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#### **An Agricultural Law Research Article**

# The Merits of Ratifying and Implementing the Cartagena Protocol on Biosafety

by

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#### **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. Under the Convention on Biological Diversity ("CBD"), an international multilateral environmental agreement established to regulate biodiversity, 130 countries have developed and adopted a bio-

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<sup>&</sup>lt;sup>1</sup> 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 ENVIL. LAW. 1, 7-8 (1997).

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

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.<sup>3</sup> 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").<sup>4</sup> 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.<sup>5</sup> Presently, eighty-one parties have signed the Protocol, while only two have ratified it.<sup>6</sup> However, the Protocol will only enter into legal force after fifty parties have ratified it.<sup>7</sup>

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.

<sup>&</sup>lt;sup>2</sup> 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.

 $<sup>^3</sup>$  Id

<sup>&</sup>lt;sup>4</sup> 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/cbdre pi.html (last visited Feb. 8, 2001) [hereinafter Cartagena Protocol Press Release].

<sup>&</sup>lt;sup>5</sup> George Mwagni, Environmental-Safeguards Agreed On, Associated Press, May 26, 2000

<sup>&</sup>lt;sup>6</sup> 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].

<sup>&</sup>lt;sup>7</sup> 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. Living modified organisms ("LMOs")<sup>9</sup> are defined as "any living organism[s] that possess[] a novel combination of genetic material obtained through the use of modern biotechnology." By manipulating DNA, scientists can engineer plants and animals to have particular traits. Scientists can use gene-splicing technologies, transferring genes from one plant to another to create a "transgenic" plant, one with new characteristics. For example, Monsanto Corporation, of St. Louis, Missouri, manufactures Roundup Ready soybean seeds that are genetically engineered to be resistant to certain insects.<sup>13</sup>

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

<sup>&</sup>lt;sup>8</sup> Redick et al., supra note 1, at 6.

<sup>&</sup>lt;sup>9</sup> 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.

<sup>&</sup>lt;sup>10</sup> 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].

<sup>11</sup> Redick et al., supra note 1, at 6.

<sup>&</sup>lt;sup>12</sup> Bill Lambrecht, World Recoils at Monsanto's Brave New Crops; The St. Louis Company's Political Clout Has Turned the President and Cabinet Secretarties into Pitchmen, St. Louis Post-Dispatch, Dec. 27, 1998, at A1.

<sup>&</sup>lt;sup>13</sup> Jack Epstein, Brazil Battles Over Ban on Altered Beans, WASH. TIMES, Aug. 30, 1999, at A14.

<sup>&</sup>lt;sup>14</sup> Susan Boensch Meyer, Land and Resource Management: Genetically Modified Organisms, 1998 Colo. J. Int'l Envtl. L. & Pol'y Y.B. 102 (1998).

<sup>15</sup> Id

<sup>&</sup>lt;sup>16</sup> *Id*.

<sup>1&#</sup>x27; Id. at 102-03

<sup>&</sup>lt;sup>18</sup> 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.<sup>20</sup> Monsanto, the world's second-largest seed and third-largest agrochemical company, is the world leader in the production of GMOs.<sup>21</sup> Opposition to the release of GMOs into the environment often targets its protests against Monsanto.<sup>22</sup> However, other companies, such at Novartis, a Swiss Company, and AgrEvo, a German company, also use gene-altering technologies to produce GMOs.<sup>23</sup>

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. Deliberate release is the introduction of GMOs into the environment. Controversy stems from the deliberate release of GMOs, including both enhanced seed systems and transgenic seeds. 6

#### B. Potential Benefits of GMOs

Monsanto and other GMO manufacturers market their products as tools to feed the world and protect the environment. A current global environmental concern is how to create an adequate food supply as the world's population increases. 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. Scientists genetically engineer crops to resist plant viruses that would otherwise destroy part of the crop. Thus, genetically modified crops contain less viral contamination than unmodified crops, increasing both crop yield and quality. 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

<sup>&</sup>lt;sup>19</sup> See Meyer, supra note 14, at 102.

