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The 2010 Nagoya-Kuala Lumpur Supplementary Protocol: A New Treaty Assigning Transboundary Liability and Redress for Biodiversity Damage Caused by Genetically Modified Organisms

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Introduction

Conceptually and legally, living modified organisms (LMOs)^[1] make both environmentalists and policy makers nervous.^[2] While generations of humans have been selectively breeding crops and livestock, it is only recently that humans have been able to genetically modify species on a gene-by-gene basis. Scientists

and civil society express concern regarding the unknown risks associated with the recent large-scale introduction of LMOs^[3] including, for example, the outcompeting of native heritage corn species in Mexico by self-replicating American corn seed^[4] or the unintended consequences for the ecosystem of introducing transgenic mosquitoes engineered to replace existing mosquitoes who carry malaria and dengue fever.^[5]

Proponents of biotech transfer argue that developing and distributing LMOs in transboundary trade is not inherently environmentally harmful but in fact may produce positive externalities for the environment.^[6] Proponents also champion LMOs as alleviating strains on fragile ecosystems by reducing the amount of land necessary for farming through increased crop yields.

It is in response to this debate that the international community has negotiated a combination of binding legal and procedural safeguards in the Nagoya-Kuala Lumpur Supplementary Protocol.^[7] This multilateral environmental treaty approved by 116 States was the culmination of almost ten years of negotiation. Not all stakeholders were satisfied with the negotiated outcome. What had started out as an opportunity to create new legally binding international rules had largely become a text allowing Parties to address LMO damage through existing civil liability systems or through newly developed civil liability mechanisms.

Context for the Nagoya-Kuala Lumpur Supplementary Protocol

The Cartagena Protocol,^[8] negotiated under Article 19 of the Convention on Biological Diversity,^[9] focused on “safe transfer, handling and use of any

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living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.” While the Cartagena Protocol was negotiated to bridge the gap between economic priorities of the biotech industries and environmental concerns of States,^[10] the Nagoya-Kuala Lumpur Supplementary Protocol is intended to bridge the gap between the economic priorities of industry and the concern of States to hold biotech companies accountable for damage caused by the intentional or accidental introduction of living modified organisms into the environment.

Drafters of the Cartagena Protocol introduced procedures for certain categories of LMOs requiring “Advanced Informed Agreements” between States and foreign biotech corporations. As negotiated, these agreements require exporters of LMOs to inform importing countries of their intent to ship and to wait until they have received authorization to make the shipments.^[11] However, not every biotech corporation is required to enter into these agreements. They are not mandated by the Cartagena Protocol when a LMO is not “likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.” Instead exporters can simply inform States of their intent to introduce into the market a given LMO through the Biosafety Clearinghouse. Explicit exceptions have also been made to the prior informed consent procedure for LMOs “intended for direct use as food or feed, or for processing.”^[12] Under the Cartagena Protocol, States have the right to exercise the precautionary approach and decline the importation of a LMO product especially where there are prevailing “socio-economic considerations . . . especially with regard to the value of biological diversity to indigenous and local communities.”^[13]

Even when States exercise the precautionary approach, States may err. The Cartagena Protocol, in Article 27, recognized that the international legal regime for LMOs may result in damage to a State’s biodiversity. Article 27 provided that States would create a process for “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.” The process was initiated in 2004 with the creation by the Conference of Parties to the Protocol of an Open-ended Ad Hoc Working Group of Legal and Technical Experts.^[14]

Content of the Nagoya-Kuala Lumpur Supplementary Protocol

Parties negotiated and adopted, on October 15, 2010,^[15] the Nagoya-Kuala Lumpur Supplementary Protocol to harmonize the international legal principles applicable to environmental and human health risk from living modified organisms. As an extension of the Cartagena Protocol, the Supplementary Protocol builds on existing international environmental law principles. In particular, the preamble of the Supplementary Protocol makes reference to Principle 13 of the Rio Declaration urging States to both “develop national law regarding liability and compensation for the victims of . . . other environmental damage” and “to develop further international law regarding liability and compensation for adverse effects of environmental damage caused by activities within their jurisdiction or control to areas beyond their

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jurisdiction.”^[16] The Supplementary Protocol also reiterates the commitment to the precautionary approach as articulated in Principle 15 of the Rio Declaration and the preamble of the Cartagena Protocol.

