHAPTER II, Article 41

Text proposed by the European Commission	***CoR amendment***
Professional operators, which produce PRM, shall: […]	Professional operators, ***which are not micro-enterprises***, which produce PRM ***with the aim of commercial exploitation,*** shall: […] ***This article does not apply to professional operators producing or marketing PRM in accordance with Articles 28,29 and 30.***

Reason
In line with the principle of proportionality, micro-enterprises should be exempt from these new obligations for professional operators. There is already an obligation for (all) professional operators to identify and monitor the critical points of plant and seed production for plant health under Regulation 2016/2013 – this remains unchanged

Amendment 100

CHAPTER II, Article 42

Text proposed by the European Commission	*CoR amendment*
Traceability	**Traceability**
1. Professional operators shall ensure that PRM is traceable at all stages of production and marketing.	1. Professional operators shall ensure that PRM is traceable at all stages of production and marketing.
2. For the purposes of paragraph 1, professional operators shall keep information allowing them to identify:	2. For the purposes of paragraph 1, professional operators shall keep information allowing them to identify:
(a) the professional operators, which have supplied them with the seeds and the material concerned;	(a) the professional operators, which have supplied them with the seeds and the material concerned;
(b) the persons to whom they have supplied PRM and the PRM concerned, except in case of final users.	(b) the persons to whom they have supplied PRM and the PRM concerned, except in case of final users.
On request, they shall make such information available to the competent authorities.	On request, they shall make such information available to the competent authorities.
3. Professional operators shall keep records of the PRM and the professional operators and persons referred to in paragraph 2 for 3 years after that material has been respectively supplied to or by them.	3. Professional operators shall keep records of the PRM and the professional operators and persons referred to in paragraph 2 for 3 years after that material has been respectively supplied to or by them.
	4. Micro-enterprises are exempt from the obligations in paragraphs 1 to 3.
	5. This provision does not apply to professional operators producing or marketing PRM in accordance with Articles 28,29 and 30.

Reason

In line with the principle of proportionality, micro-enterprises should be exempt from these new obligations for professional operators, which represent a very significant administrative burden.

Amendment 101

CHAPTER II Article 44(1)

Text proposed by the European Commission	*CoR amendment*
Each Member State shall establish and publish, in electronic format, and shall keep updated a single national register of varieties ('national variety register') containing: (a) all varieties registered pursuant to the procedure set out in Articles 55 - 68; (b) the conservation varieties referred to in Article 26 and registered pursuant to Article 53.	Each Member State shall establish and publish, in electronic format, and shall keep updated a single national register of varieties ('national variety register') containing: (a) all varieties registered pursuant to the procedure set out in Articles 55 - 68; (b) the conservation varieties referred to in Article 26 and registered pursuant to Article 53***;*** ***(c) the organic varieties referred to in recital 50 and Articles 47(2b), 52, and 77(1);*** ***(d) heterogeneous material referred to in Articles 3(27) and 27***.

Reason
All cultivar types, varieties, conservation varieties, organic varieties, and heterogeneous material should be published on the EU plant variety portal to provide transparency of available PRM.

Amendment 102

CHAPTER II Article 46

Text proposed by the European Commission	*CoR amendment*
1. The national variety registers and Union variety register shall contain all the elements set out in Annex VII, concerning the varieties	1. The national variety registers and Union variety register shall contain all the elements set out in Annex VII, concerning the varieties

referred to in Article 44(1), point (a). In the case of the conservation varieties referred to in Article 44(1), point (b), those registers shall indicate at least a brief summary of the officially recognised description, the initial region of their origin, their denomination and the person that maintains them. 2. The Commission is empowered to adopt a delegated act in accordance with Article 75, in order to amend Annex VII, taking into account the technical and scientific developments, and on the basis of gained experience indicating the need of competent authorities or professional operators to obtain more precise information about the registered varieties.	referred to in Article 44(1), point (a). In the case of the conservation varieties referred to in Article 44(1), point (b), those registers shall indicate at least a brief summary of the officially recognised description, the initial region of their origin, their denomination and the person that maintains them. 2. The Commission is empowered to adopt a delegated act in accordance with Article 75, in order to amend Annex VII ***only to further add elements that need to be included in the variety registers***, taking into account the technical and scientific developments, and on the basis of gained experience indicating the need of competent authorities or professional operators to obtain more precise information about the registered varieties.

