

Winter 2001

Merits of Ratifying and Implementing the Cartagena Protocol on Biosafety

Jonathan A. Glass

Follow this and additional works at: <http://scholarlycommons.law.northwestern.edu/njilb>



Part of the [Food and Drug Law Commons](#), and the [Health Law Commons](#)

Recommended Citation

Jonathan A. Glass, Merits of Ratifying and Implementing the Cartagena Protocol on Biosafety, 21 Nw. J. Int'l L. & Bus. 491 (2000-2001)

This Comment is brought to you for free and open access by Northwestern University School of Law Scholarly Commons. It has been accepted for inclusion in Northwestern Journal of International Law & Business by an authorized administrator of Northwestern University School of Law Scholarly Commons.

COMMENTS

The Merits of Ratifying and Implementing the Cartagena Protocol on Biosafety

Jonathan A. Glass^{*}

I. INTRODUCTION

The trade of genetically modified organisms ("GMOs") has become a source of controversy around the world. While industrialized countries generally argue for limited regulations on GMOs to facilitate trade of these products, most nongovernmental organizations ("NGOs") and developing countries have called for the adoption of a stringent protocol that regulates the trade of GMOs.¹ Under the Convention on Biological Diversity ("CBD"), an international multilateral environmental agreement established to regulate biodiversity, 130 countries have developed and adopted a bio-

^{*} J.D. Candidate, May 2001, Northwestern University School of Law; B.A., 1996, Washington University. I would like to thank Professor Anthony D'Amato and Marybelle Ang for their helpful comments and suggestions for this article. I would also like to thank Elissa Germaine and my family for their constant loyal support.

¹ See Thomas P. Redick et al., *Private Legal Mechanisms For Regulating The Risks of Genetically Modified Organisms: An Alternative Path Within The Biosafety Protocol*, 4 ENVTL. LAW. 1, 7-8 (1997).

safety protocol that establishes standard international regulations governing the transboundary movement of living modified organisms ("LMOs").²

In a meeting in Cartagena, Colombia in February 1999, parties to the CBD, known as the Conference of the Parties ("COP"), could not agree on the proposed biosafety protocol drafted in prior meetings.³ However, in January 2000, in a meeting in Montreal, the parties to the CBD finally adopted the draft protocol, naming it the Cartagena Protocol on Biosafety ("Cartagena Protocol or Protocol").⁴ When the Cartagena Protocol opened for signature at the CBD's COP meeting in Nairobi in May 2000, sixty-four governments and the European Union signed the Protocol.⁵ Presently, eighty-one parties have signed the Protocol, while only two have ratified it.⁶ However, the Protocol will only enter into legal force after fifty parties have ratified it.⁷

This comment argues that each party to the COP should ratify and implement the Protocol as soon as possible. This comment also critiques the provisions of the Protocol and alternatives to the Protocol, namely the voluntary regulation of GMOs. Part II begins with a discussion of the background of GMOs. Next, Part III discusses the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") and its agricultural safety provisions. Part IV continues with a description of the CBD, the history of the development of the Cartagena Protocol, and a discussion of important Protocol language. Part V analyzes the merits of the Protocol and why it should be ratified and implemented. Finally, this comment concludes with a discussion of alternatives to the Protocol, with an emphasis on voluntary regulations.

² See Bill Lambrecht, *Compromise Is Proposed For Pact On Genetically Altered Products; New Rules Could Exempt Some Farm Commodities*, ST. LOUIS POST-DISPATCH, Feb. 22, 1999, at A5.

³ *Id.*

⁴ Press Release, Convention on Biological Diversity, Cartagena Protocol on Biosafety Adopted (29 Jan. 2000), at <http://www.biodiv.org/press/pr-2000-01-28-biosafety.html/cbdrepi.html> (last visited Feb. 8, 2001) [hereinafter Cartagena Protocol Press Release].

⁵ George Mwagni, *Environmental-Safeguards Agreed On*, ASSOCIATED PRESS, May 26, 2000.

⁶ Cartagena Protocol on Biosafety to the Convention on Biological Diversity (29 Jan. 2000), at <http://www.biodiv.org/biosafe/protocol/signinglist.asp> (last visited Feb. 8, 2001) [hereinafter Cartagena Signing List].

⁷ Cartagena Protocol Press Release, *supra* note 4.

II. BACKGROUND

A. Genetically Modified Organisms

Genetically modified organisms ("GMOs") include plants and animals that scientists have genetically altered.⁸ Living modified organisms ("LMOs")⁹ are defined as "any living organism[s] that possess[] a novel combination of genetic material obtained through the use of modern biotechnology."¹⁰ By manipulating DNA, scientists can engineer plants and animals to have particular traits.¹¹ Scientists can use gene-splicing technologies, transferring genes from one plant to another to create a "transgenic" plant, one with new characteristics.¹² For example, Monsanto Corporation, of St. Louis, Missouri, manufactures Roundup Ready soybean seeds that are genetically engineered to be resistant to certain insects.¹³

There are two methods of genetically engineering plants: (1) enhanced seed systems and (2) transgenic seeds.¹⁴ First, enhanced seed systems allow the seed and a chemical to work in conjunction with one another.¹⁵ For example, Monsanto's Roundup Ready soybeans are designed to be resistant to glyphosate, a chemical used in Monsanto's herbicide Roundup Ultra.¹⁶ Thus, farmers of Roundup Ready soybean crops can use Roundup Ready Ultra herbicides on their fields without killing the soybeans.¹⁷ Second, transgenic seeds produce plants "designed to kill predators or to enhance a certain property, such as oil or sugar content."¹⁸ For example, *Bacillus*

⁸ Redick et al., *supra* note 1, at 6.

⁹ The Protocol uses the term "living modified organisms". This article uses the terms "genetically modified organisms" and "living modified organisms" interchangeably – a common practice used in public debate on the subject.

¹⁰ Report of the Sixth Meeting of the Conference to the Parties to the Convention on Biological Diversity, United Nations Environment Programme (UNEP), at <http://www.biodiv.org/excop1/cbdrepi.html> (last visited Oct. 31, 1999) [hereinafter BSWG Report 6].

¹¹ Redick et al., *supra* note 1, at 6.

¹² Bill Lambrecht, *World Recoils at Monsanto's Brave New Crops; The St. Louis Company's Political Clout Has Turned the President and Cabinet Secretaries into Pitchmen*, ST. LOUIS POST-DISPATCH, Dec. 27, 1998, at A1.

¹³ Jack Epstein, *Brazil Battles Over Ban on Altered Beans*, WASH. TIMES, Aug. 30, 1999, at A14.

¹⁴ Susan Boensch Meyer, *Land and Resource Management: Genetically Modified Organisms*, 1998 COLO. J. INT'L ENVTL. L. & POL'Y Y.B. 102 (1998).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.* at 102-03.

¹⁸ *Id.* at 103 (quoting Ronald E. Yates, *Genetic Engineering Moves into Corn, Soy Beans, "Break-through" Seeds Likely to Boost Yields, Transform Industries*, CHI. TRIB., Mar. 17, 1996, at C1).

thuringiensis corn hybrid (Bt corn) is designed to destroy the European corn borer, an insect that plagues corn fields across the world.¹⁹

There are only a few major manufacturers of GMOs.²⁰ Monsanto, the world's second-largest seed and third-largest agrochemical company, is the world leader in the production of GMOs.²¹ Opposition to the release of GMOs into the environment often targets its protests against Monsanto.²² However, other companies, such as Novartis, a Swiss Company, and AgrEvo, a German company, also use gene-altering technologies to produce GMOs.²³

After companies produce GMOs, they attempt to sell their products to customers who will use them. Experts refer to the use of GMOs as deliberate release.²⁴ Deliberate release is the introduction of GMOs into the environment.²⁵ Controversy stems from the deliberate release of GMOs, including both enhanced seed systems and transgenic seeds.²⁶

B. Potential Benefits of GMOs

Monsanto and other GMO manufacturers market their products as tools to feed the world and protect the environment.²⁷ A current global environmental concern is how to create an adequate food supply as the world's population increases.²⁸ Monsanto argues that if farmers use genetically altered seeds that are resistant to pests and plant viruses, they can increase crop yield without having to convert additional lands for agricultural uses.²⁹ Scientists genetically engineer crops to resist plant viruses that would otherwise destroy part of the crop.³⁰ Thus, genetically modified crops contain less viral contamination than unmodified crops, increasing both crop yield and quality.³¹ Biotechnology companies also contend that future technology may allow for the creation of more nutritious foods and perhaps even foods that could prevent or treat illness.³²

¹⁹ See Meyer, *supra* note 14, at 102.

