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Information Based Regulation and International Trade in Genetically Modified Agricultural Products: An Evaluation of The Cartagena Protocol on Biosafety

Michael P. Healy*

INTRODUCTION

This Article considers the regulation of international trade in genetically modified agricultural products. Specifically, it addresses both products released into the environment as seeds and products intended for consumption as food. The first part of the Article describes the significance of genetically modified organisms (GMOs) in modern agriculture, especially agriculture in the United States.¹ This discussion summarizes the risks and potential benefits associated with the use of agricultural GMOs, especially the risks and benefits related to biodiversity. The Article then briefly describes the approaches to the regulation of these products adopted in the Cartagena Protocol to the Convention on Biological Diversity (Protocol).² The Protocol basically pursues two different regulatory

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1. See *infra* Part I.

2. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, art. 4, Jan. 29, 2000, 39 I.L.M. 1027 (2000), available at <http://www.biodiv.org/convention/articles.asp?lg=0&a=cbd-04.htm> (last visited Feb. 10, 2002) [hereinafter Protocol]. Part II *infra* discusses the Protocol's requirements. Eleven nations have ratified the Protocol. See <http://www.biodiv.org/biosafety/signinglist.asp?order=date> (last visited Jan. 29, 2002). Article 37 provides that "[t]his Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or

approaches. The Protocol adopts a regime of Advanced Informed Agreement (AIA) for the transboundary import of genetically modified food products released into the environment. Genetically modified agricultural products intended for consumption as food are subject to a more ambiguous regulatory scheme, which includes a labeling requirement for product shipments.

The next two parts of the Article consider these different regulatory approaches in greater detail. The Article criticizes the details of each of the Protocol's two regulatory regimes. One fault is that the Protocol does not help allocate the burden of proof with respect to the importing nation's decision to accept genetically modified products' introduction into the environment.³ The Protocol is incoherent in two respects regarding the regime for the import of genetically modified food products. First, when an importing nation accepts genetically modified products that pose risks to biological diversity, including human health, the Protocol should require a label that identifies the product as genetically modified.⁴ Second, the Protocol is flawed because it requires labels for shipments of genetically modified food products even if they pose no identifiable risk to consumers.⁵ Generally, however, the Protocol's regime should be lauded because it may provide consumers with the information they need to make informed decisions about the foods they consume.

I. BIOTECHNOLOGY, BIOLOGICAL DIVERSITY, AND THE CARTAGENA PROTOCOL

Article 2 of the 1992 Convention on Biological Diversity broadly defines "biotechnology" as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."⁶ Biotechnology is

regional economic integration organizations that are Parties to the Convention." 39 I.L.M. 1027, 1042 (2000).

3. See *infra* Part III.

4. See *infra* Part IV.

5. See *infra* Part IV.

6. 31 I.L.M. 818, 823 (1992) (entered into force on Dec. 29, 1993). The United States signed the treaty on June 4, 1993, but has not ratified the treaty. See Parties to the Convention on Biological Diversity/Cartagena Protocol on Biosafety, available at <http://www.biodiv.org/world/parties.asp> (last visited Jan. 24, 2002).

an increasingly important issue in international relations,⁷ and it plays an especially important role in modern agriculture.⁸ Two specific examples of biotechnology's impact on agriculture are "roundup ready" soybeans and "Bt" corn. The genetic material of these plants is engineered in the first case to survive the application of a herbicide,⁹ and in the second to kill insects eating the plant.¹⁰ There are numerous other examples of such crops.¹¹

The significance of biotechnology for modern agriculture can be assessed from several perspectives. Although specific estimates vary, an inescapable conclusion is that modern agricultural production yields very substantial and growing amounts of GMOs.¹² Production

7. See Stephen McCaffrey, *Biotechnology: Some Issues of General International Law*, 14 TRANSNAT'L LAW. 91, 92 (2001). "[T]he rules of international law must be applied to many different forms of genetically-engineered products: from pharmaceuticals made from samples taken in developing countries, to GM food, crops, and seeds." *Id.*

8. See Gareth W. Schweizer, Note, *The Negotiation of the Cartagena Protocol on Biosafety*, 6 ENVTL. LAW. 577, 594 (2000). "Food commodities make up the largest group of [GMOs] . . ." *Id.* (footnote omitted).

