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Does a Genetically Modified Rose Still Smell as Sweet: Labeling of Genetically Modified Organisms under the Biosafety Protocol

Lisa A. Tracy

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**Does a Genetically Modified Rose Still Smell as Sweet? -
Labeling of Genetically Modified Organisms Under the
Biosafety Protocol**

Lisa A. Tracy*

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Introduction

It belies its magnitude to say the debate surrounding international regulation of the biotechnology industry is contentious and rife with competing interests.¹ It is, instead, a high-stakes game pitting a billion dollar industry against conceivably priceless biological diversity.² It is the struggle to balance unknown risks against almost limitless potential.³ Biotechnology, a much older

¹ See Angela Sanchez, *Environment: Debate Over Transgenics Heats Up*, INTER PRESS SERVICE, Feb. 23, 1999, in 1999 WL 5947186 (quoting Colombian President Andres Pastrana as he enumerated the competing interests in his opening remarks to the convention and urged the international community to “responsibly tackle issues involving biodiversity, such as global food security, health, cultural diversity, traditional systems of production and an equitable future, in the industrialized world and developing nations”); see also *id.* (explaining the debate between developing countries and industrialized countries); see also Andrew Pollack, *U.S. Rejects Pact on Genetically Altered Goods Treaty Called Insufficient, Restrictive*, NEW ORLEANS TIMES-PICAYUNE, Feb. 25, 1999, at A 15 (describing the various interests of different countries in the debate on a Biosafety Protocol).

² See *European BioNews - Special Issue*, (visited Aug. 6, 1999) <http://ecom1.netbeat.com/news_europabio/news.taf?_function=details&id=50> (noting that the European biotech industry alone was worth an estimated ECU 40 billion in 1997 and predicting that the industry could be worth ECU 250 billion by 2005).

³ See Frank Bajak, *Critics Claim U.S. Greed is at Root of Refusal to Sign Biosafety Treaty*, SUN SENTINEL (Ft. Lauderdale), Feb. 24, 1999, at 18A (explaining that proponents of biotech emphasize the ability to potentially ensure global food security, while opponents of biotech predict “a biological time bomb” if the genetically modified products go awry); see also, Karen Graziano, *Biosafety Protocol: Recommendations to Ensure the Safety of the Environment*, 7 COLO. J. INT’L ENVTL. L. & POL’Y 179, 185 (1996) (weighing bioengineering’s risks against the perceived benefits). It is difficult to identify the potential risks associated with genetic engineering and this difficulty is exacerbated by the speed with which

science than many are aware,⁴ has become associated in modern times with the alteration of plant and animal deoxyribonucleic acid (“DNA”).⁵ The science of biotechnology has been used to create living modified organisms (“LMOs”), organisms which have their genetic structure altered in an effort to remove their naturally-occurring unfavorable characteristics or enhance genetically favored characteristics.⁶ Recognizing the diverse applications of this type of technology, yet sobered by the potential to do irrevocable damage to

bioengineered products are being developed and released into the environment. *See id.*; *see also* THE UNION OF CONCERNED SCIENTISTS, THE NEED FOR GREATER REGULATION AND CONTROL OF GENETIC ENGINEERING: A STATEMENT BY SCIENTISTS CONCERNED ABOUT CURRENT TRENDS IN THE NEW BIOTECHNOLOGY 11 (1994) (claiming that biotech companies produce much of the world’s bioengineered crops in Third World countries and disregard these ecosystems making them susceptible to potentially catastrophic environmental damage); *cf.* Steven W. Frank, *Food Additive Models for the Regulation of Recombinant DNA Technology Under the Federal Food, Drug, and Cosmetic Act*, 45 FOOD DRUG COSM. L.J. 169, 173-79 (1990) (describing the range of potential food uses of biotechnology).

⁴ *See* Thomas Redick, et al., *Private Legal Mechanisms For Regulating the Risks of Genetically Modified Organisms: An Alternative Path Within the Biosafety Protocol*, 4 ENVTL. L. 1, 11 (1997) (noting that humans began modifying the genetic structure of plants at the dawn of modern agriculture).

⁵ *See* Draft Protocol on Biosafety at Annex V, art. 3(i), U.N. Doc. UNEP/CBD/ExCOP/1/L.2/Rev.1 (1999) [hereinafter Draft Protocol] (defining modern biotechnology as “(i) *In vitro* nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, (ii) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive of recombination barriers and that are not techniques used in traditional breeding and selection”).

⁶ *See id.* art. 3(g) (defining a living modified organism as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology”). The phrase “living modified organism” is used interchangeably with the common phrase “genetically modified organism” (“GMO”). However, the phrase LMO appears more frequently in official United Nations documents. *See id.*

the environment,⁷ the parties to the United Nations' Convention on Biological Diversity ("CBD") called for consideration of the need for a Biosafety Protocol.⁸

CBD member countries held meetings to determine the need for a protocol.⁹ They concluded that guidelines on biosafety were

⁷ See Secretary of Agriculture Dan Glickman, *New Crops, New Century, New Challenges: How Will Scientists, Farmers and Consumers Learn to Love Biotechnology And What Happens If They Don't?*, Address before the National Press Club (Jul. 13, 1999) (transcript available in the USDA Sec. 3/3) [hereinafter Statement of Sec. Glickman] (listing numerous positive potential applications of biotechnology). Biotechnology has been employed to reduce the use of pesticides, reduce the acreage of land necessary to cultivate for food production, improve the nutritional content of various foods, reduce water usage and develop more environmentally sound methods of ink removal from pulp. *See id.* But see John E. Losey, Linda S. Rayor, & Maureen E. Carter, *Transgenic Pollen Harms Monarch Larvae*, NATURE 214, 399 (May 19, 1999) (announcing results of a experiment which revealed that monarch larvae raised on leaves dusted with pollen from bioengineered corn suffered a higher mortality rate than those larvae raised on natural corn pollen); see also *Genetic Engineering: When Science Becomes a Menace* (visited Aug. 9, 1999) <<http://www.newage.com.au/library/gentic.html>> (describing various instances where bioengineered products had negative unintended consequences). In one example, the United States government attempted to engineer a "super pig" by inserting human growth genes into the pig's genetic code. Rather than being born far larger than normal, the pig was born bow-legged, arthritic and cross-eyed. *See id.*

⁸ See United Nations Conference on Environment and Development: Convention on Biological Diversity, opened for signature at United Nations Conference on Environment and Development, June 5, 1992, art. 19, para. 3, reprinted in 31 I.L.M. 818 (entered into force Dec. 29, 1993) [hereinafter Convention on Biological Diversity] (calling for the parties to the Convention on Biological Diversity to examine "the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organisms resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity").

⁹ See Ad Hoc Working Group of Experts on Biological Diversity, U.N. Environment Program (UNEP), 3d Sess., at 9-10, UNEP/Bio.Div.3/Inf.5 (1990) [hereinafter Ad Hoc Working Group]; see also Graziano, *supra* note 3, at 196 (discussing arguments for and against a biosafety protocol). But see UNEP, Expert Panel, Report of Panel IV, Annex V: Socio-Economic Conditions and the

essential for the safe transfer and development of LMOs.¹⁰ Since this determination, representatives from the biotech industry, numerous nongovernmental organizations, and the CBD member countries have been meeting to work on the development of a Biosafety Protocol.¹¹ These meetings were intended to culminate in a final meeting in Cartagena, Colombia in February 1999 for the purpose of finalizing the Biosafety Protocol and submitting it to the first extraordinary meeting of the Conference of Parties (“ExCOP”).¹² However, by the final day of negotiations, a small United States-led coalition known as the “Miami Group”¹³ managed to stall any further negotiation of a treaty.¹⁴ On February twenty-fourth, 1999, the President of the

Conservation of Biological Diversity, Figure 2 Explanatory Notes, at VI-6, note 11 (Apr. 28, 1993)(concluding prior to the development of the CBD, that a protocol was unnecessary because it would be outdated before it could be agreed upon). The UNEP panel also concluded that “[t]he targeting of biotechnology by an international protocol stigmatizes the techniques and increases public concerns, hence diverting resources, political attention, and delaying innovative and beneficial developments that will help the conservation and sustainable development of biological diversity.” *See id.* at note 11.

¹⁰ *See Ad Hoc Working Group, supra* note 9.

¹¹ *See Paul E. Hagen et al., The Road From Rio: International Environmental Issues For U.S. Business in 1997*, SB79 ALI-ABA 65, 86 (describing various ongoing efforts by countries and NGOs to develop guidelines on the safe use of modified organisms).

¹² *See Draft Report of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity*, U.N. Doc. UNEP/CBD/ExCOP/1/L.2/Rev.1 at para. 4 (1999) [hereinafter *Draft Report on Biosafety*] (noting that the first extraordinary meeting of the Conference of the Parties was convened for the purpose of adopting a biosafety protocol).

¹³ *See Bill Lambrecht, Talks Collapse on Rules For Genetic Crops U.S., Allies Blocked International Accord*, ST. LOUIS POST-DISPATCH, Feb. 25, 1999, at A1 (listing the member countries of the Miami Group — the United States, Canada, Australia, Argentina, Chile and Uruguay).

¹⁴ *See id.* (claiming that the United States and its allies were concerned that labeling laws, and additional proposals pending before the COP would threaten international trade in LMOs). Rafe Pomerance, Deputy Assistant Secretary of State and one of the chief United States negotiators, claimed that “the solidarity of the Miami group was key to [the] outcome” in Cartagena and that the Miami

ExCOP, Mr. Laszlo Miklos, was forced to call a suspension of discussions for the purpose of continued informal negotiation with representatives of the Miami Group countries.¹⁵

Formal talks are scheduled to continue in May 2000, at which point it is hoped the Parties will achieve a final agreement on a Biosafety Protocol.¹⁶ In anticipation of the resumed talks in May 2000 and further informal meetings to be held later this year,¹⁷ this Comment examines the labeling issues which proved to be one source of the deadlock¹⁸ this past February in Cartageña and argues that the United States must accept the labeling provisions of the Biosafety Protocol in order to protect the market in biotechnology. Part I of this Comment provides a brief overview of the events leading up to the meetings in Cartageña and the development of a Biosafety Protocol. Part II discusses the various proposals examined by the Biosafety Working Group, focusing specifically on the proposed labeling requirements and advanced informed agreement ("AIA")

group's interests were "too big . . . to be ignored." *See id.*

¹⁵ See Draft Report on Biosafety, *supra* note 12, para. 40-50 (recording the decision of President Miklos and the negotiating parties to suspend the discussion to provide for consideration of two proposals, one from the European Union and the other from the Miami group).