²⁰ See Redick et al., *supra* note 1, at 59.

²¹ Epstein, *supra* note 13, at A14.

²² *Id.*

²³ *Id.*

²⁴ Anne Marie Solberg, *Genetically Engineered Produce Travels North America Under NAFTA: An Issue Ripe for Consideration*, 18 HAMLINE L. REV. 551, 555 (1995).

²⁵ *Id.*

²⁶ See *id.*

²⁷ Tom Rhodes, *Bitter Harvest: The Real Story of Monsanto and GM Food*, SUN. TIMES (LONDON), August 22, 1999, at 1.

²⁸ Redick et al., *supra* note 1, at 7.

²⁹ *Id.*

³⁰ Solberg, *supra* note 24, at 554.

³¹ *Id.*

³² See David Barboza, *Biotech Companies Take On Critics of Gene-Altered Food*, N.Y. TIMES, Nov. 12, 1999, at A1.

In addition, farmers and consumers are concerned with the amount of herbicides and pesticides used in farming practices today.³³ Scientists have used biotechnology to develop herbicide and pest-resistant crops that can potentially decrease the amount of pesticides and herbicides released into the environment.³⁴

Farmers may also gain an economic benefit by using genetically altered seeds. For example, in the United States, Canada, and Argentina, farmers grow genetically altered soybeans commercially in order to increase crop yield.³⁵ Thus, in countries like Brazil, which also compete as world leaders in the soybean market, farmers argue for the use of genetically altered crops to maintain a competitive edge in crop yield.³⁶

C. Potential Dangers of GMOs

Opponents to the deliberate release of GMOs argue that there are potential dangers in the use of GMOs—specifically, dangers to human health and the environment.³⁷ The biological and ecological sciences cannot surely predict that the deliberate release of GMOs will be harmless.³⁸

While supporters of GMOs argue that their release will benefit humans, opponents contend that there are risks of potential side effects on human health.³⁹ For example, in August 1999, the Codex Alimentarius Commission, the United Nations Food Safety Agency, ruled unanimously to enforce a 1993 European moratorium on Monsanto's genetically engineered hormonal milk ("rBGH").⁴⁰ The European Commission's public health committee confirmed that the genetic alteration of rBGH increased levels of naturally occurring Insulin like Growth Factor One ("IBF 1") in milk.⁴¹ Those increased levels of IBF 1 both potentially increased the risks of cancer and promoted the growth of cancer cells in humans.⁴²

Another potential problem for human consumption stems from the alteration of proteins in foods derived from genetically engineered crops.⁴³ Genes encode proteins, and when scientists alter the genetic makeup of

³³ Solberg, *supra* note 24, at 553.

³⁴ *Id.*

³⁵ Epstein, *supra* note 13, at A14.

³⁶ *See id.*

³⁷ Solberg, *supra* note 24, at 555.

³⁸ *Id.* at 554-555.

³⁹ *See id.* at 556.

⁴⁰ Press Release, Monsanto's Genetically Modified Milk Ruled Unsafe by the United Nations, Chemical Business Newsbase, (Aug. 25, 1999).

⁴¹ *Id.*

⁴² *Id.*

⁴³ Solberg, *supra* note 24, at 556.

seeds, new proteins may form.⁴⁴ Changes in the level and form of proteins, in addition to increases in the levels of other constituents that affect protein absorption, may inhibit the way the human body absorbs proteins.⁴⁵

Genetic engineering could also increase levels of toxins in crops.⁴⁶ Plants produce natural toxins, and foods generated from non-engineered plants contain a safe level of toxins.⁴⁷ Genetically engineered plants may manufacture new proteins that could potentially increase the level of these naturally occurring toxins.⁴⁸ Thus, food from genetically engineered crops may contain levels of toxicity dangerous to human health.⁴⁹

Finally, genetic modification can dangerously change the level of allergens in foods.⁵⁰ For example, scientists found soybeans modified from brazil nuts to contain brazil nut allergens, posing potential health problems for those allergic to nuts.⁵¹ Other modified soybeans were found to contain 27% more trypsin-inhibitor, a major allergen, than unmodified soybeans.⁵² Therefore, consumers must consider the potential danger of allergens when eating genetically altered foods.

In addition to potential dangers to human health, some scientists argue that the deliberate release of GMOs poses potential threats to the environment.⁵³ The greatest source of apprehension for ecological scientists is the potential danger of the introduction of non-native organisms into foreign environments.⁵⁴

One danger is the hybridization of GMOs and naturally occurring microorganisms—a process called outcrossing.⁵⁵ Genetically engineered microorganisms have the potential to exchange genetic material, or hybridize, with natural occurring microorganisms.⁵⁶ This hybridization, or outcrossing, can potentially disrupt the ecology of an environment.⁵⁷ For example, wheat that is genetically engineered to resist certain pests can pass this characteristic onto weeds, potentially creating a more powerful weed and

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ Solberg, *supra* note 24, at 556.

⁴⁹ *Id.*

⁵⁰ Holly Saigo, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12 GEO. INT'L ENVTL. L. REV. 779, 792 (2000).

⁵¹ *See id.*

⁵² *Id.*

⁵³ *See* Judy J. Kim, *Out of the Lab and Into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms*, 16 FORDHAM INT'L L.J. 1160, 1163 (1992 - 93).

⁵⁴ *See id.* at 1166.

⁵⁵ *See id.* at 1168; *see also* Saigo, *supra* note 50, at 787.

⁵⁶ Kim, *supra* note 53, at 1167.

⁵⁷ *See id.* at 1168.

disrupting the environment.⁵⁸ Although outcrossing commonly occurs in conventional agronomy, a recent study has discovered that genes from transgenic plants may be twenty times more likely to hybridize into relative species than a plant's natural genes.⁵⁹

Another potential danger of the deliberate release of GMOs is the risk to wildlife.⁶⁰ For example, English Nature, a British environmental group, has posited that releasing untested GMO crops could cause bird species, such as the skylark, corn bunting, and linnet, to become extinct because GMO crops may displace the seeds and insects they eat.⁶¹

Because of these potential health and environmental dangers, the parties to the CBD should ratify the Protocol in order to implement the standard set of regulations established in the Protocol. These regulations should reduce the potential dangers of the release of GMOs into the environment, while allowing the trade and development of GMO products to continue in a controlled manner.

III. THE WORLD TRADE ORGANIZATION'S AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

Treaties that govern international trade include provisions to protect human, animal, or plant life or health.⁶² However, while these regulations provide helpful guidance in the creation of a biosafety protocol, they do not specifically address the dangers accompanied by the trade of GMOs.⁶³ For example, in 1994, the World Trade Organization ("WTO"), an international world trading regime, was established to increase free trade amongst its parties.⁶⁴ Under the WTO umbrella agreement, parties established the WTO structure, including the General Agreement on Tariffs and Trade ("GATT"), the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), and other agreements to which all member states must subscribe.⁶⁵ Under GATT, member states must "enter into 're-

⁵⁸ *Id.*

⁵⁹ Saigo, *supra* note 50, at 787.

⁶⁰ See Meyer, *supra* note 14, at 102.

