Part Two:
Prevention of Transboundary Harm

Chapter 3:
The Regulation of Biotechnology in International Law

This chapter analyses the international regulation of biotechnology and genetically modified organisms at the global level. The principal instrument in this context is the *Cartagena Protocol on Biosafety*, which has been developed under the *Convention on Biological Diversity* (A.). Although the Protocol's provisions are much more detailed, the pertinent rules contained in the Convention have not become irrelevant due to its broader, near-universal membership (B.).

Besides, a number of other international agreements also contain relevant obligations in the context of regulating risks resulting from the application of biotechnology. In particular, international trade law under the auspices of the *World Trade Organization* might considerably limit the liberty of states to restrict international trade of LMOs (C.). The *International Plant Protection Convention* and the measures adopted within its framework seek to prevent the spread of plant pests, which under certain circumstances may include LMOs (D.). The *World Organisation for Animal Health* serves a similar objective with respect to animal diseases (E.). The *Codex Alimentarius* is a set of standards on food safety and also addresses foods obtained from modern biotechnology (F.). The *United Nations Convention on the Law of the Sea* is relevant with regard to the protection of the high seas beyond the limits of national jurisdiction (G.). International regulations on the transport of hazardous goods and substances also address safeguarding measures for LMOs (H.). When a biotechnology product causes a transmissible disease in humans, international health law becomes relevant (I.). Finally, certain applications of biotechnology may also fall within the scope of the *Biological Weapons Convention* and rules of humanitarian international law (J.).

The instruments analysed in the present chapter primarily address the *prevention of damage*, but they are also relevant for questions relating to *liability for damage* in a number of aspects. First and foremost, the Cartagena Protocol prejudices the scope of application of the *Supplementary Protocol on Redress and Liability*, which was developed to complement the Cartagena Protocol with rules on operator liability and which is analysed

further below.[1] Moreover, the Cartagena Protocol, as well as the other relevant instruments, create binding legal obligations for their respective parties, breaches of which may give rise to the accountability of these states under the law of state responsibility.[2]

A. *The Cartagena Protocol on Biosafety*

The *Cartagena Protocol on Biosafety* of 2000[3] is the only global multilateral agreement specifically dealing with molecular biotechnology.[4] It was negotiated within the framework of Article 19(3) of the *Convention on Biological Diversity* of 1992 (CBD),[5] which committed its parties to consider the need for, and modalities of, a protocol relating to the products of modern biotechnology. The Protocol entered into force in 2003 and has 173 parties including the European Union.[6] However, a number of states that play key roles in biotechnology have not ratified the Protocol, including Argentina, Australia, Canada, Israel, Singapore, and the United States.[7]

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1 See chapter 6.
2 See chapter 9.
3 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (29 January 2000; effective 11 September 2003), 2226 UNTS 208 (hereinafter 'Cartagena Protocol' or 'CP').
4 For general discussions of the Cartagena Protocol, see *Riccardo Pavoni*, Assessing and Managing Biotechnology Risk Under the Cartagena Protocol on Biosafety, 10 (2000) Italian YBIL 113; *Robert Falkner*, Regulating Biotech Trade: The Cartagena Protocol on Biosafety, 76 (2000) International Affairs 299; *Barbara Eggers/Ruth Mackenzie*, The Cartagena Protocol on Biosafety, 3 (2000) J. Int. Econ. L. 525; *Terence P. Stewart/David S. Johanson*, A Nexus of Trade and the Environment: The Relationship Between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization, 14 (2003) Colorado Journal of International Environmental Law and Policy 1; *Ruth Mackenzie* et al., An Explanatory Guide to the Cartagena Protocol on Biosafety (2003); *Catherine Redgwell*, Biotechnology, Biodiversity and International Law, 58 (2005) Current Legal Problems 543; *Marie-Claire Cordonier Segger/Frederic Perron-Welch* et al. (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013).
5 Convention on Biological Diversity (05 June 1992; effective 29 December 1993), 1760 UNTS 79 (hereinafter 'CBD').
6 UN OLA, Status of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, United Nations Treaty Collection, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-a&chapter=27&clang=_en (last accessed 28 May 2022).
7 For a ranking of 54 countries based on innovation potential in biotechnology, see *Jeremy Abbate* et al., Scientific American Worldview: A Global Biotechnology

Pursuant to its Article 1, the objective of the 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'.*

The subject matter regulated by the Cartagena Protocol is 'living modified organisms resulting from modern biotechnology'. The recent advances in modern biotechnology set out in the first chapter, particularly genome editing techniques and engineered gene drives, raise questions as to the exact scope of the Protocol (I.). Substantively, most of the Protocol's provisions concern the 'transboundary movement' of LMOs, which denotes the importation, but also unintentional movements of LMOs from one party's territory into that of another. In addition, some of the Cartagena Protocol's provisions also apply to domestic uses (II.).

I. Scope

According to its Article 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'.*

This provision can be divided into three separate elements: Firstly, the *subject matter* covered by the Protocol is 'living modified organisms' (LMOs), which is a technical term defined in Article 3 of the Protocol (1.). Secondly, Article 4 CP refers to LMOs 'that may have adverse effects', which raises the question of whether the Cartagena Protocol only applies to hazardous LMOs (2.). Thirdly, Article 4 specifies the *activities* to which the Cartagena Protocol applies, namely 'transboundary movement, transit, handling, and use' of LMOs (3.). Moreover, under Article 5 CP the 'trans-

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Perspective (2016), 26–28. For an overview of the commercial use of GM crops, see International Service for the Acquisition of Agri-biotech Applications, Global Status of Commercialized Biotech/GM Crops in 2019, ISAAA Brief 55 (2019). Data on international trade in genetically modified organisms and products thereof seem not to be available, but see *Vargas M. Xanat* et al., International Trade of GMO-Related Agricultural Products, 52 (2018) Quality & Quantity 565.

boundary movement of LMOs which are pharmaceuticals for humans' is exempted from the scope of the Cartagena Protocol (4.).

1. Subject Matter: Living Modified Organisms Obtained Through Modern Biotechnology

The Cartagena Protocol applies to 'living modified organisms', which is defined in Article 3(g) as

> *'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'.*

As noted earlier, the Cartagena Protocol uses this term instead of the more common phrases 'genetically modified organism' (GMO) and 'genetically engineered organism', which are used in most national and regional biosafety regimes.[8] Most of these regimes were developed in the light of conventional techniques of genetic engineering, which commonly involve the insertion of genetic material from another species. However, as set out in the first chapter, more recently developed genome editing techniques allow to genetically modify an organism with much higher precision than before and, in some instances, without permanently introducing exogenous genetic material.[9]

Against this background, there have been fierce debates about whether organisms modified with these new techniques fall within the scope of the existing regulatory frameworks for GMOs. Currently, genome-edited organisms are regulated like conventional GMOs in some jurisdictions but are exempt from regulation in others.[10] It is also controversial whether

8 See chapter 2, section A; also see *Markus Böckenförde*, Biological Safety, in: Wolfrum/Peters (ed.), MPEPIL, MN. 6.

9 See chapter 1, section B.

10 See *Maria Lusser/Howard V. Davies*, Comparative Regulatory Approaches for Groups of New Plant Breeding Techniques, 30 (2013) New Biotechnology 437; *Dennis Eriksson* et al., A Comparison of the EU Regulatory Approach to Directed Mutagenesis with that of Other Jurisdictions, Consequences for International Trade and Potential Steps Forward, 222 (2019) New Phytologist 1673; *Steffi Friedrichs* et al., An Overview of Regulatory Approaches to Genome Editing in Agriculture, 3 (2019) Biotechnology Research and Innovation 208; *Hans-Georg Dederer/David Hamburger* (eds.), Regulation of Genome Editing in Plant Biotechnology (2019).

genome-edited organisms fall within the scope of the Cartagena Protocol.[11]

According to the aforementioned definition in Article 3(g), the Cartagena Protocol applies to any living organism (a)) the genetic material (b)) of which has a novel combination (c)) that was obtained through the use of modern biotechnology (d)). It is therefore submitted that most genome editing techniques, as well as all current techniques involving engineered gene drives, fall within the scope of the Cartagena Protocol (e)).

a) Living Organism

The term 'living organism' is defined in Article 3(h) CP as

> *'any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids'.*

This definition takes a central role in determining the meaning of a 'living modified organism'. When both definitions are read together, the Protocol applies to any biological entity capable of transferring or replicating genetic material (i.e. a *living organism*) that possesses a novel combination of genetic material obtained through the use of modern biotechnology (i.e. a living *modified* organism). The term 'biological entity' is unspecific and may refer to any being.[12] The decisive criterion is whether such an entity is 'capable of transferring or replicating genetic material'.[13] This excludes, most importantly, products derived from LMOs which are no longer

11 Cf. AHTEG on Synthetic Biology, Report of the Ad Hoc Technical Expert Group on Synthetic Biology: Montreal, Canada, 4–7 June 2019, UN Doc. CBD/SYNBIO/AHTEG/2019/1/3 (2019), para. 17; *Felicity Keiper/Ana Atanassova*, Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols, 8 (2020) Front. Bioeng. & Biotechnol. 310, 16; see *Motoko Araki* et al., Caution Required for Handling Genome Editing Technology, 32 (2014) Trends in Biotechnology 234, 234–235; *Sam O. Callebaut*, New Developments in Modern Biotechnology: A Survey and Analysis of the Regulatory Status of Plants Produced Through New Breeding Techniques, Master Thesis (2015), 46–50; *Eva Sirinathsinghji*, Why Genome Edited Organisms Are Not Excluded from the Cartagena Protocol on Biosafety, TWN Biosafety Briefing (2020).

12 Cf. 'entity', in: *James Murray* et al., Oxford English Dictionary, Online Edition, available at: http://www.oed.com/ (last accessed 28 May 2022).

13 Cf. *Piet van der Meer*, Definitions, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 281, 284.

able to transfer or replicate genetic material.[14] Viruses and viroids, which by themselves cannot actively replicate genetic material,[15] are expressly included in the definition.[16]

b) Genetic Material

The term 'genetic material' is of particular relevance for the scope of the Protocol, as it is used in the definitions of both a *living organism* (which is characterized by its capability to transfer or replicate genetic material) and a *living modified organism* (which possesses a novel combination of genetic material). While the Protocol itself does define this term, a definition of 'genetic material' is included in Article 2 CBD. Although the Cartagena Protocol does not expressly incorporate the definitions contained in the CBD,[17] they can still be referred to as part of the 'relevant rules of interna-

14 *Eggers/Mackenzie* (n. 4), 529; *Sean D. Murphy*, Biotechnology and International Law, 42 (2001) Harv. Int'l L. J. 47, 77; *Jan Husby*, Definitions of GMO/LMO and Modern Biotechnology, in: Terje Traavik/Li C. Lim (eds.), Biosafety First (2009) 365, 370–371. The Cartagena Protocol refers to LMOs and 'products thereof', see Article 23(3)(c) CP. The inclusion of 'products thereof' into the scope of the Cartagena Protocol was highly contentious during the negotiations, see *Helen Marquard*, Scope, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 289, 297–298. Note that three of the Protocol's provisions on risk assessment, namely Article 23(3)(c), Annex I(i) and Annex III(5), explicitly address LMOs and products thereof, which are defined as 'processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology', see *Mackenzie* et al., IUCN Guide (n. 4), MN. 85. During the negotiations of the Supplementary Protocol, the inclusion of 'products thereof' was discussed again, see chapter 6, section B.1.2.

15 *Bruce Albers* et al., Molecular Biology of the Cell (6th ed. 2015), 18.

16 *Mackenzie* et al., IUCN Guide (n. 4), MN. 204.

17 Most protocols to framework instruments expressly provide that the definitions contained in the framework instrument also apply for the purposes of the respective protocol, see, e.g., Article 2(1) Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (15 October 2010; effective 05 March 2018), UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 64; 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 (29 October 2010; effective 12 October 2014), UN Doc. UNEP/CBD/COP/DEC/X/1; Kyoto Protocol to the United Nations Framework Convention on Climate Change (11 December 1997; effective 16 February 2005), 2303 UNTS 162.

tional law applicable in the relations between the parties' in the sense of Article 31(3)(c) of the *Vienna Convention on the Law of Treaties* (VCLT).[18]

According to the definition in Article 2 CBD, 'genetic material' means

> *'any material of plant, animal, microbial or other origin containing functional units of heredity'.*

The central element of this definition is 'functional units of heredity', which is defined neither in the Cartagena Protocol nor elsewhere in the international biodiversity regime.[19] It also seems not to be an established term in scientific literature.

In biology, the term 'heredity' denotes the transmission of genetically based characteristics from parents to offspring.[20] The basic unit of heredity is the gene, which is a sequence of nucleic acid that exerts its influence on the organism's form and function by encoding and directing the synthesis of a protein or certain forms of RNA.[21]

The definition requires that these units of heredity must be 'functional'. This appears to be introduced to distinguish genes from non-coding DNA sequences (also called 'junk DNA'), which were, at the time when the CBD was adopted, believed to have no specific function.[22] However, it is now assumed that non-coding DNA contains genetic information essential for important biological functions such as gene expression, replication and transmission.[23] For this reason, there are currently no units of heredity

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18 Vienna Convention on the Law of Treaties (23 May 1969; effective 27 January 1980), 1155 UNTS 331 (hereinafter 'VCLT'); cf. *Oliver Dörr*, Article 31 VCLT, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 95–96; see *Mackenzie* et al., IUCN Guide (n. 4), MN. 198.

19 The term resembles the notion of 'heritable material' used in the legislation of the European Union on Genetically Modified Organisms. On the relationship between the Cartagena Protocol and EU legislation, see *infra* section A.IV.

20 Cf. 'heredity', in: *Eleanor Lawrence* (ed.), Henderson's Dictionary of Biology (16th ed. 2016), 256; similarly *B. Fedder*, Marine Genetic Resources, Access and Benefit Sharing (2013), 35; *Albers* et al. (n. 15), 2.

21 Cf. 'gene', in: Henderson's Dictionary of Biology (n. 20), 224; *Albers* et al. (n. 15), 182; see *Fedder* (n. 20), 35.

22 *Morten W. Tvedt/Peter J. Schei*, "Genetic Resources" in the CBD: The Wording, the Past, the Present and the Future, UN Doc. UNEP/CBD/WG-ABS/9/INF/1, Annex (2010); cf. *L. E. Orgel/F. H. C. Crick*, Selfish DNA, 284 (1980) Nature 604; but see *James A. Shapiro*, Revisiting the Central Dogma in the 21st Century, 1178 (2009) Annals of the New York Academy of Sciences 6, 12.

23 *James A. Shapiro/Richard* von *Sternberg*, Why Repetitive DNA Is Essential to Genome Function, 80 (2005) Biological Reviews of the Cambridge Philosophical

(or DNA sequences) that can be characterized with scientific certainty as 'non-functional'.[24] Hence, 'functional units of heredity' denote any kind of genetic information stored in nucleic acid.[25] Consequently, 'genetic material' encompasses any biological material that contains nucleic acid, including living cells in any appearance and parts of organisms, as well as isolated DNA or RNA in the form of chromosomes, plasmids or parts thereof.[26]

c) 'Novel Combination' of Genetic Material

The Cartagena Protocol covers living organisms that possess a 'novel combination of genetic material'. Again, the term 'novel combination' is not defined by the Protocol. It is questionable whether it covers any change to the genetic material or whether the change must be of a certain quality. In particular, it could be argued that the term 'novel combination' refers to 'recombinant DNA', which is generally understood as DNA that has been modified *in vitro* to introduce foreign genetic information.[27] According to this understanding, point mutations and other changes not including the insertion of foreign genetic material would be excluded from the Protocol's scope.

However, the *travaux préparatoires* of the Protocol, which can be relied upon as a subsidiary means of interpretation,[28] show that the presence of foreign genetic material in the resulting organism was rejected as a criterion for the LMO definition. During the negotiations, representatives of the so-called *Miami Group* – consisting of the United States, Canada, Australia, Argentina, Chile and Uruguay – proposed to include that the

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Society 227; *Shapiro* (n. 22), 12; *ENCODE Project Consortium*, An Integrated Encyclopedia of DNA Elements in the Human Genome, 489 (2012) Nature 57.

24 Cf. *Tvedt/Schei* (n. 22), 16; *Benjamin A. Pierce*, Genetics (7th ed. 2020), 637–638.

25 *Morten W. Tvedt/Tomme R. Young*, Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD, ABS Series No. 2 (2007), 55.

26 *Mackenzie* et al., IUCN Guide (n. 4), MN. 199–200 and Box 14 on p. 44; *Tvedt/Schei* (n. 22), 21; *Fedder* (n. 20), 36.

27 Cf. 'recombinant DNA', in: Henderson's Dictionary of Biology (n. 20), 500–501.

28 Cf. Article 32(a) VCLT (n. 18), see *Oliver Dörr*, Article 32 VCLT, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 11–21.

resulting organism should be 'unlikely to occur in nature'.[29] Others, including representatives from developing and Nordic countries, suggested defining 'novel' as 'not known to occur in nature'.[30] According to a third proposal, the resulting organism should have 'traits novel to the species in the receiving country'[31] or the 'receiving environment'.[32]

Ultimately, however, all these proposals were rejected in favour of the phrase 'novel combination of genetic material', which was understood to be more comprehensive.[33] Notably, suggestions that an LMO should contain 'foreign' or 'transgenic' genetic material were also rejected.[34] The negotiating history of the Cartagena Protocol thus clearly indicates that the presence of foreign genetic material in the resulting organism is not a constitutive criterion for what constitutes an LMO.

Consequently, the term 'novel combination' should be construed in a broad sense as simply referring to any change in the composition of genetic material, regardless of its origin. Whether the resulting genotype or phenotype could have also arisen naturally is irrelevant to whether an organism is an LMO under the Protocol.[35] What is decisive is less the quality of the change but rather that this change is 'obtained through the use of modern biotechnology'. In this sense, a novel combination could arise from a change to even a single nucleotide in a nucleotide sequence.[36]

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29 *Aarti Gupta*, Framing "Biosafety" in an International Context: The Biosafety Protocol Negotiations, ENRP Discussion Paper E-99–10 (1999), 23; cf. BSWG, Report of the Third Meeting, UN Doc. UNEP/CBD/BSWG/3/6 (1997), 39; BSWG, Revised Consolidated Text of the Draft Articles (From the Fourth Meeting), UN Doc. UNEP/CBD/BSWG/5/Inf.1 (1998), 11; BSWG, Compilation of Definitions and Terms Relevant to a Biosafety Protocol, UN Doc. UNEP/CBD/BSWG/3/Inf.1 (1997), 19.

30 *Gupta* (n. 29), 23; cf. BSWG, Consolidated Text from Fourth Meeting (n. 29), 11.

31 BSWG, Compilation of Definitions (n. 29), 19; BSWG, Report of the Third Meeting (n. 29), 39.

32 BSWG, Consolidated Text from Fourth Meeting (n. 29), 11.

33 Cf. IISD, Report of the Fourth Session of the Ad Hoc Working Group on Biosafety: 5–13 February 1998, ENB Vol. 9 No. 85 (1998), 5; *Gupta* (n. 29), 23.

34 Cf. BSWG, Consolidated Text from Fourth Meeting (n. 29), 11; ENB Summary of BSWG-4 (n. 33), 5.

35 *Mackenzie* et al., IUCN Guide (n. 4), MN. 214; also see *Sirinathsinghji* (n. 11), 3.

36 *Mackenzie* et al., IUCN Guide (n. 4), MN. 212.

d) Obtained Through the Use of Modern Biotechnology

In order to qualify as an LMO, the organism must possess a novel combination of genetic material which has been 'obtained through the use of modern biotechnology'. The notion of 'modern biotechnology' is defined in Article 3(i) CP as

> *'the application of*
> *a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
> *b. Fusion of cells beyond the taxonomic family,*
> *that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection'.*

This definition consists of three elements that must be fulfilled cumulatively: The first element describes the techniques that are encompassed, i.e., *in vitro* nucleic acid techniques and cell fusion (aa)). The second element provides that these techniques need to overcome natural physiological reproductive or recombination barriers (bb)). Thirdly, these techniques must not be techniques used in traditional breeding and selection (cc)).

aa) 'Application of in vitro nucleic acid techniques…'

The first element of the definition specifies the laboratory techniques encompassed by the definition of modern biotechnology, namely '*in vitro* nucleic acid techniques' and 'fusion of cells beyond the taxonomic family'. The latter, *cell fusion*, means the process of merging two different cells into a single hybrid cell.[37] Since genome editing does not involve cell fusion, this element can be left aside for the purposes of the present study. The only relevant criterion is whether genome editing techniques can be regarded as '*in vitro* nucleic acid techniques'. In this regard, the Protocol provides two examples of what constitutes such a technique, namely 'recombinant deoxyribonucleic acid (DNA)' and 'direct injection of nucleic acid into cells or organelles'.

As to the first example, the term 'recombinant DNA' denotes the insertion of foreign DNA into the genome of the target organism.[38] While

37 Cf. 'Cell fusion', in: *Richard Cammack/Teresa K. Attwood* et al. (eds.), Oxford Dictionary of Biochemistry and Molecular Biology (2nd ed. 2006), 107.

38 Cf. 'recombinant DNA', in: Henderson's Dictionary of Biology (n. 20), 500–501.

this has been possible by conventional genetic engineering techniques, it can be achieved with higher precision through more recent *genome editing* techniques.[39] The development of engineered gene drives will usually involve the insertion of foreign DNA and thus constitute a recombinant DNA technique.[40] On the other hand, genome editing techniques used to produce endogenous changes to the genome without inserting foreign DNA, such as targeted point mutations, cannot be regarded as recombinant DNA techniques.

The second example of techniques provided by the definition is 'direct injection of nucleic acid into cells'. In the case of CRISPR/Cas, the *guide RNA* (one of the components prepared *in vitro*) constitutes nucleic acid, and direct injection is one of the available means to insert the guide RNA into the target organism (besides direct injection, a frequently used approach is transfection).[41] Hence, depending on the specific approach, the CRISPR/Cas technique may involve 'direct injection of nucleic acid' in the sense of Article 3(i) CP.

In any case, the notion '*in vitro* nucleic acid techniques' is not limited to the examples mentioned in the definition, as the term 'including' indicates that the examples are not meant to be exhaustive. During the negotiations of the Protocol, it was expressly recognized that the definition of 'modern biotechnology' should be phrased in a manner that would cover new techniques which were not yet envisaged at that time.[42] Therefore, it was deliberately left open whether, besides the two existing examples, new techniques would constitute '*in vitro* nucleic acid techniques'.[43] Hence, the phrase 'in vitro nucleic acid techniques' refers to any technique that

39 It is undisputed that any technique that involves the insertion of foreign DNA into the organism, including ZFN-3, is covered by the protocol, cf. European Commission, New Techniques Working Group (NTWG): Final Report, not officially published (2012), 19–20; *Jens Kahrmann* et al., Aged GMO Legislation Meets New Genome Editing Techniques, 15 (2017) EurUP 176, 177 n. 11; Dutch Commission on Genetic Modification (COGEM), The Status of Oligonucleotides Within the Context of Site-Directed Mutagenesis: 100701–03 (2010), 10; *Thorben Sprink* et al., Regulatory Hurdles for Genome Editing: Process- vs. Product-Based Approaches in Different Regulatory Contexts, 35 (2016) Plant Cell Reports 1493, 1497.

40 See chapter 1, section C.II.

41 See chapter 1, section B.II.3.

42 Cf. ENB Summary of BSWG-4 (n. 33), 5; *Mackenzie* et al., IUCN Guide (n. 4), MN. 217–218.

43 *Ibid.*

involves the handling of nucleic acid *in vitro*, i.e. outside the target organism.[44]

Consequently, '*in vitro* nucleic acid techniques' includes all laboratory procedures where nucleic acid is modified or synthetically produced outside of the organism and subsequently inserted into the target organism. This includes the CRISPR/Cas technique, regardless of how the effector complex is inserted into the target organism. The ODM technique is covered by the definition too, as the oligonucleotides used in this technique also constitute nucleic acid. SDN-2 techniques, which involve the insertion of a DNA snippet as a 'repair template', also fall under the definition.[45]

In contrast, some older genome editing techniques do not involve any *in vitro* handling of nucleic acid. For instance, the TALENs and ZFN-1 techniques rely on engineered nucleases, which are enzymes that cleave DNA at specific target sequences once inserted into the cell.[46] Technically, however, these techniques do not involve any *in vitro* handling of nucleic acid. It could, therefore, be questioned whether they are covered by the definition of 'modern biotechnology'.[47] At the same time, these techniques are still *in vitro* techniques used to modify the target organism's DNA (i.e. nucleic acid). An extensive interpretation would also find support in the Protocol's negotiating history since, as noted above, the parties wanted to ensure that the definition also covered future techniques.[48] But including *any* laboratory technique to modify genetic information would certainly overstretch the notion of '*in vitro* nucleic acid techniques'. An interpretation that excludes techniques involving engineered nucleases from the scope of the Protocol would also not be 'manifestly absurd or unreasonable', which would be necessary to deviate from the grammatical and textual interpretation of the term. Therefore, techniques not involving

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44 The literal meaning of *in vitro* is 'in glass', cf. Oxford Dictionary of Biochemistry and Molecular Biology (n. 37), 351.

45 It is undisputed that any technique that involves the insertion of foreign DNA into the organism, including ZFN-3, is covered by the protocol, cf. New Techniques Working Group, Final Report (n. 39), 19–20; *Kahrmann* et al. (n. 39), 177 n. 11; Dutch Commission on Genetic Modification (COGEM) (n. 39), 10; *Sprink* et al. (n. 39), 1497.

46 See chapter 1, sections B.II.1 and B.II.2.

47 See *Jens Kahrmann/Georg Leggewie*, CJEU's Ruling Makes Europe's GMO Legislation Ripe for Reformation, 16 (2018) EurUP 497, 502, although the main argument of these authors is that targeted mutagenesis does not overcome natural physiological and reproductive barriers (see next section).

48 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 217–218.

the *in vitro* use of nucleic acid but of other mutagenic substances, such as engineered nucleases, are arguably not covered by the Protocol's definition of 'modern biotechnology'.[49] However, these methods have largely been replaced by the more efficient CRISPR technique and are unlikely to be used widely in the future.[50]

bb) '… that overcome natural physiological reproductive or recombination barriers…'

The definition further requires that the application of the aforementioned techniques must 'overcome natural physiological reproductive or recombination barriers'. It has been suggested that 'natural barriers' are such that would normally prevent the exchange or recombination of DNA.[51] Hence, the definition would apply when DNA sequences are introduced from species that would not be able to exchange genetic material with the target organism (e.g., through mating) under natural conditions. But in some applications of genome editing techniques, especially when used to create point mutations, there is no exchange or recombination of DNA at all. The wording of this criterion is therefore inconclusive with regard to more recent biotechnological techniques.[52]

According to one possible interpretation, the condition of 'overcoming natural barriers' requires that the resulting genotype could not even theoretically arise in a natural way through recombination or reproduction.[53] Since point mutations can also result from natural processes, their creation through genome editing techniques would not amount to overcoming natural barriers, and the resulting organisms would not constitute LMOs in the sense of the Protocol.[54]

However, it should not be overlooked that the criterion of 'overcoming natural barriers' is used to characterize the *techniques* of genetic modifica-

49 Likewise *Sirinathsinghji* (n. 11), 3–4.
50 *Ibid.*, 4; *Heidi Ledford*, CRISPR, the Disruptor, 522 (2015) Nature 20, 21–22.
51 *Mackenzie* et al., IUCN Guide (n. 4), 50; also see 'recombination', in: Henderson's Dictionary of Biology (n. 20), 501.
52 Cf. *van der Meer* (n. 13), 286.
53 Cf. *Callebaut* (n. 11), 53.
54 Cf. *Kahrmann/Leggewie* (n. 47), 502.

tion rather than the *result* of such modification.[55] As shown above, the Cartagena Protocol's LMO definition refers to both the resulting organism (which has to possess a 'novel combination of genetic material') and the techniques through which this result is obtained ('application of modern biotechnology').[56] The requirement that natural barriers need to be overcome is included in the definition of the latter term, modern biotechnology, and thus refers to the *means* of modification and not to its *result*.[57] Consequently, the decisive question is not whether the resulting organism could also occur naturally, but whether the techniques employed are capable of achieving genetic changes that cannot be achieved by relying on natural reproduction and recombination mechanisms. This includes the creation of targeted point mutations through genome editing techniques: although point mutations do also occur naturally, only genome editing techniques allow to introduce them at specific locations of the genome.

This interpretation is also supported by the negotiating history of the Cartagena Protocol.[58] As noted earlier, it was long proposed during the negotiations to define an LMO by whether its genetic material is unlikely (or unknown) to occur in nature.[59] This element was eventually dropped in favour of the broader requirement that there must be a 'novel combination' of genetic material.[60] Around the same time, it was agreed that the definition should refer to both the techniques of modification and the resulting organism.[61] The 'novel combination' criterion was then used to define the resulting organism, while the reference to 'overcoming natural and reproductive barriers' was included in the definition of modern

55 The context in which a term is used is, besides the term's ordinary meaning, a primary factor for its interpretation. See Article 31(1) VCLT (n. 18); cf. *Dörr*, Article 31 VCLT (n. 18), MN. 43–51.

56 Cf. ENB Summary of BSWG-4 (n. 33), 5; *van der Meer* (n. 13), 285.

57 But see *Callebaut* (n. 11), 53, who argues that 'the phrasing of this provision necessarily also relates to the result, i.e. the new (novel) combination of genetic material obtained through the use of these techniques'. The same seems to be assumed by *Piet van der Meer* et al., The Status Under EU Law of Organisms Developed Through Novel Genomic Techniques (2021) European Journal of Risk Regulation 1, 15.

58 See *supra* n. 28.

59 Cf. BSWG, Consolidated Text from Fourth Meeting (n. 29), 10–11; see ENB Summary of BSWG-4 (n. 33), 5; *Gupta* (n. 29), 23; *van der Meer* (n. 13), 285.

60 Cf. BSWG, Draft Negotiating Text (From the Fifth Meeting), UN Doc. UN Doc. UNEP/CBD/BSWG/6/2 (1998), 6; *Gupta* (n. 29), 23; see *supra* section A.I.1.c).