¹⁶ See Pollack, *supra* note 1 (explaining that the delegates decided to suspend the meeting and resume talks no later than May 2000).

¹⁷ See Letter from Laszlo Miklos, President of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity, to National Focal Points (May 31, 1999)(on file with author)(acknowledging that significant progress could be made via informal discussions of the negotiating groups prior to the resumption of the formal talks).

¹⁸ See *U.S. - European Union Trade Issues: Hearing Before the Subcomm. on International Trade of the Senate Finance Comm.*, 106th Cong. 5 (1999) (statement of Stuart E. Eizenstat, Under Secretary for Economic, Business and Agricultural Affairs U.S. Department of State) [hereinafter Statement of Stuart E. Eizenstat] (pointing out that the United States' position on labeling required the European Union and a Biosafety Protocol to provide more specific labeling guidelines for United States companies and that the Cartageña talks had failed in this regard).

procedures.¹⁹ Part III takes a closer look at the United States' reasons for actively opposing the current protocol and looks at the United States' internal regulatory and labeling system for genetically modified goods. Part IV looks at international reaction to the outcome of negotiations at Cartageña and also examines the United States response in the months following the Cartageña talks. Finally, Part V recommends that the United States-led Miami Group must accede to an international standard for labeling of bioengineered products. This Comment further suggests that United States participation in the development of a Biosafety Protocol must be guided by a better understanding of the global market, including the increased premium placed on safely engineered food products.

I. Biosafety Protocol

A. Background

Article 19, paragraph 3 of the Convention on Biological Diversity calls for an examination of the need for a protocol on biosafety,²⁰ and, in December of 1994, the Conference of the Parties voted to establish an Open-ended Ad Hoc Group of Experts to assess this need and report their findings before the second meeting of the Conference of the Parties (COP II) in November of 1995.²¹ The Open-ended Ad Hoc Group of Experts concluded that a Biosafety Protocol was necessary for the safe and continued trade and development of LMOs, and, on the basis of this opinion, the COP II established an Open-ended Ad Hoc Working Group on Biosafety (the

¹⁹ See Draft Protocol, *supra* note 5, art. 5 (describing the application of the advance informed agreement procedures). For the purposes of this article, AIA procedures are those procedures which a nation may employ to control the transboundary movements of goods across their sovereign borders. See *id.*

²⁰ See Convention on Biological Diversity, *supra* note 8 (defining the goal of the Convention with regard to Biosafety).

²¹ See generally Ad Hoc Working Group, *supra* note 9 (discussing the recommendations of the Ad Hoc working Group).

“BWG”) to begin work on developing the protocol.²² The BWG was tasked specifically with assessing the threat transboundary movement of LMOs posed to the sustainable use of biological diversity.²³ Between July 1996 and February 1999, the BWG held six different meetings aimed at developing the final protocol.²⁴ The sixth meeting, held from February fourteenth through the nineteenth in Cartageña²⁵, was intended to be the final meeting to work out the remaining differences regarding a Biosafety Protocol before ultimately submitting the protocol to the ExCOP for adoption.²⁶ Despite the previous five meetings, the BWG still had numerous issues

²² See *id.* at para. 40 (calling for the creation of a Biosafety Working Group to begin coordination of a Draft Protocol).

²³ See *id.*

²⁴ See *Report of the Sixth Session of the Open-ended Ad Hoc Working Group on Biosafety and the First Extraordinary Session of the CBD Conference of the Parties*, EARTH NEGOTIATIONS BULL. (Int'l Inst. for Sustainable Dev.), Feb. 26, 1999, at 1-2 [hereinafter Report of the Sixth Session] (summarizing the goals and accomplishments of the five meetings leading up to the sixth and final meeting of the BWG in Cartageña). The first meeting of the Conference of the Parties was held in July 1996 to discuss preliminary issues, define key terms to be used in the drafting of a protocol, delineate the relevant categories of LMOs resulting from modern biotechnology and formulate the scope of advance informed agreement procedures. The second meeting was held in May 1997 to initiate discussion of a protocol and call for draft proposals. The third meeting was held in October 1997 and a draft text was developed to provide the basis for negotiations in future meetings. The fourth meeting was held in February 1998 and consisted largely of negotiating sessions. The fifth meeting was held in May 1998 and served mainly to provide clarification on key elements of the protocol and sharpen the final issues for debate. *Id.*

²⁵ See *id.* at 1 (listing the session dates for the Sixth Session of the Open-Ended Ad Hoc Working Group on Biosafety which was followed immediately by the first extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity held February twenty-second through the twenty-fourth).

²⁶ See *id.* at 2-3 (discussing thirty articles in the draft negotiating text which remained unresolved at the beginning of the sixth meeting of the BWG); see also UNEP Press Release, *Governments Postpone Adoption of Biosafety Treaty*, (visited Aug. 6, 1999) <<http://www.biodiv.org/press/pr2-99-BSWG6.html>> (explaining that any protocol ultimately approved by the countries will form a binding protocol under the 1992 Convention on Biological Diversity).

remaining.²⁷ On February twenty-fourth 1999, the President of the ExCOP, Mr. Juan Mayr Maldonado, announced that the BWG had failed to reach a consensus on a Biosafety Protocol.²⁸ In lieu of a final protocol, the negotiating parties submitted two different proposals, one on behalf of the European Union and one on behalf of the Miami Group.²⁹ The President subsequently suspended the ExCOP and called for the meeting to be resumed at a later date.³⁰

The structure and language of the labeling provisions under the proposed Biosafety Protocol proved to be one of the biggest stumbling blocks in negotiations between the European Union countries and the Miami Group.³¹ Therefore, to understand the legal arguments that form the debate over labeling issues, it is important to first understand the goals, the structure and formative history of the Draft Biosafety Protocol.

²⁷ See Report of the Sixth Session, *supra* note 24, at 15 (explaining the creation the "Group of Ten" established by ExCOP President Mayr in an effort to reach consensus on the remaining issues of the BWG). The group revisited the remaining outstanding issues, as identified by the various negotiating groups, but reached no consensus. *See id.*

²⁸ *See id.*

²⁹ See Draft Protocol, *supra* note 5, Annex II and Annex III (detailing the respective proposals submitted by the European Union and the Miami group).

³⁰ See Draft Report on Biosafety, *supra* note 12, para. 55 (calling for an official suspension of the meetings in Cartageña and stating that talks should resume no later than the Fifth Meeting of the Conference of the Parties scheduled to be held in Nairobi in May 2000).

³¹ See *Highlights From BSWG-6 Monday, 15 February 1999*, EARTH NEGOTIATIONS BULL. (Int'l Inst. for Sustainable Dev.), Feb. 16, 1999, at 2 [hereinafter *Highlights From BSWG-6*](describing the debate during the meeting of the BWG regarding labeling and detailing the numerous varying proposals submitted for the consideration of the committee); see also Padmaja Padman, *Crossing Swords Over Transgenic Foods*, NEW STRAITS TIMES, Mar. 21, 1999, at A7 (explaining that talks ended with a compromise text because the United States and its allies were adamantly opposed to "full disclosure of information, including the name and address of companies in some cases, to the public").

B. Goals and Structure of a Draft Biosafety Protocol

The first article of the Draft Protocol delineates the agreed upon objective of a Biosafety Protocol - the protection of biological diversity³² through "adequate" regulation of transfer, handling and use of bioengineered products.³³ The language in Article 1 indicates an intent to provide only a basic regulatory structure for safe trade in LMOs,³⁴ and further provisions of the Draft Protocol emphasize the sovereign right of member nations to implement stricter regulatory requirements.³⁵ Any agreed upon Protocol will therefore represent the lowest regulatory threshold for biosafety, while leaving stricter

³² See J.B. Ruhl, *Biodiversity Conservation and the Ever-expanding Web of Federal Laws Regulating Nonfederal Lands: Time for Something Completely Different?*, 66 U. COLO. L. REV. 555, 570 (1995) (defining biological diversity as "the full range of variability among living organisms and the natural communities in which they occur" and explaining that this definition is derived from legislation proposed by the United States Congress but never passed). Biological diversity is also perceived as having four hierarchical levels which include: regional ecosystem diversity; local ecosystem diversity; species diversity; and genetic diversity. See *id.* at 570.

³³ See Draft Protocol, *supra* note 5, art. 1 (stating that the objective of a 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 effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.") (emphasis added).

³⁴ See *id.* (defining the objectives of the Draft Protocol).

³⁵ See, e.g., *id.* at art. 4 (discussing the scope of the protocol and noting that, although the draft protocol is not intended to apply to those LMOs intended to be used for pharmaceuticals, the Protocol does not affect "the right of the Parties to subject *all* living modified organisms to risk assessment prior to the making of decisions on import") (emphasis added). But see Susan H. Bragdon, *National Sovereignty and Global Environmental Responsibility: Can the Tension Be Reconciled for the Conservation of Biological Diversity?*, 33 HARV. INT'L L.J. 381, 391 (1992) (admitting that sovereign rule is compromised by concessions to global treaties which protect the resources of a particular country disproportionately).

requirements to the discretion of individual nations.³⁶ As a result, the United States-led Miami Group's failure to agree upon a minimum set of standards at Cartageña creates a troubling perception that the United States and its allies are only content with meaningless controls and an impotent, ineffectual Biosafety Protocol.³⁷

The Draft Protocol goes on to delineate the application of an advance informed agreement ("AIA") procedure for transboundary movements of LMOs.³⁸ The AIA procedures, combined with the labeling requirements of Article 15, form the core strength of the Biosafety Protocol.³⁹ Far from inflexible, these guidelines allow for changes in scientific knowledge and provide a method by which a country of import may change or revoke a previous decision regarding a particular LMO.⁴⁰ Remaining articles are less substantive,

³⁶ See Ellen Hey, *Increasing Accountability for the Conservation and Sustainable Use of Biodiversity: An Issue of Transnational Global Character*, 6 COLO. J. INTL. ENV'T L. & POL'Y 1, 23 (1995) (advocating a strict regulation of sustainable development activities under the Convention on Biological Diversity but conceding that negotiating concessions would probably make that an impossibility).