Reason
Annex VII includes essential information that should only be expanded by the Commission and not removed or reduced. Delegating power is acceptable only when it involves adding valuable information to be included in variety registers, considering potential scientific and technological advancements.

Amendment 103

CHAPTER II Article 47(1)

Text proposed by the European Commission	***CoR amendment***
Varieties shall be registered in a national variety register in accordance with Articles 55 to 68, only if: (a) they have: (i) an official description showing	Varieties shall be registered in a national variety register in accordance with Articles 55 to 68, only if: (a) they have: (i) an official description showing

compliance with the requirements of distinctness, uniformity and stability set out in Articles 48, 49 and 50, and fulfil the requirements for satisfactory value for sustainable cultivation and use, as set out in Article 52; or (ii) an officially recognised description pursuant to Article 53, if they are conservation varieties; […]	compliance with the requirements of distinctness, uniformity and stability set out in Articles 48, 49 and 50, and ***only for arable crops listed in Annex I (A)*** fulfil the requirements for satisfactory value for sustainable cultivation and use, as set out in Article 52; or (ii) an officially recognised description pursuant to Article 53, if they are conservation varieties; […]

Reason
If VSCU is extended to all crop groups including vegetable, fruit and grapes crops, this will cause additional efforts for the examination offices and further costs and burdens for the breeders. Instead, additional funding should be made available for post-registration testing of non-arable crops conducted under low-input on-farm conditions, like described in the following document, result of the LIVESEED Horizon 2020 project: https://www.liveseed.eu/wp-content/uploads/2021/02/21-01-29-LIVESEED_D2_3_final-compressed.pdf.

Amendment 104

CHAPTER II, Article 47(1), points (f) and (g)

Text proposed by the European Commission	***CoR amendment***
(f) where the varieties are tolerant to herbicides, they are subject to cultivation conditions for the production of PRM and for any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been	(f) where the varieties are tolerant to herbicides, they are subject to cultivation conditions for the production of PRM and for any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been

adopted, as adopted by the competent authorities ***responsible for registration***, to avoid the development of herbicide resistance in weeds due to their use; (g) where the varieties have particular characteristics other than the ones referred to in point (f) that may lead to undesirable agronomic effects, they are subject to cultivation conditions for the production of PRM and any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been adopted, as adopted by the competent authorities ***responsible for their registration***, to avoid those particular undesirable agronomic effects, such as the development of resistance of pests to the respective varieties or undesirable effects on pollinators.	adopted, as adopted by the competent authorities ***of all of the Member States in which the variety will be marketed,*** to avoid the development of herbicide resistance in weeds due to their use. ***These conditions will be subject to a public consultation process by the competent authority before they are adopted;*** (g) where the varieties have particular characteristics other than the ones referred to in point (f) that may lead to undesirable agronomic effects, they are subject to cultivation conditions for the production of PRM and any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been adopted, as adopted by the competent authorities ***of the Member States in which the variety will be marketed,*** to avoid those particular undesirable agronomic effects, such as the development of resistance of pests to the respective varieties or undesirable effects on pollinators. ***These conditions will be subject to a public consultation process by the competent authority before they are adopted.***

Reason
The proposal foresees that only one Member State – the one which processes the application for variety registration – defines the cultivation conditions for the whole of the EU. This is problematic, given the differences in the farming systems across the Union. The amendment therefore provides that the cultivation conditions are defined at the national level, by every Member State where the variety will be marketed. To ensure the conditions are most appropriate for the national circumstances, the competent authority should be obliged to carry

out a public consultation before it adopts the conditions.