61 Cf. ENB Summary of BSWG-4 (n. 33), 5; *van der Meer* (n. 13), 285.

biotechnology, reportedly to resolve a dispute about whether and to what extent cell fusion should be included in the Protocol's scope.[62]

Consequently, the decisive criterion is whether a natural process of genetic alteration is being replaced by techniques that can only be applied *in vitro* by overcoming natural barriers. Since genome editing techniques generally involve the insertion of endonucleases or nucleic acids that were specifically modified or synthetically produced *in vitro*, their application generally overcomes natural reproductive or recombination barriers in terms of the Protocol.

cc) '… and that are not techniques used in traditional breeding and selection'

Lastly, the definition of modern biotechnology requires that the techniques applied are not 'techniques used in traditional breeding and selection'. While this phrase seems self-explanatory at first glance, the notion of 'traditional' is ambiguous and leaves much room for interpretation.[63] It would not seem to have been the subject of closer legal analysis so far.[64]

In its ordinary meaning, which is the starting point for interpretation pursuant to Article 31(1) VCLT, the adjective 'traditional' characterizes something as long-established, customary or conventional.[65] In the present context, 'traditional' appears to denote methods of breeding and selection that have been subject to continuous and widespread use for a long period of time. This would include the most conventional forms of breeding plants and animals, which have been practised by humankind for hundreds of years. In essence, all these techniques rely on selecting individuals that exhibit desired traits and mating them with other individuals from the same or closely related species.[66] Deliberate hybridization – i.e., crossing

62 *Van der Meer* (n. 13), 286; see IISD, Highlights of BSWG-5 #9: Wednesday, 26 August 1998, ENB Vol. 9 No. 106 (1998), 2.

63 *Van der Meer* (n. 13), 286.

64 The only detailed discussion appears to be *Mackenzie* et al., IUCN Guide (n. 4), MN. 221–226; for a scientific perspective, see *Clemens van die Wiel* et al., Traditional Plant Breeding Methods (2010).

65 Cf. 'traditional', in: Oxford English Dictionary (n. 12).

66 *Mackenzie* et al., IUCN Guide (n. 4), MN. 221; see generally *Rolf H. J. Schlegel*, Concise Encyclopedia of Crop Improvement (2007), 5–52; *Noël Kingsbury*, Hybrid: The History and Science of Plant Breeding (2009), 39–54; *George Acquaah*, Conventional Plant Breeding Principles and Techniques, in: Jameel M.

different varieties or species to produce new ones – has been practised since the late seventeenth century and would equally constitute a traditional technique.[67] The same is true for a range of other strategies used to facilitate the selection of desired traits and the exchange of genetic material.[68]

However, the term is generally deemed to include not only century-old practices, but also more sophisticated techniques which were developed since the twentieth century and which operate on the molecular level, such as methods to create interspecific hybrids by overcoming sexual crossing barriers and approaches to increase the amount of genetic variation by exposing an organism to mutagenic agents.[69]

At first sight, this seems to contradict – or at least substantially modify – the aforementioned meaning of 'traditional'. However, the wording does not expressly require the technique *itself* to be traditional, but rather that it is a technique used in *traditional breeding and selection*. The main characteristic of traditional breeding and selection is that it relies on *random* genetic change,[70] as opposed to breeding methods that rely on introducing *specific* changes in the genetic material. In that sense, the term 'traditional' appears to be synonymous with 'conventional' rather than referring to a certain history of application. Referring to 'methods not involving recombinant DNA techniques'[71] would result in circular reasoning and thus be of little use, because 'recombinant DNA' is a separate element used in the LMO definition.[72]

At the same time, whether or not a certain technique used in traditional breeding has a long-standing history of application is not relevant. What counts instead is whether a technique is used in breeding methods that rely on random genetic change rather than targeted interventions in the genome. Consequently, genome editing techniques that allow genetic

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Al-Khayri/Mohan Jain/Dennis V. Johnson (eds.), Advances in Plant Breeding Strategies (2015) 115.

67 See *Schlegel* (n. 66), 42–52; *Kingsbury* (n. 66), 71.

68 See *Schlegel* (n. 66), 85–135; *Mackenzie* et al., IUCN Guide (n. 4), MN. 225.

69 *Mackenzie* et al., IUCN Guide (n. 4), MN. 221–225; see *Acquaah* (n. 66), 150–151; for an extensive overview of 'traditional' yet modern techniques (in the context of European legislation), see *van die Wiel* et al. (n. 64), 6.

70 *Caius M. Rommens*, Intragenic Crop Improvement: Combining the Benefits of Traditional Breeding and Genetic Engineering, 55 (2007) Journal of Agricultural and Food Chemistry 4281, 4281–4282: see *Hermann J. Muller*, Artificial Transmutation of the Gene, 66 (1927) Science 84.

71 Cf. *van die Wiel* et al. (n. 64), 5.

72 See *supra* section A.I.1.d)aa)).

modification at the level of single nucleotides (or 'base pairs') cannot be construed as 'techniques used in traditional breeding and selection'.

e) Coverage of Certain New and Emerging Techniques

aa) Genome Editing

The preceding analysis has shown that the Cartagena Protocol is wide in scope and capable of capturing the recent progress made in biotechnology. Its definition of the term 'living modified organism' has been deliberately drafted in anticipation of scientific developments that would occur after the adoption of the Protocol. The definition refers to both the *resulting organism*, which is expected to contain a novel combination of genetic material (but not necessarily exogenous DNA), and the *technique of modification*, which must be one of modern biotechnology.

Arguably, the requirement that the technique must 'overcome natural physiological barriers' introduces a certain level of ambiguity that might lead to different interpretative results. However, the drafting history of this element clearly shows that it is not the *product*, but the *process* of genetic modification that must overcome natural barriers. The definition does not exclude organisms from its scope that were produced by *in vitro* nucleic acid techniques but could – hypothetically – also arise from natural processes.

Based on the above analysis, it is concluded that modified organisms resulting from any genome editing technique using site-specific nucleases (SDN), including the CRISPR/Cas technique, are covered by the Cartagena Protocol even when they only carry targeted point mutations resulting from the application of these techniques (SDN-1 and SDN-2).[73]

On the other hand, it seems to be undisputed that the Cartagena Protocol is applicable to modified organisms that carry exogenous genetic information, regardless of whether these elements were inserted by conventional means of genetic engineering or by genome editing techniques (SDN-3).[74]

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73 *Sirinathsinghji* (n. 11).
74 *Araki* et al. (n. 11), 234–235.

bb) Engineered Gene Drives

The scope of the Cartagena Protocol also includes *engineered gene drives*. As outlined in the first chapter, gene drives are currently developed by integrating genes for the drive mechanism along with any desired payload genes into the genome of the target organism.[75] This necessarily implies that foreign genetic material is permanently introduced into the organism.

Organisms equipped with engineered gene drives therefore possess a novel combination of material obtained through modern biotechnology, namely through in vitro nucleic acid techniques. Since the genes encoding for the drive mechanism could not be inserted into the host organism's genome in a natural way, the modification also overcomes natural physiological reproductive and recombination barriers. Therefore, organisms carrying engineered gene drives based on techniques like CRISPR-Cas constitute LMOs in terms of Article 3(h) of the Cartagena Protocol.[76]

It has been suggested that once an engineered gene drive is released into the environment, the progeny might cease to constitute LMOs and thus fall outside the scope of the Cartagena Protocol.[77] According to this view, engineered gene drives use natural reproduction in order to diffuse traits into their target population and, for this reason, do not overcome *re-*

75 See chapter 1, section C.II.

76 AHTEG on Synthetic Biology, Report of the Ad Hoc Technical Expert Group on Synthetic Biology: Montreal, Canada, 5–8 December 2017, UN Doc. CBD/SYNBIO/AHTEG/2017/1/3 (2017), para. 28; *Li C. Lim/Li L. Lim*, Gene Drives: Legal and Regulatory Issues (2019), 27; *Keiper/Atanassova* (n. 11), 15; *Greet Smets/Patrick Rüdelsheim*, Study on Risk Assessment: Application of Annex I of Decision CP 9/13 to Living Modified Organisms Containing Engineered Gene Drives, UN Doc. CBD/CP/RA/AHTEG/2020/1/4, Annex (2020), 30; *Delphine Thizy* et al., Providing a Policy Framework for Responsible Gene Drive Research: An Analysis of the Existing Governance Landscape and Priority Areas for Further Research, 5 (2020) Wellcome Open Research 173, 13. For similar reasons, these organisms are also covered by the EU's legislation on GMO as well as laws of EU member states implementing that legislation, cf. *Marion Dolezel* et al., Beyond Limits – The Pitfalls of Global Gene Drives for Environmental Risk Assessment in the European Union, 15 (2020) BioRisk 1, 5–6. For instance, the German Central Committee on Biological Safety deems recombinant gene drive systems based on the CRISPR-Cas technique to be covered by the scope of the German Genetic Engineering Law, cf. ZKBS, Position Statement of the ZKBS on the Classification of Genetic Engineering Operations for the Production and Use of Higher Organisms Using Recombinant Gene Drive Systems, Az. 45310.0111 (2016).

77 *Florian Rabitz*, Gene Drives and the International Biodiversity Regime, 28 (2019) RECIEL 339, 345.

productive barriers in the sense of the definition of 'modern biotechnology' in Article 3(i) CP.[78] It was further suggested that engineered gene drives do not necessarily overcome *recombination barriers*, because 'the trait itself may well be inside the normal evolutionary boundaries'.[79] But these assumptions are rooted in a misconception of the functioning of engineered gene drive systems. As shown earlier, nuclease-based gene drive systems operate by performing a genetic modification in each progeny, thereby guaranteeing their own inheritance to further offspring.[80] Each of these modifications overcomes natural reproductive and recombination barriers, as the DNA encoding for the drive system is copied onto the chromosome inherited from the wild-type parent. Hence, all progeny of an organism carrying an engineered gene drive constitute LMOs.

However, as noted in the first chapter, the efficacy of engineered gene drives is not always 100 %.[81] Due to a number of factors, the drive system may not succeed in every individual, leaving some of the progeny unmodified. Moreover, evolutionary factors might lead to the emergence of resistances, which may cause the drive to (partly) phase out.[82] Against this background, it has been argued that progeny that no longer carries the DNA encoding for the drive system would not constitute LMOs.[83] In principle, this appears to be correct. But it could well be argued that progeny of LMOs are legally presumed to be LMOs too unless it is proven that their genome no longer contains any novel combination of DNA obtained through modern biotechnology. Moreover, it is impossible to predict which of the offspring will not inherit the drive system. In any event, it seems impossible to determine with certainty that a gene drive, once released, has been completely eradicated from the environment. For these reasons, the fact that the drive system may become lost in some (or even all) of the progeny has no bearing on the regulation of the parent organisms to be released into the environment.

78 *Ibid.*
79 *Ibid.*
80 See chapter 1, section C.II.
81 See chapter 1, section C.IV.1.
82 *Ibid.*
83 *Rabitz* (n. 77), 345.

cc) Genetically Modified Viruses

Genetically modified viruses, regardless of the way they are used,[84] are also covered by the Cartagena Protocol's scope. As shown above, viruses are not themselves capable of replicating genetic material, but are expressly included in the definition of 'living organism'.[85] In most cases, these modifications will involve recombinant DNA, i.e. the insertion of transgenic material from other viruses or organisms. However, as shown above, the Cartagena Protocol also applies to modified organisms (and viruses) which do not carry foreign genetic material.[86] Consequently, the Cartagena Protocol applies to all applications of modified viruses discussed in the first chapter.

dd) Techniques That Harness Natural Mechanisms of Self-Propagation (Wolbachia)

In contrast to synthetic gene drives and genetically modified viruses, techniques that harness naturally occurring mechanisms of self-propagation without genetically modifying the target organism are outside the scope of the Cartagena Protocol. This concerns, in particular, undertakings aimed at releasing mosquitoes infected with the heritable *Wolbachia* bacterium in order to reduce the mosquitoes' potential to transmit human pathogens such as *Zika* and *Dengue*.[87] As long as neither the genetic material of the insect nor that of the bacterium are modified by means of modern biotechnology, they are not covered by the Cartagena Protocol.[88] However, because certain *Wolbachia* strains cause significant physiological changes to

84 See chapter 1, sections D, E.I, and E.II.
85 See *supra* section A.I.1.a).
86 See *supra* section A.I.1.e)aa).
87 See chapter 1, section E.IV.; see World Mosquito Program, FAQ, available at: https://www.worldmosquitoprogram.org/en/learn/faqs (last accessed 28 May 2022), which notes: 'Our method is not genetic modification, as the genetic material of the mosquito has not been altered. Neither the Aedes aegypti mosquitoes nor the Wolbachia have been genetically modified in the lab and the strain of Wolbachia we are using is naturally occurring.'
88 This view is shared by *John M. Marshall*, The Cartagena Protocol and Releases of Transgenic Mosquitoes, in: Brij K. Tyagi (ed.), Training Manual: Biosafety for Human Health and the Environment in the Context of the Potential Use of Genetically Modified Mosquitoes (GMMs) (2015) 163, 168, who warns that: 'It would be unfortunate if a method of modification were chosen first and foremost

the infected mosquitoes, it has been argued that the biosafety implications involved with these approaches are similar to those of genetic modifications.[89]

2. Restriction to Hazardous LMOs?

According to Article 4, the Cartagena Protocol applies to all LMOs

> *'that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'*.[90]

According to some authors, this phrase has the effect of limiting the Protocol's scope to only those LMOs that 'may have' the said effects, thereby excluding LMOs which are unlikely to have adverse effects.[91]

Such a substantial restriction of the Protocol's scope can, however, not be simply assumed. There is no express provision which imposes such a (potentially far-reaching) restriction on the Protocol's scope of application, and the Protocol contains neither substantive criteria nor a procedure for excluding certain organisms from the scope of the entire Protocol.[92] Instead, Article 7(4) provides a dedicated procedure to exempt LMOs that are 'not likely to have adverse effects' from the Protocol's *Advance Informed Agreement* procedure,[93] albeit not from the Protocol as a whole. Such an exemption requires an express decision by the meeting of the parties to the

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for its immunity to excessive regulatory requirements, rather than on the basis of its safety and efficacy.'

89 Cf. *John M. Marshall*, The Cartagena Protocol and Genetically Modified Mosquitoes, 28 (2010) Nature Biotech. 896, 897; *Guy R. Knudsen*, International Deployment of Microbial Pest Control Agents: Falling Between the Cracks of the Convention on Biological Diversity and the Cartagena Biosafety Protocol, 30 (2012) Pace Envtl. L. Rev. 625.

90 The same wording can be found in Article 1, which lays down the Protocol's objective. On considerations for risks to human health, see *Nathalie Bernasconi-Osterwalder*, The Cartagena Protocol on Biosafety: A Multilateral Approach to Regulate GMOs, in: Edith Brown Weiss/John H. Jackson/Nathalie Bernasconi-Osterwalder (eds.), Reconciling Environment and Trade (2nd ed. 2008) 645, 649.

91 This interpretation seems to be adopted, even though without reasoning, by *Pavoni* (n. 4), 118 at footnote 17; *Ezra Ricci*, Biosafety Regulation: The Cartagena Protocol (2004), 17; *John Komen*, The Emerging International Regulatory Framework for Biotechnology, 3 (2012) GM Crops & Food 78, 80.

92 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 168.

93 See *infra* section A.II.1.

Cartagena Protocol (COP-MOP).[94] To date, the procedure of Article 7(4) has never been used.[95]

Hence, LMOs are not *included* in the Protocol's scope because they are deemed hazardous, but rather can be *excluded* from certain provisions when they are deemed unlikely to have adverse effects.[96] This approach is an implementation of the precautionary principle:[97] LMOs are subject to the Protocol even when there is no scientific certainty about their hazardousness, as long as they have not proven to be safe.[98] This interpretation is also coherent with Articles 10(6) and 11(8) of the Protocol, which allow states to unilaterally restrict the import of LMOs on grounds of the precautionary approach when there is a lack of scientific certainty regarding the extent of their potential adverse effects.[99]

At the same time, it should be noted that the Cartagena Protocol does not consider LMOs as *generally* and *inherently* hazardous or dangerous to the environment.[100] This is an important difference from other interna-

94 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 279; see *Jutta Brunnée*, COPing with Consent: Law-Making Under Multilateral Environmental Agreements, 15 (2002) Leiden J. Int'l L. 1, 22–23, noting that this mechanism allows the parties to the Cartagena Protocol to modify the substantive terms of the instrument, namely to reduce the scope of the agreement, by simple decision instead of a formalized amendment procedure. *René Lefeber*, Creative Legal Engineering, 13 (2000) Leiden Journal of International Law 1, 6–8, notes that this modification might even be decided by majority vote, and thus against the express will of a minority of parties. On the role of COP decisions, also see chapter 5, section B.

95 Cf. CBD Secretariat, COP-MOP Decisions on AIA (Art. 7–10), available at: https://bch.cbd.int/protocol/decisions/?subject=cpb-art7-10 (last accessed 28 May 2022).

96 *Eggers/Mackenzie* (n. 4), MN. 528; *Aarti Gupta*, Creating a Global Biosafety Regime, 2 (2000) International Journal of Biotechnology 205, 218–219; *Mackenzie* et al., IUCN Guide (n. 4), MN. 168.

97 References to the precautionary approach contained in Principle 15 of the Rio Declaration can be found can be found in several provisions of the Cartagena Protocol, including the Preamble and Article 1. For a detailed assessment of the precautionary principle, see chapter 4, section B.VI.

98 *Mackenzie* et al., IUCN Guide (n. 4), MN. 279.

99 Cf. *Komen* (n. 91), 80; *Mackenzie* et al., IUCN Guide (n. 4), MN. 339–341; see *infra* sections A.II.1.d) and f).

100 *Worku D. Yifru* et al., The Decision-Making Procedures of the Protocol, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 78, 86; *Akiho Shibata*, A New Dimension in International Environmental Liability Regimes: A Prelude to the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 17, 21.

tional agreements such as the 1989 *Basel Convention*[101] and the 1998 *Rotterdam Convention*,[102] in which the parties agree on the hazardousness of certain substances specifically listed in annexes to these Conventions.[103] In contrast, under the Cartagena Protocol, the ultimate decision on whether a certain LMO is deemed to be hazardous is made individually by the country of import, namely after an assessment of the *potential* risks in accordance with the Protocol's provisions.[104] Consequently, the reference to adverse effects in Article 4 is of merely declaratory value and does not restrict the Protocol's scope. The Protocol applies to *any* LMO, while LMOs that have proven to be safe can be exempted from the AIA procedure pursuant to Article 7(4) CP.[105]

3. Activities Covered by the Protocol

Article 4 CP also specifies the activities involving LMOs to which the Cartagena Protocol applies, namely the 'transboundary movement, transit, handling and use' of LMOs.

The term transboundary movement is defined in Article 3(k) CP as the 'movement of a living modified organism from one Party to another Party'.[106] This refers predominantly to intentional transboundary movements, i.e. the import of an LMO into the territory of another state. But transboundary movements may also occur unintentionally, which is specifically

101 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (22 March 1989; effective 05 May 1992), 1673 UNTS 57 (hereinafter 'Basel Convention').

102 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (10 September 1998; effective 24 February 2004), 2244 UNTS 337 (hereinafter 'Rotterdam Convention').

103 *Redgwell* (n. 4), 555.

104 *Ibid.*, 555–556; *Peter-Tobias Stoll*, Controlling the Risks of Genetically Modified Organisms: The Cartagena Protocol on Biosafety and the SPS Agreement, 10 (1999) YB Int'l Env. L. 82, 95.

105 *Mackenzie* et al., IUCN Guide (n. 4), MN. 168; also see *Tomme R. Young*, National Experiences with Legislative Implementation of the Protocol, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 329, 346–348.

106 Article 3(k) further provides that, for the purposes of the Protocol's provisions on unintentional transboundary movements in Article 17 and on transboundary movements to non-parties in Article 24, the term transboundary movement also extends to movements between parties and non-parties.

addressed in Article 17 CP.[107] For the purposes of this provision, the term transboundary movement also extends to movements between parties and non-parties to the Cartagena Protocol; the same applies to Article 24 which specifically addresses the role of non-parties.[108]

Since the notion of 'transboundary movement' is expressly defined as a movement '*from* one Party *to* another Party'[109] and Article 24 only applies to transboundary movements '*between* parties and non-parties',[110] the Cartagena Protocol seems not to apply to transboundary movements from parties into areas beyond national jurisdiction, especially the high seas.[111] Article 2(3) CP expressly provides that the Protocol shall not affect the rights and freedoms of states under international law of the sea. However, Article 196(1) of the *UN Convention on the Law of the Sea* (UNCLOS)[112] obliges states to prevent the introduction of 'new' species, which arguably includes LMOs,[113] into the marine environment.[114]

The other activities listed in Article 4 CP – transit, handling, and use – are not defined in the Protocol. However, some guidance concerning 'transit' is provided by Article 6(1) CP, which refers to the right of each party to regulate the transit of LMOs 'through its territory'. This implies that 'transit' refers to the passage of an LMO through or across the territory of one or several states.[115] With regard to 'use', reference can be made to the definition of 'contained use' in Article 3(b) CP, which suggests that 'use' can mean *any* operation which involves LMOs. Hence, it can be assumed that while the terms 'transboundary movement' and 'transit' refer to specific forms of carriage of LMOs, 'handling and use' cover any activity

107 See *infra*, section A.II.2.b).
108 See *infra* section A.II.4.
109 Article 3(k) CP (emphasis added).
110 Emphasis added.
111 *Mackenzie* et al., IUCN Guide (n. 4), MN. 234.
112 United Nations Convention on the Law of the Sea (10 December 1982; effective 16 November 1994), 1833 UNTS 3 (hereinafter 'UNCLOS').
113 *Markus Böckenförde*, The Introduction of Alien or New Species into the Marine Environment: A Challenge for Standard Setting and Enforcement, in: Peter Ehlers/Elisabeth Mann-Borgese/Rüdiger Wolfrum (eds.), Marine Issues (2002) 241, 250–251; *Detlef Czybulka*, Article 196 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017), MN. 14.
114 See *infra* section G.
115 This is also consistent with the use of the term 'transit' in other international agreements, cf. UNCLOS (n. 112), Article 124(1)(c); Basel Convention (n. 101), Article 2(12); also see *Marquard* (n. 14), 295–297; *Mackenzie* et al., IUCN Guide (n. 4), MN. 234.

involving LMOs, regardless of whether they remain in containment or are released into the environment.

4. Exemption for Transboundary Movement of LMOs Which Are Pharmaceuticals (Article 5)

According to Article 5, the Cartagena Protocol does not apply to

> *'the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations'.*

Article 5 only encompasses 'living modified organisms which are pharmaceuticals', which implies that the LMO itself must be the pharmaceutical.[116] Moreover, the pharmaceutical must be addressed by other agreements or organizations.[117] This may be the case for *in vivo* uses of genetically modified bacteria or viruses as vaccines[118] or to deliver drugs, therapeutic proteins or gene therapy vectors to the human body with higher specificity than by conventional means.[119] At the same time, appli-

116 See *Marquard* (n. 14), 294–295.

117 Relevant instruments in this context are the Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products (08 October 1970; effective 26 May 1971), 956 UNTS 3, which has been extended by the (informal) Pharmaceutical Inspection Co-operation Scheme (PIC/S), see PIC/S, Introduction, available at: https://www.picscheme.org/en/about (last accessed 28 May 2022), and the World Health Organization's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, cf. *A. Wehrli*, The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, 31 (1997) Drug Information Journal 899.

118 Cf. *Joachim Frey*, Biological Safety Concepts of Genetically Modified Live Bacterial Vaccines, 25 (2007) Vaccine 5598; *Elena Angulo/Juan Bárcena*, Towards a Unique and Transmissible Vaccine Against Myxomatosis and Rabbit Haemorrhagic Disease for Rabbit Populations, 34 (2007) Wildlife Research 567; *Anne I. Myhr/Roy A. Dalmo*, DNA Vaccines: Mechanisms and Aspects of Relevance for Biosafety, in: Terje Traavik/Li C. Lim (eds.), Biosafety First (2009) 253; *Young* (n. 105), 384.

119 Cf. *Manoj Kumar* et al., Bioengineered Probiotics as a New Hope for Health and Diseases: An Overview of Potential and Prospects, 11 (2016) Future Microbiology 585; see *Gupta* (n. 96), 212.

cations in which LMOs are used outside the organism (*in vitro*) to produce non-living drugs or vaccines are not covered by Article 5.[120]

Applications involving the *in vivo* injection of nucleic acids or nucleases for therapeutic purposes, such as mRNA vaccines developed against SARS-CoV-2[121] and the injection of preassembled CRISPR-Cas components to treat sickle-cell anaemia,[122] are not covered by Article 5. While these applications rely on the use of modern biotechnology, especially *in vitro* nucleic acid techniques in the sense of Article 3(i) CP,[123] they do not involve the creation of a living modified organism. For this reason, these applications fall entirely outside the scope of the Cartagena Protocol.

It has been proposed that LMOs used for disease control purposes might constitute pharmaceuticals in the sense of Article 5.[124] According to such an interpretation, insects equipped with transgenes or engineered gene drives could be exempted from large parts of the Protocol when they are used for disease control purposes.[125] The same would apply to genetically modified viruses and transmissible vaccines. However, such an interpretation is not persuasive for three reasons: Firstly, in its ordinary meaning the noun 'pharmaceutical' refers to a 'medicinal drug'.[126] This is confirmed, secondly, by the use of this term in international agreements relating

120 *Mackenzie* et al., IUCN Guide (n. 4), MN. 243. A different view is taken by *Odile J. Lim Tung*, Genetically Modified Organisms and Transboundary Damage, 38 (2013) SAYIL 67, 71, who assumes that LMOs intended as raw materials for the production of pharmaceuticals or nutraceuticals may not be covered by the Cartagena Protocol and the Supplementary Protocol. However, this view is not further substantiated and also ignores the wording of Article 5 CP, which unequivocally refers to LMOs 'which are pharmaceuticals' rather than LMOs which are intended for being processed to pharmaceuticals. Article 7(2) CP demonstrates that the Protocol indeed makes such a distinction between LMOs intended for direct use and LMOs intended for processing.

121 See *Lindsey R. Baden* et al., Efficacy and Safety of the MRNA-1273 SARS-CoV-2 Vaccine, 384 (2021) N. Engl. J. Med. 403.

122 Cf. *Heidi Ledford*, CRISPR Deployed to Combat Sickle-Cell Anaemia, Nature News, 12 October 2016, available at: https://www.nature.com/news/crispr-deployed-to-combat-sickle-cell-anaemia-1.20782 (last accessed 28 May 2022); see Chapter 1, section B.III.2.

123 See *supra* A.I.1.d)aa).

124 *Lim Tung* (n. 120), 71; *Odile J. Lim Tung*, Transboundary Movements of Genetically Modified Organisms and the Cartagena Protocol: Key Issues and Concerns, 17 (2014) Potchefstroom Electronic Law Journal 1739, 1744–1745.

125 On the use of engineered gene drive systems for disease vector control, see chapter 1, section C.III.1.

126 Cf. 'pharmaceutical', in Oxford English Dictionary (n. 12).

to pharmaceutical products,[127] which also refer to medicines and similar products for human or animal use.[128] Thirdly, Article 5 expressly refers to 'pharmaceuticals for humans', which semantically rules out products which are not *applied* to humans but only indirectly improve human health, such as genetically modified insects released to limit the spread of certain diseases. Consequently, LMOs intended for disease control purposes are not excluded from the scope of the Protocol.[129]

Article 5 is subject to two important caveats. Firstly, the exemption expressly retains the right of parties to subject LMOs excluded under Article 5 to a risk assessment before making a decision on their import.[130] Secondly, Article 5 stipulates that it only applies to the transboundary movement of said LMOs. This means that the Protocol's general provisions not relating to transboundary movement, in particular those on risk management,[131] remain applicable.[132]

5. Conclusions

The above analysis has shown that the Cartagena Protocol is wide in scope and capable of covering techniques developed after its adoption. The definition of the term 'living modified organism' consists of two elements that refer to both the technique employed ('use of modern biotechnology') and the characteristics of the resulting organism ('novel combination of genetic material').

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127 Pursuant to Article 31(3)(c) VCLT, any relevant rules of international law applicable in the relations between the parties shall be taken into account together with the context of a treaty's terms.

128 See references in *supra* n. 117.

129 Cf. *Marshall* (n. 88), 167, assuming that 'the interpretation of [genetically modified mosquitoes] as pharmaceuticals is not widespread'.

130 Cf. *Pavoni* (n. 4), 124; *Mackenzie* et al., IUCN Guide (n. 4), MN. 245.

131 See *infra* section A.II.2.

132 *Mackenzie* et al., IUCN Guide (n. 4), MN. 242; but see *Eggers/Mackenzie* (n. 4), 529; *Falkner* (n. 4), 307, assuming that pharmaceuticals are entirely excluded from the scope of the Protocol. However, see *Tewolde Berhan Gebre Egziabher*, The Cartagena Protocol on Biosafety: History, Content and Implementation from a Developing Country Perspective, in: Terje Traavik/Li C. Lim (eds.), Biosafety First (2009) 389–405, 399, indicating that excluding the pharmaceuticals from the scope of the AIA mechanism, but not from the Protocol as a whole, was a compromise reached during the negotiations.

The criterion of a 'novel combination' is broad; it neither requires that the resulting organism contains foreign genetic material nor that the combination could not have arisen naturally. Hence, the more decisive criterion is whether the organism was obtained through modern biotechnology, particularly through *in vitro* nucleic acid techniques that overcome natural physiological reproductive or recombination barriers. In this regard, it is important to note that the technique employed, and not the resulting organism, must overcome natural barriers. This requires that the natural process of genetic alteration – which relies, in one form or another, on random genetic change – is replaced by techniques that allow generating targeted genetic changes.

As a result, it is submitted that the Cartagena Protocol applies to all modified organisms resulting from the application of site-specific nucleases, including the CRISPR/Cas technique, regardless of whether it involves the introduction of foreign genetic material into the target organism. While this may be controversial concerning organisms modified through genome editing, there appears to be no doubt that organisms carrying engineered gene drives are covered by the Cartagena Protocol.

The Cartagena Protocol applies to all activities involving LMOs, both in contained use and when released into the environment. Contrary to what the wording of Article 4 might imply, it is not limited to LMOs identified as involving a particular risk for biodiversity. LMOs that are pharmaceuticals for humans can be excluded from the Protocol's provisions on transboundary movement, provided they are addressed by other relevant international agreements or organisations.

II. Substantive Provisions

The substantive provisions of the Cartagena Protocol can be divided into provisions on international trade in LMOs on the one hand and general provisions on risk management in relation to LMOs on the other. International trade is regulated by the establishment of an *Advance Informed Agreement* mechanism, which establishes a harmonized procedure for obtaining the advance consent of the importing party prior to the first importation of a particular LMO (1.).