9. *Id.* at 581. "Roundup-Ready crops are genetically engineered to resist glyphosate, a common herbicide, so that only the crop will survive after spraying." *Id.* (footnote omitted).

10. *Id.* "[B]t, or Bacillus Thuringiensis, is a bacteria that is toxic to insects. In [Bt corn], the Bt toxin is incorporated into the DNA of every cell of a plant so that insects die if they eat the plant." *Id.* (footnotes omitted).

11. McCaffrey, *supra* note 7, at 93. "Since 1992, dozens of [these crops] have been approved for sale to American farmers and hundreds more are in the pipeline, with genes borrowed from every form of life: bacterial, viral, insect, even animal." *Id.* (internal quotations and footnote omitted); see also Marc Victor, *Precaution or Protectionism? The Precautionary Principle, Genetically Modified Organisms, and Allowing Unfounded Fear to Undermine Free Trade*, 14 TRANSNAT'L LAW. 295, 296 (2001). "The U.S. Department of Agriculture has approved fifty plant varieties, termed Genetically-modified Organisms (GMO), for use within the United States. In contrast, the EU has only approved eighteen GMOs." *Id.* (footnote omitted).

12. See McCaffrey, *supra* note 7, at 94. "Farmers have embraced [genetically-modified] products to the extent that biotech seeds are used in plants that produced twenty to forty-five percent of the corn, soybean, and cotton produced in the United States in 1999 (although the experience with StarLink corn has had a chilling effect on the use of GM seeds)." *Id.* (footnotes omitted); see also Victor, *supra* note 11, at 296 (stating "[n]early half of the soybeans and a third of the corn grown in the United States is [sic] genetically altered") (footnote omitted); Mary Lynne Kupchella, Note, *Agricultural Biotechnology: Why it Can Save the Environment and Developing Nations, but May Never Get a Chance*, 25 WM. & MARY ENVTL. L. & POL'Y REV. 721, 724 (2001) (stating "[i]n 1998, genetically engineered crops accounted for 25% of corn acreage planted in the United States, 38% of soy bean acreage, and 45% of cotton acreage, for a total of 45 million acres, an increase of 250% from 1997. In 1999, biotechnology plantings in the U.S. increased to 62 million acres . . .") (footnotes and internal quotations omitted).

of roundup ready soybeans¹³ and Bt corn¹⁴ contribute to the striking growth in production. This growth in production is matched by a growth in the level of consumption of genetically engineered food products.¹⁵

Not surprisingly, the economic stakes associated with opportunities for unrestricted trade in genetically modified agricultural products are already high and are steadily increasing.¹⁶ Countries that have an economic interest in trading these products, most especially the United States,¹⁷ have promoted their interests in unimpeded trade.¹⁸ Moreover, this interest in the rules of trade for

13. See Schweizer, *supra* note 8, at 581 n.22. "Roundup-Ready soybeans were planted on over half of the United States's soy acres last year." *Id.* (citation omitted).

14. *Id.* at 582 n.29. "Bt corn was approved for sale in 1996. In 1997, about 5 percent of the nation's corn crop was Bt corn. By 1999, more than one-third of U.S. corn acres were Bt corn." *Id.* (citations omitted).

15. See McCaffrey, *supra* note 7, at 94. "Most Americans have probably eaten some food made with genetically-modified soy or corn." *Id.* (internal quotations and footnote omitted); see also Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 ANN. SURV. INT'L & COMP. L. 129, 131 (2000). Also note that "60% to 70% of foods sold in the U.S.A contain substances developed through genetic engineering." *Id.* (footnote omitted). "Nowadays about 2.5 billion people have been eating GMP directly or indirectly, knowingly or not." *Id.* at 140-41. "[A]ccording to Mothers for Natural Law) 60 to 70 percent of foods on U.S. grocery store shelves contain genetically engineered substances." *Id.* at 141 (footnote and internal quotation omitted).

