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ESTUDIOS

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¿Podrían las nuevas propuestas regulatorias de la UE en materia de fitomejoramiento comprometer la innovación? Entre las expectativas generadas por la propuesta sobre Nuevas Técnicas Genómicas y el sinsentido de la propuesta sobre Material de Reproducción Vegetal

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Abstract

The European Commission new regulatory proposals on new genome-edited plants and on plant reproductive material are set to revolutionize plant breeding and agriculture in the EU. This short communication analyzes the main features of such proposals with respect to the current regulatory frameworks in the EU, and discusses their foreseeable impact on European plant breeding innovation and agriculture. While there is no denying the potential advantages that the proposal on new genome-edited plants might bring, the proposed regulation is also complex and ambiguous, a matter already acknowledged by the specialized literature, and about which even some of the strongest advocates of the proposed regulation appear to show a certain degree of concern. If this is not corrected, the successful implementation of the proposal could be compromised. The proposal on plant reproductive material threatens to create new and probably unnecessary burdens for European plant breeders, farmers, and end consumers. Addressing the identified issues in the proposal on genome-edited plants, and drafting a new proposal on plant reproductive material aiming at reducing inefficiencies is suggested.

Keywords

Plant Breeding; New Genomic Techniques; Plant Reproductive Material; Biosafety Law; Intellectual Property.

Resumen

Las nuevas propuestas reglamentarias de la Comisión Europea sobre nuevas plantas editadas genéticamente y sobre material de reproducción vegetal están llamadas a revolucionar el fitomejoramiento y la agricultura en la UE. En este breve artículo se analizan las principales características de dichas propuestas en relación con el marco normativo vigente en la UE y se examina su impacto previsible en la innovación en los ámbitos del fitomejoramiento y la agricultura europeas. Aunque no pueden negarse las ventajas potenciales de la propuesta sobre nuevas plantas editadas genéticamente, el régimen legal propuesto es complejo y ambiguo, una cuestión reconocida ya por la literatura especializada, y sobre la que incluso algunos de los más firmes partidarios del reglamento propuesto parecen mostrar cierto grado de preocupación. Si ello no se aborda debidamente, el éxito de su aplicación podría verse comprometido. La propuesta sobre material de reproducción vegetal amenaza con crear nuevas cargas, probablemente innecesarias, para los obtentores, agricultores y consumidores finales europeos. Se sugiere abordar los problemas identificados en la propuesta sobre plantas editadas genéticamente, así como redactar una nueva propuesta sobre material de reproducción vegetal con el objetivo de reducir sus ineficiencias.

Palabras clave

Fitomejoramiento; Nuevas Técnicas Genómicas; Material de Reproducción Vegetal; Derecho sobre Bioseguridad; Propiedad Industrial.

Summary: I. Brief introduction. II. The European Commission's Proposal on NGTs. III. The European Commission's PRM Proposal. IV. Conclusions.

I. BRIEF INTRODUCTION

The European Commission adopted two new regulatory proposals, «*on plants obtained by certain new genomic techniques and their food and feed*» («*NGTs*»)[2] and «*on plant reproductive material*» («*PRM*»)[3] under the *European Green Deal*[4] which are expected to have a major impact on plant breeding[5].

[2] European Commission, «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)» (Brussels: European Commission, 2023), https://food.ec.europa.eu/document/download/c03805a6-4dcc-42ce-959c-e4d609010fa3_en?filename=gmo_biotech_ngt_proposal.pdf. Henceforth, the European Commission's Proposal on NGTs (COM(2023) 411 final).

[3] European Commission, «Proposal for a Regulation of the European Parliament and of the Council on the Production and Marketing of Plant Reproductive Material in the Union (COM(2023) 414 Final)» (Brussels: European Commission, 2023), https://food.ec.europa.eu/document/download/0f4f74a3-9cce-44dd-93e2-3a2dc8372555_en?filename=prm_leg_future_reg_prm.pdf. Known as the «*PRM proposal*». European Commission, «Frequently Asked Questions: New Rules for Improved Plant and Forest Reproductive Material» (2023), https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_3567.

[4] «*The proposal is part of the overall policies of the European Green Deal and related strategies: the Farm to Fork and Biodiversity strategies, the Union's Strategy on Adaptation to Climate Change and the planned initiative on a legislative framework for a sustainable food system. It is consistent with these strategies' objectives.*» European Commission, «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)», 4. In addition to such a mention in the «*Explanatory Memorandum*» of the European Commission's Proposal on NGTs (COM(2023) 411 final), other references to the «*European Green Deal*» are found in the recitals of the proposed regulation itself (*see*, particularly, recitals (3) and (10)). As for the «*Explanatory Memorandum*» of the of European Commission's PRM Proposal (COM(2023) 414 final), the following statement is made in it: «*The proposed Regulation is submitted within this context. It is also part of the overall policies of the European Green Deal*[…] *and the related strategies: the Farm to Fork Strategy*[…]*, the Biodiversity Strategy*[…] *and the EU Strategy on adaptation to climate change*[…].» European Commission, «Proposal for a Regulation of the European Parliament and of the Council on the Production and Marketing of Plant Reproductive Material in the Union (COM(2023) 414 Final)», 3. An additional reference to the «*European Green Deal*» is found in recital (33) of the proposed regulation on PRM.

[5] Erik Stokstad, «European Commission Proposes Loosening Rules for Gene-Edited Plants», *Science* (2023), https://www.science.org/content/article/european-commis-

