Gutachten zur Vereinbarkeit des EU-Vorschlags für eine Verordnung über mit bestimmten neuen genomischen Techniken (NGT) gewonnenen Pflanzen mit dem Cartagena Protokoll über die biologische Sicherheit

Compatibility of the EU proposal for a regulation on plants based on certain new genomic techniques with the Cartagena Protocol on Biosafety

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April 2025

Inhaltsübersicht

Zusammenfassung

Die Europäische Kommission (KOM) hat neue Vorschriften für Pflanzen vorgeschlagen, die mit bestimmten neuen genomischen Techniken gewonnen wurden (NGT-Pflanzen), und beabsichtigt, diese von herkömmlichen genetisch veränderten Organismen (GVO) zu unterscheiden. Die zentrale Fragestellung dieses Gutachtens ist, ob der vorliegende Vorschlag, der 2023 von der KOM veröffentlicht wurde, in der revidierten Fassung, wie sie im Februar 2024 im Rat der Europäischen Union diskutiert wurde (Ratsversion), mit dem *Cartagena Protokoll über die biologische Sicherheit zum Übereinkommen über die biologische Vielfalt* im Einklang steht. Dieses völkerrechtlich bindende Abkommen regelt die grenzüberschreitende Verbringung lebender veränderter Organismen (LMOs), um die biologische Vielfalt und die menschliche Gesundheit zu schützen. Es wird argumentiert, dass die Ratsversion bezüglich der Deregulierung sogenannter NGT-1-Pflanzen **in mehreren Aspekten nicht mit dem Cartagena Protokoll vereinbar** ist. In dem vorliegenden Gutachten wird die Notwendigkeit betont, dass die EU ihre neuen Vorschriften an ihre völkerrechtlichen Verpflichtungen anpasst, um die Biosicherheitsstandards des Cartagena Protokolls zu wahren und gleichzeitig wissenschaftlichen und technologischen Fortschritt zu ermöglichen.

Der KOM-Vorschlag unterscheidet zwei Kategorien: **NGT-1-Pflanzen** unterliegen weitgehender Deregulierung, sofern sie bestimmte Äquivalenzkriterien mit konventionell gezüchteten Pflanzen erfüllen, die im Vorschlag definiert sind. Diese Klassifizierung basiert auf genetischen Modifikationsgrenzwerten. **NGT-2-Pflanzen** sind alle NGT-Pflanzen, die diese Kriterien nicht erfüllen; sie bleiben unter der bestehenden EU-GVO-Gesetzgebung mit gewissen prozeduralen Anpassungen strikt reguliert.

Eine zentrale rechtliche Frage ist, ob NGT-Pflanzen, wie sie in der Ratsversion definiert sind, als LMOs im Sinne des Cartagena Protokolls einzustufen sind. LMOs sind im Cartagena Protokoll definiert als jeder lebende Organismus *„der eine neuartige Kombination genetischen Materials aufweist, die durch die Nutzung moderner Biotechnologie erzielt wurde“.* In dem vorliegenden Gutachten wird dargelegt, dass NGT-Pflanzen gemäß der Definition im Cartagena Protokoll als LMOs anzusehen sind, da sie *„moderne Biotechnologie“* nutzen und die angewandten Techniken grundsätzlich in der Lage sind, genetische Veränderungen herbeizuführen, die mit natürlichen Reproduktions- und Rekombinationsmechanismen nicht erzielt werden können. Zudem erfordert der vorsorgeorientierte Ansatz des Cartagena Protokolls eine weite Auslegung, sodass NGT-Pflanzen den Verpflichtungen unterliegen sollten, unabhängig davon, ob sie fremde DNA enthalten. Da die Praxis der Vertragsparteien bisher inkohärent ist, kann - nach den Vorgaben der Wiener Vertragsrechtskonvention - auch nicht von einer abweichenden Auslegung des Cartagena Protokolls ausgegangen werden, die bestimmt wird durch die Staaten, die NGT-1-Pflanzen in ihrer nationalen Gesetzgebung oder Praxis deregulieren.

Für Organismen, die als LMOs einzustufen sind, schreibt das Cartagena Protokoll drei zentrale Maßnahmen vor: (1) Risikobeurteilungen, (2) Anmelde- und Mitteilungspflichten, sowie (3) Kennzeichnungsvorgaben, insbesondere für die beabsichtigte grenzüberschreitende Verbringung von LMOs. Die Ratsversion kann hinsichtlich der Risikobeurteilungen (1) noch als konform mit dem Cartagena Protokoll betrachtet werden, da es wissenschaftlich vertretbar ist, Risiken von NGT-1-Pflanzen als Fallgruppe zu bestimmen und anschließend zu überprüfen, ob eine spezifische Pflanze anhand vordefinierter Kriterien in diese Gruppe fällt. Allerdings **verstößt die Ratsversion gegen das Cartagena Protokoll in Bezug auf die Anmelde- und Mitteilungspflichten sowie die Kennzeichnungspflichten,** da sie NGT-1-Pflanzen von diesen Anforderungen ausnimmt. Sie enthält keine Mechanismen zur Sicherstellung der in den Artikeln 8 und 11 des Cartagena Protokolls festgelegten Anmelde- und Mitteilungspflichten (2) gegenüber anderen Vertragsstaaten in Bezug auf NGT-1-Pflanzen. Zudem entfällt die Pflicht zur Kennzeichnung (3) von NGT-1-Pflanzen und deren Produkten, mit Ausnahme der begrenzten Kategorie von Pflanzenvermehrungsmaterial, das NGT-1-Pflanzen enthält oder aus ihnen besteht. Dies steht im Widerspruch zu Artikel 18 des Cartagena Protokolls.

Um die Einhaltung des Cartagena Protokolls sicherzustellen, sollte eine zukünftige EU-Verordnung folgende Elemente enthalten: **Beibehaltung der Anmelde- und Mitteilungspflichten für NGT-1-Pflanzen** gemäß den Anforderungen des Cartagena Protokolls; **Verpflichtung zur Kennzeichnung aller NGT-1-Pflanzen und ihrer Produkte**, einschließlich der Pflicht zur Gewährleistung ihrer Rückverfolgbarkeit innerhalb der EU.

Executive Summary

The European Commission (COM) has proposed new regulations for plants obtained by certain new genomic techniques (NGT plants), aiming to differentiate them from traditional genetically modified organisms (GMOs). The key question addressed in this opinion is whether the COM proposal, published in 2023, in its revised version as discussed in the Council of the European Union in February 2024 (Council version), aligns with the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, a binding international agreement regulating the transboundary movement of living modified organisms (LMOs) to protect biological diversity and human health. It is argued that the Council version **fails to comply with the Cartagena Protocol in several areas** in its approach to deregulate so-called NGT 1 plants. This opinion underscores the need for the EU to align its new regulations with its international law obligations, preserving the Cartagena Protocol's biosafety standards while fostering scientific and technological advancement:

The COM proposal establishes a new regulatory framework for NGT plants. It classifies them into two categories: **NGT 1 plants** are subject to far-reaching deregulation if they meet specific criteria of equivalence with conventionally bred plants defined by the proposal. The classification hinges on genetic modification thresholds. **NGT 2 plants** are all NGT plants that do not fulfil these criteria, and they remain under the existing EU GMO legislation with some procedural modifications.

A key legal question is whether NGT plants, as defined in the Council version, qualify as LMOs under the Cartagena Protocol. The Cartagena Protocol applies to all LMOs, defined as *"living organism[s] that [possess] a novel combination of genetic material through the use of modern biotechnology."* The opinion finds that NGT plants as defined in the Council version meet the definition of LMOs as defined in the Cartagena Protocol because they involve *"modern biotechnology"* and the techniques used are in principle capable of achieving genetic changes that cannot be achieved with natural reproduction and recombination mechanisms. Besides, the Cartagena Protocol's precautionary approach requires a broad interpretation, meaning that NGT plants should be subject to its obligations regardless of whether they contain foreign DNA. Since the practice of the contracting parties has been inconsistent so far, no divergent interpretation of the Cartagena Protocol can be assumed—under the provisions of the Vienna Convention on the Law of Treaties—based on the approach of states that deregulate NGT-1 plants in their national legislation or practice.

For organisms that qualify as LMOs, the Cartagena Protocol mandates three core requirements: (1) risk assessments, (2) notification and information obligations as well as (3) labeling requirements to ensure environmental and human safety, particularly for the intentional transboundary movements of LMOs.

The Council version can be seen to comply with (1) the obligations of the Cartagena Protocol on risk assessment, as it is scientifically justifiable to determine risks associated with NGT 1 plants as a group of cases and then to verify, on the basis of pre-determined criteria, whether a specific plant falls within this group.

However, the Council version **fails to comply with the Cartagena Protocol regarding the notification and information obligations as well as labeling requirements,** as it removes NGT 1 plants from the scope of these obligations. The Council version provides no mechanism to ensure (2) notification and information to other States Parties as mandated by Arts 8 and 11 Cartagena Protocol regarding NGT 1 plants. The Council version also eliminates (3) mandatory labeling for NGT 1 plants and their products, except for the limited category of plant reproductive material containing or consisting of NGT 1 plants, contradicting Art. 18 Cartagena Protocol. Therefore, the Council version, through the deregulation of NGT 1 plants in its current form, violates the Cartagena Protocol.

To ensure compliance, a future EU regulation should maintain **notification and documentation requirements** for NGT 1 plants under the conditions set out in the Cartagena Protocol; and it should require **labeling** of all NGT 1 plants and their products, which includes the obligation to ensure their traceability within the EU.

I. Introduction

There is an ongoing debate about the proportional regulation of plants obtained by certain new genomic techniques (in the following: NGT plants), especially in the European Union (EU).

The European Commission (COM) published, in 2023, a 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"* (in the following: COM proposal).[1] It was drafted after a study commissioned by the COM from 2021 saw *"strong indications"* that the current EU legislation on genetically modified organisms *"is not fit for purpose for some NGTs and their products, and that it needs to be adapted to scientific and technological progress."*[2]

Beginning of 2024, the Belgian Presidency of the Council of the European Union proposed a revised version as a draft mandate of the Council for negotiations with the European Parliament (EP) and the COM (trilogue).[3] The original title was therein changed to *"Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their products ~~food and feed~~, and amending Regulation (EU) 2017/625".*The present opinion will be based on this draft Council version of the COM proposal (in the following: Council version). A newly revised version of this draft Council mandate, proposed by the Polish Presidency, was accepted by the EU member states in March 2025 with no changes to the parts relevant for this opinion, compared to the draft version from early 2024. Major changes of the EP as compared to the text proposed by the COM are also taken into account. This opinion analyses whether and in which regard the Council version is compatible or incompatible with the relevant international law treaty in this field, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity[4] (Cartagena Protocol).

The EU and all EU Member States, including Germany, are Parties to the Cartagena Protocol.[5] The EU regulation must therefore comply with the requirements set out in the Cartagena Protocol. This also follows from Art. 216(2) of the Treaty on the Functioning of the European Union[6] (TFEU) which stipulates that international agreements concluded by the EU are binding on its institutions and on the Member States. This means that secondary EU legislation must conform to and be interpreted in light of such international treaties.[7]

Following an overview of the content of the Council version (II) and of the regulatory framework of the Cartagena Protocol (III), the present analysis proceeds in two steps: *first,* to determine whether NGT plants, as defined in the Council version, fall within the scope of application of the Cartagena Protocol (IV) and, *second*, if so, whether the rules applicable to NGT plants

[1] 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, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0411.

[2] European Commission, Commission Staff Working Document SWD(2021) 92 final, Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16 (29 April 2021) 59 et seq.

[3] Council of the European Union, 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 – (draft) Mandate for negotiations with the European Parliament, ST 16714 2023 INIT, available at https://data.consilium.europa.eu/doc/document/ST-16714-2023-INIT/en/pdf.

[4] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (adopted 29 January 2000, entered into force 11 September 2003), 2226 UNTS 208.

[5] UN Office of Legal Affairs, Status of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, UNTS, available at https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-a&chapter=27&clang=_en#7.

[6] Treaty on the Functioning of the European Union, 115 OJ 144, 9 May 2008.

[7] See European Court of Justice, Case C-265/19, *Recorded Artists Actors Performers Ltd* [2020] ECLI:EU:C:2020:677, para. 62.

under the Council version, especially those dealing with the extensive deregulation of so-called NGT 1 plants, comply with the substantive provisions of the Cartagena Protocol (V). Lastly, the opinion proposes changes to ensure compliance of the EU regulation with the Cartagena Protocol that are outlined at the end (VI).

II. Council version of the COM proposal on the regulation of NGT plants and context

Currently, NGT plants and their products are regulated as genetically modified organisms (GMOs) by five legislative acts of the EU: (first) the Directive 2001/18/EC,[8] (second) the Regulation (EC) No 1829/2003, in the case of food and feed obtained from these plants, (third) [9] the Regulation (EC) No 1830/2003,[10] (fourth) the Regulation (EC) No 1946/2003[11] in the case of transboundary movements to third countries and (fifth) the Directive 2009/41/EC[12] in the case of the contained use of plant cells. These acts in particular provide for a strict authorisation procedure including a comprehensive environmental risk assessment,[13] as well as notification, identification and labelling requirements.

The COM proposal[14] and the Council version[15] aim to deregulate the current EU legislation on GMOs by establishing the new category of plants obtained by certain new genomic techniques (NGT plants). It contains specific rules for the placing on the market of food and feed or other products containing, consisting of, or produced from such plants, and for deliberate release into the environment for any other purpose than placing on the market, in particular research field trials.[16]

Last year, the EP agreed on amendments to this COM proposal.[17] Where relevant, these amendments are briefly discussed in this opinion. In February 2024, the European Economic

[8] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2001] OJ L 106/1, available at http://data.europa.eu/eli/dir/2001/18/oj.

[9] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2003] OJ L268/1, available at http://data.europa.eu/eli/reg/2003/1829/oj.

[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 [2003] OJ L268/24, available at http://data.europa.eu/eli/reg/2003/1830/oj.

[11] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms [2003] OJ L287/1, available at http://data.europa.eu/eli/reg/2003/1946/oj.

[12] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms [2009] OJ L125/75, available at http://data.europa.eu/eli/dir/2009/41/oj.

[13] Under current EU GMO legislation, when the deliberate release of a GMO or the placing on the market of GMO products is pursued, the applicant is obligated to carry out an environmental risk assessment before the submission of his application (Art. 4 (2) Directive 2001/18/EC). The aim of this assessment is to identify and evaluate, on a case-by-case basis, any direct, indirect, immediate or delayed adverse effects of GMOs on human health and the environment that may arise from the deliberate release or placing on the market of GMOs (Annex II, Section A of Directive 2001/18/EC). It contains a qualitative and – where possible – quantitative assessment of the overall risk posed by the GMO, enabling the competent authority to gain an overview of the risks posed by the GMO and to take appropriate precautionary measures, up to and including rejecting the application (Art. 4 (1)–(4) and Annex II, Section C.3 No.6 and Section D of Directive 2001/18/EC). For a comprehensive overview of this procedure and an assessment by the author cf. *Schreiber*, Recht und Ethik der Risikoregulierung in der Grünen Gentechnik (2023) 228–252.

[14] See above (n 1).

[15] See above (n 3).

[16] *Kahrmann/Leggewie*, European Commission's Plans for a Special Regulation of Plants Created by New Genomic Techniques, 9(1) European Papers 2024, 21, available at https://doi.org/10.15166/2499-8249/740, 23.

[17] European Parliament, Texts Adopted (7 February 2024), P9_TA(2024)0067, available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=EP%3AP9_TA%282024%290067, confirmed at first reading (24 April 2024).

and Social Committee[18] and in June 2024, the European Committee of the Regions[19] recommended amendments to the COM proposal. Currently, in March 2025, the Council, under the Polish Presidency, accepted a revised version of the Council version from February 2024 as mandate for negotiations with the EP.[20] The negotiations between the Council, EP and COM about the final text of the regulation are soon to begin. Depending on progress, Denmark, as the next Presidency after Poland, might continue the negotiations for the Council from July 2025.[21]

1. ECJ´s judgment in case C-528/16 (*Confédération paysanne*)

In its 2018 judgment in case C-528/16,[22] the European Court of Justice (ECJ) ruled that organisms obtained by the techniques of targeted mutagenesis (such as CRISPR-Cas9) fall under the definition of GMO within the meaning of Directive 2001/18/EC. This means that gene-edited crops are subject to the same strict regulations as traditional GMOs in the EU and are subject to the authorisation procedure under the current EU GMO legislation.[23] The ECJ argued that concerning the organisms obtained by the techniques of targeted mutagenesis the *"risks for the environment or for human health have not thus far been established with certainty."*[24] The ECJ also relies on the precautionary principle in this decision,[25] which is enshrined as a guiding principle in Art. 1 of Directive 2001/18/EC and part of EU law.[26] Many scientists and companies opposed the decision, arguing that it failed to recognize the fundamental difference between those old genetic modification techniques which introduce foreign DNA and new gene-editing methods. Also some EU Member States expressed concern that this ruling would put European farmers at a disadvantage compared to other countries, where gene-editing is not regulated as strictly as GMOs in the EU.[27]

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[18] Opinion of the European Economic and Social Committee - New genomic techniques (6 February 2024) C/2024/893, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52023AE3330.

[19] Opinion of the European Committee of the Regions – New genomic techniques and plant reproductive materials (26 June 2024) OJ C/2024/3674, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C_202403674; for an overview about the legislative process cf. Procedure 2023/0226/COD, available at https://eur-lex.europa.eu/procedure/EN/2023_226.

[20] Council of the European Union, 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 – Mandate for negotiations with the European Parliament, ST 6426 2025 INIT, available at https://data.consilium.europa.eu/doc/document/ST-6426-2025-INIT/en/pdf.

[21] See Council Decision (EU) 2016/1316 of amending Decision 2009/908/EU, laying down measures for the implementation of the European Council Decision on the exercise of the Presidency of the Council, and on the chairmanship of preparatory bodies of the Council [2016] OJ L208/42 (44).

[22] European Court of Justice, Case C-528/16 *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt* [2018] ECLI:EU:C:2018:583.

[23] ECJ (n 22) paras 38, 54. For a detailed analysis of the court´s judgment cf. *van der Meer* et al., The Status under EU Law of Organism Developed through Novel Genomic Techniques, 14(1) Eur. J. Risk Regul. 2023, 93, available at https://doi.org/10.1017/err.2020.105, 96–104; *Schreiber*, Recht und Ethik der Risikoregulierung in der Grünen Gentechnik (2023) 85–101.

[24] ECJ (n 22) para. 47.

[25] ECJ (n 22) paras 50–53.

[26] Art. 191 (2) TFEU: "*Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.*".

[27] Cf. instead of many *van der Meer* et al. (n 23), 103f; *Voigt*, EU regulation of gene-edited plants – A reform proposal, 5 Front. Genome Ed. 2023, available at https://doi.org/10.3389/fgeed.2023.1119442; *Nationale Akademie der Wissenschaften Leopoldina/Union der Deutschen Akademien der Wissenschaften/Deutsche Forschungsgemeinschaft*, Statement – Towards a scientifically justified, differentiated regulation of genome edited plants in the EU (2019), 58–60. For a comprehensive discussion of the various reform proposals cf. *Schreiber/Andersen*, European GMO Regulation in Need of Change? Ways to the Future Regarding the Risk Regulation of Genome Editing Techniques, 20(4) EurUP 2022, 443.