⁶¹ *Id.*

⁶² See, e.g., Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994 [hereinafter WTO Agreement], Annex 1A, reprinted in JOHN H. JACKSON, WILLIAM J. DAVEY, & ALAN O. SYKES, JR., 1995 DOCUMENTS SUPPLEMENT TO LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS, at 121 (3rd ed. 1995) [hereinafter SPS Agreement]; see also Solberg, *supra* note 24, at 561-564 (for a similar discussion regarding NAFTA's sanitary and phytosanitary standards).

⁶³ For a discussion of how the Cartagena Protocol specifically addresses these dangers, see *infra* Section V.

⁶⁴ See MICHAEL J. TREBILCOCK & ROBERT HOWSE, THE REGULATION OF INTERNATIONAL TRADE 25 (2d ed. 1999).

⁶⁵ See *id.*

ciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international commerce.”⁶⁶

The WTO governs the trade of agricultural products under the SPS Agreement.⁶⁷ The SPS Agreement allows its members to establish regulations to protect human, animal, and plant life from the potential dangers posed by agricultural trade, such as pests, contaminants, toxins, or disease-carrying organisms.⁶⁸ It provides “a legal framework which can address the fundamental issue of whether a measure validly exists to protect consumers or is merely a sham to protect domestic producers.”⁶⁹

The SPS Agreement gives its member countries some discretion in determining which sanitary and phytosanitary measures to use to protect plant and animal life.⁷⁰ A member country determines the specific risks of animal or plant pests or disease in a particular region, taking into account available scientific evidence.⁷¹ That country can then adopt sanitary or phytosanitary measures to adequately address the possible danger, as long as those measures do not “result in discrimination or a disguised restriction on international trade.”⁷²

Because the WTO is an effort to loosen trade restrictions amongst member countries, it allows member countries to maintain some autonomy in establishing their own safety standards.⁷³ However, to achieve harmonization, the SPS Agreement requires that members base their measures on international standards where those standards exist.⁷⁴ In addition, members must accept measures from other countries if an exporting member can prove to an importing member that its measures are equivalent, achieving the same appropriate level of protection.⁷⁵

While the SPS Agreement requires members to model their measures after international guidelines, it still allows members to apply “measures which will result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines, or recommendations”⁷⁶ However, if a member

⁶⁶ See *id.* at 25.

⁶⁷ See *id.* at 145.

⁶⁸ See *id.*

⁶⁹ *Id.*

⁷⁰ See *id.* at 145; see also SPS Agreement, *supra* note 62, art. 2.

⁷¹ *Id.* art. 5.

⁷² *Id.*

⁷³ See *id.*; see also TREBILCOCK & HOWSE, *supra* note 64, at 147.

⁷⁴ See *id.* at 145; see also SPS Agreement, *supra* note 62, art. 3(1).

⁷⁵ See SPS Agreement, *supra* note 62, art. 4(1).

⁷⁶ See *id.* arts. 3(1), 3(3).

country decides to adopt more stringent standards, it must base its rationale upon a scientific justification.⁷⁷

Under the SPS Agreement, representatives from member countries form a Committee on Sanitary and Phytosanitary Measures that must convene regularly or as the need arises.⁷⁸ The Committee must “implement the provisions of this Agreement, . . . encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary and phytosanitary issues, . . . and monitor the process of international harmonization [of sanitary and phytosanitary measures]”⁷⁹

The adopted Protocol, which is analyzed later in this comment, has wisely borrowed some of the flexible safety principles implemented in the SPS Agreement. Like the SPS Agreement, the adopted Protocol sets a minimum standard of regulation, but allows its members to maintain some national political sovereignty and policy autonomy in establishing their own regulations as long as those regulations are at least equivalent to the minimum requirements.⁸⁰ In addition, both the SPS Agreement and the Protocol illustrate how countries can maintain the goals of economic growth through cooperation, while establishing human and environmental protections.

However, as discussed later in an analysis of the adopted Protocol, there is a need for a protocol that specifically addresses issues surrounding the trade of GMOs. For example, because the SPS Agreement requires members to adopt measures based on scientific evidence, it makes it difficult for members to adopt measures when there are *potential* dangers that scientists have yet to prove. Because the trade of GMOs involves many *potential*, yet scientifically unproven dangers, the SPS Agreement does not adequately address those issues.

IV. THE CONVENTION ON BIOLOGICAL DIVERSITY

While the WTO has established provisions to regulate agricultural trade amongst its members, countries from around the world have made attempts to establish an international agreement to regulate biodiversity. In June 1992, countries met at the Earth Summit in Rio de Janeiro to discuss various environmental issues.⁸¹ Out of the Earth Summit, parties formed a

⁷⁷ See *id.* art. 3(3); see also Paul E. Hagen & John Barlow Weiner, *SYMPOSIUM ARTICLE: The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified Organisms*, 12 GEO. INT'L ENVTL. L. REV. 697, 710 (2000) (stating that while the SPS agreement also permits WTO members to take interim measures in the absence of scientific evidence under article 5, parties generally cannot do so).

⁷⁸ See SPS Agreement, *supra* note 62, arts. 12(1), 12(7).

⁷⁹ *Id.* arts. 12(1), 12(2), 12(4).

⁸⁰ See TREBILCOCK & HOWSE, *supra* note 64, at 147; for a more lengthy discussion of flexibility of regulations, see *infra* Section IVE2.

⁸¹ See *Biosafety Protocol Could Hinder International Biotech Trade, Says Analyst*, FOOD LABELING NEWS, (Information Access Company Newsletter Database), Nov. 18, 1998, at 6.

multilateral treaty, the Convention on Biological Diversity ("CBD"), to protect biodiversity.⁸²

The CBD establishes a method for countries to work together "to encourage sustainable development and to slow the destruction of biodiversity."⁸³ There are currently 179 parties to the Convention.⁸⁴ While the United States is an observing participant, it is not a party to the treaty and therefore has no voting rights regarding the provisions of the CBD.⁸⁵ Thus, the United States can participate in negotiations, but it does not have a final vote in the adoption of any measures taken by the CBD, nor is the United States required to abide by the CBD.

A. Biosafety Protocol

One of the goals of the CBD is to create a "biosafety protocol" to regulate the trade of GMOs.⁸⁶ Specifically, the parties to the CBD want to establish "minimum regulatory standards for the exports of GMOs" to ensure that GMOs are safe for the environment and human health.⁸⁷

To establish the biosafety protocol, parties to the CBD continued to deal with key controversial issues, such as advanced informed agreement ("AIA"), risk assessments, and information exchange.⁸⁸ A proposed AIA provision would have required prior governmental approval for every exchange of GMO products among scientists and every shipment of widely traded commodities containing GMOs, including soybeans and corn.⁸⁹ There was disagreement among parties on whether consent should be necessary for every shipment and on whether both the importing country and the exporting country must complete risk assessments.⁹⁰ Another issue was the creation of more effective information technology to enhance the exchange of information about GMOs.⁹¹

B. Debate Over Biosafety Protocol

There has been great controversy over the final establishment of a biosafety protocol.⁹² Developing countries and many NGOs generally argue

⁸² *Id.*

⁸³ See Redick et al., *supra* note 1, at 16.

⁸⁴ *The Convention on Biological Diversity has 179 Parties: 178 Countries and the European Union*, at <http://www.biodiv.org/conv/cbd-ratification.asp?date> (last visited on Jan. 17, 2001).

⁸⁵ Redick et al., *supra* note 1, at 16.

⁸⁶ See *id.* at 5.

⁸⁷ *Id.* at 5-6.

⁸⁸ See *id.* at 21.

⁸⁹ See *supra* note 81.

⁹⁰ See Redick et al., *supra* note 1, at 21.