sion-proposes-loosening-rules-gene-edited-plants; Per Henriksson, «The Swedish Presidency – A Time of Anticipation Pending the New Regulatory Texts From COM», *EuropeanSeed* May 31 (2023), https://european-seed.com/2023/05/the-swedish-presidency-a-time-of-anticipation-pending-the-new-regulatory-texts-from-com/. Other scientists/scientific organizations, while welcoming the proposal with optimism and praising its benefits compared to the current regulatory framework, remain slightly more critical. *See*: Hervé Vanderschuren et al., «A New Chance for Genome Editing in Europe», *Nature Biotechnology* 41 (October 14, 2023): 1378-80, https://doi.org/10.1038/s41587-023-01969-4; Nature Plants, «EU Rethinks Genome Editing», *Nature Plants* 9, no. 8 (2023): 1169-70, https://doi.org/10.1038/s41477-023-01505-x; EPSO, «EPSO First Reaction to the European Commission's Legal 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» (2023), https://epsoweb.org/download/23-07-06_epso_1st_reaction_ec_proposal_ngts/?tmstv=1688649797; EPSO, «Proposal for a Regulation of the European Parliament and of He Council on Plants Obtained by Certain New Genomig Techniques Ad Their Food and Feed, and Amending Regulation (EU) 2017/625 [5 Novemeber 2023]» (Brussels, 2023), 1, https://epsoweb.org/download/2023-11-05_epso_statement_ec_legal_proposal_ngts/?tmstv=1699260264; Devang Mehta, «EU Proposal on Gene-Edited Crops Doesn't Go Far Enough», *Nature* 619 (2023): 437, https://doi.org/10.1038/d41586-023-02328-8; European Parliament's Committee on the Environment Public Health and Food Safety, «DRAFT REPORT on the Proposal for a Regulation of the European Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and Amending Regulation (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – (2023)0226(COD))» (2023), 21, https://www.europarl.europa.eu/doceo/document/ENVI-PR-754658_EN.pdf; AFBV and WGG, «AFBV and WGG Welcome EU Proposals for the Regulation of NGTs as a Step in the Right Direction», *Press Release Paris, Frankfurt/Main, July 5* (2023), https://www.wgg-ev.de/app/download/13228264299/PRESS+RELEASE+AFBV+WGG+on+NGT+plants.pdf?t=1692000859; AFBV and WGG, «Detailed Comments on the Commission's Proposal for NGT Plants» (2023), 1, https://www.biotechnologies-vegetales.com/wp-content/uploads/2023/10/Detailed-comments-on-Commission-proposal-for-NGT-plants-AFBV-WGG-14-October-2023.pdf; WGG and VBIO, «Neue Genomische Techniken (NGT): VBIO Und WGG Begrüßen Evidenzbasierten Regulierungsentwurf Der EU-Kommission» (2023), https://www.wgg-ev.de/app/download/13228222199/PM_VBIO_WGG_Entwurf+NGT-Pflanzen.pdf?t=1688581412; COPA-COGECA, «Position Paper on the Commission's proposal on plants obtained by certain new genomic techniques (NGTs) and their food and feed, and amending Regulation (EU) 2017/625[.] 16th October 2023» (2023), 3, https://copa-cogeca.eu/Flexpage/DownloadFile/?id=13462320; Petra Jorasch, «Resurrection of Plant Breeding Innovation in the EU?», *Europeanseed*, October (2023), https://european-seed.com/2023/10/resurrection-of-plant-breeding-innovation-in-the-eu/; ARRIGE, «Statement about EC Proposal on New Genomic Techniques Regulation in Plants[.] July 2023», (2023), 3, https://www.arrige.org/wp-content/uploads/2023/07/ARRIGE_SC_statement_NGTs.pdf; Oana Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», *Trends in Plant Science* 28, no. 12 (2023): 1352, https://doi.org/10.1016/j.tplants.2023.09.014; Jany Klaus-Diete and Dietz Karl-Josef, «Open Letter to the Federal Minister of Food and Agriculture, Cem Özdemir the Federal Minister for the Environment, Nature Conservation, Nuclear Safe-

This paper provides a preliminary analysis of both regulatory proposals, focusing less on their merits than on those aspects that should be improved to increase their chances of success.

II. THE EUROPEAN COMMISSION'S PROPOSAL ON NGTS[6]

The European Commission's Proposal on NGTs (COM(2023) 411 final) aims at overcoming the limitations of the current European Union (EU) regulatory framework on genetically modified organisms (GMOs) with respect to crops modified by means of modern genome-editing techniques, particularly apparent after the Judgment of the Court of Justice of the EU (CJEU) of 25 July 2018[7] in

ty and Consumer Protection, Steffi Lemke and the Federal Minister of Education and Research, Bettina Stark-Watzinger», (2023), https://www.wgg-ev.de/app/download/13269967099/OpenLetter_BMEL_BMVU_BMBF01.pdf?t=1701014651. Indeed, as noted by Dima et al.: «*The plant science network European Sustainable Agriculture through Genome Editing (EU-SAGE) and many other actors in the agri-food value chain welcome the EC proposal*». However, according to Katsarova: «*Feedback from stakeholders is mixed. While industry interest groups hailed the 'game-changing proposals' bringing innovation in plant breeding, the organic food and farming movement criticised the Commission's plan to take NGTs out of the existing legal framework, as it could leave organic food systems unprotected.*» Ivana Katsarova, «Plants Produced by New Genomic Techniques[.] PE 754.549 – October 2023», *BRIEFING[.] IEU Legislation in Progress* (Strasbourg, 2023), 1, https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/754549/EPRS_BRI(2023)754549_EN.pdf.

[6] While this paper was in the process of completion, a «*draft report*» from the Committee on the Environment, Public Health and Food Safety of the European Parliament was published (*see* European Parliament's Committee on the Environment Public Health and Food Safety, «DRAFT REPORT on the Proposal for a Regulation of the European Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and Amending Regulation (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – (2023)0226(COD)»). Although some references to that document are included in this paper (relevant insofar as they relate to aspects discussed in it), that document is not analyzed in more detail here. Within the legislative process, other documents, of greater or lesser relevance in the context of this paper, have been published since then. This paper focuses on the Proposal adopted by the Commission, not on the legislative process nor on the above-mentioned documents.

[7] Stokstad, «European Commission Proposes Loosening Rules for Gene-Edited Plants»; Henriksson, «The Swedish Presidency – A Time of Anticipation Pending the New Regulatory Texts From COM» *See also* Vanderschuren et al., «A New Chance for Genome Editing in Europe», 1378. *Also* Tomasz Zimny, «New Genomic Techniques and Their European Union Reform. Potential Policy Changes and Their Implications», *Frontiers in Bioengineering and Biotechnology* 10 (September 30, 2022): 2, https://doi.org/10.3389/FBIOE.2022.1019081/BIBTEX; Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1350; Ying Wang et al., «Regulatory Policies of Genome Editing Products around the World», *Journal of Biomedical*

case C-528/16[8]. Indeed, as the European Commission reminds in its very regulatory proposal:

> «*(5) In its judgment in case C-528/16 Confédération paysanne and Others12 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.*
>
> […]
>
> *(8) It is therefore necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market.*»

The Proposal expands the current EU regulatory framework on GMOs by adding two new legal «*categories*» of genetically modified plants[9]: «*category 1 NGT plants*» and «*category 2 NGT plants*»[10]. It defines a «*NGT plant*» as «*a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant*»[11]. In turn, a «*category 1 NGT plant*» is described as «*a NGT*

Research & Environmental Sciences 4, no. 10 (2023): 1449, https://doi.org/10.37871/jbres1817.