The Protocol's general rules primarily address the prevention of both unintentional and illegal transboundary movements (2.). Furthermore, there are provisions concerning the exchange of information (3.), the application of the Protocol in relation to third states (4.), and the right

of parties to adopt more rigid standards than those laid down in the Cartagena Protocol (5.). Finally, the Protocol contained a mandate for elaborating an additional instrument on liability, which later resulted in the *Nagoya–Kuala Lumpur Supplementary Protocol* (6.).

1. Advance Informed Agreement Procedure for Transboundary Movements of LMOs

The *Advance Informed Agreement* (AIA) procedure, which is laid down in Articles 7 to 10 and 12, is the Cartagena Protocol's central mechanism for regulating the transboundary movement of LMOs.[133] The underlying principle of the AIA mechanism is that LMOs shall not be imported into the territory of any contracting party without that party's prior and express consent.[134] Thus, the party of export is required to ensure that the party of import is notified of any intended transboundary movement of an LMO.[135] The competent authority of the party of import shall ensure that a risk assessment is carried out for the LMO in question,[136] and subsequently render a decision on whether the transboundary movement may proceed.[137] The AIA mechanism under the Cartagena Protocol was modelled after the *Prior Informed Consent* procedures previously adopted in two other multilateral agreements on hazardous substances, namely the *Basel Convention* on transboundary movements of hazardous wastes of 1989,[138] and the *Rotterdam Convention* of 1998,[139] which established a Prior Informed Consent procedure for international trade in certain hazardous chemicals.[140]

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133 *Yifru* et al. (n. 100), 78; *Tobias Sdunzig*, Die UN-Konvention über Biodiversität und ihre Zusatzprotokolle (2017), 243.

134 *Mackenzie* et al., IUCN Guide (n. 4), MN. 264; see *Thomas O. McGarity*, International Regulation of Deliberate Release Biotechnologies, in: Francesco Francioni/Tullio Scovazzi (eds.), International Responsibility for Environmental Harm (1991) 319, 336–338.

135 Article 8(1) CP.

136 Articles 10(1) and 15(2) CP.

137 Article 10(2) CP; cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 264.

138 Basel Convention (n. 101).

139 Rotterdam Convention (n. 102).

140 Cf. *Stoll* (n. 104), 91; *Eggers/Mackenzie* (n. 4), 529; *Redgwell* (n. 4), 555; *Yifru* et al. (n. 100), 83–86; *Shibata* (n. 100), 21.

a) Scope of the AIA Provisions

The scope of the AIA mechanism is defined in Article 7(1). According to this provision, the Advance Informed Agreement of the party of import shall be obtained

> *'prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import'.*

The term 'transboundary movement' is defined by Article 3(k) CP as the 'movement of a living modified organism from one Party to another Party'. The *Court of Justice of the European Union* found this definition to be 'particularly wide', as it encompassed not only movements of LMOs of an agricultural nature, but also movements for charitable or scientific purposes and movements serving the public interest.[141]

However, the AIA mechanism only applies to LMOs 'for intentional introduction into the environment of the Party of import'. Thus, a number of scenarios are excluded from the scope of the AIA procedure: Firstly, the AIA procedure does not apply to the transit of LMOs through a party's territory.[142] Secondly, no AIA is required for LMOs 'destined for contained use', which refers to LMOs for which no environmental release is intended.[143] Thirdly, LMOs intended for direct use as food or feed or for processing are not subject to the AIA procedure but to a simplified approval mechanism under Article 11 CP.[144] Finally, as mentioned above, the AIA mechanism does not apply to LMOs identified in a decision by the meeting of parties as 'being not likely to have adverse effects on the conservation and sustainable use of biological diversity'.[145]

141 CJEU, Cartagena Protocol, Opinion 2/00, 06 December 2001, 2000 ECR I-09713, para. 38.

142 Article 6(1) CP; cf. *Marquard* (n. 14), 295–296; *Eric Schoonejans*, Advance Informed Agreement Procedures, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 299–320, 317–318.

143 Article 6(2) CP; cf. *Marquard* (n. 14), 291–293.

144 Article 7(2) and (3) CP; see *infra* section A.II.1.f).

145 Article 7(4) CP; see *supra* section A.I.2.

b) Procedure of Obtaining an Advance Informed Agreement From the Party of Import

The procedure of obtaining an AIA for an intended transboundary movement is comprised of several steps and commences with a notification submitted to the competent authority of the party of import. The exporting state party shall either submit the notification itself or require the exporter to ensure that the importing party is notified.[146] The notification shall contain detailed information about the LMO, including its origin, the means of modification, the resulting characteristics and its intended use.[147] The party of import has to acknowledge receipt of the notification.[148] Within 270 days, it shall then render a decision whether it allows, conditionally allows, or prohibits the import.[149] Unless the party of import unconditionally approves the import, it is required to set out the reasons on which it based its decision.[150] When new scientific information about potential adverse effects of an LMO becomes available, the part of import is entitled to review and change an earlier decision.[151] Similarly, the exporter may request the importing party to review an earlier decision when circumstances have changed or when additional information has become available that may influence the outcome of the decision.[152]

c) Risk Assessment

According to Article 10(1) of the Cartagena Protocol, each decision under the AIA mechanism shall be based on a risk assessment carried out in a scientifically sound manner. Article 15(1) stipulates that the objective of such risk assessments is to identify and evaluate the possible adverse effects of LMOs on biodiversity.[153] To that end, risk assessments shall be carried

146 Article 8 CP. On the decision to impose a notification duty on the exporting party, see *Schoonejans* (n. 142), 307–308.
147 See Annex I to the Cartagena Protocol.
148 Article 9 CP.
149 Article 10(3) CP; see *Pavoni* (n. 4), 121.
150 Article 10(4) CP.
151 Article 12(1) CP.
152 Article 12(2) CP.
153 See *Ryan Hill*, Risk Assessment and Risk Management, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 63.

out in a scientifically sound manner, taking into account recognized risk assessment techniques, and shall at least be based on the information submitted by the notifier as well as 'other available scientific evidence'.[154] The party of import may require the exporter to either carry out the risk assessment itself or to bear the costs for it.[155]

Annex III stipulates extensive requirements that a risk assessment carried out under the Cartagena Protocol must fulfil.[156] As a general principle, the Annex provides that 'lack 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'.[157] Moreover, it stipulates that the risks should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.[158]

With regard to methodology, the Annex provides for a number of steps a risk assessment should include: First of all, any novel characteristics of the LMO that may have adverse effects in the likely potential receiving environment should be identified.[159] Then, both the likelihood of these adverse effects[160] and the consequences if they materialize shall be evaluated.[161] These factors shall be combined into an estimation of the overall risk posed by the LMO.[162] The risk assessment procedure shall culminate in a recommendation as to whether the risks are manageable, as well as identify appropriate strategies to manage these risks.[163] Any remaining uncertainty about the level of risk shall be addressed by requesting further information or by implementing appropriate risk management strategies and/or monitoring the LMO in the receiving environment.[164] This multi-step process is common to many international and domestic risk assessment frameworks relating to genetically modified organisms.[165]

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154 *Ibid*.
155 Article 15(2) and (3) CP.
156 See *Bernasconi-Osterwalder* (n. 90), 652–653.
157 Annex III to the Cartagena Protocol, para. 4.
158 *Ibid.*, para. 5.
159 *Ibid.*, para. 8(a).
160 *Ibid.*, para. 8(b).
161 *Ibid.*, para. 8(c).
162 *Ibid.*, para. 8(d).
163 *Ibid.*, para. 8(e).
164 *Ibid.*, para. 8(f).
165 Cf. Codex Alimentarius Commission, Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (2011), CAC/GL 44–2003; OIE, Guidelines for Assessing the Risk of Non-Native Animals Becoming Invasive (Novem-

The Annex also provides a list of issues that should be considered in a risk assessment, including the biological characteristics of the recipient organism or the parental organism, the donor organism, and the vector.[166] The genetic characteristics of the inserted nucleic acid and the function it specifies, and/or the characteristics of the modification introduced, should also be considered in the risk assessment.[167] Moreover, the identity of the LMO and its differences from the recipient or parental organism should be considered as well as suggested detection and identification methods.[168] Finally, the risk assessment should also take into account information relating to the intended use of LMO and the characteristics of the likely potential receiving environment.[169]

d) Role of the Precautionary Principle in Decision-Making (Article 10(6))

Article 10(6) CP provides that lack of scientific certainty regarding the extent of potential adverse effects of the LMO shall not prevent the party of import 'from taking a decision, as appropriate, with regard to the import of the living modified organism in question […], in order to avoid or minimize such potential adverse effects'.[170] Although it cannot easily be derived from a literal reading, the provision is generally regarded as imple-

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ber 2011); International Plant Protection Convention/FAO, International Standard for Phytosanitary Measures No. 11: Pest Risk Analysis for Quarantine Pests, last amended in April 2013 (hereinafter 'ISPM 11'); Australian Government, Office of the Gene Technology Regulator, Risk Analysis Framework (4th ed. 2013); Commission Directive (EU) 2018/350 of 8 March 2018 Amending Directive 2001/18/EC of the European Parliament and of the Council as Regards the Environmental Risk Assessment of Genetically Modified Organisms (2018), OJ L 67, p. 30 (hereinafter 'Commission Directive (EU) 2018/350'); see *Hill* (n. 153), 67–69; CBD Secretariat, Risk Assessment and Risk Management (Articles 15 and 16): Note by the Executive Secretary, UN Doc. UNEP/CBD/BS/COP-MOP/2/9 (2005).

166 Annex III to the Cartagena Protocol, paras. 9(a)–(c).

167 *Ibid.*, para. 8(d).

168 *Ibid.*, paras. 8(e)–(f).

169 *Ibid.*, paras. 8(g)–(h).

170 On the implementation of the precautionary principle in the Cartagena Protocol generally, see *Ruth Mackenzie/Philippe Sands*, Prospects for International Environmental Law, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 457, 461–463.

menting the precautionary approach.[171] When the conditions of Article 10(6) are met, a party of import may invoke the precautionary approach[172] to deny its approval in order to avoid or minimize such potential effects.[173]

According to its wording, the provision only applies when there is scientific uncertainty about the *extent* of potential adverse effects, but not about the *level* of risk or regarding the *nature* or *likelihood* of potential adverse effects.[174] In most cases concerning LMOs, scientific uncertainty will concern the *existence* and *nature* of a risk rather than its *extent*.[175] Against this background, it appears justifiable to construe the term 'extent' broadly as comprising any scientific uncertainty about the potential adverse effects of an LMO on the conservation and sustainable use of biological diversity.[176]

e) Role of Socio-Economic Considerations in Decision-Making (Article 26)

Article 26 CP allows parties to take into account socio-economic considerations arising from the impact of LMOs on biodiversity, provided that they are consistent with their international obligations.[177] An agreed definition of the term 'socio-economic considerations' can neither be found in the text of the Protocol nor in the relevant scholarly literature.[178]

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171 *Mackenzie* et al., IUCN Guide (n. 4), MN. 339; *Stoll* (n. 104), 98; *Böckenförde* (n. 8), MN. 13; *Laurence Graff*, The Precautionary Principle, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 410, 418–419.

172 On the precautionary principle or approach generally, see *Alan E. Boyle/Catherine Redgwell*, Birnie, Boyle, and Redgwell's International Law and the Environment (4th ed. 2021), 170–183; also see chapter 4, section B.VI.

173 *Graff* (n. 171), 418; *Pavoni* (n. 4), 128–134; *Mackenzie* et al., IUCN Guide (n. 4), MN. 341.

174 Cf. *Stoll* (n. 104), 98–99; *Böckenförde* (n. 8), MN. 13.

175 Cf. *Stoll* (n. 104), 116.

176 Cf. *ibid.*, 99; *Graff* (n. 171), 418–419. National implementation in many states appears to be based on this interpretation, see *Young* (n. 105), 348–350.

177 *Gregory Jaffe*, Implementing the Cartagena Biosafety Protocol Through National Biosafety Regulatory Systems: An Analysis of Key Unresolved Issues, 5 (2005) Journal of Public Affairs 299, 305–306.

178 *Graff* (n. 171), 419; *Karinne Ludlow* et al., Introduction to Socio-Economic Considerations in the Regulation of Genetically Modified Organisms, in: Karinne Ludlow/Stuart J. Smyth/José B. Falck-Zepeda (eds.), Socio-Economic Considerations in Biotechnology Regulation (2014) 3, 8–9.

Generally, the term 'socioeconomics' denotes a (scientific) approach that observes the interdependencies between the economy and other spheres of social life, such as culture, politics, technology and social relations.[179] In the present context, 'socio-economic considerations' can thus be construed as referring to the economic, environmental, social, cultural, and impacts an LMO might have.[180] The notion also correlates with that of 'sustainable development', which refers to the interplay between economic, social and cultural development.[181] Consequently, the term covers 'a broad spectrum of concerns about the actual and potential consequences of biotechnology'.[182] The five most common issues considered by those countries that integrate socio-economic considerations in their domestic biosafety regimes are food security, health-related impacts, the coexistence of LMOs and non-GM agriculture, impact on market access, and compliance with biosafety measures.[183] However, the meaning and scope of Article 26 CP remain subject to controversy.[184]

The need to further clarify the meaning of Article 26 CP was also recognized by the meeting of the parties to the Cartagena Protocol (COP-MOP), which set up a working group in 2016 to develop 'conceptual clarity' on

179 Cf. *Simon N. Hellmich*, What Is Socioeconomics? An Overview of Theories, Methods, and Themes in the Field, 46 (2017) Forum for Social Economics 3, 3.

180 *Kathryn Garforth*, Socio-Economic Considerations in Biosafety Decision-Making: An International Sustainable Development Law Perspective, CISDL Working Paper (2004), 19–22; also see *Fransen* et al. (n. 180), 2–3.

181 *Frederic Perron-Welch*, Socioeconomics, Biosafety, and Sustainable Development, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 147, 149.

182 *Antonio La Vina/Lindsey Fransen*, Integrating Socio-Economic Considerations into Biosafety Decisions: The Challenge for Asia (2004), 3.

183 CBD Secretariat, Summary Report on the Survey on the Application of and Experience in the Use of Socio-Economic Considerations in Decision-Making on Living Modified Organisms: Note by the Executive Secretary, UN Doc. UNEP/CBD/BS/COP-MOP/5/INF/10 (2010), 5; cf. *Perron-Welch* (n. 181), 154–156; *Ludlow* et al. (n. 178), 8–10 with references to further lists of socio-economic issues related to biotechnology drawn up by various institutions; for the EU, also see European Commission, Report on Socio-Economic Implications of GMO Cultivation on the Basis of Member States Contributions, as Requested by the Conclusions of the Environment Council of December 2008, SANCO/10715/2011 Rev. 5 (2011).

184 *José B. Falck-Zepeda*, Socio-Economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What Are the Issues and What Is at Stake?, 12 (2009) AgBioForum 90, 95–96.

this provision.[185] Among other issues, the working group developed an operational definition of the term 'socio-economic considerations', which reads:

> *'Socio-economic considerations in the context of Article 26 of the Cartagena Protocol may, depending on national or regional circumstances and on national measures to implement the Protocol, cover economic, social, cultural/traditional/religious/ethical aspects, as well as ecological and health-related aspects, if they are not already covered by risk assessment procedures under Article 15 of the Protocol'.*[186]

In 2017, the working group elaborated 'Guidance' outlining principles and a procedural framework for assessing socio-economic considerations when preparing a decision on the import of LMOs.[187] The working group noted that taking socio-economic considerations into account in the decision-making on the import of LMOs must be consistent with international obligations arising from trade, environmental and human rights agreements.[188] It also concluded that the assessment of socio-economic considerations 'should be science-based and evidence-based and lead to defendable results'.[189] Subsequently, the Guidance outlines a multi-stage process that resembles the guidelines for risk assessment contained in Annex III to the Cartagena Protocol[190]. It suggests identifying possible socio-economic effects based on a 'problem statement' and that a 'wide array of methodological approaches is available to assess socio-economic effects, including both quantitative and qualitative methods, as well as participatory approaches'.[191]

Notably, the meetings of the parties to the Cartagena Protocol refused to 'welcome' the Guidance, as was proposed by the working group,[192]

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185 CP COP-MOP, Decision BS-VI/13. Socio-Economic Considerations, UN Doc. UNEP/CBD/BS/COP-MOP/6/18, p. 93 (2016), para. 4.
186 AHTEG on Socio-Economics, Revised Framework for Conceptual Clarity on Socio-Economic Considerations, UN Doc. UNEP/CBD/BS/COP-MOP/8/13, Annex (2016).
187 AHTEG on Socio-Economics, Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety, UN Doc. CBD/CP/MOP/9/10, Annex (2018).
188 *Ibid.*, 5.
189 *Ibid.*
190 See *supra* section A.II.1.c).
191 AHTEG on Socio-Economics (n. 187), 7.
192 Cf. *ibid.*, para. 10(1).

but instead only 'took note' of it.[193] Consequently, the Guidance is neither legally binding nor can it be said to constitute quasi-normative 'soft law'.[194]

Moreover, the working group appears to have overlooked that, according to its wording, Article 26 is limited to socio-economic considerations that arise 'from the impact of LMOs on biological diversity'.[195] This means that the provision only applies when the release of an LMO affects biological diversity in a way that raises socioeconomic concerns.[196] Only in such cases may a party rely on Article 26 to justify the denial of its advance agreement or other restrictions on the import and use of an LMO.[197] It may be argued that measures to accommodate socio-economic concerns not covered by Article 26 may nevertheless be imposed because the Protocol only provides for a minimum standard and parties are free to adopt more protective measures.[198] In any event, the boundaries for such measures are less likely to arise from the Cartagena Protocol than from international trade law, which sets high thresholds for justified trade restrictions.[199] This is also recognized in Article 26, which provides that any decision based on socio-economic considerations must be in accordance with the parties' other international obligations.[200]

f) Rules for LMOs Intended for Direct Use as Food or Feed, or for Processing (Article 11)

Article 11 CP establishes a separate process for LMOs that are not designated for intentional introduction into the environment but for direct use as food or feed, or for processing (LMO-FFPs).[201] Although each party

193 Cf. CP COP-MOP, Decision 9/14. Socio-Economic Considerations (Article 26), UN Doc. CBD/CP/MOP/DEC/9/14 (2018), para. 1.
194 See *Brunnée* (n. 94); for a detailed discussion of the normative quality of COP/MOP decisions, see chapter 5, section B.
195 *Mackenzie* et al., IUCN Guide (n. 4), MN. 628; *Perron-Welch* (n. 181), 153.
196 *Mackenzie* et al., IUCN Guide (n. 4), MN. 628–629; *Falck-Zepeda* (n. 184), 95; *Perron-Welch* (n. 181), 153.
197 Cf. *Falck-Zepeda* (n. 184), 95.
198 Article 2(4) CP; cf. *La Vina/Fransen* (n. 182), 3; *Garforth* (n. 180), 23–29; *Ludlow* et al. (n. 178), 8–9; *Falck-Zepeda* (n. 184), 95.
199 See *infra* section C.
200 *Eggers/Mackenzie* (n. 4), 532; *Mackenzie* et al., IUCN Guide (n. 4), MN. 633; *Stoll* (n. 104), 97.
201 See *Yifru* et al. (n. 100), 80–83.

remains free to decide on the import, domestic use and placing on the market of these organisms, the Protocol does not impose an obligation of prior notification or prior consent on the exporter.[202] Instead, each party is required to inform the other parties through the Biosafety Clearing-House of any final decision taken on the domestic use or marketing of LMO-FFPs that may be subject to transboundary movement.[203] Hence, the parties of import need to proactively regulate the import and use of LMO-FFPs if they wish to do so.[204] Notably, developing countries that do not yet have a domestic framework to regulate the import of LMO-FFPs may invoke Article 11(6), which means that imports must nonetheless be notified and are subject to approval by the receiving state.[205] However, this exception has only been used by two states.[206] Many other states have instead extended their regular AIA procedures to LMO-FFPs, which is deemed to constitute a lawful upward derogation under Article 2(4) CP.[207]

g) Exemption of Contained Use and LMO-FFP: The 'Intended Use' Problem

As noted above, the AIA procedure does not apply to LMOs which are 'destined' for contained use or 'intended' for direct use as food or feed, or for processing.[208] Hence, whether the AIA procedure applies does not depend on objectively identifiable characteristics of the LMO, but on the intended use of the LMO in the party of import.

202 Cf. *Pavoni* (n. 4), 122; *Gupta* (n. 96), 213–214.
203 *Yifru* et al. (n. 100), 81–82.
204 *Young* (n. 105), 344–346; *Böckenförde* (n. 8), MN. 14; *François Pythoud*, Commodities, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 321, 325–328.
205 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 365–369; *Böckenförde* (n. 8), MN. 15.
206 Namely Barbados and Saint Lucia, see Biosafety Clearing-House, available at: http://bch.cbd.int/ (last accessed 28 May 2022).
207 *Young* (n. 105), 344–346.
208 See Articles 6(2) and 7(2) CP; see *supra* section A.II.1.a).

aa) Genuine and Disguised Changes to the Intended Use

Since the 'intended use' is not an objective characteristic that is inherent in the LMO itself, the applicability of the AIA procedure ultimately relies on the stated intentions of the actors involved in the transboundary movement. However, there is no procedure for verifying these statements. Even more, neither the exporter nor the importer is required to make a formal declaration about how the LMO will be used after being imported. There is also no provision expressly barring subsequent changes of the 'intended use' after the transboundary movement has taken place.

This problem is illustrated by a case concerning the transboundary movement of genetically modified mosquitoes. As noted in the first chapter,[209] the international research consortium *Target Malaria*[210] imported a genetically modified strain of the *Anopheles gambiae* mosquito from Italy to Burkina Faso in November 2016.[211] Reportedly arguing that the mosquitoes were imported 'for an initial period of contained use' and thus were not subject to the AIA procedure,[212] the exporters did not notify the transboundary movement in accordance with Regulation (EC) No 1946/2003,[213] which implements the Cartagena Protocol into European Union law.[214] After being brought to Burkina Faso, the mosquitoes were

209 See chapter 1, section C.III.1.c).

210 Target Malaria is an international research consortium that aims to develop gene drives to reduce the transmission of malaria, see Target Malaria, Who We Are, available at: https://targetmalaria.org/who-we-are/ (last accessed 28 May 2022).

211 The modified strain does not contain a gene drive, but was modified to yield males that are sterile (i.e. incapable of sexual reproduction) and carry fluorescent markers, which allows to identify modified individuals, see *Keith R. Hayes* et al., Risk Assessment for Controlling Mosquito Vectors with Engineered Nucleases: Controlled Field Release for Sterile Male Construct: Risk Assessment Final Report (2018), 14; *Nikolai Windbichler* et al., Targeting the X Chromosome During Spermatogenesis Induces Y Chromosome Transmission Ratio Distortion and Early Dominant Embryo Lethality in Anopheles Gambiae, 4 (2008) PLOS Genetics e1000291, 2.

212 It appears that Target Malaria have not made this statement publicly, but only in communication towards the British NGO *Genewatch UK*, cf. African Centre for Biodiversity et al., GM Mosquitoes in Burkina Faso: A Briefing for the Parties to the Cartagena Protocol on Biosafety (2018), 6; *Hayes* et al. (n. 211).

213 Cf. *ibid.*; see Regulation (EC) No 1946/2003 on Transboundary Movements of Genetically Modified Organisms (15 July 2003), OJ L 287, p. 1 (hereinafter 'Regulation 1946/2003').

214 On the pertinent EU legislation, see *infra* section A.IV.

mated with local strains of *Anopheles coluzzii* and subsequently released into the environment.[215] This raises the question whether a period of contained use or subsequent changes to the LMO (such as back-crossing with local strains) can indeed waive the requirement to notify the transboundary movement and to seek the AIA of the receiving state.

The Cartagena Protocol does not specifically address subsequent changes to the use of an LMO once it has been imported. In particular, it does not expressly require the exporter to ensure that an LMO destined for contained use is only used in containment and that the containment standards are adequate.[216] Furthermore, once the import has been completed, subsequent changes to the intended use have no retroactive effect on the import procedure. Consequently, only the *first* intended use of the LMO in the importing state is decisive for whether the AIA procedure applies, regardless of any subsequent uses already envisaged at the time of import. Therefore, a phase of initial containment after the import might effectively sidestep the AIA procedure prescribed by the Cartagena Protocol, including the requirement to carry out a risk assessment.[217]

Set aside situations of a genuine subsequent change to the intended use, importers may exploit the 'contained use' exception to circumvent the AIA procedure. While this would not affect any domestic regulations applicable to a later release in the receiving state, a plausible motive could be to avoid more stringent requirements that apply in the state of origin. For example, EU legislation requires that if an LMOs intended for deliberate release is moved into a non-member state, a risk assessment must be conducted according to the same standards that apply for environmental releases in EU member states,[218] which are more far-reaching than the re-

215 See chapter 1, section C.III.1.c); also see African Centre for Biodiversity et al. (n. 212), 6.

216 *Mackenzie* et al., IUCN Guide (n. 4), MN. 259. On containment standards, see chapter 5, section C.III.

217 *John M. Marshall*, Commentary: The Cartagena Protocol in the Context of Recent Releases of Transgenic and Wolbachia-Infected Mosquitoes, 19 (2011) Asia-Pacific Journal of Molecular Biology and Biotechnology 91, 95; *Marshall* (n. 88), 169; also see *Yifru* et al. (n. 100), 87; *Marshall* (n. 89), 897.

218 Pursuant to Annex I of Regulation 1946/2003 (n. 213), lit. k, a notification prior to the first intentional transboundary movement of an LMO must contain a previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms (12 March 2001), OJ L 106, p. 1 (hereinafter 'Directive 2001/18/EC').

quirements laid down in Annex III to the Cartagena Protocol.[219] Another motivation for attempting to evade the AIA mechanism could be to avoid the early disclosure of the transboundary movement through the Biosafety Clearing-House.[220]

bb) Responsibilities of Exporting Parties

The responsibility to prevent such behaviour is shared by exporting and importing parties to the Cartagena Protocol alike. If an exporting state is a party to the Cartagena Protocol, it is obliged to implement the Protocol in good faith.[221] Under Article 8(1), it must ensure that the receiving state is notified about any intended transboundary movement that is subject to the AIA mechanism and originates from its jurisdiction.[222] The notification must include information about the intended use of the LMO.[223] Article 8(2) requires the party of export to 'ensure that there is a legal requirement for the accuracy of information provided by the exporter'.[224] In the context of information, the term 'accurate' means 'conforming exactly with the truth'.[225]

Hence, any party to the Cartagena Protocol is obliged to ensure that transboundary movements originating from its jurisdiction and subject to the AIA mechanism are duly notified to the receiving state and that the intended use of the LMO is truthfully stated. It must also ensure that private actors under its jurisdiction comply with these requirements, if necessary, by penalizing exports carried out in contravention of the pertinent implementing measures.[226] At the same time, the exporting state has no means to prevent *genuine* subsequent changes to the use of an LMO.

219 See Principles for Environmental Risk Assessment, contained in Annex II to Directive 2001/18/EC, as revised by Commission Directive (EU) 2018/350 (n. 165).
220 See *infra* section A.II.3.
221 Cf. Article 2(1) CP and Article 26 VCLT (n. 18).
222 *Schoonejans* (n. 142), 307; see *Young* (n. 105), 332–336.
223 Annex I to the Cartagena Protocol, paras. (i).
224 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 283.
225 Cf. 'accurate, adj.' in: Oxford English Dictionary (n. 12).
226 Article 25(1). On the question whether this provision directly applies to exporting parties, see *infra* section A.II.2.c)aa).

cc) Responsibilities of Importing Parties

Parties of import should insist on the application of the AIA procedure – as implemented in their domestic law – whenever it appears *possible* or *likely* that an LMO initially imported for contained use will subsequently be released into the environment. Such possibility or likelihood must be assessed by objective standards rather than the stated intentions of the exporter.[227] Furthermore, LMOs imported for contained use should be subject to a general prohibition of release into the environment, which would only be lifted once an AIA has been sought and granted *post hoc*. Such domestic requirements are consistent with the requirement to (effectively[228]) implement the Cartagena Protocol into domestic law laid down in Article 2(1) CP. In any event, they would constitute an upward derogation permitted by Article 2(4) CP.[229]

One reason why the AIA procedure does not apply to LMOs intended for contained use is that it requires an evaluation of the effects that an LMO may have on the 'likely potential receiving environment'.[230] However, LMOs imported for contained use have no destined 'receiving environment', and even where a subsequent release is planned, the release site may not yet be determined.[231] Yet, this could be resolved by not waiving the AIA requirement entirely, but only the requirement of assessing the receiving environment for LMOs destined for contained use, or by limiting this assessment to a generic evaluation of the conditions in the receiving state.[232]

Admittedly, these approaches require a robust administrative apparatus in the receiving state, which may not always be given, particularly in developing countries. For this reason, it is important to stress the aforementioned responsibilities of exporting states, which often will be industrialized states with sufficient scientific and regulatory capacities.

227 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 259.
228 Cf. *Dörr*, Article 31 VCLT (n. 18), MN. 56.
229 See *infra* section A.II.5.
230 Cf. Annex III to the Cartagena Protocol, paras. 8 and 9(h).
231 *Marshall* (n. 217), 95.
232 *Ibid.*

h) Conclusions

The AIA procedure for transboundary movements of LMOs is one of the key features of the Cartagena Protocol. However, as the procedure only applies to LMOs intended for deliberate release into the environment, the percentage of internationally traded biotechnology products that are subject to an AIA is rather small.[233] In practice, the main subjects of the AIA mechanism are genetically modified seeds and live fish.[234] In addition, imports of LMOs wrongly declared to be intended for contained use only, or subsequent changes in the intended use of an LMO after import, threaten to undermine the effectiveness of the AIA mechanism. However, exporting and importing parties bear a joint responsibility to prevent the mechanism from being circumvented. Most importantly, the requirements for obtaining a release permit in the receiving state should not be more lenient than those for obtaining the AIA at the time of import.

Where the AIA mechanism applies, the Cartagena Protocol merely governs the procedure of obtaining an AIA from the receiving state. However, it does not provide any substantive criteria to guide the actual decision-making about whether to allow or deny the import of a specific LMO.[235] The Protocol does not contain any material agreement between the parties on the grounds on which a state may legitimately refuse to import a certain LMO.[236] In principle, states are therefore free in their decision-making and may admit or refuse LMOs as they deem fit. This is also confirmed by Article 2(4) CP, which provides that states may take measures that are *more protective of biodiversity* than those stipulated in the Protocol.[237] However, this freedom is significantly restricted by the rules of international trade law, as shown below.[238]

233 *Gupta* (n. 96), 214; *Schoonejans* (n. 142), 306; *Stewart/Johanson* (n. 4), 7.
234 *Stewart/Johanson* (n. 4), 7; *Bernasconi-Osterwalder* (n. 90), 646; see US Department of State, Fact Sheet: Cartagena Protocol on Biosafety (2000).
235 *Hill* (n. 153), 70.
236 Cf. *Stoll* (n. 104), 95; *Pavoni* (n. 4), 115–116; *Jaffe* (n. 177), 303–305; *Redgwell* (n. 4), 556.
237 See *infra* section A.II.5.
238 See *infra* section C.