Amendment 105

CHAPTER II Article 47(1), point (h) (new)

Text proposed by the European Commission	*CoR amendment*
	(h) Any Member State or region may, upon an application which shall be dealt with under the procedure referred to in Article 76, be authorised to prohibit the use of the variety in all or in part of its territory or to lay down appropriate conditions for cultivating the variety, particularly varieties consisting of a GMO or a category 1 NGT plant as defined in Article 3(7) of Regulation (EU) …/… or of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation ...), where it is established that the cultivation of the variety could be harmful from the point of view of plant health to the cultivation of other varieties or species; or where it has valid reasons other for considering that the cultivation of the variety in their territory presents a risk for human health or the environment.

Reason
Mirroring the provisions of Article 16 of Directive 2015/412 to allow Member States to prohibit or lay down specific cultivation conditions for varieties that consists of GMOs, NGT 1 or NGT 2 plants.

Amendment 106

CHAPTER II Article 47(4)

Text proposed by the European Commission	*CoR amendment*
For the purpose of registering a variety in its national variety register, a competent authority ***shall*** accept, without any further examination, an ***official*** description or an official examination of the requirements for value for sustainable cultivation and use, as referred to in paragraph 1, point (a)(i), which has been produced by a competent authority of another Member State.	For the purpose of registering a variety in its national variety register, a competent authority ***may*** accept, without any further examination, an official description***,*** an ***officially recognised*** description or an official examination of the requirements for value for sustainable cultivation and use, as referred to in paragraph 1, point (a)(i), which has been produced by a competent authority of another Member State.

Reason
Given the differences in pedo-climatic conditions and farming systems between the Member States, it should remain at the discretion of a competent authority as to whether it accepts, without any further examination, the description and VCU results from another Member States.

Amendment 107

CHAPTER III, Article 52(4)

Text proposed by the European Commission	*CoR amendment*
For the purposes of registration of organic varieties suitable for organic production as defined in Article 3(19) of Regulation (EU) 2018/848, the examination of the value for ***sustainable*** cultivation and use shall be conducted under organic conditions, in accordance with that Regulation, and in particular Article 5, points (d), (e), (f) and	***The*** examination of the value for cultivation and use shall be conducted under organic conditions, in accordance with that Regulation, and in particular Article 5, points (d), (e), (f) and (g), and Article 12 thereof and Part I of Annex II to that Regulation. ***For the purposes of registration of organic varieties suitable for organic production as***

(g), and Article 12 thereof and Part I of Annex II to that Regulation. ***Where*** competent authorities are not able to carry out an examination under organic conditions, or the examination of certain characteristics, including disease susceptibility, testing may be carried out under low-input conditions and with only the absolutely necessary for the completion of the testing treatments with pesticides and other external inputs.	***defined in Article 3(19) of Regulation (EU) 2018/848 no exemptions from organic testing conditions should be made. For all other varieties, where*** competent authorities are not able to carry out an examination under organic conditions, or the examination of certain characteristics, including disease susceptibility, testing may be carried out under ***organic conversion or*** low-input conditions and with only the absolutely necessary for the completion of the testing treatments with pesticides and other external inputs. ***Where applicable, the Member States must report yearly to the European Commission on the reasons behind and implementation of testing under non-organic conditions, and the measures foreseen to enable this transition in future. These reports should be published annually by the European Commission.***

Reason
The proposal rightly aims to "contribute to sustainable agricultural production, adapted to current and future projected climatic conditions". To best achieve this, the proposal should mandate that variety testing, particularly the VCU, occurs under organic conditions. This would incentivise breeders to create new varieties independent of chemical inputs and synthetic fertilisers, facilitating farmers' transition to more resilient and sustainable cultivation methods.