16. See Victor, *supra* note 11, at 309. "In 1998, the United States lost \$200 million in corn sales alone because of delays in the EU's approval process for GMOs." *Id.* (footnote omitted). See also de Oliveira Souza, *supra* note 15, at 140-41 (stating "[e]ach day more countries are allowing cultivation of GMP, in a market that will reach US\$ 500 billions/year in the next few years") (footnote omitted); McCaffrey *supra* note 7, at 94 (stating "[s]eed and chemical companies stand to make huge profits from these new products").

17. Kupchella, *supra* note 12, at 732. "Of the thirty-five million hectares planted in 1998 of genetically-modified crops, eighty-eight percent were planted in North America, and less than one percent was planted in Europe." *Id.* (footnote omitted); see also de Oliveira Souza, *supra* note 15, at 141. "[A]ccording to Charles Margulis, a genetic engineering campaigner for Greenpeace, it is estimated that 75 percent of all bio-engineered crops are grown in the U.S . . ." *Id.* (internal quotations omitted).

18. In the negotiation of the Protocol

[t]he Miami Group represented nations most opposed to efforts to control [GMOs] and claimed to harbor an overall concern for harmonizing environmental protection with sustainable growth of agricultural economies. These industrialized countries stood to suffer the most economic loss by regulations imposed on [GMOs], and they feared that elaborate paperwork needed to enforce such controls on commodities . . . would create insuperable obstacles for international trade, given the huge number of transboundary movements each year.

Schweizer, *supra* note 8, at 587 (footnotes and internal quotations omitted).

genetically engineered agricultural products has implications for trade in all agricultural products.¹⁹

Commentators who laud the "immense" benefits of biotechnology welcome figures that demonstrate the growing significance of biotechnology in modern agriculture.²⁰ Those promoting the agricultural applications of biotechnology cite several benefits. First, genetically modified crops may reduce the need for, and application of, such agricultural toxins as herbicides²¹ or insecticides.²² Second, genetically modified crops may provide higher yields of crops and thereby reduce demand for land dedicated to agricultural use.²³

19. Schweizer, *supra* note 8, at 592 (footnotes omitted):

For example, in the United States, the largest producer of bioengineered crops, mixes grains that have been genetically modified with unadulterated grains distributed in commerce. An AIA applicable to all GMOs could severely harm the American grain trade because it would impact almost all grain exported from the United States.

20. Kupchella, *supra* note 12, at 722. "While there are potential risks to agricultural biotechnology, and the long-term effects are unknown, the benefits of this technology are immense." *Id.* (footnote omitted). "Agricultural biotechnology has the potential to solve many of the most daunting environmental problems facing the world, such as a decrease in biodiversity and shortages of food. With proper regulation, biotechnology can save biodiversity and solve numerous other environmental concerns." *Id.* at 721 (footnotes omitted); see also Richard M. Saines, *Rotterdam Treaty on PIC and Biosafety Protocol: Examples of Increased Transparency, Technology Sharing, and Accountability in International Law*, 24 *Int'l Env't Rep. (BNA)* 623, 626 (2001). "Proponents of biotechnology see the genetic modification of organisms as a powerful tool in the global battle against hunger and poverty, as well as a means to improve the environment by reducing the need for pesticides and other chemicals to produce food." *Id.*

21. Kupchella, *supra* note 12, at 724-25. "The use of herbicide-resistant crops will likely cause a reduction in the quantities of herbicides used. . . . Proponents of resistant crops also believe that they will allow older, more toxic and generally more harmful herbicides to be replaced with ones which are more environmentally favorable." *Id.* (footnotes omitted).

22. Schweizer, *supra* note 8, at 581. "[Bt] crops will require fewer insecticide applications." *Id.* (footnote omitted).

23. *Id.* "Cultivating Bt crops in place of non-GMOs can stimulate higher yields from the same plot of land . . . In 1998, 4 billion more pounds of field corn were produced because of Bt technology than would have been available without such technology." *Id.* (footnote and internal quotations omitted); see also Kupchella, *supra* note 12, at 727-28.