³⁷ See, e.g., Brian Halweil, *U.S. Derails Biosafety Protocol*, 12 WORLD WATCH 3 (May 1999) (claiming that the United States derailed the negotiations at Cartageña by rejecting an already "watered-down proposal" because they felt it would inhibit the growth of the biotechnology industry).

³⁸ See Draft Protocol, *supra* note 5, art. 5, para. 29 (discussing the application of the advance informed agreement procedure). Under this application, exporters of LMOs are required to notify, in writing, an importing country when they intend to ship a LMO to a point within the importing country. The country of import must then acknowledge receipt of the notification and decide whether to allow the import of the LMO to proceed or prohibit importation. See *id.*

³⁹ See *id.*, art. 15 (requiring LMOs falling under the purview of the Protocol to be clearly identified and calling for further consideration of the identification and packaging standards).

⁴⁰ See, e.g., *id.*, art. 9 (stating that a party may "in light of new scientific information . . . review and change its decisions regarding intentional transboundary movements").

more procedural and serve to provide a strong regulatory framework which countries may rely upon to protect their biodiversity interests.⁴¹

Article 15 regarding the handling, transport, packaging and identification of LMOs, proved to be an extremely divisive issue at Cartageña, and continues to feature prominently in trade talks which have ensued in the months since the Cartageña discussions.⁴²

C. Labeling Under the Biosafety Protocol

Article 15 enumerates the procedures for handling, transport, packaging and identification of LMOs subject to the scope of the protocol.⁴³ This article requires transported LMOs to be accompanied by documentation including information such as traits and characteristics of the organism, instructions for safe handling and transport of the organism, a contact point for obtaining further information, and a declaration that the transboundary movement is being conducted in compliance with the requirements of the Protocol.⁴⁴ There is no explicit mention of "labeling" within the

⁴¹ See *id.*, arts. 16-39 (providing for the ratification of the treaty, creation of a biosafety clearing-house, treatment of non-parties to the convention, public awareness efforts, financing of future conferences, etc.); see also S. Gopikrishna Warriar, *Biodiversity Legislation Derailed*, BUSINESS LINE, May 20, 1999 at 2 (explaining that a Biosafety Protocol also serves the useful purpose of providing developing countries, lacking in expertise or legislation, with a framework to regulate the spread of GMOs).

⁴² See *infra* notes 94-96 and accompanying text (discussing the various European Union Directives which have been initiated in the months subsequent to the talks in Cartageña); see also U.S. Asks WHO To Put Food Safety On The Table For 2000, CONGRESSDAILY (National Journal), Aug. 12, 1999 at 3 (stating that the growing sensitivity over food safety has prompted the United States to ask the World Health Organization to add food safety issues to its agenda for the executive board meeting to be held in January 2000).

⁴³ See Draft Protocol, *supra* note 5, art. 15 (delineating the rules for safe handling, packaging and transport of bioengineered products under the Protocol).

⁴⁴ See *id.*, art. 15 (b)(i)-(iv) (describing various documentation requirements such as storage and transport requirements and name and address of importer and exporter).

Draft Protocol, and the use of this terminology in itself was a stumbling block for the United States and its allies.⁴⁵ However, it is understood that Article 15 contains the guidelines that companies must comply with in identifying their product as an LMO.⁴⁶ Parties were aware of the discord that explicit labeling requirements would provoke, and, in an effort to circumvent the issues of labeling, the Protocol leaves development of further labeling and transport standards open for future meetings.⁴⁷

The Protocol however, does require the Parties to conduct public outreach efforts in their countries to encourage public awareness of safe-handling and use of LMOs.⁴⁸ These goals are

⁴⁵ See *Highlights From BSWG-6*, *supra* note 31, at 2 (explaining that the term "Labeling" was bracketed in the title of Article 15 and thus had not been officially included as part of Article 15). The highlights of the debate from February sixteenth go on to explain that delegates remain undecided as to whether LMO products should be accompanied by documentation, be physically labeled as a GMO or some combination of both labeling and documentation. *See id.*

⁴⁶ See generally *id.* (noting that labeling issues are almost exclusively discussed within the debate surrounding Article 15). According to the report, working group "discussions centered on labeling/identification, relevant international rules and standards, and development of new standards under the Protocol." *See id.* Most developing countries supported a mandatory provision on handling, transport, packaging and labeling. However, some supported a clearly defined label on the package or the container in addition to accompanying documentation. *See id.* One delegation, it was noted, requested that workers handling the LMOs be made aware of proper storage and risks associated with handling LMOs. *See id.* Surprisingly, many developed countries preferred to exclude labeling from Article 15, citing sufficiency of identification. *See id.* Numerous countries did not support documentation requirements, claiming that these requirements, like labeling for consumers, are a domestic policy matter. *See id.*

⁴⁷ See Draft Protocol, *supra* note 5, art. 15(2) (stating that the Parties "shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, taking into consideration the results of consultations with other international bodies").

⁴⁸ *See id.* at art. 20(1) (stating that the Parties shall "promote and facilitate public awareness, education and participation concerning safety in transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human

accomplished primarily through public awareness of and access to a "Biosafety Clearing-House" and public consultation in the decisionmaking process regarding LMOs.⁴⁹ The emphasis on public outreach reflects international understanding of the need for better public awareness of genetic modification; although the side-effects of LMOs are unknown, public awareness requirements place some control in the hands of the individual.⁵⁰ The United States has not advertised domestic LMO content in its food products, but international initiatives such as the Biosafety Protocol are slowly triggering American awareness of these safe handling and labeling issues.⁵¹

Treatment and application of the Protocol's regulations by those countries who are not parties to the Convention on Biological Diversity is addressed within the Protocol and essentially requires those countries wishing to deal with member countries to comply with the requirements, including the labeling requirements, of the

health").

⁴⁹ See *id.* at art. 20(2) (requiring the Parties to "consult the public in the decision-making process regarding living modified organisms"). Also Article 17 provides:

(1) A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms;

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing countries, in particular the least developed countries and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin.

Draft Protocol, *supra* note 5, art. 17.

⁵⁰ See *id.*

⁵¹ See *infra* text accompanying notes 108-10 (discussing recent efforts by citizens groups to force the FDA to begin labeling of LMO products).

Protocol.⁵² Any shipment failing to comply with the terms of the Protocol is deemed illegal.⁵³ As a result, the United States biotech industry stands to be greatly affected by any resulting Biosafety Protocol regardless of the United States' status as non-party to the CBD.⁵⁴

II. The Counter Proposals

Many of the key articles discussed in Part I of this Comment provoked heated debate and resulted in the lack of consensus at Cartageña.⁵⁵ The stalemate prompted the introduction of three competing proposals, one from the Miami-group, one from the European Union and one from a group calling themselves the "like-minded" countries.⁵⁶ By examining the differences between the Miami-group proposal and the European Union proposal it is easy to discover the heart of the labeling controversy that contributed to the stalemate at Cartageña.⁵⁷

⁵² See Draft Protocol, *supra* note 5, art. 21 (regulating the treatment of non-parties to the CBD and stating that such treatment should "be consistent with the objective and principles of [the Biosafety] Protocol").

⁵³ See *id.* at arts. 23-25 (discussing the penalties for noncompliance with the Biosafety Protocol). In addition to these penalties, the Protocol calls for the Conference of the Parties to adopt, at its first meeting, a set of international guidelines for the establishment of liability and the calculation of damages resulting from unintentional transboundary movement of LMOs. The liability concerns surrounding the import/export of LMOs are contentious in their own right and have triggered intense debate. These issues are, however, beyond the scope of this article. *Id.*

⁵⁴ See *infra* note 79 and accompanying text (discussing the status of United States ratification of the Convention on Biodiversity).

⁵⁵ See generally *supra* note 24 (summarizing the remaining points contention with regard to development of a Biosafety Protocol and explaining the various positions of the member countries).

⁵⁶ See *id.* at paras. 40-44 (listing the three reports presented by the European Union, the Miami group and the group of like-minded countries).

⁵⁷ See generally *supra* note 23 and accompanying text.

A. The European Union Labeling Proposal

The proposal offered by the European Union (“EU proposal”), like the proposal offered by the Miami Group, is set forth as a series of amendments to the Draft Biosafety Protocol.⁵⁸ With regard to labeling, the EU proposal would require that LMOs intended for use as “food, feed or processing [be] clearly indicated as living modified organisms,” be accompanied by documentation listing the relevant LMO involved and list a contact point where further information may be obtained.⁵⁹

The Draft Protocol does not make a special distinction for those LMOs intended for use as “food, feed or processing,” and it does not require labeling on the product itself as the EU Proposal would appear to do.⁶⁰ These amendments offered by the European Union are reflective of legislative initiatives pending before the legislative bodies of various European Union countries and the European Commission which would make LMO-derived food products more easily identifiable for consumers.⁶¹ Such initiatives are a result of consumer lobbying efforts and general public demand for

⁵⁸ See Package Proposal on the Text of the Draft Protocol: Submission By the European Union, U.N. Doc. UNEP/CBD/ExCOP/1/L.2/Rev.1 at annex II [hereinafter EU Proposal](describing European Union proposed amendments to the current Draft Biosafety Protocol).