2. Risk Management and Preparedness

Articles 16–18 and 25 of the Cartagena Protocol contain general provisions on risk management. These provisions operate outside the AIA framework and therefore, subject to the limitations discussed below, apply regardless of whether an LMO is or is not subject to an (intentional) transboundary movement.[239]

a) Risk Management (Article 16)

Article 16 is the Cartagena Protocol's core provision on risk management. The first paragraph stipulates a general obligation to establish and maintain appropriate measures to manage the risks associated with LMOs (aa)). The second paragraph specifically addresses the prevention of adverse effects that imported LMOs may have on the biological diversity in the territory of the importing state (bb)). The third paragraph stipulates an obligation to prevent unintentional transboundary movements of LMOs (cc)). The fourth paragraph requires that any LMO, even when it is developed and used locally, is subjected to an appropriate observation period before it is put to its intended use (dd)). Finally, the fifth paragraph provides an obligation to cooperate in the identification and management of risks of LMOs (ee)).

aa) Obligation to Establish Appropriate Risk Management Measures (para. 1)

Under Article 16(1) CP, parties are required to establish and maintain appropriate mechanisms, measures, and strategies to regulate, manage and control the risks associated with the use, handling, and transboundary movement of LMOs. The provision refers to the general provision contained in Article 8(g) of the CBD, which requires parties to establish or maintain means to regulate, manage, or control the risks associated with the use and release of LMOs.[240]

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239 Cf. *Sandrine Maljean-Dubois*, Biodiversité, biotechnologies, biosécurité: Le droit international désarticulé (2000) Journal du Droit International 947, 981–982.

240 See *infra* section B.III.

Article 16(1) CP applies to 'risks identified in the risk assessment provisions of this Protocol'. In its ordinary meaning, the phrase 'risks *identified* in the risk assessment provisions' suggests that the risk assessment provisions specify the risks to be addressed.[241] However, the Protocol's provisions on risk assessment – namely, Article 15 and Annex III – do not name any specific risks but rather provide a framework for determining these risks on a case-by-case basis.[242] Hence, the reference to 'risks identified *in the risk assessment provisions*' makes little sense and seems best explained by a drafting error.[243]

A possible solution would be to understand the reference to 'risks' to mean the risks identified during a risk assessment carried out in accordance with the risk assessment provisions of the Protocol. This would resolve the discrepancy while keeping the interpretation as close as possible to the ordinary meaning of the provision. But at the same time, such an interpretation would limit the scope of Article 16(1) CP to only those LMOs for which an AIA has been sought, because, as shown above, the Protocol's provisions on risk assessment operate within the AIA mechanism.[244] This may be inconsistent with the wording of the provision, which applies to the 'use, handling *and* transboundary movement' of LMOs, while risk assessments are only required for the latter. Moreover, confining the first paragraph of Article 16 CP to transboundary situations would also strip the relevance of the second paragraph, which specifically provides for risk management measures based on risk assessment following the transboundary movement of an LMO.[245] Finally, the provision's reference to Article 8(g) CBD also contradicts this interpretation because the latter generally refers to managing the risks associated with the use and release of LMOs, not to transboundary movements.

Consequently, it appears more appropriate to construe the notion of risks in Article 16(1) CP as generally referring to the risks that LMOs may pose to the conservation and sustainable use of biological diversity, taking

241 Cf. 'identify', in Oxford English Dictionary (n. 12).

242 Annex III to the Cartagena Protocol, para. 5; cf. *Jaffe* (n. 177), 303; see *supra* section A.II.1.c).

243 Other language versions seem to be coherent in this regard, as the French version refers to 'les risques définis par les dispositions du Protocole relatives à l'évaluation des risques' and the Spanish version uses 'los riesgos determinados con arreglo a las disposiciones sobre evaluación del riesgo del presente Protocolo'.

244 Cf. *Pavoni* (n. 4), 119.

245 See *infra* section bb).

also into account human health (i.e. all risks covered by the scope of the Cartagena Protocol).[246] This not only accommodates the concerns raised by the interpretation discussed before, but also better suits the substance of the provision, which broadly refers to 'mechanisms, measures and strategies to regulate, manage and control risks […] associated with the use, handling and transboundary movement' of LMOs. Thus, the scope is not limited to the transboundary movement of LMOs, but also extends to their use and handling in a domestic context. Finally, this approach brings the provision in line with the subsequent paragraphs of Article 16, which separately address deliberate and indeliberate transboundary movements as well as purely domestic uses of LMOs.

In any case, the substantive content of Article 16(1) CP remains broad and unspecific. The Protocol offers no distinction between the terms 'mechanisms', 'measures', and 'strategies'. The same applies to notions of regulation, management, and control of risks, which the Protocol also does not further specify.[247] The only criterion is that the measures adopted by the parties must be 'appropriate'. This term indicates that the present obligation is one of *due diligence*, which means that the parties shall take all reasonable steps to effectively address the risks in question.[248] However, the occurrence of harm does not automatically indicate that a state has not taken all appropriate steps to prevent harm.[249] It is doubtful whether it is at all possible to review the compliance of parties with this obligation.

bb) Imposition of Preventive Measures Based on Risk Assessment (para. 2)

Article 16(2) CP provides that measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects on the biological diversity within the territory of the party of import. Since it expressly addresses the protection of biodiversity in the territory of importing parties, the provision only applies to LMOs that were subject to a transboundary movement. Hence, the risk assessment on which measures shall be based will usually be that already carried out during the AIA procedure. But

246 This seems to be implied by *Mackenzie* et al., IUCN Guide (n. 4), MN. 444.
247 For an overview of risk management measures commonly applied, see *ibid.*, MN. 447–448.
248 Cf. *Joanna Kulesza*, Due Diligence in International Law (2016), 187; see chapter 4, section C.
249 See chapter 4, section E.I.

the provision also applies to LMOs for which no AIA was obtained, for instance because they were declared to be intended for contained use at the time of import.[250]

Article 16(2) CP provides that measures shall be imposed 'to the extent necessary' to prevent adverse effects. This implies a double threshold: on the one hand, the measures must be actually capable of handling the risks that have been identified, but on the other hand, they shall not go beyond what is required for achieving an adequate level of protection. In this understanding, the requirement of 'necessary' measures reminds of the necessity requirement under international trade law.[251] Interestingly, the provision does not specify the bearer of the obligation it stipulates. While the importing party usually will be in the best position to impose the required measures, the exporting party may also be required to take measures to prevent adverse effects in the importing party's territory. This may especially be the case when the importing party lacks adequate regulatory capacities capable of imposing and enforcing the required measures.[252]

cc) Prevention of Unintentional Transboundary Movements (para. 3)

Article 16(3) CP requires each party to take appropriate measures to prevent unintentional transboundary movements of LMOs.

(1) The Notion of 'Unintentional Transboundary Movement'

The provision applies to any LMO which may be subject to an *unintentional* transboundary movement, regardless of whether it is also subject to *intentional* transboundary movements. Article 16(3) CP complements the AIA mechanism by ensuring that no transboundary movements occur without the express approval of the receiving state. It relates to Article 25, which addresses *illegal transboundary movements*, i.e., movements carried

250 Cf. *Young* (n. 105), 372–374; see *supra* section A.II.1.g).

251 Cf. General Agreement on Tariffs and Trade 1994 (15 April 1994; effective 01 January 1995), 1867 UNTS 187, Annex 1A (hereinafter 'GATT 1994'), Article XX; see *Pavoni* (n. 4), 133 and *infra* section C.

252 See *Young* (n. 105), 340.

out intentionally but in contravention of the state's domestic measures implementing the Cartagena Protocol, including the AIA mechanism.[253]

The term 'transboundary movement' is defined by Article 3(k) CP as the 'movement of a living modified organism from one Party to another Party'.[254] Since the term *movement* is not further specified, it presumably covers all possibilities of how an LMO may travel from one state's territory into another, regardless of whether it migrates naturally, is carried by another organism or parts of it (such as animals, crop or pollen), or is unintentionally transported by humans.

In a decision adopted by COP-MOP 8, the term 'unintentional transboundary movement' was defined as 'a transboundary movement of a living modified organism that has inadvertently crossed the national borders of a Party where the living modified organism was released'.[255] This definition adds little clarity, as it essentially replaces 'unintentional' with the term 'inadvertently', which is largely synonymous.[256] Yet, with regard to the ordinary meaning of these terms, a transboundary movement can be deemed 'unintentional' in terms of the present provision when it is not carried out by at least one human person acting in a wilful manner.[257] Unintentional transboundary movements can result from both intentional and accidental releases, such as when an LMO escapes a contained use

253 See *infra* section A.II.2.c).

254 It can be assumed that the present provision also provides for the prevention of unintentional movements into the territory of non-parties. Article 3(k) provides that, for the purposes of Articles 17 and 24, the term transboundary movement extends to movement between parties and non-parties. Article 17 provides for the notification of affected states in case unintentional transboundary movements occur (see *infra* section A.II.2.b). Since it would be incoherent to assume that the Protocol covered response measures to unintentional movements to non-parties but not their prevention in the first place, Article 16(3) should be interpreted extensively in this regard.

255 CP COP-MOP, Decision VIII/16. Unintentional Transboundary Movements and Emergency Measures (Article 17), UN Doc. CBD/CP/MOP/DEC/VIII/16 (2016), Annex. The definition goes on to restrict the scope of the duty to notify in cases of unintentional transboundary movements pursuant to Article 17 to LMOs which are likely to have significant adverse effects, see *infra* section A.II.2.b).

256 Cf. 'inadvertence, n.', in: *Bryan A. Garner* (ed.), Black's Law Dictionary (11th ed. 2019), 908; 'inadvertently, adv.', in: Oxford English Dictionary (n. 12).

257 Cf. 'unintentional act', in: Black's Law Dictionary (n. 256), 32; 'unintentional, adj.', in: Oxford English Dictionary (n. 12).

facility.[258] Hence, the present provision also covers negligent conduct that leads to an unintentional transboundary movement.[259]

(2) Obligation to Take 'Appropriate Measures'

According to Article 16(3) CP, each party is required to take 'appropriate measures to prevent unintentional transboundary movements'. The Protocol does not define what is required by 'appropriate measures'. However, Article 16(3) resembles the obligation to prevent significant transboundary under general international law, which, according to the seminal codification by the *International Law Commission* (ILC), requires all states to 'take all appropriate measures to prevent significant transboundary harm'.[260] In this context, the duty to take 'appropriate measures' denotes an obligation to act with *due diligence*.[261] Since Article 16(3) CP also seeks to avoid undue transboundary environmental interference, its reference to 'appropriate measures' arguably incorporates this general due diligence standard.[262]

The obligation to exercise due diligence requires the responsible state to exercise a reasonable degree of care commensurate to the risk at stake. Practically, it must adopt appropriate legislative rules and measures and

258 *Mackenzie* et al., IUCN Guide (n. 4), MN. 467.

259 If not inherent in the term 'unintentional', the term 'inadvertently' used in the COP-MOP decision clearly points to negligent conduct, see the references in n. 256.

260 ILC, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, with Commentaries (2001), YBILC 2001, vol. II(2), p. 148 (hereinafter 'ILC, Articles on Prevention'), Art. 3. Similar provisions can be found in numerous international soft-law documents and treaties, e.g., UNCLOS (n. 112), Article 192; CBD (n. 5), Article 3; Rio Declaration on Environment and Development (14 June 1992), UN Doc. A/CONF.151/26/Rev.1 (Vol. I) (hereinafter 'Rio Declaration 1992'), Principle 2. For a detailed account, see chapter 4, section A.

261 ILC, Report of the International Law Commission on the Work of Its Fifty-Second Session, YBILC 2000, vol. II(2) (2000), para. 718; see *Leslie-Anne Duvic-Paoli*, The Prevention Principle in International Environmental Law (2018), 200–207.

262 *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73, 77; *Felix Beck*, The International Regime on Liability for Damage Arising from the Use of Genome Editing and Gene Drives in Agriculture: Current Shortcomings and Pathways for Future Improvement, in: Christian Dürnberger/Sebastian Pfeilmeier/Stephan Schleissing (eds.), Genome Editing in Agriculture (2019) 135, 142.

ensure their effective implementation, including by exercising administrative control over both public and private operators.[263] However, obligations of due diligence are not obligations of result,[264] which means that even full compliance does not guarantee that the undesired event will not occur in any case.[265] Hence, while the state is required to take all reasonable steps to prevent unintentional transboundary movements, the occurrence of such a movement does not automatically indicate that the state violated its obligation.[266] To invoke another state's responsibility for a breach of Article 16(3), a claimant state would have to prove that the responsible state has not taken 'all appropriate measures' – in the sense of all measures a 'reasonable government' would have taken under normal conditions[267] – and that this was causal for the unintended transboundary movement.[268]

(3) Requirement of a Risk Assessment

Article 16(3) further provides that the appropriate measures to be taken shall include 'such measures as *requiring a risk assessment* to be carried out prior to the first release'[269] of an LMO. It is questionable whether this phrase introduces a general obligation to carry out risk assessments for *all* LMOs before their first release, regardless of whether they have been subject to intentional transboundary movements. Such an obligation would be in line with a recent development in customary international

263 ICJ, Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment of 20 April 2010, ICJ Rep. 14, 197; ITLOS, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, Advisory Opinion of 01 November 2011, Case No. 17, ITLOS Rep. 10, paras. 110–120, see *Lefeber* (n. 262), 77; *Duvic-Paoli* (n. 261), 207–210.

264 ILC, Draft Articles on the Law of the Non-Navigational Uses of International Watercourses and Commentaries Thereto, YBILC 1994, vol. II(2), p. 89 (1994), Art. 7 para. 4.

265 Cf. *ibid.;* ILC, Articles on Prevention (n. 260), Commentary to Article 3, para. 7; ITLOS, Responsibilities and Obligations of States (n. 263), para. 110; *Lefeber* (n. 262), 77; see chapter 4, section E.I.

266 *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 61–62; also see ITLOS, Responsibilities and Obligations of States (n. 263), MN. 189.

267 ILC, Articles on Prevention (n. 260), Commentary to Article 3, para. 17.

268 *Beck* (n. 262), 143.

269 Emphasis added.

law, which increasingly requires environmental impact or risk assessments to be carried out for projects that may potentially have negative transboundary effects.[270] However, the term 'such […] as' could imply that risk assessments are merely given as an example of what appropriate measures could comprise, without stipulating a specific obligation in this regard. Furthermore, since a general obligation to require risk assessments would be a very far-reaching obligation, it could be argued that such an obligation would need to be expressly provided for by the Protocol rather than merely be mentioned in the apodosis of a single provision.[271]

Another argument against the assumption that Article 16(3) CP introduces a general obligation to require risk assessments can be drawn from the fourth paragraph of the same Article, which stipulates that states shall 'endeavour to ensure' appropriate observation periods for LMOs before they are put to their intended use. This provision, which is weaker but expressly applies to 'any LMO', would run empty if Article 16(3) CP was interpreted to require a risk assessment for all LMOs in all cases.

dd) Appropriate Observation Period for Any LMO (para. 4)

Pursuant to Article 16(4) CP, parties shall 'endeavour to ensure' that any LMO, whether imported or locally developed, be subjected to an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use. As shown above, the Cartagena Protocol's provisions on risk assessment, which are contained in Article 15 and Annex III, only apply to LMOs that are subject to transboundary movements of LMOs.[272] Therefore, Article 16(4) CP defines a minimum standard of care for those organisms that are not subject to any transboundary movement but are developed and used domestically. In any case, the scope of the provision also includes imported LMOs, although these

270 Cf. ICJ, Pulp Mills (n. 263), para. 204; ITLOS, Responsibilities and Obligations of States (n. 263), para. 145; ICJ, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicaragua) and Construction of a Road in Costa Rica along the San Juan River (Nicaragua v. Costa Rica), Merits Judgment of 16 December 2015, ICJ Rep. 665, para. 104; see chapter 4, section D.II.

271 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 270), para. 164, which held that the similar provision in Article 14(1)(a) CBD did 'not create an obligation to carry out an environmental impact assessment'. For a discussion, see *infra* section B.VI.

272 See *supra* section A.II.1.a).

LMOs are already addressed by the more stringent requirements contained in Article 16(2) CP, which stipulates the obligation of the importing party to adopt preventive measures based on the risk assessment carried out during the AIA procedure.

In principle, Article 16(4) CP establishes a legal obligation like most other of the Protocol's provisions. However, the wording of this provision is particularly lenient, since it merely requires states to 'endeavour to ensure' that LMOs have undergone appropriate observation periods before they are put to their intended use. Thus, it is doubtful whether this provision establishes any specific procedural duties whose implementation by parties can be reviewed and enforced.[273]

ee) Obligation to Cooperate (para. 5)

Finally, Article 16(5) CP requires parties to cooperate in two specific ways. First, states shall cooperate in identifying LMOs or specific traits that may have adverse effects on biodiversity. This primarily concerns the exchange of information about hazardous LMOs or traits as well as cooperation in the identification of new hazards. The second element relates to the appropriate treatment of LMOs or traits that have been identified as hazardous. It has been suggested that this may include the development and implementation of joint strategies to address these risks or, once they have materialized, mitigate adverse effects.[274]

b) Notification in Case of Unintentional Transboundary Movements (Article 17)

Article 17 provides for an obligation of parties to notify other states in the event of an unintentional transboundary movement. It applies when a party knows of an 'occurrence' under its jurisdiction resulting in a release that leads (or may lead) to an unintentional transboundary movement. An 'occurrence' may constitute an accidental release, a failure in risk management measures, or an unexpected spread of an LMO within the party of origin. Whether a release 'leads or may lead' to an unintentional transboundary movement depends on the factual circumstances, including

273 *Pavoni* (n. 4), 119.
274 *Mackenzie* et al., IUCN Guide (n. 4), MN. 460.

the capacity of the LMO to spread and the proximity to the border of other states.[275]

Moreover, the LMO in question must be 'likely to have significant adverse effects' on biodiversity. A decision adopted by COP-MOP 8 clarified that the requirements of Article 17 only apply when the LMO involved is likely to have significant adverse effects on biodiversity in the affected or potentially affected states.[276] Whether this is the case will largely depend on the individual characteristics of the LMO and the likely receiving environment. However, the purpose of the obligation, which is to allow other states to take necessary response action, implies that notifications should rather err on the side of caution.[277]

Article 17(3) CP specifies the minimum information that any notification to affected or potentially affected states should contain.[278] This includes any available information on the estimated quantities and relevant characteristics or traits of the LMO, the possible adverse effects the LMO may have, and possible risk management measures. According to Article 17(2) CP, each state shall communicate its point of contact to receive these notifications. Moreover, Article 17(4) CP requires the responsible party to immediately consult the affected or potentially affected states 'to enable them to determine appropriate responses and initiate necessary action, including emergency measures'.

Apart from notifying and consulting with the affected state, the Cartagena Protocol does not oblige the responsible state to offer any other response to an unintentional transboundary movement. This falls short of the provision on *illegal* transboundary movements in Article 25(2), which requires the responsible state to dispose of the LMO at its own expense by repatriation or destruction.[279] The Cartagena Protocol contains no comparable obligation to contain and dispose of an LMO in cases of unintentional transboundary movements. Since the scope of Article 25 is expressly limited to intentional transboundary movements,[280] there is

275 *Ibid.*, MN. 483.

276 CP COP-MOP Decision VIII/16 (2016) (n. 255), Annex; see *Lim/Lim* (n. 76), 32–33.

277 *Mackenzie* et al., IUCN Guide (n. 4), MN. 484–485.

278 See *Young* (n. 105), 337–338.

279 See *infra* section A.II.2.c)bb).

280 *Susanne Förster*, Internationale Haftungsregeln für schädliche Folgewirkungen gentechnisch veränderter Organismen (2007), 55, discusses whether unintentional transboundary movements could also constitute illegal transboundary movements. However, the phrase '*carried out* in contravention' in Article 25(1)

also no room for an extensive interpretation of that provision. Hence, the Cartagena Protocol does not provide any substantive obligations (besides notification and consultation) in cases of unintentional transboundary movements.

c) Illegal Transboundary Movements (Article 25)

Article 25 CP concerns intentional[281] but illegal transboundary movements, which are defined as movements carried out in contravention of the party's domestic measures to implement the Cartagena Protocol.

aa) Prevention of Illegal Transboundary Movements (para. 1)

Article 25(1) CP provides that states shall adopt appropriate measures[282] to prevent illegal transboundary movements. In principle, the provision applies to both exports and imports of LMOs.[283] *Importing parties* are required to enforce their domestic implementation of the AIA mechanism. This means that states shall not admit the import of LMOs into their territory unless their competent authority has approved the import in accordance with the domestic laws implementing the AIA mechanism. Moreover, as the scope of Article 25(1) CP is not limited to LMOs that are subject to the AIA procedure, the provision also applies to any other domestic measures to implement the Protocol.[284]

The obligations of *exporting parties* under Article 25(1) CP are more difficult to identify. As noted earlier, Article 8 requires exporting parties to ensure that the competent authority of the importing party is duly notified prior to the intended transboundary movement.[285] However, the Cartagena Protocol does not contain an express provision obliging the exporting party to prevent and penalize exports of LMOs without the AIA of the importing party. This sharply contrasts with comparable instruments,

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clearly indicates that the provision only concerns intentional transboundary movements.

281 See previous footnote.

282 See *supra* section A.II.2.a)cc)(2).

283 *Mackenzie* et al., IUCN Guide (n. 4), MN. 616.

284 *Ibid.*, MN. 618.

285 See *supra* sections A.II.1.b) and A.II.1.g)bb).

such as the Basel Convention[286] and the Amsterdam Convention[287], which expressly require their respective parties to prohibit exports when the consent of the importing state is pending or has been denied.[288] Nevertheless, the practical differences appear to be negligible: in the European Union, Article 5 of Regulation 1946/2003[289] provides that transboundary movements to states outside the customs territory of the EU shall not be made without the 'prior written express consent' of the importing state.[290] According to Article 18 of Regulation 1946/2003, the EU member states shall implement 'effective, proportionate and dissuasive penalties' for infringements of the Regulation.[291] In Germany, for instance, any intentional transboundary movement made in violation of Article 5 of Regulation 1946/2003 shall be punishable by up to three years imprisonment.[292]

Notably, under Article 25(1) CP, the illegal nature of a transboundary movement is judged exclusively against a party's domestic implementing measures, not the provisions of the Protocol itself.[293] Hence, the obligation presumes that the parties concerned have adopted appropriate domestic measures to implement the Cartagena Protocol, as required by Article 2(1) CP. However, parties enjoy much leeway how they implement the

286 Pursuant to Article 4(1) of the Basel Convention (n. 101), parties shall prohibit or shall not permit the export of hazardous wastes if the state of import has prohibited the import of such wastes, or does not consent in writing to the specific import.

287 Pursuant to Article 11 of the Rotterdam Convention (n. 102), each party shall take appropriate legislative or administrative measures to ensure that exporters within its jurisdiction comply with decisions of the importing party about the import of chemicals governed by the Convention, and shall ensure that chemicals are not exported when the importing party has failed to communicate a decision.

288 *Stoll* (n. 104), 91.

289 Regulation 1946/2003 (n. 213); see *infra* section A.IV.1.

290 Note that Regulation 1946/2003 not only applies to transboundary movements to third states which are parties to the Cartagena Protocol, but expressly includes transboundary movements to non-parties.

291 For examples from other jurisdictions, see *Young* (n. 105), 367–370.

292 See Gesetz zur Durchführung der Verordnungen der Europäischen Gemeinschaft oder der Europäischen Union auf dem Gebiet der Gentechnik und über die Kennzeichnung ohne Anwendung gentechnischer Verfahren hergestellter Lebensmittel (Act Implementing the Regulations of the European Community or of the European Union in the Field of Genetic Engineering and on Labelling of Food Manufactured without using Genetic Engineering Procedures) (22 June 2004), as last amended by ordinance of 4 July 2021 (Bundesgesetzblatt Pt. I, p. 3274), Section 6(2).

293 *Mackenzie* et al., IUCN Guide (n. 4), MN. 619.

Cartagena Protocol's provisions into their domestic law.[294] Consequently, the Protocol does not necessarily provide a universal standard of what is considered an illegal transboundary movement.[295]

Therefore, a particular transboundary movement may be illegal under the laws of the receiving state even if it was lawful under the measures of the party of export.[296] Moreover, the Protocol does not expressly address situations in which a party has failed to enact appropriate domestic implementation measures.[297] In such a case, Article 25(1) might be inapplicable. The legal consequences of such a situation, which would constitute a breach of the Cartagena Protocol, are governed by the general international law on state responsibility.[298]

bb) Obligation to Dispose of the LMO in Case of an Illegal Transboundary Movement (para. 2)

Article 25(2) CP provides that when an illegal transboundary movement occurs, the affected party may request the party of origin to dispose of the LMO in question by repatriation or destruction at its own expense. Although a literal reading might suggest otherwise,[299] it is not at the discretion of the party of origin whether it complies with such a request. Instead, the phrase 'may request' implies the right of the affected party to choose whether it wants the LMO to be disposed of, with the party of origin being legally required to comply with such a request. The responsible

294 *Ibid.*, MN. 178; see *Kirsten Schmalenbach*, Article 26, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 47, who points out that 'numerous treaties explicitly address the duty to take measures of domestic implementation […] without constraining the party's freedom of choice with respect to the manner of domestic implementation'.

295 *Mackenzie* et al., IUCN Guide (n. 4), MN. 619.

296 *Ibid.*

297 *Ibid.*

298 Note that Article 11 of the Nagoya/Kuala Lumpur Supplementary Protocol expressly states that the international law of state responsibility shall remain unaffected by said protocol. See *Lefeber* (n. 262), 76–78 and chapter 6, section E.III. On the law of state responsibility, see chapter 9.

299 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 622, who suggest that it could be at the discretion of the responsible party whether it complies with a request under Article 25(2) CP, contrasting the present provision with Article 9 of the Basel Convention (n. 101) which provides that the responsible party 'shall ensure' that the wastes are appropriately disposed of.

party does not necessarily have to take the necessary measures itself. It may also require the person or entity responsible for the illegal transboundary movement to implement these measures, or commission a third party to take the required action.[300] However, the responsible party remains fully responsible for the fulfilment of its obligation. Article 25(2) does not stipulate a mere procedural obligation but provides for a particular result, namely the complete removal of the LMO from the territory of the affected party.

The consequences of this provision are potentially far-reaching, as they could amount to a form of *de facto* 'strict state liability' for illegal transboundary movements, which would apply independently from whether the state of origin has itself breached its obligation to prevent such movements.[301] A similar obligation can be found in the *Basel Convention on Hazardous Wastes*: if a transboundary movement of hazardous wastes is illegal due to the conduct of the generator or exporter, the state of export shall ensure that the wastes in question are taken back into its territory or otherwise disposed of lawfully.[302] Thus, whereas an illegal transboundary movement does not by itself give rise to the international responsibility of the state of export, non-compliance with the obligations to take back such wastes may entail state responsibility.[303]

Nevertheless, the precise content of the obligation in Article 25(2) is ambiguous. The LMO in question shall be disposed of by 'repatriation or destruction'. 'Repatriation' means the re-import of the LMO to its state of origin.[304] As 'destruction' is mentioned as an alternative to its 'repatriation', it can be assumed that destruction could also be carried out within the territory of the affected party. However, the Protocol does not further indicate how the repatriation or destruction of the LMO shall be achieved. While this may be rather easy to accomplish as long as the LMO is held in containment, it is not clear how an LMO shall be repatriated or destroyed once it has been released into the environment of the affected party. This is especially true in the context of self-spreading LMOs such as engineered gene drives or viruses.

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300 *Mackenzie* et al., IUCN Guide (n. 4), MN. 621.

301 See chapter 10.

302 Basel Convention (n. 101), Article 8(2).

303 See *Katharina Kummer Peiry*, Transboundary Movement of Hazardous Waste and Chemicals, in: André Nollkaemper/Ilias Plakokefalos et al. (eds.), The Practice of Shared Responsibility in International Law (2017) 936, 947–949.

304 *Mackenzie* et al., IUCN Guide (n. 4), MN. 620; cf. 'repatriation, n.', in Oxford English Dictionary (n. 12).

Moreover, the Protocol does not address cases in which both repatriation and destruction are materially impossible or would involve a burden out of all proportion. Hence, the obligation is breached whenever the state of origin neither repatriates nor disposes of the LMO, regardless of the reasons. However, in some cases, the international responsibility of the state of origin may nevertheless be precluded if its failure to dispose of the LMO is owed to *force majeure*.[305] It has also been suggested that if the situation requires urgent action, the affected party might take the required measures and subsequently claim reimbursement of the necessary expenses from the responsible party.[306]

Finally, Article 25(2) CP insufficiently addresses situations in which an LMO that was subject to an illegal transboundary movement has already caused damage in the territory of the affected party.[307] In these cases, the affected party needs to resort to the provisions on liability and redress contained in the Supplementary Protocol (insofar as they are applicable)[308] or to the principles of state responsibility (insofar as a failure of the exporting party to adequately regulate and oversee the conduct of the relevant private actors can be established).[309]

d) Handling, Transport, Packaging, and Identification (Article 18(1))

In order to avert adverse effects on biodiversity, Article 18(1) requires that LMOs subject to intentional transboundary movement are 'handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards'.[310] Such rules and standards are

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305 Cf. ILC, Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries (2001), YBILC 2001, vol. II(2), p. 31, Article 23; see chapter 9, section A.IV.4.

306 *Gurdial S. Nijar* et al., Developing a Liability and Redress Regime Under the Cartagena Protocol on Biosafety: For Damage Resulting from the Transboundary Movements of Genetically Modified Organisms (2005), 60.

307 *Förster* (n. 280), 202, referring to *Nijar* et al. (n. 306), 61, who suggest that when the presence has created an irreversible situation that cannot be restored by the destruction of the LMO, Article 25(2) could also give rise to other forms of reparation.