⁹¹ See *id.*

⁹² See *id.* at 7.

for the establishment of a biosafety protocol with international standards that all countries must meet in order to release GMOs into the environment.⁹³ Because these developing countries do not have the resources to conduct proper risk assessments on GMOs, they support universal standards that require risk assessments, labeling requirements, and other safety measures.⁹⁴ Many NGOs are wary of the possible risks that GMOs pose to the environment, specifically the risk of disruption of the ecological balance of areas where they are introduced.⁹⁵

However, many industrialized countries, such as the United States, advocate voluntary guidelines rather than a biosafety protocol to regulate the international trade of GMOs.⁹⁶ Because industrialized countries have used GMOs for some time, they are more familiar with the risks and benefits of GMOs.⁹⁷ Industrialized countries and biotechnology companies in those countries contend that because many biotechnology companies already comply with existing standards under the International Bio-Industry Forum ("IBF") Pledge, the risks of GMOs are insignificant and preventable.⁹⁸ Industrialized countries also call for less stringent, voluntary standards regulating GMOs because of the agricultural benefits of GMO crops, such as genetically engineered resistance to certain insects.⁹⁹

C. Meetings Under Convention on Biological Diversity

Prior to CBD, the United Nations Environmental Programme ("UNEP") had already begun to debate whether a biosafety protocol should be established.¹⁰⁰ In 1993, a UNEP panel of scientific experts found that there was inadequate scientific evidence to warrant a scientific protocol.¹⁰¹ However, the UNEP experts did concede that a biosafety protocol "could harmonize regulations."¹⁰²

After these UNEP findings, parties to the CBD met for the first time at the first Conference of the Parties ("COP I") in Nassau, Bahamas from November 28 to December 9, 1994.¹⁰³ At COP I, NGOs in attendance proposed a moratorium on the export of GMOs until a biosafety protocol was

⁹³ *Id.*

⁹⁴ *See id.* at 7-8.

⁹⁵ *See id.* at 7.

⁹⁶ *See* Redick et al., *supra* note 1, at 8.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *See id.*

¹⁰⁰ *See* Redick et al., *supra* note 1, at 37.

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*, citing Report of the First Meeting of the Conference to the Parties to the Convention on Biological Diversity, United Nations Environment Programme (UNEP), at <http://www.biodiv.org/cop1/cbdrepi.html> (last visited Oct. 31, 1999) [hereinafter Cop I Report].

established.¹⁰⁴ The parties did not grant the moratorium.¹⁰⁵ During COP I, the parties created an open-ended ad hoc working group of experts to consider the issue of biosafety ("Ad Hoc Group").¹⁰⁶ The purpose of the Ad Hoc Group was to consider the merits of a biosafety protocol and to discuss the potential risks that GMOs posed to biodiversity and the various risk assessment procedures to control potential risks.¹⁰⁷

In an attempt to achieve its goals, the Ad Hoc Group met from July 24 to July 28, 1995 in Madrid, Spain.¹⁰⁸ Because of its "open designation," the meeting included attendees from eighty-four countries, seven UN bodies, two intergovernmental organizations, and twenty-two NGOs.¹⁰⁹ The debate between industrialized and developing countries ensued.¹¹⁰ As discussed previously, while most industrialized nations argued for a voluntary system of regulation of GMOs, developing countries and NGOs argued for a global ban of GMOs.¹¹¹ While the parties did not reach an agreement on this issue, they did agree that a protocol should be established to regulate GMOs with possible adverse effects on biodiversity.¹¹² In addition, they agreed that there was a need for risk assessment and management procedures and methods of information exchange.¹¹³

At its second meeting in November 1995 ("COP II"), the COP created a new working group, the Open-Ended Ad-Hoc Working Group on Biosafety ("Biosafety Working Group").¹¹⁴ The parties created this working group "to begin addressing AIA and the transboundary movement of GMOs."¹¹⁵

D. Sixth Meeting of the Biosafety Working Group

On February 22 and 23, 1999, in Cartagena Columbia, the Biosafety Working Group met for its sixth and final meeting to date.¹¹⁶ One hundred and thirty countries, various UN organizations, intergovernmental organiza-

¹⁰⁴ Redick et al., *supra* note 1, at 38.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*; see also COP I Report, *supra* note 103.

¹⁰⁸ Redick et al., *supra* note 1, at 39; see also Report of the Open-ended Ad Hoc Group of Experts on Biosafety, UNEP Conference of the Parties to the Convention on Biological Diversity, at <http://www.upep.ch/bio/cp2-&.html> (last visited Oct. 31, 1999) [hereinafter UNEP Conference of the Parties-2d Mtg].

¹⁰⁹ Redick et al., *supra* note 1, at 39.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.* at 42.

¹¹⁵ Redick et al., *supra* note 1, at 42.

¹¹⁶ BSWG Report 6, *supra* note 10.

tions, and NGOs attended to negotiate a compromise on a biosafety protocol.¹¹⁷ They drafted a protocol that would exempt gene-altered farm commodities and pharmaceuticals from regulation.¹¹⁸ This exemption was the focus of debate amongst the parties.¹¹⁹ While the Miami Group, a conglomeration of countries including the United States, Canada, Australia, Argentina, Uruguay and Chile argued that strict regulations on GMO crops and pharmaceuticals would hinder international trade, Europe and most developing nations argued for stricter rules that would include the regulation of these products.¹²⁰

On February 24, 1999, negotiations collapsed as the parties could not reach a compromise on a biosafety protocol.¹²¹ Although more than 110 countries had agreed on a potential protocol, the Miami group blocked it.¹²² The United States and its supporters were concerned with strict regulatory measures, such as labeling requirements, included in the proposed protocol by European and developing countries.¹²³ European countries and developing countries proposed the strict safety standards to prevent potential environmental and health problems associated with the deliberate release of GMOs.¹²⁴ Many European countries advocate a ban or a serious restriction on the release of GMOs for reasons of environmental and human safety, and ethical objections to the manipulation of DNA in foods.¹²⁵ Although talks ceased, the Biosafety Working Group agreed to continue to negotiate a protocol before or during the May 2000 Conference of the Parties in Nairobi.¹²⁶

E. Montreal Meeting—January 24 to 29, 2000 and Beyond

After five years of negotiations, officials from the 130 CBD countries finalized a legally binding protocol, the Cartagena Protocol on Biosafety ("Cartagena Protocol or Protocol"), to regulate the international trade of GMOs at a CBD meeting in Montreal.¹²⁷ Over 700 delegates from governments, intergovernmental organizations, and NGOs attended the meeting to negotiate the Cartagena Protocol, named for the place where it was

¹¹⁷ *Id.*

¹¹⁸ *Id.*; see also Lambrecht, *supra* note 2, at A5.

¹¹⁹ See Lambrecht, *supra* note 2, at A5.

¹²⁰ *Id.*

¹²¹ Bill Lambrecht, *Talks Collapse on Rules for Genetic Crops; U.S., Allies Blocked International Accord*, ST. LOUIS POST-DISPATCH, Feb. 25, 1999, at A1.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ See Lambrecht, *supra* note 12, at A1.

¹²⁶ Angela Sanchez, *Environment: New Delay for Biosafety Protocol*, INTER PRESS SERVICE, Feb. 25, 1999.

¹²⁷ See Cartagena Protocol Press Release, *supra* note 4.

drafted.¹²⁸ The CBD opened for signature the agreed text of the Cartagena Protocol at its COP meeting in Nairobi on May 15 to 26, 2000 (Fifth Session of the Conference of the Parties to the Convention on Biological Diversity—"COP 5").¹²⁹ At COP 5, sixty-four governments and the European Union signed the Protocol, indicating their general support for the agreement and their intention to be become legally bound by it.¹³⁰ Since COP 5, a total of eighty-one parties have signed the Protocol.¹³¹ However, only two parties, Bulgaria and Trinidad and Tobago, have ratified it, thus becoming legally bound to adhere to its principles.¹³² Upon the ratification of the Protocol by fifty CBD countries, the Protocol will take legal force for its members.¹³³

1. Safety Measures in the Cartagena Protocol

The Cartagena Protocol contains many safety provisions to protect biodiversity.¹³⁴ The parties premised the Protocol on the "precautionary approach," as contained in the Rio Declaration on the Environment and Development, which permits parties to act absent clear scientific evidence or based on non-scientific criteria.¹³⁵ Thus, parties can act to prevent potential damage from the release of GMOs before that damage is definitively proven. For example, Article 1 of the Protocol states:

*In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.*¹³⁶

In Articles 7 through 10, the Protocol defines the Advance Informed Agreement procedure ("AIA").¹³⁷ At its meeting in Montreal, the parties agreed that these strict AIA procedures only apply to seeds, live fish, and

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ See Mwagni, *supra* note 5; see also *Frequently Asked Questions about the Cartagena Protocol on Biosafety*, at <http://www.biodiv.org/biosafe/protocol/FAQs.html> (last visited Dec. 13, 2000) [hereinafter *Frequently Asked Questions*].