⁵⁹ See *id.* at para. 2(2)(c)(regulating the labeling of LMOs intended for consumption).

⁶⁰ See Draft Protocol, *supra* note 5, annex V, art. 15 (requiring the identification of only those LMOs “subject to international transboundary movement within the scope of the protocol”); see also Ways and Means to Promote and Facilitate Access to, and Transfer and Development of, Technology, Including Biotechnology, UNEP Subsidiary Body on Scientific Technical and Technological Advice, 2d Mtg., Item 3, para. 59-66, U.N. Doc UNEP/CBD/SBSTTA/2/6 (1996) (visited Aug. 1, 1999) <<http://www.biodiv.org/sbstta2/sb206.html>> (pioneering the creation of a biological database maintaining consumer information regarding the content and manufacturing process of LMOs).

⁶¹ See, e.g. *infra* notes 94-96 and accompanying text (describing a United Kingdom directive which has been agreed upon and will require labeling of all GMO products containing a threshold level of genetically modified product).

labeling of genetically modified products.⁶² Regardless of their merit or necessity in the regulation of genetically altered goods, these initiatives signify the concerns of the people who make up the consumer base for the biotechnology industry.⁶³ The United States, ignoring this market reality, took a decidedly different approach with its proposal.

B. The Miami Group Labeling Proposal

While the EU Proposal would broaden the scope of a Biosafety Protocol, the Miami Group Proposal seeks to narrow the application of the labeling requirements.⁶⁴ Specifically, the Miami Group Proposal would have Article 15 apply only to those LMOs which are within the “scope of the AIA procedure” rather than the broader category of LMOs regulated by the Protocol in general.⁶⁵

In addition, the Miami Group Proposal would modify Article 4 of the Draft Protocol regarding the scope of a Biosafety Protocol.⁶⁶ The Draft Protocol currently exempts certain types of LMOs from

⁶² See Links to Genetic Campaigns, Educational information, & other associated sites, (visited on Aug. 9, 1999) <<http://www.essential-trading.co.uk/gfalinks.htm>> (listing various international grassroots campaigns organized to promote labeling of genetically modified goods); see also *Biosafety Protocol Fails to Pass Muster in Colombia*, 10 *BIOWORLD TODAY* 46, May 12, 1999 (noting that the European Union vote on the Biosafety Protocol was an attempt to gain political cache with their constituents back home).

⁶³ See *infra* note 122 and accompanying text (describing the general feeling that biotech companies hope to gain from the public’s ignorance).

⁶⁴ See Outstanding Issues and Necessary Revisions to the Text of the Draft Protocol: Submission by the Miami Group, U.N. Doc. UNEP/CBD/ExCOP/1/L.2/Rev.1, at Annex III [hereinafter Miami Group Proposal] (representing the package of amendments offered by the United States and its allies).

⁶⁵ See *id.* at para. 2(a) (substituting “scope of the AIA procedure” for “scope of the Protocol”).

⁶⁶ See Draft Protocol, *supra* note 5, art. 4 (defining the scope of the draft protocol on biosafety).

regulation under a Biosafety Protocol.⁶⁷ However, Article 4(2)(b) of the Draft Protocol does not exempt LMOs subject to transit from the rules applicable under Article 15.⁶⁸ The Miami Group Proposal seeks to remove the reference to Article 15 in Article 4, effectively creating an exemption from handling and documentation rules of Article 15 for LMOs in transit.⁶⁹

Each of these proposals are offshoots of the Miami Group's concern for unrestricted trade and the desire to save the biotech industry from cumbersome and costly labeling and documentation requirements.⁷⁰ The position of the Miami Group is that it is better to have no Protocol than the current Protocol, but this view is short sighted in light of the powerful role which the United States plays in the biotechnology industry and the role it assumed at the Cartageña talks.⁷¹ The desire to avoid the creation of a Biosafety Protocol hurts the United States' reputation in the biotechnology market and creates a negative perception among future consumers of United States biotech products.⁷²

⁶⁷ See, e.g. *id.* (exempting those LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity).

⁶⁸ See *id.* at art. 4(2)(b) (stating that the Protocol will not apply to "[t]ransit of living modified organisms, except as regards Articles 2, 14 and 15").

⁶⁹ See Miami Group Proposal, *supra* note 64, para. 2(b) (proposing that the Parties "[i]n article 4, subparagraph 2(b), delete the reference to article 15 connected with transit").

⁷⁰ See Statement of Stuart E. Eizenstat, *supra* note 18, at 7 (explaining that "certain proposals would have created disguised barriers to trade . . . would have led to unnecessary trade restrictions on the world's food supply and limited the ability of other nations to enjoy the benefits of modern biotechnology").

⁷¹ See Frank Bajak, *International Treaty Talks on Gene Technology Collapse*, THE SEATTLE TIMES, Feb. 24, 1999, at A7 (quoting Rafe Pomerance, deputy chief of the United States delegation, as saying that "[n]o deal was better than a bad deal, and that was the outcome" in Cartageña).

⁷² See Financial Digest, THE WASHINGTON POST, June 24, 1999, at E1 (reprinting the statement by French Minister of Agriculture, Jean Glavany, that "American's have the worst food in the world").

1. The United States' Role

The United States is a well-known leader in the biotechnology industry.⁷³ United States companies produce \$50 billion annually in agricultural exports, and it is expected that over the next few years, one hundred percent of United States agricultural exports will be either genetically modified or mixed with genetically modified products.⁷⁴ Consequently, the United States has a significant incentive to protect the unrestricted trade in genetically modified products. The blind march toward unregulated trade, however, has hurt the United States' credibility in its dealings with the international community.⁷⁵ The seemingly intractable position of the Miami Group at Cartagena angered many of the member countries who viewed the United States-led opposition as an effort to create a "biotrade" protocol rather than a "biosafety" protocol.⁷⁶

Further resentment was fueled by the perception that the United States was actively working behind the scenes to derail negotiations.⁷⁷ This perception was aided by the fact that the United

⁷³ 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 (noting that Monsanto Co., an American company, is the world leader in genetic technologies).

⁷⁴ See Statement of Stuart E. Eizenstat, *supra* note 18, at 3 (discussing the steady growth of trade in bioengineered products).

⁷⁵ See *infra* notes 98-99 and accompanying text.

⁷⁶ See Brian Halweil, *supra* note 37 (stating that Sateaved Seebaluck, a delegate from Mauritius, complained that the final result of the Biosafety Protocol to preserve biodiversity resembled more of a "biotrade" protocol); see also, Angela Sanchez, *Environment: New Delay For Biosafety Protocol*, INTER PRESS SERVICE, Feb. 25, 1999, available in 1999 WL 5947236 (quoting attorney Chee Yoke, saying that "[f]rom the start, the biotechnology industry, protected by the United States and other industrialized countries, demonstrated what was confirmed here: the Miami Group never wanted a Biosafety Protocol, but rather a free trade treaty").

⁷⁷ See Sanchez, *supra* note 1 (describing tactics employed by the United States which were perceived as efforts to derail the negotiations). Delegates felt that United States efforts to break up discussions into a large number of groups and sub-groups was an attempt to dilute support for various proposals. Delegates were

States participated in the Cartageña talks as an official United Nations observer.⁷⁸ Although the United States has taken steps to become a signatory to the Convention on Biodiversity, the United States Congress has failed to ratify the Convention.⁷⁹ Numerous member countries concluded that the United States would rather employ subversive tactics to derail negotiations than negotiate a compromise agreement.⁸⁰

The United States' position with regard to labeling at the Cartageña convention was buttressed by the belief that current United States standards for regulating the release of LMOs are sufficient and should serve as a model for other countries looking to develop their own biotech regulatory system.⁸¹ It is useful therefore to examine the internal regulatory system which the United States employs for regulation of its own biotech industry.

also angered by the exclusive use of English in the texts under negotiation. *See id.*

⁷⁸ *See id.* (quoting Greenpeace International's Liza Covantes saying that "history repeats itself, as occurred seven years ago at the Earth Summit, the United States, despite being the only non-signatory to the accords and thus not officially part of the negotiation, has once again imposed its interests").

⁷⁹ *See Redick, supra* note 4, at 17 (discussing the failure of the United States to ratify the CBD and explaining that, as an "observer" the United States still plays an important role in the development of a biosafety protocol); *see also Report of the First Meeting of the Conference of the Parties to the Convention on Biological Diversity*, United Nations Environment Programme (UNEP), Item 2, para. 15, U.N. Doc. UNEP/CBD/COP/1/17 (1995), available in, <<http://www.biodiv.org/cop1/cbdrepi.html>> (visited Aug. 1, 1999) (listing all member countries to the CBD); *see also 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 (explaining that despite efforts by the Clinton administration, the Republican-controlled Senate has actively blocked approval of the CBD).

⁸⁰ *See supra* notes 76-78 and accompanying text.

⁸¹ *See Statement of Stuart E. Eizenstat, supra* note 18, at 4 (contrasting the "rigorous examination process" which the United States employs to ensure the safety of its food products with the "EU's weak decision-making machinery in [the biotechnology industry]").

III. Policy Regarding The Labeling of Genetically Modified Organisms

A. National Requirements for Regulating Genetically Modified Goods Within the United States

Currently within the United States, labeling regulation authority of food products rests with the Food and Drug Administration.⁸² Foods developed via bioengineering must only be labeled if they “differ significantly” from their conventional counterparts.⁸³ The United States policymakers insist that this is adequate to ensure the safety of the American consumer because LMO products still go through the same “rigorous examination process” for safety that all food and feed products go through.⁸⁴ This examination takes place under the “Coordinated Framework for Regulation of Biotechnology” which was articulated in 1986.⁸⁵

⁸² See USDA and Biotechnology Q & A (visited Aug. 6, 1999) <<http://www.usda.gov/news/bioqa.htm>> (answering the question “Are products derived from biotechnology required to be labeled?”); see also Food and Drug Administration, Food Labeling: Foods Derived from New Plant Varieties, 58 Fed. Reg. 25, 837 (1993) (detailing the United States’ most comprehensive national labeling system in regard to food products).