308 See chapter 6.

309 See chapter 9.

310 For an account of relevant international instruments, see *Stoll* (n. 104), 92. For a review of national laws dealing with handling, transport, packaging, and identification of LMOs, see *Thomas P. Redick*, Handling, Transport, Packaging, and In-

promulgated, for example, in the measures adopted under the frameworks of the International Plant Protection Convention,[311] the World Organisation for Animal Health,[312] and the *Codex Alimentarius*.[313] Moreover, specific international rules exist on the transport of hazardous goods, which may also apply to certain LMOs.[314] Article 18(2) CP requires that LMOs are accompanied by documentation that identifies them as LMOs, specifies any requirements for their safe handling and use, and declares a point of contact for obtaining further information.[315] With regard to LMO-FFPs, COP-MOP 3 adopted additional requirements for documentation.[316]

e) Conclusions

In principle, the risk management provisions in Articles 16–18 and 25 of the Protocol are independent of the Protocol's AIA mechanism. Yet, most of these provisions still focus on the transboundary movement of LMOs. Articles 16(2) and 18 CP only apply to LMOs that are subject to intentional transboundary movement, while Articles 16(3), 17 and 25 CP provide for the prevention of unintentional and illegal transboundary movements, as well as for response measures where such movements occur nevertheless. Only Article 16(1), (4) and (5) CP apply to all LMOs regardless of whether they are subject to transboundary movement. But these provisions are particularly vague and merely require states to cooperate and to 'endeavour' to subject all LMOs to adequate observation periods.

This shows that the present provisions are not so much aimed at protecting biodiversity as a global common, but rather at protecting the national sovereignty of receiving states and their environment.[317] Within certain limits, each state is free to determine its own standard of care[318] as long as

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formation, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 89, 95–107.

311 See *infra* section D.

312 See *infra* section E.

313 See *infra* section F.

314 See *infra* section H.

315 Cf. *Eggers/Mackenzie* (n. 4), 532–533; *Bernasconi-Osterwalder* (n. 90), 653–654.

316 Cf. CP COP-MOP, Decision BS-III/10. Handling, Transport, Packaging and Identification of Living Modified Organisms: Paragraph 2 (A) Of Article 18, UN Doc. UNEP/CBD/BS/COP-MOP/3/15, p. 60 (2006).

317 Cf. *Pavoni* (n. 4), 118–120.

318 Cf. *ibid.*, 116; *Falkner* (n. 4), 311; *Jaffe* (n. 177), 304.

it ensures that LMOs are not unintentionally or illegally moved into the territory of other states.

3. Information-Sharing Through the Biosafety Clearing-House (Article 20)

Article 20 of the Protocol establishes the so-called *Biosafety Clearing-House* (BCH), an internet platform facilitating the exchange of scientific, technical, environmental and legal information relating to the use of and trade in LMOs.[319] The Cartagena Protocol specifies categories of information that parties are required to submit to the BCH.[320] Most importantly, parties shall notify their final decisions regarding the importation or release of LMOs.[321] Moreover, parties must make available summaries of their risk assessments or environmental reviews generated by their regulatory processes in accordance with Article 15 CP.[322]

In the aforementioned case concerning the transboundary movement of modified mosquitoes to Burkina Faso, the government reportedly authorized experimental releases of genetically modified mosquitoes.[323] As of May 2022, no information has been made available on the BCH.[324] However, there is no deadline for submitting risk assessment summaries

319 Biosafety Clearing-House (n. 206); see CP COP-MOP, Decision BS-I/3. Information-Sharing and the Biosafety Clearing-House (Article 20): Modalities of Operation of the Biosafety Clearing-House, UN Doc. UNEP/CBD/BS/COP-MOP/1/15, p. 35 (2004); also see *Tomme R. Young*, Use of the Biosafety Clearing-House in Practice, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 137.

320 For a full list of the categories of information that parties are required to submit to the BCH, see CP COP-MOP Decision BS-I/3 (2004) (n. 319), Annex, Part A; *Mackenzie* et al., IUCN Guide (n. 4), MN. 542.

321 Article 20(3)(d) CP.

322 Article 20(3)(c) CP. Note that this provision could also be interpreted as only requiring the submission of assessments carried out pursuant to Article 15, which means within an AIA procedure. However, the provision expressly refers to assessments and reviews 'generated by [the party's] regulatory process' besides those carried out in accordance with Article 15.

323 See *supra* section A.II.1.g).

324 Cf. Biosafety Clearing-House, Burkina Faso: Country's Decision or Any Other Communication, available at: https://bch.cbd.int/en/countries/BF/DEC (last accessed 28 May 2022).

and release permits to the BCH.[325] Burkina Faso previously notified its authorizations with significant delays of one year and longer.[326]

Besides the aforementioned information, parties shall share relevant information on their domestic regulatory framework implementing the Cartagena Protocol and any relevant international arrangements.[327] Parties must also notify unintentional transboundary movements and illegal transboundary movements.[328] In addition, the BCH is meant to assist parties in implementing the Protocol and to facilitate information-sharing between governments and researchers.[329] Most information shared with the BCH is publicly available,[330] and non-parties to the Cartagena Protocol are expressly encouraged to contribute appropriate information to the BCH.[331]

325 Such a deadline has been set neither in Article 20 CP nor in COP decision BS-I/3 of 2004 establishing the modalities of operation for the Biosafety Clearing-House. Also see UNEP-GEF BCH Project, An Introduction to the Biosafety Clearing House (2011), 21, which indicates that no timeframe is specified for reporting information pursuant to Article 20(3) CP. In contrast, within the AIA procedure, state parties must to communicate their decision whether or not to allow the import of an LMO to the Biosafety Clearing-House and the notifier within 270 days of the date of receiving the notification.

326 See Biosafety Clearing-House (n. 324).

327 Article 20(3)(a) CP.

328 Articles 17(1) CP and 25(3) CP.

329 Cf. *Kirsty G. McLean*, Bridging the Gap Between Researchers and Policy-Makers: International Collaboration Through the Biosafety Clearing-House, 4 (2005) Environmental Biosafety Research 123.

330 On this issue, see *Aarti Gupta*, Transparency to What End? Governing by Disclosure Through the Biosafety Clearing House, 28 (2010) Environment and Planning C: Government and Policy 128.

331 Cf. Article 24(2) Cartagena Protocol.

4. Application in Relation to Non-Parties (Article 24)

In principle, international treaties only create rights and obligations between their parties.[332] Hence, a non-party[333] is neither bound by the provisions of the Cartagena Protocol nor can it derive any rights from it. This raises the question of how transboundary movements between parties and non-parties to the Cartagena Protocol should be governed.

Some multilateral environmental agreements on trade in potentially harmful substances prohibit transactions with non-parties unless the non-party fulfils certain minimum standards of protection.[334] The Cartagena Protocol does not contain such a provision but merely stipulates in Article 24 CP that transboundary movements between parties and non-parties shall be 'consistent with the objective of this Protocol'.[335]

According to Article 1 CP, the general objective of the Protocol is to ensure an adequate level of protection in the field of the safe transfer, handling and use of LMOs. This is mainly implemented through the Protocol's AIA mechanism, under which transboundary movements of LMOs shall be subject to the prior consent of the importing party.[336] It appears safe to conclude that this also forms part of the Protocol's objective. Consequently, it follows from Article 24 CP that transboundary movements

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332 See Article 34 VCLT (n. 18), which reads: 'A treaty does not create either obligations or rights for a third State without its consent', while 'third State' is defined in Article 2(1)(h) VCLT as a state not party to the treaty. Also see PCIJ, Certain German Interests in Polish Upper Silesia, Merits Judgment of 25 May 1926, PCIJ Rep. Ser. A, No. 7, 29, which observed: 'A treaty only creates law as between the States which are parties to it; in case of doubt, no rights can be deduced from it in favour of third States.'

333 The term 'non-Party' is not defined in the CBD or the Cartagena Protocol, but appears to be synonymous to that of a 'third State' as defined in Article 2(1)(h) VCLT (n. 18) (see preceding footnote).

334 Cf. Convention on International Trade in Endangered Species of Wild Fauna and Flora (03 March 1973; effective 01 July 1975), 993 UNTS 244, Article X; Montreal Protocol on Substances that Deplete the Ozone Layer (16 September 1987; effective 01 January 1989), 1522 UNTS 3, as last amended by the Meeting of Parties in 2018, Article 4; Basel Convention (n. 101), Articles 4(5) and 11; see *Mackenzie* et al., IUCN Guide (n. 4), Box 42 on p. 154; *Bernasconi-Osterwalder* (n. 90), 654–655.

335 See generally *Kate Cook*, Non-Parties, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 351.

336 See *supra* section A.II.1.h).

of LMOs shall not be conducted without obtaining the consent of the importing party.[337]

The consequences of this principle differ according to whether the party to the Protocol is importing an LMO *from* a non-party or exporting an LMO *to* a non-party. When the party is the importing state, Article 24 CP requires it not to allow imports of LMOs intended for release into the environment without prior authorization by its national authorities based on a risk assessment.[338] However, the exporting non-party is not bound by the Cartagena Protocol and therefore not obliged to ensure prior notification of the receiving state under Article 8 CP. The importing party should attempt to compensate this by requiring a prior notification from the importer under its domestic legislation and by prohibiting and penalizing imports of LMOs carried out without authorization by its competent national authority.[339] In practice, this will often result in extending the domestic laws implementing the AIA mechanism to imports from non-parties.[340] However, the party must ensure that its requirements are compatible with its obligations under international trade law, because it cannot rely on the Cartagena Protocol to justify trade restrictions vis-à-vis the non-party.[341]

When the party is the exporting state, Article 24 CP requires it to ensure that a non-party is notified prior to any intended transboundary movement, either according to Article 8 CP or in another appropriate way that allows the importing party to deny or approve the movement.[342] Moreover, parties shall ensure that a risk assessment is carried out in line with the standards of the Cartagena Protocol.[343] An exporting party, however, is not required to wait for the receiving state to agree to the

337 See *Bernasconi-Osterwalder* (n. 90), 655, who assumes that trading with non-parties is not necessarily subject to the specific provisions on AIA or risk assessment, but that parties are required to apply a precautionary approach in the sense of Principle 15 of the Rio Declaration 1992 (n. 260).

338 *Cook* (n. 335), 360; *Mackenzie* et al., IUCN Guide (n. 4), MN. 612.

339 Cf. CP COP-MOP, Guidance on the Transboundary Movement of Living Modified Organisms Between Parties and Non-Parties, Annex to Decision BS-I/11, UN Doc. UNEP/CBD/BS/COP-MOP/1/15, p. 139 (2004), para. 1d.

340 Cf. *ibid.*

341 See *infra* section C.

342 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 612; CP COP-MOP, Guidance on Transboundary Movements between Parties and Non-Parties (2004) (n. 339), paras. 1a and 1b.

343 CP COP-MOP, Guidance on Transboundary Movements between Parties and Non-Parties (2004) (n. 339), para. 1c.

transboundary movement because the latter, as a non-party, cannot derive any rights from the Protocol.[344] If the receiving state does not react to a notification, it could, therefore, be assumed that it has acquiesced to the transboundary movement.[345] However, when the receiving state has no appropriate regulatory framework to regulate the use and environmental release of LMOs,[346] it may be problematic to assume consent by acquiescence. In these situations, it may be questioned whether an export is at all consistent with the objective of the Protocol, as required by Article 24.[347] This is particularly relevant for LMOs that are capable of self-propagation and, therefore, may have a lasting impact on the environment of the receiving state.

5. Upward Derogation (Articles 2(4) and 14)

The Cartagena Protocol contains several provisions that expressly allow for 'upward derogation',[348] which means that parties are free to adopt stricter rules than those foreseen in the Protocol. The most important of these clauses is Article 2(4), which generally allows parties to take action that is 'more protective' of biodiversity than provided for in the

344 But see *Cook* (n. 335), 353. On the question of treaties conferring rights on third parties, see *Alexander Proelß*, Article 34, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 27–28.

345 On acquiescence in international law generally, see *Nuno S. M. Antunes*, Acquiescence, in: Wolfrum/Peters (ed.), MPEPIL; *Christian J. Tams*, Waiver, Acquiescence and Extinctive Prescription, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 1035, 1042–1045. In the European Union, Article 5(1) of Regulation 1946/2003 (n. 213) governing transboundary movements to and from third states provides: 'A failure by the Party of import to acknowledge receipt of a notification or to communicate its decision shall not imply its consent to an intentional transboundary movement. No first intentional transboundary movement may be made without prior written express consent of the Party or, where appropriate, non-Party of import.' It can clearly be inferred from this provision that the failure of a non-party to reply shall not be regarded as an implied consent either.

346 A number of developing states are not members to the Cartagena Protocol, including Equatorial Guinea, Haiti, Nepal, and Sierra Leone (see UN OLA (n. 6)), and it is questionable whether these states have adopted domestic regulatory frameworks on biotechnology and biosafety without participating in the relevant international forum.

347 *Mackenzie* et al., IUCN Guide (n. 4), MN. 612.

348 Cf. *Redgwell* (n. 4), fn. 52 on p. 556; see *Pavoni* (n. 4), 114–115.

Protocol, provided that such action is consistent with both the Protocol and with that party's international obligations under international (e.g. trade) law.[349] Similarly, Article 14 allows parties to conclude bilateral, regional or multilateral agreements on the transboundary movement of LMOs, provided that such agreements do not result in a lower level of protection than provided for by the Protocol.

6. Liability and Redress (Article 27)

The Cartagena Protocol does not contain substantive provisions relating to liability for damage resulting from transboundary movements of LMOs. Instead, Article 27 committed the parties to enter into negotiations on liability after the Protocol entered into force.[350] Deferring the issue of liability to a separate instrument was a compromise reached during the negotiations of the Cartagena Protocol, where it was highly controversial whether the Protocol should include rules on liability at all.[351] Many developing countries insisted on the inclusion of substantive provisions on liability, arguing that they were not prepared to bear the risks associated with the transboundary movement of LMOs into their territories, particularly in light of their often very limited capacities to carry out adequate risk assessments.[352] Many developed countries opposed the inclusion of provisions on liability altogether, arguing that this issue could be dealt with by domestic legislation, private international law,[353] and the international law of state responsibility.[354] Eventually, it was agreed to detach and postpone the deliberations of liability and to adopt an 'enabling clause' in

349 Cf. *Redgwell* (n. 4), 555; *Bernasconi-Osterwalder* (n. 90), 648.

350 Article 27 of the Cartagena Protocol reads: 'The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.'

351 See generally *Kate Cook*, Liability: 'No Liability, No Protocol', in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 371.

352 *Ibid.*, 373–374.

353 *Mackenzie* et al., IUCN Guide (n. 4), MN. 643.

354 *Cook* (n. 351), 374.

Article 27.[355] Negotiations based on this mandate led to the adoption of the *Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress* in 2010, which is assessed in chapter 6 below.

III. Conclusions

The preceding analysis has shown that the Cartagena Protocol is primarily concerned with ensuring that products of modern biotechnology that are permitted under the jurisdiction of one state and are, in principle, freely available in international markets do not cause harm to the environment of other states.[356] To this end, the Cartagena Protocol contains detailed rules on the procedure of seeking an AIA and the associated risk assessment. At the same time, the Cartagena Protocol contains no material provision outlining under what circumstances an import should be allowed, subjected to conditions, or denied entirely. Instead, the standardized procedure and the harmonized risk assessment are only in place to enable the receiving state to take a sovereign decision in line with its risk management demands and the level of environmental protection chosen for its national territory.[357] The regulatory pathway chosen for the AIA mechanisms reflects the Protocol's overall spirit: The Protocol is not meant not to establish a comprehensive regime on trade in LMOs but rather follows a 'minimal harmonization' approach.[358] On the procedural side, the Protocol establishes guardrails for coordinating transboundary situations

355 Cf. IISD, Report of the Sixth Session of the Open-Ended Ad Hoc Working Group on Biosafety and the First Extraordinary Session of the CBD Conference of the Parties: 14–23 February 1999, ENB Vol. 9 No. 117 (1999), 8.

356 *Pavoni* (n. 4), 118.

357 *Ibid.*, 127. In this respect there is a striking similarity to environmental human rights law, where international judicial bodies often confer strong procedural and participatory rights to the affected individuals while leaving states a wide margin of discretion with regard to the material questions, i.e. the outcome of decision-making processes, see *Silja Vöneky/Felix Beck*, Umweltschutz und Menschenrechte, in: Alexander Proelß (ed.), Internationales Umweltrecht (2nd ed. 2022) 191, MN. 158.

358 *Pavoni* (n. 4), 114. But see *Sdunzig* (n. 133), 398–401, who concludes that the preciseness and specificity of the obligations laid down in the Cartagena Protocol are quite high, in particular when compared to the CBD.

while, in substantive terms, it retains the sovereign right of parties to set the level of biosafety protection they deem appropriate.[359]

In any case, while the Cartagena Protocol broadly retains the right of each state to take sovereign decisions about whether or not to allow the import and use of certain LMOs, it appears likely that international trade law will largely restrict this broad margin of discretion.[360]

The Cartagena Protocol also contains a range of provisions that apply regardless of whether an LMO is subject to a (deliberate) transboundary movement and thus regulated by the AIA mechanism. However, many of these provisions remain rather vague and it is questionable how compliance with them can be reasonably monitored. In this regard, the subsequent work done by the COP-MOP and a number of subsidiary bodies is of special relevance.[361]

IV. Excursus: The Relationship Between the Cartagena Protocol and EU Biotechnology Law

It is widely assumed that the European Union's (EU) regulatory framework on *genetically modified organisms* (GMOs) is in line with the Cartagena Protocol's provisions on *living modified organisms* (LMOs).[362] It is questionable, however, whether the scopes of both regimes are indeed fully congruent. The present section firstly provides an overview of the European legal framework for GMOs, including the regulation implementing the Cartagena Protocol (1.), before discussing the scope of the European regime in light of the judgment on *targeted mutagenesis* rendered by the

359 Cf. *Pavoni* (n. 4), 114–116; *Gregory Jaffe*, Crafting National Biosafety Systems, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 48, 56.

360 See *infra* section C.

361 For an analysis on the ongoing discussion about the international regulation of engineered gene drives, see chapter 5.

362 See, e.g., *Christoph Bail* et al., European Union, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 166; Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council on the Transboundary Movement of Genetically Modified Organisms, Explanatory Memorandum (25 June 2002), COM(2002) 85 final – 2002/0046(COD) (hereinafter 'Commission Proposal on Directive 1946/2003'); *Callebaut* (n. 11), 47; *Kahrmann/Leggewie* (n. 47), 501–502.

Court of Justice of the European Union in 2018 (2.). A comparison of the European regime with the Cartagena Protocol shows that the scope of the latter is significantly wider, which must be taken into account when discussing a reform of the EU's GMO legislation (3.).

1. The European Union's Legal Framework for GMOs

The EU's biotechnology legislation consists of a complex web of Regulations and Directives.[363] The most important of these instruments is *Directive 2001/18/EC*, which addresses the deliberate release of GMOs into the environment.[364] Under this Directive, authorization must be obtained before a GMO is released into the environment or placed on the market for the first time.[365] The Directive provides for a case-by-case assessment of the potential adverse effects a particular GMO may have on human health and the environment, which is conducted under the auspices of the *European Food Safety Authority* (EFSA). Authorizations shall be recognized throughout the EU, although member states are allowed to unilaterally restrict or prohibit the release of a GMO even if it has been authorized at the European level.[366] For genetically modified food and feed, a similar authorization procedure has been introduced by Regulation (EC) No 1829/2003.[367]

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363 For an overview of the pertinent legal acts, see European Commission, GMO Legislation, available at: https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-legislation_en (last accessed 28 May 2022). For general introductions to the regulation of GMOs in the EU, see *Maria Lee*, EU Regulation of GMOs (2008); *Hans-Georg Dederer*, Options for the Regulation of Genome Edited Plants – Framing the Issues, in: Christian Dürnberger/Sebastian Pfeilmeier/Stephan Schleissing (eds.), Genome Editing in Agriculture (2019) 77.

364 Directive 2001/18/EC (n. 218).

365 See Articles 4, 6 and 13 of Directive 2001/18/EC. For an overview of the Directive's key mechanisms, see *Paula Rey García*, Directive 2001/18/EC on the Deliberate Release into the Environment of GMOs: An Overview and the Main Provisions for Placing on the Market, 3 (2006) JEEPL 3.

366 See Article 26b of Directive 2001/18/EC, which was introduced by Directive (EU) 2015/412 Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of Genetically Modified Organisms (GMOs) In Their Territory (11 March 2015), OJ L 68, p. 1.

367 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed (22 September 2003), OJ L 268, p. 1.

Directive 2001/18/EC can be described as the 'centrepiece' of the European Union's GMO legislation because it contains the decisive definition of what constitutes a 'genetically modified organism' and sets the substantive requirements for the risk assessment. All other European legislative instruments on GMOs either refer to this definition[368] or use nearly identical language to determine their own scope.[369]

Both the European Union and all of its member states have signed and ratified the Cartagena Protocol on Biosafety.[370] To implement the Protocol's provisions in internal law, the European Union has adopted Regulation (EC) No 1946/2003,[371] which aims to 'ensure coherent implementation of the provisions of the Protocol on behalf of the Community'.[372] The Regulation applies to the transboundary movement of LMOs between the EU and third states, but not to intentional transboundary movements among EU member states.[373] This is in accordance with Article 14(3) of the Cartagena Protocol, which allows other agreements to take precedence over the Protocol, provided that these agreements are consistent with the objective of the Protocol and do not result in a lower level of protection.[374] The EU regime on GMOs, which provides for a Union-wide authorization procedure for the placing on the market and deliberate environmental release of such organisms,[375] is deemed to constitute such a separate agreement that is consistent with the requirements of Article

368 Cf. *ibid.*, Article 2(5); Regulation (EC) No 1830/2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms (22 September 2003), OJ L 268, p. 24, Article 3(1); Regulation 1946/2003 (n. 213), Article 2(5). All these provisions apply to 'genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC'.

369 Cf. Directive 2009/41/EC on the Contained Use of Genetically Modified Micro-Organisms (06 May 2009), OJ L 125, p. 75, Article 2 lit. b, which provides that '"genetically modified micro-organism" (GMM) means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.

370 Cf. UN OLA (n. 6); see Council of the European Communities, Council Decision Concerning the Conclusion of the Convention on Biological Diversity (93/626/EEC) (25 October 1993), OJ L 309, p. 1.

371 Regulation 1946/2003 (n. 213).

372 *Ibid.*, Article 1.

373 *Ibid.*, Article 3(14).

374 Cf. Commission Proposal on Directive 1946/2003 (n. 362).

375 Cf. Directive 2001/18/EC (n. 218).

14(1) of the Cartagena Protocol.[376] The EU legislation also covers imports of GMOs from third states into the European Union. This is in line with Article 14(4) of the Cartagena Protocol,[377] which allows parties to use their domestic regulations instead of the Cartagena Protocol's AIA procedure for regulating specific imports into its territory.[378]

2. Scope of the GMO Regime in the European Union

Unlike the Cartagena Protocol, the European Union's biosafety legislation does not apply to *LMOs*, but to *GMOs*. The term 'genetically modified organism' is defined in Article 2(2) of Directive 2001/18/EC as

> *'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.*

The definition is complemented by three lists in an Annex to the Directive. The first list specifies certain techniques that are deemed to result in GMOs in terms of the Directive.[379] The second list specifies techniques that are deemed *not* to result in GMOs.[380] The third list contains techniques that, despite being deemed to result in a genetic modification, are exempted from regulation under certain conditions.[381] This third list includes the term 'mutagenesis' but does not further define this term.[382]

There has been fierce controversy over whether the current regulatory regime for GMOs in the EU applies to organisms (in particular, plants[383]) in which the genetic material has been altered with *targeted mutagenesis techniques*. This denotes applications of genome editing where only point mutations are created without (permanently) inserting foreign DNA into

376 Commission Proposal on Directive 1946/2003 (n. 362).
377 *Mackenzie* et al., IUCN Guide (n. 4), 411–413; Commission Proposal on Directive 1946/2003 (n. 362).
378 Regulation 1946/2003 (n. 213), Recitals 13–14 and Article 3(2).
379 Cf. Directive 2001/18/EC (n. 218), Annex I A Part 1.
380 Cf. *ibid.*, Annex I A Part 2.
381 Cf. *ibid.*, Annex I B; also see Directive 2001/18/EC (n. 218), Article 3(1).
382 Cf. *ibid.*, Annex I B, para. 1.
383 In the controversy over the regulation of genome-edited crops in the European Union, frequent use is made of the term 'New Plant Breeding Techniques' which includes not only genome editing techniques but also a number of other modern breeding methods such as *agro-infiltration*, *grafting* and *reverse breeding*, cf. New Techniques Working Group, Final Report (n. 39).

the genome of the target organism.[384] According to proponents of these techniques, targeted mutagenesis leads to genetic modifications which cannot be distinguished from mutations that (could) have occurred naturally and that the resulting organisms should therefore not be regulated as GMOs.[385]

In July 2018, the *Court of Justice of the European Union* held that organisms whose genetic material has been modified by targeted mutagenesis techniques fall within the scope of the Directive 2001/18/EC and thus are subject to regulation as GMOs in the EU.[386] In particular, the Court held that organisms bred with these techniques were not covered by the aforementioned exemption of 'mutagenesis' techniques, because this exemption did not apply to techniques that have emerged since the Directive was adopted in 2001.[387] Consequently, more recent mutagenesis techniques do not benefit from the exemption and are thus fully covered by the regulatory regime set out in Directive 2001/18/EC and most other of the EU's GMO regulations.[388] Notably, it seems undisputed that this also ap-

384 Cf. *Hans-Georg Dederer*, The Challenge of Regulating Genetically Modified Organisms in the European Union: Trends and Issues, in: Yumiko Nakanishi (ed.), Contemporary Issues in Environmental Law (2016) 139; *Sprink* et al. (n. 39).

385 *Lusser/Davies* (n. 10), 440–441; *Frank Hartung/Joachim Schiemann*, Precise Plant Breeding Using New Genome Editing Techniques: Opportunities, Safety and Regulation in the EU, 78 (2014) The Plant Journal 742, 749; *Callebaut* (n. 11), 75; *Sprink* et al. (n. 39), 1499–1450; *Kahrmann* et al. (n. 39), 180; *Dennis Eriksson*, Recovering the Original Intentions of Risk Assessment and Management of Genetically Modified Organisms in the European Union, 6 (2018) Front. Bioeng. & Biotechnol. 845, 1–2.

386 CJEU, Confédération paysanne et al. v. Premier ministre et al., Judgment of 25 July 2018, C-528/16. For a detailed assessment of the judgment, see *Felix Beck*, All About that Risk? A (Re-)Assessment of the CJEU's Reasoning in the "Genome Editing" Case, 17 (2019) EurUP 246.

387 CJEU, Confédération paysanne et al. v. Premier ministre et al. (n. 386), para. 51. For comparisons with other jurisdictions, see *supra* n. 10.

388 *Ibid.*, para. 54. For a discussion on consequences of this judgment, see *Martin Wasmer*, Roads Forward for European GMO Policy, 7 (2019) Front. Bioeng. & Biotechnol. 367. But see *van der Meer* et al. (n. 57), 6–12, who contend that the decisive criterion remained whether the resulting organism is 'altered in a way that does not occur naturally by mating and/or natural recombination' (as required by the GMO definition in Article 2(2) of Directive 2001/18/EC) and that, as long as an organism could have occurred naturally, the scope of the 'mutagenesis' exemption (in Annex I A, part 2) and its interpretation by the CJEU was irrelevant (*ibid*., p. 10). But this rests on an overspecific interpretation of the judgment. The Court clearly recognized that it was 'called upon to rule, in particular, on the techniques/methods of *directed mutagenesis* involving the

plies to self-spreading techniques such as engineered gene drives, as they commonly involve the use of recombinant DNA in the target organism.[389]

3. Compatibility of the European GMO Regime With the Cartagena Protocol

When ratifying the Cartagena Protocol, the European Commission assumed that the Protocol's definition of the term *living modified organism* was 'largely consistent' with the definition of a *genetically modified organism* under the European Directive 2001/18/EC, and that the existing differences were 'not likely to impinge on operational aspects of the legislation'.[390] The Commission did not provide a reasoning for this conclusion. In fact, it is questionable whether both definitions are indeed fully congruent in scope. In contrast to the definition under EU law, the Cartagena Protocol does not focus on whether the genetic material 'has been modified in a way that does not occur naturally'.[391] Instead, it contains two separate elements that clearly distinguish between the process of modification (i.e. 'application of modern biotechnology') and its result (i.e. 'a novel combination of genetic material').[392]

In specifying the meaning of 'modern biotechnology', the Cartagena Protocol uses the generic term '*in vitro* nucleic acid techniques', whereas the EU Directive refers to '*recombinant* nucleic acid techniques'.[393] This

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use of genetic engineering which have appeared or have been mostly developed since Directive 2001/18 was adopted' (CJEU, Confédération paysanne et al. v. Premier ministre et al. (n. 386), para. 47, emphasis added). The Court also expressly held that *all* mutagenesis techniques – both conventional and those relying on 'genetic engineering' – altered the genetic material of an organism in a way that does not occur naturally in the sense of Article 2(2) (*ibid.*, para. 29). While the accuracy of this statement may be challengable from a scientific standpoint, the Court's conclusions in this regard are unequivocal, since it held that the mutagenesis exemption 'cannot be interpreted as excluding, from the scope of the directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted' (*ibid.*, para. 51; see *Beck* (n. 386), 248–253).

389 Cf. *Dolezel* et al. (n. 76), 5–6; see *supra* sections A.I.1.e)bb) and cc).

390 Commission Proposal on Directive 1946/2003 (n. 362); on the European Union's position during the negotiations of the Cartagena Protocol, see *Bail* et al. (n. 362).

391 See *supra* section A.IV.2.

392 *Callebaut* (n. 11), 49–50; *van der Meer* et al. (n. 57), 15. See *supra* section A.I.1.

393 Cf. Directive 2001/18/EC (n. 218), Annex I A, Part 1 (emphasis added).

constitutes a decisive difference between both definitions: The term 'recombinant DNA' was coined in the 1970s when DNA molecules of different origins were joined together (i.e. *recombined*) for the first time.[394] Today, the term is commonly used to denote DNA produced *in vitro* by merging genes from different sources.[395] For this reason, some authors have suggested that this could exclude genome editing techniques as long as they do not involve the (permanent) insertion of foreign DNA into the target organism.[396] In contrast, the Cartagena Protocol refers to '*in vitro* nucleic acid techniques'. As shown above, this notion is substantially wider; it does not only cover recombinant DNA techniques (and direct injection of heritable material), but rather all methods where any kind of nucleic acid is prepared *in vitro* and then inserted into the organism to modify that organism's DNA.[397]

The differences between both regimes can also be explained historically. When the European Commission proposed the first Directive on deliberate release in 1988[398] and its revision that was adopted in 2001,[399] it noted the need to periodically update the Directive in order to 'keep pace with scientific and technological progress'.[400] Hence, no need was seen

394 See *D. A. Jackson* et al., Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40, 69 (1972) PNAS 2904; *Stanley N. Cohen* et al., Construction of Biologically Functional Bacterial Plasmids in Vitro, 70 (1973) PNAS 3240.