¹³¹ See *id.*

¹³² See *id.*

¹³³ *Id.*

¹³⁴ See Cartagena Protocol on Biosafety to the Convention on Biological Diversity, at <http://www.biodiv.org/biosafe/Protocol/html/Biosafe-Prot.html> (last visited on Dec. 13, 2000) [hereinafter *Cartagena Protocol Text*].

¹³⁵ See Hagen & Weiner, *supra* note 77, at 710.

¹³⁶ *Id.* (emphasis added); see also *Cartagena Protocol Text*, *supra* note 134, art. 1 (emphasis added).

¹³⁷ See *Cartagena Protocol Text*, *supra* note 134, arts. 7-10.

other LMOs that will be intentionally introduced to the environment as opposed to LMOs intended for direct use as food or feed.¹³⁸

Under AIA requirements, the exporter of GMOs must ensure notification in writing to the importer prior to the international trade of potentially dangerous GMOs.¹³⁹ As stated in Article 8 and Annex I, information required in notifications includes the identity of the GMO, the characteristics of both the recipient and donor organisms related to biosafety, a description of the genetic modification, the quantity of the goods, suggestions of safe handling, storage, transport and use of the GMOs, and the regulatory status of the GMOs in the country of export.¹⁴⁰ After receiving notification, the party of import has ninety days to acknowledge the receipt of the notification and communicate to the notifier whether the transboundary movement may proceed under Articles 9 and 10.¹⁴¹ In addition, the party of import has 270 days from the date of receipt of notification to communicate its decision whether to proceed to the party of export and to the Biosafety Clearing-House, an international information clearing-house mechanism to facilitate the exchange of information regarding GMOs.¹⁴²

Article 12 states that a party of import "may at any time, in light of new scientific information on potential adverse effects [of LMOs] . . . review and change a decision regarding an intentional transboundary movement."¹⁴³ In turn, the party of export has an equal opportunity to dispute the changed decision by requesting the party of import to review its decision.¹⁴⁴

The parties to the CBD wisely included these strict requirements in order to prevent the accidental release of potentially dangerous GMOs.

The adopted Protocol also contains labeling requirements.¹⁴⁵ Under Article 18, when shipping LMOs that are intended for intentional introduction into the environment, parties must provide accompanying documentation that:

[C]learly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.¹⁴⁶

¹³⁸ Cartagena Protocol Press Release, *supra* note 4.

¹³⁹ See Cartagena Protocol Text, *supra* note 134, art. 8.

¹⁴⁰ *Id.* art. 8, annex I.

¹⁴¹ See *id.* art. 9.

¹⁴² *Id.* art. 10.

¹⁴³ *Id.* art. 12.

¹⁴⁴ Cartagena Protocol Text, *supra* note 134, art. 12.

¹⁴⁵ See *id.* art. 18.

¹⁴⁶ *Id.*

Parties should use these labeling requirements to avoid any potential adverse effects on biodiversity, including risks to human health, by the release of LMOs into the environment.¹⁴⁷

However, at the Montreal meeting, the United States negotiated a concession with respect to the labeling requirement: bulk shipments of goods for food, feed, or processing only require a label that states that the products "may contain" GMOs.¹⁴⁸ This concession only weakens the labeling requirement measure slightly because the dangers of transboundary movement of food, feed, or processing goods does not warrant the specific labeling requirements necessary for more experimental GMOs, such as GMO seeds, intended for intentional introduction into the environment. However, the Protocol's labeling requirements for food do not address the concerns of consumers who want to make conscious decisions about whether to ingest GMO foods; the label is only seen by the actual producers and buyers of shipments and not by the consumers.

Not only does the Protocol require parties to label LMOs, it also requires parties to establish and maintain risk management procedures to regulate potential risks of the transboundary movement of LMOs.¹⁴⁹ Under Article 16, each party must adopt measures that require risk assessments to be conducted prior to the initial release of an LMO.¹⁵⁰ In addition, each party must ensure that "any living modified organism . . . has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use."¹⁵¹

The Protocol contains a retroactive safety provision, Article 17, which discusses the unintentional transboundary movements of LMOs and emergency measures addressing these unintentional movements.¹⁵² If a party unintentionally releases LMOs into the environment, it must immediately notify affected and potentially affected countries, the Biosafety Clearing-House, and, where appropriate, international organizations with jurisdiction in the affected area or areas.¹⁵³ Moreover, the party responsible for the release must consult with the affected or potentially affected parties to determine any appropriate emergency measures to minimize adverse effects on biodiversity.¹⁵⁴

¹⁴⁷ See *id.*

¹⁴⁸ See Bill Lambrecht, *Nations OK Pact on Genetically Modified Foods; Treaty Regulates Technology but Allows Its Use; Monsanto, Greenpeace Hail Accord*, ST. LOUIS POST-DISPATCH, Jan. 30, 2000, at A1; see also Cartagena Protocol Text, *supra* note 134, art. 18.

¹⁴⁹ See Cartagena Protocol Text, *supra* note 134, art. 16.

¹⁵⁰ See *id.*

¹⁵¹ *Id.*

¹⁵² See *id.* art. 17.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

Finally, the Protocol also requires the establishment of procedures for liability and redress under Article 27.¹⁵⁵ The Protocol calls for the adoption of “a process . . . of international rules and procedures in the field of liability and redress for damage resulting from the transboundary movement of living modified organisms” within four years.¹⁵⁶

2. Facilitation of Procedures in the Protocol

Not only does the Protocol provide various safety measures, it also contains provisions that facilitate the transboundary movement of LMOs.¹⁵⁷ Article 13 of the Protocol provides a simplified procedure for the transboundary movement of LMOs previously established as safe.¹⁵⁸ The party of import may specify in advance to the Biosafety Clearing-House cases in which the transboundary movement of LMOs and the notification can take place simultaneously.¹⁵⁹

In addition, under Article 14, the adopted Protocol allows parties to enter into multilateral, bilateral, and regional agreements and arrangements with other parties and non-parties that can substitute for adherence to the Protocol.¹⁶⁰ These agreements must include safety provisions that “do not result in a lower level of protection than that provided for by the Protocol.”¹⁶¹ Parties must inform each other, using the Biosafety Clearing-House, of any such agreements.¹⁶² The provisions of the Protocol will not affect intentional transboundary movements under these bilateral, regional, or multilateral agreements.¹⁶³ This article also allows a party to determine whether its own domestic regulations should apply to specific imports to it, as long as the party notifies the Biosafety Clearing-House of its decision.¹⁶⁴

Under Article 20, the Protocol encourages free exchange of information regarding LMOs.¹⁶⁵ As discussed above, the Protocol establishes a Biosafety Clearing-House in order to “[f]acilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms.”¹⁶⁶ This free exchange of information addresses the inability of developing countries to make informed decisions on whether to permit the import of LMOs and how to implement the Proto-

¹⁵⁵ See Cartagena Protocol Text, *supra* note 134, art. 27.

¹⁵⁶ *Id.*

¹⁵⁷ See generally Cartagena Protocol Text, *supra* note 134.

¹⁵⁸ See Cartagena Protocol Text, *supra* note 134, art. 13.