[8] Judgement of the Court of Justice of the EU (CJEU) of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583. On the judgment and its implications, *see*, e.g., Kai P Purnhagen et al., «EU Court Casts New Plant Breeding Techniques into Regulatory Limbo», *Nature Biotechnology* 36, no. 9 (September 6, 2018): 799-800, https://doi.org/10.1038/nbt.4251; Juan Antonio Vives-Vallés and Cécile Collonnier, «The Judgment of the CJEU of 25 July 2018 on Mutagenesis: Interpretation and Interim Legislative Proposal», *Frontiers in Plant Science* 10 (March 3, 2020): 1813, https://doi.org/10.3389/fpls.2019.01813.

[9] «*(13) This Regulation should distinguish between two categories of NGT plants.*» European Commission's Proposal on NGTs (COM(2023) 411 final).

[10] *See*, particularly, recitals (14) and (15) as well as Article 3(7) and (8) of the European Commission's Proposal on NGTs (COM(2023) 411 final).

[11] Article 3(2) of the European Commission's Proposal on NGTs (COM(2023) 411 final). The Committee on the Environment, Public Health and Food Safety of the European Parliament proposed to eliminate «*genetically modified*» from that definition, under the «[j]*ustification*» that «[t]*he wording "genetically modified" would indicate that the process of using NGT techniques would change the DNA of an organism by introducing elements of DNA from a different organism. It should therefore be deleted.*» European Parliament's Committee on the Environment Public Health and Food Safety, «DRAFT REPORT on the Proposal for a Regulation of the European

plant that […] fulfils the criteria of equivalence to conventional plants, set out in Annex I»[12], systematized according to their quantitative or qualitative nature in Table 1[13]. While a «*'category 2 NGT plant' means a NGT plant*

Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and Amending Regulation (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – (2023)0226(COD))», 11 («*Amendment 10*»). However, it also proposed to change the wording «*1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants*» to «*1. The rules which apply to GMOs in Union legislation shall not apply to category 1 NGT plants*» (European Parliament's Committee on the Environment Public Health and Food Safety, 13-14 («*Amendment 15*»)), thus falling into a clear contradiction. According to Katsarova: «*The text proposed by the presidency features a new definition of NGT plants excluding the term 'genetically modified'. Instead, an NGT plant is defined as 'obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant'.*» Katsarova, «Plants Produced by New Genomic Techniques[.] PE 754.549 – October 2023», 10.

[12] Article 3(7)(a) of the European Commission's Proposal on NGTs (COM(2023) 411 final).

[13] Rognli on behalf of EPSO raises the following questions:

> «*1. Is the maximum number of modifications per haploid/monoploid genome?*
> *2. Do the 20 modifications refer to intended modifications, or do they also include possible off-targets?*
> *3. In the case of the latter, what type of documentation is needed? Where will the burden of evidence lie, i.e. how can you know if any given mutation is off-target or spontaneous?*
> *a. What do you mean by similarity, i.e. do you have a threshold in mind? Does this mean all applications must be accompanied by an assembled genome sequence?*
> *b. What would, in that case, be the comparator?*
> *4. Is it possible to cross two verified NGT1 plants and retain the NGT1 status even if the number of modifications exceeds 20?*
> *5. In relation to cisgenesis, what do you mean by "targeted"?*
> *a. Do you limit targeted to allele replacement, or could it also include a safe "landing pad"?*
> *b. How about Agro-mediated insertions that meet the criteria of a safe landing pad?* […]».

Odd Arne Rognli, «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», in *4th PlantEd Conference – Faculty of Pharmacy, University of Porto, Portugal, 18-20 Sept 2023* (2023), 3-4. *See also* EPSO, «Proposal for a Regulation of the European Parliament and of He Council on Plants Obtained by Certain New Genomig Techniques Ad Their Food and Feed, and Amending Regulation (EU) 2017/625 [5 Novemeber 2023]», 2. Similarly, although with a more critical view on the matter, *see* Testbiotech, «New Genetic Engineering: EU Com-

other than a category 1 NGT plant»[14], which is neither considered to be a traditional GMO.

Most importantly, the Proposal excludes «*NGT Plants*» and «*products*» from the current EU legal regime on GMOs, either completely (in the case of «*category 1 NGT plants*»[15]) or only partially (in the case of «*category 2 NGT plants*»[16]). Thus, contrary to *category 2 NGT plants* and *products*, *category 1 NGT plan*ts will be exempted from «*risk assessment*» and «*authorization*»[17], and *products* thereof will also be exempted from a mandatory

mission Proposal for New Regulation Endangers Nature, the Environment and Our Future Livelihoods» (Munich, 2023), 8, https://www.testbiotech.org/sites/default/files/Testbiotech_Background_NGT_Regulation_final_0.pdf. According to Vanderschuren et al.: «*It is also unclear whether this refers to separate instances of genome modification –for example, 20 single-base-pair changes– or whether changes of up to 20 consecutive nucleotides are included.*» Vanderschuren et al., «A New Chance for Genome Editing in Europe», 1379. The Committee on the Environment, Public Health and Food Safety of the European Parliament proposed changes to «*Annex I*» of the Proposal. *See*, respectively, European Parliament's Committee on the Environment Public Health and Food Safety, «DRAFT REPORT on the Proposal for a Regulation of the European Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and Amending Regulation (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – (2023)0226(COD)», 18-19 (*Amendments* 22 and 23). The *Association Française des Biotechnologies Végétales* and the *Wissenschaftlerkreis Grüne Gentechnik e.V.* in a joint statement, COPA-COGECA, Petra Jorasch from Euroseeds, EPSO, and others also insist on the matter. *See* AFBV and WGG, «Detailed Comments on the Commission's Proposal for NGT Plants», 1-5; COPA-COGECA, «Position Paper on the Commission's proposal on plants obtained by certain new genomic techniques (NGTs) and their food and feed, and amending Regulation (EU) 2017/625[.] 16th October 2023», 4; Jorasch, «Resurrection of Plant Breeding Innovation in the EU?»; EPSO, «Proposal for a Regulation of the European Parliament and of He Council on Plants Obtained by Certain New Genomig Techniques Ad Their Food and Feed, and Amending Regulation (EU) 2017/625 [5 Novemeber 2023]», 1-2; Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1350, 1351. Others have noted the lack of sense of some of the criteria set out in Annex I. *See* especially Testbiotech, «New Genetic Engineering: EU Commission Proposal for New Regulation Endangers Nature, the Environment and Our Future Livelihoods», 4, 5, 6 and footnote 21.