Higher-yielding crops are yet another way in which biotechnology will aid agricultural output. . . . If higher-yielding crops are not used, wild lands will have to be used for agriculture. On the other hand, if the same product can be produced with less cultivated land, then more land can be returned to a natural habitat. Genetically-modified crops will also result in land that needs less tilling, benefiting the environment through decreased erosion and soil infertility.

Id. (footnotes omitted).

Lastly, genetically modified crops may provide food products with an enhanced nutritional value and thereby alleviate the scale of human malnutrition.²⁴

The important role that biotechnology plays in modern agriculture has grown rapidly despite the risks that genetic modification poses for the environment and human health. The greatest concern about the genetic modification of plants is the threat to biological diversity.²⁵

The use of genetically modified agricultural products is understood to pose two general threats to biodiversity. First is “[t]he risk that altered DNA will contaminate an ecosystem,” referred to as “genetic pollution.”²⁶ Such pollution was recently identified in Mexico, where “DNA from genetically modified corn has found its way into native corn varieties growing in remote southern Mexico, heightening fears about the dangers of bioengineered crops.”²⁷ Apparently, the polluting DNA came from consumable modified corn

24. See Kupchella, *supra* note 12, at 726. “Biotechnology will also be able to solve nutritional deficiencies in developing nations. Approximately 400 million women suffer from iron deficiency in third-world nations where the staple diet is rice. A new variety of rice containing iron and vitamin A will be able to decrease this number.” *Id.* (footnotes omitted); see also de Oliveira Souza, *supra* note 15, at 138.

The main benefits of biotechnology can be summarized in the following way: (a) it contributes to the human food supply and to the protection of biodiversity, allowing a more efficient use of land, and a more productive harvest; (b) it improves the quality of food; (c) it may contribute to reducing the use of agrochemicals and pesticide; and finally (d) it may be helpful for the maintenance of germplasm collections.

Id. (footnotes omitted).

25. Jim Chen, *Diversity and Deadlock: Transcending Conventional Wisdom on the Relationship Between Biological Diversity and Intellectual Property*, 31 *Envtl. L. Rep.* 10,625, 10,627 (2001) (footnotes omitted). Professor Chen has argued forcefully that

[b]iodiversity preservation is arguably humanity’s greatest challenge. It certainly qualifies if the relevant gauge is the duration and difficulty of corrective measures. According to the geological record of previous extinction spasms, the “full recovery of biodiversity” after a catastrophe such as a meteor strike “require[s] between 10 and 100 million years.” By this measure, “the loss of genetic and species diversity by the destruction of natural habitats” is probably the contemporary crisis “our descendants [will] most regret” and “are least likely to forgive.”

Id.

26. See Schweizer, *supra* note 8, at 583 (footnote omitted).

27. Alex Dominguez, *Scientists Find Genetically-Modified Corn DNA has Spread to Mexican Maize*, ASSOCIATED PRESS, Nov. 29, 2001, at 1 (copy on file with author).

used as seed.²⁸ The effects of genetic pollution are difficult to predict and are likely to vary,²⁹ but could potentially include super insects³⁰ and super weeds.³¹

Related to the phenomenon of genetic pollution is the threat that "the use of GMOs may also cause the loss of diversity in a gene pool, a process also known as 'genetic erosion.'"³² Such erosion may occur as the ecosystem changes in response to its newly modified organisms.³³ Moreover, biotechnology may have more direct, though unintended, consequences for species in the affected ecosystem.³⁴

28. *Id.* "Researchers suspect imported genetically-modified corn was handed out by a government agency as food and may have been planted by recipients near their traditional crops." *Id.*

29. See Kupchella, *supra* note 12, at 728, 729 (footnotes omitted):

Yet unknown is what types of interactions genetically-modified plants will have with other species. There is a fear that genetically altered organisms will become agricultural pests or colonize natural ecosystems, disturbing balances, especially where characteristics would allow it to compete successfully. It is possible that these new organisms will hybridize with a related wild species thereby producing hybrid progeny that are harder to control. Even plants which are unlikely to escape into the wild can potentially change populations of microorganisms in the soil and the types and numbers of insects and other animals in surrounding areas.