2. Council version of the COM proposal

Since this ruling, the COM has explored potential regulatory changes to allow for flexible rules for gene-edited crops. As mentioned above, the COM proposal and Council version suggest the deregulation for certain gene-edited crops, differentiating them from traditional GMOs. A key aspect of the Council version is the differentiation of different so-called NGT plants. Most importantly, "category 1 NGT plants" (in the following: NGT 1 plants) shall be excluded from the current GMO legislation (Art. 5 (1) Council version). Concerning "category 2 NGT plants" (in the following: NGT 2 plants) minor adjustments to the existing authorisation procedure shall be established (Arts 12–23 Council version). Nevertheless, NGT plants are not allowed in organic production according to the Council version (Arts 5 (2), 12 Council version).[28]

Before spelling out the new rules covering NGT 1 and NGT 2 plants according to the Council version, it shall be clarified how NGT plants are defined.

a) NGT plants

The Council version states as a definition that:

> "*'NGT plant' means a ~~genetically modified~~ plant obtained by* ***targeted mutagenesis or cisgenesis****, or a combination thereof, on the condition that it does not contain any* ***genetic material originating from outside the breeders' gene pool*** *that temporarily may have been inserted during the development of the NGT plant*" (Art. 3 (2) Council version, **bold emphasis added**).[29]

The key notions of *"targeted mutagenesis or cisgenesis"* as well as *"genetic material originating from outside the breeders' gene pool"* are discussed in the following:

(1) Targeted mutagenesis and cisgenesis

Targeted mutagenesis within this meaning is defined by the proposal as "*mutagenesis techniques resulting in modification(s) of the DNA sequence at ~~precise~~ targeted locations in the genome of an organism*" (Art. 3 (4) Council version). Examples for targeted mutagenesis are zinc finger nucleases,[30] transcription activator-like effector nucleases (TALENs)[31] and – most prominent and widely used – the CRISPR-Cas techniques,[32] together with related techniques such as base and prime editing.

Cisgenesis is defined as "*techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool"* (Art. 3 (5) sentence 1 Council version). Cisgenesis in the sense of this definition involves – in contrast to targeted mutagenesis – the insertion of genetic material from another plant that belongs to the same "*breeders´ gene pool*" as the modified plant.[33] The genetic material may be

[28] Arts 5 (f) (iii), 11 Regulation 2018/848 continue to apply, which state a full prohibition of GMOs, and products produced from them or by them, in the organic production. Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 [2018] OJ L150/1, available at http://data.europa.eu/eli/reg/2018/848/oj; criticising this *Winter*, The European Union's deregulation of plants obtained from new genomic techniques: a critique and an alternative option, 36 Environ. Sci. Eur. 2024, Article no 47, available at https://doi.org/10.1186/s12302-024-00867-z, 11.

[29] Deletions and underlines are part of the draft proposal, here and in following citations.

[30] Cf. *Beck*, Self-Spreading Biotechnology and International Law (2022) 59–60; *Berlincourt-Heinecke*, Chancen und Risiken von Pflanzeninnovationen im Recht (2016) 36–37 with further references.

[31] Cf. *Beck* (n 30) 60–61 with further references.

[32] Cf. *Schreiber* (n 13) 66–68 with further references; *Beck* (n 30) 61–64.

[33] An example of plants modified with cisgenesis are field studies with a cultivar apple, which was genetically modified with genes from a wild apple species containing fire-blight-resistance, cf. *Kost* et al., Development of the First Cisgenic Apple with Increased Resistance to Fire Blight (2015), PLoS One 10 (12), e0143980.

incorporated in two different ways, either as "*a continuous (exact) copy*", which is labelled in the proposal as "*cisgenesis in the strict sense*", or as "*a re-arranged copy of sequences already present in the breeders´ gene pool*", which is labelled as "*intragenesis, also considered a subset of cisgenesis in a broader sense"* (Art. 3 (5) sentence 2 Council version).

The main purpose of restricting the NGT definition to targeted mutagenesis and cisgenesis is, according to the COM, to exclude other genomic techniques involving the insertion of genetic material from non-crossable species,[34] e.g., transgenic techniques.[35] In addition, techniques involving the fusion of cells, like the protoplast fusion,[36] are also excluded from the definition of NGTs by this restriction to targeted mutagenesis and cisgenesis.

Nevertheless, it is not clear whether the insertion of transgenic material is completely excluded by this NGT definition, as this depends on the definition of the term "*breeders' gene pool*".

(2) Exclusion of foreign genetic material (transgenes)

It is unclear what exactly is intended by the phrase that NGT plants must 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"* (Art. 3 (2) Council version). Since the scope of the Council version is restricted to NGT plants and food, feed and other products derived from them (Art. 2 Council version), a precise definition is crucial, especially concerning the question of whether or not the NGT plant could potentially contain foreign genetic material (transgenes). One can understand foreign genetic material (transgenes) in the context of genetic engineering as (natural, i.e. non-synthetic) genetic information from a different (sexually incompatible) species.[37] According to the express wording in Recitals (2) and (9) Council version, it seems clear that the insertion of genetic material from non-crossable species by transgenesis techniques is excluded from the scope of this proposed regulation:

> "[…] *Among NGTs, targeted mutagenesis and cisgenesis (including intragenesis) introduce genetic modifications without inserting genetic material from non-crossable species (transgenesis). They rely only on the breeders' gene pool, i.e. the total genetic information that is available for conventional breeding including from distantly related plant species that can be crossed by advanced conventional breeding techniques* […]*"* (Recital (2) Council version),
>
> "[…] *Such NGT plants do not carry genetic material from non-crossable species. GMOs produced by other new genomic techniques that introduce into an organism genetic material from non-crossable species (transgenesis) should remain subject only to the Union GMO legislation, given that the resulting plants might bear specific risks associated to the transgene* […]*"* (Recital (9) Council version).

This is reinforced by Art. 3 (2) Council version clarifying that genetic material originating from outside the breeders' gene pool that was temporarily inserted (most often in order to introduce the CRISPR-Cas system into the plan) must be completely removed (crossed out). Any remaining such material is sufficient to exclude a plant from the NGT plant definition. Nevertheless, it is unclear whether the insertion of foreign DNA is completely excluded according to this

[34] Cf. Recital (9) Council version.

[35] For a detailed description of these techniques in plant breeding cf. *Kumar Singh* et al., Transgenesis in Plants: Principle and Methods, in: Lakhan Singh/Mondal/Parihar/Kumar Singh (eds), Plant Genomics for Sustainable Agriculture (2022) 41–70.

[36] For a detailed description of this technique in plant breeding cf. *Mukundan/Satyamoorthy/Sankar Babu*, Advancing plant protoplasts: innovative techniques and future prospects, Plant Biotechnol. Rep. 2025 (published online 29 January 2025), available at https://doi.org/10.1007/s11816-025-00957-1; for a current example cf. *Ovcharenko/Rudas/Kuchuk*, Protoplast Fusion for Cellular Engineering of the Brassicaceae, 57 (5) Cytol. Genet. 2023, 432.

[37] Cf. for this definition of transgenes *Beck* (n 30) 109 with further references.

definition of NGT plants. This is important concerning the proposed deregulation of NGT 1 plants, as the insertion of foreign DNA can pose specific risks.

The Council version defines the notion of "*breeders' gene pool*" in Art. 3 (6). According to this "*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**). *Kahrmann/Leggewie* state that this definition is a *"rather extensive approach"*, *"compared to other hypothetical approaches to such a definition (e.g. limiting the breeders' gene pool to plants that can be cross-bred without the use of technology)".*[38] It is indeed convincing to argue that the definition is extensive as advanced breeding methods in current plant breeding may insert genetic material that originates from *"distantly related plant species"* (Recital (2) Council version). Some of these insertions may also include contributions from several originally incompatible species, e.g., by using the bridge crossing-technique, in which two incompatible plants species are crossed with each other via a third plant with which both species are compatible.[39]

Therefore, although the mentioned "*advanced techniques*" are classified as conventional breeding techniques,[40] the question remains whether there is a possibility to insert foreign genetic material within this definition of NGT plants according to Art. 3 (6) Council version.

In the end, the answer depends on the definition of the term "*taxonomic species*", and what exactly can be considered as *"alien species".*[41] Some might argue that these notions have to be defined by biologists as they spell out on how to determine species and species boundaries. However, it is more convincing to argue that every notion that is part of a regulation has to be determined in the context of the rule, its object and purpose. Therefore, an interpretation has to take into account the notions as used in biology but is not restricted to those definitions.[42]

For this opinion, it is not necessary to decide this dispute and it shall consider both possible answers. This means – on the one hand –, that the insertion of foreign DNA is *excluded* by the definitions of "*NGT plant*" and "*breeders´ gene pool*" in Art. 3 (2) and (6) Council version; and – on the other hand – that the insertion of foreign DNA is *not per se excluded* by the definitions of "*NGT plant*" and "*breeders´ gene pool*" in Art. 3 (2), (6) Council version.

b) Distinction between NGT 1 and NGT 2 plants

As written above, it is a core aspect of the COM proposal and the Council version that NGT plants are divided into the two categories of NGT 1 plants and NGT 2 plants (Art. 3 (7), (8) Council version). While NGT 2 plants remain subject to the (former) EU GMO

[38] *Kahrmann/Leggewie* (n 16) 23; similarly *Winter* (n 28) 5; *Spranger*, Expert Opinion on the proposal for a regulation on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (2023), available at https://www.bfn.de/sites/default/files/2023-11/spranger-expert-opinion-on-the-proposal-regulation-NGT-VO-E-2017-625-PAC2021_0.pdf, 8–9.

[39] Cf. *Messmer* et al., Plant Breeding Techniques – An assessment for organic farming (2015), 16.

[40] Cf. European Commission, *High Level Group of Scientific Advisors*, Explanatory Note 02/2017 – New Techniques in Agricultural Biotechnology (28 April 2017) 29–36.

[41] Concerning the discussion of the term *alien species* as stated in Art. 8 (h) Convention on Biological Diversity, cf. *Beck* (n 30) 209–212 with further references.

[42] There is not one final answer to this question, but rather different (biological as well as legal and philosophical) approaches to define species boundaries and taxonomic species; cf. *Hine*, Oxford Dictionary of Biology (8th edition, 2019), "*species*": "*A group of organisms that resemble each other more than they resemble members of other groups and cannot be subdivided into two or more species. The precise definition of what constitutes a species differs depending on which species concept is applied. According to the biological species concept, a species comprises a group of individuals that can usually breed among themselves and produce fertile offspring. However, many other species concepts have been proposed, including the phylogenetic species concept and various typological species concepts.* […]"; cf. also *Mayr*, The Growth of Biological Thought – Diversity, Evolution and Inheritance (1982) 251 et seq.; from a philosophical point of view, cf. *Ereshefsky,* 'Species', in Zalta (ed.), *The Stanford Encyclopedia of Philosophy* (Summer 2022 Edition), available at https://plato.stanford.edu/archives/sum2022/entries/species/.

legislation with minor amendments (Arts 12–23 Council version), NGT 1 plants are no longer subject to the previous GMO legislation and no authorisation procedure with risk assessment is applicable (Art. 5 (1) Council version).

The key question is how NGT 1 and 2 plants can be differentiated. According to Art. 3 (8) Council version, NGT 2 plant "*means a NGT plant other than a category 1 NGT plant*". Therefore, the definition of NGT 1 plants is decisive. According to Art. 3 (7) Council version, a NGT 1 plant is given if it:

> "*(a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, and does not include tolerance to herbicides among the intended traits conveyed by the genetic modification, or*
>
> *(b) is progeny of the NGT plant(s) referred to in point (a), including progeny obtained ~~derived~~ by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003*."

Through its reference to Annex I Council version, the crucial specification for the distinction between NGT 1 and NGT 2 plants are the so-called "*criteria of equivalence to conventional plants"* (besides the exclusion of herbicide tolerant plants from NGT 1 plants).[43] According to the COM, this "equivalence" of NGT 1 plants means that their risks are comparable to conventional plants, and hence they should be regulated in the same way.[44]

Annex I Council version states that a NGT plant "*is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications per monoploid genome of the types referred to in points 1 to ~~54~~, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.* [...]."

The genetic modifications spelled out in paragraphs (1)–(4) Annex I Council version are separated into criteria specific to the use of targeted mutagenesis and criteria specific to the use of cisgenesis. The latter completely excludes the possibility of plants obtained by the technique of intragenesis as a NGT 1 plant. According to a technical paper from the EU services, this exclusion of intragenesis from NGT 1 was already part of the COM version: "*Based on EFSA's conclusion that intragenic plants may entail additional hazards compared to conventionally bred plants intragenesis was excluded from the criteria by setting, under criterion 3, the two conditions of (i) no interruption of an endogenous gene and (ii) insertion of (criterion 3a) or substitution with (criterion 3b) a contiguous DNA sequence."*[45] In the Council version, it has now been made even clearer by the added description of "*cisgenesis in the strict sense"* in Art. 3 (5) sentence 2 as an incorporation of genetic material "*as a **continuous** (exact) copy*", which correspond to the (modified) requirements for the use of cisgenesis in Annex I, spelled out the "*~~targeted~~ insertion of a ~~contiguous~~ **continuous** DNA sequence […]"* (Annex I, paragraph (3)

[43] The differentiation by the EU Commission is based on the principle of *substantial equivalence* (to the conventional counterpart), which was first formulated by the *OECD Group of National Experts on Safety of Biotechnology* in 1993 (cf. *OECD*, Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles), and has since become established as a principle for the safety assessment of genetically modified food in international *soft law* and also in certain national regulation systems, particularly in the United States. Cf. *Berlincourt-Heinecke* (n 30) 179, 214 with further references; also *World Health Organization*, Safety aspects of genetically modified foods of plant origin – Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology (2000), WHO/SDE/PHE/FOS/00.6, 7–8; *Codex Alimentarius Commission*, Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants, CAC/GL 45-2003 paras 12–13.

[44] Cf. Recitals (12), (14) Council version.

[45] General Secretariat of the Council, Regulation on new genomic techniques (NGT) – Technical paper on the rationale for the equivalence criteria in Annex I (16 October 2023) 2023/0226(COD), 4.

(c)) as well as the "~~*targeted*~~ *substitution of an endogenous DNA sequence with a* ~~*contiguous*~~ ***continuous*** *DNA sequence […]*" (Annex I, paragraph (3) (d)) (**bold emphasis added**).[46]

These controversial[47] criteria in paragraphs (1)–(4) Annex I Council version are very detailed such as the "substitution or insertion of no more than 20 nucleotides" (1), the *"deletion of any number of nucleotides"* (2) in the case of targeted mutagenesis, or the *"targeted inversion of a sequence of any number of nucleotides"* (4) in the case of cisgenesis. These criteria are mostly based on the observed genetic modifications resulting from random mutagenesis techniques using chemicals or various types of irradiation.[48]

From a legal point of view, it has to be noted that, although the *"equivalence of NGT plants to conventional plants"* is the main reason for the deregulation, the term itself is not defined in abstract terms or a general manner in the COM proposal or the Council version.[49]

Furthermore, the COM proposal and the Council version provide that the COM shall be competent ("empowered") to adopt delegated acts to amend these criteria of equivalence "*in order to adapt them to scientific and technological progress, to the extent justified by advances in scientific knowledge, as regards the types and extent of modifications which can occur naturally or through conventional breeding*" (Art. 5 (3) Council version). This could lead to a far-reaching expansion of what is considered equivalent in the future.

Art. 5 (3) Council version therefore might violate the principle stated in Art. 290 (1) TFEU, that the essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power.[50] However, according to the Council version, this authorisation of the COM should be subject to the condition that the COM publishes a report, including "*an up-to-date scientific literature review*", which justifies that, "*on the basis of scientific evidence, the criteria of equivalence laid down in Annex I no longer reflect what can occur naturally or through conventional breeding*" (Art. 5 (3) (a) Council version). Additionally, the COM, where applicable, shall take into account any relevant new or updated scientific opinions from the European Food Safety Authority (Art. 5 (3) (b) Council version).

Moreover, before adopting the delegated act, the COM shall consult experts designated by each Member State (Art. 26 (4) Council version), and the delegated act only enters into force if no objection against it has been expressed (with qualified majority) either by the EP or by the Council within a period of two months after being notified (Art. 26 (6) Council version).

As legal rules have to be adaptive to new technological developments, especially in a fast-moving field like the genome editing of plants, in the end the approach as proposed by the Council seems justified and no violation of Art. 290 (1) TFEU.

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[46] This exclusion results from the requirement in Annex I (3) that the insertion or substitution must occur with a "continuous" DNA sequence, cf. Council version Recitals (2) and (14 bis).

[47] In response to the diverging reactions about these criteria, a Technical Paper by the EU Commission Services with a rationale for these "equivalence criteria" was published on 16 October 2023, see General Secretariat of the Council (n 45). Herein, they justified the type of genetic modifications, the size of limits of individual genetic modifications and the numerical limit of individual genetic modifications per plant included in the criteria, on the basis of a literature analysis of 90 scientific, peer-reviewed original studies and reviews on plants obtained by conventional breeding methods and on genetic variations in plants.

[48] Plants modified with such techniques are not regulated as genetically modified organisms. Cf. Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, Annex I B, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001L0018-20210327.

[49] *Winter* (n 28) 3, 5.

[50] *Spranger* (n 38) 17–18; *Winter* (n 28) 4, 10.

c) Amendments regarding NGT 1 plants (compared to current GMO legislation)

As written above, according to the COM proposal and the Council version, NGT 1 plants are no longer subject to the current EU GMO legislation (Art. 5 (1) Council version). This is the core element of the future deregulation. Most importantly, the status of NGT 1 plants must be confirmed in a *"verification procedure"* before being released deliberately (for testing) or being placed on the market (Arts 6, 7 Council version). In case of deliberate releases, the verification decision has to be declared in principle (in the absence of any "*reasoned objections to the verification report*" made by the other Member States or the COM, Art. 6 (7), (8) Council version) by the relevant EU Member State authority (Art. 6 (1), (8) Council version).[51] In case of placing on the market, the European Food Safety Authority (EFSA) prepares a statement and the COM takes the decision (with the member states) (Art. 7 (1), (6) Council version). Once a NGT plant is verified as NGT 1 plant, this decision remains valid for all purposes, e.g. a plant that has been categorised as NGT 1 plant according to the Art. 6 verification procedure can also be placed on the market without further Art. 7 verification procedure (Art. 7 (1), rec. 18).

A verification procedure is no authorisation procedure in the strict meaning. This means that irrespective of whether "only" the deliberate release of the plant or the placing on the market is *"requested"* (cf. Arts 6 (1) and 7 (1) Council version), a decisive difference to the current regulation is the absence of an authorisation procedure including the absence of a prior environmental risk assessment.[52] Also, all notification and identification requirements, as contained in Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms, do not apply any more for NGT 1 plants. Furthermore, there are no post-market monitoring measures of products containing NGT 1 plants, as currently laid down in the Directive 2001/18/EC.[53]

In line with these deregulation efforts, the labelling requirements for NGT 1 plants are reduced according to Arts 5 (1), 10 Council version. According to the current EU legislation, all products consisting of, containing or produced from GMOs must be labelled as such.[54] The COM proposal and the Council version state, on the contrary, that only NGT 1 "*plant reproductive material*", including for breeding and scientific purposes, has to be labelled as "*cat 1 NGT*", and that plants officially recognized as NGT 1 plants are being listed in a publicly available database (Art. 10 Council version). Plant reproductive material within the meaning of Art. 10 Council version is defined as living plants or living parts of them (like, inter alia, seeds, plant tissues cultures (including cell cultures), buds, budwood, cuttings, scions, grafts) capable of, and intended for, producing entire plants (Art. 3 (1) Council version, in conjunction with Art. 3 (1) of the Proposal for a Regulation on plant reproductive material,[55] and Art. 2 (1) of the Regulation (EU) 2016/2031)[56]. Since NGT 1 plants are no longer subject to the current GMO regulation

[51] The competent authorities in the Member States remain the same as under the Directive 2001/18/EC, as Art. 6 (1) Council version in this respect refers to Art. 4 (4) Directive 2001/18/EC.

[52] See (n 13).

[53] According to Arts 13 (2) (e), 19 (3) (f) and Annex VII Directive 2001/18/EC, the applicant must submit a "monitoring plan" that contains specific mechanisms for the systematic monitoring of the release of the GMO. These mechanisms confirm the acceptance of the environmental risk assessment on the one hand, and can also identify harmful effects of the GMO that were not foreseen in the environmental risk assessment on the other hand.

[54] See Arts 4, 5 Regulation (EC) No 1830/2003.

[55] 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) (5 July 2023) COM(2023) 414 final, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52023PC0414.

[56] Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC,

(Art. 5 (1) Council version), there is no labelling requirement along the chain and for the consumable end products, including food or feed, which consist of, contain or are produced of NGT 1 plants.