[14] Article 3(8) of the European Commission's Proposal on NGTs (COM(2023) 411 final).

[15] Article 5(1) of the European Commission's Proposal on NGTs (COM(2023) 411 final).

[16] Article 12 of the European Commission's Proposal on NGTs (COM(2023) 411 final).

[17] Eric Meunier, «The European Commission Wants to Put an End to GMOs» (2023), https://www.infogm.org/7834-european-commission-wants-to-put-an-end-to-gmos?lang=fr. As stated in recital (20) of the European Commission's Proposal on NGTs

«*labelling*»[18]. The Proposal also creates an *incentivized* (and, in the case of SMEs, financially supported) pathway «*for category 2 NGT plants* […] *containing traits relevant for sustainability*»[19].

(COM(2023) 411 final): «*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.* […]». *See also* Stokstad, «European Commission Proposes Loosening Rules for Gene-Edited Plants»; Jorasch, «Resurrection of Plant Breeding Innovation in the EU?»; Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1351; Wang et al., «Regulatory Policies of Genome Editing Products around the World», 1449. *Also* Katsarova, «Plants Produced by New Genomic Techniques[.] PE 754.549 – October 2023», 8-9, and, especially, 10, in which Katsarova reports that: «*The verification procedure allowing an NGT plant to be granted Category 1 status has also been modified. Any EU country and the Commission would have the possibility to file reasoned objections instead of simply making comments to the verification report.*» Katsarova, 10.

[18] Noted also by Meunier, «The European Commission Wants to Put an End to GMOs». While the European Commission's Proposal on NGTs (COM(2023) 411 final) has a provision especially devoted to the «[l]*abelling of authorised category 2 NGT products*» (Article 23), there is no equivalent provision for *category 1 NGT products*. However, as noted also by Meunier «*seed labelling for farmers is planned*». Meunier. Indeed, such mandatory *labelling* for «*category 1 NGT plant reproductive material, including breeding material*» is covered by Article 10, and mentioned in recitals (21) and (24) of the European Commission's Proposal on NGTs (COM(2023) 411 final). However, the Committee on the Environment, Public Health and Food Safety of the European Parliament proposed to eliminate such an obligation, under the following «[j]*ustification*»: «*Seed bag labelling for verified conventional-like NGT plants is discriminatory. Conventional-like NGT plants should be treated conventionally, this extra requirement is creating unjustified distinctions and administrative burden. Transparency and consumer choice can be fully ensured by making information about the use of NGTs publicly available (public databases). The additional seed bag labelling provisions create a third category of plant products between conventional and GMOs. This is not in line with the approaches taken in other countries and will create trade issues.*» European Parliament's Committee on the Environment Public Health and Food Safety, «DRAFT REPORT on the Proposal for a Regulation of the European Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and Amending Regulation (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – (2023)0226(COD)», 6 («*Amendment 5*»). *See also* «*Amendment 21*» in European Parliament's Committee on the Environment Public Health and Food Safety, 17. While breeders appear to be aligned with such a position (*see*, e.g., Jorasch, «Resurrection of Plant Breeding Innovation in the EU?»), according to Dima et al.: «[…] *seed bags will need to be labeled appropriately to enable freedom of choice by farmers.*» Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1351.

[19] Article 22 of the European Commission's Proposal on NGTs (COM(2023) 411 final). *See also* Katsarova, «Plants Produced by New Genomic Techniques[.] PE 754.549 – October 2023», 9.

Table 1. «*Criteria of equivalence of NGT plants to conventional plants*» from Annex I of the NGT Proposal, classified by its quantitative or qualitative nature

Legal provision from the NGT Proposal (Annex I)	«[T]*ype*» of «*genetic modifications*»	Quantitative *criteria*		Qualitative *criteria*		
		≤ «*20 genetic modifications*» (applicable to a specific «*type*» or combinations thereof[20])	≤ «*20 nucleotides*»[21]	«[G]*enetic modification does not interrupt an endogenous gene*»	«[B]*reeder's gene pool*»	Qualitatively limited (only) by the very «*type*» of the «*genetic modifications*»
Point (1)	«*substitution or insertion*»	√	√			
Point (2)	«*deletion of any number of nucleotides*»	√				√
Point (3), letter (a)	«*targeted insertion of a contiguous DNA sequence*»	√		√	√	
Point (3), letter (b)	«*targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence*»	√		√	√	
Point (4)	«*targeted inversion of a sequence of any number of nucleotides*»	√				√
Point (5)	«*any other targeted modification of any size*»	√			√	

Source: Own elaboration.

[20] Aligned with Meunier's analysis of this specific matter, in Meunier, «The European Commission Wants to Put an End to GMOs». However, Meunier seems to hold a much more negative view of the European Commission's Proposal on NGTs (COM(2023) 411 final) than the authors of this paper.

[21] As stated by Vanderschuren et al.: «*The threshold of 20 nucleotides that can be replaced or added appears seemingly arbitrary as it is apparently based* […]». Vanderschuren et al., «A New Chance for Genome Editing in Europe», 1378. According to ARRIGE: «*The limits of the maximum number of genetic modifications (20) or the number of nucleotide changes/introduced in each modification (also 20) can be criticised as they are completely arbitrary and lack scientific support. Also the difference tolerance between insertions and deletions does not seem to be scientifically justified.*» ARRIGE, «Statement about EC Proposal on New Genomic Techniques Regulation in Plants[.] July 2023», 3. In the same vein, *see* Testbiotech, «New Genetic Engineering: EU Commission Proposal for New Regulation Endangers Nature, the Environment and Our Future Livelihoods», 4, 5; Vanderschuren et al., «A New Chance for Genome Editing in Europe», 1378; newgmo.org, «Open Letter: Serious Concerns about the EU Commission Proposal on New Genomic Techniques» (2023), https://newgmo.org/2023/11/19/open-letter-serious-concerns-about-the-eu-commission-proposal-on-new-genomic-techniques/; Christophe Noisette, «GMOs/NGTs: Consumers Want a Choice», *infOGM*, (2023), https://www.infogm.org/7899-une-large-gamme-d-acteurs-opposes-a-la-dereglementation-des-ogm?lang=fr. *See also* Nature Plants, «EU Rethinks Genome Editing», 1169.