30. Schweizer, *supra* note 8, at 582. "Regular exposure to Bts can result in insects developing a resistance to the toxin, thus becoming 'super-insects.'" *Id.*; see also de Oliveira Souza, *supra* note 15, at 139. "[W]hile crops may be engineered to contain natural insecticides, insects can adapt, becoming resistant much more quickly than expected." *Id.* (internal quotations omitted).

31. See Schweizer, *supra* note 8, at 581. "The main risk surrounding Roundup-Ready crops is that if bees or wind transfer the pollen from these crops to wild plants, weeds can also develop resistance to herbicides." *Id.* (footnote omitted). de Oliveira Souza elaborates further about these risks.

[T]he first risks are indicated by FAO in the following way "The inclusion of novel genes for herbicide resistance in plants may increase the occurrence of weeds with resistance to certain agrochemicals, the [FAO] reported warned. The inclusion of pest resistance in plants should be carefully evaluated for potential development of resistance in pests and possible side-effects on beneficial organisms.

de Oliveira Souza, *supra* note 15, at 138-39 (footnotes omitted).

32. Schweizer, *supra* note 8, at 583.

33. de Oliveira Souza, *supra* note 15, at 139 (internal quotations and footnote omitted):

The introduction of any new organism into an ecosystem might affect the dynamics of the ecosystem or the gene pool of wild relatives. These effects can happen whether the new organism is a new crop variety or a new microorganism introduced for disease control, and whether it is genetically-engineered, bred by traditional means, or simply from a different ecosystem.

34. Schweizer, *supra* note 8, at 582. "[Bt crops] can kill beneficial insects, such as bees

Choices by farmers may increasingly limit the range of plants grown for agricultural purposes.³⁵ This latter effect may yield adverse economic, as well as environmental, effects.³⁶ Genetic pollution and genetic erosion are present in certain geographic areas located in less-developed nations that have richly diverse ecosystems which are untested in terms of the impacts on biodiversity.³⁷

When compared to the risks that agricultural biotechnology poses to the environment, the risks posed to human health so far appear more limited. Genetic engineering poses risks related to human allergies.³⁸ Significant uncertainty prevails in this area, because

and ladybugs, when they eat the engineered crop." *Id.* (footnotes omitted).

35. de Oliveira Souza, *supra* note 15, at 139. "[A]nother risk is the loss of diversity provoked by the widespread use of one—or a few—species of crops." *Id.* (footnote omitted). Cf. John Ntambirweki, *Biotechnology and International Law Within the North-South Context*, 14 *TRANSNAT'L LAW* 103, 104 (2001). Uganda has traditionally grown more than thirty species of bananas, but today "[t]he plant breeders have now come in with their few varieties. Everybody is rushing for the new bigger banana bunches which fetch more in the market. The diversity that was conserved by farmers for millennia is being steadily lost." *Id.*

36. de Oliveira Souza, *supra* note 15, at 138 (citation, footnote, and internal quotations omitted):

[S]mall farmers fear that a small number of large corporations will be able to corner the market on genetically engineered animals, thereby depriving the small family farms of their livelihood. Additionally, the farmers are concerned that the initial acquisition price of genetically altered animals, and the subsequent royalties, will increase rather than decrease the costs for farmers and consumers.

37. See Schweizer, *supra* note 8, at 584 (footnotes omitted):

Although industrialized countries have tested the environmental impact of GMOs on their own land, testing in these countries may not necessarily prove that GMOs are safe in a different ecological setting. As a result of these unknown risks, environmental activists have petitioned for a global ban on GMOs until the long-term safety of their use is better understood.

Cf. *id.* at 583 (footnote omitted):

Exposing crops to the wild genes preserved in centers of origin, natural areas where wild relatives of cultivated crops grow, helps to restore vigor to a crop. If GMOs were mistakenly released in a center of origin, the genetic make-up of the gene pool could become permanently altered.