In some regards, however, the deregulation is limited: Recital (22) Council version stresses that "*category 1 NGT food featuring a significantly changed composition or structure that affects the nutritional value, metabolism or level of undesirable substances of the food will be considered as novel food and thus fall into the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council and will be risk assessed in that context.*" This is consistent with the rules laid down in Regulation (EU) 2015/2283 on novel foods.[57] According to this, *"food consisting of, isolated from or produced from plants or their parts"* obtained by *"non-traditional propagating practices"* – which include NGT – is considered a *"novel food"* if it *"give[s] rise to significant changes in the composition of the food affecting its nutritional value, metabolism or level of undesirable substances"* (Art. 3 (2) (a) (iv) 2nd var. Regulation (EU) 2015/2283). Also, inter alia, the novel food category includes "*food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997"* (Art. 3 (2) (a) (i) Regulation (EU) 2015/2283) might apply. These novel foods are subject to an authorisation procedure before being placed on the market, which requires, inter alia, "*scientific evidence demonstrating that novel food does not pose a safety risk to human health"* (Art. 10 (2) (e) Regulation (EU) 2015/2283). This remains unchanged by the Council version.

One can conclude that the deregulation concerning NGT 1 plants by the COM proposal and the Council version is far reaching, as the status of NGT 1 plants must be confirmed in a "verification procedure" before being released deliberately (for testing) or being placed on the market (Arts 6, 7 Council version), only, which is no authorisation procedure in the strict sense.

d) Amendments regarding NGT 2 plants (compared to current GMO legislation)

Different to NGT 1 plants, NGT 2 plants remain subject to the current EU GMO legislation (Art. 12 Council version), including the authorisation procedure and environmental risk assessment before the deliberate release or placing on the market, as well as the obligations for notification, identification and labelling.[58] Deviating from the current GMO legislation, the risk assessment, detection method and monitoring requirements are, however, adapted[59] (Chapter III Section 2 and 3 Council version) and the duration of the validity of the authorization is unlimited after the first renewal (Arts 17 and 21 Council version).

Nevertheless, some procedural *"incentives"* are laid down in the Council version for NGT 2 plants "*containing traits relevant for sustainability*" like improved yield or tolerance/resistance to biotic or abiotic stresses (Art. 22 and Annex III Council version). These incentives are a pre-submission advice by the EFSA (Art. 22 (3) Council version), a shortened deadline in the authorisation procedure (Art. 22 (2) (a) Council version), and additional facilitations for small and medium-sized enterprises like the exemption from participation in the costs of the application (Art. 22 (2) (b) Council version). The GMO label can be complemented by a voluntary label to indicate the purpose of the genetic modification (Art. 23 Council version).

98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC [2016] OJ L317/4, available at http://data.europa.eu/eli/reg/2016/2031/oj.

[57] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2015] OJ L327/1, available at http://data.europa.eu/eli/reg/2015/2283/oj.

[58] See above Part II on page 2.

[59] https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en.

Altogether, these are minor changes only compared to the current EU GMO legislation that remains applicable.

3. Main Amendments proposed by the EP

In its above-mentioned amendments to the COM proposal,[60] the EP proposes to amend the term *"breeders´ gene pool"* to "*gene pool for conventional breeding purposes*", as part of the definition of NGT plants.[61] This can be seen as an attempt to exclude the possibility to introduce foreign DNA into NGT plants. Nevertheless, it should be noted that, apart from this change of term, no amendments were proposed to the above-mentioned definition of "*breeders´ gene pool*" (or "*gene pool for conventional breeding purposes*" according to this amendment).

Moreover, concerning the distinction between NGT 1 and NGT 2 plants, the EP has proposed significantly different requirements as part of Annex I.[62] Besides, the EP proposes to extend the labelling requirement for NGT 1 plants not only to plant reproductive material, but also for NGT 1 plants and products containing or consisting of NGT 1 plants.[63] The label shall indicate the words *"New Genomic Techniques"* instead of "cat 1 NGT".[64]

Last but not least, the EP aims to include an obligation for "*appropriate document-based traceability*" for NGT plants, which shall be provided "*by the transmission and holding of information that products contain or consist of NGT plants and product, and unique codes for those NGTs, at each stage of their placing on the market*".[65]

This extends well beyond the norms contained in the COM proposal and the Council version, which only provide for the labelling of NGT 1 plant reproductive material and do not include any provisions on the traceability of NGT 1 plants placed on the market as detailed above.

4. Summary

The COM proposal and the Council version deregulate plants based on new biotechnologies and – for this purpose – introduce the new category of NGT plants. This covers plants obtained by targeted mutagenesis, cisgenesis and transgenesis. It differentiates between NGT 1 plants and NGT 2 plants, and deregulates the former:

NGT 1 plants are subject only to a verification procedure and the previously mandatory obligations of an authorisation procedure, including an environmental risk assessment, as well as notification and identification requirements do not apply to NGT 1 plants according to the Council version. A labelling requirement only applies to plant reproductive material, but not to any other products, including food or feed, consisting of, containing or produced from NGT 1 plants.

The definition of NGT 1 plants is decisive: These plants are those that fulfil the criteria of equivalence to conventional plants. This requires that they remain below the limits of genetic modifications defined in Annex I. This assumed equivalence to conventional plants is the reason for

[60] Cf. European Parliament (n 17).

[61] *Ibid,* amendments 25, 27.

[62] *Ibid,* amendments 71–77. According to these, a NGT 1 plant has to fulfil two different cumulative conditions:

- the plant shall be "*considered equivalent to conventional plants*" if it has no more than three specific genetic modifications (= the "*substitution or insertion of nor more than 20 nucleotides*" or the "*deletion of any number of nucleotides*") per "*protein-coding sequence*", excluding "*mutations in introns and regulatory sequences*", and

- (a) the "*insertion of continuous DNA sequences existing in the gene pool for breeding purposes*", (b) the "*substitution of endogenous DNA sequences with continuous DNA sequences existing in the gene pool for breeding purposes*", as well as (c) the "*inversion or translocation of continuous endogenous DNA sequences existing in the gene pool for breeding purposes*", must not "*create a chimeric protein that is not present in species from the gene pool for breeding purposes"*, or disrupt "*an endogenous gene*".

[63] *Ibid,* amendment 264.

[64] *Ibid,* amendment 264.

[65] *Ibid,* amendments 243, 265.

the deregulation. NGT 1 plants – according to the Council version – cannot be linked to specific risks as compared to conventionally bred plants, contrary to NGT 2 plants, whose genetic modifications exceed these limits.

For NGT 2 plants, the current EU GMO legislation continues to apply with minor changes, and no deregulation is proposed.

One crucial question is, regarding these extensive deregulations of NGT 1 plants, whether the exclusion of foreign genetic material in NGT plants can be affirmed. This is, however, unclear according to the Council version´s definitions. One can conclude that it depends on the definition of species and species boundaries, as stated above, which is neither a purely biological question nor a solely legal or philosophical one.

III. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity

1. Overview

a) Background and Negotiating History of the Cartagena Protocol

International efforts to formulate legally-binding rules on the safe use of living modified organisms (LMO) emerged in the 1990s and led to the inclusion of the issue in the negotiations to the Convention on Biological Diversity which entered into force in 1993.[66] But as no consensus on the appropriate framework on LMOs could be reached before its adoption,[67] Art. 19(3) Convention on Biological Diversity stipulates that *"[t]he Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity."* The corresponding negotiations were opened in 1995 and led to the adoption of the Cartagena Protocol in 2000, which entered into force in 2003.[68] The Convention on Biological Diversity Conference of the Parties serves as the meeting of the Parties to the Protocol (COP-MOP).[69] By 2025, it has held eleven meetings.[70]

[66] Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993) 1760 UNTS 79. See Art. 8 (g) Convention on Biological Diversity which provides that *"[e]ach Contracting Party shall, as far as possible and as appropriate: (g) [e]stablish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health".*

[67] For details see *Böckenförde,* Biological Safety, in Peters (ed.) (formerly Wolfrum (ed.)), *Max Planck Encyclopedia of Public International Law*, Online Edition, April 2011, available at https://opil.ouplaw.com/display/10.1093/law:epil/9780199231690/law-9780199231690-e1563?rskey=JKOF7Q&result=4&prd=MPIL, paras 4–7.

[68] All documents pertaining to the negotiation process are on the website to the Convention on Biological Diversity, The Cartagena Protocol, available at https://bch.cbd.int/protocol/background.

[69] Art. 29 (1) Cartagena Protocol.

[70] The outcomes of these meetings take the form of, for example, decisions or guidelines that play an important role in the development of the legal framework under the Cartagena Protocol. They can generally be considered soft law, if no special status is awarded to them by the Cartagena Protocol. In this study, the term soft law is understood to include rules that cannot be attributed to a formal legal source of law and that are, therefore, not directly legally binding, although they possess normative force as they are agreed upon by subjects of international law, i.e. States and International Organizations ('IOs'). See for this definition *Voeneky,* Human Rights and Legitimate Governance of Existential and Global Catastrophic Risks, in Voeneky/Neuman (eds), *Human Rights, Democracy, and Legitimacy in a World of Disorder* (2018), 138, 147–149; and, for a similar definition, *Thürer,* Soft Law, in Peters (ed.) (formerly Wolfrum (ed.)), Max Planck Encyclopedia of Public International Law, Online Edition, March 2009, available at https://opil.ouplaw.com/display/10.1093/law:epil/9780199231690/law-9780199231690-e1469?rskey=4kUG1k&result=1&prd=MPIL, para. 9.

Before the Cartagena Protocol, a legal framework on genetically modified organisms (GMOs) was already in place within the European Community. Council Directive 90/219/EEC[71] was intended to provide a harmonised regulatory framework for all contained uses of genetically modified micro-organisms, while Council Directive 90/220/EEC[72] provided rules for the deliberate release of GMOs into the environment. This legislation was amended and renewed after the adoption of the Cartagena Protocol.[73]

b) States Parties to the Cartagena Protocol

As of March 2025, the Cartagena Protocol was ratified by 173 States.[74] The EU and all Member States are Parties, as well as – for instance – Brazil, China, Mexico, New Zealand or India.[75] Other States that are important actors in the field of biotechnology are, however, not Parties to the Cartagena Protocol, as the United States, Canada and Argentina.[76] They are part of the top five commercial users of genetically modified crops[77] but not bound by the Cartagena Protocol.[78]

c) Objective of the Cartagena Protocol

The objective of the Cartagena Protocol is defined in its Art. 1 as follows:

> *"In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.*"

As a protocol to the Convention on Biological Diversity, the Cartagena Protocol centres environmental concerns over biological diversity as its objective of protection.[79] It remains disputed

[71] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms [1990] OJ L117/1, available at http://data.europa.eu/eli/dir/1990/219/oj.

[72] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [1990] OJ L117/15, available at http://data.europa.eu/eli/dir/1990/220/oj.

[73] For an overview of the legal rules in place since, see Part II. At EU level, the term GMO was maintained rather than adopting the term LMO that is used in the Convention on Biological Diversity and in the Cartagena Protocol and it was held that both terms largely overlap. On this, see *Beck* (n 30) 202 with further references. The inclusion of the term LMO in the international legal documents was favoured mostly by the United States who thereby sought to reduce their scope of application by placing the focus on the product rather than the method by which it was created, see *Gupta,* Global biosafety governance: Emergence and evolution, in Young/Chambers/Kim/then Have (eds), *Institutional Interplay: Biosafety and Trade* (2008), 19, 27.

[74] UN Office of Legal Affairs (n 5).

[75] *Ibid.*

[76] Other States that are not party to the Cartagena Protocol include Andorra, Australia, Brunei, Chile, Cook Islands, Equatorial Guinea, Haiti, Holy See, Iceland, Israel, Liechtenstein, Federated States of Micronesia, Monaco, Nepal, Russian Federation, San Marino, Sao Tome and Principe, Singapore, South Sudan, Timor-Leste, Tuvalu, and Vanuatu. See overview available at https://bch.cbd.int/en/countries/status/nonparty?status=nonparty.

[77] See *Cheng et al.,* Trends in the Global Commercialization of Genetically Modified Crops in 2023, 23(12) Journal of Integrative Agriculture 2024, 3943 and *Beck* (n 30) 133–134 with further references.

[78] See Art. 26 Vienna Convention on the Law of Treaties (adopted on 12 May 1968, entered into force on 27 January 1980), 1155 UNTS 331 (VCLT). The VCLT is an international treaty that contains rules on, inter alia, the conclusion and interpretation of treaties under international law. States such as Canada and Argentina, who have signed but not ratified the Cartagena Protocol, are under the (limited) obligation under international law to refrain from acts which would defeat the object and purpose of the Cartagena Protocol, see Art. 18 (a) VCLT.

[79] Cf. the ECJ's ruling in its Opinion 2/00, in which the Court determined that Art. 175 EC (now Art. 192 TFEU) is the appropriate legal basis for concluding the Cartagena Protocol on behalf of the European Community. To this end, the Court interpreted the Protocol in accordance with Art. 31 VCLT and concluded that it is principally

whether concerns over human health, such as consumer safety, – because of the term *"taking also into account risks to human health"* contained in Art. 1 Cartagena Protocol and in multiple operative provisions of the Protocol[80] – form a second, self-standing objective of protection of the Protocol. The wording of the Cartagena Protocol is open to both interpretations: it could mean, *first*, that direct effects of LMOs on human health must be considered on equal footing with effects on biological diversity or, *second*, that only indirect effects on human health caused by an impact on biodiversity are relevant.[81] For the purposes of this analysis, this question does not need to be answered. In the following, it is assumed that both answers may be correct.

d) Content of the Cartagena Protocol

The Cartagena Protocol lays down different obligations for the implementation of this objective. This part of the opinion provides an overview of these obligations, with a focus on those provisions relevant for the analysis of the compatibility of the Council version with the substantive provisions of the Cartagena Protocol that is discussed in further detail below (Part V).

Aside from general obligations on information sharing, capacity building, public awareness and participation (Arts 20–22 Cartagena Protocol), States Parties are, *on the one hand*, obliged to take appropriate measures to prevent the *unintentional* transboundary movement of LMOs (Art. 16 (3) Cartagena Protocol). Should such an unintentional transboundary movement nevertheless take place, States Parties are under the obligation to notify and inform the other Parties (Art. 17 Cartagena Protocol). *On the other hand,* States Parties are subject to detailed procedural requirements in the context of the *intentional* transboundary movement of LMOs. The obligations differ for different categories of living modified organisms:

At the centre of the Cartagena Protocol's regulatory framework on the intentional transboundary movement of LMOs is the *advanced informed agreement (AIA) procedure*, as laid down in Arts 7, 8–10 Cartagena Protocol. This procedure consists of two elements. *First,* the Party of export must notify and inform the Party of import about the intended transboundary movement of an LMO. This must include a risk assessment consistent with Annex III of the Cartagena Protocol (Art. 8 Cartagena Protocol and Annex I thereto). *Second,* the Party of import conducts a subsequent decision procedure; it also includes a risk assessment consistent with Annex III of the Cartagena Protocol. In the end, the Party of import has to decide to either approve or prohibit the import and communicates its decision to the Party of export (Arts 9, 10 and 15 Cartagena Protocol).

As a general rule, the AIA procedure applies to the *"first intentional transboundary movement of LMOs intended for intentional introduction into the environment of the Party of import"* (Art. 7 (1) Cartagena Protocol). There are different exceptions to this rule: the AIA procedure does not apply in such cases of transboundary movement to such LMOs excluded from the AIA procedure by a decision of the COP-MOP[82] (Art. 7 (4) Cartagena Protocol) or to LMOs intended for direct use as food or feed, or for processing (in the following: LMOs-FFP) which are subject to a simplified procedure (Art. 7 (2) Cartagena Protocol). It also does not apply to

concerned with environmental protection, and not with international trade policy. See CJEU, *Opinion 2/00* [2001] ECLI:EU:C:2001:664, paras 24–44.

[80] See Arts 2 (1), 4, 7 (4), 10 (6), 11 (8), 12, 15 (1), 16 (2), 16 (5) (a), 17 (1), 17 (3) (c), 17 (4), 18 (1), 21 (6) (c) and 23 (1) (a) Cartagena Protocol as well as Annex III thereto, paragraphs (1) and (8) (a).

[81] For further information and references see *Böckenförde* (n 67) paras 5 and 10; *Andrén/Parish*, Risk assessment, in Bail/Falkner/Marquard (eds), *The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment & Development* (2002), 329, 330–331; *Marquard*, Scope, in id, 289, 293.

[82] No such decision to exempt certain LMOs *"identified […] as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health"* has taken as of March 2025, see Convention on Biological Diversity Secretariat, COP-MOP Decisions on AIA (Arts 7–10), available at https://bch.cbd.int/protocol/decisions?subject=cpb-art7-10.

LMOs in transit (Art. 6 (1) Cartagena Protocol) or to LMOs destined for contained use (Art. 6 (2) Cartagena Protocol). Furthermore, an individual State Party, as Party of import, may adopt a simplified procedure for cases in which the import may take place at the same time as notification and in which the import is exempted from the AIA procedure (Art. 13 Cartagena Protocol).

LMOs-FFP are subject to a *separate procedure* under Art. 11 Cartagena Protocol. According to this the Party of export must inform the other Parties when making a *"final decision on domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing"* (Art. 11 (1) Cartagena Protocol and Annex II thereto). The information shall contain a risk assessment consistent with Annex III of the Cartagena Protocol. The potential subsequent decision of the Party of import on the import of such LMOs will generally be taken according to its domestic regulatory framework (Art. 11 (4) Cartagena Protocol). The Party of import can exceptionally take its decision based on a risk assessment consistent with Annex III of the Cartagena Protocol, but only when that Party is a developing State or a State with an economy in transition that does not have a domestic regulatory framework (Art. 11 (6) Cartagena Protocol).

Additionally, for all intentional transboundary movement of LMOs within the scope of the Cartagena Protocol, States Parties must follow requirements for handling, transport, packaging and identification (documentation) (Art. 18 Cartagena Protocol). States must also adopt appropriate measures for preventing transboundary movements carried out in contravention of domestic measures implementing the procedural requirements outlined here (Art. 25 Cartagena Protocol).

Lastly, States Parties are obliged to manage risks (Art. 16 Cartagena Protocol), that includes the obligation to *"establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment"* (Art. 16 (1) Cartagena Protocol) and to impose measures *"to prevent adverse effects"* (Art. 16 (2) Cartagena Protocol). Furthermore, States Parties shall *"endeavour to ensure that any [LMO], whether imported or locally developed, has undergone an appropriate period of observation […] before it is put to its intended use"* (Art. 16 (4) Cartagena Protocol). They shall cooperate to identify LMOs or their specific traits that may have adverse effects; and they have to take appropriate measures regarding the treatment of such LMOs or specific traits (Art. 16 (5) Cartagena Protocol).

Through these obligations, the Cartagena Protocol frames important parts of the procedures to be applied to the transboundary movement, transit, handling and use of LMOs.

2. Scope of application of the Cartagena Protocol

According to its Art. 4, the Cartagena Protocol applies "*to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health*." Exempted from the scope of application of the Protocol are *"pharmaceuticals for humans that are addressed by other relevant international agreements or organisations"*, though States Parties reserve the right to subject such LMOs to risk assessment prior to making a decision on import (Art. 5 Cartagena Protocol).

For the purpose of this opinion, the present analysis focuses on two elements: the phrase *"living modified organisms"* as a technical term defined in Art. 3 Cartagena Protocol, which is analysed in detail in Part IV; and the phrase *"that may have adverse effects […] taking also into account risks"* in Art. 4 Cartagena Protocol.

It is unclear whether the latter reference (*"that may have adverse effects […] taking also into account risks"* restricts the Cartagena Protocol's scope of application in the sense that it applies only to hazardous LMOs, i.e. LMOs for which such adverse effects or risks are expected, or whether this term is of merely declaratory value.[83] This has to be answered as an important starting point for deciding whether (and in which regard) the Cartagena Protocol covers NGT plants as part of the Council version, as discussed above.