As, an «*'NGT plant' means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool* […]»[22], *transgenesis* is excluded. However, as noted by Meunier[23], the new legal scheme could potentially open the door to transgenesis. If «*the* '*breeders' gene pool*'»[24] constraint was to be interpreted *dynamically*[25], that could end being the case[26]. Such an interpretation might in turn

[22] Article 3(2) of the European Commission's Proposal on NGTs (COM(2023) 411 final).

[23] Meunier, «The European Commission Wants to Put an End to GMOs».

[24] According to Article 3 («*Definitions*»): «*(6) 'breeders' gene pool' means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses;*» (emphasis added). Both the reference to «*advanced*» and «*such as*» are particularly suggestive. The former is indicative of the legislator's inclination towards an expansive, perhaps even dynamic, interpretation; the latter reinforces the former, by making it clear that the examples given next by the provision are merely just that, examples, and can be extended, probably even with new «*advanced techniques*». Recital (2) goes even further by making clear that such a notion must be understood as entailing «*the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced breeding techniques.* […]» (emphasis added).

[25] I.e., «*in light of their present societal, political, and legal context*». William N. Eskridge, «Dynamic Statutory Interpretation» *University of Pennsylvania Law Review* 135 (1987): 1479, http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=3967&context=penn_law_review.

[26] Noted by Meunier: «[W]*ith the semantics used in this list, it is difficult to see which genetically modified plants would continue to be defined as GMOs. Once a breeder has a transgenic plant in his gene pool, it would be possible for him to claim that transferring this transgene from maize to soybeans is a "targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool".* […] *Finally, the only case in which a transgenic plant could be defined as a GMO would be if the inserted transgene did not come from the breeder's gene pool. But any subsequent insertion in another species would make it a category 1 "NGT", and therefore excluded.*» Meunier, «The European Commission Wants to Put an End to GMOs». Meunier's interpretation is not the only possible one, nor does it seem to take into account recital (9) of the European Commission's Proposal on NGTs, but it is within the realm of possibility. In fact, organizations such as EPSO (European Plant Science Organisation) seem to be advocating precisely for dynamic interpretations of the regime under the new European Commission's Proposal on NGTs (COM(2023) 411 final): «*EPSO notes that standards for evaluating the equivalence between NGTs and conventional crops may need to be clarified on the basis of scientific evidence.* Alan Schulman, of the Natural Resource Institute Finland, observes that "genomes are highly dynamic, so sequence-based equivalence needs careful definition."» (Underlined added). EPSO, «EPSO First Reaction to the European Commission's Legal 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», 2. All the above also shows the fierce contest between

be prevented by considering recital (9)[27] of the Proposal on NGTs. Thus, while Article 3(6) and recital (2) still rely on the liquid and *sui generis* «*breeder's gene pool*» concept, recital (9), as the very title of the European Commission's Proposal on NGTs[28], reminds that the proposed regulation «*only cover plants obtained by certain NGTs*», and, more importantly, that «*GMOs produced by other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) should remain subject only to the Union GMO legislation*». This way, by resorting to recital (9), Meunier's fears of an expansive interpretation of «*the breeders' gene pool*» are appeased, and the problem then boils down to demarcating what is meant by «*transgenesis*» in the context of the proposed regulation, which, given the intricate architecture of the proposal itself and its (intra-systemic) conceptual *complexity*[29], might be not as obvious as it seems. Such reliance on the recitals was in fact the path taken by the CJEU in case C-528/16, with recital (17) of Directive 2001/18/EC[30] instead. However,

the two factions against and in favour of GMOs and plant biotechnology in the EU, which has now intensified with the European Commission's Proposal on NGTs (COM(2023) 411 final).

[27] Recital (9) of the European Commission's Proposal on NGTs (COM(2023) 411 final): «[…] *this Regulation should only cover plants obtained by certain NGTs: targeted mutagenesis and cisgenesis (including intragenesis) (hereinafter 'NGT plants'), but not by other new genomic techniques*. […] *GMOs produced by other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) should remain subject only to the Union GMO legislation*[…]» (emphasis added). It must be noted that while the authors of this paper are not opposed to transgenesis, the very European Commission's Proposal on NGTs is, as shown, e.g., by recital (9). It is therefore a matter of consistency that either the interpretation of the *NGT* concept and *categories*, and the *empowerment* of the EC of Article 5(3) be clarified in the direction of recital (9), or the very regime under Directive 2001/18/EC be reformed to provide more leeway to transgenesis. In fact, in the view of the authors of this paper, both tasks (the clarification of the EC Proposal on NGTs, and a deep reform of Directive 2001/18/EC providing more leeway to transgenesis) should be pursued. Moreover, it would have been preferable to solely opt for deeply reforming the entire Directive 2001/18/EC regime in both respects (i.e., aiming a wise deregulation of both, NGTs and transgenesis) instead of adding new legislation and bureaucracy.

[28] «*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*» (emphasis added).

[29] *Complexity* acknowledged by Dima et al., and also by Zimny (in this last case even well before the very proposal was born). *See* Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1352; Zimny, «New Genomic Techniques and Their European Union Reform. Potential Policy Changes and Their Implications», 6; footnotes 37, 38 and text to footnotes 37, 38.

[30] E.g., Purnhagen et al., «EU Court Casts New Plant Breeding Techniques into Regulatory Limbo», 799; Vives-Vallés and Collonnier, «The Judgment of the CJEU of 25 July 2018 on Mutagenesis: Interpretation and Interim Legislative Proposal», 2-3.