⁸³ See *supra* note 82 and accompanying text; see also Statement of Stuart E. Eizenstat, *supra* note 18 at 25 (explaining that under the current United States regulatory framework for labeling of GMOs and GMO products, genetically modified high-oleic canola would have to be labeled in the United States only because it has an oil content higher than conventional canola oil, not because it is a product of genetic modification).

⁸⁴ See Statement of Stuart E. Eizenstat, *supra* note 18 and accompanying text; but see LYNNE. MURRY, GENETICALLY MODIFIED FOODS: SAFETY ISSUES 113 (Karl-Heinz Engel et al. eds., American Chemical Society Series 605, 1995) (claiming that key safety requirements are necessary for the safe consumption of GMOs and casting doubt on the current labeling requirements in the United States).

⁸⁵ See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (Off. of Sci. & Tech. Pol’y 1986) (announcement of policy) (describing “the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products”).

Under this approach, biotechnology products are regulated using existing statutes and a patchwork oversight system involving three federal agencies.⁸⁶

The agencies primarily responsible for regulating biotechnology in the United States are the United States Department of Agriculture ("USDA"), Environmental Protection Agency ("EPA"), and the Food and Drug Administration ("FDA").⁸⁷ Products are regulated according to their intended use, with some products being regulated under more than one agency.⁸⁸ Prior to commercialization, genetically engineered organisms must conform with standards set by State and Federal marketing statutes.⁸⁹

Since 1994, twenty genetically modified agricultural products have moved successfully through the United States regulatory system and begun the commercialization and marketing phases of their development.⁹⁰ United States policymakers credit the transparency

⁸⁶ See *id.* (explaining that the agencies should "seek to operate their programs in an integrated and coordinated fashion and together should cover the full range of plants, animals and microorganisms derived by the new genetic engineering techniques").

⁸⁷ See United States: Regulatory Oversight in Biotechnology (visited Aug. 9, 1999) <<http://www.aphis.usda.gov/biotech/OECD/usregs.htm>> (explaining the oversight process and providing examples of the breakdown of Agency responsibility with regard to specific genetically modified goods).

⁸⁸ See *id.*

⁸⁹ See *id.* (providing examples of the various statutes which must be complied with).

⁹⁰ See Statement of Stuart E. Eizenstat, *supra* note 18, at 22 (touting the successes of the United States regulatory framework for the biotechnology industry and expressing the hope that the international community would join the United States in creating a system of oversight which is both transparent and predictable); see also 7 C.F.R. § 340.3(b); *cf.* APHIS, U.S. DEP'T OF AGRIC., USER'S GUIDE FOR INTRODUCING GENETICALLY ENGINEERED PLANTS AND MICROORGANISMS, Tech. Bull. No. 1783, § VI (rev. 1997) (describing, generally, the procedures for the release and transfer of genetically modified crops into the environment).

and predictability of the United States regulatory process with the general consumer acceptance which genetically modified products seem to enjoy in the United States markets.⁹¹

B. International Labeling Requirements for Genetically Modified Goods

The United States, in contrast, likes to portray the European market as one governed by fear and characterized by unpredictable rules based on political whim rather than scientific research.⁹² Regardless of the merits of this argument, international response to the labeling issue has been more expedient and substantive than the United States response.⁹³ For example, in the United Kingdom, the

⁹¹ See Statement of Stuart E. Eizenstat, *supra* note 18, at 22 (claiming that the “transparency and predictability of [the] process” can be credited with encouraging consumer acceptance). *But see* DRAFT UNITED STATES COMMENTS TO THE PROPOSED DRAFT RECOMMENDATIONS ON THE LABELING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY, at 3-4 (Proposed Draft Amendment to the General Standard for the Labeling of Prepackaged Foods, at Step 3 of the procedure app. VI, P60) (Oct. 10, 1997) (stating that the United States has found it unnecessary to regulate LMOs as a class because there is no scientific evidence to support a conclusion that LMOs are inherently unsafe). Regardless of statements by the USDA and the Clinton Administration, FDA has maintained their position that special labeling for LMO products would be inappropriate, and the FDA has yet to hold a public information hearing, originally announced in 1993, on labeling issues for newly engineered food varieties. *See* 58 Fed. Reg. 25, 837 (Apr. 28, 1993).

⁹² See Statement of Stuart E. Eizenstat, *supra* note 18, at 22 (claiming that the European public is “susceptible to ill-informed scare tactics” because there is “no scientifically based governmental system to approve GMO products”). United States policymakers refer to clearly defined rules and regulations which are judged in a predictable fashion as transparency. United States characterization of European regulatory controls as non-transparent is a reference to European regulation on a case-by-case basis. *See id.*

⁹³ See *infra* notes 94-96 and accompanying text (describing the required labeling practices of genetically modified food and feed products in the United Kingdom).

novel foods regulations governing the release of genetically modified goods maintain the need to label genetically modified foods.⁹⁴ Although genetically modified soybean and maize crops were approved for food use before the novel foods regulations came into force, the government quickly enacted Regulation 1813/97 which applies the labeling provisions in the novel foods regulation to soya and maize.⁹⁵ Furthermore, detailed rules for labeling these products were agreed to in a deal brokered under the U.K. Presidency, and will

⁹⁴ See DEPARTMENT OF TRADE AND INDUSTRY, BIOGUIDE: REGULATIONS, INFORMATION AND SUPPORT FOR BIOTECHNOLOGY IN THE UK *available in* <<http://www.dti.gov.uk/public/frame4.html>> (visited Aug. 8, 1999) [hereinafter BIOGUIDE] (explaining that GMOs must be labeled as such if “(1)[a]ny characteristic or food property renders a novel food or food ingredient no longer substantially equivalent to an existing food or food ingredient, (2) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff may have implications for the health of certain sections of the population, or (3) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff gives rise to ethical concerns”); *see also* EU/US Perspectives on Labeling Genetically Engineered Foods, FOOD CHEM. NEWS, Special Report, at 21 (describing the key differences between United States and European Union labeling policies).

⁹⁵ See BIOGUIDE, *supra* note 94, at 30 (describing the regulatory controls in the United Kingdom for the regulation of biotechnology). Under the U.K. labeling requirements, labeling is compulsory if it can be scientifically proven that the characteristics of novel food differ from those of a chemical food or ingredient. *See id.* According to new proposed regulations, labels are to be one of three types: (1) if it is certain that food contains genetically modified DNA or genetically modified proteins, then the label must read “product based on genetically modified soya or maize,” (2) if there is uncertainty as to whether substances in food originate from genetically modified maize or soya, then the label must read “this product may have been produced from modified maize or soya,” (3) if it is certain that there are no GMOs in food, then a label stating so may be used. *See id.*; *see also* Judith E. Beach, *No “Killer Tomatoes”: Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD DRUG L.J. 181, 187 (describing the issuance of the novel food regulations and their treatment of soya and maize products which form the majority of United States exports to the European Union markets).

require the labeling of all products which contain protein or DNA resulting from the genetic modification, where these exceed a threshold level.⁹⁶

Other countries have developed entirely different labeling laws from either the U.K. or U.S. systems, and one of the chief aims of the Biosafety Protocol was a harmonization of these regulatory standards.⁹⁷ Failing in this goal, countries have been left to establish their own regulatory standards which have included moratoriums on import and export of all LMOs in some countries.⁹⁸ While this reaction was anticipated, it could have been avoided if the United States had adopted a more conciliatory position with regard to the labeling provisions of the Cartagena Protocol.⁹⁹ Instead, countries have been left with the impression that the United States and its

⁹⁶ See BIOGUIDE, *supra* note 94, at 30 (explaining the recent enactment of a new directive which requires stricter labeling requirements). However, the proposed regulations point out that requiring that products be labeled raises the question of how to deal with cases where a GMO is present in trace amounts, or impurities, in a non-GMO product, or where similar GMO and non-GMO products are mixed together, as occurs with commodities. One possibility is the establishment of a mechanism to determine thresholds for specific classes of GMO products or individual GMOs rather than to fix a single cut-off point for labeling. *See id.*

⁹⁷ See Padman, *supra* note 31 (explaining that global biotechnology giants were welcoming the push for harmonized regulatory approvals which would enhance the business development of GMOs); *see also* South Africa's White Paper on Biological Diversity, A BIODIVERSITY POLICY AND STRATEGY FOR SOUTH AFRICA, Ch.3, 1.7 (discussing South Africa's policy on genetically modified organisms and describing newly proposed legislation to create and support national training and capacity-building programs in risk assessment and risk management for the safe transfer, handling, use and release of genetically modified organisms).

⁹⁸ See *Biosafety Protocol's Failure May Sour Trade*, FINANCIAL TIMES, Feb. 26, 1999, at C12 (claiming that European Union officials feared that the failure of talks in Cartagena would strengthen those in Europe who advocated a total ban on GMOs). Officials called the outcome "disastrous" and said it was likely to be "spun" as a case of American sabotage. *See id.*

⁹⁹ See Padman, *supra* note 31 (noting that many delegates felt that without a protocol, a moratorium on the commercialization of LMO crops was the safest route for countries to take).

biotech companies intend to continue shipping their genetically modified goods across their borders disguised as conventional food products.¹⁰⁰

IV. Reaction to The Cartagena Negotiations

A. International Trade Conditions in the Wake of the Failed Negotiations

Since the halt in negotiations at Cartagena, the European backlash to United States opposition to the proposed Biosafety Protocol has been considerable.¹⁰¹ Many predicted the imposition of across-the-board moratoriums on the import of LMOs, and, in fact, numerous countries implemented bans on trade in genetically modified goods.¹⁰² In May, France began to require segregation of

¹⁰⁰ See *id.* (discussing the broader implications of corporate domination of the biotechnology industry and noting that the five major bioengineering companies seem to be moving rapidly toward commercialization of their products while the world remains unable to keep pace with any comprehensive regulatory system).