Amendment 108

CHAPTER IV, Article 56(1), points (p) and (q) (new)

Text proposed by the European Commission	*CoR amendment*
Contents of the application for registration of a variety	**Contents of the application for registration of a variety**
1. The application for registration of a variety in a national variety register shall consist of the following:	1. The application for registration of a variety in a national variety register shall consist of the following:
(a) a request for registration;	(a) a request for registration;
…	…
	(p) the breeding methods used for the development of the variety;
	(q) the existence of intellectual property rights covering the variety as a whole or its components or the genetic information contained therein, including, where applicable, the number of any relevant patent(s).

Reason
To ensure the highest level of transparency for users of the variety, applicants should provide information on the breeding methods used, and whether the use of the variety for breeding or farming is restricted as a whole or in its components. The inclusion of this obligation in the registration application is needed to ensure that the requirements of Annex VII can be met, with regard to the information to be contained and made publicly available on the national and EU variety registers.

Amendment 109

CHAPTER IV, Article 61(1)

Text proposed by the European Commission	*CoR amendment*
By way of derogation from Article 59(2), the	By way of derogation from Article 59(2), the

technical examination of whether the variety has a ***sustainable*** value for cultivation and use, in accordance with Article 52, or part of it, may be carried out by the applicant if: (a) that applicant has been authorised by the competent authority of the respective Member State; (b) the examination is carried out under the official supervision and guidance of the competent authority concerned; and (c) the examination is carried out in the premises dedicated to that purpose	technical examination of whether the variety has a value for cultivation and use, in accordance with Article 52, or part of it, may be carried out by the applicant if: (a) that applicant has been authorised by the competent authority of the respective Member State; (b) the examination is carried out under the official supervision and guidance of the competent authority concerned; and (c) the examination is carried out in the premises dedicated to that purpose ***Paragraph 1 does not apply in the cases where the variety:*** ***(a) contains or consists of a genetically modified organism, evidence that the genetically modified organism in question is authorised for cultivation in the Union, in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, or, where applicable, in the respective Member State in accordance with Article 26b of Directive 2001/18/EC;*** ***(b) contains or consists of a category 1 NGT as defined in Article 3(7) of Regulation (EU) …/… of the European Parliament and of the Council (Office of Publications, please insert reference to NGT Regulation), evidence that the plant has obtained a declaration of category 1 NGT plant status pursuant to Article 6 or 7 of that Regulation or is progeny of such plant(s);*** ***(c) contains or consists of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation), indication of that fact; is tolerant to herbicides pursuant***

	to Article 47(1)(f) or has particular characteristics that may lead to undesirable agronomic effects pursuant to Article(1)(g).

Reason
While official supervision of professional operators for seed lot certification may be acceptable for overall system efficiency, it should not apply for varieties containing or consisting of GMOs or NGTs, as well as those with potential undesirable agronomic effects.

Amendment 110

CHAPTER IV, Article 63(2)

Text proposed by the European Commission	***CoR amendment***
In the case of varieties of PRM intended exclusively for the production of agricultural raw materials for industrial purposes, certain elements of the technical examination and the intended uses of those varieties, whose public disclosure may affect the competitive position of the applicant, shall be treated as confidential, if that applicant requests so.	

Reason
Transparency should be key regarding the information contained in the variety registers, especially information related to the potential uses of the variety regarding its exclusive use for the production of agricultural raw materials for industrial purposes.

Amendment 111

CHAPTER IV Article 66

Text proposed by the European Commission	***CoR amendment***
After the formal examination of the	After the formal examination of the

application provided for in Article 57, and prior to the registration of a variety in a national variety register pursuant to Article 67, the competent authority shall consult the CPVO ***on the variety denomination proposed by the applicant.*** ***The CPVO*** shall submit to the competent authority a recommendation on the suitability of the variety denomination proposed by the applicant, in accordance with Article 54. The competent authority shall inform the applicant on ***that*** recommendation.	application provided for in Article 57, and prior to the registration of a variety in a national variety register pursuant to Article 67, the competent authority shall ***consult relevant stakeholders at national level, as well as the Committee mentioned in Article 76(1) on the suitability of the variety denomination proposed by the applicant in light of the requirements of Article 54. The competent authority may also*** consult the CPVO, ***which*** shall submit to the competent authority a recommendation on the suitability of the variety denomination proposed by the applicant, in accordance with Article 54. The competent authority shall inform the applicant on ***the*** recommendation.