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under the new Proposal on NGTs the European Commission also decided to vest itself with the authority to «*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*»[31]. Thus, if the European Commission were to exercise such prerogative, the practical consequence could well be that *genetic modifications* currently leading to GMOs (according to Directive 2001/18/EC) or to *category 2 NGT plants* (according to the Proposal on NGTs) might later result in *category 1 NGT plants*, so equating them to conventional ones[32]. Whether or not the Commission decides to go down this road, Article 5(3) may also imply that the European legislator actually advocates for dynamic interpretations, so reinforcing the possibility of interpreting «*the breeders' gene pool*» in that manner. Perhaps more importantly, this legal provision suggests that in arguably the most science-driven EU regulatory proposal on plant biotechnology ever[33], there seems to be a widespread readiness, or at least tolerance, for scientific terms being twisted, even perverted[34], in the interest of new biotechnology.

[31] Article 5(3) of the European Commission's Proposal on NGTs (COM(2023) 411 final).

[32] Noted also by Meunier: «*Above all, by means of what are known as delegated acts, the Commission is asking to be given the power to modify alone annex 1 listing the types of genetic modification leading to the legal status "NGT 1". This blank check for the future is seen as a small but necessary measure to avoid hampering industrial competitiveness, should the notion of "conventional techniques" become broader than it is today.*» Meunier, «The European Commission Wants to Put an End to GMOs». However, it must be noted that even COPA-COGECA favours such an *empowerment*: «*Copa and Cogeca support the delegation of power to the Commission to adapt the equivalence criteria to be in line with scientific and technological progress as well as extending the list of permitted modifications regarded as occurring naturally or those produced through old conventional breeding.*» COPA-COGECA, «Position Paper on the Commission's proposal on plants obtained by certain new genomic techniques (NGTs) and their food and feed, and amending Regulation (EU) 2017/625[.] 16th October 2023», 4.

[33] «*EPSO sees the move towards a proportionate, more product-based regulatory environment, with evaluation on a case-by-case basis, as an important step into the future.*» EPSO, «EPSO First Reaction to the European Commission's Legal 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», 1. As stated by Vanderschuren et al.: «*Compared to current rules, the new law relies more on published scientific evidence,* […]». Vanderschuren et al., «A New Chance for Genome Editing in Europe», 1378. *See also* Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1350.

[34] Observed also by Meunier, «The European Commission Wants to Put an End to GMOs». If the understanding of what is «*natural*» is subject «*to scientific and technological*

Whatever the case may be, all this ambiguity[35] (*see* Fig. 1) undoubtedly exceeds any desirable margin of flexibility, and if not corrected during the legislative procedure ahead, and as noted by the specialized literature even before the adoption of the Proposal[36], is likely to raise controversy and problems in practice.

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progress», and, above all, to the will of the European Commission, then it does not even make sense to devote academic efforts to discussing the specifics. This is all the more ironic in view of the fact that for years the scientific community has been objecting to the use of «*natural*» when it was used as a restriction of the GMO concept under Directive 2001/18/EC (*see*, e.g., Alan McHughen, «Fatal Flaws in Agbiotech Regulatory Policies» *Nature Biotechnology* 25, no. 7 (July 1, 2007): 725-726, https://doi.org/10.1038/nbt0707-725). And while the authors of this paper are in favour of plant biotechnology and innovation, and also welcome the European Commission's regulatory proposal, they do acknowledge however that the European Commission has made it easy to criticize it (*see*, e.g., Meunier, «The European Commission Wants to Put an End to GMOs»; Testbiotech, «New Genetic Engineering: EU Commission Proposal for New Regulation Endangers Nature, the Environment and Our Future Livelihoods»; footnote 42 and the references cited therein).

[35] Even scientific organizations, scholars and EU bodies strongly advocating in favour of the Proposal recognize, somewhat and at least to a certain extent, the *ambiguity* and complexity of Annex I. Thus, AFBV and WGG stess that «[i]*t is important that these criteria* [i.e., the «[c]*riteria for classifying NGT plants as category 1 (NGT-1) – (Annex I)*»] *be simple, precise and clear*.» AFBV and WGG, «Detailed Comments on the Commission's Proposal for NGT Plants», 1. *See also* AFBV and WGG, 1-5; Rognli, «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», 3-4; EPSO, «Proposal for a Regulation of the European Parliament and of He Council on Plants Obtained by Certain New Genomig Techniques Ad Their Food and Feed, and Amending Regulation (EU) 2017/625 [5 Novemeber 2023]», 2; Vanderschuren et al., «A New Chance for Genome Editing in Europe», 1379; European Parliament's Committee on the Environment Public Health and Food Safety, «DRAFT REPORT on the Proposal for a Regulation of the European Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and Amending Regulation (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – (2023)0226(COD)», 18-19 (*Amendments* 22 and 23); Testbiotech, «New Genetic Engineering: EU Commission Proposal for New Regulation Endangers Nature, the Environment and Our Future Livelihoods», 8; COPA-COGECA, «Position Paper on the Commission's proposal on plants obtained by certain new genomic techniques (NGTs) and their food and feed, and amending Regulation (EU) 2017/625[.] 16th October 2023», 4; Jorasch, «Resurrection of Plant Breeding Innovation in the EU?»; EPSO, «Proposal for a Regulation of the European Parliament and of He Council on Plants Obtained by Certain New Genomig Techniques Ad Their Food and Feed, and Amending Regulation (EU) 2017/625 [5 Novemeber 2023]», 1-2; Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1351; footnote 13 and text to footnote 13.

[36] *See* Zimny, «New Genomic Techniques and Their European Union Reform. Potential Policy Changes and Their Implications», 5 and footnotes 38, 39, and text to footnotes 38, 39.