395 Cf. 'recombinant DNA', in: Henderson's Dictionary of Biology (n. 20), 500–501.

396 New Techniques Working Group, Final Report (n. 39), 6; EFSA, EFSA Response to Mandate M-2015–0183: Request for EFSA to Provide Technical Assistance with Regard to Issues Related to the Legal Analysis of New Plant Breeding Techniques (2015), 1–2; *Callebaut* (n. 11), 62–64; *Kahrmann* et al. (n. 39), 181.

397 See *supra* section A.I.1.d)aa).

398 Commission of the European Communities, Proposal for a Council Directive on the Deliberate Release to the Environment of Genetically Modified Organisms, Explanatory Memorandum (04 May 1988), COM(88) 160 final – SYN 131, 7–10; which states: '[Annex I] is intended to provide, through a periodical update, as [sic] a clarification of what techniques can make an organism 'genetically modified' within the meaning of this Directive'; also see Arts. 18–20 of the proposal, which were eventually not adopted in the Directive.

399 Commission of the European Communities, Report of the Review of Directive 90/220/EC in the Context of the Commission's Communication on Biotechnology and the White Paper (10 December 1996), COM(96) 630 final.

400 *Ibid.*, 10. See *Eriksson* (n. 385).

to further specify the actual definition of the term 'genetically modified organism' contained in Article 2(2) of Directive 2001/18/EC.[401]

Like the European legislator, the drafters of the Cartagena Protocol also envisaged that there would be scientific and technological progress after the adoption of the Protocol. They agreed that its scope should be defined in a manner so as to include future techniques that were still unknown at the time.[402] However, including lists of techniques that were to be updated periodically – like originally envisaged in the EU – was not an option for the Cartagena Protocol, as the process of amending multilateral treaties is time-consuming and succeeds only rarely.[403] For this reason, the definition of the terms 'living modified organism' (in Article 3(g) CP) and 'modern biotechnology' (in Article 3(i) CP) were of special relevance for the scope of the entire Protocol and had to be crafted in a manner that would include potential future techniques. This can also be seen from the intense negotiations that were conducted on the wording of these definitions.[404]

As a result, the scope of the EU's regulatory framework for GMOs might 'largely correspond'[405] to that of the Cartagena Protocol, but the scope of both regimes is not identical. Instead, the definition of the term 'living modified organism' in the Cartagena Protocol is significantly wider than the respective definition of the term 'genetically modified organism' under European law. A future reform of the EU's legal framework for GMOs, for

401 In fact, however, neither the annexes nor the GMO definition itself have ever been amended, apart from editorial changes. The Directive has been amended five times since its adoption, but none of these amendments addressed the GMO definition or other provisions pertaining the scope of the regime: Regulation (EC) 1829/2003 concerned GM food and feed; Regulation (EC) 1830/2003 concerned rules on traceability; Directive 2008/27/EC changed rules on implementing powers conferred on the Commission; Directive (EU) 2015/412 introduced the 'opt-out' mechanism (see fn. 366 and accompanying text); and Commission Directive (EU) 2018/350 amended the rules on environmental risk assessment of GMOs. Also see *Callebaut* (n. 11), 18–19.

402 Cf. ENB Summary of BSWG-4 (n. 33), 5; see *supra* section A.I.1.d)aa).

403 See Article 39 VCLT (n. 18), which lays down rules on the amendment of multilateral treaties; also see *Jan Klabbers*, Treaties, Amendment and Revision, in: Wolfrum/Peters (ed.), MPEPIL, MN. 19–21.

404 Cf. *Gupta* (n. 29), 23; *van der Meer* (n. 13); see *supra* section A.I.1.c).

405 *Callebaut* (n. 11), 47.

which there have been calls[406] and proposals[407], should ensure compatibility with the obligations assumed by the EU and its member states under the Cartagena Protocol.

B. Convention on Biological Diversity

The *Convention on Biological Diversity* of 1992 (CBD) aims to ensure the conservation and sustainable use of biological diversity as well as the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.[408] The CBD contains a number of provisions which are relevant to the regulation of biotechnology and living modified organisms. Although the Cartagena Protocol, which was negotiated within the framework of Article 19(3) CBD, addresses LMOs in much greater detail, the CBD's provisions have not become irrelevant. This is mainly because a number of states that are major stakeholders in the area of modern biotechnology have not ratified the Cartagena Protocol.[409] In contrast, the CBD has been ratified by virtually all states except the United States,[410]

406 Cf. *Agnes E. Ricroch* et al., Editing EU Legislation to Fit Plant Genome Editing, 17 (2016) EMBO Reports 1365; *Sanwen Huang* et al., A Proposed Regulatory Framework for Genome-Edited Crops, 48 (2016) Nature Genetics 109; *Eriksson* (n. 385); *Wasmer* (n. 388); *Petra Jorasch*, Will the EU Stay Out of Step with Science and the Rest of the World on Plant Breeding Innovation?, 39 (2020) Plant Cell Reports 163.

407 Cf. *Dennis Eriksson* et al., Options to Reform the European Union Legislation on GMOs: Scope and Definitions, 38 (2020) Trends in Biotechnology 231; *Juan A. Vives-Vallés/Cécile Collonnier*, The Judgment of the CJEU of 25 July 2018 on Mutagenesis: Interpretation and Interim Legislative Proposal, 10 (2019) Frontiers in Plant Science 1813, 8–9.

408 Article 1 CBD. On the CBD generally, see *Lyle Glowka* et al., A Guide to the Convention on Biological Diversity (1994); *Fiona McConnell*, The Biodiversity Convention (1996); *Désirée M. McGraw*, The CBD – Key Characteristics and Implications for Implementation, 11 (2002) RECIEL 17; *Nele Matz-Lück*, Biological Diversity, International Protection, in: Wolfrum/Peters (ed.), MPEPIL, MN. 25–48; *Philippe Sands* et al., Principles of International Environmental Law (4th ed. 2018), 388–397.

409 See *supra* n. 7 and accompanying text.

410 The United States has signed the CBD in 1993 but has not ratified it since. Besides the United States, only the Holy See is not a party to the CBD, see UN OLA, Status of the Convention on Biological Diversity, United Nations Treaty Collection, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8&chapter=27&clang=_en (last accessed 28 May 2022).

thus establishing rules which are – apart from this one exception – universally applicable.[411]

I. Jurisdictional Scope (Article 4)

Article 4 CBD governs the jurisdictional scope of the Biodiversity Convention. With respect to the *components of biological diversity*,[412] the CBD applies to areas within the limits of national jurisdiction. At the same time, the scope is considerably broader for *processes and activities*: the CBD applies to all processes and activities, regardless of whether their effects occur, that are carried out under the party's jurisdiction or control. This expressly includes activities that are conducted in areas beyond the limits of national jurisdiction, such as vessels flying the flag of a party when they are on the high seas.[413] At the same time, the phrase 'regardless of whether their effects occur' signifies that the CBD's scope also includes effects that occur in areas beyond national jurisdiction.[414] Consequently, the CBD applies to both activities conducted and effects occurring in areas beyond national jurisdiction, provided that the activity in question was carried out under the jurisdiction or control of a party to the Convention.[415]

II. Prevention of Transboundary Harm (Article 3)

Article 3 CBD provides that states have the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of national jurisdiction. The CBD has been the first legally binding instrument to en-

411 Cf. *Redgwell* (n. 4), 551.

412 The term 'components of biological diversity' is defined nowhere in the CBD. Depending on the context in which it is used, it refers either to the three conceptual levels of biodiversity (ecosystem/species/genetic diversity), or to specific tangible entities such as specific ecosystems; cf. *Glowka* et al., IUCN Guide to the CBD (n. 408), 16. For the purpose of delimiting the scope of the CBD, it suffices to conclude that the term refers to those parts of the variability among living organisms from all sources (cf. Art. 2 CBD) that are permanently or temporarily present in areas within the limits of a party's national jurisdiction; cf. *Glowka* et al., IUCN Guide to the CBD (n. 408), 28.

413 *A. Charlotte de Fontaubert* et al., Biodiversity in the Seas (1996), 3.

414 *Redgwell* (n. 4), 552–553.

415 *Glowka* et al., IUCN Guide to the CBD (n. 408), 28.

shrine this principle, which originated from the Stockholm Declaration of 1972.[416] Interestingly, Article 3 refers not to the CBD's contracting parties as the bearers of the obligation, but to 'States'. Moreover, the provision stipulates that the obligation shall be performed 'in accordance with the Charter of the United Nations and the principles of international law'. This indicates that the drafters of the CBD felt that Article 3 reiterated a principle that was already binding upon states as customary international law. An expert group on liability established by the Conference of Parties to the CBD (CBD COP) assumed that the ILC's *Articles on Prevention*[417] could provide 'useful guidance' for states with respect to Article 3 CBD.[418] The substantive content of Article 3 CBD thus appears to reflect the general 'no harm' doctrine.[419]

III. Regulation and Control of Risks Associated With the Use and Release of Living Modified Organisms (Article 8(g))

Article 8(g) CBD provides that contracting parties shall establish 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*'.

Unlike the Cartagena Protocol, the present provision applies not only to LMOs resulting from 'modern biotechnology' but from 'biotechnology' generally, which is defined in Article 2 CBD as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'.[420] As shown above, the Cartagena Protocol contains a distinct definition of 'modern

416 *Ibid.*, 26.
417 ILC, Articles on Prevention (n. 260).
418 CBD COP, Report of the Group of Legal and Technical Experts on Liability and Redress in the Context of Paragraph 2 of Article 14 of the Convention on Biological Diversity, UN Doc. UNEP/CBD/COP/8/27/ADD3 (2005), para. 33.
419 See chapter 4.
420 Notably, the term 'biotechnology' already emerged in the 1920s, see 'biotechnology', in: Oxford English Dictionary (n. 12); Henderson's Dictionary of Biology (n. 20), 68.

biotechnology', which specifically refers to *in vitro* nucleic acid techniques and cell fusion.[421] Therefore, the meaning of 'biotechnology' under the CBD is broader than that of 'modern biotechnology' under the Cartagena Protocol.[422] Consequently, the term 'living modified organism' also has a broader meaning under the CBD than it has under the Cartagena Protocol.[423] If certain applications of genome editing fell outside the scope of the Cartagena Protocol, they would thus still be covered by Article 8(g) CBD.[424]

Article 8(g) CBD applies to LMOs 'which are likely to have adverse environmental impacts'. Whether this is the case is usually not known *ab initio*, but needs to be determined in a risk assessment. Hence, the provision has been interpreted as requiring states to approach the potential risks of LMOs 'in a rational, precautionary manner based on the assessment and subsequent regulation, management or control of the risks'.[425] This is supported by Article 7(c) CBD, which provides that parties shall identify processes and activities which have or are likely to have significant adverse impacts on biodiversity.[426] The degree of control applied should be premised on the likelihood that an organism will have adverse impacts.[427]

The CBD COP has only rarely addressed Article 8(g). Instead, its focus was mostly on the need for, and modalities of, a protocol on biosafety as envisioned in Article 19(3) CBD.[428] After the adoption of the Cartagena Protocol, most of the work on LMOs was conducted in the framework of the meeting of the parties to the latter. At first sight, this may seem like a mere formality, as the CBD COP also serves as the meeting of parties to the Cartagena Protocol (COP-MOP).[429] However, since fewer states have ratified the Cartagena Protocol than the CBD, any decisions adopted

421 See Article 3(i) CP and *supra* section A.I.1.d).
422 Report of the AHTEG on Synthetic Biology 2019 (n. 11), para. 21.
423 See chapter 2, n. 5 and accompanying text.
424 Report of the AHTEG on Synthetic Biology 2019 (n. 11), para. 20.
425 *Glowka* et al., IUCN Guide to the CBD (n. 408), 45.
426 Cf. *Lim/Lim* (n. 76), 10.
427 *Glowka* et al., IUCN Guide to the CBD (n. 408), 46.
428 See CBD Secretariat, Handbook of the Convention on Biological Diversity (3rd ed. 2005), 131–132 with further references.
429 Cf. Article 29(1) CP. According to Article 29(2) CP, parties to the CBD which are not parties to the Cartagena Protocol may participate as observes in the proceedings of the meeting of parties to the latter, but decisions under the Cartagena Protocol shall be taken only by those that are parties to it.

under the CBD have a significantly larger international reach than those adopted under the Cartagena Protocol.[430]

IV. Provision of Information to Parties Receiving LMOs (Article 19(4))

Article 19(4) is the only provision of the CBD that directly addresses the transboundary movement of LMOs.[431] It provides that when LMOs are to be introduced from one party into another party, the party of origin shall share two types of information with the receiving party. Firstly, it shall provide 'any available information about the use and safety regulation it requires in handling such organisms'[432] This overlaps with Article 20(3)(a) CP, which requires parties to the Cartagena Protocol to provide information about their national biosafety regimes to the Biosafety Clearing-House. Secondly, it shall provide 'any available information on the potential adverse impact of the specific organisms concerned' that are to be introduced into the territory of the other party.[433] The party of origin shall provide this information either directly, or require any natural or legal person under its jurisdiction 'providing the organisms', i.e. the developer, producer or exporter. Although this obligation has been superseded by the more specific information-sharing obligations under the Cartagena Protocol, especially as part of the AIA mechanism[434] and through the Biosafety Clearing-House,[435] Article 19(4) CBD nevertheless remains relevant in respect to those states which are not parties to the Cartagena Protocol.

V. Control of Invasive Alien Species (Article 8(h))

Pursuant to Article 8(h) CBD, each contracting party to the CBD is required to 'prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species'. The provision refers to what is more commonly known as *invasive* alien species, which is

430 Cf. *Lim/Lim* (n. 76), 23; see chapter 5, section B.
431 See *Redgwell* (n. 4), 553.
432 *Glowka* et al., IUCN Guide to the CBD (n. 408), 98–99.
433 *Ibid.*, 99.
434 Cf. Article 8(1); see *supra* section A.II.1.b).
435 Cf. Article 20(3)(c) CP; see *supra* section A.II.3.

defined as any species which is introduced into the environment outside its natural habitat, is an agent of change, and threatens native biological diversity.[436]

The CBD COP has addressed the topic of invasive species under Article 8(h) CBD in a number of decisions.[437] At COP 6 in 2002, the parties adopted a set of Guiding Principles on invasive species, which call on states to recognize the risk that activities within their jurisdiction or control may pose to other states as a potential source of invasive alien species and to take appropriate measures to minimize that risk.[438] Examples of such potentially hazardous activities include the intentional transfer of invasive species to another state (even if it is harmless in the state of origin), and the intentional introduction of alien species into the environment of their own state if there is a risk of that species subsequently spreading into another state (with or without a human vector) and becoming invasive there.[439]

It has been argued that Article 8(h) CBD 'theoretically covers any self-dispersive GMO that threatens to become invasive'.[440] In scholarship, LMOs and invasive species are usually treated separately, which is probably because they are subject to different regulatory regimes.[441] In fact, however, it is recognized that LMOs and synthetic organisms can become just as invasive as 'traditional' invasive species.[442] At the same time, it has also

436 See the definition of '*alien invasive species*', in: IUCN, Guidelines for the Prevention of Biodiversity Loss Caused by Alien Invasive Species (2002), 4; the terms 'alien invasive species' and 'invasive alien species' are used interchangeably, cf. CBD COP, Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species that Threaten Ecosystems, Habitats or Species, Annex to Decision VI/23, UN Doc. UNEP/CBD/COP/6/20, p. 256 (2002), fn. 57.

437 See CBD Secretariat, Handbook to the CBD (n. 428), 133–138.

438 CBD COP (n. 436), Guiding Principle 4, para. 1.

439 *Ibid.*, Guiding Principle 4, para. 2(a) and (b).

440 *Elena Angulo/Ben Gilna*, When Biotech Crosses Borders, 26 (2008) Nature Biotech. 277, 280.

441 See, e.g., IUCN (n. 436), 3, arguing that many of the issues and principles laid out in the principles could also apply to genetically modified organisms; *Clare Shine*, Invasive Species in an International Context: IPPC, CBD, European Strategy on Invasive Alien Species and Other Legal Instruments, 37 (2007) EPPO Bulletin 103, assuming that GMOs fall outside the scope of the aforementioned Guiding Principles adopted by the CBD-COP (see *supra* fn. 438). Also see *Young* (n. 105), 379–380, noting that many national laws on 'alien species' technically include LMOs unless specifically exempt.

442 *Jonathan M. Jeschke* et al., Novel Organisms: Comparing Invasive Species, GMOs, and Emerging Pathogens, 42 (2013) Ambio 541, 542–543. Also see

been pointed out that organisms with engineered gene drives intended to genetically modify *native* species in their natural habitat could not be regarded as 'alien', and thus could not be regarded as invasive alien species in the sense of Article 8(h) CBD.[443] Yet, where a gene drive system or other genetically modified organism spreads beyond the species' geographic range and caused damage to biodiversity there, it would constitute an invasive alien species in the sense of Article 8(h) CBD and states would be obliged to prevent their introduction into the environment.

In 2006, COP 8 expressly addressed the potential risks of biocontrol[444] agents as invasive alien species.[445] It also urged the parties to the CBD to evaluate and take appropriate measures (e.g., develop guidance or codes of practice regarding the trade and use of biocontrol agents) at national, regional and global levels to address these potential risks.[446] Moreover, the decision also encouraged parties, other governments and relevant international bodies to ensure that relevant laws and provisions (such as those related to conservation) do not inadvertently constrain the use of appropriate measures to address invasive alien species.[447] Hence, it is recognized by the parties to the CBD that biocontrol agents might themselves become invasive. This not only applies to conventional means of biocontrol but also to more recent approaches, including the use of engineered gene drive systems to suppress or eradicate agricultural pests, weeds, or disease vectors.

On the other hand, when self-spreading LMOs (namely, engineered gene drives) are applied to control invasive non-GM species, the (intended) effect on the targeted species would not be regarded as adverse but beneficial since the invasive species already negatively affected other species in

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IUCN (n. 436), 4, noting that the Guidelines 'do not address the issue of genetically modified organisms, although many of the issues and principles stated here could apply'.

443 *Rabitz* (n. 77), 343.

444 The term 'biocontrol' refers to the control of pests and weeds by other living organisms, usually other insects, bacteria or viruses, or by biological products such as hormones, see 'biological control', in: Henderson's Dictionary of Biology (n. 20), 67. Besides, it may also encompass the control of disease vectors such as mosquitoes.

445 CBD COP, Decision VIII/27. Alien Species that Threaten Ecosystems, Habitats or Species (Article 8 (H)): Further Consideration of Gaps and Inconsistencies in the International Regulatory Framework, UN Doc. UNEP/CBD/COP/DEC/VIII/27 (2006), para. 55.

446 *Ibid.*

447 *Ibid.*, para. 64.

the receiving environment.[448] In this case, the call to 'not inadvertently constrain the use of appropriate measures' could even be invoked to justify the use of gene drives.

VI. Impact Assessment and Minimization of Adverse Impacts (Article 14(1))

Article 14 CBD contains a range of general provisions relating to the prevention of adverse impacts on biodiversity.

1. Environmental Impact Assessments (lit. a)

Article 14(1)(a) provides that parties shall, as far as possible and appropriate, 'introduce appropriate procedures requiring environmental impact assessment of proposed projects that are likely to have significant adverse effects on biological diversity'.[449]

In its merits judgment in the *Certain Activities* case of 2016, the International Court of Justice (ICJ) held that this provision

> *'does not create an obligation to carry out an environmental impact assessment before undertaking an activity that may have significant adverse effects on biological diversity'.*[450]

The Court thereby followed an argument made by Costa Rica that the provision only concerned the 'introduction of appropriate procedures', which Costa Rica claimed it had in place.[451] But this interpretation is overly formalistic. It also disregards the object and purpose of Article 14(1)(a) CBD, which is to ensure that an EIA is carried out for hazardous activities that threaten biodiversity. While this needs to be implemented into domestic environmental and planning laws, such laws cannot be deemed

448 *Axel Hochkirch* et al., License to Kill?, 11 (2018) Conservation Letters e12370, 3; *Heidi J. Mitchell/Detlef Bartsch*, Regulation of GM Organisms for Invasive Species Control, 7 (2020) Front. Bioeng. & Biotechnol. 927, 8.

449 See *Lim/Lim* (n. 76), 10–11, who assume that the release of a gene drive-bearing organism would 'clearly fall under these broad obligations' contained in Article 14(1)(a) CBD.

450 ICJ, Certain Activities/Construction of a Road (Merits) (n. 270), para. 164.

451 Cf. *ibid.*, para. 163; see *Sands* et al. (n. 408), 393.

'appropriate' in the sense of Article 14(1)(a) if they do not actually require an EIA for projects that pose said threats.[452]

Notably, while the Court denied a violation of Article 14(1)(a) CBD, it found that Costa Rica had breached its obligation to carry out an EIA under 'general international law'.[453] Hence, it seems that the Court deemed the obligation under customary international law to be stronger and more far-reaching than that stipulated in the CBD. Again, this is questionable given that Article 14(1)(a) CBD has arguably played a significant role in the emergence of the respective customary obligation.[454]

2. Procedural Obligations (lit. c and d)

Pursuant to Article 14(1)(c) CBD, parties shall promote, on the basis of reciprocity, notification, information exchange and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other states or areas beyond the limits of national jurisdiction.

Article 14(1)(d) CBD provides that, 'in the case of imminent or grave danger or damage' to biodiversity in the territory of other states or in areas beyond national jurisdiction originating under their jurisdiction or control, parties are required to immediately notify the potentially affected states and to initiate action to prevent or minimize such danger or damage. This refers not to situations of a general risk or threat, but to emergencies where transboundary damage is about to occur.[455] Notification duties in case of imminent damage are also laid down in the Cartagena Protocol.[456]

VII. Examination of the Issue of Liability and Redress (Article 14(2))

Pursuant to Article 14(2), the Conference of Parties to the CBD shall 'examine, on the basis of studies to be carried out, the issue of liability

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452 Cf. *Glowka* et al., IUCN Guide to the CBD (n. 408), 72.

453 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 270), para. 104; see ICJ, Pulp Mills (n. 263), para. 204; also see chapter 4, section D.II.

454 Cf. ILC, Articles on Prevention (n. 260), Commentary to Article 7, fn. 900, which notes Article 14(1)(a) and (b) of the CBD as one of the international treaties incorporating a requirement to assess the adverse effects of activities.

455 *Glowka* et al., IUCN Guide to the CBD (n. 408), 74.

456 See especially Article 17(1); see *supra* section A.II.2.b).

and redress […] for damage to biodiversity, except where such liability is a purely internal matter'. At COP 6 in 2002, the parties to the CBD requested the Executive Secretary to convene a *Group of Legal and Technical Experts on Liability and Redress*, which was mandated to clarify basic concepts and to develop definitions for the elements of Article 14(2) CBD, including the concept of 'damage to biological diversity'.[457] The group met once in 2005, at a time when the negotiations of a liability instrument specifically addressing damage resulting from LMOs had already commenced in a separate *Technical Group of Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety.*[458] In contrast, the mandate of the CBD working group was to deliberate on liability for biodiversity damage in general, and not just for damage resulting from LMOs. Nevertheless, it must be seen in this context that the working group stated in its report that 'it may be premature at this time to draw a conclusion that an international regime focused on damage to biodiversity should either be developed or not developed'.[459]

At COP 9 in 2008, the Executive Secretary tabled a *Synthesis Report* on technical information relating to biodiversity damage and approaches to valuation and restoration.[460] At COP 10 in 2010, at the same meeting where the parties to the Cartagena Protocol adopted the Supplementary Protocol, the parties to the CBD welcomed the Executive Secretary's synthesis report but deferred the issue to COP 12. At COP 12 in 2014, the parties commended the adoption of the Supplementary Protocol as well as the 2010 UNEP Guidelines on Environmental Liability[461] and decided

457 CBD COP, Decision VI/11. Liability and Redress (Article 14, Paragraph 2), UN Doc. UNEP/CBD/COP/6/20, p. 178 (2002), para. 1.

458 The CBD working group even received a report on the developments within the framework of Art. 27 CP, see Report of the Expert Group on Liability under Article 14(2) CBD (n. 418), 4.

459 *Ibid.*, Annex, para. 1.

460 CBD COP, Synthesis Report on Technical Information Relating to Damage to Biological Diversity and Approaches to Valuation and Restoration of Damage to Biological Diversity, as Well as Information on National/Domestic Measures and Experiences: Note by the Executive Secretary, UN Doc. UNEP/CBD/COP/9/20/Add.1 (2008).

461 Cf. UNEP, Guidelines for the Development of Domestic Legislation on Liability, Response Action and Compensation for Damage Caused by Activities Dangerous to the Environment: Annex to Governing Council Decision SS.XI/5 B, UN Doc. A/26/25, p. 16 (2010).

to further defer the matter to COP 14.[462] At COP 14 in 2018, the parties welcomed the entry into force of the Supplementary Protocol and again deferred the issue of liability and redress under the CBD to COP 16,[463] which was postponed due to the COVID-19 pandemic and might take place in 2024. Also considering the decreasing length of the aforementioned COP decisions, it appears safe to conclude that there is currently no interest among the parties to the CBD to address the issue of liability for biodiversity damage in addition to – and separately from – what is already addressed by the Supplementary Protocol, namely liability for biodiversity damage caused by LMOs.

VIII. Are Eradication Programmes Prohibited Under the CBD?

As noted in the first chapter, one possible application of engineered gene drives could be to suppress or even eradicate species that are vectors of human pathogens, agricultural pests, or invasive species that cause damage to local ecosystems.[464] However, it has been argued that the deliberate eradication of an entire species may not be in line with the CBD.[465] While the CBD does not contain an express prohibition to eradicate an entire species, this could be contrary to the Convention's objective to conserve biological diversity.[466] Moreover, the CBD's definition of biological diversity encompasses 'the variability among living organisms from all sources'.[467] It thus ascribes an intrinsic value to all species, regardless of their value for humankind.[468]

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462 CBD COP, Decision XII/14. Liability and Redress in the Context of Paragraph 2 of Article 14 of the Convention, UN Doc. UNEP/CBD/COP/DEC/XII/14 (2014).

463 CBD COP, Decision 14/21. Liability and Redress (Article 14, Paragraph 2), UN Doc. CBD/COP/DEC/14/21 (2018).

464 See chapter 1, section C.III.

465 *Hochkirch* et al. (n. 448), 2.

466 *Ibid.*

467 Article 2 CBD.

468 *Hochkirch* et al. (n. 448), 2, referring to UNGA, World Charter for Nature, UN Doc. A/RES/37/7, Annex (1982), which states that 'every form of life is unique, warranting respect regardless of its worth for man'. The same objection is raised by the Swiss Federal Ethics Committee on Non-Human Biotechnology, Gene Drives: Ethical Considerations on the Use of Gene Drives in the Environment (2019), 5. But see *Tina Rulli*, CRISPR and the Ethics of Gene Drive in Mosquitoes, in: David Boonin (ed.), The Palgrave Handbook of Philosophy

Under Article 8(h) CBD, eradications are justified for conservation purposes when an invasive alien species threatens local ecosystems, habitats or species.[469] If, however, an eradication program targeted a species in its native range and was successful, the species would become threatened with extinction and, in turn, become eligible for protection under the CBD.[470]

As far as known, all suppression drives currently considered for potential environmental release are not aimed at eradicating entire species, but only at suppressing them locally.[471] It is also assumed that many drive systems require repeated subsequent releases because mutations conferring resistance to the drive would occur over multiple generations.[472] If, however, a programme in fact aimed at eradicating a species as a whole, it would most likely be incompatible with the CBD's object and purpose and, therefore, be unlawful.[473]

IX. Conclusions

The foregoing analysis has shown that the CBD contains a number of provisions relevant to the international regulation of biotechnology.[474] These rules might become relevant in situations concerning organisms which are not covered by the scope of the Cartagena Protocol or involving states which are no party to the Cartagena Protocol. At the same time, many of the obligations stipulated by the CBD are broad and unspecific, or subject to softening criteria like 'as appropriate'.[475] Ultimately, the standard of conduct required by the CBD is *due diligence*, which means that whether a state has complied with a particular obligation largely depends on the individual circumstances of each case.[476] However, programmes aimed at

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and Public Policy (2018) 509, 514–517, arguing against the assumption that mosquito species have an intrinsic value.

469 See *supra* section B.V.

470 *Hochkirch* et al. (n. 448), 3.

471 See chapter 1, section C.III.1.b).

472 See chapter 1, section C.IV.1.

473 *Hochkirch* et al. (n. 448), 3.

474 Cf. *Redgwell* (n. 4), 552–553; *Förster* (n. 280), 35–37; *Sands* et al. (n. 408), 396–397.

475 See *McGraw* (n. 408), 19, who characterizes the CBD as a framework convention establishing 'general, flexible obligations that parties may apply through national laws and policies'. Also see *Glowka* et al., IUCN Guide to the CBD (n. 408), 1.

476 See chapter 4, section C.

completely eradicating a species within its native habitat range may be in breach of the CBD and thus be prohibited by international law altogether.

C. International Trade Law

International trade law aims at reducing barriers to international trade in order to enhance economic development (I.). Thus, while the AIA mechanism under the Cartagena Protocol enables states to restrict the import of LMOs into their territory, international trade law restrains the liberty of states to impose such restrictions, causing a source of tension between both regimes (II.). How these potential conflicts can be resolved is still subject to controversy (III.).

I. Key Provisions of International Trade Law

The main rules of international trade law are contained in the *General Agreement on Tariffs and Trade* (GATT)[477] and a number of subsidiary agreements. In 1994, the *World Trade Organization* (WTO) was established to facilitate the implementation of these agreements, provide a forum for negotiations between member states, and establish a system for the settlement of trade disputes.[478] The WTO has currently 164 member states, including all countries which are key actors in the area of molecular biotechnology.[479]

The main objectives of the WTO agreements are to substantially reduce tariffs and other barriers to international trade and to eliminate discriminatory treatment in international commerce.[480] According to the *most-favoured-nation rule* stipulated in Article I GATT, parties to the Agreement shall apply uniform trade conditions to all other parties and must not accord more favourable conditions to any single party than to all others. Moreover, the *principle of domestic treatment* enshrined in Article III(4)

477 General Agreement on Tariffs and Trade (30 October 1947; effective 01 January 1948), 64 UNTS 187, revised in GATT 1994 (n. 251).

478 Agreement Establishing the World Trade Organization (15 April 1994; effective 01 January 1995), 1867 UNTS 154.

479 Cf. WTO, Members and Observers, available at: https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last accessed 28 May 2022); see *Abbate* et al. (n. 7).