38. See Committee on Genetically Modified Pest-Protected Plants, National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* (2000) [hereinafter *NRC Report*], which reported that:

The potential risks of transgenic pest-protected plants to human health are generally related to the possibility of introducing new allergens or toxins into food-plant varieties, the possibility of introducing new allergens into pollen, or the possibility that previously unknown protein combinations now being produced in food plants will

allergenicity risks are extremely difficult to assess³⁹ and testing for human health effects has been sporadic and inconsistent.⁴⁰ Moreover, incidents of serious risks to human health arising from adaptations to the genetic material of traditional food products⁴¹ give rise to concerns that engineered changes in plant genes may cause other, similar risks to human health.⁴² Interestingly, the Protocol itself defines the scope of the agreement by reference to "adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."⁴³ The Protocol thereby makes protection of human health subsidiary to the protection of biological diversity.

II. THE CARTAGENA PROTOCOL REQUIREMENTS

This Article will now describe the regulatory approach to genetically modified agricultural products defined by the Protocol.⁴⁴ Congress adopted the Protocol "[o]n 29 January 2000, after some five years of difficult negotiations."⁴⁵ In the view of one observer, negotiations reflected the policy concerns of environmental, rather than agricultural, ministries⁴⁶ and made evident that "the underlying

have unforeseen secondary or pleiotropic effects. . . .

Id. at 62-63; de Oliveira Souza, *supra* note 15, at 139. "The main risk to health is allergy, and one example is found in the allergic side effects provoked by the addition of Brazil nut protein in a soybean." *Id.* (footnote omitted); see also Kupchella, *supra* note 12, at 730. "One of the strongest arguments for the regulation of transgenic food concerns the spread of allergenicity throughout the food supply." *Id.*

39. See NRC Report, *supra* note 38, at 66 ("Allergenicity is difficult to test, in part because prior exposure is a prerequisite to an allergic reaction."); see also *id.* at 68-69 (discussing difficulty of testing because of dietary limits and limited time).

40. See *id.* at 63 (describing limited "detailed assessments of safety for humans or domestic animals").

41. See *id.* at 70-71 (describing human health risks resulting from conventionally-bred varieties of potatoes and celery).

42. See *id.* at 66 (referring to the human health risk posed by genetic engineering of soybeans). See generally George Van Cleve, *Regulating Environmental and Safety Hazards of Agricultural Biotechnology For A Sustainable World*, 9 WASH. U. J.L. & POL'Y 245 (2002).

43. Protocol, *supra* note 2, at Art. 4.

44. 39 I.L.M. 1027 (2000).

45. Peter-Tobias Stoll, *Controlling the Risks of Genetically-Modified Organisms: The Cartagena Protocol on Biosafety and the SPS Agreement*, 10 Y.B. OF INT'L ENVTL. L. 82, 82 (1999); see *id.* at 86-87 (summarizing interests represented in the negotiations).

46. See Thomas Jacob, *The Cartagena Protocol: A First Step to a Global Biosafety*

notion that most of the countries brought to the table was that genetically modified organisms [] are inherently dangerous."⁴⁷

In considering the structure of the regulatory scheme adopted in the Protocol, the parties notably refrained from using the more common term, GMO, and instead substituted the apparently more restrictive term, "living-modified organism" (LMO). An LMO is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."⁴⁸ The regulatory scheme then establishes

Structure?, 14 TRANSNAT'L LAW. 79, 81 (2001):

By and large, most of the countries came to the table with their environment ministries, leaving their agricultural ministries at home. Lacking was the kind of interdisciplinary and/or interagency process that the United States and a number of other countries use in negotiation of these types of international agreements ensuring that all the interests of a particular country and society are integrated. The fact that most countries did not involve their agricultural ministries is also important because much of the Protocol is focused on agricultural applications. The individuals in those ministries have the expertise regarding application of the existing international agriculture and food safety instruments. On the other hand, among the environment ministry participants, in some cases there was very little involvement and awareness of those existing instruments.