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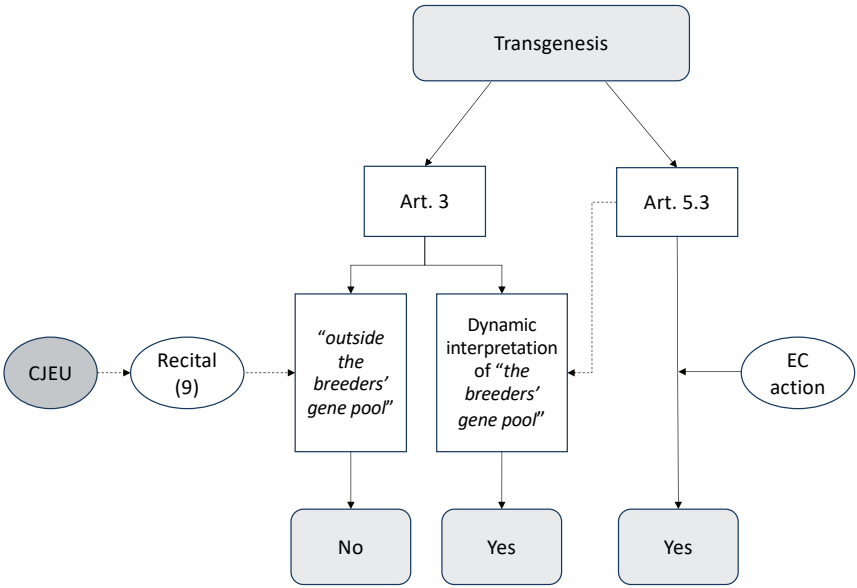
Fig. 1. Potential coverage of *transgenesis* by the European Commission's Proposal on NGTs (COM(2023) 411 final) depending on the interpretative pathways adopted and on whether further action is taken by the European Commission. It must be reminded that the interpretative path of Art. 3 favourable to the inclusion of transgenesis is not the most reasonable one, and, in fact, it is limited by the recital (9) of the proposal itself; but it shows the potential cracks existing in the proposed legislation, the exploitation of which, by sectors opposed to the new biotechnology, might end up compromising its success, and, consequently, innovation in this field



Source: Own elaboration.

After the implementation of the Proposal on NGTs, the EU regulatory framework on GMOs will not only be more ambiguous, but also more «*complex*»[37] due to the new *categories of NGT plants*[38]. The risk of confusing

[37] According to Dima et al.: «[…] *the introduction of the two additional categories of plants creates a relatively complex regulatory situation.*» Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1352. *See also* Zimny, «New Genomic Techniques and Their European Union Reform. Potential Policy Changes and Their Implications», 6, and footnote 38.

[38] Envisaged by Zimny as early as 2022: «*Should the EU succeed in adopting a new legislation* […]*, the formal situation of researchers will become more complicated than*

farmers and, above all, end consumers is not negligible[39]. Consumer reaction against *NGT plants* and *products*[40], and, in general, of GM crops, could be an unintended consequence[41], which could in turn hamper innovation in plant breeding and agriculture in the EU, even triggering a backlash against the regulation itself[42]. This, in a context where GMOs' consumer rejection

currently. Instead of having to consider three categories of organisms, as is currently the case [non-GMOs, regulated GMOs and GMOs exempted from legislation (Custers, 2017)] they may need to consider several additional categories–various NGT products that will legally be GMOs with an altered level of regulation.» Zimny, «New Genomic Techniques and Their European Union Reform. Potential Policy Changes and Their Implications», 6.

[39] According to Zimny «[t]*he adoption of this policy option* [i.e., «*an exemption of some products from the regulation*»; Zimny, 5]*, even for a limited group of plants, would however have some significant drawbacks. Firstly the official control over such products would be much lower than in the remaining scenarios discussed here. Transparency, particularly perceived by the general population would also suffer, with lack of official oversight and reporting or labelling duties.*» Zimny, 5. A Nature Plants' Editorial goes even further, by stating that «*category 1 plants pose a threat to markets that have developed around a 'GMO-free' label, as possible contamination is not sufficiently traceable to the production process*» (Nature Plants, «EU Rethinks Genome Editing», 1169) and that «[a]*s long as the broad public does not agree on the definition of a GMO, markets based on a GMO-free label will try to defend their grounds against any technology*» (Nature Plants, 1170).

[40] As reported by infOGM –«*Association loi de 1901, Inf'OGM est une veille citoyenne qui décrypte l'actualité mondiale et propose un service unique d'information francophone sur les OGM, les biotechnologies et, depuis 2013, également sur les semence*»; infOGM, «Mission et Valeurs» (2013), https://www.infogm.org/spip.php?page=spipdf&spipdf=spipdf_article&id_article=5517&nom_fichier=infogm-article-5517, some European consumer associations have already spoken out against the proposal. *See*: Eric Meunier and Hervé Le Meur, «Une Large Gamme d'acteurs Opposés à La Dérèglementation Des» *infOGM* (2023), https://www.infogm.org/7899-une-large-gamme-d-acteurs-opposes-a-la-dereglementation-des-ogm?lang=fr; Noisette, «GMOs/NGTs: Consumers Want a Choice».

[41] According to Zimny: «*This* [such a «*policy option*»; Zimny, «New Genomic Techniques and Their European Union Reform. Potential Policy Changes and Their Implications», 5 and footnote 39] *might lower the trust in the biosafety system as such.*» Zimny, 5. In fact, as noted by Vanderschuren et al.: «*During preliminary discussions at the European Council*[…]*, some member states have asked for the ability to ban the cultivation of specific NGT plants in their territories.*» Vanderschuren et al., «A New Chance for Genome Editing in Europe», 1379.

[42] For some critical voices, *see* the already cited: Meunier and Le Meur, «Une Large Gamme d'acteurs Opposés à La Dérèglementation Des»; newgmo.org, «Open Letter: Serious Concerns about the EU Commission Proposal on New Genomic Techniques»; Noisette, «GMOs/NGTs: Consumers Want a Choice»; Testbiotech, «New Genetic Engineering: EU Commission Proposal for New Regulation Endangers Nature, the Environment and Our Future Livelihoods». *Also*, IFOAM-Organics Europe, «NGT Proposal a

appears to be declining in the EU[43], would be particularly unfortunate. Furthermore, even passing and succeeding also at the implementation level, the Proposal might[44] block or significantly defer a needed[45] deep reform of the EU legal regime on GMOs.

III. THE EUROPEAN COMMISSION'S PRM PROPOSAL

In addition to the regulatory regime outlined above, new *NGT plant* varieties will have to comply with further regulatory requirements under the new European Commission's «*PRM proposal*»[46] (COM(2023) 414 final)[47]. This

Step Backward for Biosafety, Freedom of Choice» 2023, https://www.organicseurope.bio/news/ngt-proposal-a-step-backward-for-biosafety-freedom-of-choice-and-consumers-information/.

[43] Cf. European Commission, «Special Eurobarometer 334» (Brussels, 2010), https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/reporten.pdf; European Commission, «Special Eurobarometer Wave EB91.3» (Brussels, 2019), https://doi.org/10.2805/661752. Such a development is also in line with the «*increasingly positive attitudes towards NGT use* […]» reported by EPSO, «EPSO First Reaction to the European Commission's Legal 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», 1.