<sup>&</sup>lt;sup>20</sup> See Redick et al., supra note 1, at 59.

<sup>&</sup>lt;sup>21</sup> Epstein, supra note 13, at A14.

<sup>22</sup> Id

 $<sup>^{23}</sup>$  Id

<sup>&</sup>lt;sup>24</sup> Anne Marie Solberg, Genetically Engineered Produce Travels North America Under NAFTA: An Issue Ripe for Consideration, 18 HAMLINE L. REV. 551, 555 (1995).

<sup>&</sup>lt;sup>25</sup> *Id*.

<sup>&</sup>lt;sup>26</sup> See id.

<sup>&</sup>lt;sup>27</sup> Tom Rhodes, Bitter Harvest: The Real Story of Monsanto and GM Food, SUN. TIMES (LONDON), August 22, 1999, at 1.

<sup>&</sup>lt;sup>28</sup> Redick et al., supra note 1, at 7.

<sup>&</sup>lt;sup>29</sup> Id

<sup>&</sup>lt;sup>30</sup> Solberg, supra note 24, at 554.

<sup>31 11</sup> 

<sup>&</sup>lt;sup>32</sup> 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.<sup>33</sup> 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.<sup>34</sup>

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.<sup>35</sup> 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.<sup>36</sup>

#### 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.<sup>37</sup> The biological and ecological sciences cannot surely predict that the deliberate release of GMOs will be harmless.<sup>38</sup>

While supporters of GMOs argue that their release will benefit humans, opponents contend that there are risks of potential side effects on human health. 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"). 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. Those increased levels of IBF 1 both potentially increased the risks of cancer and promoted the growth of cancer cells in humans.

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

<sup>33</sup> Solberg, supra note 24, at 553.

<sup>34</sup> Id

<sup>35</sup> Epstein, supra note 13, at A14.

<sup>&</sup>lt;sup>36</sup> See id.

<sup>&</sup>lt;sup>37</sup> Solberg, *supra* note 24, at 555.

<sup>&</sup>lt;sup>38</sup> *Id.* at 554-555.

<sup>&</sup>lt;sup>39</sup> See id. at 556.

<sup>&</sup>lt;sup>40</sup> Press Release, Monsanto's Genetically Modified Milk Ruled Unsafe by the United Nations, Chemical Business Newsbase, (Aug. 25, 1999).

<sup>41</sup> Id.

<sup>&</sup>lt;sup>42</sup> Id.

<sup>&</sup>lt;sup>43</sup> Solberg, supra note 24, at 556.

seeds, new proteins may form.<sup>44</sup> 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.<sup>45</sup>

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. For example, scientists found soybeans modified from brazil nuts to contain brazil nut allergens, posing potential health problems for those allergic to nuts. Other modified soybeans were found to contain 27% more trypsin-inhibitor, a major allergen, than unmodified soybeans. 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. 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.<sup>55</sup> Genetically engineered microorganisms have the potential to exchange genetic material, or hybridize, with natural occurring microorganisms.<sup>56</sup> This hybridization, or outcrossing, can potentially disrupt the ecology of an environment.<sup>57</sup> For example, wheat that is genetically engineered to resist certain pests can pass this characteristic onto weeds, potentially creating a more powerful weed and

<sup>&</sup>lt;sup>44</sup> Id

<sup>&</sup>lt;sup>45</sup> Id.

<sup>&</sup>lt;sup>46</sup> Id.

<sup>47</sup> y J

<sup>&</sup>lt;sup>48</sup> Solberg, supra note 24, at 556.

<sup>&</sup>lt;sup>49</sup> Id

<sup>&</sup>lt;sup>50</sup> Holly Saigo, Agricultural Biotechnology and the Negotiation of the Biosafety Protocol, 12 Geo. Int'l Envtl. L. Rev. 779, 792 (2000).