¹⁰¹ See Lambrecht, *supra* note 13 (describing the European Commission's recent rejection of Monsanto's application to grow genetically engineered cotton); see also Statement of Sec. Glickman, *supra* note 7 (stating that "distrust [of LMOs] is scientifically unfounded. It comes in part from the lack of faith in the EU to assure the safety of their food. They have no independent regulatory agencies . . . [t]hey've had many food scares in recent years . . . that have contributed to a wariness of any food that is not produced in a traditional manner notwithstanding what the science says").

¹⁰² See Report on the Sixth Session, *supra* note 24, at 12 (noting that Denmark has called for a one-year moratorium on genetically-modified crops and generally describing protests in various countries against genetically modified goods); see also Simon Coss, *EU: Ministers Debate EU-wide Moratorium on GM Crops*, THE ECONOMIST, Dec. 17, 1998, at 5 (discussing the debate over a moratorium that took place in the European Union just prior to the talks in Cartagena). EU governments were acutely aware of public concerns about food safety in the wake of the 'mad cow' crisis and ministers expressed a desire to err on the side of extreme caution more than they would have three years ago. See *id.* A European Union group called BEUC has argued strongly, since the beginning of last year, that shoppers should have the right to choose whether to buy GMO

bioengineered and natural grains, a requirement which has imposed significant hardship on American farmers.¹⁰³

With regard to labeling, a European Union directive passed earlier this year will require the introduction of a labeling system for labeling of all foods containing LMOs.¹⁰⁴ This proposed system is due out by September 1999 and will ultimately regulate the labeling of all food products within the E.U. system.¹⁰⁵ Reactions such as this emphasize the steady movement toward international labeling requirements, and the United States failure to participate in this movement adds to the mistrust surrounding United States manufactured LMOs.¹⁰⁶

produce or not, and it claims the Union's current rules for labeling foods that contain GMOs are unclear and misleading. *See id.*

¹⁰³ See Tim Todd, *World Ag Forum: Industry Looks For Answers to EU GMO Issue*, MONEYCENTER, May 24, 1999, at B1 (noting the inability of most grain processing mechanisms to segregate genetically modified grain products from those products which are free from genetic modification); *see also* Marian Burros, *U.S. Plans Long-Term Studies on Safety of Genetically Altered Foods*, N.Y. TIMES, Jul. 14, 1999, at A16 (pointing out that European bans on genetically modified grains have damaged the corn export industry, costing American farmers about \$200 million per year); *see also* Anne Cook, *Tribune Business News*, THE NEWS-GAZETTE, May 23, 1999 at B3 (describing the procedures for processing corn in the United States and explaining why segregation causes problems in modern grain elevators); *see also* A. Novotny, *EU Directive on Labeling Genetically Modified Organisms Creates Confusion for U.S. Industry, Government*, FOOD LABELING & NUTRITION NEWS, July 10, 1997, at 3-4 (discussing segregation and claiming that in addition to being unnecessary, segregation is commercially impossible for the United States agriculture industry).

¹⁰⁴ See James Walsh, *Alien Seed?*, 152 TIME MAGAZINE INT'L 8 (Aug. 1999)(stating that by September, the European Union is supposed to introduce a scheme for advising the general public as to whether and to what extent GMOs figure in food products).

¹⁰⁵ See *id.* and accompanying text.

¹⁰⁶ See Walsh, *supra* note 104 (discussing the disdain in European markets for American-produced food products).

B. The United States Response

Some have labeled the measures taken by the European community as reactionary, irrational and lacking in scientific basis.¹⁰⁷ However, American consumers have begun to question the safety of LMO products as well.¹⁰⁸ Recently, more than 500,000 people signed a petition requesting the FDA to begin mandatory labeling of genetically modified foods.¹⁰⁹ The Center for Food Safety, a nonprofit group, has also filed suit against the FDA to take the necessary steps to reclassify gene modification as an additive so that it would require labeling.¹¹⁰ In a recent speech, United States Department of Agriculture Secretary, Dan Glickman, conceded that the ill-effects of bioengineering are yet unknown, and, as a safeguard, urged policymakers to keep pace with the technology.¹¹¹ It is apparent that the backlash against United States LMO exports has caused the United States to rethink its current policy regarding the biotech industry.¹¹²

¹⁰⁷ See Padman, *supra* note 31 (quoting an impromptu outburst by United States Department of Agriculture Official Dr. S. Shantaram saying that the debate over biosafety was being conducted by “ignoramuses, technology activists, fear-mongers, scientists, non-scientists and pseudo-scientists”); see also *supra* note 87 and accompanying text.

¹⁰⁸ See Burros, *supra* note 103 (discussing the fact that Americans, until recently, have been relatively accepting of genetically modified products, but heightened disputes with other nations at Cartagena have provoked Americans to start up activist labeling campaigns).

¹⁰⁹ See *id.*

¹¹⁰ See *id.* (noting also that the FDA does not require testing of genetically modified products); see also Greenpeace, et. al. v. Browner, U.S. Dist. Ct. for Dist. of Columbia (filed Feb. 18, 1999) (filing suit against the EPA for violations of national environmental laws for allowing genetically engineered corn onto the market).

¹¹¹ See Statement of Sec. Glickman, *supra* note 7 (discussing the new principles which will guide the regulation of the biotechnology industry).

¹¹² See Anita Manning, *Altered Food Might Mutate Trade*, USA TODAY, Jul. 14, 1999, at A7 (pointing out that Secretary Glickman’s comments represent a change for the Clinton Administration, but noting that volunteer labeling

In the Secretary's speech before the National Press Club, he announced five principles which will guide the United States in its development and regulation of the biotech industry.¹¹³ Notably, he addressed the need for voluntary labeling and conceded that there must be "a role for information labeling."¹¹⁴ However, it is not enough to ask companies to begin voluntarily labeling their LMO products.¹¹⁵ Clearly defined labeling guidelines must be established, and the United States government needs to take a more aggressive role in that process.¹¹⁶ The statements of Secretary Glickman mark a shift in United States trade policy, one which should also be translated into an acceptance of stronger labeling requirements under the Biosafety Protocol.¹¹⁷

requirements fall short of the guarantees which consumer advocacy groups had been pushing for).

¹¹³ See Statement of Sec. Glickman, *supra* note 7 (delineating five principles which should guide the United States approach to biotechnology in the 21st century). The principles announced are: (1) An Arm's Length Regulatory Process, (2) Consumer Acceptance, (3) Fairness to Farmers, (4) Corporate Citizenship, and (5) Free and Open Trade). *Id.*

¹¹⁴ See *id.* at 4 (explaining that there has been much discussion over labeling issues and expressing his feelings that labeling was "likely to happen"). The phrasing of Secretary Glickman's speech is symptomatic of the United States desire to avoid trade and domestic implications that are inevitable with labeling requirements. Although officials feel the inevitability of labeling requirements they shy away from embracing any policy stricter than voluntary mechanisms. See *id.*

¹¹⁵ See USDA and Biotechnology: Q and A, *supra* note 82 (stating that "in an effort to provide consumers with more information, Secretary Glickman actively encourages *voluntary* labeling of biotechnology-derived products").

¹¹⁶ See *id.* (describing the current United States labeling policy).

¹¹⁷ See Burros, *supra* note 103 (noting that Secretary Glickman had likened the regulation of the biotech industry to the regulation of nuclear power twenty years ago, and urging stricter controls which are in tune with trade goals).

C. Resolving the Conflict Between the Biotech Industry and the International Consumer

Secretary Glickman also warned against an “if-you-grow-it-they-will-come mentality.”¹¹⁸ The emphasis on building consumer acceptance is of paramount importance to United States biotech companies.¹¹⁹ Biotech companies have been loath to realize that global markets do not stand with open arms ready to receive these miracles of modern science.¹²⁰

Instead, genetically modified crops have created a market for safety.¹²¹ Widespread resistance to so-called “Frankenstein foods” predominates the European Union market and places a premium on proven safety and a well-informed public.¹²² Rather than creating the

¹¹⁸ See Statement of Sec. Glickman, *supra* note 7, at 4 (stating also that the industry needs to become more accessible to the consumer in an effort to build trust in their products).

¹¹⁹ See *id.* at 4. (expressing his belief that consumers and farmers will eventually come to realize the many benefits of LMOs if only the biotech industry will place a priority on gaining their acceptance through proven safety). The Secretary also stressed that corporations need to build consumer confidence in the same way that airlines and banks build confidence. See *id.* However, the Secretary’s statements argued for a strong public education effort to be fostered by both government and private industry. See *id.* Many have challenged the idea that consumers can be won over by public perception campaigns, and in Europe, Monsanto was forced withdraw a public ad campaign designed to dispel consumer fear over GMOs after it was widely criticized as patronizing. See Todd, *supra* note 103.

¹²⁰ See, e.g. Graziano, *supra* note 3, at 197 (explaining that while the biotech industry has developed products with the potential to aid in development of third world countries, these possibilities have yet to be put into practice and arguing that greater advancement in biotechnology needs to be made before the average consumer will begin to view LMOs as a viable, worthwhile endeavor).

¹²¹ See *id.* at 197-200 (describing the push toward harmonization of safety regulations to increase the public’s confidence in food imports).