For the purposes of the Supplementary Protocol, a party bringing a claim for liability or redress must demonstrate that: 1) there has been an adverse effect on conservation or sustainable use of biological diversity or risks to human health; 2) the effect is measurable or observable for the purposes of attribution of impacts; and 3) the adverse effect is significant.^[17]

The key actors who may potentially trigger a claim under the Supplementary Protocol are the “operators” who include any person in “direct or indirect control” of an LMO. Just as the International Convention on Civil Liability for Compensation for Oil Pollution Damage was negotiated to apply to private actors,^[18] the term “owner” in the Supplementary Protocol was defined broadly to include non-state actors, including any group in the chain of custody of LMOs.^[19]

A major source of contention was whether the text would cover not just LMOs but “products thereof” (such as tofu produced from transgenic soybeans). Some States argued that the language “products thereof” would expand the Supplementary Protocol beyond the scope of the Cartagena Protocol. The language was ultimately removed from the text, but the Parties agreed that States could apply the Supplementary Protocol to damage caused by processed materials from LMOs as long as a causal link is established.^[20] Applying domestic law on causation, a claimant must demonstrate a causal link between the claimed damage and the introduction of an LMO across a boundary.^[21]

Where there is a damage claim ripe for adjudication, claimants may be entitled to “response measures,” including measures to “prevent, minimize, contain, mitigate, or otherwise avoid damage” as well as actions to restore biological diversity either “to the condition that existed before the damage occurred or its nearest equivalent.”^[22] When *in situ* restoration is impossible, operators are expected to replace biological diversity with species and genetic material that is functionally similar either at the place where the damage occurred or “as appropriate, at an alternative location.”^[23]

The requirement in Article 5 for States to design a domestic legal framework to provide “response measures” to address transboundary environmental damage by LMOs is the primary new contribution of the Supplementary Protocol. To address concerns that the “competent authority” could exercise unjust *ultra vires* powers over private operators, the negotiating Parties agreed that operators must have access to administrative or judicial review of response measures under domestic law.^[24]

While some stakeholders in the negotiating process argued for specific international regulations to be negotiated within the Supplementary Protocol, the document as adopted clarifies that there are no internationally agreed upon substantive rules or regulations on the transboundary transfer of LMOs. Rather, Parties will defer to the wisdom and capacity of States operating under

their domestic law. For example, many States and civil society stakeholder groups argued for financial guarantees, such as mandatory insurance for operators, or a fund. These proposals were in keeping with the international framework for liability for oil pollution found in the International Convention on the Establishment of an International Fund for Oil Pollution Damage.^[25] These efforts to seek internationally based financial security for the movement of any LMOs ultimately were defeated because of concerns by industry that these mechanisms would result in higher prices for genetically modified crops and animals. Instead, States were given the option of whether to require financial security through their domestic law.^[26]

In nearly a decade of negotiations leading up to the Supplementary Protocol, several developing States, working in conjunction with environmental and human health non-governmental organizations, failed to prevail on a single standard of strict liability for damage caused by transboundary movements of LMOs. These groups hoped that strict liability would be imposed as the international liability standard in light of the strict liability standards provided under a number of treaties involving hazardous activities, including nuclear energy treaties,^[27] outer space treaties,^[28] marine treaties,^[29] and hazardous waste treaties.^[30] The regional Lugano Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment imposes strict liability, including liability for damage caused by living modified organisms.^[31] While there was State and public interest in setting a strict liability standard for transboundary harm caused by LMOs, the issue was dropped in the final negotiations.^[32]

The expectations for collective State action to reduce damage from LMOs are minimal. Instead, the Supplementary Protocol chiefly requires States to “provide, in their domestic law, for rules and procedures that address damage” by providing “response measures” either from their existing civil liability law or through new law.^[33] It was agreed that new civil liability laws to address transboundary LMOs should include “as appropriate” damage, standards of liability, channeling of liability, and standing concerns.^[34]

What the specialized LMO civil liability regimes will look like remains unknown. While draft guidelines on civil liability and redress had been circulated to Protocol members in hopes of providing models for States without any liability regime for LMOs, all references to these draft guidelines were removed from the adopted text.^[35]

The Supplementary Protocol provides a wide berth for States to internally negotiate which liability and redress portions of the Supplementary Protocol will be translated into domestic law. Article 6 provides States with the blanket exception that Parties “may provide, in their domestic law, for any other exemptions or mitigations as they may deem fit.” This opens up the possibility that non-State Parties engaged in trade in LMOs could put pressure on Parties to make exemptions in their domestic law regarding, for example, specific LMOs subject to the Supplementary Protocol. This section may have been politically necessary because the Supplementary Protocol does not allow for any treaty reservations.^[36]

Like the Cartagena Protocol, the Secretariat for the Convention on Biological Diversity in Montreal, Canada will administer the Supplementary Protocol.[\[37\]](#) The Supplementary Protocol will be open for signature at the UN Headquarters from March 7, 2011, to March 6, 2012,[\[38\]](#) and will go into effect after the fortieth ratification.[\[39\]](#)

