

The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified Organisms

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On January 29, 2000, the Parties to the Convention on Biological Diversity (CBD)¹ adopted a Protocol to the Convention, to address risks associated with trade in genetically-modified organisms (GMOs), including genetically-modified agricultural seeds and commodities. The Cartagena Protocol on Biosafety

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1. Convention on Biological Diversity, U.N. Conference on Environment and Development, June 5, 1992, U.N. Doc. UNEP/Bio.Div/N7-INC.S/4, *reprinted in* 31 I.L.M. 818 [hereinafter CBD].

establishes an international regime primarily aimed at regulating trade in GMOs intended for release into the environment (e.g., seeds for planting). The Protocol also imposes certain information-sharing requirements for GMOs shipped in bulk as commodities for use as human food or animal feed, or in processed goods.² The Protocol brought to a close more than three years of contentious negotiations. If implemented, the Protocol will establish a new global legal regime governing world agricultural trade. The Protocol will likely provide a baseline of legal controls on the import and export of GMOs that will be translated into national legal regimes in a number of developed and developing countries. The Protocol is already serving as a source of international precedents for future multilateral environmental agreements addressing trade, risk assessment, and risk management.

I. INTRODUCTION

A. THE INTERNATIONAL CONTEXT FOR BIOSAFETY NEGOTIATIONS

Commercialized transgenic crops were first planted in the United States in 1995.³ Since that time, commercial planting of transgenic crops has increased dramatically in the United States. Some 70 million acres of transgenic crops were grown in the United States in 1999.⁴ The global area of GMO crop plantings increased by 44% to 39.9 million hectares in 1999.⁵ U.S. plantings of genetically modified (GMO) crops accounted for 72% of this acreage in 1999.⁶ However, other developed and developing countries, such as Argentina, Australia, Canada, the People's Republic of China, and South Africa, have

2. Cartagena Protocol on Biosafety to the Convention Biological Diversity, Feb. 23, 2000 (visited Apr. 18, 2000) <<http://www.biodiv.org/biosafe/BIOSAFETY-PROTOCOL.htm>> [hereinafter Cartagena Protocol].

3. COMMITTEE ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION xi (2000) [hereinafter NATIONAL RESEARCH COUNCIL STUDY].

4. According to the National Research Council, approximately 30 million acres in the United States were planted with transgenic pest-protected crop varieties that contained the bacillus thuringiensis (Bt) gene and with varieties that were genetically modified to be herbicide-tolerant. *See id.* The National Research Council estimates that 25% of the U.S. cotton acreage and 21% of the U.S. corn acreage were planted with varieties containing Bt genes in 1998. *See id.*

5. *See* Clive James, Global Status of GM Crops and Their Contribution to Food Security and a More Sustainable Agriculture; The Role of Public-Private Sector Partnership in Biotechnology Transfer Systems, Keynote Presentation at the China Agriculture & Food Biotechnology Conference at 1 (Apr. 4-5, 2000) [hereinafter Clive Study].

6. *See id.* at 2.

contributed significantly to the global distribution of commercialized GMO crops.⁷

Soybean, corn/maize, cotton, and canola/rapeseed accounted for most of the transgenic crop plantings in 1999.⁸ Transgenic potato, squash, and papaya also were commercially planted in 1999 but represented less than one percent of the global area planted in GMO crops.⁹ Despite consumer concerns (particularly in Europe) and related uncertainties in the commodities markets for GMO commodities, planting of transgenic crops has continued to expand in the United States and elsewhere. This is due largely to the benefits that transgenic crops deliver to farmers by providing more effective pest control and lower costs.¹⁰

The Biosafety Protocol negotiations represent the first attempt by governments to agree upon a *binding* global regime addressing risks associated with biotechnology in a manner conducive to its productive development and use. The Protocol does not, however, represent the first (nor the last) effort by the international community to address biosafety issues.

At the 1992 United Nations Conference on Environment and Development in Rio de Janeiro (Rio Summit), over one hundred governments adopted Agenda 21: Earth's Action Plan, a non-binding agenda for the international community to address a wide array of environmental and developmental issues well into the twenty-first century, including the environmentally sound management of biotechnology.¹¹ Chapter 16 of Agenda 21 recognizes the promise of biotechnology for agriculture, health care, and the environment and calls upon the international community to ensure that biotechnology is developed and applied in an ecologically sound manner that will promote development on a global basis.¹² In December 1995, a group of government-selected experts (the Global Consultation of Government-Designated Experts) adopted the most recent edition of the United Nations Environment Programme's International Technical Guidelines for Safety in Biotechnology (UNEP Technical Guidelines).¹³ The UNEP Technical Guidelines are intended to contribute to the implementation of

7. *See id.* at 2, 21. Other countries planting GMO crops in 1999 included France, Mexico, Portugal, Romania, Spain, and Ukraine. *See id.*

8. *See id.*

9. *See id.* at 2, 21.

10. *See* NATIONAL RESEARCH COUNCIL STUDY, *supra* note 3, at xi. Development of genetically modified animals is also underway. Animals modified to increase growth and nutritional value, or to serve as living "factories" for pharmaceutical products are being developed and may soon come to market. *See* Carol Kaesuk Yoon, *Altered Salmon Lead the Way to the Dinner Plate, But Rules Lag*, N.Y. TIMES, May 1, 2000, at A1; Carol Kaesuk Yoon, *If It Walks and Moos Like a Cow, It's a Pharmaceutical Factory*, N.Y. TIMES, May 1, 2000, at A20.

11. *Report of the U.N. Conference on Environment and Development*, Agenda 21, U.N. Doc. A/CONF.151/21 (1992).

12. *See id.* ch. 16.

13. United Nations Environment Programme, *International Technical Guidelines for Safety in Biotechnology* (Dec. 1995) (visited Apr. 18, 2000) <<http://www.unep.org/unep/program/natres/biodiv/irb/unepgds.htm>>.