<sup>51</sup> See id.

<sup>52</sup> Id

<sup>&</sup>lt;sup>53</sup> 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).

<sup>&</sup>lt;sup>54</sup> See id. at 1166.

<sup>55</sup> See id. at 1168; see also Saigo, supra note 50, at 787.

<sup>&</sup>lt;sup>56</sup> Kim, *supra* note 53, at 1167.

<sup>&</sup>lt;sup>57</sup> See id. at 1168.

disrupting the environment.<sup>58</sup> 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.<sup>59</sup>

Another potential danger of the deliberate release of GMOs is the risk to wildlife. 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.<sup>62</sup> 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.<sup>63</sup> For example, in 1994, the World Trade Organization ("WTO"), an international world trading regime, was established to increase free trade amongst its parties.<sup>64</sup> 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.<sup>65</sup> Under GATT, member states must "enter into 're-

<sup>&</sup>lt;sup>58</sup> Id

<sup>&</sup>lt;sup>59</sup> Saigo, *supra* note 50, at 787.

<sup>60</sup> See Meyer, supra note 14, at 102.

<sup>61</sup> Id

<sup>&</sup>lt;sup>62</sup> See, e.g., Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Martakesh 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).

<sup>&</sup>lt;sup>63</sup> For a discussion of how the Cartagena Protocol specifically addresses these dangers, see *infra* Section V.

<sup>&</sup>lt;sup>64</sup> See Michael J. Trebilcock & Robert Howse, The Regulation of International Trade 25 (2d ed. 1999).

<sup>65</sup> 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."

The WTO governs the trade of agricultural products under the SPS Agreement.<sup>67</sup> 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.<sup>68</sup> 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."<sup>69</sup>

The SPS Agreement gives its member countries some discretion in determining which sanitary and phytosanitary measures to use to protect plant and animal life. A member country determines the specific risks of animal or plant pests or disease in a particular region, taking into account available scientific evidence. 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."

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.<sup>73</sup> However, to achieve harmonization, the SPS Agreement requires that members base their measures on international standards where those standards exist.<sup>74</sup> 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.<sup>75</sup>

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 . . . ." However, if a member

<sup>&</sup>lt;sup>66</sup> See id. at 25.

<sup>&</sup>lt;sup>67</sup> See id. at 145.

<sup>&</sup>lt;sup>68</sup> See id.

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<sup>&</sup>lt;sup>70</sup> See id. at 145; see also SPS Agreement, supra note 62, art. 2.

<sup>&</sup>lt;sup>71</sup> *Id.* art. 5.

 $<sup>^{72}</sup>$  Id.

<sup>&</sup>lt;sup>73</sup> See id.; see also Trebilcock & Howse, supra note 64, at 147.

<sup>&</sup>lt;sup>74</sup> See id. at 145; see also SPS Agreement, supra note 62, art. 3(1).

<sup>&</sup>lt;sup>75</sup> See SPS Agreement, supra note 62, art. 4(1).

<sup>&</sup>lt;sup>76</sup> See id. arts. 3(1), 3(3).

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

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. 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. <sup>80</sup> 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.<sup>81</sup> Out of the Earth Summit, parties formed a

<sup>&</sup>lt;sup>77</sup> 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 ENVIL. 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).

<sup>&</sup>lt;sup>78</sup> See SPS Agreement, supra note 62, arts. 12(1), 12(7).

<sup>&</sup>lt;sup>79</sup> *Id.* arts. 12(1), 12(2), 12(4).

<sup>&</sup>lt;sup>80</sup> See Treblicock & Howse, supra note 64, at 147; for a more lengthy discussion of flexibility of regulations, see *infra* Section IVE2.