Conclusion: Challenges Ahead for the Supplementary Protocol

As with the Cartagena Protocol, many of the same key biotech-promoting States who did not sign the Protocol will not be signatories to the Supplementary Protocol.[\[40\]](#)

Biologically diverse States, without large biotech operations and current signatories to the Cartagena Protocol, will likely sign the Supplementary Protocol. This augurs well for creating a fledgling set of universal legal standards for liability and redress for actors involved in the creation, distribution, and the transfer of LMOs. If the 160 Parties to the Cartagena Protocol ratify the Supplementary Protocol, they may create adequate political and legal pressure to require non-Parties to demonstrate that they are prepared to hold their “operators” accountable for damage caused by LMOs. Ratification by a majority of States would send a clear message that it is internationally unacceptable for any State to cause “significant” adverse environmental effects by trading in LMOs without proper risk management and assessment.

For the time being, however, the failure to attract ratifications from major biotech producing States raises questions about the legitimacy of the Supplementary Protocol as a tool for ensuring appropriate liability and redress for ecological damage and impacts on human health. As noted in the Conference of Parties Decision BS-V/11, the private sector has undertaken some initiatives to ensure recourse in the event of environmental damage caused by LMOs.[\[41\]](#) Some argue that it was the leadership from the private biotech sector, by agreeing to subject its industry to civil liability to ensure a generally liberalized market in LMOs, that made it possible for States to accept the current draft of the Supplementary Protocol. In 2010, BASF, Bayer CropScience, Dow AgroSciences, DuPont, Monsanto, and Syngenta signed “The Compact: A Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by the Release of a Living Modified Organism.”[\[42\]](#) As members to the Compact, these companies agreed to binding arbitration under the auspices of the Permanent Court of Arbitration if a company has released an LMO that is alleged to have caused damage to biological diversity. As corporate leaders, these companies indicated that they expect Compact members to be properly insured to absorb potential financial losses.

Interestingly enough, the Compact, in contrast to the Supplementary Protocol, provided for specifically elaborated legal standards[\[43\]](#) and an industry contract to limit the parties’ liability.[\[44\]](#) Similarly, where the Supplementary Protocol requires a response for damage arising from both intentional and unintentional transboundary movements,[\[45\]](#) the Compact members limited

member liability for transboundary movements of LMOs to misuses.^[46] Likewise, where the Supplementary Protocol provides an open-ended definition for “significant” adverse effects, the Compact specifically limited compensable environmental damage.^[47] Notably, the Compact, unlike the Supplementary Protocol, does not explicitly address adverse effects on human health.

Time will tell whether the legal framework for liability and redress for damage caused by LMOs will be governed primarily by public actors concerned with preserving both biodiversity and sovereignty or largely by private multinational actors concerned with preserving open markets. In the meantime, the international community must hope that the Supplementary Protocol is just a precautionary extension of the legal principles of risk management and assessment embodied in the Cartagena Protocol and that future generations will not need to invoke any of the Supplementary Protocol’s operative measures.

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ENDNOTES

[1] Living modified organisms include what are popularly labeled Genetically Modified Organisms and refer to transgenic plant, animal, and viral organisms that are able to self-replicate. Transgenic organisms are any organisms where one gene or several genes have been deliberately selected from a donor organism and transferred to a recipient organism. Example of transgenic organisms range from the “FlavrSavr” tomato, *Bacillus thuringiensis* (*Bt*) cotton, to transgenic salmon. *See also* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 (the term “Living modified organism” is broadly defined as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.” *Id.* art. 3(g). Modern biotechnology refers to “in vitro nucleic acid techniques . . . [and] 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.” *Id.* art. 3(i).

[2] *See* Martina Newell-McGloughlin, *Overview of Current Commercial Applications, LMOs and the Environment: Proceedings of an International Conference*, 30 (Organisation of Economic Cooperation and Development, 2002) (citing Horticulturalist Luther Burbank, who said “We have recently advanced our knowledge of genetics to the point where we can manipulate life in a way never intended by nature. We must proceed with the utmost caution in the application of this newfound knowledge.”).

[3] Hazards identified with the introduction of LMOs include displacement of endemic threatened biodiversity, changes in pathogenicity of species, adverse effects on larger ecosystems, and changes in environmental tolerances leading to the geographical spread of LMOs. *See, e.g.*, Food and Agriculture

Organization/International Atomic Energy Agency, *Status and Risk Assessment of the Use of Transgenic Arthropods in Plant Protection*, IAEA-TECDOC-1483 (Mar. 2006).