Starting from the wording of Art. 4 Cartagena Protocol, both interpretations of the phrase *"that may have adverse effects […] taking also into account risks"* are possible: *first,* it could be read as an additional criterion to narrow down the scope of application of the Protocol to *only those* LMOs *that may have adverse effects*, or, *second,* it could be read in conjunction with the term LMO as a descriptive element that simply states *that* LMOS *may have adverse effects.*

The context of the Protocol, however, provides clear arguments for the second reading, i.e., that it has merely declaratory value. Hence, the Cartagena Protocol applies, as a general rule, to *all* LMOs. For one, in the substantive provisions of the Protocol on risk assessment, States Parties are obliged to *"identify and evaluate the possible adverse effects […] taking also into account risks to human health"* (Art. 15 (1) Cartagena Protocol). This means that the determination whether LMOs may have adverse effects or can be linked to risks should take place within the framework of the Protocol and subject to the specific conditions set out therein.[84]

Also, there is a dedicated procedure for the States Parties to identify LMOs that are *"not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health"* and to exclude them from certain procedural requirements (Art. 7 (4) Cartagena Protocol). This exemption requires an express decision by the meeting of the Parties, which, conversely, implies that in a first step and as a general rule *all* LMOs are included in the scope of application of the Protocol.[85]

This is confirmed by the negotiating history of the Protocol as a supplementary means of treaty interpretation under international law[86]: it had been proposed during the negotiations to prepare a list of LMOs as part of an Annex that had been shown not to cause adverse effects and that were thus exempted from the Protocol. It would allow authorities to focus on those LMOs with harmful effects.[87] However, this proposal was not supported. Some States held that the Protocol should cover *all* LMOs, and others were of the view that questions as central as the scope of application of the Protocol should be dealt with in the text, not in an Annex.[88]

This means that for answering the question whether an organism falls within the scope of application of the Cartagena Protocol, or is excluded, one cannot rely on the argument that it should be *excluded* because it has not yet proven to be harmful.[89]

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[83] Cf. *Mackenzie et al.,* An Explanatory Guide to the Cartagena Protocol on Biosafety, IUCN Environmental Policy and Law Paper No. 46 (2003), available at https://portals.iucn.org/library/efiles/documents/eplp-046.pdf, para. 168.

[84] See *Beck* (n 30) 151–152.

[85] Coming to the same conclusion *Beck* (n 30) 151.

[86] See Art. 32 VCLT.

[87] See Convention on Biological Diversity, Report of the First Meeting of the Open-Ended Ad Hoc Working Group on Biosafety, 22–26 July 1996, UNEP/CBD/BSWG/1/4, available at https://www.cbd.int/doc/meetings/bs/bswg-01/official/bswg-01-04-en.pdf, para. 103.

[88] See the summary of *Helen Marquard,* UK negotiator during the drafting process, on the debate regarding the annex: *Marquard* (n 81) 293–294.

[89] An additional argument to support this result can be found in an interpretation of the notion of "risk". There is no commonly accepted definition of the term "risk" in international law. It is unclear whether and how a risk would be different from a threat, a danger or a hazard. We rely on a broad definition: a risk is understood as an unwanted event that may or may not occur, i.e. an unwanted hypothetical future event. This includes situations of uncertainty where no probabilities can be assigned for the occurrence of damage. See *Voeneky* (n 70) 139, 140 *et seq*. and *Hansson*, 'Risk', in: Zalta (ed.), Stanford Encyclopedia of Philosophy (Summer 2023 edition), available at

This interpretation is in line with the *precautionary approach* that forms part of the Cartagena Protocol.[90] Through the references to the precautionary approach in the Preamble[91] and in Art. 1 Cartagena Protocol, it becomes clear that the Protocol *itself* is already a reflection of this kind of precaution in its composition and structure.[92] The provisions on risk assessment in the Protocol contain an operationalisation of this approach. It is stated that *"[l]ack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk".*[93] Taking into account that the risk assessment serves the purpose to *"identify and evaluate the possible adverse effects […] taking also into account risks"* (Art. 15 (1) Cartagena Protocol), as mentioned above, this supports the interpretation that the Cartagena Protocol and its procedural requirements apply to *all* LMOs as new technologies even if they have not yet proven to be harmful.[94]

Additionally, the severity of risk or lack thereof is no valid argument to restrict the scope of application of the Cartagena Protocol. The Cartagena Protocol does not set a qualitative threshold in its operative clauses referring to the precautionary approach that speak only of *"potential adverse effects […] taking also into account risks"*.[95]

This has important implications for this analysis, as this means that for determining whether NGT plants as defined in the Council version fall within the scope of application of the Cartagena Protocol, one cannot rely on the argument that NGT plants should be *excluded* from the scope of application of the Cartagena Protocol because they allegedly entail minimal adverse effects or risks for protected interests.

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https://plato.stanford.edu/search/r?entry=/entries/risk/&page=1&total_hits=442&pagesize=10&archive=None&rank=0&query=risk. Thus, even if one would adopt a reading of Art. 4 Cartagena Protocol in which the term *"that may have adverse effects […] taking also into account risks"* is interpreted as an additional criterion, organisms could not be excluded from the scope of application of the Protocol *unless there is scientific certainty* that they are safe, as, conversely, the existence of uncertainty implies the existence of a risk. This does not, however, mean that the Cartagena Protocol considers LMOs as generally or inherently hazardous or dangerous, see *Beck* (n 30) 152 with further references.

[90] The existing debate in international law whether the precautionary approach or principle forms part of customary international law is therefore not relevant for the present analysis, as it explicitly forms part of the regulatory framework of the Cartagena Protocol. The EU is bound to apply the precautionary principle also as a matter of EU law, see Art. 191(2) TFEU.

[91] Preamble, Recital 4 Cartagena Protocol: *"*Reaffirming *the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development".* See *UN Conference on Environment and Development*, Rio Declaration on Environment and Development, UN Doc A/CONF.151/26, Vol. I (1992), Principle 15: *"Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.".*

[92] *Böckenförde* (n 67) para. 12; *Graff,* The Precautionary Principle, in Bail/Falkner/Marquard (eds), *The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment & Development* (2002), 410, 417.

[93] Annex III (4) Cartagena Protocol. See also Annex III (8) (f) Cartagena Protocol that provides that *"[w]here there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.".*

[94] For this interpretation see *Beck* (n 30) 153; *Andrée,* The Cartagena Protocol on Biosafety and Shifts in the Discourse of Precaution, 5(4) Global Environmental Politics 2005, 25; *Mackenzie et al.* (n 83) para. 168; *Graff* (n 92) 418–419. The subsequent question, that is whether States may prohibit the import of LMOs based on precautionary considerations in the case of scientific uncertainty regarding the *existence or nature* of a risk or whether this is only possible in the case of scientific uncertainty regarding the *extent or level* of such a risk, is not relevant for this analysis. Based on the wording of Arts 10 (6) and 11 (8) Cartagena Protocol, that contain a further operationalisation of the precautionary approach, different positions have been maintained. See *Graff,* id, 418–419 and *Böckenförde* (n 67) para. 13 for arguments on both positions.

[95] Arts 10 (6) and 11 (8) Cartagena Protocol. Cf. *Graff* (n 92) 417–418. Other definitions of the precautionary approach contain a qualitative threshold, see Principle 15 of the Rio Declaration (n 91) that applies only *"[w]hen there are threats of serious or irreversible damage"* and the Convention on Biological Diversity, in Recital 9 of its Preamble, which notes that *"where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such risk.".*

3. Summary

The Cartagena Protocol covers all LMOs, and contains different procedural requirements for the transboundary movement, transit, handling and use of LMOs. As the EU and all EU Member States are Parties to the Cartagena Protocol, EU legislative and other measures regarding LMOs must comply with the provisions of this international law treaty. This means that the rules of the future EU regulation on NGT plants must not violate or contradict the Cartagena Protocol.

IV. Applicability of the Cartagena Protocol to NGT plants as defined in the Council version

Based on the definition contained in the Cartagena Protocol, it is analysed to what extent NGT plants are "*living modified organisms*". According to the definition, an LMO is "*any living organism that possesses a novel combination of genetic material through the use of modern biotechnology*" (Art. 3 (g) Cartagena Protocol). It consists of several elements, some of which are defined within the same article, and it combines two approaches: on the one hand, a product-related approach, which is illustrated by the term "*novel combination of genetic material*", and on the other hand, a process-related approach, demonstrated by the term "*through the use of modern biotechnology*".[96]

It is discussed whether NGT plants within the meaning of the Council version constitute a "*living organism*" (1.) and whether they possess "*a novel combination of genetic material*" (2.) "*obtained through the use of modern biotechnology*" (3.).

1. NGT plants as "living organisms"

According to Art. 3 (h) Cartagena Protocol, the term "*living organism*" "*means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids*". NGT plants according to the Council version are biological entities within the meaning of this provision, as the term "*biological entity*" basically refers to any entity and does not presuppose any further specific characteristics.[97]

The definition contained in Art. 3 (h) Cartagena Protocol further requires that NGT plants according to the Council version have to be "*capable of transferring or replicating genetic material*" in order to be labelled as a "*living*" organism. This clarifies that products in which LMOs have been processed and which are not living or capable of replication, such as processed foods (e.g. wheat flour or soybean oil) and clothing made from genetically modified cotton, are excluded from the Cartagena Protocol's scope.[98]

In order to determine what constitutes "*genetic material*", reference has been made by several scholars to the definition in Art. 2 Convention on Biological Diversity.[99] According to this treaty the term refers to "*any material of plant, animal, microbial or other origin containing functional units of heredity*". From a doctrinal and systematic point of view, however, this recourse to the definition of the Convention on Biological Diversity is not convincing, since the States Parties to the Cartagena Protocol decided against a reference to the definitions in the Convention on

[96] *Jacobsen/Schouten*, Cisgenesis: an important sub-invention for traditional plant breeding companies, Euphytica 2009, 235, 242; *Voigt*, Genomeditierung bei Pflanzen: Rechtsrahmen und Reformoptionen (2023), 380.

[97] For the latter see *Beck* (n 30) 135 with further references.

[98] *Jaffe/Meissa Dieng*, Implementing the Cartagena Protocol in West Africa, in Cordonier Segger/Perron-Welch/Frison (eds), *Legal Aspects of Implementing the Cartagena Protocol on Biosafety* (2013), 246, 254; *Böckenförde*, Grüne Gentechnik und Welthandel (2004), 148; *Till*, Erhaltung und nachhaltige Nutzung der Biodiversität, in Proelß (ed.), *Internationales Umweltrecht* (2022), para. 51.

[99] See, e.g., *Beck* (n 30) 136 et seq., according to whom Art. 2 Convention on Biological Diversity constitutes a relevant rule of international law applicable in the relations between the parties within the meaning of Art. 31 (3) (c) VCLT; likewise *Mackenzie et al* (n 83) paras 198 et seq.

Biological Diversity[100] – unlike, for example, in the second protocol to the Convention on Biological Diversity.[101] Another argument in favour of an autonomous definition of the term "*genetic material*" within the regime of the Cartagena Protocol is that the definition chosen in the Convention on Biological Diversity provides little insight due to the vague and controversial concept of "*functional units of heredity*".[102]

Ultimately there is no need to answer this question, as it is clear that both approaches (an autonomous interpretation of the term and an interpretation based on the definition contained in the CBD) lead to the conclusion that "*genetic material*" constitutes any biological material that contains nucleic acid,[103] i.e., in any case, entire organisms or parts of organisms.[104] As all NGT plants according to the Council version are organisms containing living cells, they constitute "*genetic material*" and are, moreover, "*capable of transferring or replicating*" such material.

NGT plants within the meaning of the Council version are therefore *"living organisms"* as defined by Art. 3 (g) Cartagena Protocol.

2. NGT plants as organisms possessing a "novel combination of genetic material"

The term "*novel combination of genetic material*" is not defined in the Cartagena Protocol. Such a "*novel combination of genetic material*" exists in any case if foreign DNA is inserted into the organism. As was discussed above, it is unclear whether the Council version excludes the insertion of foreign DNA in NGT plants.[105]

If one agrees with those who argue that it is not excluded, NGT plants in which foreign DNA has been inserted possess a *"novel combination of genetic material"* within the meaning of the Cartagena Protocol.

However, if one argues that the Council version excludes the insertion of foreign DNA in NGT plants, the question arises whether these NGT plants nevertheless possess a *"novel combination of genetic material"* and are included in the scope of application of the Cartagena Protocol. There are several States Parties to the Cartagena Protocol which have exempted such NGT plants from their national GMO legislation.[106] Scholars have suggested that if the modified sequence obtained by targeted mutagenesis or cisgenesis does not contain foreign DNA, it is not "*novel*". Hence, according to these views, it does not fall within the definition of an LMO under the Cartagena Protocol.[107] If this were the case, NGT plants would be exempt from the Cartagena Protocol. Contrary to this, another view ascribes only a reinforcing character to this criterion. It is argued that since the *"novelty"* is already implicitly contained in the application of *"modern biotechnology"*, this element of the definition has no significance of its own.[108]

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[100] This is also demonstrated by the fact that even existing definitions in the Convention on Biological Diversity, such as the term "*regional economic integration organisation*", were defined independently by the Cartagena Protocol. Furthermore, according to Art. 32 Cartagena Protocol, only the provisions of the Convention relating to its Protocols apply to the Cartagena Protocol.

[101] Cf. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (adopted 29 October 2010, entered into force 12 October 2014) 3 UNTS 3008, Art. 2: "*The terms defined in Article 2 of the Convention shall apply to this Protocol*".

[102] Cf. *Walløe Tvedt/Young*, Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD, IUCN Environmental Policy and Law Paper No. 67(2) (2007), 54 et seq.; *Ciesielczuk*, Defining Marine Genetic Resources, in Platjouw/Pozdnakova (eds), *The Environmental Rule of Law for Oceans* (2023), 178, 183 et seq.

[103] *Beck* (n 30) 137 et seq.; *Walløe Tvedt/Young* (n 102) 54 et seq.; *Barber/Glowka/La Viña*, Developing and implementing national measures for genetic resources access regulation and benefit-sharing, in Laird (ed.), *Biodiversity and Traditional Knowledge* (2002), 363, 364; *Mackenzie* et al. (n 83) para. 201.

[104] Cf. *Gerdung*, Internationale Regulierung der Risiken grüner Gentechnik, 2022, 139.

[105] See Part I 2 a) (2).

[106] See Part IV 2 b).

[107] See, e.g., in relation to plants obtained through cisgenesis: *Jacobsen/Schouten* (n 96) 242.

[108] *Böckenförde* (n 98) 149.

The following section will analyse the term "*novel combination*" with the help of the standards established by the Vienna Convention of the Law of Treaties (VCLT)[109] and recognised under customary international law,[110] which also apply to the Cartagena Protocol.

The analysis relies on the ordinary meaning (Art. 31 (1) VCLT) of the term "*novel combination of genetic material*" (a)). Then, it is examined whether the aforementioned State practice amounts to subsequent practice informing the context of the Cartagena Protocol – and, accordingly, its interpretation – within the meaning of Art. 31 (3) (b) VCLT (b)). Third, the Cartagena Protocol's object and purpose has to be taken into account (c)) and last the relevance of supplementary means according to Art. 32 VCLT is examined for the present case (d)).

a) Ordinary meaning

According to the wording of the Cartagena Protocol as the main reference point for interpretation under Art. 31 (1) VCLT, there is no indication that the term "*novel combination of genetic material*" is limited to the insertion of foreign genetic material. Rather, all authentic language versions of the treaty focus only on the aspect of a "*combination*". This notion, regarding its ordinary meaning,[111] can be interpreted in the sense of a *"change"* or a different *"arrangement"* of genetic material.[112]

The aspect of *"novelty"* merely implies that it must be a previously unprecedented combination of genetic material (cf. in particular the French wording: "*combinaison […] inédite*"), but not that the insertion of foreign DNA is required for this purpose.[113]

b) Context and subsequent practice

As indicated above, there exists national legislation of some States Parties to the Cartagena Protocol defining the term "*novel combination of genetic material*" ((1)). To provide further context, the practice of non-contracting States in this regard is also analysed ((2)). However, it is concluded that existing State practice is not sufficient to be taken into account for the interpretation of the Cartagena Protocol as it does not fulfil the requirements of *"subsequent practice"* in Art. 31 (3) (b) VCLT ((3)).

(1) Practice of States Parties to the Cartagena Protocol

In the following, State practice in the form of national legislation that may inform the interpretation of the expression "*novel combination of genetic material*" is stressed.

Colombia uses the term "LMO" as defined by the Cartagena Protocol and, accordingly, also the expression "*novel combination of genetic material*", as part of its national legislation. The latter is defined as "*change produced in the genome of the organism by the incorporation, in a stable and cohesive manner, of one or more genes or nucleic acid sequences which are part of one or more genes or nucleic acid sequences which form part of a defined genetic construct that is transcribed and/or translated*".[114] Although this definition does not explicitly include the

[109] See (n 78).

[110] Cf. *Herdegen*, Interpretation in International Law, in Peters (ed.) (formerly Wolfrum (ed.)), Max Planck Encyclopedia of Public International Law, Online Edition, November 2020, available at https://opil.ouplaw.com/display/10.1093/law:epil/9780199231690/law-9780199231690-e723?rskey=g4Yso2&result=3&prd=MPIL, para. 7.

[111] Cf. *Mackenzie* et al. (n 83) para. 210.

[112] *Mackenzie* et al. (n 83) para. 211; *Beck* (n 30) 138 et seq.; *Sirinathsinghji*, Why genome edited organisms are not excluded from the Cartagena Protocol on Biosafety, Biosafety Briefing, December 2020, available at https://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/genome-edited-biobrief-dec2020-sirinathsinghji.pdf, 1, 3.

[113] *Mackenzie* et al. (n 83) para. 211.

[114] Translation by the authors. Original Spanish version: "*Cambio producido en el genoma del organismo por la incorporación, en forma estable y conjunta, de uno (1) o más genes o secuencias de ácido nucleico que forman parte de una construcción genética definida que se transcribe y/o se traduce*" (Instituto Colombiano Agropecuario,

term “foreign DNA”, the practice of the competent authority shows that in past decisions genome-edited plants not containing foreign DNA were not considered LMOs.[115] Colombia’s example is followed by other Latin American States that are also party to the Cartagena Protocol, such as Costa Rica.[116] This practice implies a *restriction* of the notion of LMOs to organisms that contain foreign DNA.

Other States Parties, such as Japan, do not use or define the term “*novel combination*”, even though their national legislation explicitly refers to the Cartagena Protocol’s LMO definition. Japan ultimately also dismisses organisms in which no “foreign DNA” has been inserted as not constituting LMOs; however, it should be noted that according to the Japanese legislation, the criterion “foreign DNA” is not a technical or legislative term contained therein and therefore the criterion is not in itself decisive in determining whether an organism constitutes an LMO.[117] Nevertheless, the Japanese practice might be seen to indicate a *restriction* of the notion of LMOs to organisms that contain foreign DNA.

Some States Parties, such as Brazil, do not refer to the Cartagena Protocol at all in their legislation, defining the term “LMO” autonomously. In practice, they are largely exempting NGT plants not containing foreign DNA.[118] India’s legislation, which came into force before the Cartagena Protocol was negotiated, does not use the term “LMO” either, but uses the notion of

Resolución No. 00022991 (11/11/2022), § 3.11, available at https://www.ica.gov.co/getattachment/e4b3a97e-b44e-4974-8bb0-f3b947063e67/2022R22991.aspx.

[115] Cf. with further references, *Rosado/Eriksson*, Biosafety legislation and the regulatory status of the products of precision breeding in the Latin America and the Caribbean region, Plants People Planet (2022), 214, 226.

[116] Cf. Decreto No 44244 – Reforma Reglamento a la Ley de Protección Fitosanitaria No 44244 – MAG, 10 November 2023, available at http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=100731&nValor3=138361&strTipM=TC; for an English translation of the definitions cf. USDA, Costa Rica Opens Door to Innovative Biotechnologies, Report, 27 February 2024, available at https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Costa%20Rica%20Opens%20Door%20to%20Innovative%20Biotechnologies_San%20Jose_Costa%20Rica_CS2024-0004.pdf. For an overview over the (very dynamic) state of regulation in Latin America regarding genome-edited plants cf. *Fernandes* et al., Regulation of CRISPR-edited plants in Latin America, in Abd-Elsalam (ed.), *Global Regulatory Outlook for CRISPRized Plants* (2024), 197, 203.