480 GATT 1994 (n. 251), Preamble, Recital 2.

GATT provides that parties shall not treat imported goods less favourable than like[481] domestic products. The most relevant rule in the present context, which is laid down in Article XI(1) GATT, provides that parties must not establish any prohibitions or restrictions on the trade, import or export of any product other than duties, taxes, or other charges. This runs fundamentally against the idea of the Cartagena Protocol that states are free to decide whether to allow or deny the import of a particular LMO into their territory.[482]

However, the prohibition of trade restrictions in WTO law is not without exception: pursuant to Article XX GATT, member states may impose restrictions on a number of grounds, including measures that are 'necessary to protect human, animal or plant life or health' (lit. b) and 'relating to the conservation of exhaustible natural resources' (lit. g). Further conditions under which parties may lawfully impose restrictions on international trade are set out in a number of subsidiary agreements.

II. Agreement on Sanitary and Phytosanitary Measures: Potential Source of Conflict With the Cartagena Protocol

In the context of international trade in LMOs and products thereof, the most relevant subsidiary agreement to the GATT is the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement).[483] The SPS Agreement governs the imposition of 'sanitary and phytosanitary measures which may, directly or indirectly, affect international trade'.[484] A *sanitary or phytosanitary measure* (SPS measure) is defined as any measure

481 Note that it is also disputed whether GMO and non-GMO products are sufficiently 'like' to fall under this provisions, cf. *Simonetta Zarrilli*, International Trade in GMOs and GM Products (2015), 33–34.

482 Cf. *Stoll* (n. 104), 111. See *supra* section A.II.1.h).

483 Agreement on the Application of Sanitary and Phytosanitary Measures (15 April 1994), 1867 UNTS 493 (hereinafter 'SPS Agreement'). Besides, the Agreement on Technical Barriers to Trade (15 April 1994), 1868 UNTS 120, might be relevant for international trade in LMOs. However, when a trade restriction qualifies as a *sanitary or phytosanitary measure*, the SPS Agreement prevails over the TBT agreement pursuant to Article 1.5 of the latter. Moreover, the Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994), 1869 UNTS 299, might be important for the availability of patents on inventions in the field of biotechnology, see *Debra M. Strauss*, The Application of TRIPS to GMOs, 45 (2009) Stan. J. Int'l L. 287.

484 SPS Agreement (n. 483), Article 1(1).

to protect humans, animals and plants from the risks arising from diseases, pests and disease-carrying organisms as well as from toxins and contaminants in food, beverages and feedstuff.[485] In the *EC-Biotech* case, the panel appointed by the WTO's *Dispute Settlement Body* (DSB)[486] held that the *European Communities*' regulatory framework on the release of GMOs into the environment constituted SPS measures within the meaning of the SPS Agreement.[487]

According to the SPS Agreement, member states have the right to impose trade restrictions when they are necessary for the protection of human, animal or plant life or health.[488] However, such measures are only justified where they are applied only to the extent necessary to protect human, animal or plant life or health, and when they are based on scientific principles, and supported by scientific evidence.[489] Consequently, any SPS measure must be based on a scientific assessment of the pertinent risks.[490] According to WTO case law, such a risk assessment must (1) identify the sanitary or phytosanitary risks in question, (2) evaluate the likelihood of their realization, and (3) evaluate how the measure would mitigate the risk.[491] While the evaluation of likelihood does not need to establish a certain magnitude or threshold level of risk,[492] the assessment must be

485 *Ibid.*, Annex A, para. 1.

486 On the WTO's dispute settlement mechanism generally, see *Peter-Tobias Stoll*, World Trade Organization, Dispute Settlement, in: Wolfrum/Peters (ed.), MPEPIL. The legal framework for dispute settlement within the WHO is the Understanding on the Rules and Procedures Governing the Settlement of Disputes, Annex 2 to the Agreement Establishing the World Trade Organization (15 April 1994), 1869 UNTS 401.

487 WTO DSB, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, Report of the Panel of 29 September 2006, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 8.4, see *Jacqueline Peel*, A GMO by Any Other Name … Might Be an SPS Risk!, 17 (2006) EJIL 1009.

488 SPS Agreement (n. 483), Article 2.1.

489 *Ibid.*, Article 2(2)d.

490 Article 5(1) SPS Agreement; see *Joanne Scott*, The WTO Agreement on Sanitary and Phytosanitary Measures (2007), 104–110.

491 WTO DSB, Australia – Measures Affecting Importation of Salmon, Report of the Appellate Body of 20 October 1998, WT/DS18/AB/R, para. 135; see *Scott* (n. 490), 92; *Lee A. Jackson*, Risk Assessment Frameworks in the Multilateral Setting, in: Stuart Smyth/Peter Phillips/David Castle (eds.), Handbook on Agriculture, Biotechnology and Development (2014) 203, 206.

492 WTO DSB, Australia – Salmon, Appellate Body report (n. 491), para. 124.

sufficiently specific to the issue at hand[493] and also consider alternative policy options.[494] Risks that are merely theoretical or uncertain cannot justify measures under the SPS Agreement.[495] Furthermore, measures shall not be more trade-restrictive than required to achieve an appropriate level of sanitary or phytosanitary protection.[496] Where available, SPS measures shall be based on international standards, guidelines or recommendations, including those elaborated under the *International Plant Protection Convention*,[497] the *World Organisation for Animal Health*,[498] and in the *Codex Alimentarius Commission*.[499] SPS measures that are based on such international standards are presumed to be consistent with the SPS Agreement and the GATT.[500]

In cases where the relevant scientific information is 'insufficient', member states may adopt *provisional* sanitary or phytosanitary measures on the basis of the available pertinent information.[501] At first sight, this resembles the precautionary principle embodied in the Cartagena Protocol, which provides that states may refuse the import of an LMO when there is a lack of scientific certainty regarding the extent of potential adverse effects of the LMO in question.[502] However, the WTO Appellate Body has held that 'scientific uncertainty' and 'insufficient scientific information' represent two distinct concepts that are not interchangeable.[503]

Hence, under the SPS Agreement provisional measures may only be adopted in cases of scientific *insufficiency*, but not in cases of scientific *uncertainty*. According to the WTO Appellate Body, scientific evidence is 'insufficient' in terms of the SPS Agreement when the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate risk assessment as required by the Agreement.[504] This is an important difference from the Cartagena Protocol, which does not require that insufficiency of scientific information renders

493 WTO DSB, Japan – Measures Affecting the Importation of Apples, Report of the Appellate Body of 26 November 2003, WT/DS245/AB/R, para. 202.
494 Cf. *Scott* (n. 490), 96, with further references.
495 *Stoll* (n. 104), 107.
496 SPS Agreement (n. 483), Article 5(6).
497 See *infra* section D.
498 See *infra* section E.
499 See *infra* section F.
500 SPS Agreement (n. 483), Article 3(2).
501 *Ibid.*, Article 5(7).
502 See *supra* section A.II.1.d).
503 WTO DSB, Japan-Apples, Appellate Body report (n. 493), para. 184.
504 *Ibid.*, para. 179.

an adequate risk assessment as such impossible, but only that insufficiency of information leads to a lack of scientific certainty as to the risks in question.[505]

In sum, the margin of appreciation awarded to states to deny the import of LMOs into their territory on grounds of their environmental risks under the SPS Agreement is much smaller than under the Cartagena Protocol, which strongly endorses the sovereign decision-making of each state party over the import of LMOs.[506] This may lead to situations in which measures permitted – or even required – by the Cartagena Protocol are not in accordance with the requirements under the SPS Agreement (or, in some instances, *vice versa*).[507] This is further complicated by the fact that the membership to both instruments is only partially overlapping since some parties to the Cartagena Protocol are not WTO members and *vice versa*.[508]

505 Cf. *Robyn Neff*, The Cartagena Protocol and the WTO: Will the EU Biotech Products Case Leave Room for the Protocol?, 16 (2005) Fordham Environmental Law Review 261, 274. Interestingly, the panel in EC-Biotech noted that the European Communities had performed a risk assessment on the products in question and held that this created a 'presumption' that the relevant scientific information was not insufficient, cf. WTO DSB, EC-Biotech (n. 487), 7.3260.

506 Cf. *Balakrishna Pisupati*, Biotechnology, Cartagena Protocol and the WTO Rules, 7 (2005) Asian Biotechnology and Development Review 75, 80.

507 Cf. *Stoll* (n. 104), 117; *Gabrielle Z. Marceau*, Conflicts of Norms and Conflicts of Jurisdictions, 35 (2001) Journal of World Trade 1081, 1097, who distinguishes between situations in which the disputed measure is required by an environmental treaty and situations in which the measure is (only) permitted by that treaty or taken in furtherance of its goals.

508 Out of the 164 members of the WTO, the following are currently no parties to the Cartagena Protocol: Argentina, Australia, Brunei, Canada, Chile, Haiti, Iceland, Israel, Liechtenstein, Nepal, Russia, Sierra Leone, Singapore, United States and Vanuatu. Conversely, of the 171 parties to the Cartagena Protocol, the following are no WTO members: Algeria, Azerbaijan, Bahamas, Belarus, Bhutan, Bosnia and Herzegovina, Comoros, Democratic People's Republic of Korea, Eritrea, Ethiopia, Iran, Iraq, Kiribati, Lebanon, Libya, Marshall Islands, Nauru, Palau, Palestine, Serbia, Somalia, Sudan, Syria, and Turkmenistan. Consequently, 149 states are both members of the WTO and parties to the Cartagena Protocol. The Cartagena Protocol's 'parent' convention, the Convention on Biological Diversity, has 196 parties, including all WTO members except the United States.

III. Resolving Potential Conflicts Between International Trade Law and the Cartagena Protocol

According to general international law on the law of treaties, potential conflicts between norms from different sources shall be avoided primarily by way of interpretation.[509] Pursuant to Article 31(3)(c) VCLT, any relevant rules of international law applicable in the relations between the parties shall be taken into account when interpreting a treaty. Only when a conflict of obligations cannot be avoided, general rules of international law help to determine which obligation takes precedence: First, where available, specific provisions of a treaty governing its relation to other treaties shall be considered.[510] Recital 10 of the preamble to the Cartagena Protocol provides that the Protocol 'shall not be interpreted as implying a change in the rights or obligations of a party under any existing international agreements'. This would mean that the SPS Agreement, which was concluded before the Cartagena Protocol, prevailed. But at the same time, Recital 11 states that the earlier recital was 'not intended to subordinate this Protocol to other international agreements'. Hence, the Cartagena Protocol remains inconclusive as to its relationship to other rules of international law.[511] At the same time, neither the GATT nor the SPS Agreement contains expressions regarding their relation to other rules of international law.

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509 *Manfred Zuleeg*, Vertragskonkurrenz im Völkerrecht, 20 (1977) German YBIL 246, 256; *Seyed-Ali Sadat-Akhavi*, Methods of Resolving Conflicts Between Treaties (2003), chapter 2; in the present context, see *Marceau* (n. 507), 1086–1090 with further references. Positivist scholars even deny the possibility of conflicts of norms, cf. *Hans Kelsen*, Principles of International Law (1952), 426–427, who argues that the 'specific function of juristic interpretation is to eliminate these contradictions by showing that they are merely sham contradictions'.

510 Article 30(2) VCLT; see generally *Sadat-Akhavi* (n. 509), 61–63.

511 But see *Sabrina Safrin*, The Relationship with Other Agreements: Much Ado About a Savings Clause, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 438, 446–447, who argues that understanding Recital 11 as undoing Recital 12 would ignore the 'clear ordinary and unambiguous meaning' of the former and would violate the duty to interpret a treaty in good with. In her view, Recital 12 was introduced to indicate that 'environmental agreements are not of lower status, class, significance or importance than trade agreements and that the inclusion of a savings clause in the protocol should not be understood to lower or lessen it'. Yet, the author does not elucidate why Recital 11 should be construed as a legally relevant *savings clause* whereas the relevance of Recital 12 would only be declaratory or sentimental.

In the absence of special provisions, the principles of *lex posterior* and *lex specialis* apply. The *lex posterior* rule provides that the treaty which was concluded later in time shall prevail over the earlier treaty on the same subject matter.[512] According to the *lex specialis* rule, provisions which are more specific in content prevail over more general ones.[513] Against this background, some authors have argued that a conflict between WTO law and the Cartagena Protocol would most likely be resolved in favour of the latter, as it was both the more specific and the more recent agreement.[514] This conclusion, however, is questionable: the scope of WTO law has become so broad that it cuts across almost all other areas of international law; yet, it specifically relates to matters of free trade.[515] Furthermore, as shown above, the SPS Agreement stipulates highly specific conditions under which WTO members may restrict trade for sanitary and phytosanitary measures,[516] whereas the Cartagena Protocol contains no substantive rules on the circumstances under which the import of an LMO may be denied.[517] Hence, it cannot generally be assumed that the Cartagena Protocol is more specific than the SPS Agreement.[518]

The relationship between WTO law and other rules of international law was also a major issue in the aforementioned *EC-Biotech* case before the WTO's DSB. The European Communities had argued that the SPS Agreement had to be interpreted consistently with other rules of international law, namely the CBD and the Cartagena Protocol.[519] This could be required by Article 30(3)(c) VCLT, which provides that when interpreting a treaty, account shall be taken of 'any relevant rules applicable in the relations between the parties'. But in the view of the panel, the phrase 'applicable in relations between the parties' implies that Article 30(3)(c) VCLT only applies to rules 'which are applicable in the relations between all parties to the treaty which is being interpreted'.[520] Consequently, the

512 Article 30(3) and (4) VCLT.

513 The *lex specialis* rule is not explicitly mentioned in the VCLT, but is nevertheless recognized as a general rule of international law, see *Dorota M. Banaszewska*, Lex Specialis, in: Wolfrum/Peters (ed.), MPEPIL, MN. 11–20; *Marceau* (n. 507), 1090.

514 *Stoll* (n. 104), 117; *Zarrilli* (n. 481), 38.

515 *A. Lindroos*, Dispelling the Chimera of 'Self-Contained Regimes' International Law and the WTO, 16 (2005) EJIL 857, 864.

516 See *supra* section C.I.

517 See *supra* section A.II.1.h).

518 Cf. *Lindroos* (n. 515), 864.

519 Cf. WTO DSB, EC-Biotech (n. 487), paras. 7.52 – 7.55.

520 *Ibid.*, para. 7.70.

panel held that only rules of international law that bind *all* WTO members would have to be taken into account under Article 30(3)(c) VCLT.[521] Since neither the CBD nor the Cartagena Protocol has been ratified by all WTO members, the panel refused to take into account either of the instruments when interpreting the pertinent provisions of the SPS Agreement.[522]

The panel's narrow understanding of Article 31(3)(c) VCLT was heavily criticized in scholarship,[523] *inter alia* for increasing the fragmentation of international law.[524] It has also been questioned whether the decision would have been upheld by the WTO's *Appellate Body*, which had noted in earlier decisions that WTO law was not 'not to be read in clinical isolation from public international law'.[525] Notably, rules of international environmental law, including the CBD, have already been considered by the Appellate Body in earlier cases.[526] However, since neither of the parties appealed against the panel decision in *EC-Biotech*, it was not reviewed by the Appellate Body.

After all, the relationship between international trade law and international environmental law, particularly the Cartagena Protocol, is still unsettled. The WTO agreements are likely to significantly limit the liberty of states to restrict the import of LMOs into their territory. Under the WTO agreements, especially the SPS Agreement, trade restrictions are only permissible when they are justified by strictly scientific evidence.[527] Unlike international environmental law, a lack of knowledge can only be invoked

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521 *Ibid.*, para. 7.68.

522 *Ibid.*, paras. 7.73 – 7.75.

523 See *Robert Howse/Henrik Horn*, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, 8 (2009) World Trade Review 49, 53–62; *Denise Prévost*, Opening Pandora's Box: The Panel's Findings in the EC-Biotech Products Dispute, 34 (2007) Legal Issues of Economic Integration 67, 92; *Caroline Henckels*, GMOs in the WTO: A Critique of the Panel's Legal Reasoning in EC-Biotech, 7 (2006) Melb. J. Int'l L. 278, 297–301.

524 *Martti Koskenniemi*, Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law: Report of the Study Group of the International Law Commission, UN Doc. A/CN.4/L.682 (2006), para. 471.

525 WTO DSB, United States – Standards for Reformulated and Conventional Gasoline, Appellate Body Report of 29 April 1996, WT/DS2/AB/R, 17; see *Howse/Horn* (n. 523), 61; *Lindroos* (n. 515).

526 WTO DSB, United States – Import Prohibition of Certain Shrimp and Shrimp Products, Report of the Appellate Body of 12 October 1998, WT/DS58/AB/R, paras. 130, 168, see *Howse/Horn* (n. 523), 60–61.

527 Article 5(1) SPS Agreement; cf. WTO DSB, Australia – Salmon, Appellate Body report (n. 491), paras. 112–135; see *supra* section C.II.

to justify preliminary measures when it results from a lack of available data, but not from a general uncertainty about the potential or perceived risks of LMOs.

In addition, the WTO has established a comprehensive dispute settlement mechanism with compulsory jurisdiction.[528] By comparison, the system for dispute settlement under the Convention on Biological Diversity is rather weak, as it only requires states to participate in a non-binding 'conciliation' procedure which merely renders a non-binding proposal for resolving the dispute.[529] Hence, any dispute related to the international trade in LMOs or products thereof will most likely be brought before the WTO DSB rather than a CBD arbitral tribunal or the International Court of Justice.[530] It remains to be seen whether the Dispute Settlement Body will find ways to integrate its jurisprudence into the wider body of international law, and thus avoid further fragmentation and the creation of conflicting obligations.

D. International Plant Protection Convention

The *International Plant Protection Convention* of 1951[531] aims at securing common and effective action to prevent and control the introduction and spread of pests in plants and plant products.[532] Although the IPPC's main focus is on international trade in plants and plant products, its scope also extends to the protection of the natural flora.[533] The Convention, which was substantially revised in 1997, currently has 183 parties, including all major biotechnology nations.[534] In 2004, the FAO (which administers the IPPC) and the CBD Secretariat signed a Memorandum of Cooperation

528 See generally *Stoll* (n. 486).
529 Cf. Article 27(4) and Annex II, Part 2, of the CBD; see chapter 9, section C.III.2.
530 *Stoll* (n. 104), 117; *Zarrilli* (n. 481), 39.
531 International Plant Protection Convention (New Revised Text) (17 November 1997; effective 02 October 2005), 2367 UNTS 223 (hereinafter 'IPPC 1997').
532 *Ibid.*, Article I(1).
533 Cf. *ibid.*, Article 4(c)(b).
534 Cf. UN OLA, Status of the International Plant Protection Convention (New Revised Text), United Nations Treaty Collection, available at: https://treaties.un.org/Pages/showDetails.aspx?objid=0800000280066b19&clang=_en (last accessed 28 May 2022).

recognizing the 'overlapping objectives' of the IPPC and the CBD in the international regulation of biotechnology.[535]

The IPPC has established a *Commission on Phytosanitary Measures*,[536] which adopts *International Standards for Phytosanitary Measures* (ISPMs).[537] Although the ISPMs are not legally binding under the IPPC, they have gained legal relevance as reference standards under the *SPS Agreement*, as phytosanitary measures that conform to the ISPMs are presumed to also comply with the SPS Agreement.[538]

A number of ISPMs apply to Living Modified Organisms.[539] For instance, ISPM 11 on *Pest Risk Assessment for Quarantine Pests* sets out standards to identify plant pests and to evaluate their risk, identify endangered areas and, if appropriate, identify risk management options.[540] The standard expressly acknowledges that some LMOs may present phytosanitary risks.[541] In order to be categorized as a plant pest, an LMO has to be injurious or potentially injurious to plants or plant products under conditions in the relevant area.[542] The types of LMOs that may pose such risks include plants used for agricultural or industrial purposes modified to improve their performance, as well as organisms whose pathogenic characteristics have been modified to make them useful for biological

535 Memorandum of Cooperation Between the Food and Agriculture Organization of the United Nations and the Secretariat of the Convention on Biological Diversity on Cooperation Between the Secretariat of the Convention on Biological Diversity and the Secretariat of the International Plant Protection Convention (25 February 2004); see *Ayse-Martina Böhringer*, Die Kooperationsvereinbarungen der Sekretariate multilateraler Umweltschutzübereinkommen (2014), 170–172.

536 The term 'phytosanitary' (from the ancient Greek term φυτόν) refers to the health of plants, cf. 'phytosanitary, adj.', in: Oxford English Dictionary (n. 12).

537 See Articles X and XI of IPPC 1997 (n. 531).

538 Cf. SPS Agreement (n. 483), Annex A, para. 3(c); see *Jackson* (n. 491), 209–210; on the SPS Agreement, see *supra* section C.II.

539 See International Plant Protection Convention, Overview on International Standards for Phytosanitary Measures (ISPMs) And Their Application to Living Modified Organisms (LMOs) (2016); cf. *Jackson* (n. 491), 209; CBD Secretariat, Standards for Shipments of Living Modified Organisms: Outcomes of an Online Forum, CBD Biosafety Technical Series 01 (2011), 34–39.

540 ISPM 11 (n. 165), 7. For a detailed analysis, see *Meredith T. Mariani*, The Intersection of International Law, Agricultural Biotechnology, and Infectious Disease (2007), 132–138.

541 ISPM 11 (n. 165), 8. On the application of ISPM 11 to LMOs, see *Lim/Lim* (n. 76), 52–53.

542 ISPM 11 (n. 165), 9.

control purposes.[543] With regard to phytosanitary risks related to gene flow, ISPM 11 recognizes that an LMO constitutes a potential vector for the introduction of a genetic construct of phytosanitary concern rather than a pest in and of itself.[544] Therefore, ISPM 11 proposes the term 'pest' to be understood to include the potential of an LMO to act as a vector for introducing genes presenting a potential phytosanitary risk into the environment.[545] Consequently, ISPM 11 also covers some risks involved with the unintentional dissemination of engineered gene drives.[546]

Although the IPPC does not establish substantive rules on the conditions under which LMOs may be released, ISPM 11 signifies a consensus among the parties to the Convention that LMOs may constitute plant pest vectors that require risk assessment and, if necessary, regulation. In this regard, ISPM 11 specifies – at least by way of *soft law* – requirements for risk assessments with regard to potential hazardous effects of LMOs on cultivated plants and wild flora that may be of particular relevance for LMOs with the capacity of self-propagation.[547]

E. World Organisation for Animal Health

The *World Organisation for Animal Health* (OIE) is an intergovernmental organization created to control the spread of animal diseases.[548] It was established by means of an international agreement concluded in 1924.[549] Today, the OIE has 182 member states, including all nations with major biotechnology industries.[550] Each member state is required to report animal diseases that it detects on its territory; such information is then disseminated to the other member states in order to allow them to take

543 *Ibid.*, 8.
544 *Ibid.*, 30.
545 *Ibid.*; cf. *Jackson* (n. 491), 210.
546 *Lim/Lim* (n. 76), 54.
547 Cf. *Angulo/Gilna* (n. 440), 281.
548 The organization, previously called *Office International des Epizooties*, was renamed in 2003 but retained its historical acronym *OIE* until recently, when the acronym was changed to *WOAH*.
549 Arrangement international pour la création, à Paris, d'un Office international des épizooties (25 January 1924; effective 11 June 1926), 57 LNTS 135.
550 Cf. OIE, Member Countries, available at: https://www.woah.org/en/who-we-are/members/ (last accessed 28 May 2022).

preventive action.[551] The OIE also facilitates the exchange of veterinary scientific information, encourages international solidarity in the control of animal diseases, and provides technical support to affected member states.[552] Besides, the OIE elaborates standards for international trade in animals and animal products which, like the ISPM developed under the IPPC,[553] formally only have *soft law* status but are recognized by the WTO as reference international sanitary rules under the SPS Agreement.[554]

Although the OIE has dealt with biotechnology-related matters from a number of perspectives,[555] it has not specifically addressed genetically modified animals.[556] Nevertheless, its *Terrestrial and Aquatic Animal Health Codes* contain guidelines for import risk analysis aimed at providing importing countries with an 'objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material'.[557] The stated purpose of risk assessments is to provide importing countries with clear reasons for the imposition of import conditions or refusal to import,[558] i.e. reasons that would withstand scrutiny under WTO law. In 2011, the OIE published *Guidelines for Assessing the Risk of Non-Native Animals Becoming Invasive*.[559] The purpose of these guidelines is to assist in determining whether imported animal species are likely to become harmful to the environment, animal or human health, or the economy.[560] Similar to ISPM 11 for invasive plants, these guidelines may provide guidance in determining the risks potentially associated with an LMO that could also be classified as an invasive, non-native species.[561]

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551 OIE, Our Missions, available at: https://www.woah.org/en/who-we-are/mission/ (last accessed 28 May 2022).
552 *Ibid.*; see *Mariani* (n. 540), 124–125.
553 See *supra* section D.
554 OIE (n. 551); cf. SPS Agreement (n. 483), Annex A, para. 3(b).
555 See, e.g. OIE, Resolution No. XXVIII. Applications of Genetic Engineering for Livestock and Biotechnology Products. Adopted by the International Committee of the OIE During Its 73rd General Session (27 May 2005); OIE, Role of the OIE in Improving Animal Health by Using Biotechnologies: OIE Bulletin 2007–4, 3–14; cf. *Mariani* (n. 540), 124–127.
556 *Jackson* (n. 491), 210.
557 OIE, Terrestrial Animal Health Code (2019), Article 2.1.1.
558 *Ibid.*
559 Guidelines for Assessing the Risk of Non-Native Animals Becoming Invasive (n. 165).
560 *Ibid.*, 2.
561 Terrestrial Animal Health Code (n. 557), Article 2.1.1.

F. Codex Alimentarius

The *Codex Alimentarius* is a collection of standards, guidelines and recommendations on food, food production, and food safety.[562] Its texts are developed and maintained by the *Codex Alimentarius Commission*, which has been established by the *Food and Agriculture Organization of the United Nations* and the *World Health Organization* in 1963.[563] Although not legally binding in formal terms, the Codex texts are generally regarded as internationally recognized[564] and are referenced by the SPS Agreement as the relevant international standards on food safety.[565] The Codex Alimentarius Commission currently has 189 members, including all states which are major stakeholders in molecular biotechnology as well as the European Union.[566]

The Codex Alimentarius Commission has developed a number of documents relevant in the context of biotechnology,[567] including the *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*.[568] The purpose of these principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology.[569] However, the document expressly states that it 'does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods'.[570] These issues are outside the scope of the Codex Alimentarius, which is exclusively focused on food safety.

562 See *Gerald G. Sander*, Codex Alimentarius Commission (CAC), in: Wolfrum/Peters (ed.), MPEPIL.
563 *Ibid.*
564 *Mariani* (n. 540), 62–63.
565 SPS Agreement (n. 483), Annex A, para. 3(a).
566 FAO/WHO, Codex Alimentarius: Members, available at: http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/ (last accessed 28 May 2022).
567 See *Mariani* (n. 540), 66–73; *Markus Böckenförde*, Genetically Modified Organisms, in: Wolfrum/Peters (ed.), MPEPIL, MN. 23; *Jackson* (n. 491), 208–209.
568 Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (n. 165); see *Mariani* (n. 540), 66–69.
569 Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (n. 165), para. 7. Notably, the definition of 'modern biotechnology' used by the Codex is identical to that of the Cartagena Protocol, cf. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (n. 165), para. 8.
570 *Ibid.*, para. 7.

Besides the aforementioned Principles, the Codex Alimentarius also contains Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants[571] and animals[572] or produced using recombinant-DNA microorganisms.[573] Moreover, the Codex contains provisions for the labelling of foods derived from modern biotechnology.[574]

G. *United Nations Convention on the Law of the Sea*

The *United Nations Convention on the Law of the Sea* of 1982 (UNCLOS)[575] does not directly address biotechnology, nor does the current draft for an implementing agreement on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction.[576] However, Article 196(1) UNCLOS requires states to take

> *'all measures necessary to prevent, reduce and control […] the intentional or accidental introduction of species, new or alien, to a particular part of the marine environment, which may cause significant and harmful changes thereto'.*

The meaning of the term 'alien species' corresponds to that of the same term in Article 8(h) CBD,[577] while 'new species' refers to those that have been bred traditionally or through modern biotechnology, which includes LMOs.[578] Article 196 UNCLOS extends to all activities under the jurisdic-

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571 Codex Alimentarius Commission, Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2008), CAC/GL 45–2003; see *Mariani* (n. 540), 69–71.

572 Codex Alimentarius Commission, Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (2008), CAC/GL 68–2008.

573 Codex Alimentarius Commission, Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (2003), CAC/GL 46–2003; see *Mariani* (n. 540), 72–73.

574 Codex Alimentarius Commission, Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology (2011), CAC/GL 76–2011.

575 See *supra* n. 112.

576 Cf. UNGA, Draft Text of an Agreement Under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction, UN Doc. A/CONF.232/2019/6, Annex (2019).

577 *Böckenförde* (n. 113), 261–262; *Czybulka*, Article 196 UNCLOS (n. 113), MN. 14.