¹²² See *Biotech Needs to Get People on its Side*, STAR TRIBUNE, Mar. 21, 1999, at 27A (stating that measuring biotech’s risks and benefits is remarkable complex, and, as a result, the major biotechnology companies have nothing to gain from public ignorance); see also Social Responsibility: Bio-engineering/GMOS,

intended demand for their genetically modified products, biotech companies have created an alternate market demand for organic goods; this is a direct result of failure to label their genetically modified products.¹²³ If genetically-engineered products are the huge leap forward which they bill themselves as, the market will accept them but only if consumers are given an informed choice.¹²⁴ In fact, consumers are extremely interested in products which provide them with improved capabilities, regardless of their genetic content, but this is true only when the products involved represent a dramatic improvement over the naturally-occurring version of the product.¹²⁵

(last visited Aug. 2, 1999) <http://www.altgreen.com.au/sr/bio_index.html> (discussing the fact that Europeans have dubbed GMO food products "Frankenfoods" and arguing that this term is popular but harmful to a reasoned debate over the regulation of genetically engineered food products). However, a panel of doctors in the United Kingdom recently told parliament that too little is known about the effects of GM foods and therefore, they could not recommend its safety to human health. *See id.*; *see also* Phillip J. Longman, *The Curse of Frankenfood: Genetically Modified Crops Stir Up Controversy at Home and Abroad*, U.S. NEWS & WORLD RPT., July 26, 1999, at 38 (observing that even reputable journals in Europe have adopted the term "Frankenfood").

¹²³ *See* "Certified Organic By" Labeling on Meat and Poultry Products, 64 Fed. Reg. 69 (1999) (labeling guidance) (announcing that the USDA received approximately 280,000 public comments in response to a call for comment on organic standards); *see also*, National Organic Program Proposed Rule: Labeling and Market Information Fact Sheet, U.S. DEPT. OF AGRICULTURE (press release) (explaining the Organic rule was promulgated to ensure consumers that food labeled as organic had met threshold criteria necessary to be labeled as such).

¹²⁴ *See* Statement of Sec. Glickman, *supra* note 7 (describing the importance of informed choice, however this statement is made in connection with his statements urging companies to begin voluntary labeling).

¹²⁵ *See* *Altered Foods Won't Harm Us*, *infra* note 156 (describing, generally, the markets where genetically modified products have become commercially successful). *But see* ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, MODERN BIOTECHNOLOGY AND THE OECD (June 1999) (noting that any genetic modification of food is subject to higher scrutiny and a stronger desire to see the market regulated). Concerns about genetically modified foods tend to fall into three categories: human health-related concerns, environmental concerns and ethical concerns. *See id.*

It is an absolute imperative, therefore, that LMOs be presented to consumers without the taint of deceptive marketing implied by a failure to label the products.

V. Recommendations

The debate over the Biosafety Protocol marks a paradigm shift taking place in most global economies.¹²⁶ The shift to a market economy demands that governments operate with more transparency to accommodate the needs of industry.¹²⁷ At the same time, corporations are fiercely protective of their products and processes.¹²⁸ So there is a natural urge for the biotechnology-based industries to prompt the United States Government to veto the biosafety protocol.¹²⁹ This reaction could prove short-sighted, however, if the global market for safety is not taken into account.¹³⁰ Product safety issues have created the market demand for safe food products, and the negotiation of a Biosafety Protocol should be viewed as rich ground from which the biotech industry may begin to fulfill this market demand.¹³¹ The United States, in its role as the lead exporter of

¹²⁶ See generally S. Gopikrishna Warriar, *supra* note 41 (discussing the new paradigm created by a shift to market economies).

¹²⁷ See *id.* at 4.

¹²⁸ See *id.* (explaining why this shift to a global market economy requires that countries reassess their goals and work harder to protect their individual interests).

¹²⁹ See *id.* (contrasting the United States goals of protecting their trade interests with India's need to protect their biological diversity). While United States interests naturally provoke a policy requiring them to veto the Biosafety Protocol, India's interests dictate the development of a strong Biosafety Protocol to protect their main resource - biological diversity. See *id.*

¹³⁰ See *supra* notes 58, 117 and accompanying text.

¹³¹ See *Biotechnology: UCS's Position*, <<http://www.ucsusa.org/agriculture/index.html>> (visited Aug. 1, 1999) (expressing the opinion of the Union of Concerned Scientists on biotechnology and stating that neither extreme position should dominate the debate over the benefits of biotechnology). Neither the presumption that biotechnology is beneficial and necessary nor the position that it is inherently harmful is a useful position and the Union of Concerned Scientists advocates a regulatory debate which is

LMOs, has naturally sought to facilitate the free trade goals of the biotech industry.¹³² The current market requires a more sophisticated understanding of ways these goals will be achieved.¹³³

A. Accepting a Meaningful Leadership Role Under the Convention on Biological Diversity

The Biotechnology industry continues to produce genetically-engineered crops, produce and pharmaceuticals at a rapid pace.¹³⁴ International policymakers admit to the inadequacies of the current regulatory framework.¹³⁵ The Protocol on Biosafety was an attempt to provide at least some minimum set of guidelines to protect countries from the potentially harmful affects of the modern applications of biotechnology. Unfortunately, the United States' role in negotiating the Draft Protocol has led the international community to conclude that the United States is only interested in protecting its trade interests.¹³⁶ However, rather than protecting it's trade interests in the European market, United States objection to the labeling

nonpolarized. *See id.*; *see also* Guarding the Green Choice: Environmental Labeling and the Rights of Green Consumers, National Wildlife Federation and Environment Report, Washington, D.C., (1996) at 4-5 (copy on file with The Environmental Lawyer) (noting that some companies view the labeling process as a marketing tool and welcome the opportunity to designate their products as genetically enhanced). Companies who view labels as a marketing tool generally seek to improve consumer awareness of the technology and its benefits for the environment. *See id.*

¹³² *See supra* notes 18, 64 and accompanying text.

¹³³ *See* S. Gopikrishna Warriar, *supra* note 41 (arguing that societies bring many interests to the trade negotiating table and that it is necessary for other countries to have a full understanding of these externalities to effectively protect their own trade resources).

¹³⁴ *See supra* note 70 and accompanying text.

¹³⁵ *See* Statement of Sec. Glickman, *supra* note 7 (calling for independent review of biotechnology via a newly created review commission and acknowledging the fact that developers of bioengineered products are outpacing the regulation of the field).

¹³⁶ *See supra* note 71 and accompanying text.

provisions under Article 15 of the Draft Biosafety Protocol has caused significant damage to the United States credibility as a world leader in biotechnology.¹³⁷ No single provision under the Draft Biosafety Protocol has garnered so much popular support as the requirements on labeling and documentation of LMOs.¹³⁸

Furthermore, it has become clear that the trade implications for the biotech industry will be severe if the United States cannot find some way to meet international consumers on common ground.¹³⁹ The first step toward avoiding another impasse in future negotiations over biotechnology regulation is United States ratification of the Convention on Biological Diversity. Perception is reality in the European Market, and, as long as the United States is perceived as a behind-the-scenes negotiator, the development of a favorable

¹³⁷ See Statement of Sec. Glickman, *supra* note 7, at 5 (stating that the stalemate over trade in LMOs has “the potential of creating a very serious trade confrontation between the United States and the European Union”). *But see* ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, MODERN BIOTECHNOLOGY AND THE OECD (June 1999) (noting the varying attitudes among OECD countries with respect to genetic modification and emphasizing the fact that companies trade interests can be affected differently by national standards). Although transparent trade standards facilitate trade, they can be a barrier to other countries trying to enter the market. These national standards also inhibit international competitiveness and distort the markets. *See id.*

¹³⁸ See, e.g. Anita Manning, *Altered Floor Might Mutate Trade*, USA TODAY, Jul. 14, 1999, at A7 (noting that protestors in Europe had torn up test plots for genetically modified crops); see also Greenpeace International Genetic Engineering Campaign Home Page, <<http://www.greenpeace.org/~geneng/main.html>> (last visited Aug. 2, 1999) (claiming that Unilever UK, the United Kingdom’s largest food manufacturing company, announced that it would be removing all genetically modified foods from its production line in an effort to meet growing customer demands for GMO-free foods). Greenpeace official, Benny Haerlin, is also quoted as saying that “[t]his is the beginning of the end of major transnational food corporations standing side-by-side with Monsanto.” *See id.*

¹³⁹ See Greenpeace International Genetic Engineering Campaign Home Page, *supra* note 130; see also Statement of Sec. Glickman, *supra* note 129 (saying that “[t]his has the potential of creating a very serious trade confrontation between the United States and the European Union”).

Biosafety Protocol is unlikely.¹⁴⁰ The United States biotech industry is aware of this troubling perception and has been a surprising advocate for United States ratification of the CBD.¹⁴¹ Ratification of the CBD will place the United States in its rightful position as a recognized leader in negotiations on issues of biotechnology.¹⁴² This will help to also dispel popular concern over the United States' observer status, and it will give the United States leverage to take a stronger position in determining other areas of the Protocol.¹⁴³

B. Development of a Comprehensive U.S. Labeling System

In addition, if the United States continues to venerate its own internal regulatory system for genetically modified goods as an example of transparency and credibility, it must be prepared to

¹⁴⁰ See *supra* note 77 and accompanying text.

¹⁴¹ See Lambrecht, *supra* note 73 (explaining that Monsanto and other biotech companies will be profoundly affected by the Biosafety Protocol and are eager for the United States to have an official vote at the negotiating table).

¹⁴² See *id.* (explaining official impact which the United States lacks in its dealings with other member countries of the CBD).