[44] A fear apparently shared also by the *Association Française des Biotechnologies Végétales* and the *Wissenschaftlerkreis Grüne Gentechnik e.V.*: «We suggest deletion of the sentence: "Moreover, there is no indication that current requirements in the Union GMO legislation for GMOs obtained by transgenesis need adaption at the present time." *How transgenesis is regulated is not the subject of the current mandate but this topic remains heavily debated.* […] *For many years, many stakeholders and EFSA have been asking for an adjustment of the studies to be carried out depending on the nature of the GM plant. Flexibility must be introduced and the systematic need for animal feeding experiments revisited. The treatment of transgenesis could be the subject of a future specific revision.*» AFBV and WGG, «Detailed Comments on the Commission's Proposal for NGT Plants», 6. Whether the Proposal on NGTs will end working as a catalyst for the loosening of GMO rules in the EU or rather as a brake remains to be seen; but, certainly, the rhetoric used in recital (9) of the Proposal is not an encouraging sign.

[45] *See*, generally, Mehta, «EU Proposal on Gene-Edited Crops Doesn't Go Far Enough». *Also* Vives-Vallés and Collonnier, «The Judgment of the CJEU of 25 July 2018 on Mutagenesis: Interpretation and Interim Legislative Proposal», 13.

[46] European Commission, «Frequently Asked Questions: New Rules for Improved Plant and Forest Reproductive Material».

[47] Indeed, as observed by COPA-COGECA: «*6) The Plant Reproductive Material and the Forest Reproductive Material pieces of legislation are closely interlinked with the NGT regulation. The proposed regulation on NGT plants alone is not sufficient to allow European farmers to obtain access to improved plant and forest reproductive materials (PRM/FRM). PRM and FRM must be tested, certified and registered according to the PRM/FRM Regulation to be placed on the EU market as plant varieties.*» COPA-COGECA, «Position Paper on the Commission's proposal on plants obtained by certain new

proposal turns current «*Value for cultivation and use ('VCU')*»[48] trials ant tests into «*value for sustainable cultivation and use (VSCU)*» ones[49], which will not be restricted to *agricultural* species, but will also cover *fruits* and *vegetables*[50].

As acknowledged by the European Commission, such a reform «*presents considerable economic costs for operators and competent national authorities*»[51]. Paradoxically, as the European Commission also points out, «[p]*lant breeders and most competent national authorities recognised that the current VCU requirements for agricultural plant species already contribute to this objective, as they allow for the acceptance of varieties with characteristics such as disease resistance, nutrient efficiency, drought tolerance and increased yield*[…]»[52]. In other words, the new *VSCU* setting will pose a new barrier to the industry. And, since such a scheme will «*not apply to* […] *PRM produced for export to third countries*»[53], European farmers and end consumers will pay de price.

IV. CONCLUSIONS

It can be concluded that although the Proposal on NGTs presents interesting advantages[54], its ambiguity[55] and complexity[56] make its implementation

genomic techniques (NGTs) and their food and feed, and amending Regulation (EU) 2017/625[.] 16th October 2023», 3. *See also* COPA-COGECA, 4.

[48] European Commission, «Proposal for a Regulation of the European Parliament and of the Council on the Production and Marketing of Plant Reproductive Material in the Union (COM(2023) 414 Final)», 6.

[49] European Commission, 13.

[50] European Commission, 13.

[51] European Commission, 9.

[52] European Commission, 6.

[53] Article 2(4)(c) of the European Commission's PRM Proposal (COM(2023) 414 final). «*Copa and Cogeca want the NBT plant regulation to pursue the following objectives:*

[…]

d) It must avoid distortion within the EU and between the EU and imported products despite the impossibility of analytically detecting the production technique for most of the agricultural products obtained. The regulation must be compatible with third countries' legislation and not lead to significant product divergence, nor cause any market disruption or additional bureaucracy. Divergent legislation must not put the EU at a disadvantage.» COPA-COGECA, «Position Paper on the Commission's proposal on plants obtained by certain new genomic techniques (NGTs) and their food and feed, and amending Regulation (EU) 2017/625[.] 16th October 2023», 3. The fact is that the same could have been said of the European Commission's PRM Proposal, but COPA-COGECA in such a statement only refers to the European Commission's Proposal on NGTs.

[54] *See* footnote 5.

[55] *See* footnotes 13, 35 and all the references there acknowledged.

[56] *See* Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1352; Zimny, «New Genomic Techniques and Their European

challenging[57], especially in terms of consumer acceptance[58], which, contrary to the widespread enthusiasm within the scientific community, might end hampering the implementation of proposal itself, ultimately affecting innovation in plant breeding and agriculture. Chances of success would be further increased if, as suggested[59], the Proposal is simplified, especially as regards the «*NGT plants*» concept and «*category 1 NGT plants*». Efforts should be devoted to promoting consensus among the different interests in the EU, thus reducing the risks of a backlash from factions against science and biotechnology in plant breeding. The PRM Proposal may exacerbate those risks, by adding new and likely unnecessary costs. Considering the foregoing, an in-depth reform of the EU regulatory framework on GMOs would have been preferable to just patching it, even if significantly, through the Proposal on NGTs. The bright side of it is that there is still room within the legislative procedure ahead to improve the Proposal on NGTs. But what should still be promoted without fail is the drafting of a new PRM proposal, this time with a greater involvement of breeders, farmers, and specialized EU agencies and Member States' bodies, to achieve a PRM regulation with fewer inefficiencies.

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Union Reform. Potential Policy Changes and Their Implications», 6; footnotes 29, 37, 38 and text to footnotes 29, 37, 38.

[57] Already foreseen by Zimny, «New Genomic Techniques and Their European Union Reform. Potential Policy Changes and Their Implications». *See*, particularly, Zimny, 5-6; Dima et al., «EU Legal Proposal for Genome-Edited Crops Hints at a Science-Based Approach», 1352; footnotes 37, 38, 39, 41 and text to those footnotes in this paper.

[58] *See* Nature Plants, «EU Rethinks Genome Editing», 1169-1170; footnote 39 and text to footnote 39.

[59] *See* AFBV and WGG, «Detailed Comments on the Commission's Proposal for NGT Plants», 1; footnotes 13, 35 and all the references therein.

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