[4] Commission for Environmental Cooperation, *Independent Secretariat Report, Maize and Biodiversity: The Effects of Transgenic Maize in Mexico: Key Findings and Recommendations* (2004), available at www.cec.org/maize.

[5] Katherine Nightingale, *GM Mosquito Wild Release Takes Campaigners By Surprise*, SciDEV NET (Nov. 11, 2010), <http://www.scidev.net/en/news/gm-mosquito-wild-release-takes-campaigners-by-surprise.html> (reporting that Cayman Island released genetically modified mosquitoes in 2009); Shioh Chin Tan, *Malaysia to Release GM Mosquitoes Into the Wild*, SciDEV NET (Nov. 2, 2010), <http://www.scidev.net/en/news/malaysia-to-release-gm-mosquitoes-into-the-wild.html> (reporting that Malaysia intends to release genetically modified male mosquitoes into their environment to combat dengue fever).

[6] For example, proponents of LMO trade cite the genetic introduction of an enzyme into a plant breed used for animal feed which renders unnecessary the practice of supplementing livestock diets with large quantities of phosphate to ensure adequate levels of phosphorous. This ability to specifically manipulate plant stocks so that livestock no longer need additional mineral supplementation combats the eutrophication problems caused by excessive phosphorous in animal waste. See Newell-McGloughlin, *supra* note 2, at 34.

[7] Nagoya-Kuala Lumpur Supplementary Protocol, Oct.15, 2010, UNEP/CBD/BS/COP-5/17, Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, Decision BS-V/11, 62-71, available at <http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-17-en.pdf> or http://bch.cbd.int/protocol/NKL_decision.shtml [hereinafter Supplementary Protocol].

[8] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *supra* note 1 (currently 160 parties have signed the Protocol. Notable non-parties include the United States, Canada, Russia, Australia, and South Korea).

[9] Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 (1992).

[10] *Id.* art. 1.

[11] The concept behind the prior and informed consent procedure was to give States a substantive opportunity to decide whether to import a LMO and to impose necessary national safeguards and conditions on importation.

[12] *Id.* art. 7(2).

[13] *Id.* art. 26.

[14] Decision BS-I/8 (Feb. 2004), *available at* <http://www.cbd.int/decision/mop/?id=8290>.

[15] Supplementary Protocol, *supra* note 7. Conference of Parties, Decision BS-V/11, *supra* note 7.

[16] Rio Declaration on Environment and Development, June 13, 1992, 31 I.L.M. 874 (1992).

[17] Supplementary Protocol, *supra* note 7, art. 2(2)(b). There is no single definition for what constitutes a “significant” adverse effect. Rather, Parties are expected to rely on an array of factors including whether the change is long-term or permanent (i.e. cannot be redressed within a reasonable period of time by natural recovery), whether there are certain types of qualitative or quantitative changes, whether there is interference with the delivery of ecosystem goods and services, and whether there are negative impacts on human health. *Id.* art. 2(3).

[18] International Convention on Civil Liability for Oil Pollution Damage, Nov. 29, 1969, 973 U.N.T.S. 3.

[19] Thus, the market distributor, the scientific developer, and the transporter of the LMO are within the meaning of the term “owner.”

[20] UNEP/CBD/BS/COP-MOP/5/17, Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, 21, ¶ 133 (Nov. 29, 2010) (“It was noted that it had emerged during the negotiations of the Supplementary Protocol that Parties to the Protocol hold different understandings of the application of Article 27 of the Protocol to processed materials that are of living modified organism-origin. One such understanding is that Parties may apply the Supplementary Protocol to damage caused by such processed materials, provided that a causal link is established between the damage and the living modified organism in question.”).

[21] *Id.* art. 4. For the purposes of assessing liability, it does not matter whether the LMO has been intentionally introduced, accidentally released, or even illegally traded. Where damage is identified, operators must immediately inform the “competent authority” (an administrative agency vested with authority by each State), evaluate the extent of the damage, and implement “response measures.” *Id.* art. 5(1). Concurrently, States, through their designated “competent authority,” must identify the “operator” causing the damage, evaluate damage, and determine which “response measures” must be implemented. *Id.* art. 5(2). Where an “operator” fails to act, the “competent authority” may be empowered to implement “response measures” to redress the damages.

[22] Supplementary Protocol, *supra* note 7, art. 2(2)(d).

[23] *Id.* art. 2(2)(d)(ii)(b).

[24] *Id.* art. 5(6).

[25] International Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage, Dec. 18, 1971, 10 I.L.M. 137 (1971) (entered into force Oct. 16, 1978).