<sup>&</sup>lt;sup>81</sup> 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." There are currently 179 parties to the Convention. 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. 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. 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. 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. 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. Another issue was the creation of more effective information technology to enhance the exchange of information about GMOs. 191

#### B. Debate Over Biosafety Protocol

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

<sup>82</sup> Id.

<sup>83</sup> See Redick et al., supra note 1, at 16.

<sup>&</sup>lt;sup>84</sup> 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).

<sup>85</sup> Redick et al., supra note 1, at 16.

<sup>&</sup>lt;sup>86</sup> See id. at 5.

<sup>&</sup>lt;sup>87</sup> Id. at 5-6.

<sup>&</sup>lt;sup>88</sup> See id. at 21.

<sup>&</sup>lt;sup>89</sup> See supra note 81.

<sup>90</sup> See Redick et al., supra note 1, at 21.

<sup>91</sup> See id.

<sup>92</sup> 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. 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. 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. <sup>96</sup> Because industrialized countries have used GMOs for some time, they are more familiar with the risks and benefits of GMOs. <sup>97</sup> 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. <sup>98</sup> 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. <sup>99</sup>

#### 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. In 1993, a UNEP panel of scientific experts found that there was inadequate scientific evidence to warrant a scientific protocol. However, the UNEP experts did concede that a biosafety protocol "could harmonize regulations." In 1922

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

<sup>&</sup>lt;sup>93</sup> Id.

<sup>94</sup> See id. at 7-8.

<sup>&</sup>lt;sup>95</sup> See id. at 7.

<sup>&</sup>lt;sup>96</sup> See Redick et al., supra note 1, at 8.

<sup>&</sup>lt;sup>97</sup> Id.

<sup>&</sup>lt;sup>98</sup> Id.

<sup>99</sup> See id

<sup>100</sup> See Redick et al., supra note 1, at 37.

<sup>&</sup>lt;sup>101</sup> *Id*.

<sup>102</sup> Id

<sup>&</sup>lt;sup>103</sup> 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"). 105 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. Because of its "open designation," the meeting included attendees from eighty-four countries, seven UN bodies, two intergovernmental organizations, and twenty-two NGOs. The debate between industrialized and developing countries ensued. 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. 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. In addition, they agreed that there was a need for risk assessment and management procedures and methods of information exchange.

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"). 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. One hundred and thirty countries, various UN organizations, intergovernmental organiza-

<sup>104</sup> Redick et al., supra note 1, at 38.

<sup>105</sup> Id.

<sup>&</sup>lt;sup>106</sup> *Id*.

<sup>107</sup> Id.; see also COP I Report, supra note 103.

<sup>108</sup> 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].

<sup>109</sup> Redick et al., supra note 1, at 39.

<sup>110 14</sup> 

<sup>&</sup>lt;sup>111</sup> *Id*.

<sup>112</sup> Id.

<sup>&</sup>lt;sup>113</sup> Id.

<sup>114</sup> Id. at 42.

<sup>115</sup> Redick et al., supra note 1, at 42.

<sup>116</sup> BSWG Report 6, supra note 10.

tions, and NGOs attended to negotiate a compromise on a biosafety protocol. They drafted a protocol that would exempt gene-altered farm commodities and pharmaceuticals from regulation. This exemption was the focus of debate amongst the parties. 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. <sup>121</sup> Although more than 110 countries had agreed on a potential protocol, the Miami group blocked it. <sup>122</sup> 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. <sup>123</sup> European countries and developing countries proposed the strict safety standards to prevent potential environmental and health problems associated with the deliberate release of GMOs. <sup>124</sup> 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. <sup>125</sup> 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. <sup>126</sup>

#### 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. Over 700 delegates from governments, intergovernmental organizations, and NGOs attended the meeting to negotiate the Cartagena Protocol, named for the place where it was

<sup>&</sup>lt;sup>117</sup> Id.

<sup>118</sup> Id.; see also Lambrecht, supra note 2, at A5.