Agenda 21. These Guidelines recommend approaches for risk assessment and management for biotechnology, as well as for capacity building and public participation, to address human health and environmental safety considerations relating to all types of applications of biotechnology.

In addition, many of the world's leading economies have already made attempts to address biosafety at the national level by establishing regulatory regimes to evaluate GMOs for environmental safety purposes and determine whether to permit their use, importation, and release into the environment. Typically, these national programs regulate the development, field-testing, and commercialization of GMOs. Many developing countries, however, do not yet have biosafety regimes in place to evaluate GMOs before their introduction into the ecosystems that exist in their countries.

B. MANDATE AND NEGOTIATION HISTORY FOR THE BIOSAFETY PROTOCOL

The CBD, adopted on May 22, 1992, entered into force on December 29, 1993. As of February 14, 2000, 177 governments are Parties to the CBD.¹⁴ The principal aims of the CBD are the conservation and the equitable and sustainable use of biological diversity. The United States has signed the Convention, manifesting its intent to become a Party, but the Senate has not yet provided its consent to ratification. Despite its non-party status, the United States actively participated in the Biosafety Protocol negotiations. Article 19(3) of the CBD calls upon Parties to the CBD to consider the need for and content of a protocol to the CBD to address the safe transfer, handling, and use of living modified organisms derived from modern biotechnology "that may have adverse effect on the conservation and sustainable use of biological diversity."¹⁵ Pursuant to Article 19(3), the Conference of the Parties (COP) to the CBD, at its first meeting (COP-1), established an Open-Ended Ad Hoc Group of Experts to consider the need for a protocol.¹⁶

On the basis of the final report and recommendations of that expert group, the COP decided at its second meeting (COP-2) to establish a working group to prepare a draft protocol.¹⁷ COP-2 took place in Jakarta, Indonesia, in November 1995. Decision II/5 (the Jakarta Mandate) initiated the negotiation process to develop a protocol to address the safe transfer, handling, and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity.¹⁸ The Protocol was to focus on the transboundary movement of such

14. *Convention on Biological Diversity, Ratification Status* (visited Mar. 21, 2000) <<http://www.biodiv.org/conv/background.html>>.

15. See CBD, *supra* note 1, art. 19(3).

16. See Decision I/9 in *Report of the First Meeting of the Conference of the Parties to the Convention on Biological Diversity* at 66, U.N. Doc. UNEP/CBD/COP/1/17 (1995).

17. See Decision II/5 in *Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity* at 47-48, U.N. Doc. UNEP/CBD/COP/2/19 (1995).

18. See *id.*

GMOs and set out a procedure for advanced informed agreement (AIA) for their importation. The Decision also established the Open-Ended Ad Hoc Working Group (also called the Biosafety Working Group, or BSWG) to undertake these negotiations, and called upon the BSWG to complete the draft text by the end of 1998 if possible. Relying upon the report of the Open-Ended Ad Hoc Group of Experts, the COP asked the BSWG to develop a protocol that would fall within the scope of the Convention; take into account the “precautionary principle” in addressing the risks of GMOs; and seek to minimize unnecessary negative impacts on biotechnology. The COP stipulated that the BSWG rely upon the best available science for this work and proceed in a manner conducive to attracting the largest number of ratifications possible.¹⁹

The BSWG met a total of six times, beginning in July 1996, and concluded its work in February 1999 at its sixth meeting (BSWG-6). Over one hundred governments, including the United States, participated in the negotiation of the Draft Protocol. In accordance with Decision IV/3 of the COP, the BSWG completed a controversial draft text (the Draft Protocol) in Cartagena and referred it to an extraordinary meeting of the COP (Ex-COP) for possible adoption.²⁰ The Ex-COP opened February 22, 1999 in Cartagena, Colombia. However, disagreements concerning central features of the Draft Protocol, particularly concerning its scope and impact upon trade in GMOs, proved insurmountable. Unable to arrive at a text acceptable to all 134 CBD Parties in attendance, the COP decided to suspend the extraordinary meeting and reconvene no later than COP-5, scheduled to occur in May 2000.

Three major blocs of governments emerged in the negotiations: the European Union (EU), the “Like-Minded Group” of developing countries, and the “Miami Group” of major agricultural exporting countries.²¹ Other significant issues that remained unresolved after the Cartagena meeting included: scope (e.g., whether the AIA procedure should be extended to pharmaceuticals); regulation of contained uses of GMOs; application of the AIA procedures; and trade with non-parties. In addition, the Central and Eastern European countries formed a negotiating group, and several additional countries outside of the EU that did not wish to join the Miami Group (e.g., Switzerland) formed their own “Compromise Group.” The EU, Like-Minded Group, and Miami Group

19. Specifically, the COP authorized the BSWG to address in the Protocol: risks to biodiversity arising from activities related to GMOs, including from handling, use, transfer and disposal; transboundary movement of GMOs; release of GMOs in centers of origin (areas of particular importance to biological diversity); advance informed agreement procedures; risk assessment and management mechanisms; information exchange; capacity-building; socio-economic considerations; liability and compensation for injury caused by GMOs; and financial considerations. *See id.*

20. *See* Decision IV/3, *Conference of the Parties on the Convention of Biodiversity* (1998) available at (visited Apr. 12, 2000) <<http://www.dainet.de/FIZ-AGRAR/CHMDOC/eng.htm>>.