[117] Although LMOs are mentioned in the Japanese Cartagena Act, they are defined independently from the Cartagena Protocol’s definition as “*an organism that possesses nucleic acid, or a replicated product thereof, obtained through use of […] technologies […] as stipulated in the ordinance of the competent ministries, for the processing of nucleic acid extracellularly […] [and] for fusing of the cells of organisms belonging to different taxonomical families obtained through the use of one of the specified technologies*” (Art. 2 (2) of the Japanese Cartagena Act, available at https://www.biodic.go.jp/bch/english/law.html). In practice, these technologies exclude technologies that use, inter alia, nucleic acid from organisms belonging to the same species as the organism from which the cell was derived and nucleic acid from organisms belonging to the species that naturally exchanges nucleic acid with the species of the organism from which the cells were derived. See *Ishii*, Regulation of Genome Editing in Plant Biotechnology: Japan, in Dederer/Hamburger (eds), *Regulation of Genome Editing in Plant Biotechnology* (2019), 239, 243 et seq.; cf. also *Tsuda*, Regulatory Status of Genome-Edited Organisms Under the Japanese Cartagena Act, 7 Frontiers in Bioengineering and Biotechnology 2019, 387 et seq. *Tsuda* et al. make clear that according to the Japanese Cartagena Act the insertion even of short sequences (by so-called SDN-2 techniques using a “template”) is leading to an LMO requesting risk assessment and labelling - as these organisms/plants “contain inserted nucleic acids processed extracellularly”. In contrast, the same plant would be categorised as NGT 1 plant in the EU as long as the introduced sequence does not exceed 20 nucleotides, according to the COM proposal and the Council version, with no risk assessment and labelling requirements.

[118] In Brazil’s Lei No. 11.105 of 24 March 2005, available at https://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/l11105.htm, an LMO is defined as “*organismo cujo material genético – ADN/ARN tenha sido modificado por qualquer técnica de engenharia genética*” (see Art. 3 V), meaning that the term “*novel combination*” is not used. However, given the criteria listed in § 3 in CTNBio, Resolução Normativa Nº 16, de 15 de Janeiro de 2018, available at https://ctnbio.mctic.gov.br/resolucoes-normativas/-/asset_publisher/OgW431Rs9dQ6/content/resolucao-normativa-n%C2%BA-16-de-15-de-janeiro-de-2018, it can be deduced that an organism must contain foreign DNA in order to constitute an LMO; cf. for an English summary of the Brazilian regulations: *Vieira* et al., Regulatory framework of genome editing in Brazil and worldwide, EMBRAPA 2021, available at https://www.alice.cnptia.embrapa.br/alice/bitstream/doc/1132164/1/Regulatory-framework-of-genome-CAP-5.pdf.

"*genetically engineered organisms/micro-organisms and cells*".[119] However, since 2022, plants not containing foreign DNA are exempt from this term,[120] because, as the corresponding guidelines state, such plants "*do not contain new combinations of genetic material as will be arising from the incorporation of exogenous DNA, and thus the final products are equivalent to naturally occurring loss of function or a change in the activity of a gene mutations or those induced via mutation breeding*".[121]

Another example of the use of the term "*novel combination*" as part of a national legislation of a State Party is the regulation by the Philippines. There, the expression "*contain a novel combination of genetic material obtained through the use of modern biotechnology*" is used, although the regulation itself does not use the term "LMO", but "genetically modified organisms (GMOs)".[122] The term "*novel combination*" is defined "*as a resultant genetic combination in a living organism that is not possible through conventional breeding*".[123] However, it is still unclear how the definition will be applied in practice and how it will relate to the presence of foreign DNA. In any case, the definition itself *does not imply a restriction* of the notion of LMOs to organisms that contain foreign DNA.

It should be mentioned that the often-cited deregulation in the case of the United Kingdom only applies to England, not the whole of the United Kingdom.[124] This legislation is not applicable in Scotland, Wales and Northern Ireland and therefore does not constitute State practice attributable to the United Kingdom as a State Party to the Cartagena Protocol.

Hence, one can conclude that the practice of some States, as Colombia and other Latin American States, due to their national legislation or due to other practice not formally linked to the Cartagena Protocol, might be seen as limiting the notion of LMOs to organisms that contain foreign DNA.

(2) Practice of non-States Parties

The public debate on the deregulation of genome-edited plants to which *no foreign DNA* has been added is also influenced by the practice of States that are not States Parties to the Cartagena Protocol or are only signatory States. This practice is outlined here to provide context.

For example, Colombia's aforementioned approach has been preceded by other Latin American States, notably Chile, which, despite not being a State Party to the Cartagena Protocol, uses the Cartagena Protocol's LMO definition.[125] Chile defines the term "*novel combination*",[126]

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[119] See Rule 2 (1) of the Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, available at https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115121526033_Rules-for-the-manufacture-use-import-export-and-storage-1989.pdf.

[120] Cf. Government of India/Ministry of Environment, Forest and Climate Change, Office Memorandum F. No. C - 12013/3/2020-CS-III dated 30.03.2022 regarding Exemption of the Genome Edited plants under Rule 20 of Rules, 1989, available at https://dbtindia.gov.in/sites/default/files/Final_%2011052022_Annexure-I%2C%20Genome_Edited_Plants_2022_Hyperlink.pdf, 22 et seq.

[121] Government of India/Ministry of Science and Technology, Guidelines for Safety Assessment of Genome Edited Plants (2022), available at https://dbtindia.gov.in/sites/default/files/Final_%2011052022_Annexure-I%2C%20Genome_Edited_Plants_2022_Hyperlink.pdf, 5.

[122] Republic of the Philippines/Office of the Secretary, Rules and Procedure to Evaluate and Determine When Products of Plant Breeding Innovations (PBIs) are Covered Under the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, series of 2021 (JDC1, s2021) based on the NCBP Resolution No. 1, series of 2020, Memorandum Circular No. 8, Series of 2022, available at https://ncbp.dost.gov.ph/policies/memorandums/, 2 (Section 1 a.).

[123] *Ibid.*

[124] Cf. for an overview over the so-called Genetic Technology (Precision Breeding) Act: *Watson/Hayta*, Precision breeding in agriculture and food systems in the United Kingdom, 33 Transgenic Research 2024, 539, 541.

[125] Ministerio de Agricultura/Servicio Agrícola y Ganadero, Resolución 1523, available at https://www.bcn.cl/leychile/navegar?idNorma=187630, Art. 1 (I).

[126] Cf. Ministerio de Agricultura/Servicio Agrícola y Ganadero, Aplicabilidad de Resolución N° 1.523/2001 en material de propagación desarrollado por nuevas técnicas de fitomejoramiento, available at https://www.sag.cl/ambitos-

but interprets it in such a way that NGT plants not containing foreign DNA are not regulated as LMOs.[127] This is a far-reaching deregulation regarding some NGT plants by Chile.

Argentina is said to have been the main driver of the approach of most Latin American States with regard to the deregulation of NGT plants. However, it does not – contrary to some reports[128] – use the definition of LMO of the Cartagena Protocol as part of its legislation, but a modified version. This modified version does not in itself contain the term "*novel combination of genetic material*".[129] In later regulations, Argentina also refers to this particular term from the Cartagena Protocol's LMO definition.[130] While this definition of "*novel combination*" does not imply that NGT plants not containing foreign DNA are not covered by the term, the practice of the competent authority shows that NGT plants not containing a permanent insertion of foreign DNA are de facto not treated as LMOs.[131] In practice, this means a far-reaching deregulation regarding NGT plants by Argentina.

Similarly, though they are not using the Cartagena Protocol's terms and definitions, other non-member States, such as the United States[132] or Australia[133] have also exempted genome-edited plants not containing foreign DNA from specific national regulation based, however, on different regulatory approaches.

Regarding the criterion "*novel*", reference should also be made to the legislation of Canada. Canada does not use the Cartagena Protocol's definition of LMO or the term itself in its legislation, either, but nevertheless stipulates the aspect of "novelty" as the decisive criterion for the deregulation of genome-edited plants. The regulation is based on the concept of "*plants with novel traits*" which must be authorised prior to their release into the Canadian environment. Plants are considered "*plants with novel traits*" if "*the new trait is not present in stable, cultivated populations of the plant species in Canada, or the trait is present at a level significantly outside the range of that trait in stable, cultivated populations of that plant species in Canada,*

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de-accion/aplicabilidad-de-resolucion-ndeg-15232001-en-material-de-propagacion-desarrollado-por-nuevas-tecnicas-de-fitomejoramiento.

127 Cf. *Goberna* et al., Genomic Editing: The Evolution in Regulatory Management Accompanying Scientific Progress, Frontiers in Bioengineering and Biotechnology 2022, available at https://doi.org/10.3389/fbioe.2022.835378.

128 Cf., e.g., *Sánchez*, The Global Advance of Genome-Edited Plants to the Market: The Key Role of Chile in Its Development, 13 (3597) Plants 2025, 1 (2).

129 See Secretaría de Agricultura, Ganadería y Pesca, Resolución 701/2011, available at https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-701-2011-189067/texto: "*Organismo Vegetal Genéticamente Modificado (OVGM): organismo vegetal que posea una combinación de material genético que se haya obtenido mediante la aplicación de la biotecnología moderna.*".

130 See Secretaría de Agricultura, Ganadería y Pesca, Resolución 173/2015, Artículo No. 2, https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-173-2015-246978/texto: "*En el marco de dicha ICP, el interesado solicitará que la CONABIA se expida sobre si el resultado del proceso de mejoramiento constituye una nueva combinación de material genético. Para que un cambio genético sea considerado una nueva combinación de material genético, se analizará si se ha producido una inserción en el genoma en forma estable y conjunta de UNO (1) o más genes o secuencias de ADN que forman parte de una construcción genética definida.*".

131 Cf. *Kuiken/Kuzma*, Genome Editing in Latin America: Regional Regulatory Overview (2021), available at http://dx.doi.org/10.18235/0003410, 10.

132 The current status of the United States' framework concerning genome-edited plants, however, is unclear at the moment since the APHIS's biotechnology regulations finalised in 2020 were vacated by the U.S. District Court for the Northern District of California on 2 December 2024. This means that in principle, the legal framework that was in place before 2020 is now re-established; however, the Court's summary judgment did not include the most recent exemptions which became effective in November 2024. See https://www.aphis.usda.gov/biotechnology/vacatur-2020-regulations and for an overview, *Ward* et al., An InSECURE Future: Court Ruling Guts USDA Regs on Genetically Engineered Plants, Morrison Foerster, 19 December 2024, available at https://lifesciences.mofo.com/topics/an-insecure-future-court-ruling-guts-usda-regs-on-genetically-engineered-plants.

133 See, for an overview, *Thygesen*, Regulation of genome edited organisms in Australia, 33 Transgenic Research 2024, 545 et seq.; see also Australian Government, Department of Health, Overview – status of organisms modified using gene editing and other new technologies, 2021, available at https://www.ogtr.gov.au/sites/default/files/2021-11/overview_-_status_of_gene_editing_and_other_new_technologies.pdf and *Mallapaty,* Australian gene-editing rules adopt 'middle ground', Nature News, 23 April 2019, available at https://doi.org/10.1038/d41586-019-01282-8.

and where the new trait has the potential to negatively affect environmental safety."[134] Accordingly, the categorisation of a plant as "*plants with novel traits*" "*is determined by the presence of a novel trait in a plant, irrespective of the method used to introduce it.*"[135] In practice, this means that for plants containing foreign DNA[136] or plants with a new commercially-viable herbicide tolerance trait (but no inclusion of foreign DNA), an authorisation has to be obtained.[137] Accordingly, most genome-edited plants do not require such an authorisation and there is no requirement to notify the competent authority and receive an authorisation prior to environmental release.[138]

To conclude, legislation in non-States Parties to the Cartagena Protocol shows far-reaching deregulation regarding NGT plants.

(3) Non-fulfilment of the requirements for subsequent practice

It must be answered whether it is possible to derive a "*subsequent practice*" according to Art. 31 (3) (b) VCLT from the State practice outlined above, to the effect that the term LMO contained in the Cartagena Protocol has to be interpreted in such a way that organisms that do not contain foreign DNA are excluded. Legislation of States Parties can in principle be used for the interpretation of international treaties, such as the Cartagena Protocol, and may be classified as "*subsequent practice*" within the meaning of Art. 31 (3) (b) VCLT.[139]

To this end, it is generally necessary, *first,* that it is the practice of States Parties or that the referred conduct is at least attributable to them.[140] This is not the case for the practice of States that are not Parties to the Cartagena Protocol as outlined in Part IV 2 b) (2) and for the reason mentioned above also not for the United Kingdom, whose practice can therefore not be taken into account for the interpretation of the Cartagena Protocol.

Second, it is a precondition that the State practice referred to meets the further requirements specified in Art. 31 (3) (b) VCLT. It is shown that these requirements established for the interpretation of the Cartagena Protocol as a treaty under international law are not met in the present case:

As an objective criterion, a uniform and consistent pattern has to be established in order to constitute sufficient practice within the meaning of Art. 31 (3) (b) VCLT.[141] If recourse is made to national legislation to determine the existence of subsequent practice, the wording of the national legislation needs to be carefully observed as even minor deviations can call into question the existence of sufficient practice.[142]

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[134] Government of Canada, Directive 94-08, Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits, https://inspection.canada.ca/en/plant-varieties/plants-novel-traits/applicants/directive-94-08#a21, Section 2.1.

[135] *Ibid*.

[136] Foreign DNA is defined as "*DNA that is originally sourced from genetic sources outside the plant species and cannot be introduced into that plant species using conventional breeding methods*", see Government of Canada, Directive 2009-09: Plants with novel traits regulated under Part V of the Seeds Regulations: Guidelines for determining when to notify the CFIA, Updated May 3, 2023, available at https://inspection.canada.ca/en/plant-varieties/plants-novel-traits/applicants/directive-2009-09, Appendix 1 – Glossary of terms.

[137] See Government of Canada (n 136) Sections 4.2.2. and 4.2.3.

[138] See Government of Canada (n 136) Section 4.3.

[139] *Dörr*, in Dörr/Schmalenbach (eds), *Vienna Convention on the Law of Treaties* (2018), Art. 31 para. 79; cf. also WTO, *US – Section 110(5) of the US Copyright Act– Report of the Panel* (15 June 2005) WT/DS160/R, para. 6.55.

[140] *Dörr* (n 139) Art. 31 para. 83.

[141] See ECtHR, *Case of Loizidou v. Turkey (Preliminary Objections)*, Application no. 15318/89, 23 March 1995, para. 82; cf. also WTO, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts – Report of the Appellate Body* (12 September 2005) WT/DS269/AB/R, para. 26 with further references; *Dörr* (n 139) Art. 31 para. 80 with further references.

[142] Cf. WTO, *United States – Laws, Regulations and Methodology for Calculating Dumping Margins ("Zeroing"), Report of the Panel* (31 October 2005) WT/DS294/R, para. 7.217.

As was shown, the practice of the States Parties to the Cartagena Protocol is far from uniform.[143] The term "*novel combination*" is only used and defined by some States, whereby none of the definitions explicitly state that term "*novel combination*" means that an organism must contain foreign DNA.

Even States Parties such as China, which have issued regulations on genome-edited plants and differentiate in principle between plants with exogenous DNA and plants without exogenous DNA, continue to be rather restrictive: although both forms of plants are subject to different guidelines, in the case of genome-edited plants that do not contain foreign DNA, there is no deregulation per se.[144]

Likewise, when looking at the national legislation of other States Parties of the Cartagena Protocol, several of these States continue to regulate plants produced using genome editing techniques as GMOs, regardless of whether the plants contain foreign DNA. This is the case regarding EU Member States, and, inter alia, Norway,[145] Switzerland,[146] New Zealand,[147] Peru,[148] Mexico,[149] Venezuela,[150] Egypt,[151] Algeria[152] and South Africa.[153]

Even though debates on deregulation of certain NGT plants are currently ongoing in almost all of the States mentioned above, such future changes in legislation cannot be taken into account for the purposes of Art. 31 (3) (b) VCLT. The determination of subsequent practice

[143] For a recent overview over current or planned legislation with regard to NGT plants in 56 countries plus the European Union, see *Caradus*, Processes for regulating genetically modified and gene edited plants, 14 (1) GM Crops & Food 2023, 1, 17.

[144] Cf. *Yang/Zheng/Yao*, China's regulatory change toward genome-edited crops, 42 (7) Trends in Biotechnology 2024, 801 et seq.

[145] In the case of Norway, in principle, any modification to the plant or animal genome, including gene editing falls under Norway's Gene Technology Act, since the Act only provides an exception similar to the LMO definition in the Cartagena Protocol, stating that "*the Act does not apply to the production of the following by means of cell technology: genetically modified plant cells where the same result can be obtained by means of traditional breeding methods*" (cf. Government of Norway, Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms, etc., available at https://www.regjeringen.no/en/dokumenter/gene-technology-act/id173031/).

[146] According to Art. 5 (2) of the Swiss Gene Technology Act (*Bundesgesetz über die Gentechnik im Ausserhumanbereich*, 21 March 2003), GMOs are defined as organisms whose genetic material has been modified in a way that does not occur naturally through cross-breeding or natural recombination. In 2005, Switzerland imposed a twenty-year moratorium in the form of a temporary ban on the cultivation of genetically modified plants in agriculture, which was extended in 2021 and is now to be extended again until 2030, cf. Schweizerische Eidgenossenschaft, Der Bundesrat unterstützt die Verlängerung des Gentechnik-Moratoriums, 29 January 2025, available at https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-103951.html.

[147] Cf. for an overview over New Zealand's regulatory approach *Fritsche* et al., A New Zealand Perspective on the Application and Regulation of Gene Editing, 9 Frontiers in Plant Science 2018, Article no. 1323, 1, 4 et seq.

[148] In 2021, the Peruvian Congress extended a moratorium until 31 December 2035 for all LMOs, see Ley no. 31111 – Ley que modifica la ley 29811, ley que establece la moratoria al ingreso y producción de organismos vivos modificados al territorio nacional por un periodo de 15 años; a fin de establecer la moratoria hasta el 31 de diciembre de 2035, available at https://busquedas.elperuano.pe/dispositivo/NL/1917468-1.

[149] Cf. *Zarate* et al., Assessing agricultural gene editing regulation in Latin America: an analysis of how policy windows and policy entrepreneurs shape agricultural gene editing regulatory regimes, 11 Frontiers in Bioengineering and Biotechnology 2023, 1209308, 1, 4, with further references.

[150] Cf. *Rozas* et al., Genetically modified organisms: adapting regulatory frameworks for evolving genome editing technologies, 55 (31) Biological Research 2022, 1, 6, with further references.

[151] Cf. USDA, 'Agricultural Biotechnology Annual: Egypt', 20 November 2024, Report Number EG2024-0027, available at https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Biotechnology%20and%20Other%20New%20Production%20Technologies%20Annual_Cairo_Egypt_EG2024-0027.pdf.

[152] Cf. USDA, 'Agricultural Biotechnology Annual: Algeria', 20 November 2024, Report Number AG2024-0010, available at https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Algiers_Algeria_AG2024-0010.pdf.

[153] Cf. the recent decision by the South African Minister of Agriculture to allow NGT plants to remain subject to general GMO regulation: Minister's final decision on the appeal lodged by agricultural business chamber under the GMO act, 11 August 2023, available at https://acbio.org.za/wp-content/uploads/2024/02/Minister-final-decision-on-AGBIZ-appeal.pdf.

presupposes actual, empirically ascertainable practice of States Parties, and possible future developments are of no relevance.

No other result can be based on the claim that subsequent practice can also be such that the States Parties' practice of non-application of the treaty is decisive. It is correct that conclusions may be drawn "*from the fact that the parties did not apply their treaty when treaty provisions might have been thought to be applicable*".[154] However, no such pattern can be established here that implies that the States Parties all – or almost all – assume that the Cartagena Protocol is not applicable to genome-edited plants. Rather, the developments in State practice are – at least partly – in contradiction to each other.