<sup>119</sup> See Lambrecht, supra note 2, at A5.

<sup>&</sup>lt;sup>120</sup> *Id*.

<sup>&</sup>lt;sup>121</sup> Bill Lambrecht, Talks Collapse on Rules for Genetic Crops; U.S., Allies Blocked International Accord, St. Louis Post-Dispatch, Feb. 25, 1999, at A1.

<sup>&</sup>lt;sup>122</sup> Id.

<sup>&</sup>lt;sup>123</sup> Id.

<sup>&</sup>lt;sup>124</sup> Id

<sup>&</sup>lt;sup>125</sup> See Lambrecht, supra note 12, at A1.

<sup>&</sup>lt;sup>126</sup> Angela Sanchez, Environment: New Delay for Biosafety Protocol, INTER PRESS SERVICE, Feb. 25, 1999.

<sup>127</sup> See Cartagena Protocol Press Release, supra note 4.

drafted. <sup>128</sup> 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"). <sup>129</sup> 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. <sup>130</sup> Since COP 5, a total of eighty-one parties have signed the Protocol. <sup>131</sup> However, only two parties, Bulgaria and Trinidad and Tobago, have ratified it, thus becoming legally bound to adhere to its principles. <sup>132</sup> Upon the ratification of the Protocol by fifty CBD countries, the Protocol will take legal force for its members. <sup>133</sup>

#### 1. Safety Measures in the Cartagena Protocol

The Cartagena Protocol contains many safety provisions to protect biodiversity. 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. 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").<sup>137</sup> At its meeting in Montreal, the parties agreed that these strict AIA procedures only apply to seeds, live fish, and

<sup>&</sup>lt;sup>128</sup> *Id*.

<sup>129</sup> Id.

<sup>130</sup> 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].

<sup>&</sup>lt;sup>131</sup> See id.

<sup>132</sup> See id.

<sup>&</sup>lt;sup>133</sup> Id.

<sup>&</sup>lt;sup>134</sup> 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].

<sup>135</sup> See Hagen & Weiner, supra note 77, at 710.

<sup>&</sup>lt;sup>136</sup> Id. (emphasis added); see also Cartagena Protocol Text, supra note 134, art. 1 (emphasis added).

<sup>&</sup>lt;sup>137</sup> 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.<sup>139</sup> 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.<sup>140</sup> 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.<sup>141</sup> 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.<sup>142</sup>

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." 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. 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

<sup>138</sup> Cartagena Protocol Press Release, supra note 4.

<sup>&</sup>lt;sup>139</sup> See Cartagena Protocol Text, supra note 134, art. 8.

<sup>140</sup> Id. art. 8, annex I.

<sup>&</sup>lt;sup>141</sup> See id. art. 9.

<sup>142</sup> *Id.* art. 10.

<sup>143</sup> Id. art. 12

<sup>&</sup>lt;sup>144</sup> Cartagena Protocol Text, supra note 134, art. 12.

<sup>&</sup>lt;sup>145</sup> See id. art. 18.

<sup>&</sup>lt;sup>146</sup> *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.<sup>147</sup>

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. <sup>149</sup> Under Article 16, each party must adopt measures that require risk assessments to be conducted prior to the initial release of an LMO. <sup>150</sup> 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." <sup>151</sup>

The Protocol contains a retroactive safety provision, Article 17, which discusses the unintentional transboundary movements of LMOs and emergency measures addressing these unintentional movements. <sup>152</sup> 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. <sup>153</sup> 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. <sup>154</sup>

<sup>147</sup> See id.

<sup>&</sup>lt;sup>148</sup> 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.

<sup>&</sup>lt;sup>149</sup> See Cartagena Protocol Text, supra note 134, art. 16.

<sup>150</sup> See id.

<sup>&</sup>lt;sup>151</sup> *Id*.

<sup>&</sup>lt;sup>152</sup> See id. art. 17.