¹⁵⁹ See *id.*

¹⁶⁰ See *id.* art. 14.

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ See *id.*

¹⁶⁴ See Cartagena Protocol Text, *supra* note 134, art. 14.

¹⁶⁵ See *id.* art. 20.

¹⁶⁶ *Id.*

col.¹⁶⁷ The Biosafety Clearing-House serves as the means to provide access to information made available by the parties.¹⁶⁸ The Clearing-House will use the Internet as a main vehicle to distribute information.¹⁶⁹ This information includes national regulations for the implementation of the Protocol, information required in AIA procedures, any multilateral, bilateral, and regional agreements, summaries of risk assessments or environmental review of LMOs, and final decisions regarding the import of specific LMOs.¹⁷⁰ Under the Cartagena Protocol, governments will indicate whether they are willing to accept imports of agricultural goods that contain LMOs by communicating their decisions to this Internet-based Biosafety Clearing-House.¹⁷¹

Finally, Article 22 of the Protocol addresses capacity-building.¹⁷² The parties recognize that for the purpose of effectively implementing the Protocol, they must develop and strengthen human resources and institutional capacities in biosafety in developing countries, especially in least developed and small island developing states.¹⁷³ When addressing this issue of capacity-building in biosafety, parties must consider a developing country's needs for financial resources and access to, and transfer of, technology.¹⁷⁴ Thus, for developing country parties to meet the requirements of the Protocol, all parties must facilitate the development of institutional resources in those countries with both financial and technological support.

3. *Financial Mechanism for the Protocol*

An analysis of the financial mechanism behind the Protocol is also important to determine whether the Protocol will be effective. Before the Protocol is implemented, it is difficult to determine whether its funding is adequate to implement the day-to-day procedures (e.g., filing documents, maintaining the Biosafety Clearinghouse, keeping records of dangerous GMO products) necessary to enforce the procedures established under the Protocol. This section gives a brief description of some of the funding already set aside to implement the Cartagena Protocol to give readers a basic understanding of its financial mechanism.¹⁷⁵

¹⁶⁷ See *id.*

¹⁶⁸ See *id.*

¹⁶⁹ See Cartagena Protocol Press Release, *supra* note 4.

¹⁷⁰ See Cartagena Protocol Text, *supra* note 134, art. 20.

¹⁷¹ See Cartagena Protocol Press Release, *supra* note 4; see also Cartagena Protocol Text, *supra* note 134, art. 20.

¹⁷² See *id.* art. 22.

¹⁷³ See *id.*

¹⁷⁴ See *id.*

¹⁷⁵ Please note that the following is only a brief summary. It was difficult to obtain complete information on the subject of funding. In addition, a complete analysis of funding would go beyond the scope of this article.

In Article 28, the parties define the financial mechanism and resources for the Protocol.¹⁷⁶ The Protocol incorporates the financial resources and mechanism provisions of the Convention on Biological Diversity, Articles 20 and 21 respectively.¹⁷⁷

Article 20 of the CBD states that each contracting party to the CBD must provide “financial support and incentives” for national activities that attempt to achieve protection of biodiversity.¹⁷⁸ In addition, developed countries must provide additional financial resources “to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil[sic] the obligations of this Convention.”¹⁷⁹ In addition to requiring financial support, Article 20 encourages voluntary contributions from parties as well.¹⁸⁰ Finally, developed countries may also provide financial resources to developing countries through bilateral, regional, and other multilateral channels.¹⁸¹

Article 21 provides for a financial mechanism “for the provision of financial resources to developing country Parties . . . on a grant or concessional basis.”¹⁸² The mechanism functions under the authority and guidance of the Conference of the Parties (“COP”).¹⁸³ At its first meeting, the COP decided that the Global Environmental Facility (“GEF”) would continue as the institutional structure to operate the financial mechanism of the CBD.¹⁸⁴ The GEF is a restructured financial institutional structure, “established to forge international cooperations and finance action to address four critical threats to the global environment . . . [including] biodiversity loss”¹⁸⁵ Article 21 also reiterates encouragement for voluntary contributions from developed country parties and by other countries and sources.¹⁸⁶

Article 28 of the Protocol also addresses the need for financing capacity-building of developing countries, as described above.¹⁸⁷ It requires the

¹⁷⁶ See Cartagena Protocol Text, *supra* note 134, art. 28.

¹⁷⁷ See *id.*

¹⁷⁸ Convention on Biological Diversity – Convention Text: Article 20. Financial Resources, at <http://www.biodiv.org/chm/conv/art20.htm> (last modified May 25, 2000) [hereinafter CBD Article 20].

¹⁷⁹ *Id.*

¹⁸⁰ See *id.*

¹⁸¹ See *id.*

¹⁸² Convention on Biological Diversity – Convention Text: Article 21. Financial Mechanism, at <http://www.biodiv.org/chm/conv/art21.htm> (last modified May 25, 2000) [hereinafter CBD Article 21].

¹⁸³ *Id.*; see also *Financial Mechanism*, at <http://www.biodiv.org/fm/fm.html> (last modified May 25, 2000).

¹⁸⁴ See *id.*

¹⁸⁵ *What is the Global Environment Facility?*, at http://www.gefweb.org/What_is_the_GEF/what_is_the_gef.html (last visited Jan. 18, 2001) [hereinafter *What is the GEF*].

¹⁸⁶ See CBD Article 21, *supra* note 182.

¹⁸⁷ See Cartagena Protocol Text, *supra* note 134, art. 28.

COP to take into account the financial needs of developing countries, including least developed and small island developing states, in their efforts to implement their capacity-building requirements.¹⁸⁸

Adhering to its Article 28 requirements, the COP reconfirmed its approved year 2000 budget of US\$ 1,078,800 for the Protocol on Biosafety at its January meeting in Montreal.¹⁸⁹ The COP also noted funds received from the Special Voluntary Trust Fund ("BE") for Additional Voluntary Contributions in Support of Approved Activities, a trust of voluntary funds discussed above, in the amount of US\$ 306,000 for 1999-2000.¹⁹⁰ The COP used these voluntary funds for meetings, the Biosafety Clearing-House, and a roster of experts in fields relevant to risk assessment and management.¹⁹¹ At its meeting in Nairobi in May 2000, the COP set its budget for the biennium 2001-2002.¹⁹² The budget includes the following funding for the Biosafety Protocol: US\$ 100,000 per year for regional meetings of the Biosafety Protocol, US\$ 483,600 per year for the ICCP, an undecided amount for implementation, and an undecided amount for biosafety in general.¹⁹³

4. Relationship with Other International Agreements

One of the most disputed issues that the parties negotiated when establishing the Cartagena Protocol is the relationship between the Protocol and other international agreements, specifically agreements under the World Trade Organization ("WTO").¹⁹⁴ The dispute stems from the different premises on which the agreements operate.¹⁹⁵

While environmental agreements [like this Protocol] are premised on the precautionary principle (which states that potentially dangerous activities can be restricted even before they can be scientifically proven to cause serious damage), decisions under trade law [WTO] require "sufficient scientific evidence."¹⁹⁶

¹⁸⁸ See *id.*

¹⁸⁹ See Decisions of the Conference of Parties, Montreal 2000: EM-I/3. Adoption of the Cartagena Protocol and Interim Arrangements, at <http://www.biodiv.org/decisions/ExCOP1/html/excop-1-dec-03-e.htm> (last visited Dec. 13, 2000) [hereinafter EM-I/3 Decision].

¹⁹⁰ See *id.* § IV.

¹⁹¹ See *id.* §§ IV, III.

¹⁹² See Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at Its Fifth Meeting, Nairobi, 15-26 May 2000: V/22. Budget for the Programme of Work for the Biennium 2001-2002, at <http://www.biodiv.org/decisions/cop5/html/COP-5-Dec-22-e.htm> (last visited Jan. 18, 2001) [hereinafter V/22 Decision].

¹⁹³ See *id.* Table 1.