21. The so-called “Miami Group” was comprised of Argentina, Australia, Canada, Chile, Uruguay, and the United States.

remained fundamentally divided following the Cartagena meetings. The most significant areas of disagreement among them concerned the extension of obligations established under the Protocol to commodities intended for food or feed, or for processing, and the Protocol's relationship to international trade law.²²

Before reconvening the Ex-COP, the negotiating governments met informally three times. They first met in July 1999 in Montreal, where they affirmed their political commitment to finalize the Protocol and agreed to hold another round of informal consultations prior to reconvening the Ex-COP.²³ In mid-September, they met again in Vienna, Austria for a combination of intra-group and inter-group discussions. The negotiating groups agreed upon some basic concepts concerning commodities and relations to other international agreements, but their negotiating positions remained essentially unchanged. However, they agreed to meet again in January 2000 in Montreal to reconvene the Ex-COP.²⁴ The January meeting began with a final four-day round of informal consultations, followed by five full days of formal negotiations by the Ex-COP, ultimately extending well into the early morning hours of a sixth day before the Parties adopted the Protocol.²⁵ The Agreement opens for signature on May 15, 2000 and will enter into force ninety days after upon the ninetieth day following ratification by fifty countries that are Parties to the CBD.²⁶

22. Apparently as a negotiating tactic, the Like-Minded Group subsequently called for the Protocol to address as a general matter "products thereof" (i.e., substances made with or from GMOs, but not including them, such as processed foods and pharmaceuticals, as well as textiles and paper goods). However, the Like-Minded Group in Cartagena effectively took this issue off the table, though the Group did attempt to revive the issue subsequently to no avail. The Protocol now addresses products thereof in three places: in Article 20, which requires Parties to submit summaries of risk assessments undertaken, including any results regarding products thereof, to a Biosafety Clearing-House, as discussed at note 38 *infra* and accompanying text; in Annex I to the Protocol, which requires Parties to provide information concerning the intended use of products thereof, as part of the advance notice mandated for LMOs that are to be exported for release into the environment, discussed at notes 30-45 *infra* and accompanying text; and in the general principles for proper risk assessment detailed in Annex III to the Protocol.

23. See *Aide Memoire, Chairman's Summary of Informal Consultations* (July 14, 1999) (available from the Secretariat for the Convention on Biological Diversity).

24. See *Informal Consultations on Biosafety Protocol, Vienna 15-19 September 1999; Chairman's Summary* (available from the Secretariat for the Convention on Biological Diversity).

25. See, e.g., *Report of the Resumed Session of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity: 24-28 January 2000*, 9 EARTH NEGOTIATIONS BULLETIN 1 (2000) <<http://www.iisd.ca/biodiv>>.

26. See Cartagena Protocol, *supra* note 2, art. 37.

II. THE CARTAGENA PROTOCOL

The Cartagena Protocol regulates “transboundary movement, transit [movement through countries other than the country of initial export and final import], handling and use of 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.”²⁷ Human pharmaceuticals “addressed” by other “relevant international agreements or organisations” are excluded from the protocol.²⁸ “Living Modified Organism” (LMO) is a defined term that captures a wide range of genetically modified organisms.²⁹ The Protocol addresses two general categories of LMOs: those intended for release into the environment (e.g., seeds for cultivation and animals for breeding) and those intended for use in food or feed, or for processing (e.g., bulk commodities, such as corn, cotton, and soy). Processing is not a defined term, and therefore, may include production of textiles and other products that are not consumed by animals or humans.

Throughout the negotiations, the Miami Group opposed provisions that would allow governments to subject commodities to advanced informed agreement procedures or documentation requirements (both of which are discussed more fully below) as these obligations would require segregation of LMOs from traditional agriculture products. The Protocol reflects a compromise struck among the Miami Group, Like-Minded Group, and EU in particular, under which LMOs intended for use in food or feed, or for processing are subject to a less onerous regime than LMOs intended for release into the environment.

The Like-Minded Group had also pressed unsuccessfully for the Protocol’s AIA procedure to be expanded to cover products derived from LMOs. Including so-called “Products Thereof” within the scope of the Protocol could have dramatically expanded the scope of the Protocol and its impact upon a wide range of products such as cereals and beverages made from genetically modified corn and blue jeans produced from genetically modified cotton. Recognition that products derived from LMOs would not present risks to biodiversity and that many governments have limited capacity available to regulate the import and export of such products eventually led to a consensus that the Protocol should address actual LMOs but not non-living derivative products.

27. *Id.* art. 4.

28. *Id.* art. 5. While this provision could be expected to place human pharmaceuticals beyond the scope of the Protocol, the terms “addressed” and “relevant international agreements or organisations” might be interpreted so as to make some human pharmaceuticals subject to obligations established in the Protocol. In any event, the exclusion is explicitly limited to human pharmaceuticals, apparently leaving subject to the Protocol any veterinary pharmaceuticals that otherwise qualify as LMOs under the Protocol.

29. *See id.* art. 3(g) (providing a definition of “living modified organism”); art. 3(h) (providing a definition of “living organism”); art. 3(i) (providing a definition of “modern biotechnology”).

A. ADVANCED INFORMED AGREEMENT AND REGULATORY ACTION
NOTIFICATION OBLIGATIONS

The heart of the Protocol is the obligation on Parties to apply an “advanced informed agreement” or “AIA” procedure to the first intentional transboundary movement of a LMO that is intended to be released into the environment of the importing Party.³⁰ LMOs intended for direct use as food or feed or for processing are not subject to the AIA procedure.³¹ The Protocol also provides for the Meeting of the Parties (MOP) to exclude certain LMOs from the AIA procedure when the Parties agree that the 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.”³²

Under the AIA process, a Party from which an LMO is exported (Party of export) to another Party (Party of import) for the first time must provide advance notice to the Party of import.³³ The Party of import then has the right to permit, to permit subject to conditions, or to deny permission to import the LMO.³⁴ The Party of import must ensure that a scientifically sound risk assessment is carried out for these decisions.³⁵ As discussed more fully below, the AIA provisions explicitly recognize the right of Parties of import to make decisions that would avoid or reduce potential adverse effects in the face of scientific uncertainty due to insufficient scientific information and knowledge.³⁶ The Party of import may also take into account, “consistent with its international obligations,” socio-economic considerations relating to the impact of LMOs on the conservation and sustainable use of biodiversity.³⁷ This provision arguably grants Parties of import substantial discretion to regulate trade in LMOs not only for environmental protection purposes but also to protect domestic social and economic interests. The Protocol imposes time limits for the Party of import to respond to the advance notice and to make a final decision, and requires the Party of import both to justify its decisions and to make a summary of its risk assessment and its final decision generally available through a “Biosafety Clearing-House.”³⁸ Written consent from the importing Party is required before import of a covered LMO, and the Protocol makes clear that a failure to respond or make a final decision does not constitute tacit consent.³⁹

30. *See id.* art. 7.