<sup>&</sup>lt;sup>153</sup> Id.

<sup>154</sup> Id.

Finally, the Protocol also requires the establishment of procedures for liability and redress under Article 27. 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. These agreements must include safety provisions that "do not result in a lower level of protection than that provided for by the Protocol." Parties must inform each other, using the Biosafety Clearing-House, of any such agreements. The provisions of the Protocol will not affect intentional transboundary movements under these bilateral, regional, or multilateral agreements. 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-

<sup>&</sup>lt;sup>155</sup> See Cartagena Protocol Text, supra note 134, art. 27.

<sup>&</sup>lt;sup>156</sup> Id.

<sup>&</sup>lt;sup>157</sup> See generally Cartagena Protocol Text, supra note 134.

<sup>&</sup>lt;sup>158</sup> See Cartagena Protocol Text, supra note 134, art. 13.

<sup>&#</sup>x27;'' See id

<sup>&</sup>lt;sup>160</sup> See id. art. 14.

<sup>&</sup>lt;sup>161</sup> *Id*.

<sup>&</sup>lt;sup>162</sup> Id.

<sup>163</sup> See id.

<sup>&</sup>lt;sup>164</sup> See Cartagena Protocol Text, supra note 134, art. 14.

<sup>165</sup> See id. art. 20.

<sup>&</sup>lt;sup>166</sup> *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.<sup>172</sup> 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.<sup>173</sup> 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.<sup>174</sup> 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. <sup>175</sup>

<sup>&</sup>lt;sup>167</sup> See id.

<sup>&</sup>lt;sup>168</sup> See id.

<sup>169</sup> See Cartagena Protocol Press Release, supra note 4.

<sup>&</sup>lt;sup>170</sup> See Cartagena Protocol Text, supra note 134, art. 20.

<sup>&</sup>lt;sup>171</sup> See Cartagena Protocol Press Release, supra note 4; see also Cartagena Protocol Text, supra note 134, art. 20.

<sup>172</sup> See id. art. 22.

<sup>173</sup> See id.

<sup>&</sup>lt;sup>174</sup> See id.

<sup>&</sup>lt;sup>175</sup> 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. 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. 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." In addition to requiring financial support, Article 20 encourages voluntary contributions from parties as well. Finally, developed countries may also provide financial resources to developing countries through bilateral, regional, and other multilateral channels.

Article 21 provides for a financial mechanism "for the provision of financial resources to developing country Parties . . . on a grant or concessional basis." The mechanism functions under the authority and guidance of the Conference of the Parties ("COP"). 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. He 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.

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

<sup>&</sup>lt;sup>176</sup> See Cartagena Protocol Text, supra note 134, art. 28.

<sup>177</sup> Canid

<sup>&</sup>lt;sup>178</sup> 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].

<sup>&</sup>lt;sup>179</sup> Id.

<sup>&</sup>lt;sup>180</sup> See id.

<sup>&</sup>lt;sup>181</sup> See id.

<sup>&</sup>lt;sup>182</sup> 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].

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

<sup>&</sup>lt;sup>184</sup> See id.

<sup>185</sup> What is the Global Environment Facility?, at http://www.gefweb.org/What\_is\_the\_G EF/what is\_the\_gef.html (last visited Jan. 18, 2001) [hereinafter What is the GEF].

<sup>&</sup>lt;sup>186</sup> See CBD Article 21, supra note 182.

<sup>&</sup>lt;sup>187</sup> 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.<sup>188</sup>

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. 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. 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. At its meeting in Nairobi in May 2000, the COP set its budget for the biennium 2001-2002. 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

<sup>&</sup>lt;sup>188</sup> See id.

<sup>&</sup>lt;sup>189</sup> 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].

<sup>&</sup>lt;sup>190</sup> See id. § IV.

<sup>&</sup>lt;sup>191</sup> See id. §§ IV, III.