Reason
The CPVO focuses on protecting plant varieties. While getting its input on denomination is helpful, it cannot replace discussions with other Member States and stakeholders. Denomination issues go beyond existing varieties and involve broader concerns for the public good, as noted in Article 54.

Amendment 112

CHAPTER IV, Article 68

Text proposed by the European Commission	***CoR amendment***
1. By way of derogation from Articles 54 to 67, the competent authorities shall immediately register in their national variety registers all varieties officially accepted or registered before … *[the date of the entry into force of this Regulation]*, in the catalogues,	1. By way of derogation from Articles 54 to 67, the competent authorities shall immediately register in their national variety registers all varieties officially accepted or registered before … [*the date of the entry into force of this Regulation*], in the catalogues, lists or registers established by their Member States

lists or registers established by their Member States pursuant to Article 5 of Directive 68/193/EEC, Article 3 of Directive 2002/53/EC, Article 3(2) of Directive 2002/55/EC and Article 7***(4)*** of Directive 2008/90/EC, without applying the registration procedure set out by those Articles. 2. By way of derogation from Article 53, varieties accepted in accordance with Article 3 of Directive 2008/62/EC and Article 3(1) of Directive 2009/145/EC before… [OJ, please, insert the date of the entry into force of this Regulation] shall be immediately registered in the national variety registers as conservation varieties provided with an officially recognised description without applying the registration procedure set out by that Article.	pursuant to Article 5 of Directive 68/193/EEC, Article 3 of Directive 2002/53/EC, Article 3(2) of Directive 2002/55/EC and ***varieties with an official description pursuant to*** Article 7 of Directive 2008/90/EC, without applying the registration procedure set out by those Articles. 2. By way of derogation from Article 53, varieties accepted in accordance with Article 3 of Directive 2008/62/EC, Article 3(1) ***and Article 21(1)*** of Directive 2009/145/EC ***and varieties with an officially recognised description pursuant to Article 7 of Directive 2008/90/EC*** before… [OJ, please, insert the date of the entry into force of this Regulation] shall be immediately registered in the national variety registers as conservation varieties provided with an officially recognised description without applying the registration procedure set out by that Article.

Reason
It is important to allow the registration of varieties currently classified as "vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions" under Directive 2009/145/EC into national registers after the proposal takes effect. These varieties, often sold to home gardeners, also include new ones developed for specific agro-climatic regions outside commercial crop production. It is crucial to include them in the redefined conservation variety regime to accurately reflect this diversity.

Amendment 113

CHAPTER V Article 81

Text proposed by the European Commission	***CoR amendment***
Amendment of Regulation (EU) 2018/848 ***Regulation (EU) 2018/848 is amended as***	

follows: ***(1) Article 3 is amended as follows:*** ***(a)point (17) is replaced by the following:*** ***'(17) 'plant reproductive material' means plant reproductive material as defined in Article 3(1) of Regulation (EU) …/… of the European Parliament and Council(*)+;';*** ***[…]*** ***(2) Article 13 is deleted.*** ***(3) The second paragraph of Point 1.8.4. of Part I of Annex II to Regulation (EU) 2018/848 is replaced by the following: "All multiplication practices, except plant tissue cultures, cell cultures, germplasm, meristems, chimaeric clones, micro-propagated material, shall be carried out under certified organic management".***	

Reason
There is no amendment needed for the Organic Regulation (EU) 2018/848 as this bears the risk that a further secondary act (Article 27(3) of the PRM Regulation) will weaken the definition. The Organic Regulation has set an ambitious target to end derogations to use non-organic PRM in organic production, and both the OHM and organic varieties regimes have been developed to increase the offer of organic seeds and of plant material adapted to organic growing conditions.