578 *Böckenförde* (n. 113), 250–251; *Czybulka*, Article 196 UNCLOS (n. 113), MN. 14.

tion or control of states parties to the Convention, regardless of their geographical location.[579] Hence, the Convention requires its states parties to prevent the release of LMOs into the marine environment, provided that said LMOs 'may cause significant and harmful changes' to the marine environment. Moreover, the notion 'may' clearly indicates that the obligation is not only triggered when there is certainty about the adverse effects but already when there is a certain likeliness of damage. Consequently, the wording of Article 196(1) UNCLOS requires states to apply a precautionary approach and to carry out early risk assessments for relevant activities, in accordance with Article 206 UNCLOS.[580]

H. International Regulations on the Transport of Hazardous Goods

LMOs are also subject to international regulations concerning the transport of hazardous goods and substances.[581] The principal instrument in this context is the *UN Recommendations on the Transport of Dangerous Goods*, which is a non-binding *soft law* instrument developed by an expert committee of the *United Nations Economic and Social Council* (ECOSOC) and presented in the form of *Model Regulations*.[582] These Model Regulations contain a list of dangerous goods commonly subject to transport as well as provisions relating to their identification and classification, standards for packing and the design of packaging, as well as rules on consignment procedures and transport operations. The Model Regulations' *Dangerous Goods List* includes 'Genetically modified micro-organisms' (GMMs) and 'Genetically modified organisms' (GMOs).[583] The Model Regulations also contain a *Packing Instruction* specifically for GMMs and GMOs.[584] This Packing Instruction requires, *inter alia*, that packaging shall consist of multiple layers and must be leak-proof or sift-proof. Moreover, the Packing Instruction provides for a label that shall be attached to the outer packaging of GMMs or GMOs.[585] GMMs and GMOs packed and marked in accordance with these instructions are not subject to any other requirements

579 *Czybulka*, Article 196 UNCLOS (n. 113), MN. 13.
580 *Ibid.*, MN. 19.
581 See CBD Secretariat (n. 539), 29–56.
582 United Nations, Recommendations on the Transport of Dangerous Goods: Model Regulations, ST/SG/AC.10/1/Rev.22 (22nd ed. 2021).
583 *Ibid.*, section 2.9.2, vol. I at p. 170.
584 *Ibid.*, Packing Instruction P904, section 4.1.4.1, vol. II at page 94.
585 *Ibid.*

stipulated in the Model Regulations.[586] Moreover, GMMs and GMOs shall not be subject to the Model Regulations when they are 'authorized for use by the competent authorities of the countries of origin, transit and destination'.[587] However, when a GMM or GMO meets the definition of a *toxic substance* or an *infectious substance*, it is subject to the stricter requirements that apply to these types of substances.[588]

Based on the Model Regulations, several legally binding instruments have been developed to govern the international transport of hazardous goods and substances. At the universal level, instruments governing the transport of hazardous goods exist for transport by air[589] and by sea.[590] A number of similar instruments concerning transport by rail,[591] road,[592] and inland waters,[593] are geographically limited to Europe and neighbouring regions. All of these agreements largely mirror the rules in the Model Regulations and are usually harmonized with the amendments made to them.

586 *Ibid.*, section 3.3.1.219, vol. I at p. 322.
587 *Ibid.*, section 2.9.2, vol. I at p. 170.
588 *Ibid.*, section 3.3.1.219, vol. I at p. 322.
589 ICAO, Convention on International Civil Aviation, Annex 18: The Safe Transport of Dangerous Goods by Air, 4th edition 2011, incorporating all amendments adopted by the ICAO council effective as from 17 November 2011; ICAO, Technical Instructions for the Safe Transport of Dangerous Goods by Air, ICAO Doc. 9284, 2021–2022 edition.
590 IMO, International Maritime Dangerous Goods Code, 2020 edition, as amended by amendment 40–20 (effective 1 June 2020).
591 OTIF, Regulations Concerning the International Carriage of Dangerous Goods by Rail, Appendix C to the Convention Concerning International Carriage by Rail, with amendments as effective from 1 January 2021.
592 UNECE, European Agreement Concerning the International Carriage of Dangerous Goods by Road (30 September 1957; effective 29 July 1968), 619 UNTS 77, with amendments to Annexes A and B as applicable from 1 January 2021, consolidated version in UN Doc. ECE/TRANS/300, Vol. I and II.
593 UNECE, European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways (26 May 2000; effective 29 February 2008), 2497–2500 UNTS, with amendments to the annexed Regulations as applicable from 1 January 2021, consolidated version in UN Doc. ECE/TRANS/301, Vol. I and II.

I. International Health Regulations

The *International Health Regulations* (IHR) become relevant when a product of biotechnology, such as a genetically modified virus, causes a disease in humans.[594] Last revised in 2005, the IHR are a legally binding instrument adopted by the World Health Assembly, the decision-making body of the *World Health Organization* (WHO), in accordance with Article 21(a) of the WHO's Constitution.[595] Since all UN member states except for Liechtenstein are also members of the WHO,[596] the IHR have a quasi-universal effect.

The IHR's objective is to prevent the international spread of diseases, while at the same time ensuring that public health responses are 'commensurate with and restricted to public health risks, and […] avoid unnecessary interference with international traffic and trade'.[597] Member states must notify the WHO about all events which may constitute a so-called 'public health emergency of international concern',[598] which is defined as

> '*an extraordinary event which is determined […] (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response*'.[599]

When the WHO determines that such an event occurs, it may issue temporary recommendations about specific health measures to be implemented by the state experiencing the outbreak.[600] It may also issue temporary recommendations to other states concerning measures to prevent or reduce the international spread.[601]

Although these recommendations are formally non-binding,[602] measures not recommended by the WHO 'shall be not more be more restric-

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594 WHO, International Health Regulations (2005) (23 May 2005; effective 15 June 2007), WHO Doc. WHA58.3.
595 Constitution of the World Health Organization (22 July 1946; effective 07 April 1948), 14 UNTS 185, as last amended by resolution WHA39.6 of 16 May 1998 (effective 15 September 2015).
596 UN OLA, Status of the Constitution of the World Health Organization, available at: https://treaties.un.org/Pages/showDetails.aspx?objid=080000028002d899&clang=_en (last accessed 28 May 2022).
597 IHR 2005 (n. 594), Article 2.
598 *Ibid.*, Article 6(1).
599 *Ibid.*, Article 1(1).
600 *Ibid.*, Articles 15–18.
601 *Ibid.*, Article 15(2).
602 *Ibid.*, Article 1(1).

tive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection'.[603] Against this background, it has been argued that the imposition of travel restrictions not recommended by the WHO was in breach of international law.[604]

In principle, the IHR apply to any outbreak of a transmissible disease,[605] including such caused by pathogens modified through biotechnology. However, the practical effectiveness of the IHR has recently been called into question, since many developing states lack the necessary resources to implement surveillance systems to early identify outbreaks of transmissible diseases.[606] It has also been contended that states have repeatedly delayed notifications of disease outbreaks to avoid the imposition of restrictions harmful to their tourism and trade.[607] During the COVID-19 pandemic, the WHO was criticized for not reacting quickly enough, whereas states have only inconsistently complied with the WHO's recommendations.[608]

J. Disarmament and Humanitarian International Law

Finally, certain applications of biotechnology may fall within the scope of international law that prohibits both the acquisition of biological weapons and the conduct of 'environmental warfare', namely the Biologi-

603 *Ibid.*, Article 43(1).

604 *Lawrence O. Gostin* et al., The International Health Regulations 10 Years on: The Governing Framework for Global Health Security, 386 (2015) The Lancet 2222, 2225; *Roojin Habibi* et al., Do Not Violate the International Health Regulations During the COVID-19 Outbreak, 395 (2020) The Lancet 664; *Benjamin M. Meier* et al., Travel Restrictions Violate International Law, 367 (2020) Science 1436.

605 *Morten Broberg*, A Critical Appraisal of the World Health Organization's International Health Regulations (2005) In Times of Pandemic: It Is Time for Revision, 11 (2020) European Journal of Risk Regulation 202, 205.

606 *Gostin* et al. (n. 604), 2223–2224; *Broberg* (n. 605), 206–207.

607 *Broberg* (n. 605), 207; *Lawrence O. Gostin* et al., Has Global Health Law Risen to Meet the COVID-19 Challenge? Revisiting the International Health Regulations to Prepare for Future Threats, 48 (2020) The Journal of Law, Medicine & Ethics 376, 378–379.

608 *Broberg* (n. 605), 205; *Barbara J.* von *Tigerstrom* et al., The International Health Regulations (2005) and the Re-Establishment of International Travel Amidst the COVID-19 Pandemic, 27 (2020) Journal of Travel Medicine 1; *Gostin* et al. (n. 607), 378–379.

cal Weapons Convention (I.), the ENMOD Convention (II.), and the rules of international humanitarian law (III.).

I. Biological Weapons Convention

The *Biological Weapons Convention* of 1972 (BWC)[609] is a disarmament treaty which prohibits the development, production, stockpiling, and other means of acquiring biological weapons or their means of delivery. It currently has 183 states parties, including all relevant states engaged in molecular biotechnology except Israel.[610] The obligation not to possess biological weapons is also part of customary international law,[611] as is their 'use', which is not explicitly prohibited by the BWC.[612] Pursuant to Article I(1) BWC,

609 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) And Toxin Weapons and on Their Destruction (10 April 1972; effective 26 March 1975), 1015 UNTS 163; for a general introduction, see *Jozef Goldblat*, The Biological Weapons Convention: An Overview, 37 (1997) International Review of the Red Cross Archive 251.

610 UNOG, Lists of States Parties, Signatory States and Non-Signatory States of the Biological Weapons Convention, available at: https://www.un.org/disarmament/biological-weapons/about/membership-and-regional-groups (last accessed 28 May 2022). However, Israel is a party to the 1925 Geneva Protocol, see Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (17 June 1925; effective 09 May 1926), 94 LNTS 65; UN OLA, Status of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, available at: https://treaties.un.org/Pages/showDetails.aspx?objid=0800000280167ca8&clang=_en (last accessed 28 May 2022).

611 Cf. *Jean-Marie Henckaerts/Louise Doswald-Beck*, Customary International Humanitarian Law (2005), 256–258. Also note that the UN Security Council, acting under Chapter VII of the UN Charter (and thus acting with legislative powers binding all UN member states according to Article 25 of the UN Charter), decided in 2004 that all states shall refrain from providing any form of support to non-state actors that attempt to develop, acquire, or use chemical or biological weapons and their means of delivery, and that states shall take effective measures to prevent the proliferation of such weapons, see UNSC, Resolution 1540 (2004). Non-Proliferation of Weapons of Mass Destruction (28 April 2004), UN Doc. S/RES/1540 (2004), operative paras. 1–3.

612 Yet, states parties to the BWC have agreed that the use of biological weapons would be 'effectively a violation of Article I', cf. BWC Implementation Support Unit, Additional Understandings and Agreements Reached by Previous Review Conferences Relating to Each Article of the Convention: Background Informa-

> *'each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain*
> *(1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;*
> *(2) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict'.*

The Convention does not provide a definition of what constitutes a 'biological agent'. In a resolution adopted by the UN General Assembly in 1969 (i.e. before the BWC was adopted), the notion 'biological agents of warfare' was defined as

> *'living organisms, whatever their nature, or infective material derived from them, which are intended to cause disease or death in man, animals or plants, and which depend for their effects on their ability to multiply in the person, animal or plant attacked'.*[613]

According to this definition, a key characteristic of a biological warfare agent is that it multiplies in the target organism and thereby exerts its harmful effects. This would exclude from the scope of the BWC a range of applications of synthetic biology which do not rely on 'multiplication' in the target organism, such as engineered gene drives. But it is questionable whether this requirement applies to the BWC, because Article I(1) not only refers to microbial agents (i.e. microorganisms) but also includes 'other biological agents'. Indeed, there appears to be a wide consensus that the BWC is not limited to organisms that cause or spread diseases,[614] but also encompasses all other biological agents which can be used to harm or to cause death to humans, animals, or plants, insofar as these organisms are of types and quantities not justified for exclusively peaceful purposes.[615]

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tion Document for the Seventh Review Conference of the States Parties to the BWC, UN Doc. BWC/CONF.VII/INF.5 (2011), paras. 8–10; also see *William H. Boothby*, Weapons and the Law of Armed Conflict (2nd ed. 2016), 113.

613 UNGA, Resolution 2603 (XXIV). Question of Chemical and Bacteriological (Biological) Weapons, UN Doc. A/Res/2603(XXIV) (1969), para. (b).

614 See *Joseph P. Dudley/Michael H. Woodford*, Bioweapons, Biodiversity, and Ecocide: Potential Effects of Biological Weapons on Biological Diversity, 52 (2002) BioScience 583.

615 *Stefan Oeter*, Methods and Means of Combat, in: Dieter Fleck (ed.), The Handbook of International Humanitarian Law (3rd ed. 2013) 115, MN. 441; also see *Goldblat* (n. 609), 254, noting that there have never been disputes among the parties regarding the definition of biological agents or toxins.

Consequently, whether these effects are caused through multiplication in the target organism does not seem to be a constitutive element of a 'biological agent'. In fact, nothing in the BWC justifies the assertion that the notion of a 'biological agent' is limited to living organisms or 'biological materials'.[616] The BWC also applies to 'toxins',[617] which means 'artificial nonbiological materials that mimic biological effects that impair specific biological functions for malign purposes'.[618] Non-biological materials or substances that cause harmful effects to organisms are covered by the *Chemical Weapons Convention*.[619]

At the *Review Conferences* of the BWC, states parties have repeatedly affirmed that Article I BWC covers all scientific and technological developments relevant to the Convention.[620] The fourth Review Conference in 1996 concluded that the undertaking in Article I BWC also applied, *inter alia*, to applications of 'microbiology, biotechnology, genetic engineering and, any applications resulting from genome studies and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention'.[621]

The eighth Review Conference in 2017 noted that the Convention was comprehensive in its scope and covered 'all naturally or artificially created

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616 But see *Durward Johnson/James Kraska*, Some Synthetic Biology May Not Be Covered by the Biological Weapons Convention (18 May 2020), available at: https://www.lawfareblog.com/some-synthetic-biology-may-not-be-covered-biological-weapons-convention (last accessed 28 May 2022), arguing that the BWC may not apply to certain application of synthetic biology, including so-called 'biomimetics'.

617 See *Goldblat* (n. 609), 253–254, noting that: 'Toxins are poisonous products of organisms; unlike biological agents, they are inanimate and not capable of reproducing themselves. The Convention applies to all natural or artificially created toxins, "whatever their origin or method of production" (Article I). It thus covers toxins produced biologically, as well as those produced by chemical synthesis.'

618 Cf. *Johnson/Kraska* (n. 616).

619 See Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction (03 September 1992; effective 29 April 1997), 1974 UNTS 45, Article II(2), which defines a toxic chemicals as '[a]ny chemical which through its chemical action on life processes can cause death, temporary incapacitation or permanent harm to humans or animals. This includes all such chemicals, regardless of their origin or of their method of production, and regardless of whether they are produced in facilities, in munitions or elsewhere'.

620 BWC Implementation Support Unit (n. 612), paras. 13–15.

621 BWC COP, Fourth BWC Review Conference: Final Declaration (1996), UN Doc. BWC/CONF.IV/9, p. 13, Article I, para. 6.

or altered microbial and other biological agents and toxins, as well as their components, regardless of their origin and method of production and whether they affect humans, animals or plants' that have no justification in accordance with Article I BWC.[622] The Conference also expressly reaffirmed that 'Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the Convention'.[623] Notably, the ILC has cited the decisions of the BWC Review Conferences as examples of decisions embodying a 'subsequent agreement between the parties regarding the interpretation of a treaty' in the sense of Article 31(3)(a) VCLT.[624] Consequently, the notion of a biological agent under the BWC is broad and includes any types of organisms or parts thereof which are genetically modified or even synthetically produced.[625]

According to the so-called 'general purpose criterion',[626] the BWC prohibits the development, production, stockpiling etc., of biological agents and toxins 'of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes'. Hence, a party engaged in developing biological agents for which a hostile use case is plausible must present acceptable explanations that its research is justified by prophylactic, protective, or other peaceful purposes.[627]

However, it may at times be difficult to draw a clear line between research aimed at developing agents for civilian purposes (such as vaccines) and research that is not justifiable under the BWC.[628] If a military or hostile use appears more plausible than the stated peaceful purpose, mere claims of peaceful intentions may be insufficient.[629] In evidentiary terms, the wording of the prohibition as set out in the BWC does not require a claimant state to prove that a certain undertaking serves a military objective. Instead, the state engaging in the relevant conduct must substantiate

622 BWC COP, Eighth BWC Review Conference: Final Declaration (25 November 2016), UN Doc. BWC/CONF.VIII/4, p. 9, Article I, para. 1.

623 *Ibid.*, Article I, para. 2.

624 Cf. ILC, Draft Conclusions on Subsequent Agreements and Subsequent Practice in Relation to the Interpretation of Treaties, with Commentaries (2018), UN Doc. A/73/10, p. 12, Conclusion 11(2) and Commentary thereto, para. 16–18.

625 On the potential of synthetic biology to develop biological weapons, see *Alexander Kelle*, Prohibiting Chemical & Biological Weapons (2014), 37–40.

626 Cf. *ibid.*, 49.

627 See *Daniel M. Gerstein*, National Security and Arms Control in the Age of Biotechnology (2013), 87–90.

628 *Goldblat* (n. 609), 254–255; similarly *Kelle* (n. 625), 223.

629 *Silja Vöneky*, Limiting the Misuse of the Environment during Peacetime and War – The ENMOD Convention, FIP 5/2020 (2020), 14.

its claim that peaceful purposes justify its undertaking.[630] At the same time, however, there mere possibility of a 'dual use' does not *per se* give rise to a breach of the BWC.[631]

Against this background, the development of self-spreading genetic elements such as gene drives or genetically modified viruses may run the risk of being perceived as a violation of the BWC.[632] As shown above, a United States government agency funded the development of insect-delivered genetically modified viruses engineered to perform genome editing of susceptible crops in already-planted fields.[633] However, there is no clear regulatory pathway toward the use of such a technique in agriculture. In most national regulatory regimes, genetic homogeneity is a basic precondition for the authorization of releases of genetically engineered organisms; this is also an implied requirement in the rules on the transboundary movement of LMOs under the Cartagena Protocol.[634] But such homogeneity seems highly unlikely to achieve with the proposed method.[635] Nor will it be possible to confidently determine which plants have been infected by the genetically modified virus.[636] At the same time, a weaponization of the approach seems to be more realistic to achieve than the stated agricultural use.[637] For this reason, the program could be perceived as an effort to

630 See *Rüdiger Wolfrum/Mirka Möldner*, International Courts and Tribunals, Evidence, in: Wolfrum/Peters (ed.), MPEPIL, MN. 64; ICJ, Certain Activities Carried out by Nicaragua in the Border Area (Costa Rica v. Nicaragua), Compensation Owed by Nicaragua to Costa Rica, Judgment of 02 February 2018, ICJ Rep. 15, para. 147; ICJ, Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo), Merits Judgment of 30 November 2010, ICJ Rep. 639, para. 55.

631 *Vöneky* (n. 629), 15.

632 *R. Guy Reeves* et al., Agricultural Research, or a New Bioweapon System?, 362 (2018) Science 35.

633 Cf. DARPA, Broad Agency Announcement: Insect Allies: HR001117S000 (2016); see chapter 1, section D.

634 Cf. Annex I, para. h, and Annex III, para. 9(d) of the Cartagena Protocol.

635 *Reeves* et al. (n. 632), 36; also see *Samson Simon* et al., Scan the Horizon for Unprecedented Risks, 362 (2018) Science 1007, noting that the proposed application 'is beyond any risk assessment ever performed in the field of biotechnology'.

636 *Reeves* et al. (n. 632), 36.

637 *Ibid.*

develop biological agents for hostile purposes.[638] Similar concerns have been raised concerning research on engineered gene drives.[639]

II. ENMOD Convention

The *ENMOD Convention* of 1976[640] prohibits the use of environmental degradation as a weapon in armed conflict.[641] It currently has 78 states parties including China and the United States, but excluding many states in South-East Asia, Latin America, and Africa.[642]

Article I of the ENMOD Convention prohibits the military or any other hostile use of environmental modification techniques which have widespread, long-lasting or severe effects[643] as the means of destruction, damage or injury to any other state party. The term 'environmental modification technique' is defined in Article II of the Convention as

> *'any technique for changing – through the deliberate manipulation of natural processes – the dynamics, composition or structure of the Earth, including its biota, lithosphere, hydrosphere and atmosphere, or of outer space'.*

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638 *Ibid.*, 35; also see *Todd Kuiken*, DARPA's Synthetic Biology Initiatives Could Militarize the Environment: Is that Something We're Comfortable with? (28 March 2018), available at: http://www.slate.com/articles/technology/future_tense/2017/05/what_happens_if_darpa_uses_synthetic_biology_to_manipulate_mother_nature.html (last accessed 28 May 2022); *Simon* et al. (n. 635).

639 *David Gurwitz*, Gene Drives Raise Dual-Use Concerns, 345 (2014) Science 1010; *Kuiken* (n. 638); *Lim/Lim* (n. 76), 59–61.

640 Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques (10 December 1976; effective 05 October 1978), 1108 UNTS 151. For a general introduction, see *Boothby* (n. 612), 78–81; *Vöneky* (n. 629).

641 On the status of this prohibition in customary international law, see *Henckaerts/Doswald-Beck* (n. 611), 151–158.

642 UN OLA, Status of the Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques, United Nations Treaty Collection, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVI-1&chapter=26&clang=_en (last accessed 28 May 2022).

643 According to an 'understanding' attached to the ENMOD Convention, there was agreement during the negotiations that 'widespread' should be interpreted as encompassing an area on the scale of several hundred square kilometres, that 'long-lasting' should mean lasting for a period of months, or approximately a season; and that 'severe' should involve serious or significant disruption or harm to human life, natural and economic resources or other assets.

In its ordinary meaning, the term 'biota' refers to the collective animal and plant life.[644] Hence, the Convention also applies to techniques of molecular biotechnology in so far as they are deliberately used to manipulate animal and plant life in order to cause injury to another state party in armed conflict. This includes any military uses of self-spreading biotechnology, such as engineered gene drives or (potentially insect-delivered) genetically modified viruses employed to modify crop plants or other organisms to the detriment of an adversary state.[645] On the other hand, the Convention expressly provides in Article III(1) that it shall not hinder the use of environmental modification techniques for peaceful purposes in accordance with the general rules of international law concerning such use. This raises similar problems in the context of dual-use techniques as the BWC.[646]

III. International Humanitarian Law

The law of armed conflict (*ius in bello*) prohibits using the environment as a means of warfare. Under Article 35(3) of the Additional Protocol I to the Geneva Conventions,[647] it is 'prohibited to employ methods or means of warfare which are intended, or may be expected, to cause widespread, long-term and severe damage to the natural environment'.[648] Moreover, Article 55(1) prohibits the use of these means insofar as they inflict environmental damage which may prejudice the health and survival of the population.[649] The Protocol has 174 states parties, excluding, *inter alia*, India, Israel, and the United States.[650] However, the basic rule that

644 Cf. 'biota, n.', in: Oxford English Dictionary (n. 12).
645 Cf. *Lim/Lim* (n. 76), 63.
646 *Vöneky* (n. 629), 14–15; see *supra* section J.I.
647 Protocol Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflicts (Protocol I) (08 June 1977; effective 07 December 1978), 1125 UNTS 3.
648 Cf. *Boothby* (n. 612), 81–83.
649 Also see ICJ, Legality of the Threat or Use of Nuclear Weapons, Advisory Opinion of 08 July 1996, ICJ Rep. 226, para. 31.
650 Switzerland, Département fédéral des affaires étrangères, Etats parties au Protocole additionnel aux Conventions de Genève du 12 août 1949 relatif à la protection des victimes des conflits armés internationaux, available at: https://www.eda.admin.ch/dam/eda/fr/documents/aussenpolitik/voelkerrecht/geneve/1977-PROT-1_fr.pdf (last accessed 28 May 2022).

'destruction of the natural environment may not be used as a weapon' appears to be universal customary international law.[651]

IV. Conclusions

Although the BWC, the ENMOD Convention and the provisions of international humanitarian law have significant differences both in focus and scope,[652] this does not diminish their relevance in the context of self-spreading biotechnology. Under all three, the development of techniques that have no plausible peaceful use is prohibited. Moreover, the use of biotechnology as a weapon in international armed conflict is prohibited at least where the (potential) damage would be widespread, long-term and severe.

K. Summary

The present chapter has analysed the rules of international law applicable to the development, transboundary movement, and use of products of biotechnology. The analysis of the Cartagena Protocol's scope has shown that recent scientific and technological development can make it hard to determine whether these new techniques and the products they yield are covered by the existing instruments. Yet, the definition of the term 'living modified organism' is significantly wider than the respective definition in other regulatory regimes, including that under EU law.[653] Consequently, organisms modified with recently developed genome editing techniques fall within the scope of the Cartagena Protocol even when the technique employed – unlike conventional methods of genetic engineering – does not involve the insertion of foreign genetic material into the target organism.[654] At the same time, there is no doubt that the Cartagena Protocol applies to modified organisms that carry foreign genetic elements, includ-

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651 *Henckaerts/Doswald-Beck* (n. 611), 155–156.

652 See *Eric T. Jensen*, The International Law Environmental Warfare: Active and of Passive Damage During Armed Conflict, 38 (2005) Vanderbilt Journal of Transnational Law 145, 165–177; *Waldemar A. Solf*, Article 55 AP I, in: Michael Bothe/Karl J. Partsch/Waldemar A. Solf (eds.), New Rules for Victims of Armed Conflicts (2013), para. 2.6.

653 See *supra* section A.I.1 and A.IV.3.

654 See *supra* section A.I.1.e)aa).

ing, in particular, engineered or synthetic gene drives.[655] In order not to have to return to this discussion for each of the instruments analysed subsequently, their applicability was presumed and not discussed individually. Yet, where these instruments become practically relevant, answering the question of applicability will be not only inevitable but also difficult, as many instruments lack clear definitions of what they refer to as LMOs or GMOs.

The purpose of the Cartagena Protocol is to ensure that each party can take sovereign decisions on whether to allow the import and environmental release of LMOs in its territory. This is achieved by a comprehensive procedural framework for obtaining the so-called *Advance Informed Agreement* of the receiving state.[656] A significant challenge to the effectiveness of the AIA mechanism is the fact that its applicability depends on the (stated) intentions about whether or not an LMO will be released into the environment once it has been imported into the receiving state.[657] At the same time, the design of the AIA mechanism also reflects the fact that there is no consensus within the international community on whether techniques of genetic engineering should generally be seen as posing threats to biological diversity, human health etc.[658] Against this background, it is not surprising that the Cartagena Protocol's provisions on risk management and preparedness remain comparatively vague.[659] States are required to act with due diligence to prevent unintentional[660] or illegal[661] transboundary movements of LMOs but are largely free to decide how to regulate the development and use of LMOs in their own territory.[662] Yet, states are required to cooperate, especially in sharing information about potential hazards originating from LMOs.[663]

A notable exception is Article 25(2), which arguably imposes a strict obligation on the state of origin to dispose of an LMO illegally imported into another state. As the lawfulness of the import depends on whether

655 See *supra* section A.I.1.e)bb) and cc).
656 See *supra* section A.II.1.
657 See *supra* section A.II.1.g).
658 Cf. *Mackenzie/Sands* (n. 170), 466. Interestingly, applications of the same techniques in human medicine seem to be much less controversial, and gene therapy applications appear to be only marginally addressed by international law.
659 See *supra* section A.II.2. Also see *Hill* (n. 153).
660 See *supra* section A.II.2.a)cc).
661 See *supra* section A.II.2.c).
662 See *supra* sections A.II.2.a) et seq.
663 See *supra* sections A.II.3 et seq.

the AIA mechanism, as well as the domestic laws of the receiving state, have been observed, this obligation is independent of any wrongdoing on the part of the state of origin. However, it remains questionable how this obligation can be implemented, especially when a (potentially self-spreading) LMO has already been released into the environment of the receiving state.[664]

Moreover, the freedom of each state to make its own decisions about whether to allow the import of LMOs into its territory may be considerably limited by international trade law, which provides that any restriction on international trade for the purpose of protecting the environment or human health must be based on scientific evidence about the risks that are to be averted.[665] In contrast to the Cartagena Protocol, states are not allowed to invoke scientific uncertainty about risks as a reason to restrict trade, but only insufficient scientific information that prevents a scientifically sound risk assessment altogether.[666] The WTO's dispute settlement mechanism, which is compulsory for all WTO member states, has yet to find a coherent approach on how to integrate WTO law into the wider body of international law.[667]

Besides the Cartagena Protocol, the provisions on biotechnology contained in the Convention on Biological Diversity remain relevant, particularly with regard to those states which have not ratified the Cartagena Protocol. At the same time, many of the obligations stipulated by the CBD are broad and unspecific, which makes it difficult to assess compliance. However, programmes aimed at completely eradicating a species within its native habitat range may be in breach of the CBD and thus be prohibited by international law altogether.[668] Moreover, the CBD and several other instruments address the risk of invasive species and it appears to be widely recognized that LMOs which may become invasive are covered by those provisions.[669] This is particularly relevant in the context of organisms equipped with self-spreading genetic elements, such as engineered gene drives or genetically modified viruses. There seems to be a universal consensus that states are obliged to prevent the spread of invasive species.

664 See *supra* section A.II.2.c)bb).
665 See *supra* section C.I.
666 See *supra* sections C.II.
667 See *supra* sections C.III.
668 See *supra* section B.
669 See *supra* sections B.V, C, E, and G.

Despite the widespread and persisting disagreement about whether LMOs are – as such and inherently – hazardous, the international treaties concerned with plant[670] and animal[671] health, food safety,[672] and international transport of hazardous goods[673] recognize that LMOs (or GMOs) may indeed pose certain risks. Yet, these instruments take a more pragmatic approach than the Cartagena Protocol by providing specific guidance on how to assess potential risks of LMOs in their specific context and on how to handle LMOs in ways that minimize these risks.

When a modified organism or pathogen causes a transmissible disease in humans, the WHO's International Health Regulations come into play. They require the state where the outbreak occurs to speedily inform the WHO, which can then issue recommendations to the affected states on how to mitigate the outbreak, and to non-affected states on how to prevent an international spread. However, the recent experience of the COVID-19 pandemic has shown that states may be reluctant to make early notifications to avert travel and trade restrictions, while non-affected states tend to implement the WHO's recommendations inconsistently.[674]

Finally, biotechnology may not necessarily be used for peaceful purposes. Fortunately, the pertinent instruments on biological weapons,[675] environmental modification techniques,[676] and international humanitarian law[677] provide rules which are broad enough to also cover more recent developments in biotechnology. Yet, ensuring compliance with these provisions remains a major challenge.

Challenges are also posed by the fact that the existing framework of international treaties and instruments may be insufficient to ensure that products of biotechnology do not cause adverse transboundary effects. As shown in the first chapter, the increasing development of self-spreading biotechnology, including engineered gene drives and modified viruses, have a high likelihood of spreading across political borders either through natural gene flow or (deliberately or inadvertently) transported by humans.[678] Although the obligation to prevent unintentional transboundary

670 See *supra* section D.
671 See *supra* section E.
672 See *supra* section F.
673 See *supra* section H.
674 See supra section I.
675 See *supra* section J.I.
676 See *supra* section J.II.
677 See *supra* section J.III.
678 See chapter 1, section C.IV.4.

movements is recognized in the Cartagena Protocol, the practical effectiveness of this obligation appears to be limited.[679] Moreover, a major shortcoming of the Cartagena Protocol is that it lacks participation by several 'key players' in the field of biotechnology, including the United States. This raises the question of whether the rules of universal customary international law on the prevention of transboundary environmental interference, which are analysed in the following chapter,[680] can fill these gaps. Subsequently, the debate on engineered gene drives is assessed as a current example of the difficulties involved in regulating emerging techniques that may have transboundary effects.[681]

679 See *supra* section A.II.2.a)cc).
680 See chapter 3.
681 See chapter 4.