<sup>&</sup>lt;sup>192</sup> 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].

<sup>193</sup> See id. Table 1.

<sup>&</sup>lt;sup>194</sup> See Cartagena Protocol Press Release, supra note 4.

<sup>&</sup>lt;sup>195</sup> Id.

<sup>&</sup>lt;sup>196</sup> Id.

Under the Cartagena Protocol, the Protocol and the WTO "are to be mutually supportive." 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. In addition, federal United States officials at the Montreal meeting stated that the United States would honor the treaty. 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. There are numerous reasons to ratify this Protocol.

First, the deliberate release of GMOs is an international issue. <sup>202</sup> 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. <sup>203</sup> For example, as discussed previously,

<sup>&</sup>lt;sup>197</sup> Id.; see also Cartagena Protocol Text, supra note 134, preamble.

<sup>&</sup>lt;sup>198</sup> Cartagena Protocol Text, *supra* note 134, preamble; *see also* Cartagena Protocol Press Release, *supra* note 4.

<sup>&</sup>lt;sup>199</sup> See Andrew Pollack, 130 Nations Agree on Safety Rules for Biotech Food, N.Y. Times, Jan. 30, 2000, at 1

<sup>&</sup>lt;sup>200</sup> Id.

<sup>&</sup>lt;sup>201</sup> 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.* 

<sup>&</sup>lt;sup>202</sup> See Kim, supra note 53, at 1168.

<sup>&</sup>lt;sup>203</sup> 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. 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. 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." 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. 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." <sup>211</sup>

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. 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. In addition, the COP should implement the Biosafety Clearing-

<sup>&</sup>lt;sup>204</sup> See id. at 1168.

<sup>&</sup>lt;sup>205</sup> See id. at 1200.

<sup>&</sup>lt;sup>206</sup> See id. For a discussion of potential risks, see supra Section IIC.

<sup>&</sup>lt;sup>207</sup> Kim, *supra* note 53, at 1200.

<sup>&</sup>lt;sup>208</sup> Id. at 1169.

<sup>&</sup>lt;sup>209</sup> Cartagena Protocol Text, supra note 134, art. 4.

<sup>&</sup>lt;sup>210</sup> See id

<sup>&</sup>lt;sup>211</sup> Id.

<sup>&</sup>lt;sup>212</sup> Id.

<sup>&</sup>lt;sup>213</sup> 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. 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.<sup>215</sup> This uniform standard has benefits for both importing countries and biotechnology companies.<sup>216</sup> 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.<sup>217</sup> Presently, companies marketing a new GMO must abide by the regulations of each country, raising the cost of marketing the product around the world.<sup>218</sup> Adoption of a uniform standard would reduce these marketing cost trade barriers to make GMOs more readily available to consumers in the global marketplace.<sup>219</sup>

The Cartagena Protocol also maintains flexibility as it allows countries to adopt equivalent standards to those in the Protocol. 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. 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.

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

<sup>&</sup>lt;sup>214</sup> 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.

<sup>&</sup>lt;sup>215</sup> See Kim, supra note 53, at 1202.

<sup>&</sup>lt;sup>216</sup> See id. at 1200.

<sup>217</sup> Id

<sup>&</sup>lt;sup>218</sup> See id. at 1196.

<sup>&</sup>lt;sup>219</sup> See id. at 1200.

<sup>&</sup>lt;sup>220</sup> See Cartagena Protocol Text, supra note 134, art. 14.

<sup>&</sup>lt;sup>221</sup> See SPS Agreement, supra note 62, art. 4.

<sup>&</sup>lt;sup>222</sup> See Cartagena Protocol Text, supra note 134, art. 14.

<sup>&</sup>lt;sup>223</sup> See Kim, supra note 53, at 1197.

<sup>&</sup>lt;sup>224</sup> Id.