Amendment 114

ANNEX VII

Text proposed by the European Commission	*CoR amendment*
The national variety registers and the Union variety register shall contain all of the following elements: (a) the name of the genus or species to which the variety belongs; (b) the denomination of the variety and, for varieties marketed before the entry into force of this Regulation, where applicable, other alternative denominations used for that variety; (c) the name and, where applicable, the reference number, of the applicant; (d) the date of the registration of the variety and, where applicable, of the renewal of the registration; (e) the date of the end of validity of registration; (f) a reference to the link of the file, where the official description of the variety, or, if applicable, the officially recognised description of the variety, can be found; (g) in the case of varieties with officially recognised description and, if appropriate, an indication of the region(s), where the variety has historically been grown and to which it is naturally adapted ('region(s) of origin');	The national variety registers and the Union variety register shall contain all of the following elements: (a) the name of the genus or species to which the variety belongs; (b) the denomination of the variety and, for varieties marketed before the entry into force of this Regulation, where applicable, other alternative denominations used for that variety; (c) the name and, where applicable, the reference number, of the applicant; (d) the date of the registration of the variety and, where applicable, of the renewal of the registration; (e) the date of the end of validity of registration; (f) a reference to the link of the file, where the official description of the variety, or, if applicable, the officially recognised description of the variety, can be found; (g) in the case of varieties with officially recognised description and, if appropriate, an indication of the region(s), where the variety has historically been grown and to which it is naturally adapted ('region(s) of origin');

(h) the name of the person responsible for the maintenance of a variety;	(h) the name of the person responsible for the maintenance of a variety;
(i) the name of the Member States having established the relevant national variety register(s);	(i) the name of the Member States having established the relevant national variety register(s);
(j) the reference under which the variety has been registered in the national variety register(s);	(j) the reference under which the variety has been registered in the national variety register(s);
(k) where applicable, the indication that the variety is an 'organic variety suitable for organic production';	(k) where applicable, the indication that the variety is an 'organic variety suitable for organic production';
(l) where applicable, the indication that the variety contains, or consists of, a genetically modified organism;	(l) where applicable, the indication that the variety contains, or consists of, a genetically modified organism;
(m) where applicable, the indication that the variety is a component variety of another registered variety;	(m) where applicable, the indication that the variety is a component variety of another registered variety;
(n) where applicable, the indication that PRM belonging to the variety is only produced and marketed in rootstocks;	(n) where applicable, the indication that PRM belonging to the variety is only produced and marketed in rootstocks;
(o) where applicable, a reference to the link of the file, where the results of the examinations for value for sustainable cultivation and use, as referred to in Article 52, can be found;	(o) where applicable, a reference to the link of the file, where the results of the examinations for value for sustainable cultivation and use, as referred to in Article 52, can be found;
(p) where applicable, an indication of the reproduction method of the variety, including information on whether it is a hybrid or a synthetic variety,	(p) where applicable, an indication of the reproduction method of the variety, including information on whether it is a hybrid or a synthetic variety,
(q) where applicable, the indication that the variety contains, or consists of a category 1 NGT plant within the meaning of Article 3(7) of Regulation	(q) where applicable, the indication that the variety contains, or consists of a category 1 NGT plant within the meaning of Article 3(7) of Regulation