31. *See id.*

32. *Id.*

33. *See id.* art. 8.

34. *See id.* art. 10.

35. *See id.* art. 15.

36. *See id.* art. 10.

37. *Id.* art. 26.

38. *See id.* arts. 9, 10, 20.

39. *See id.* arts. 9, 10.

The Protocol establishes a separate regulatory procedure for LMOs that may be exported for direct use as feed, food, or for processing.⁴⁰ Generally, a Party must notify the Biosafety Clearing-House within fifteen days of making a decision regarding domestic use, including placement on the market of an LMO that might be exported for such uses.⁴¹ In addition, Parties must make copies of applicable national laws, regulations, and guidelines available to the Clearing-House.⁴² Developing country Parties and Parties with economies in transition (i.e., from socialist into market-based economies), however, can subject such LMOs to a review procedure equivalent to the procedures established under the AIA provisions, which are otherwise only applicable for LMOs intended for release into the environment.⁴³

Rather than act in accordance with these AIA and notification requirements, Parties may establish simplified procedures if they choose, so long as these alternate measures ensure the safe transboundary movement of LMOs, in accordance with the objectives of the Protocol.⁴⁴ Parties also may enter into bilateral, regional, and multilateral arrangements governing international transboundary movement of LMOs, so long as they do not result in a lower level of protection than that provided for by the Protocol.⁴⁵

B. PRODUCT DOCUMENTATION

Parties must also require accompanying documentation for all transboundary movements of LMOs covered by the Protocol.⁴⁶ Documentation for LMOs intended for release into the environment must specifically identify the LMO and provide additional information concerning safe use, handling, and transport; a declaration that the shipment complies with applicable Protocol obligations generally; contact information for the importer and exporter; and a contact point for further information.⁴⁷ LMOs intended for food or feed, or for processing are to be accompanied with documentation stating simply that the shipment “may contain” LMOs.⁴⁸ The Protocol requires, in addition, only that the documentation states that the shipment is intended only for food or feed, or for processing and identifies a contact point for additional information.⁴⁹ This compromise allows the Miami Group and other governments to avoid requiring segregation of genetically modified crops from traditional varieties. However, the Parties to the Protocol are to decide within two years of entry into force of the

40. *See id.* art. 11.

41. *See id.* art. 11(1).

42. *See id.* art. 11(5).

43. *See id.* art. 11.

44. *See id.* art. 13.

45. *See id.* art. 14.

46. *See id.* art. 18.

47. *See id.* art. 18(2)(c).

48. *See id.* art 18(2)(a).

49. *See id.*

Protocol upon additional documentation requirements for this category of LMOs.⁵⁰ At that time, it is likely that the Parties will revisit the question of whether the Protocol should require that LMOs destined for food or feed, or for processing be segregated and subject to detailed documentation requirements.

C. OTHER OBLIGATIONS

In addition to these AIA and related information-sharing and documentation requirements, the Protocol establishes obligations: to manage risks associated with the use, handling, and transboundary movement of LMOs;⁵¹ to provide notice and information needed to address unintentional transboundary movements of LMOs;⁵² to protect confidential information;⁵³ to assist with human resource and institutional capacity building;⁵⁴ to promote and encourage public awareness, education, and participation regarding biosafety;⁵⁵ and to take steps to prevent illegal transboundary movements of LMOs.⁵⁶ The Protocol also calls upon the Parties to consider addressing additional related issues. Most significantly, the Parties to the Protocol must initiate a process at their first meeting to elaborate appropriate rules and procedures regarding liability and redress for damage resulting from transboundary movements of LMOs.⁵⁷ The Parties are also to consider establishing standards for identification, handling, packaging, and transport of LMOs.⁵⁸

III. BALANCING BIOSAFETY AND FAIR TRADE OBJECTIVES UNDER THE PROTOCOL

The substantive requirements established in the Protocol would regulate international trade in LMOs by obligating Parties to impose AIA, notification, documentation, and other regulatory requirements on transboundary movements of certain LMOs. In addition, some governments may view the mere existence of the Protocol as legitimizing additional (and more onerous) national or regional regulatory measures not required under the Protocol. As noted above, the potential impacts that the Protocol might have on international trade made the relationship between the Protocol and international trade law, specifically the Agreements of the World Trade Organization (WTO), a particularly important and contentious issue during the negotiations. In the end, the Parties to the CBD agreed upon a text that struck a somewhat ambiguous compromise. Specifically,

50. *See id.* art. 18.

51. *See id.* art. 16.

52. *See id.* art. 17.

53. *See id.* art. 21.

54. *See id.* arts. 22, 28.

55. *See id.* art. 23.

56. *See id.* art. 25.

57. *See id.* art. 27.

58. *See id.* art. 18.

the Protocol addresses—without clearly resolving—three interrelated topics: the relative legal priority of the Protocol and WTO Agreements; the role of scientific and non-scientific criteria in governmental decision-making under the Protocol; and the applicability of Protocol obligations to trade with non-party governments.

A. RELATIVE PRIORITY OF THE CARTAGENA PROTOCOL AND WTO TRADE AGREEMENTS

The legal priority of the Protocol relative to WTO Agreements is the most fundamental of the three issues. While not all of the potential Parties to the Protocol are currently Members of the WTO, the great majority are.⁵⁹ In the event of a conflict between Parties to the Protocol who are also Members of the WTO concerning rights or obligations established in the Protocol and in a WTO Agreement, the agreement having priority would prevail. As a result, determining which agreement would have priority is an issue of some importance. The Protocol addresses its priority relative to other international agreements in three places. Most generally, the Protocol Preamble states:

. . . *Recognizing* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development;

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements;

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements . . .

As preambular language, these statements carry less weight than would operative language in the body of the Protocol. Nonetheless, the Preamble could be relied upon to determine the object and purpose of the agreement.⁶⁰ However, because the last two statements appear to contradict one another, it is difficult to determine whether the rights and obligations of WTO Members who are also Parties to the Protocol remain unaltered (i.e., have priority over those established under the Protocol).⁶¹

59. Others, including China, may be included in the near future.

60. See, e.g., IAN M. SINCLAIR, *THE VIENNA CONVENTION ON THE LAW OF TREATIES* 127-28 (2d ed. 1984); Jimenez de Arechaga, *International Law in the Past Third of A Century*, 159 REC. DES COURS 42-48 (1978-I), reprinted in LOUIS HENKIN ET AL., *INTERNATIONAL LAW: CASES AND MATERIALS* 475 (3d ed. 1993).

61. The CBD itself includes a qualified “Savings Clause” (i.e., language clarifying that the Protocol does not supercede the rights and obligations of Parties under other international agreements), which states that:

This issue of priority is addressed two more times in the body of the Protocol, with regard to the rights of Parties to take measures beyond those required under the Protocol and to consider socio-economic factors when deciding whether to approve the import of LMOs under the AIA procedures. Article 2 of the Protocol includes a fairly standard provision recognizing the right of Parties:

to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and provisions of this Protocol and *is in accordance with its other obligations under international law*.⁶²

This provision appears to recognize that Parties may take actions beyond those mandated under the Protocol but only to the extent permitted by other international agreements that bind them, including those of the WTO. Standing alone, this provision would appear to guard against the adoption of discriminatory trade measures that contravene WTO disciplines.

However, the Protocol's provision authorizing Parties to take into account socio-economic considerations is ambiguous and arguably undermines the trade protections referenced in Article 2. Specifically, Article 26 of the Protocol states that:

The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.

CBD *supra* note 1, art. 22. Article 32 of the Protocol incorporates by reference provisions of the CBD "relating to its Protocols." This provision of the Protocol is probably intended to incorporate by reference only those provisions of the CBD that directly address protocols to the Convention. In fact, both the Miami Group and the EU found this language inadequate for purposes of the Protocol. In any event, if Article 22 of the CBD were incorporated by reference into the Protocol, the precise extent to which this provision would protect rights and obligations under WTO Agreements is a matter of interpretation. Also, it is not clear how the Protocol's preambular language would modify this provision of the Convention for purposes of the Protocol.

62. Cartagena Protocol, *supra* note 2, art. 2 (emphasis added); *see, e.g.*, Basel Convention on the Transboundary Movement of Hazardous Waste, Mar. 22, 1989, art. 4(11), 28 I.L.M. 649 (1989) [hereinafter Basel Convention]; U.N. Environment Programme & Food and Agriculture Organization of the United Nations, Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Sept. 10, 1998, art. 15, *in Final Act of the Conference of Plenipotentiaries on the Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, Annex III, U.N. Doc. UNEP/FAO/PIC/5 (1998).

The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.⁶³

Depending upon the priority of the Protocol relative to WTO Agreements, it is not clear whether obligations established under WTO Agreements would constitute “international obligations” binding upon Protocol Parties or would be superceded by conflicting rights or obligations established under the Protocol. In any event, it is unclear what might be considered legitimate “socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity.”⁶⁴ At a minimum, it would appear that a Party to the Protocol may be able legitimately to refuse the import of a particular genetically modified seed based on concerns that the seed may affect the livelihood of domestic agricultural interests, but arguably could not restrict imports on the basis of strong consumer preferences for GMO-free commodities.

B. USE OF SCIENTIFIC AND NON-SCIENTIFIC CRITERIA IN LMO IMPORT DECISION-MAKING

Provisions under the Protocol concerning rights and obligations regarding use of scientific and non-scientific criteria in making import decisions are significant from an international trade perspective because these rights and obligations may differ from those established under WTO Agreements concerning legitimate bases for adopting environmental, health, and safety measures. In particular, these provisions of the Protocol could conflict with provisions of the General Agreement on Tariffs and Trade (GATT),⁶⁵ the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement),⁶⁶ and the Agreement on Technical Barriers to Trade (TBT Agreement).⁶⁷

Currently, the standards for scientific evidence to justify environmental health and safety (EH&S) measures under the GATT and TBT Agreement are

63. Cartagena Protocol, *supra* note 2, art. 26.

64. *Id.*

65. General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT].

66. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND [hereinafter SPS Agreement].

67. Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND [hereinafter TBT Agreement].

not well defined. WTO Members would likely be required under each to take into account available scientific evidence. It is less clear what level of scientific evidence these agreements would require, as a minimum, to justify the application of EH&S measures or whether they would require Members to rely upon risk assessments to justify these measures.⁶⁸

The SPS Agreement addresses the issue more clearly. It explicitly requires WTO Members to take into account available scientific data and to base their measures upon risk assessments.⁶⁹ In addition, it permits WTO Members to take interim SPS measures in the absence of adequate scientific evidence of risk. However, it requires WTO Members to seek additional necessary information for a more objective assessment and to review the interim measures accordingly within a reasonable period of time.⁷⁰ Under all three agreements, socio-economic considerations as a general matter cannot be relied upon to justify a trade restrictive regulatory measure.

The Cartagena Protocol addresses in two ways the extent to which Parties can act in the absence of clear scientific evidence or on the basis of non-scientific criteria. The Protocol explicitly references a "precautionary approach," and it establishes explicit rights to act in the face of scientific uncertainty and to rely upon non-scientific criteria.