¹⁹⁴ See Cartagena Protocol Press Release, *supra* note 4.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

Under the Cartagena Protocol, the Protocol and the WTO "are to be mutually supportive."¹⁹⁷ However, the Protocol is not to affect "the rights and obligations of a Party under any existing international agreements."¹⁹⁸

This subordination to existing international agreements may reduce the effectiveness of the Protocol. For example, if WTO trading laws do not require the strict safety measures adopted in this Protocol, WTO members, even if they are also parties to the CBD, may be able to avoid compliance because of the subordinate position of the CBD. In addition, WTO and CBD members could also claim that one of their members is using a Protocol restriction, without scientific evidence, as a mere guise for trade advantage.

Because the United States is not a party to the CBD, and thus not required to follow the Protocol, the effectiveness of the Protocol may also be weakened. However, American industry must comply with the Protocol rules when exporting to countries that are parties to the CBD because if American companies do not comply, party countries will not accept American shipments.¹⁹⁹ In addition, federal United States officials at the Montreal meeting stated that the United States would honor the treaty.²⁰⁰ This promise raises the issue of whether the United States can be trusted to honor a treaty without being legally bound to it.

V. ANALYSIS OF THE PROTOCOL

Now that they have adopted the Cartagena Protocol, the parties should ratify and implement it. The two main factions, industrialized countries and developing countries, have sensibly negotiated a protocol to regulate the transboundary movement of GMOs. A compromise that establishes basic regulatory standards, like the Cartagena Protocol, will benefit both factions.²⁰¹ There are numerous reasons to ratify this Protocol.

First, the deliberate release of GMOs is an international issue.²⁰² Because the deliberate release of GMOs in one country could potentially affect the population or environment of another country or countries, international standards should be established.²⁰³ For example, as discussed previously,

¹⁹⁷ *Id.*; see also Cartagena Protocol Text, *supra* note 134, preamble.

¹⁹⁸ Cartagena Protocol Text, *supra* note 134, preamble; see also Cartagena Protocol Press Release, *supra* note 4.

¹⁹⁹ See Andrew Pollack, *130 Nations Agree on Safety Rules for Biotech Food*, N.Y. TIMES, Jan. 30, 2000, at 1.

²⁰⁰ *Id.*

²⁰¹ See Kim, *supra* note 53, at 1162. "Harmonization of international regulations for the deliberate release of GMOs into the environment is needed to encourage the development of genetically engineered products, to promote international trade, and to protect human health and the environment with common safety standards." *Id.*

²⁰² See Kim, *supra* note 53, at 1168.

²⁰³ See *id.* at 1169.

wheat grown in one country that has been genetically altered to resist pesticides could pass its pesticide-resistant genetic qualities onto weeds growing in another country, potentially disrupting the ecological cycles of the latter country's environment.²⁰⁴ Thus, if the COP can ratify international standards for the deliberate release of GMOs, all countries will receive greater protection from the potential dangers of the release.²⁰⁵

Second, because there are many potential risks to both the environment and human health from the deliberate release of GMOs, the COP should ratify the Protocol to manage these potential risks.²⁰⁶ The COP rightfully invoked the "precautionary approach" when establishing the Cartagena Protocol. Because scientists have not been able to predict the future harms of GMOs with certainty,²⁰⁷ and these harms may not be easily halted or reversed,²⁰⁸ the COP should implement strict regulations until the safety of specific GMOs can be scientifically proven.

As stated in Article 4 of its text, the Protocol regulations apply only to LMOs "that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."²⁰⁹ Thus, once scientists have proven that a specific LMO may not pose an "adverse effect," that LMO will no longer be subject to the regulations of the Protocol.²¹⁰ This gives biotechnology companies, like Monsanto, incentives to conduct scientific research to prove the safety of their products. While scientists conduct research on the safety of LMOs, the Protocol allows a loosening of regulations, such as its simplified procedures for transboundary movement of LMOs, "provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms."²¹¹

Third, the COP should ratify the adopted Protocol because it provides a central information clearing-house to disperse information about LMOs. As previously discussed, under the Protocol, the Biosafety Clearing-House becomes the central body with information about LMOs, such as potential risks and scientific studies.²¹² Thus, the free flow of information mandated in the Protocol can assist developing countries without information about GMOs in making informed decisions about whether to allow GMO imports.²¹³ In addition, the COP should implement the Biosafety Clearing-

²⁰⁴ See *id.* at 1168.

²⁰⁵ See *id.* at 1200.

²⁰⁶ See *id.* For a discussion of potential risks, see *supra* Section IIC.

²⁰⁷ Kim, *supra* note 53, at 1200.

²⁰⁸ *Id.* at 1169.

²⁰⁹ Cartagena Protocol Text, *supra* note 134, art. 4.

²¹⁰ See *id.*

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.*

House immediately in order to make information readily available for countries to establish their own laws on the regulation of GMOs until the Protocol can be ratified.²¹⁴ As use of the Internet continues to expand globally, the Biosafety Clearing-House should use the Internet as a main source of information disbursement.

Fourth, the Protocol should be ratified because it provides a minimum, uniform standard of regulation.²¹⁵ This uniform standard has benefits for both importing countries and biotechnology companies.²¹⁶ An international protocol allows for the safe trade of GMOs across international borders, while it benefits companies by establishing one set of uniform regulations that the industry must follow.²¹⁷ Presently, companies marketing a new GMO must abide by the regulations of each country, raising the cost of marketing the product around the world.²¹⁸ Adoption of a uniform standard would reduce these marketing cost trade barriers to make GMOs more readily available to consumers in the global marketplace.²¹⁹

The Cartagena Protocol also maintains flexibility as it allows countries to adopt equivalent standards to those in the Protocol.²²⁰ Under the WTO's SPS Agreement, member countries have discretion to establish their own trade regulations as long as those standards are equivalent to the importing country's appropriate level of protection.²²¹ Similarly, under the Protocol, parties can establish outside agreements regarding the transboundary movements among themselves as long as those agreements do not result in a lower level of protection provided in the Protocol.²²²

Fifth, by establishing a uniform protocol, the COP can stop the exploitation of countries with less stringent regulations or countries without regulations.²²³ Currently, biotechnology companies often choose to conduct field testing and marketing in countries with little or no regulation of GMOs.²²⁴ Usually, developing countries do not have regulations because of a lack of information or a lack of financial resources to establish regulations.²²⁵ Under the Protocol, because all countries, both industrialized and

²¹⁴ See Sanchez, *supra* note 126. "If and when it is adopted, the Cartagena Protocol must be ratified by each signatory government, meaning it could take three or four years to go into effect...." *Id.*

²¹⁵ See Kim, *supra* note 53, at 1202.

²¹⁶ See *id.* at 1200.

²¹⁷ *Id.*

²¹⁸ See *id.* at 1196.

²¹⁹ See *id.* at 1200.

²²⁰ See Cartagena Protocol Text, *supra* note 134, art. 14.

²²¹ See SPS Agreement, *supra* note 62, art. 4.

²²² See Cartagena Protocol Text, *supra* note 134, art. 14.

²²³ See Kim, *supra* note 53, at 1197.

²²⁴ *Id.*

²²⁵ See *id.*

developed, would have established regulations, biotechnology companies would have less incentive to continue to use developing countries as testing grounds for their products.

Sixth, the ratification of the Protocol may decrease public opposition to GMOs. In countries around the world, people are publicly opposing GMO foods.²²⁶ For example, in Europe, critics of GMO food have sabotaged test plots of GMO crops.²²⁷ In June 1999 in Brazil, a federal judge banned the sales of Monsanto's Roundup Ready soybean seeds until the Brazilian government could set up biosafety regulations.²²⁸ Various representatives from the Brazilian government have questioned the safety of transgenic foods.²²⁹ For example, Rio Grande do Sul Governor Olivia Dutra stopped transgenic-seed production at 79 test sites, claiming the sites lacked environment-impact studies.²³⁰ Since Brazil is the world's second-largest soybean producer, Monsanto wants to market its transgenic soybean seeds there.²³¹ If the COP can ratify and implement the Protocol, public opposition to GMO foods may decrease, opening up markets, such as Brazil, to transgenic seeds.