(EU) …/… (Office of Publications, please insert reference to NGT Regulation) and the identification number(s) referred to in Article 9(1), point (e) of [NGT Proposal] assigned to the category 1 NGT plant(s) it has been derived from;	(EU) …/… (Office of Publications, please insert reference to NGT Regulation) and the identification number(s) referred to in Article 9(1), point (e) of [NGT Proposal] assigned to the category 1 NGT plant(s) it has been derived from;
(r) where applicable, the indication that the variety contains, or consists of a category 2 NGT plant within the meaning of Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation);	(r) where applicable, the indication that the variety contains, or consists of a category 2 NGT plant within the meaning of Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation);
(s) where applicable, indication that the variety is herbicide tolerant and indication of the applicable cultivation conditions;	(s) where applicable, indication that the variety is herbicide tolerant and indication of the applicable cultivation conditions;
(t) where applicable, indication that the variety has certain characteristics, other than the one referred to in point (s), and indication of the applicable cultivation conditions.	(t) where applicable, indication that the variety has certain characteristics, other than the one referred to in point (s), and indication of the applicable cultivation conditions***;***
	u) disclose which breeding techniques have been applied for the development of the variety (e.g. cell fusion, genetic engineering, chemical or irradiation mutation breeding, microspore culture, etc.);
	(v) disclose if the respective variety, its parts or genetic components are covered by existing intellectual property rights.

Reason
It is very important for organic breeders to know the breeding history in order to choose the appropriate parental material for organic breeding programs; therefore, the breeding techniques should be declared during the registration process. Transparency is needed also for intellectual property rights to avoid unintentional infringement of patents.

II. POLICY RECOMMENDATIONS

THE EUROPEAN COMMITTEE OF THE REGIONS:

1. welcomes the efforts of the European Commission on working towards finding solutions for a sustainable future for EU agriculture. This challenge should be addressed in the CAP Strategic Plans, providing a broader array of solutions in its offerings;

2. recognises the importance of the challenges of adapting agriculture to climate change. Nevertheless, it considers that the resilience of agriculture cannot be considered more important than the development of sustainable agriculture, fair revenues for farmers, and the protection of biodiversity;

3. is concerned about the tight calendar, which does not allow proper democratic debate and citizens' and stakeholders' consultations – an indispensable part of democratic legislative processes – and asks that the necessary time be ensured for in-depth analysis and discussions;

4. highlights the fact that the introduction of the New Genomic Techniques (NGTs) in European agriculture and their liberalisation are questionable at a moment when there are only theoretical proofs of their usefulness to accompany farmers into climate adaptation;

5. refers to the report by the French National Agency for Food, Environmental and Occupational Health Safety (ANSES) which comes to the conclusion that it is necessary to follow precautionary principle, as enshrined in the primary law of the European Union, continues to serve as a cornerstone in the regulatory framework governing plants obtained through certain new genetic techniques (NGT); therefore calls for mandatory risk assessment and authorisation procedures for all NGTs;

6. highlights that until there is real evidence of their usefulness to accompany farmers into climate adaptation, all NGT plants should remain subject to GMO legislation to ensure traceability;

7. asks for full transparency and traceability, including labelling, throughout the entire value chain from the seed to the plate, in compliance with Article 11 of the Cartagena Protocol, to ensure the freedom of choice of NGT-free products for consumers and organic and/or GMO-free

agriculture actors, without passing the additional costs to the NGT-free producers and consumers;

8. in this regard, notes that the legal basis of the NGT regulation proposal, Article 114 TFEU which is supposed to defend the rights and information of consumers, is not consistent with the proposal which reduces, considerably, their level of protection in terms of liberty of choice, information and traceability;

9. notes, moreover, that the proposal is also not in line with Article 169 TFEU, which aims to protect consumers' health, safety, and economic interests, and promote their right to information;

10. highlights that the new regulation of plant reproductive material might unnecessarily increase the administrative burden on our farmers and their dependency on big seed companies, as well as increasing the administrative burden on the competent authorities;

11. asks for the modification of the EU law on intellectual property rights, to forbid patents on NGT before the two regulations enter into force;

12. calls for compliance with the precautionary principle, as the NGT proposal, in its present form, violates the Lisbon Treaty (Article 191) and the Cartagena Protocol (Article 15) by excluding measures to assess and monitor potential health or environmental effects and risks both before and after the marketing of NGT products;