In the Preamble, as well as in the body, the Protocol refers to the "precautionary approach" as contained in the Rio Declaration on the Environment and Development. Most significantly, Article 1, Objectives states that:

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to

68. See, e.g., GATT, *supra* note 65, art. XX; GATT Dispute Panel Report, Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes, adopted Nov. 7, 1990, GATT B.I.S.D. (37th Supp.) at 200 (1990) [hereinafter Thai Cigarettes] (assessing evidence of the health risk posed by tobacco products); TBT Agreement, *supra* note 67, art. 2.2.

69. See SPS Agreement, *supra* note 66, arts. 2, 5; WTO Panel Report, Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 by Canada, WT/DS18/RW (Feb. 18, 2000) [hereinafter Australian Salmon II] (interpreting SPS Agreement arts. 2.2, 5.1, 5.5, 5.6, 5.7); WTO Panel Report, Japan – Measures Affecting Agricultural Products, WT/DS76/R (Oct. 27, 1998) [hereinafter Japan Apples] (interpreting SPS Agreement arts. 2.2, 5.1, 5.2, 5.5, 5.6); Report of the WTO Appellate Body, Australia – Measures Affecting Importation of Salmon, WT/DS18/AB/R (Oct. 20, 1998) [hereinafter Australian Salmon I] (interpreting SPS Agreement arts. 2.3, 5.1, 5.5, 5.6); Report of the WTO Appellate Body, European Communities – Measures Affecting Meat and Meat Products (Hormones), WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter Beef Hormones] (addressing complaints by both the United States and Canada and interpreting SPS Agreement arts. 2.2, 5.1, 5.2, 5.5, 5.6).

70. See SPS Agreement, *supra* note 66, art. 5.7; Japan Apples, *supra* note 69; Australian Salmon, *supra* note 69.

ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.⁷¹

These references to a precautionary approach do not clearly establish any obligations beyond those explicitly articulated in the Protocol. However, Parties to the Protocol might attempt to rely upon these references, particularly in Article 1, to justify actions not actually required under the Protocol as consistent with its object and purpose.⁷²

In addition, the Protocol explicitly recognizes the right of Parties to take decisions on whether to import an LMO in the absence of adequate scientific knowledge:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party 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.⁷³

Unfortunately, this language (originally tabled in Cartagena) is complicated and ambiguous, reflecting the sensitivity of the compromise struck. Depending upon their interests, Parties may attempt to interpret the language as granting quite narrow or broad discretion to Parties of import in making import decisions. This

71. Cartagena Protocol, *supra* note 2, art. 1 (emphasis added). Principle 15 of the Rio Declaration states:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Rio Declaration on Environment and Development, June 13, 1992, U.N. Conference on Environment and Development, Agenda Item 9, U.N. Doc. A/CONF.151/5/Rev.1 (1992), reprinted in 31 I.L.M. 874 (1992).

72. See Vienna Convention on the Law of Treaties, May 23, 1969, art. 31, 1155 U.N.T.S. 331. "A treaty shall be interpreted in accordance with the ordinary meaning to be given the terms of the treaty in this context, and in light of its object and purpose." *Id.*

73. Cartagena Protocol, *supra* note 2, arts. 10, 11.

provision, when read in conjunction with the objective of the Protocol, arguably provides a legal basis for governments to restrict LMO imports in the face of contradictory scientific assessments, based on a precautionary approach, including when the weight of scientific information suggests that the LMOs in question are safe.⁷⁴ Although the impact of this language remains unclear, some European governments have subsequently proposed similar language for use in at least one other major multilateral environmental agreement.⁷⁵

Finally, as discussed above, the Protocol recognizes a right of Parties to take into account non-scientific, socio-economic considerations "arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."⁷⁶ The precise nature of potentially valid socio-economic effects that may warrant import restrictions remains to be seen. As noted above, the priority of the Protocol relative to WTO Agreements may influence whether any Parties attempt to use this provision to justify measures protecting domestic agricultural interests and other sectors that may be impacted by the introduction of LMOs into the domestic market.

C. APPLICABILITY OF PROTOCOL OBLIGATIONS TO NON-PARTIES

As a general matter, treaties cannot bind non-parties. However, multilateral environmental agreements (MEAs) have restricted the rights of parties to them to trade in covered products or wastes with non-parties, to encourage non-parties to become parties to the MEA or, at least, to comply with the obligations imposed under the MEA.⁷⁷ The consistency of such restrictions on trade with non-parties and the rights and obligations established in WTO Agreements has never been formally reviewed by the WTO membership or been the focus of a dispute

74. The issue of best available science was recently raised in the United States under an industry challenge to an EPA drinking water standard for chloroform (which the Agency considers a probable human carcinogen). In striking down the 1998 standard, the U.S. Court of Appeals for the D.C. Circuit found that the EPA acted unlawfully when it "openly overrode the 'best available' scientific evidence" and promulgated a standard based on an assumption that chloroform poses a risk of cancer at any dose. *See Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1289-90 (D.C. Cir. 2000); *see also* Terry F. Quill & David B. Fischer, *D.C. Circuit Pans EPA's Chloroform Rule: Watered-Down Science*, LEGAL TIMES, Apr. 14, 2000, at 84.

75. In the course of ongoing negotiations for a global agreement aimed at managing persistent organic pollutants (POPs), the European Commission tabled language intended to facilitate the addition of new substances for inclusion under a future POPs convention, which was based on article 10 of the Biosafety Protocol.