Furthermore, Art. 31 (3) (b) VCLT also implies a subjective component, according to which the State practice must take place "*in the application of the treaty*" and establish "*the agreement of the parties regarding [the treaty's] interpretation*". In this regard, it is disputed whether it is sufficient that the process has been tacitly acquiesced in by the other States Parties.[155] It is also disputed whether an express objection by one party automatically prevents subsequent practice from arising. From a majority, however, this is affirmed.[156]

Here, in the case of some States Parties, particularly in African States where biosafety regulations are particularly diverse[157] and States Parties such as Angola, Madagascar, Morocco,[158] Cameroon, Burundi, The Gambia[159] and Guinea[160] do not yet have regulations on genome-edited plants or even GMOs in place, it could be assumed that these States Parties have acquiesced to the exclusion of NGT plants that do not contain foreign DNA from the scope of application of the Cartagena Protocol. However, even in view of such an assumption and even though some States Parties explicitly mention and approve deregulation,[161] there is – as shown in this section – still explicit resistance or dissenting views from others.

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[154] *Dörr* (n 139) Art. 31 para. 82 with further references.

[155] *Villiger*, Commentary on the 1969 Vienna Convention on the Law of Treaties (2009), Art. 31 para. 22; *Dörr* (n 139) Art. 31 para. 88; cf. also ILC, 'Draft conclusions on subsequent agreements and subsequent practice in relation to the interpretation of treaties', contained in 'Report of the International Law Commission on the Work of its 70th Session' (30 April–1 June and 2 July–10 August 2018) UN Doc A/73/10, 75: "*Silence on the part of one or more parties can constitute acceptance of the subsequent practice when the circumstances call for some reaction.*" According to the WTO Appellate Body, however, acquiescence is not sufficient, see WTO (n 141) para. 273: "*[W]e have misgivings about deducing, without further inquiry, agreement with a practice from a party's 'lack of reaction'. […] '[L]ack of reaction' should not lightly […] be read to imply agreement with an interpretation by treaty parties that have not themselves engaged in a particular practice followed by other parties in the application of the treaty. This is all the more so because the interpretation of a treaty provision is binding on all parties to the treaty, including those that have not actually engaged in such practice*".

[156] See *Villiger* (n 155) Art. 31 para. 22; cf. also WTO (n 142) para. 7.218. Only the ECtHR's case law takes a special path here; the ECtHR considers it possible, even in the case of individual deviations among the contracting States, to establish a subsequent practice within in the meaning of Art. 31 (3) (b) VCLT (cf. *Dörr* (n 139) Art. 31 para. 79). Even according to this less stringent view of the ECtHR, "*the evidence of a practice denoting practically universal agreement amongst Contracting Parties*" is a prerequisite for such practice, see ECtHR (n 141) para. 80. This shows that the ECtHR ultimately also imposes strict conditions for determining whether State practice takes the form of subsequent practice. In any case, it seems questionable whether the standards of the ECtHR can be transferred to the Cartagena Protocol, since the European Convention on Human Rights constitutes a very specific and – in view of the composition of the contracting parties and their small number compared to the Cartagena Protocol – fundamentally different regime.

[157] Cf., for an overview, *Abkallo* et al., Making genome editing a success story in Africa, 42 Nature Biotechnology 2024, 551, 553; *Runo* et al., Africanizing genome editing for food sustainability, 42 Global Food Security 2024, 100785, 1, 6.

[158] Cf. USDA, 'Agricultural Biotechnology Annual: Morocco', 20 November 2024, Report Number MO2024-0016, available at https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Rabat_Morocco_MO2024-0016.pdf.

[159] Cf. USDA, 'Agricultural Biotechnology Annual: Senegal', 21 November 2024, Report Number SG2024-0011, available at https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Dakar_Senegal_SG2024-0011.pdf, 12.

[160] *Ibid*.

[161] See Part IV 2 b) (1).

In the end one has to conclude that the term "*novel combination of genetic material*" within the meaning of the Cartagena Protocol *cannot be restricted to those organisms that contain foreign DNA* by referring to State practice as a means of treaty interpretation under Art. 31 (3) (b) VCLT.

c) Object and purpose of the Cartagena Protocol

The starting point for interpretation remains, therefore, the ordinary meaning of the term. This, as shown under IV. 2. a), does not imply the presence of foreign DNA in an organism. Additionally, the object and purpose of the Cartagena Protocol within the meaning of Art. 31 (1) VCLT speaks in favour of a broad understanding of the term "*novel combination*".[162]

As already shown in Part III 1 c), the Cartagena Protocol's object and purpose consists primarily in the conservation and sustainable use of biological diversity, while this objective as a whole is to be viewed in the light of the precautionary approach. In particular regarding the precautionary approach, a severe restriction of the scope of application of the Cartagena Protocol does not appear appropriate, since an interpretation in the light of this principle implies a particularly broad scope of application.

Overall, the Cartagena Protocol is drafted in such a way that the threshold for its application is low. It is only at a second stage, when the Cartagena Protocol is applicable, that it is up to the States Parties to decide to what extent an LMO should be withdrawn from the scope of the obligations contained in the Cartagena Protocol. This is in line with the interpretation of the term "*that may have adverse effects […] taking into account risks*" established above.[163]

d) Supplementary means of interpretation

The *travaux préparatoires* or preparatory work, this means the negotiating history of the Cartagena Protocol, also clearly indicate a broad understanding of the term "*novel combination of genetic material*". They can be referred to as a supplementary means of treaty interpretation under Art. 32 VCLT "*to confirm the meaning resulting from the application of article 31*".[164]

The preparatory work of the Cartagena Protocol shows that although the question of the necessity of the presence of foreign genetic material in the organism was discussed as a criterion within the definition of LMOs, it was ultimately abandoned in favour of the broader term "*novel combination of genetic material*".[165] Notably, the idea that an LMO should contain "*foreign*" or "*transgenic*" genetic material was also rejected during the negotiations.[166] The negotiating history of the Cartagena Protocol thus confirms that the presence of foreign genetic material in an organism is *not* a defining criterion for determining what constitutes an LMO.[167]

Apart from the negotiating history, there is no room for a recourse to supplementary means of treaty interpretation within the meaning of Art. 32 VCLT in the present case. In particular, the

[162] See Part III 1 c) for details on the objectives of the Cartagena Protocol.

[163] See Part III 2.

[164] But see *Beck* (n 30) 138, at footnote 28, who refers to the *travaux préparatoires* only via the determinative mode of Art. 32 (a) VCLT, that is, "*to determine the meaning when the interpretation according to article 31 […] leaves the meaning ambiguous or obscure*".

[165] Cf. *Beck* (n 30) 138 et seq. with further references.

[166] Cf. *Beck* (n 30) 139, referring to Ad Hoc Working Group on Biosafety, 'Revised Consolidated Text of the Draft Articles' (23 February 1998) UN Doc UNEP/CBD/BSWG/5/Inf.1, 11; International Institute for Sustainable Development, Report of the Fourth Session of the Ad Hoc Working Group on Biosafety: 5–13 February 1998, 9 (85) Earth Negotiations Bulletin 1998, 1, 5.

[167] Likewise *Beck* (n 30) 139.

conditions for considering the aforementioned State practice as a supplementary means are not met.[168]

According to Art. 32 VCLT, recourse to supplementary means of interpretation may be had via the provision's so-called confirmative mode, that is "*in order to confirm the meaning resulting from the application of article 31*", and via the determinative mode ("*to determine the meaning […]*").[169] In case of the latter, however, the conditions as stipulated in Art. 32 (a), (b) VCLT must be met, that is that either "*the interpretation according to article 31 […] leaves the meaning ambiguous or obscure*" (Art. 32 (a) VCLT) or "*the interpretation according to article 31 […] leads to a result which is manifestly absurd or unreasonable*" (Art. 32 (b) VCLT).

This is not the case for the term "*novel combination of genetic material*" under the Cartagena Protocol, as the interpretation established above leads to a wide understanding of the term that is in line with the Cartagena Protocol's object and purpose.

3. NGT plants and "modern biotechnology"

Regarding the definition of "*modern biotechnology*" enshrined in Art. 3 (i) Cartagena Protocol, it distinguishes between two alternatives: on the one hand, the application of "*in vitro nucleic acid techniques*" (Art. 3 (i) (a) Cartagena Protocol), and, on the other hand, the application of "*fusion of cells beyond the taxonomic family*" (Art. 3 (i) (b) Cartagena Protocol).

In both cases, these applications must be able to "*overcome natural physiological reproductive or recombination barriers*"; furthermore, they may not constitute "*techniques used in traditional breeding and selection*". As NGT plants according to the Council version do not involve fusion of cells,[170] Art. 3 (i) (b) Cartagena Protocol is of no relevance in the present case.[171] Therefore, only the applicability of Art. 3 (i) (a) Cartagena Protocol remains subject to the following analysis.

a) NGT plants and "in vitro nucleic acid techniques"

The Cartagena Protocol does not define the term "*in vitro nucleic acid techniques*" but mentions two examples to illustrate it ("*recombinant deoxyribonucleic acid (DNA)*" and "*direct injection of nucleic acid into cells or organelles*").

On the one hand, the first category ("*recombinant deoxyribonucleic acid (DNA)*") requires the insertion of foreign DNA into the genome of the target organism.[172] Accordingly, NGT plants according to the Council version, which (also) involve genome editing techniques that do not involve the insertion of foreign DNA, do not fall under this category. On the other hand, NGT plants could in principle fall under the category of "*direct injection of nucleic acid into cells*", since some forms of CRISPR/Cas technology, which is relevant for all categories of NGT plants, involve such direct injections within the meaning of Art. 3 (i) Cartagena Protocol.[173]

Ultimately, it is irrelevant whether NGT plants fall into one of the two categories listed. It is only crucial whether they are covered by the umbrella term "*in vitro nucleic acid techniques*". This term is to be understood as "*any technique involving the handling of nucleic acid in vitro, i.e. outside the target organism*".[174] It includes all laboratory procedures in which nucleic acid is

[168] State practice, even if it does not fulfil the requirements of Art. 31 (3) (b) VCLT, may still be relevant for the interpretation of the treaty as supplementary means under Art. 32 VCLT, see *Dörr*, in Dörr/Schmalenbach (eds), *Vienna Convention on the Law of Treaties* (2018), Art. 32 para. 26.

[169] Cf. *Dörr* (n 168) Art. 32 paras 30 et seq.

[170] See Part II 2 a) (1).

[171] Cf. *Beck* (n 30) 140.

[172] *Beck* (n 30) 140 et seq.

[173] *Beck* (n 30) 141.

[174] *Beck* (n 30) 141 et seq.; see also *Voigt* (n 96) 133 et seq.

produced in vitro and then introduced into the organism in order to modify the DNA of that organism.[175]

As far as can be seen, such techniques are currently used in all cases of NGT plants that are covered by the Council version.[176] However, it should be noted that there are studies on in vivo targeted mutagenesis, and it is unclear to what extent these still fall under the term "*in vitro nucleic acid techniques*".[177]

In addition, several authors come to the conclusion that regarding certain genome editing techniques not using DNA or RNA, such as TALENs and ZFN techniques, the organisms that are created by these are likely to fall outside the scope of the ordinary meaning of the term of "*in vitro nucleic acid techniques*".[178] Some of these authors state that there is no necessity or doctrinal basis for arguing for a different interpretation of the term. They claim that TALENs and ZFN "*have largely been replaced by the more efficient CRISPR technique and are unlikely to be used widely in the future*".[179] According to these, such an approach is not possible in view of the clear wording; moreover they argue that the prerequisites for an interpretation of the term that goes beyond the wording – that is, the requirement stipulated by Art. 32 (a) VCLT – are not met since "*[a]n interpretation that excludes techniques involving engineered nucleases from the scope of the Protocol would […] not be 'manifestly absurd or unreasonable'*".[180]

However, it has to be noted that, in spite of the prevalence of CRISPR/Cas, there are still examples of, e.g., NGT 1 plants where such techniques have been used.[181] Although precise statistics are lacking, studies show that all those techniques are still of relevance.[182]

Against this background, it is convincing to argue that further laboratory techniques (such as TALENs and ZFN) are covered by the notion of "*in vitro nucleic acid techniques*", despite not constituting such techniques in the strict sense of the wording. Even though the scholars denying this correctly stress that the consideration of the object and purpose must only be used to clarify the text and not to provide independent sources of meaning that contradict the text,[183] it is shown that there is a legal basis for including these techniques beyond the ordinary meaning of these notions:

In this regard, Art. 31 (4) VCLT is decisive. According to this – in deviation from the "*ordinary meaning*" (according to Art. 31 (1) VCLT) – "*[a] special meaning shall be given to a term if it is established that the parties so intended*". Art. 31 (4) VCLT, consequently, entails an exception to Art. 31 (1) VCLT "*for cases where the parties have agreed […] implicitly […] to replace the ordinary meaning of a term contained in a treaty provision by a special meaning*".[184]

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[175] *Beck* (n 30) 141, 203.

[176] Cf. *Beck* (n 30) 142; *Voigt* (n 9627) 134.

[177] Cf., e.g., *Skrekas* et al., Targeted In Vivo Mutagenesis in Yeast Using CRISPR/Cas9 and Hyperactive Cytidine and Adenine Deaminases, 12(8) ACS Synthetic Biology Journal (2023), 2278 et seq.; *Zimmermann* et al., A Cas3-base editing tool for targetable in vivo mutagenesis, 14 (3389) Nature Communications 2024.

[178] Cf. *Beck* (n 30) 142 et seq.; *Voigt* (n 96) 134; *Ishii*, Crop Gene-Editing: Should We Bypass or Apply Existing GMO Policy?, 23 (11) Trends in Plant Science 2018, 947, 948; *Sirinathsinghji* (n 112) 1, 3 et seq.

[179] *Beck* (n 30) 143.

[180] *Beck* (n 30) 142.

[181] Cf. *Parisi/Rodríguez-Cerezo*, Current and future market applications of new genomic techniques, EUR 30589 EN, Publications Office of the European Union (2021), 5, 16, referring to a soybean variety modified with TALEN, which was used to inactivate two genes involved in fatty-acid synthesis through targeted mutagenesis, by the United States-based company Calyxt as "a Group 1 NGT".

[182] Cf., e.g., *Miroshnichenko* et al., Achievements, Challenges, and Prospects in the Production of Nontransgenic, Genome-Edited Plants, 55 (9) Applied Biochemistry and Microbiology 2019, 825, 827, according to which TALEN and ZFN, next to CRISPR/Cas, still accounted for 11% of genome editing in plants in the period from 2009–2018.

[183] Cf. *Dörr* (n 139) Art. 31 para. 57 with further references.

[184] *Dörr* (n 139) Art. 31 para. 109.

This means that in such cases the intention of the States Parties are relevant rather than "*its emanation in the text, in order to establish their very own understanding of a term which they used*".[185] It is confirmed by the negotiating history that shows that the negotiating States Parties agreed that the definition of "*modern biotechnology*" and in particular "*in vitro nucleic acid techniques*" should be as broad as possible.[186] In particular, future techniques that were not yet conceivable at that time – including genome editing techniques such as ZFN and TALENs – were also to be included.[187] Consequently, it seems convincing that the term "*in vitro nucleic acid techniques*" is to be given a "*special meaning*" (Art. 31 (4) VCLT) which can be derived from the intention of the States Parties at the time of the negotiations. They aimed to include definitions in the Cartagena Protocol that are as open for technological developments and changes as possible.

Even if one does not follow this line of argumentation, one can rely on negotiating history via Art. 32 VCLT. The negotiating history indicates that the States Parties were searching for the broadest possible term, a term that should encompass future technologies.[188] Therefore, an exclusion of new technologies of modern biotechnology, which in principle fulfil the characteristics anticipated by the negotiating States Parties, but do not fulfil the technical and scientific requirements of "*in vitro nucleic acid techniques*", would contradict the spirit and purpose of the Cartagena Protocol in a particularly stark manner. It would therefore meet the threshold of manifest unreasonableness: it would hardly be possible to explain to a non-scientist why some laboratory techniques fall under the term "*in vitro nucleic acid techniques*" and some do not, even though the result is ultimately identical and the techniques interfere with or change the DNA of organisms just like "genuine" in vitro nucleic acid techniques do.

Hence as a result, one has to conclude that all genome editing techniques, even including those that do not use DNA or RNA such as ZFN and TALEN, are to be considered "*in vitro nucleic acid techniques*" within the meaning of the Cartagena Protocol.

b) NGT plants and techniques that "overcome natural physiological reproductive or recombination barriers"

Another critical factor is whether the processes of targeted mutagenesis, cisgenesis or intragenesis "*overcome natural physiological reproductive or recombination barriers*" (Art. 3 (i) Cartagena Protocol). In the case of NGT plants governed by the Council version, this criterion has been questioned for cases in which the "*use of NGT does not even cause a temporary integration e.g. to produce the CRISPR-tools in the target organism.*"[189]

It has been discussed controversially regarding Art. 3 (i) Cartagena Protocol: some authors simply seem to equate it with an element of the EU's GMO definition according to which "*the combination of genetic material needs to be beyond what can occur naturally by mating and/or natural recombination*".[190]

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[185] *Ibid*.

[186] Cf. *Beck* (n 30) 141, with further references; cf. also the summary of the negotiations contained in International Institute for Sustainable Development, Report of the Fourth Session of the Ad Hoc Working Group on Biosafety: 5–13 February 1998, 9(85) Earth Negotiations Bulletin 1998, 1, 5: "*[S]ome delegates proposed 'modified by in vitro gene technologies' while others objected to use of the term 'gene,' noting that other technologies might also be used to produce LMOs*".

[187] Cf. Part II above as well as *Mackenzie* et al. (n 83) paras 217 et seq.; *Beck* (n 30) 142.

[188] Cf. *Beck* (n 30) 141 with further references.

[189] *Kahrmann/Leggewie* (n 16) 35; cf. also *Keiper/Atanassova*, Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols, 8 Frontiers in Bioengineering and Biotechnology 2020, Article no. 310, 5.

[190] Cf. *Custers* et al., Genetic Alterations That Do or Do Not Occur Naturally; Consequences for Genome Edited Organisms in the Context of Regulatory Oversight, Perspective 2019, Article no. 213, 1, 3.

The reason for this is probably that the ordinary meaning of the term "*natural physiological reproductive barriers*" might be understood in a sense that these "*would normally prevent exchange of genetic material*",[191] and the term "*natural physiological recombination barriers*" would equally imply the "*exchange of genes*"[192]. Accordingly, the definition would only "*apply when DNA sequences are introduced from species that would not be able to exchange genetic material with the target organism […] under natural conditions*".[193] This would mean that some genome editing methods, especially those not involving the exchange or recombination of DNA, would not meet these requirements.[194]

However, this is to be disputed when looking at the systematic context of Art. 3 (i) Cartagena Protocol. The criterion "*overcome natural physiological reproductive or recombination barriers*" forms part of the process-related aspect of the definition of an LMO, i.e. it focuses on the process of modification or the techniques and not on the organism that ultimately results.[195]

Therefore, it is convincing to argue that the decisive factor is that the techniques used are in principle "*capable of achieving genetic changes that cannot be achieved with natural reproduction and recombination mechanisms*".[196]

It seems that this criterion is met in the case of NGT plants, as all genome editing techniques can in principle achieve such changes,[197] because "*[i]n comparison to methods of conventional breeding (including non-targeted mutagenesis), NGTs can overcome the boundaries of natural genome organization by repair mechanisms, gene duplications, genetic linkages and other epigenetic mechanisms and can make the genome much more extensively available for genetic changes*".[198]

Hence as a result, one can conclude that all NGT plants are obtained through techniques that "*overcome natural physiological reproductive or recombination barriers*" as required by Art. 3 (i) Cartagena Protocol.

c) NGT plants and techniques "not used in traditional breeding and selection"

The term "*techniques used in traditional breeding and selection*" (Art. 3 (i) Cartagena Protocol) seems vague. It has even been questioned by scholars whether this criterion has independent significance or whether it is only declaratory in nature.[199] After all, the use of an in vitro nucleic acid technique or a cell fusion technique to obtain an organism containing a novel combination of genetic material may already be decisive for the existence of an LMO.[200]

When trying to determine the "*ordinary meaning*" of "*techniques used in traditional breeding and selection*", it is unclear whether the term "*traditional*" reflects a historical approach and therefore must refer to "*methods of breeding and selection that have been subject to*

[191] *Mackenzie* et al. (n 83) 50.