13. asks for the principle of subsidiarity to be guaranteed in general and, in particular, for EU Member States and regions to be empowered to define NGT-free territories for organic and NGT-free agriculture, breeding, and seed production;

14. strongly supports the European Green Deal and, within that, the Farm to Fork Strategy, aiming to achieve 25% of EU agricultural land under organic farming by 2030;

15. welcomes and strongly supports the Commission's current proposal to exclude the use of NGT in organic farming in line with the ban on the use of GMOs in this sector to guarantee consumers' freedom of choice;

16. asks for measures, including financial compensation, to ensure lasting and effective protection against unintended contamination and further disadvantages for organic and GMO-free agriculture, as well as high-quality food production protected by geographical indications;

17. highlights that distributors must bear any costs for contamination in organic and GMO-free food production, and liability rules following the "polluter pays" principle must be provided for this purpose;

18. asks for the development and provision of methods by NGT developers and/or distributors to identify and analytically detect the NGT event to allow traceability and avoid fraud. Such method(s) shall be made publicly available;

19. asks for EU-level measures to be defined for the coexistence of GMO and GMO-free production before the release of NGT 1 and NGT 2 crops, as this cannot be delegated to the Member States;

20. welcomes the recognition of the diversity of operators' profiles and the possibility to sell and exchange seeds outside the legislation;

21. highlights that the proposals, in their current form, could lead to a loss of biodiversity by undermining the production and the use of traditional and newly developed conservation varieties representing a significant proportion of the genetic diversity of cultivated plant species;

22. asks to enable Plant Genetic Resource (PGR) access to farmers to promote sustainable use and on farm research, as motor of place-based innovation;

23. requests the exemption of national gene banks, organisations, and networks involved in the transfer of plant reproductive material (PRM) for the conservation and sustainable use of plant genetic resources and agro-biodiversity from the scope of regulation;

24. highlights that the new regulation of plant reproductive material might unnecessarily increase the administrative burden on our farmers and their dependency on big seed companies;

25. asks for the definitions of "marketing" and "professional operator" to be limited to cases where there is an intent to commercially exploit the PRM, excluding conservation actors such as gene banks, organisations, and networks;

26. asks for removal of the additional rules for the production of standard seeds and material that create disproportionate regulatory cost for small seed producers;

27. asks for the exemption of micro-enterprises from the new reporting, monitoring and traceability requirements for professional operators;

28. asks for the Value for Sustainable Cultivation and Use (VSCU) tests not to be extended to all crops, including vegetables and fruits, as it will cause unnecessary burden and costs for breeders;

29. asks for all cultivar types (varieties, conservation varieties, organic varieties, heterogeneous material), all intellectual property rights that are related to released varieties in the EU as well as the applied breeding methods and technologies (e.g. cell fusion, gene editing, random mutagenesis, etc.) to be made electronically available on the EU Plant Variety Portal to increase transparency of the available PRM for farmers and consumers.

Brussels, 18 April 2024

The President
of the European Committee of the Regions

Vasco Alves Cordeiro

The Secretary-General
of the European Committee of the Regions

Petr Blížkovský

III. PROCEDURE

Title	New genomic techniques and plant reproductive materials
Reference(s)	Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (COM(2023) 411 final) Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material) (COM(2023) 414 final)
Legal basis	Article 307(1)
Procedural basis	Rule 41(a)
Date of Council/EP referral/Date of Commission letter	
Date of Bureau/President's decision	
Commission responsible	Commission for Natural Resources
Rapporteur	Erik Konczer (HU/PES)
Discussed in commission	23 November 2023
Date adopted by commission	5 February 2024
Result of the vote in commission (majority, unanimity)	Majority
Date of adoption in plenary	17 April 2024
Previous Committee opinions	

Subsidiarity reference	

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