76. Cartagena Protocol, *supra* note 2, art. 26.

77. *See, e.g.*, Basel Convention, *supra* note 62, arts. 4, 11. Convention on International Trade in Endangered Species of Wild Fauna and Flora, Mar. 3, 1973, art. X, 27 U.S.T. 1087, 993 U.N.T.S. 243 (entered into force July 1, 1975) [hereinafter CITES]; Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, art. 4, 26 I.L.M. 1541 (1987) [hereinafter Montreal Protocol].

settlement decision. However, relevant factors likely to be considered would include the legitimacy of the objective served by the trade restriction and the availability of less trade-restrictive measures to accomplish the same objective.⁷⁸

The Cartagena Protocol requires that trade with non-parties be consistent with the objectives of the Protocol and urges the Parties to encourage non-parties to adhere to the Protocol.⁷⁹ This provision may be of particular interest to the United States, which cannot become a Party to the Protocol until it ratifies the CBD. While the Protocol does not appear to require compliance with any particular obligations of the Protocol when trading with non-parties, its vagueness leaves the provision open to a wide range of potential interpretations. This vagueness could increase the risk of future disputes between Parties and non-parties who believe that Parties are restricting market access unfairly. Alternatively, the language stops short of banning trade in LMOs with non-parties, a result that would almost certainly have led to a WTO challenge if the Protocol entered into force and led to significant trade disruptions.

IV. THE SIGNIFICANCE OF THE CARTAGENA PROTOCOL AS INTERNATIONAL ENVIRONMENTAL LAW PRECEDENT

If brought into force, the Cartagena Protocol would establish the first binding global biosafety regime and would establish important international obligations for the transboundary movement of certain LMOs. The Protocol is likely to serve as a starting point for many national legal regimes, and in this regard may harmonize national regimes while furthering market access. The Protocol's significance, however, may already extend beyond biotechnology. The negotiations for the Biosafety Protocol and the Protocol itself signify a potentially unstable period in international negotiations for environmental, health, and safety regimes that have significant international trade implications.

The Protocol represents the first attempt by the international community to establish a binding global environmental, health, and safety regime to regulate a core component of international trade. Past MEAs have tended to focus on narrower ranges of goods that pose easily recognized risks, such as ozone depleting substances, banned or severely restricted chemicals, or hazardous

78. See, e.g., Thai Cigarettes, *supra* note 68; SPS Agreement, *supra* note 66, art. 2.2; TBT Agreement, *supra* note 67, art. 2.2; see also Bruce Neuling, *The Shrimp-Turtle Case: Implications for Article XX of GATT and the Trade and Environment Debate*, 22 LOY. L.A. INT'L & COMP. L. REV. 1 (1999); Susan Page, *International Trade and Environmental Policy*, 86 AM. SOC'Y INT'L L. PROC. 224 (1992); Chris Wold, *Multilateral Environmental Agreements and the GATT: Conflict and Resolution?*, 26 ENVTL. L. 841 (1996). See generally Robert Housman & Durwood Zaelke, *Trade, Environment, and Sustainable Development: A Primer*, 15 HASTINGS INT'L & COMP. L. REV. 535 (1992); Daniel C. Esty, *Unpacking the "Trade and Environment" Conflict*, 25 LAW & POL'Y INT'L BUS. 1259 (1994); Steve Charnovitz, *Free Trade, Fair Trade, Green Trade: Defogging the Debate*, 27 CORNELL INT'L L.J. 459 (1994).

79. Cartagena Protocol, *supra* note 2, art. 24.

wastes. In contrast, the Biosafety Protocol regime addresses a category of goods recognized as having highly positive attributes, for which international demand is expected to grow dramatically in coming years. As a result, negotiating governments had to grapple with trade-related issues in this negotiation that they did not have to confront in so stark a fashion when negotiating other MEAs. During the negotiations, governments struggled to agree upon mechanisms, rights, and obligations that might achieve biosafety goals without facilitating protectionist practices that would unfairly and unnecessarily impede fair trade. Their task was made particularly difficult by the lack of relevant "soft law"⁸⁰ standards or related multilateral or regional agreements that could serve as reference points for the international negotiations. Consumer resistance to GMO products in Europe also mandated that certain European countries seek a protocol that fully embraced notions of "precaution." As noted above, the result is a text that could ultimately open the door to unfair and discriminatory barriers to trade in LMOs that are not justified from a scientific or risk management perspective.

A. ATTEMPTS TO BALANCE BIOSAFETY AND FAIR TRADE CONCERNS

The Protocol includes a variety of provisions intended to take into account current international trade law, enabling governments to ensure biosafety while reducing the likelihood that they will take advantage of the Protocol as a means to circumvent fair trade obligations. This is a difficult balance to strike. The more discretion Parties to the Protocol grant one another regarding procedural and substantive bases for establishing biosafety measures, the less they can rely with certainty upon international trade law rights and obligations to protect against abuses. At the same time, unless they clarify the rights they believe necessary to ensure that governments can adequately maintain biosafety, the scope of these rights may be defined solely through unguided interpretation of environmental, health, and safety exceptions to international trade law rules, by WTO dispute settlement tribunals, composed of individuals who likely have more experience with trade considerations than with biotechnology and related risk assessment, risk management, and environmental and health issues.

In many instances, the Protocol attempts to reconcile these competing environmental and trade interests by counterbalancing rights and obligations. For example, under the AIA procedures, Parties of import must meet certain deadlines and justify importation decisions, providing grounds to challenge slow or poorly justified decisions as inconsistent with fair trade obligations. At the

80. "Soft law" includes declarations, resolutions, guidance documents, and other voluntary mechanisms to which nations may agree, which manifest aspirational goals and objectives but do not have the force of binding law.

same time, the failure of a Party of import to satisfy these obligations does not constitute an implicit consent to import, which might pose a biosafety risk.

However, in some significant instances the Protocol establishes rights and obligations that can reasonably be interpreted as contradictory, rather than merely counterbalancing. For example, it is difficult to see how international trade rights and obligations can remain unchanged as the Preamble states, if, as the Preamble also states, the Protocol is not “subordinate” to WTO Agreements. Similarly, it is difficult to glean clear guidance from the Protocol’s language stating (against a backdrop of the precautionary approach) that a “lack of scientific certainty” shall not prevent a Party of import from taking a decision “as appropriate” to address a “potential adverse effect.” In the absence of adequate scientific evidence, the criteria upon which Parties can rely to make a decision are ambiguous, and at a minimum, open the door to legitimizing import decisions that might otherwise be deemed arbitrary or a disguised restriction on trade.