<sup>&</sup>lt;sup>225</sup> 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. For example, in Europe, critics of GMO food have sabotaged test plots of GMO crops. 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. Various representatives from the Brazilian government have questioned the safety of transgenic foods. For example, Rio Grande do Sul Governor Olivia Dutra stopped transgenic-seed production at 79 test sites, claiming the sites lacked environment-impact studies. Since Brazil is the world's second-largest soybean producer, Monsanto wants to market its transgenic soybean seeds there. 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. 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. 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

<sup>&</sup>lt;sup>226</sup> See Barboza, supra note 32, at A1.

 $<sup>^{227}</sup>$  Id

<sup>&</sup>lt;sup>228</sup> Epstein, *supra* note 13, at A14.

<sup>229</sup> See id.

<sup>&</sup>lt;sup>230</sup> Id.

<sup>&</sup>lt;sup>231</sup> See id.

<sup>&</sup>lt;sup>232</sup> See Redick et al., supra note 1, at 56 (citing Dorothy P. Bowers, The Alternative Path: A New Blueprint, Envil. F., Mar./Apr. 1997, at 36-7).

<sup>&</sup>lt;sup>233</sup> See Redick et al., supra note 1, at 55.

<sup>&</sup>lt;sup>234</sup> *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. Many corporations have already developed self-regulating environmental protection programs because of conscientious executives or because of the cost-effectiveness of self-regulation. 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. For example, Monsanto Corporation has already established a licensing agreement for Bollagard® cotton, where cotton growers must agree to create a buffer zone of non-genetically altered crops surrounding an area of genetically altered crops. 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. <sup>240</sup>

Another alternative discussed is the ISO series of standards.<sup>241</sup> The ISO 14000 Series of Environmental Contract Specifications are international standards for environmental management.<sup>242</sup> Redick, Reavey, and Michels suggest that the ISO series "could provide the biotechnology industry with standardized legal provisions for internal environmental corporate policies."<sup>243</sup> 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.<sup>244</sup>

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

<sup>&</sup>lt;sup>235</sup> See id.

<sup>&</sup>lt;sup>236</sup> See id. at 57.

<sup>&</sup>lt;sup>237</sup> Id. at 59.

<sup>&</sup>lt;sup>238</sup> See id. at 60.

<sup>&</sup>lt;sup>239</sup> See id. at 60.

<sup>&</sup>lt;sup>240</sup> *Id*.

<sup>&</sup>lt;sup>241</sup> See id. at 62.

<sup>&</sup>lt;sup>242</sup> Id.

<sup>&</sup>lt;sup>243</sup> Id. at 62-63 (citing Henry P. Baer, Jr., Note, ISO 14000: Potential Compliance and Prevention Guidelines for EPA and DOJ, 7 FORDHAM ENVIL. L.J. 927, 934 (1996)).

<sup>&</sup>lt;sup>244</sup> See Redick et al., supra note 1, at 63.

<sup>245</sup> See id at 72

<sup>&</sup>lt;sup>246</sup> 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." Biotechnology companies, such as Monsanto, argue that the dissemination of "new information technology may be the key to sustainable development." 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. 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."

#### 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.<sup>251</sup> 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.<sup>253</sup> 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

<sup>&</sup>lt;sup>247</sup> Redick et al., supra note 1, at 75-76.

<sup>&</sup>lt;sup>248</sup> 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).

<sup>&</sup>lt;sup>249</sup> See Redick et al., supra note 1, at 74-75.

<sup>&</sup>lt;sup>250</sup> See id. at 76.

<sup>&</sup>lt;sup>251</sup> 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.

<sup>&</sup>lt;sup>252</sup> See Barboza, supra note 32, at A26.

<sup>&</sup>lt;sup>253</sup> Id.

the United States to tour its labs.<sup>254</sup> 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.<sup>255</sup> 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.

<sup>255</sup> Id.

<sup>&</sup>lt;sup>254</sup> See Lambrecht, supra note 12, at A8.