[192] *Mackenzie* et al. (n 83) 50.

[193] Cf. *Beck* (n 30) 143 with further references.

[194] Cf. *Beck* (n 30) 143.

[195] *Beck* (n 30) 143 et seq.; *Mackenzie* et al. (n 83) para. 214.

[196] *Beck* (n 30) 144.

[197] *Beck* (n 30) 145.

[198] *Koller/Cieslak*, A perspective from the EU: unintended genetic changes in plants caused by NGT—their relevance for a comprehensive molecular characterisation and risk assessment, 11 (1276226) Frontiers in Bioengineering and Biotechnology 2023, 1, 2.

[199] See *Gerdung* (n 104) 139 at footnote 201, referring to *Böckenförde* (n 98) 149, cf. also *Mackenzie* et al. (n 83) para. 226: "*Any organism into which such a novel combination of genetic material is subsequently transferred, even if that transfer is achieved through traditional breeding and selection techniques, will also be a LMO under the terms of the Protocol*".

[200] *Ibid.*

continuous and widespread use for a long period of time";[201] or whether it also refers to more recent, and sophisticated, techniques of conventional breeding: if the term "*traditional*" is not fixed by a certain point in time, it might be possible – by way of a dynamic interpretation – to state that certain genome editing methods can be viewed as "*traditional*" at one point in the future.

However, the equally authentic French wording speaks of "*techniques utilisées pour la reproduction et la sélection de type classique*", i.e. not of the historical context of tradition. It therefore seems to argue against the notion that one day, even genome editing techniques might be referred to as "*traditional*", since the term "*classique*" implies a less value-driven approach than the term "*traditional*".

Taking this into account, it is convincing to interpret the term "*traditional breeding and selection*" in such a way that it actually refers to techniques that were perceived as "traditional" or at least "conventional" by the States Parties at the time of the negotiations.

A dynamic interpretation of the term is *not* appropriate, as otherwise the term could be misused to label new techniques of modern biotechnologies as "*traditional*" and to counteract the protection granted by the Cartagena Protocol. This would be contrary to the principle of good faith overarching the interpretation according to Art. 31 (1) VCLT.

Other authors argue that the main characteristic of the term "*techniques not used by traditional breeding and selection*" "*is that it relies on random genetic change, as opposed to breeding methods that rely on introducing specific changes in the genetic material*".[202] However, it must be remembered that there are also genome editing techniques that aim at random genetic change,[203] so that this criterion cannot be seen as the final and decisive one.

From a teleological point of view, the criterion seems primarily aimed to restrict the definition of LMOs in such a way that even more sophisticated (but) conventional techniques, which ultimately overcome natural barriers, are excluded from the scope of the Cartagena Protocol. The reason for this is that in this case too "*it is possible to make crosses, and achieve hybrids between organisms which are less closely related, and which would not interbreed under natural conditions*"[204], i.e., ultimately "*overcome natural physiological reproductive or recombination barriers*".

Nevertheless, the interpretation should not lead to an overly narrow understanding of the term, as the Cartagena Protocol also provides for corrections within the scope of application to ensure that not every LMO that falls within the definition actually triggers all the obligations provided for in the Cartagena Protocol.

Therefore, taking into account these arguments, one must conclude that it is not possible to understand genome editing techniques that enable genetic modification at the level of individual nucleotides as "*techniques used in traditional breeding and selection*".[205]

This means that NGT plants do not constitute organisms that fall outside the LMO definition of the Cartagena Protocol because of this criterion.

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[201] *Beck* (n 30) 145.

[202] *Beck* (n 30) 146 (footnotes omitted).

[203] Cf. *Naegeli* et al., 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, 18 (11) EFSA Journal 2020, 6299, 1, 7.

[204] *Mackenzie* et al. (n 83) para. 225.

[205] *Beck* (n 30) 146 et seq.

4. Result and summary

According to this analysis, every NGT plant that is covered by the Council version constitutes a "*living modified organism*" within the meaning of Art. 3 (g) Cartagena Protocol.

Even though there are some uncertainties concerning the term "*in vitro nucleic acid techniques*" that forms part of the Cartagena Protocol's definition of "*modern biotechnology*", one has to conclude that all known laboratory techniques of genome editing fall under this term, and that this term should not be interpreted too narrowly.

In any case, the most widely used CRISPR/Cas technique is covered by the Cartagena Protocol, as this technique generally constitutes an "*in vitro nucleic acid technique*".

Concerning the assessment of the impact of possible divergences of interpretation and/or practice of the States Parties through their national legislation, one has to conclude that there are no relevant effects of these national regulations: they do not constitute subsequent practice within the meaning of Art. 31 (3) (b) VCLT as in particular a uniform and consistent pattern of State practice is missing and, in view of these divergent national approaches, the subjective component, which would be necessary for a modification of the treaty through subsequent practice, cannot be assumed.

Besides, they are not supplementary means within the meaning of Art. 32 VCLT. Therefore, the term "*novel combination of genetic material*" within the meaning of the Cartagena Protocol *cannot be restricted to those organisms that contain foreign DNA* by referring to State practice as a means of treaty interpretation under Art. 31 (3) (b) VCLT. The starting point for interpretation remains, therefore, the ordinary meaning of the term.

Ultimately, arguments must be based solely on the means of Art. 31 (1) VCLT, and the interpretation of Art. 3 (g) Cartagena Protocol based on the object and purpose and the wording of the definition suggest a far-reaching interpretation. Hence, all NGT plants that are regulated as part of the Council version are covered by the Cartagena Protocol's LMO definition.

V. Compatibility of the Council version with the Cartagena Protocol

It was shown that the Cartagena Protocol applies to all NGT plants in the meaning of the Council version. In the following, it is analysed to what extent the Council version complies with the Cartagena Protocol, that is binding on the EU, and Germany, under international law.

1. NGT 1 and 2 plants

As the Council version distinguishes between NGT 1 and NGT 2 plants, the proposed rules for the two different categories must be considered separately.

For NGT 2 plants, the previous EU GMO legislation continues to apply, with some minor adjustments as mentioned before.[206] This means that these NGT 2 plants are still subject to the authorisation procedure including environmental risk assessment, as well as the notification, identification and labelling requirements from the current, various EU legal acts covering GMOs.[207] Consequently, there are no concerns in this regard considering the compatibility with the Cartagena Protocol; the same is true regarding the aforementioned minor changes. These regulatory changes are therefore not discussed below.[208]

[206] See above Part II 2 d).

[207] See above Part II.

[208] For a critical analysis of these amendments with regard to the Union law cf. *Spranger* (n 38) 27–30.

2. Compliance regarding the regulation of NGT 1 plants in the Council version

The compatibility with the Cartagena Protocol is questionable concerning the proposed EU regulation of NGT 1 plants and their products, including food and feed.

a) Risk assessment

It is shown that there are reasons to argue that the Council version and the verification procedure for NGT 1 plants laid out therein can be seen as to comply with the requirements for risk assessments under the Cartagena Protocol:

As outlined in Part III 1 d) above, risk assessments are a key requirement according to the regulatory framework of the Cartagena Protocol. They are required as part of the AIA procedure prior to the first intentional transboundary movement of LMOs, both from the Party of export[209] and from the Party of import[210], as well as prior to a decision on domestic use of LMOs-FFP[211]. This risk assessment is to be carried out in accordance with Annex III Cartagena Protocol. The objective of such a risk assessment is *"to identify and evaluate the potential adverse effects of living modified organisms […] in the likely potential receiving environment."*[212]

Under the current EU GMO legislation, all NGT plants are subject to an environmental impact assessment[213] that largely mirrors the requirements of Annex III Cartagena Protocol.[214] According to the Council version, NGT 1 plants would, however, be excluded from the scope of this legislation and, consequently, from these procedural requirements.[215] A deliberate release of NGT 1 plants for testing purposes or placing on the market would be possible following the verification procedure under Arts 6 (1), (8) and 7 (1), (6) Council version, through which the status as a NGT 1 plant is confirmed. Hence, one must answer the question whether this proposed verification procedure for NGT 1 plants according to the Council version fulfils the requirements on risk assessments set out in Annex III Cartagena Protocol.

For this analysis, it is important to note that the Cartagena Protocol frames the procedure but is silent on the evaluation of the results of the risk assessment or on the decisions to be taken based on these results.

Regarding the procedure, Annex III Cartagena Protocol specifies that risk assessments should, as a general rule, be carried out *"on a case-by-case basis".*[216] As part of the verification procedure under Arts 6 (1), (8) and 7 (1), (6) Council version, the competent authority determines whether the conditions set out in Art. 3 (7) (a) Council version are met, that is, whether a NGT plant fulfils the criteria of equivalence to conventional plants.[217] This determination does not, however, give any scope of assessment to the competent authority on potential adverse effects or risks associated with that NGT plant, but follows a set of criteria laid down in Annex I Council version. The progeny of a NGT 1 plant, including those obtained by crossing NGT 1 plants, does not have to fulfil the criteria of equivalence and is not subject to the verification procedure.

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[209] As part of the information required with notification, see Art. 8 (1) Cartagena Protocol and Annex I paragraph (k) thereto.

[210] As part of the decision process on import, see Art. 15 (1) and (2) Cartagena Protocol.

[211] See Art. 11 (1) Cartagena Protocol and Annex II paragraph (j) thereto.

[212] Annex III paragraph (1) Cartagena Protocol.

[213] See above Part II and (n 13).

[214] See Annex II to Directive 2001/18/EC.

[215] See Art. 5 (1) Council version.

[216] Annex III paragraph (6) Cartagena Protocol.

[217] For details see above Part II 2.

At first sight, the requirement of a *"case-by-case basis"* could hinder such a procedure that serves only to check that a NGT plant falls within a pre-determined group of cases, without requiring the identification and evaluation of risks specifically for that plant.

However, one can argue that the *"case-by-case basis"* requirement should not be interpreted as an overly formal standard. The Cartagena Protocol offers considerable leeway to States Parties when it comes to the depth of risk assessments when it states that *"[t]he required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment."*[218]

The decisive factor is that the risk assessment is *"carried out in a scientifically sound and transparent manner"*[219] and is *"appropriate"* to fulfil its objective.[220] Therefore, the question must be answered whether the Council version offers such an appropriate and scientifically sound way of identifying and evaluating the risks associated with NGT 1 plants.

Some argue that the general approach foreseen by the Council version – according to which whole groups of NGT plants are assessed for potential adverse effects and risks – is not scientifically justified.[221] Others advocate firmly that there is no scientifically justified cause for concern regarding risks by NGT 1 plants as a whole.[222] The latter would imply that taking decisions based on this previously determined group of cases is scientifically justifiable. Our legal opinion cannot offer a final assessment of these arguments, as these have to be based on scientific discourse.

But, with all due caution, from a legal point of view, one can argue that a scientific consensus is not necessary concerning the approach taken in the risk assessment. As mentioned, the Cartagena Protocol itself provides only that it must be appropriate to fulfil its objective as well as that it is scientifically sound. If different scientific opinions exist, States Parties therefore have discretion on the approach taken, as long as it is scientifically justifiable.[223] Ultimately, the Council version takes a two-step approach: it includes a normative determination of the acceptable threshold of risks associated with NGT 1 plants by the COM, and the verification procedure under the Council version serves to verify that a NGT plant falls within that pre-determined group of cases.

The criteria for determining NGT 1 plants as a group of cases in the Council version are based on scientific studies referred to by both the COM and the Council in their drafts.[224] The

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[218] Annex III paragraph (6) Cartagena Protocol. See also Annex III paragraph (8) Cartagena Protocol: *"risk assessment entails, as appropriate, the following steps […]"* or id, paragraph (9): *"Depending on the case, risk assessment takes into account […]".*

[219] Annex III paragraph (3) Cartagena Protocol.

[220] See Annex III paragraph (8) Cartagena Protocol.

[221] *Eckerstorfer/Dolezel/Engelhard/…/Lüthi,* Recommendations for the Assessment of Potential Environmental Effects of Genome-Editing Applications in Plants in the EU, 12(9) Plants 2023, 1764, available at https://doi.org/10.3390/plants12091764, 14–16; see also *Buchholz,* Kommissionsvorschlag einer Verordnung über Neue Genomische Techniken (NGT): Zur Verletzung des Vorsorgeprinzips. Rechtliche Stellungnahme im Auftrag der Bundestagsfraktion Bündnis 90/Die Grünen, 14 September 2023, available at https://www.gruene-bundestag.de/presse/, 29–30; *Winter* (n 28) 9.

[222] *Dederer*, Neue genomische Techniken und ihre Anwendung an Pflanzen: ein Update zum Stand der Regulierungsdebatten in der EU, in Clemens/Fehse (eds), *Im Fokus: Genomeditierung von Pflanzen. Eine aktuelle Bestandsaufnahme der Arbeitsgruppe Gentechnologiebericht* (2024), available at http://dx.doi.org/10.17169/refubium-45156, 28, 31–32, with further references. For an English translation see id, at 123.

[223] Cf. Convention on Biological Diversity, COP-MOP, Eleventh Meeting, Additional Voluntary Guidance Materials to Support Case-by-Case Risk Assessments of Living Modified Organisms Containing Engineered Gene Drives, CBD/CP/MOP/11/9, 27 August 2024, available at https://www.cbd.int/doc/c/175e/90b0/89c0c71660cccc1539adf34f/cp-mop-11-09-en.pdf, 41 as a soft law document, for details see above (n 70).

[224] See Recitals 14 et seq. Council version, and previously also id, in the COM proposal. Reference is made therein to EFSA, Panel on Genetically Modified Organisms, Scientific opinion addressing the safety assessment of plants

identification and evaluation of potential adverse effects or risks associated with such plants has therefore taken place on this abstract level when the criteria for NGT 1 plants were set up.[225] This carries with it the assertion that the potential adverse effects or risks associated with NGT 1 plants are the same for all intended use cases and for all potential receiving environments, and that any further differentiation is not scientifically necessary.

The Cartagena Protocol itself does not determine the evaluation of the results of the risk assessment or on the decisions to be taken based on these results, as mentioned before. The risk assessment is to *"inter alia, [be] used by competent authorities to make informed decisions regarding living modified organisms."*[226] It contains, as appropriate, *"[a] recommendation as to whether or not the risks are acceptable or manageable".*[227] What level of risk is acceptable is therefore a decision taken by each States Party to the Cartagena Protocol. In this regard, the Cartagena Protocol only stipulates – due to its precautionary approach – that *"[l]ack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."*[228] The COM – via the COM proposal – and the Council – via the Council version – claim that NGT 1 plants as a group pose an acceptable risk,[229] which is a decision by the COM based on the consensus of parts of the scientific community. The starting point of this assessment in the form of the *"equivalence to conventional plants"* in Art. 3 (7) Council version and the criteria thereto set out in Annex I Council version is not scientifically untenable, even if the details are ultimately the result of political compromise[230] – with one important reservation, as the insertion of foreign DNA in NGT plants is not excluded in a sufficiently clear manner by the Council version in its current form. This should be assured through an amendment of the criteria in Annex I before their adoption.

As part of the verification procedure under the Council version itself, the competent authority applies the criteria for NGT 1 plants to a concrete NGT plant submitted to it for review. This can be seen as a decision on a *"case-by-case basis"* embedded in an upstream risk assessment. One can therefore conclude that the verification procedure as a whole is still in line with the requirements for risk assessments under Annex III Cartagena Protocol.[231]

Insofar as the COM is authorised by Art. 5 (3) Council version to adopt delegated acts amending the criteria for NGT 1 plants as defined by the Council version, this procedure must also comply with the requirements for risk assessments under the Cartagena Protocol. It can be argued that the Council version contains sufficient procedural requirements for such

developed through cisgenesis and intragenesis, 10(2) EFSA Journal 2012, 2561, available at https://www.efsa.europa.eu/en/efsajournal/pub/2561; and EFSA, Panel on Genetically Modified Organisms, Updated Scientific Opinion on Plants Developed Through Cisgenesis and Intragenesis, 20(10) EFSA Journal 2022, 7621, available at https://doi.org/10.2903/j.efsa.2022.7621. These EFSA studies do not, however, specify the equivalence criteria contained in the draft proposals. Details on the scientific reasoning behind these equivalence criteria can be found in two documents issued by the Council and the COM, respectively, but these documents are not referred to in the draft proposals themselves: Council, Regulation on new genomic techniques (NGT) – Technical paper on the rationale for the equivalence criteria in Annex I, 2023/0226(COD), 16 October 2023, available at https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CONSIL:ST_14204_2023_INIT as prepared by the Commission services; and COM, Commission Staff Working Document, Impact Assessment Report, SWD(2023) 412 final, 5 July 2023, available at https://eur-lex.europa.eu/legal-content/MT/TXT/?uri=CELEX:52023SC0412, 28 et seq.

[225] Cf. *Kahrmann/Leggewie* (n 16) 34.

[226] Annex III paragraph (2) Cartagena Protocol.

[227] Annex III paragraph (8) (e) Cartagena Protocol.

[228] Annex III paragraph (4) Cartagena Protocol.

[229] See (n 224).

[230] In its Annex III paragraph (5), the Cartagena Protocol itself provides that the risks associated with LMOs or products thereof *"should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment"* which implies a comparative approach, that is therefore in principle acceptable. See also Convention on Biological Diversity, COP-MOP (n 223) 36–37. Cf. *Kahrmann/Leggewie* (n 16) 36.

[231] Cf. *Kahrmann/Leggewie* (n 16) 34.

amendments that can only take place *"to the extent justified by advances in scientific knowledge"* and must be accompanied by *"a report [that] […] shall include an up-to-date scientific literature review […] [and] take into account any relevant new or updated scientific opinions from the Authority."*[232]

As far as the Council version states that a NGT 1 plant product may fall under the definition of "novel food" within the meaning of Regulation (EU) 2015/2283 and may therefore be subject to the authorisation procedure laid out therein,[233] it should be noted that this procedure does not fulfil the requirements for risks assessments under Annex III Cartagena Protocol. The objective of protection and, consequently, the scope of the risk assessment, in Regulation (EU) 2015/2283 and the Cartagena Protocol is different. The risk assessment under the Cartagena Protocol puts a focus on environmental concerns when it requires States Parties *"to identify and evaluate* the *potential adverse effects […] on biological diversity, taking also into account risks to human health"*[234], that underlines the environmental focus of the Cartagena Protocol.[235] The authorisation procedure for novel foods under Regulation (EU) 2015/2283, however, focuses only on effects and safety risks on human health, including consumer protection.[236] Environmental considerations, such as the conservation and sustainable use of biological diversity, are not part of this assessment.[237]

To summarise, the Council version and the verification procedure for NGT 1 plants laid out therein can be seen as to comply with the requirements for risk assessments under the Cartagena Protocol.

b) Notification obligation prior to export

The question has to be answered whether the Council version violates the notification obligations prior to export under the Cartagena Protocol.

(1) Content of the notification obligations

As mentioned above, as part of the AIA procedure, a Party of export is generally subject to a notification obligation under Art. 8 Cartagena Protocol before the first intentional transboundary movement of a LMO to another State Party to the Cartagena Protocol. The notification shall contain, at a minimum, the information specified in Annex I. In addition to the biological characteristics and origin of the donor and recipient organisms and a description of possible dispersal habitats, these include, inter alia, the regulatory status of the LMO concerned in the exporting State, the results of the notification in other States, proposals for safe storage, use and disposal and the results of a risk assessment carried out in accordance with Annex III.[238]

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[232] See Art. 5 (3) Council version.

[233] See Recital (22) Council version and details above in Part II 2.

[234] Annex III paragraphs (1) and (8) (a) Cartagena Protocol.