Mr. Jacob works for DuPont, which has a significant interest in the profitability of biotechnology. *Id.* at 80. The regulatory concerns of the negotiators of the Protocol contrast with the regulatory concerns of the agency primarily responsible for regulation of genetically-modified agricultural products within the United States.

The [New York] Times report notes that the U.S. Department of Agriculture (USDA) is "the primary agency responsible for assuring the ecological safety of [genetically modified] plants," and points out that the USDA "has not rejected a single application for a genetically engineered crop." Some scientists criticize these approvals on the ground that the Agency often relies on claims and studies conducted by the seed companies themselves.

According to the report, USDA has set no scientific standards for evaluating the environmental safety of a genetically engineered plant. The Times further states that rather than demanding specific experiments and data to establish safety, as is the case in other fields, the USDA "asks only that petitioners explain why the new plant is unlikely or likely to pose a number of broadly defined risks." But USDA officials defend their decisions, even while they "acknowledge that their system for weighing applications is evolving."

McCaffrey, *supra* note 7, at 93 (footnotes and emphasis omitted).

47. Jacob, *supra* note 46, at 81.

48. See Protocol, *supra* note 2, at Art. 3(g). One commentator described the negotiation of this particular term.

One of the important roles of the Protocol was to set forth various generally acceptable definitions for many important terms, allowing for consistency in use. Since the

requirements for the transboundary shipment of LMOs for use in agricultural products and other requirements for shipments of LMOs intended for use in animal feed or for human consumption.⁴⁹ A summary of these differing regulatory approaches follows.

Articles 8, 9, 10, and 12 of the Protocol define the AIA procedure that applies "prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import."⁵⁰ The Protocol's AIA procedure "does not make any groundbreaking innovations. It simply expands upon the elements contained in Article 19 of the Convention on Biological Diversity [(CBD)]. It gives flesh to the concept of 'advance informed agreement' provided for in the CBD."⁵¹ The Protocol provides that the exporting party must notify the importing party of the intended transboundary introduction of an LMO into the importing country.⁵² The importing party must acknowledge the notice,⁵³ then decide whether to consent to the import.⁵⁴ The importing party has an obligation to provide reasons to the exporting party any time that unconditional consent is not given.⁵⁵ The standard the importing party must apply when deciding whether to consent to

Protocol was intended to be a legally binding international instrument, a lot of time went into these definitions—almost a year was spent trying to define with precision exactly what is covered under the term "living modified organism." It was decided that the generic term "genetically-modified organism" would not be used since the negotiators felt a more scientifically precise definition was needed.

Jacob, *supra* note 46, at 83.

49. See Protocol, *supra* note 2, at Art. 7. The terms of the Protocol also define three important limits on its scope. First, "Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations [sic]." *Id.* at Art. 5. Second, "the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit." *Id.* at Art. 6(1). Third, "the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import." *Id.* at Art. 6(2).

50. *Id.* at Art. 7(1).

51. Ntambirweki, *supra* note 35, at 125; see also McCaffrey, *supra* note 7, at 96. "The AIA procedure under the Protocol is generally congruent with PIC under other agreements, but contains more specific and detailed time periods for decision-making." *Id.* (footnote omitted).

52. See Protocol, *supra* note 2, at Art. 8(1).

53. See *id.* at Art. 9.

54. See *id.* at Art. 10.

55. See *id.* at Art. 10(4).

import is ambiguous under the Protocol. The Protocol provides that a party may decline to consent to import, notwithstanding a "lack of scientific certainty."⁵⁶

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimize such potential adverse effects.⁵⁷

The Protocol also includes, however, two provisions that may limit the ability of the importing party to refuse consent to importation of the LMO. First, Article 15 provides that the risk assessment, used as the basis for the consent decision, "shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques."⁵⁸ This requirement of a scientifically sound risk assessment may place the burden on the importing country to present evidence of risk in order to refuse consent.⁵⁹ Second, the preamble to the Protocol "[e]mphasiz[es] that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements."⁶⁰ This language appears to subject the Protocol to the constraints imposed on the regulation of international trade by the World Trade Organization (WTO), including the Agreement on Sanitary and Phytosanitary Standards.⁶¹ The apparent clarity of this preamble language is, however, muddled by the next clause of the Protocol's preamble,