B. POTENTIAL HURDLES TO ENTRY INTO FORCE

The inconsistent provisions cited above reflect the highly charged and political nature of the Cartagena Protocol negotiations. Ambiguous language addressing the concerns of all sides provides some protection to the interests of each. While unclear drafting need not prevent the Parties to the CBD from ratifying the Protocol, it does make the consequences of the Protocol’s implementation less predictable. This may give some governments pause as they consider whether to ratify the Agreement. Fifty Parties to the CBD must ratify the Protocol for it to enter into force.⁸¹ While the Protocol could, therefore, enter into force if any 50 of the 177 Parties to the CBD ratify it, the Protocol may be of little practical significance if key nations participating in international trade in biotechnology do not agree to be bound by it.

A number of other features of the Protocol also could make its implementation challenging. Key definitions, such as that for LMO, may prove over or underinclusive. As a practical matter, the AIA process may prove unwieldy; governments may find they do not have sufficient time to make decisions; and market participants may find it difficult to do business as a result of delays.

Also, within two years of the Protocol’s entry into force, the Parties to it must address whether to subject LMOs intended for food or feed, or for processing to additional documentation requirements that would require their segregation from non-LMOs.⁸² The possibility of such additional requirements could make some LMO-exporting governments less inclined to become Parties to the Protocol. On the other hand, failure to ratify and secure a “seat at the table” may limit a government’s influence in these subsequent negotiations. In any event, market forces may resolve this issue by compelling exporters to label such LMOs before the Protocol Parties resolve the question as a matter of law.

81. *See* Cartagena Protocol, *supra* note 2, art. 37.

82. *See id.* art. 18(2)(a).

Implementing a liability and redress regime also may present substantial challenges. As a result of their differing interests, exporting and importing, developed and developing countries are likely to hold substantially divergent views on fundamental issues such as causation, intent, scope, and duration of potential liability, choice-of-law, jurisdiction, and comity. Because the process for elaborating a liability regime is to be adopted at the first MOP,⁸³ agricultural exporting countries with substantial biotechnology interests may wish to ratify the Protocol prior to the first meeting to ensure themselves an early and influential role in the development of the mandate and scope for the negotiations.

In addition, national implementation may prove difficult for many Parties, particularly developing countries, which typically lack trained personnel, technology, and the infrastructure necessary for complex regulatory regimes. The Protocol does, however, impose obligations upon the Parties to provide financial and other capacity building assistance.⁸⁴ This may facilitate to some degree national implementation in developing countries.

C. THE CARTAGENA PROTOCOL AS A SOURCE OF "PRECEDENT" FOR FUTURE MEAS

If the Protocol enters into force, its significance will extend beyond its impact as a binding biosafety regime. It will likely serve as a source of "precedent" for future MEAs that impact international trade. Of course, governments need not adopt principles, rights, or obligations established in one agreement when negotiating another. However, when negotiating MEAs, governments do routinely rely upon prior MEAs as models. Furthermore, if governments use a similar approach in multiple MEAs, that approach, as a practical matter, may become the default. It need not be followed in subsequent negotiations but will be politically easier to follow than a divergent approach.

The provisions relied upon in the Protocol to strike a balance between biosafety and fair trade concerns are particularly noteworthy as potential sources of such "precedent." For example, the preambular language in the Cartagena Protocol concerning the relationship between the Protocol and other international agreements is derived from and similar to preambular language in the Rotterdam Convention Concerning Hazardous Chemicals and Pesticides in International Trade.⁸⁵ Now that governments have agreed to address this issue in the preamble, rather than in the text of two separate global agreements (and have agreed to use similar language in both agreements), it is more likely that this issue will be addressed in the preamble, and with similar language, rather than in the body of future agreements. Similarly, the decision to refer to a precautionary approach explicitly in the text of the Protocol, and the language agreed upon concerning the right of governments to act in the absence of scientific evidence and on socio-economic grounds, can be expected to carry some weight as

83. *See id.* art. 27.

84. *See id.* art. 28.

85. Rotterdam Convention, *supra* note 62, pmbl.

precedent in negotiations for future MEAs addressing similar risk management issues.

V. CONCLUSION

The Cartagena Protocol establishes an important framework for addressing a new technology with great potential that, nonetheless, presents risks that must be addressed. It leaves important issues unresolved, but, particularly, in the current international political climate, it represents an important step in the development, rationalization, and international harmonization of biotechnology regulation. Governments began the negotiations with the aim of ensuring that international trade in biotechnology would enable the international community to take advantage of the technologies potential without posing undue risks to the environment, health, and safety. Ultimately, the negotiations were also informed by consumer concerns and perhaps protectionist agendas as well. More broadly, they took place at a time when the international community remains divided as to the relative importance of protecting the right of nations to pursue environmental, health and safety goals and the benefits of freer, fairer trade.

Discussions and negotiations continue in a wide array of international and regional forums as well as within individual nations, as governments continue to struggle with the economic, environmental, health safety and social implications of this new technology. Tensions remain high and current trade frictions may give rise to significant disputes that could lead to new retaliatory barriers to market access not only for biotechnology but other goods and services. The Cartagena Protocol is an important achievement, but marks only the beginning of what will likely be a long and challenging process.

The Cartagena Protocol stands as the international communities' most recent attempt to further global rules for the protection of human health and the environment without undermining international rules for freer and fairer trade. Over the near term, the Protocol is likely to harmonize the approach governments take to developing their domestic biosafety regimes. In this regard, the Protocol will likely facilitate market access for transgenic crops. Governments can also be expected to revisit outstanding issues concerning the application and nature of AIA procedures, liability, and perhaps additional documentation or labeling obligations for LMOs in the not too distant future.

Over the long term, a mix of market forces, politics, and consumer demands will likely determine whether the Protocol establishes a workable global biosafety regime that is consistent with the pursuit of both sound environmental management and fair, efficient international trade.