[235] See Part III 1 c).

[236] See, for example, Arts 7, 10 (2) (e) and (3), 11 (2) Regulation (EU) 2015/2283.

[237] This follows already from the wording of Regulation (EU) 2015/2283, that formulate the general conditions for the authorisation of novel foods in its Art. 7 as follows: *"the food does not, on the basis of scientific evidence available, pose a safety risk to human health; […] the food's intended use does not mislead the consumer […]; […] where the food is intended to replace another food, it does not differ from that food in such a way that […] would be nutritionally disadvantageous for the consumer."* The term "environment" does not figure in the operative part of the Regulation. While it is mentioned in Recitals (2) and (29), respectively, this does not allow for environmental considerations to be taken into account during the authorisation procedure against the clear wording of Art. 7 Regulation (EU) 2015/2283.

[238] While a specification of the notification obligation was repeatedly discussed by the COP-MOP, no guidelines have been adopted to this date. See MOP Decision BS-VI/10 ('Notification requirements (Article 8)'), para. 2, contained in 'Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving As the Meeting of the Parties to the Cartagena Protocol on Biosafety', UNEP/CBD/BS/COP-MOP/6/18 [2012], 86.

Furthermore, according to Art. 24 (1) Cartagena Protocol, "*[t]ransboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol*". Such non-States Parties include, inter alia, major industrialised States such as the United States, Canada, Argentina, Australia but also so-called developing countries such as Haiti, Nepal and Equatorial Guinea.[239] In view of the objective of the Protocol defined in Art. 1 Cartagena Protocol as contributing to *"an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms*,[240] some authors argue that Art. 24 Cartagena Protocol contains an obligation for States Parties to obtain the consent of a non-State Party prior to import, following the AIA procedure.[241] It seems convincing to argue, in order to not defy the Protocol's object and purpose through uncontrolled transboundary movements of LMOs to third States, that an export State – that is Party to the Cartagena Protocol and intends to export LMOs into a non-contracting State – is still obliged to notify this State.[242]

This interpretation is supported by the wording of Art. 2 (2) Cartagena Protocol that does not limit the scope of the general obligation contained therein to activities relating to LMOs only vis-a-vis other States Parties to the Protocol.

While it may not be necessary that the Party of export follows the exact procedure and requirements stated by Art. 8 Cartagena Protocol, the notification to the non-State Party must be appropriate to enable that State to make an informed decision about import.[243]

(2) Compatibility of the Council version with the notification obligations

Regarding the compatibility of the Council version with the notification obligation as contained in Art. 8 (1) Cartagena Protocol, a distinction must be made between EU Member States and non-EU Member States.

Considering the relations between EU Member States and non-Member States, the notification obligation is currently implemented through Art. 4 Regulation (EC) No. 1946/2003 and Annex I thereto. However, Art. 5 (1) Council version, as spelled out above, provides that Regulation (EC) No. 1946/2003 is no longer applicable with regard to NGT 1 plants. The Council version does not provide for any alternative mechanism regarding notification of importing States for the transboundary movement of NGT 1 plants.

One therefore must conclude that the ***Council version violates the provisions of Art. 8 Cartagena Protocol*** regarding the importing States that are non-EU Member States, but Parties to the Cartagena Protocol. The same is true concerning the notification obligations under Art. 24 (1) Cartagena Protocol vis-à-vis non-States Parties to the Cartagena Protocol, i.e., **the *Council version violates the provision of Art. 24 (1) Cartagena Protocol.***

For the transboundary movement of LMOs between EU Member States, under the current EU GMO legislation, Directive 2001/18/EC provides for two different notification procedures, differentiating between the mere deliberate release of GMOs (Art. 6 Directive 2001/18/EC, "Standard authorisation procedure") and their placing on the market (Art. 13 Directive 2001/18/EC, "Notification procedure"). The exclusion of NGT 1 plants from the EU GMO legislation by Art. 5 (1) Council version also means that Directive 2001/18/EC no longer applies. However, in this case, the Council version provides for a similar procedure with the verification procedure contained in Arts 6 and 7 Council version. As was previously the case for Directive

[239] See above Part III 1 b).

[240] See, for further details, Part III 1 c).

[241] *Beck* (n 30) 192 with further references.

[242] Likewise *Beck* (n 30) 193.

[243] *Mackenzie* et al. (n 83) paras 600 and 612; *Bernasconi-Osterwalder*, The Cartagena Protocol on Biosafety: A Multilateral Approach to Regulate GMOs, in Weiss/Jackson/Bernasconi-Osterwalder, *Reconciling environment and trade* (2008), 645, 655; *Beck* (n 30) 193, with further references.

2001/18/EC, it is likely that the Council version will be classified by the EU as a "*domestic regulation*" within the meaning of Art. 14 (4) Cartagena Protocol.[244] This norm provides that any State Party *"may determine that its domestic regulations shall apply with respect to specific imports to it".*

As the Council version can therefore set out rules applicable to the import from an EU Member State into other EU Member States, there is *no violation* of the notification obligations under the Cartagena Protocol in this regard.[245]

c) Information obligation

For the same reasons as established above for Art. 8 Cartagena Protocol, the ***Council version also violates Art. 11 (1) Cartagena Protocol*** that obliges States Parties to inform the other Parties through the Biosafety Clearing-House of a final decision regarding domestic use of LMOs-FFP that may be subject to transboundary movement.

Under the current EU GMO legislation, Art. 9 Regulation (EC) 1946/2003 transposes this obligation to EU law also for all NGT plants. However, under the Council version, NGT 1 plants are exempted from this obligation by Art. 5 (1) Council version and no alternative mechanism is put in place.

d) Labelling requirements

It is shown that the Council version also violates the labelling requirements under Art. 18 Cartagena Protocol.

According to Art. 18 (1) Cartagena Protocol, each State party shall take the necessary measures to require that LMOs are "*handled, packaged and transported under conditions of safety"* for their international transboundary movement within the scope of the Cartagena Protocol. In addition to this, different labelling requirements ("*documentation*") are laid down in Art. 18 (2) Cartagena Protocol depending on the purpose of use of the LMO.

(1) Labelling requirements for LMOs-FFP

Art. 18 (2) (a) Cartagena Protocol covers the labelling of LMOs-FFP.[246] Documentation accompanying these LMOs must clearly identify that they "*may contain*" LMOs and are not intended for intentional introduction into the environment, and indicate a contact point for further information. Further details on these requirements, including specification of their identity and any

[244] Cf. Biosafety Clearing-House, 'Fourth National Report on the Implementation of the Cartagena Protocol on Biosafety' – European Union (30 September 2019), available at https://bch.cbd.int/en/pdf/documents/cpbNationalReport4/BCH-NR4-EU-248099/1, Answer to Question 60.

[245] Before the entry into force of the Cartagena Protocol, the European Commission had assumed that Art. 14 (1) Cartagena Protocol on bilateral, regional and multilateral agreements and arrangements would be applicable for EU law: *"Article 14 […] allow[s] Member States of the European Union […] to […] [u]tilise the provisions of Community legislation […] for transboundary movements of LMOs in the European Union (as provided for by Article 14.3 of the Protocol) and ultimately for movements to and from EEA countries."* See Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms, COM/2002/0085 final - COD 2002/0046, OJ 151 E (25 June 2002), 121 et seq. As such, a future modified NGT plant regulation would then be subject to the limit provided in Art. 14 (1) Cartagena Protocol that such an agreement must be "*consistent with the objective of [the] Protocol and do not result in a lower level of protection than that provided for by the Protocol*". States Parties are likely to have some discretion, as long as the arrangements are appropriate to achieve an adequate level or protection, cf. *Young*, Legislative Options for National Implementation, in Cordonier Segger/Perron-Welch/Frison, *Legal Aspects of Implementing the Cartagena Protocol on Biosafety* (2013), 205, 218. This would likely be fulfilled by the Council version.

[246] Beyond that, the labelling of LMOs-FFP shall also be part of the information about the "suggested methods for the safe handling, storage, transport and use" of LMOs-FFP, which a Party, that makes a final decision regarding domestic use of LMOs-FFP that may be subject to transboundary use, has to share with the other State Parties, Art. 11 (1) and Annex II paragraph (h) Cartagena Protocol.

unique identification, were laid down in a decision by the COP-MOP in accordance with Art. 18 (2) (a) 2nd sentence Cartagena Protocol.[247]

Accordingly, the documentation shall cover, *inter alia,* the common, scientific and, where available, commercial names of the LMOs; the unique identifier code of the LMOs if registered in the Biosafety Clearing-House, or in the absence of such code, the transformation event code of the living modified organisms; and it shall provide the details of a contact point for further information (the exporter and importer in the supply chain, and/or appropriate authority, when designated by a government as the contact point).[248]

Furthermore, it is differentiated between already known and unknown LMOs-FFP. In cases where the identity of the LMO is known (trough means such as identity preservation systems), the documentation shall state clearly that the shipment "*contains*" LMOs-FFP; in cases where the identity of the living modified organisms is not known, the documentation shall state that the shipment "*may contain*" LMOs-FFP.[249]

It is important to note that, as the requirements also apply to LMOs that are processed into food or feed at a later stage (i.e., after import), the labelling requirements from Art. 18 (2) (a) Cartagena Protocol do not address the issue of domestic food labelling requirements for consumer information. The label is only seen by the producers and buyers of shipments, and not by consumers.[250]

It is questionable if the rules on labelling of NGT 1 plants within the Council version fulfil these requirements set out in the Cartagena Protocol:

Under current EU GMO legislation, all products consisting of, containing or produced from GMOs shall be labelled as such (Arts 4, 5 Regulation (EC) No 1830/2003).[251] As they are excluded from the scope of this legislation by Art. 5 (1) Council version, this no longer applies to NGT 1 plants. Instead, according to Art. 10 Council version, only the *"plant reproductive material"* that contains or consists of category 1 plant(s) and is made available to third parties, 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[252]. "*Plant reproductive material*" within the meaning of Art. 10 Council version is defined as living plants or living parts of them capable of, and intended for, producing entire plants.[253]

This means that under the Council version there is no labelling requirement for a NGT 1 plant not intended for producing new plants, but intended for direct use as food or feed, or for processing. As this means that such NGT 1 plants, and the food and feed derived from them, no longer have to be labelled as such in the case of transboundary movement, this falls short of the labelling requirement under Art. 18 (2) (a) Cartagena Protocol for LMOs-FFP as outlined

[247] Cf. COP-MOP, Report of the second Meeting of the Conference of the Parties to the Convention on Biological Diversity as the Meeting of the Parties to the Protocol on Biosafety, UNEP/CBD/BS/COP-MOP/2/15 [2005] 60-61 (Annex III); COP-MOP, Report of the third Meeting of the Conference of the Parties to the Convention on Biological Diversity as the Meeting of the Parties to the Cartagena Protocol on Biosafety, UNEP/CBD/BS/COP-MOP/3/15 [2006] 60-62 (BS-III/10).

[248] Cf. COP-MOP, Report of the second Meeting (n 247) Annex III paras 3 (a), 3 (b).

[249] COP-MOP, Report of the third Meeting (n 247) BS-III/10 para. 4 (a) – (b).

[250] *Glass*, Merits of Ratifying and Implementing the Cartagena Protocol on Biosafety, 21 Northwest. J. Int. Law Bus. 2001, 491; *Eggers/Mackenzie*, The Cartagena Protocol on Biosafety, 3(3) J. Int. Econ. Law 2000, 532.

[251] With the exception of products containing GMO material in a proportion no higher than 0.9% of the ingredient, provided that this presence is adventitious or technically unavoidable, Arts 12 (2) and 24 (2) Regulation (EC) No 1829/2003; cf. also *Hubar-Kołodziejczyk/Purnhagen*, Regulatory Requirements for the Identification, Detection and Quantification of Gene-Edited Products in Light of the (R)evolution of New Genomic Techniques: State of the Art and Prospects for Changes, Eur. J. Risk Regul. 2025, 14.

[252] This identification number is determined in the course of the positive verification decision and then entered into a publicly available database (Cf. Art. 9 (1) (e), (2) and Recital (21) Council version).

[253] See above Part II 2 c).

above (even though the Cartagena Protocol does not contain any labelling requirements for consumable end products)[254], and hence the ***Council version also violates this labelling requirement under Art. 18 (2) (a) Cartagena Protocol*.**

In contrast, the amendments proposed by the EP in this regard extend the labelling requirement (with the amended words "New Genomic Techniques") to plant reproductive material as well as NGT 1 plants and products containing or consisting of NGT 1 plants,[255] and beyond that provide for an appropriate document-based traceability for NGTs.[256] Hence, they are more likely to comply with the above-mentioned requirements from the Cartagena Protocol regarding LMOs-FFP.

(2) Labelling requirements for LMOs destined for contained use

Art. 18 (2) (b) Cartagena Protocol provides for a labelling requirement for LMOs destined for contained use. This is not relevant regarding the proposed NGT plant regulation, as it does not apply to the contained use of NGT plants but only to their deliberate release into the environment or placing on the market of NGT plants and their products (Art. 1 Council version). Outside the scope of the proposed NGT plant regulation, the current EU GMO legislation including labelling requirements continues to apply.

(3) Labelling requirements for LMOs intended for intentional introduction into the environment of the Party of import

Art. 18 (2) (c) Cartagena Protocol covers the labelling for LMOs "*that are intended for intentional introduction into the environment*" – which corresponds to the term "*deliberate release*" in Union law[257] – and "*any other living modified organisms within the scope of the Protocol*" (this means LMOs in transit or excluded from the AIA by a decision of the COP-MOP).[258] Accordingly, each State Party shall take measures to require that the documentation accompanying these LMOs (in case of transboundary movement) "*clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter."*

According to the Council version, once a NGT plant has been verified as a NGT 1 plant prior to its deliberate release according to Art. 6 (8), (10) Council version, there is, as spelled out above, a mandatory labelling only for "*plant reproductive material*" and therefore no labelling requirement for NGT 1 plants and their products apart from this plant reproductive material.

Also, there are no post-market monitoring measures for NGT 1 plants or products containing NGT 1 plants.[259]

Therefore, for the same reasons as above mentioned, whereas the mandatory labelling requirement for "*plant reproductive material*" is in line with the Cartagena Protocol, the intended

[254] See (n 250).

[255] Cf. European Parliament (n 17) amendment 264.

[256] By the transmission and holding of information that products contain or consist of NGT plants and product, and unique codes for those NGTs, at each stage of their placing on the market; cf. European Parliament (n 17) amendments 243, 265.

[257] Cf. Art. 2 (3) Directive 2001/18/EC: "*´deliberate release´ means any intentional introduction into the environment of a GMO* […]"; cf. also *Mackenzie* et al. (n 83) 68. The COM proposal and the Council version (Art. 3 (1)) also refer to this definition of "deliberate release".

[258] Cf. above Part III 1 d). However, this phrase does not include LMOs-FFP and LMOs destined for contained use, as these are addressed separately in Article 18(2)(a) and (b) Cartagena Protocol; cf. *Mackenzie* et al. (n 83) 127.

[259] See above Part II 2 c).

deregulation for the deliberate release of NGT 1 plants and their products violates Art. 18 (2) (c) Cartagena Protocol.

3. Result and summary

As shown, it can be concluded that the Council version is in line with the provisions on risk assessments of the Cartagena Protocol. ***However, the Council version violates Arts 8, and 11 (1) and 18 (2) (a) and (c) Cartagena Protocol by excluding NGT 1 plants from notification and labelling requirements.***

VI. Proposals to ensure compliance of the Council version with the Cartagena Protocol (de lege ferenda)

The crucial aspect of the non-compatibility of the Council version with the Cartagena Protocol is that the EU must not – through its NGT plant regulation as a domestic regulatory measure – impose its deregulation of NGT 1 plants on other States Parties to the Cartagena Protocol.

By largely deregulating NGT 1 plants, especially by excluding them from notification and labelling requirements, the effect of the Council version is to *de facto* remove NGT 1 plants from the scope of application of the Cartagena Protocol. This is not in compliance with the Cartagena Protocol.[260]

While it can be argued, as written above, that the EU may determine that NGT 1 plants as a group of cases pose an acceptable risk and should to a certain extent be deregulated, the effects of this deregulation must remain within its jurisdiction to comply with the Cartagena Protocol.

The reason is that the Cartagena Protocol provides a legal framework within which each State Party is enabled to take its own decisions, for areas within its jurisdiction, on the import or domestic use of LMOs. These decisions are based on scientific considerations but leave a considerable (political) scope of assessment and discretion to each State Party to determine which adverse effects or risks associated with LMOs are deemed acceptable, and how they should be dealt with.

To comply with the Cartagena Protocol, a future modified NGT plant regulation shall therefore,

> ***first, maintain all notification and labelling requirements vis-à-vis States that are not Member States of the EU and,***
>
> ***second, ensure that NGT 1 plants are traceable also within the EU to secure the practical feasibility of notification and labelling requirements vis-à-vis these third States.***

Concerning the content of the notification and information requirements, one can conclude: as shown above, both the notification to the State of import prior to the first intentional transboundary movement of LMOs and the information to the Biosafety Clearing-House when a final decision regarding domestic use of LMOs-FFP is taken, must contain a risk assessment.

According to the current Council version, the risk assessment for NGT plants categorised as NGT 1 plants is replaced by the verification procedure. As detailed above, it can be argued

[260] As mentioned above in Parts III 1 c) and III 2, certain LMOs can only be excluded from some procedures under the Cartagena Protocol – and not from its scope of application – and only by decision of the COP, see Art. 7 (4) Cartagena Protocol; or be subjected to a simplified procedure by decision of the Party of import, see Art. 13 Cartagena Protocol.

that this verification procedure is still in line with the requirements on risk assessment under the Cartagena Protocol.

To comply with its notification and information obligations, the EU must supply the relevant details underlying this verification procedure to the Party of import or the Biosafety Clearing-House, respectively. Sufficient information must be given to allow other States Parties to the Cartagena Protocol to then conduct their own risk assessment concerning the specific NGT plant. A future NGT plant regulation therefore ***shall be based on and spell out a procedure to include in the relevant notification and information: on the one hand, the motives behind the abstract risk assessment that explains that NGT 1 plants as a group pose an acceptable risk and, on the other hand, the results of the verification procedure through which it has been verified that a specific plant falls within this group of NGT 1 plants.***

Concerning the labelling, one has to conclude that – as proposed by the EP – ***the labelling requirement shall cover not only plant reproductive material, but all NGT 1 plants and products containing or consisting of category 1 NGT plants.***

Furthermore, the EU should take the appropriate measures to ensure that the traceability of verified NGT 1 plants is guaranteed, in order to be able to ensure compliance with the above-mentioned requirements of the Cartagena Protocol in the case of transboundary movement. Otherwise, NGT 1 plants that are deliberately released or placed on the market within the EU would circulate freely between Member States without any information on their whereabouts and their classification as NGT 1 plants; if then exported to a third State outside the EU, it would be practically impossible to fulfil the notification and labelling requirements vis-à-vis these third States.

It would not be sufficient to ensure the compatibility of the NGT plant regulation with the Cartagena Protocol is a simple declaration to this end, such as the one contained in the amendment suggested by the European Committee of the Regions in its draft mentioned above.[261]

Additionally, as spelled out above, despite the explicit exclusion of transgenesis techniques from NGT plants in the recitals of the Council version, such an exclusion cannot be established with certainty according to the proposed definition of *"breeder´s gene pool"* in Art. 3, but rather depends on what exactly is meant by the term species. ***The recommendation is therefore to clarify this term, according to the biological species concept, as members of populations that actually or potentially interbreed in nature, and thus excluding the insertion of foreign genetic material (i.e. genetic material from another, sexually incompatible species) in NGT plants with certainty via the definitions.***

Freiburg, den 09.04.2025

Prof. Dr. Silja Vöneky

[261] See European Committee of the Regions (n 19), Amendment 59: *"a declaration that the placing on the market would not be in breach of the Cartagena Protocol […], and a description of how the protocol's requirements are fulfilled".* The latter part, i.e., a description of how the Cartagena Protocol's requirements are fulfilled by the proposed future modified NGT plant regulation, would of course be very welcome.