[26] *Id.* art. 10.

[27] Paris Convention on Third Party Liability in the Field of Nuclear Energy, 55 AM. J. INT'L L. 1082 (1961); Vienna Convention on Civil Liability for Nuclear Damage, 2 I.L.M. 727 (1963). (Liability is exclusive to the operators of the nuclear installations strict; operator must maintain insurance or some other financial security).

[28] Convention on International Liability for Damage Caused by Space Objects, *opened for signature* Mar. 29, 1972, 24 U.S.T. 2389 (Article II provides that a launching State is absolutely liable to pay compensation for damage caused by its space object on the surface of the earth or to aircraft in flight.); Convention on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and other Celestial Bodies, Jan. 27, 1967, 18 U.S.T. 2410 (Article VII adds that each State that launches or procures the launching of an object into space and each State from whose territory or facility an object is launched, is liable to another State or to its natural or juridical persons for harm caused by such object, or its component parts, on the Earth).

[29] 1969 International Convention on Civil Liability for Oil Pollution; 1976 International Convention on Civil Liability for Oil Pollution Damage Resulting from the Exploration for or Exploitation of Seabed Mineral Resources; 1996 International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea; and 2001 International Convention on Civil Liability for Bunker Oil Pollution Damage.

[30] Basel Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and their Disposal, Dec.10,1999 U.N. Doc. UNEP/CHW.1/WG/1/9/2 (imposes strict liability on, first, the person who provides notification of a proposed transboundary movement and then on any disposer of the waste. Parties who are potentially liable are required to carry insurance).

[31] Lugano Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, June 21, 1993, 32 I.L.M. 1228 (1993) (allows defendants to avoid strict liability where they can show that the state of scientific and technical knowledge at the time of the incident was insufficient to indicate the dangerous properties of the substance or the organism). No

parties have ratified this convention since it was adopted in 1993. See Council of Europe Treaty Signatory Page, *available at* <http://conventions.coe.int>.

[32] States have refused to ratify recent treaties with strict liability standards including the Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, the Basel Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal, and the Lugano Convention.

[33] Supplementary Protocol, *supra* note 7, art. 12(1).

[34] *Id.* art. 12(3).

[35] In her contribution to the report, Jimena Nieto, as Co-Chair of the Group of Friends on Liability and Redress, commented that future meetings could resume discussion of these draft guidelines. See Report of the Fifth Meeting of the Conference of the Parties, *supra* note 7, at 21, ¶ 129.

[36] Supplementary Protocol, *supra* note 7, art. 19.

[37] *Id.* art. 15.

[38] *Id.* art. 17.

[39] *Id.* art. 18.

[40] States, such as the United States and Canada who remain non-parties to the Cartagena Protocol, will also remain outside of the internationally negotiated biosafety liability and redress frameworks and will have no internationally recognized obligation to require U.S. based or Canadian based companies to undertake damage evaluations or implement “response measures.”

[41] Decision BS-V/11, *supra* note 7, pmb1.

[42] The Compact: A Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by the Release of a Living Modified Organism (May 17, 2010), *available at* <http://www.croplife.org/Files/Upload/Docs/Compact%20-%20Execution%20Text%20-%20PUBLIC%20-%2017%20May%202010.pdf> [hereinafter Compact].

[43] *Id.* art. 3.5.

[44] For example, causation was defined as “Cause-in-fact and proximate Cause,” and a compensable claim requires a demonstration of general causation, specific causation (damage would not have occurred *but for* the release of the LMO), and proof that “there is no superseding event or logically

unrelated or remote event that alters the chain of events that otherwise might have connected the Release of that LMO to the Damage to Biological Diversity.” *Id.* art. 2.4(x). The Compact members negotiated “clear and convincing evidence” as the standard of proof and defined it to mean that “measure or degree of proof that will produce in the mind of the decision maker a firm belief or conviction as to the truth of the allegations sought to be established.” *Id.* art. 2.4 (xlix).

[45] Under the Compact, financial limits for a single incident were capped at \$30 million Special Drawing Rights (SDR) for remediation and \$15 million SDR for compensation. For a given LMO, limits were capped at \$150 million SDR for remediation and \$75 SDR for compensation. *Id.* art. 13.

[46] Supplementary Protocol, *supra* note 7, art. 3.

[47] Compact, *supra* note 42, art. 2.4 (xli); art. 10. The Compact specifically limits environmental damages to effects on species indicating that a species is no longer viable, reduction of the natural range of species to an unsustainable level, elimination of a habitat to maintain a species on a long-term basis; or impacts on the viability of one or more other species in the affected ecosystem. *Id.* art. 8.