¹⁴³ See Redick, *supra* note 4, at 19 (stating that, regardless of the United States position as an observer to the CBD, it will still play an important role because of its position as the world leader in the biotech industry). However, Redick argues that during development of a Biosafety Protocol, the biotech industry has the opportunity to demonstrate that it is capable of working within existing frameworks to achieve adequate protection of the biodiversity interests at the heart of the CBD. See *id.* at 9. This argument is troubling in light of the corporate resistance to voluntary labeling guidelines advocated by the United States. See *id.* Redick also contends that voluntary controls provide an "alternative path" to a Biosafety Protocol. See *id.*; see also David R. Downes, *New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology, and Intellectual Property in the Convention on Biological Diversity*, 4 *TOURO J. TRANSNAT'L L.* 1,6 (1993)(arguing that increased global interest in the biotechnology market requires the United States to take a stronger role in negotiations of the CBD). There is a new strategy required for protecting resources while also protecting the trade in biological products, and this strategy should be marked by United States acceptance of increased responsibility with regard to the negotiation of international biodiversity treaties like the Kyoto Protocol and the CBD. See *id.*

include meaningful labeling requirements within its internal regulatory system.¹⁴⁴ Policymakers must do more than simply urge companies to voluntarily label their genetically modified goods.¹⁴⁵ As a leader in the area of biotechnology, the United States has a duty to develop extensive labeling guidelines which may serve as a model for other countries lacking in such regulatory experience.¹⁴⁶ United States companies are producing these bioengineered products and

¹⁴⁴ See Statement of Stuart Eizenstat, *supra* note 18, at 5 (explaining the United States policy viewpoint that the transparency of the United States regulatory system makes it superior to other systems, such as the United Kingdom, which are considered to be unpredictable). In his statement, Eizenstat also recognizes the right of countries to have mandatory food labeling restrictions which it would be necessary for United States companies to comply with. However, he emphasized voluntary labeling as a sufficient control. *See id.* But see S. 1533, 106th Cong (1999) (requiring France to label its wine exports with a message reading "Dried animal blood is occasionally used as a clarifying agent in French wines"). Recent legislation introduced by Senators Pat Roberts and Max Baucus would require labeling of French wine exports. *See id.*; see also *Fear of 'Mad Cow' Disease in French Wine Prompts Introduction of Warning Label Bill*, DAILY REPORT FOR EXECUTIVES, Aug. 13, 1999, at A-11 (noting that the senators stated that the French "have argued that their consumers need to be warned of all of the 'possible' risks of foreign-produced food products" so it is only fair that American consumers be "entitled to the same disclosure of information regarding French products").

¹⁴⁵ See *supra* note 136 and accompanying text; see also Food and Agriculture Organization of the United Nations, *Biotechnology and Food Safety: Report of a Joint FAO/WHO Consultation*, at 1, Oct. 4, 1996 (concluding that well organized regulatory controls should be established for biotech products and finding that a labeling component was necessary to this system).

¹⁴⁶ See Redick, *supra* note 4, at 19-20 (explaining that developing countries are still struggling to regulate biotechnology but noting that South Africa has taken steps to implement an information infrastructure to make information regarding GMOs readily accessible to the public); see also Statement of Stuart E. Eizenstat, *supra* note 18, at 25 (expressing concern over the number of developing countries which sided with the European Union at the negotiations in Cartageña). In his statement, Stuart Eizenstat noted that, although developing countries potentially had the most to gain from genetically enhanced crops, they were a surprising ally with Europe and expressed their desire not to become testing grounds for new releases of LMOs. *See id.*

moving them into the market.¹⁴⁷ The United States government, therefore, cannot fail to accept some level of responsibility for the regulation of these products.¹⁴⁸ United States policymakers have admitted to the inevitability of labeling laws for LMOs.¹⁴⁹ Considering this admission, the United States would be better served by leading the way towards labeling rules, rather than waiting for guidelines to be imposed upon them by their trading partners.¹⁵⁰

C. Understanding the Global Market

Resistance to the development of meaningful international labeling rules also perpetuates the belief that United States is happier without regulation because they really are trafficking in products which are unhealthy or dangerous to the environment.¹⁵¹ For this

¹⁴⁷ See Lambrecht, *supra* note 13 (describing Monsanto's business practice of redirecting all profits from the sale of GMO products back into further research and development of genetically engineered food products).

¹⁴⁸ See A. Dan Tarlock, *Local Government Protection of Biodiversity: What Is Its Niche?*, 60 U. CHI. L. REV. 555 (1993) (explaining that even local governments have a duty to protect the natural biodiversity of their region and this duty translates up the ladder to federal and international governments).

¹⁴⁹ See Statement of Sec. Glickman, *supra* note 7 (noting that the concept of labeling is not "radical" and advocating some informational labeling, but stating that it is imperative that such labeling initiatives not undermine trade).

¹⁵⁰ But see Beach, *supra* note 95, at 191 (arguing that special labeling requirements for genetically modified crops are not required because scientific evidence does not warrant such regulation). However, Dr. Beach's analysis of the need for labeling is governed by current scientific thinking related to the safety of LMOs, and it does not include a discussion of consumer acceptance and current disparities between United States consumers and the market currently being experienced by the United States' trading partners.

¹⁵¹ See *supra* note 71 and accompanying text; see also *Irresistible Force, Immovable Object*, ST. LOUIS POST-DISPATCH, Mar. 1, 1999, at D14 (stating that bullying and strong-arming the public are not the way to sell LMOs). Skeptics are concerned about the business incentives for a few large companies holding the patents for biotechnology to control much of the world's food supply and consequently exert undue influence over how safety of that supply is regulated. See *id.*

reason, the United States must be willing to accept stricter labeling standards under the Biosafety Protocol.¹⁵² Recent events in Europe and the long history of exploitation experienced by developing countries has created a market for proven safety and informed choice.¹⁵³ International consumers are demanding labeling standards which allow them the choice between genetically modified products and those goods which have not had their genetic structure altered in any way.¹⁵⁴ Although the United States, and the biotechnology industry in general, may face initial resistance to genetically modified

¹⁵² See Redick, *supra* note 4, at 20 (arguing that actions under a Biosafety Protocol must be market driven and dictated by the societal needs of the member countries); see also Graziano, *supra* note 3, at 211 (noting that a “biosafety protocol would promote a positive, safe image of the [biotech] industry and change the negative public opinion about biotechnology”).

¹⁵³ See *Biotech Needs to Get People on Its Side*, *supra* note 122 (explaining that developing countries fear that they will become dumping grounds for untested engineered traits); but see John H. Barton, *Biotechnology, the Environment, and International Agricultural Trade*, 9 GEO. INT’L ENVTL. L. REV. 95 (1997) (discussing the role of technology and biotechnology and pointing out that agricultural technology is responsible for increased yields which can prove significant to developing countries where arable land is lacking). Increasing the yield from arable land contributes to the food supply while preserving more land for diversity purposes. See *id.* It is this promising side of biotechnology which advocates point to when advocating freer trade in GMOs and unrestricted transport. See *id.*

¹⁵⁴ See *supra* note 58 and accompanying text (describing the degree to which individual consumers have felt compelled to organize campaigns for the labeling of genetically modified goods); see also, Greenpeace Policy Concerning the Labeling and Declaration of Genetically Engineered Food Products, (last visited Aug. 10, 1999) <<http://www.greenpeace.org/~comms/97/geneng/policy.html>> (detailing a proposed labeling policy and calling on the European Union to implement this policy for its citizens). Greenpeace advocates a labeling policy in which all food products that have been produced, processed, grown or cultivated under several preconditions have to be marked with a clear and easily visible label. See *id.* Greenpeace’s requirements are fairly strict and require use of a label which is either a non-removable sticker or a direct imprint on the product itself. See *id.*

goods which are labeled as such, this resistance should be viewed as the growing pains of an industry whose success depends completely on consumer acceptance.¹⁵⁵

Scientists as well as regulators point out that the biotech industry must be able to produce products which have proven value to consumers.¹⁵⁶ If genetic engineering truly holds the promising future extolled by the glossy covers of biotech company prospectuses,¹⁵⁷ then labeling of the products will simply enable consumers to better assess the risks versus the benefits of biotech products.¹⁵⁸ The international trade community has expressed its concerns that biotechnology markets tend to be skewed and inflated due to the high costs of competition relative to the demand for the product.¹⁵⁹ Clear labeling of LMO products allows consumers to

¹⁵⁵ See Donella H. Meadows, *Poor Monsanto; Monsanto Co.'s Plans for Using Transgenic Products*, *WHOLE EARTH*, June 22, 1999, at 104 (noting that in a recent *Time* Magazine poll, 81 percent of respondents said transgenic foods should be labeled and 58 percent said they wouldn't buy them if they were labeled).

¹⁵⁶ See *Altered Foods Won't Harm Us*, *CHICAGO TRIBUNE*, Mar. 3, 1999, at 15, available in, 1999 WL 2849110 (arguing that LMOs are not harmful and do not require review on a case-by-case basis, but finding that there may be merit to arguments for labeling). The article also notes that the stigma of labeling would be more easily overcome if GMOs had more to offer than a "redder tomato." See *id.*

¹⁵⁷ See Monsanto Co., 1997 Annual Report, cover (explaining that the explosion of knowledge in the bioengineering field is creating opportunity for Monsanto "to improve nutrition and health to meet the growth in world demand in a way that sustains our environment"); see also *SCIENCE FOR THE EARTH: CAN SCIENCE MAKE THE WORLD A BETTER PLACE?* 214-215 (Tom Wakefield & Martin Walters eds., 1995) (questioning whether the benefits can ever outweigh the risks in a technology field where so much has yet to be discovered).

¹⁵⁸ See *Altered Foods Won't Harm Us*, *supra* note 156 and accompanying notes.

¹⁵⁹ See *MODERN BIOTECHNOLOGY AND THE OECD*, *supra* note 136 (noting that economic stakes in the biotechnology industry are high and new regulatory standards are likely to produce further trade disputes which will have to be settled by international organizations such as the World Trade Organization and the Uruguay Round which guards against regulatory protectionism).

make more informed choices which will, in turn, create a consumer base that is more reflective of the true value of the biotechnology industry.¹⁶⁰

Conclusion

As the law struggles to keep up with technology, and as scientists admittedly require time to discover the side effects of bioengineered products, the consumer is preeminently aware that labeling may be the only way in which they may control their consumption of LMOs. The United States' failure to adopt meaningful controls regarding labeling and documentation of LMOs in Cartagena has created a blanket mistrust of United States agricultural exports. The biotech industry and the United States are better served by negotiation of a meaningful international regulatory system of labeling and the creation of meaningful internal labeling controls. Without such a labeling system, the biotech industry could fail to earn the consumer trust and find itself permanently without a market for the goods which it has spent billions of dollars to engineer.

¹⁶⁰ See Redick, *supra* note 4 and accompanying text.