VI. AN ALTERNATIVE TO THE PROTOCOL—VOLUNTARY REGULATIONS

A. Description

In addition to an international protocol, there have been other alternatives proposed to regulate the international trade of GMOs. The Aspen Institute advanced the "alternative path" concept to environmental regulation in 1993.²³² In their article, *Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path Within the Biosafety Protocol*, Thomas Redick, William Reavey, and Dirk Michels argue that the parties to the CBD should permanently adopt the "alternative path" concept to the regulation of the deliberate release of GMOs into the environment.²³³ Under the two-track approach to managing the risks of GMOs, already agreed to by the parties to the CBD, companies who could demonstrate a net environmental benefit to the release of GMOs would be subject to a voluntary monitoring system rather than the stricter case-by-case analysis under the Protocol.²³⁴

²²⁶ See Barboza, *supra* note 32, at A1.

²²⁷ *Id.*

²²⁸ Epstein, *supra* note 13, at A14.

²²⁹ See *id.*

²³⁰ *Id.*

²³¹ See *id.*

²³² See Redick et al., *supra* note 1, at 56 (citing Dorothy P. Bowers, *The Alternative Path: A New Blueprint*, ENVTL. F., Mar./Apr. 1997, at 36-7).

²³³ See Redick et al., *supra* note 1, at 55.

²³⁴ *Id.*

The authors discuss various alternatives to regulate GMOs, such as already existing programs, the ISO series of standards, and the possibility of the creation of a new corporate ethic.²³⁵ Many corporations have already developed self-regulating environmental protection programs because of conscientious executives or because of the cost-effectiveness of self-regulation.²³⁶ For example, Johnson & Johnson has established an environmental program where a steering committee, consisting of vice presidents, meets to discuss the incorporation of new environmental protection methods into the company's strategic plan.²³⁷

The authors also suggest that intellectual property licensing agreements, another already existing mechanism, could help regulate environmental risks.²³⁸ For example, Monsanto Corporation has already established a licensing agreement for Bollgard® cotton, where cotton growers must agree to create a buffer zone of non-genetically altered crops surrounding an area of genetically altered crops.²³⁹ These buffer zones diminish the exposure of insect populations to the genetically engineered crop in order to prevent the development of insect resistance to the crop.²⁴⁰

Another alternative discussed is the ISO series of standards.²⁴¹ The ISO 14000 Series of Environmental Contract Specifications are international standards for environmental management.²⁴² Redick, Reavey, and Michels suggest that the ISO series "could provide the biotechnology industry with standardized legal provisions for internal environmental corporate policies."²⁴³ Under these provisions, a party may adopt third party certification, where an outside firm confirms the party's compliance with environmental regulations as part of an environmental management system.²⁴⁴

Finally, the authors consider the possibility of multinational biotechnology companies as catalysts for environmental "sustainability."²⁴⁵ "Sustainability" is generally defined as the management of 'natural systems for the perpetuation of the human species now and in the future.'²⁴⁶ They encourage "conscientious consumers . . . , developing nations, and multina-

²³⁵ See *id.*

²³⁶ See *id.* at 57.

²³⁷ *Id.* at 59.

²³⁸ See *id.* at 60.

²³⁹ See *id.* at 60.

²⁴⁰ *Id.*

²⁴¹ See *id.* at 62.

²⁴² *Id.*

²⁴³ *Id.* at 62-63 (citing Henry P. Baer, Jr., Note, *ISO 14000: Potential Compliance and Prevention Guidelines for EPA and DOJ*, 7 FORDHAM ENVTL. L.J. 927, 934 (1996)).

²⁴⁴ See Redick et al., *supra* note 1, at 63.

²⁴⁵ See *id.* at 72.

²⁴⁶ *Id.* (citing Celia Campbell-Mohn, *Objective and Tools of Environmental Law*, in SUSTAINABLE ENVIRONMENTAL LAW: INTEGRATING NATURAL RESOURCES AND POLLUTION ABATEMENT LAW FROM RESOURCES TO RECOVERY (Celia Campbell-Mohn et al. Eds., 1993)).

tional corporations creating sustainable GMOs" to come together "to promote the use and consumption of sustainable GMOs."²⁴⁷ Biotechnology companies, such as Monsanto, argue that the dissemination of "new information technology may be the key to sustainable development."²⁴⁸ For example, because of discoveries in new information technology, scientists can genetically alter crops to be insect resistant, eliminating labor hours and toxic residues connected to the production and disbursement of pesticides.²⁴⁹ Thus, the authors argue for a biosafety protocol "that encourages exports of GMOs and requires information dissemination" in order to "unite NGO and industry interests in search for a sustainable future."²⁵⁰

B. Analysis of Voluntary Regulations

A voluntary system of self-regulation of GMOs will not lead to compliance for numerous reasons. First, there is too much money involved in the production and sale of GMOs to allow private companies, whose primary interest is to profit, to self-regulate. For example, American Home Products, which acquired Monsanto in June 1998, made over US\$ 2 billion in net agricultural sales in 1998 and projected just under US\$ 2 billion in net agricultural sales in 1999.²⁵¹ Because of this large financial interest, biotechnology companies, such as Monsanto, may be guided by economics rather than environmental safety. For instance, after a Cornell University study showed that genetically altered corn could stunt the development of the monarch butterfly, creating greater controversy regarding the safety of GMOs, some of the large biotechnology companies financed a scientific conference to discuss the safety of gene-altered corn.²⁵² However, prior to the conference, conference staff members issued a press release announcing that the conference would show that genetically engineered corn does not harm the monarch butterfly, although many scientists acknowledged that their research was incomplete.²⁵³ Announcements like this indicate that private biotechnology companies cannot be left to self-regulate.

Second, biotechnology companies' efforts to hire influential United States governmental officials in order to improve public opinion of GMO foods also indicates that the industry cannot be trusted to regulate itself. For example, in the fall of 1998, when the debate on the safety of GMO foods percolated in Ireland, Monsanto flew a group of Irish journalists to

²⁴⁷ Redick et al., *supra* note 1, at 75-76.

²⁴⁸ *Id.* at 74 (citing Joan Magretta, *Growth Through Global Sustainability: An Interview with Monsanto's CEO Robert B. Shapiro*, HARV. BUS. REV., Jan.-Feb. 1997, at 78, 82).

²⁴⁹ See Redick et al., *supra* note 1, at 74-75.

²⁵⁰ See *id.* at 76.

²⁵¹ David J. Morrow, *Market Place: Three Drug Companies are Moving to Dump their Agricultural Units as Worldwide Sales Decline*, N.Y. TIMES, June 29, 1999, at C12.

²⁵² See Barboza, *supra* note 32, at A26.

²⁵³ *Id.*

the United States to tour its labs.²⁵⁴ While in the United States, the journalists received a surprise visit to the Oval Office of the White House, coordinated by Marcia Hale, an employee of Monsanto, who was the President's director of intergovernmental affairs.²⁵⁵ Thus, Monsanto's efforts, and similar efforts by other biotechnology companies, to improve public opinion of GMO foods by doling out special favors also indicate that the biotechnology industry cannot be trusted to regulate itself.

VII. CONCLUSION

In conclusion, the dangers of the unregulated transboundary movement of GMO products calls for standard international regulations. The parties to the CBD have adopted a protocol that can curb these dangers, while still allowing for the continuation of free trade of GMOs. While the compromises in the Protocol still leave potential problems unanswered, in its entirety, the Cartagena Protocol provides sound international regulations of GMOs. Thus, because of the merits of the Cartagena Protocol, the parties to the CBD should ratify and implement it as soon as possible.

²⁵⁴ See Lambrecht, *supra* note 12, at A8.

²⁵⁵ *Id.*