56. See *id.* at Art. 10(6).

57. *Id.*

58. See *id.* at Art. 15(1).

59. See Schweizer, *supra* note 8, at 599. "By including an AIA, the Protocol gives countries the power to refuse to import a genetically modified crop. . . . [C]ountries must base any rejection of GMOs on scientific findings, and not on unfounded fears." *Id.* (footnotes omitted).

60. Protocol, *supra* note 2, at Preamble (emphasis added).

61. See *infra* Part III.

which states the “[u]nderstanding that the above recital is not intended to subordinate this Protocol to other international agreements.”⁶² The juxtaposition of the two clauses in the preamble is as striking as it is confusing.⁶³

Article 8 of the Protocol defines the procedures that apply to the transboundary movement of a LMO “for direct use as food or feed, or for processing.”⁶⁴ These products are not subject to the AIA requirement.⁶⁵ Instead, the Protocol provides vaguely that “[a] Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.”⁶⁶ Article 11 requires parties to provide information about their decisions on the import of LMOs to the Biosafety Clearinghouse, established under Article 20 of the Protocol.⁶⁷ Indeed, this reporting requirement broadly applies to the reporting of any “final decision regarding domestic use, including placing on the market, of a LMO that may be subject to transboundary movement for direct use as food or feed, or for processing.”⁶⁸

62. Protocol, *supra* note 2, at Preamble (emphasis added).

63. One commentator has written that the language of the preamble “is supremely ambiguous.” Jacob, *supra* note 46, at 86.

64. Protocol, *supra* note 2, at Art. 8.

65. For a description of the Protocol’s approach to controlling the movement of LMOs, see McCaffrey, *supra* note 7, at 95.

Not only is the Protocol limited in scope to LMOs, its basic approach to controlling the transboundary movement of those organisms—the “advanced informed agreement” (AIA) procedure . . . —does not apply to agricultural commodities. Thus, genetically engineered food, perhaps the chief concern of the public, is not subject to an AIA requirement.”

Id.; see also Jacob, *supra* note 46, at 84. “Excepted from the application of the advanced informed agreement (AIA) process were ‘living modified organisms intended for direct uses as food feed or for processing’—in essence, the commodity movement of grains and such.” *Id.* (footnotes omitted).

66. Protocol, *supra* note 2, at Art. 11(4). The Protocol also provides special rules regarding this decision-making for “[a] developing country Party or a Party with an economy in transition.” *Id.* at 11(6). If such a nation lacks the requisite domestic regulatory framework, it is authorized to “declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided . . . , will be taken” based on a risk assessment conforming to the Protocol’s requirements and completed within 270 days. See *id.*

67. See *id.* at Art. 11(1).

68. *Id.*

The Protocol also includes a requirement unrelated to the importing nation's approval of the modified food products. Genetically modified food products must bear labels "clearly identifying that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information."⁶⁹ This labeling requirement,⁷⁰ watered down by its very terms, was opposed by the major industrialized exporters of agricultural products.

While [major industrialized exporters] succeeded in preventing the Protocol from imposing strict regulations on commodities exports, the adopted Protocol does contain a provision requiring exporters to label any shipments that may include genetically altered substances with the phrase "May contain living modified organisms." As a result, importers have the option to label any products as such, and consumers will be able to decide whether or not they want to purchase products that may be genetically altered.⁷¹

These requirements fully define the Protocol's regulatory scheme for the transmission and disclosure of information among the importing and exporting parties, as well as purchasers. Parties to the Protocol will address additional rules of liability and redress, with a goal of four years set by the Protocol.⁷²

It is important to now turn to an assessment of the Protocol's regulatory regime, first with respect to the AIA procedure and then with respect to the labeling requirement.

69. *Id.* at Art. 18(2).

70. See Saines, *supra* note 20, at 627. "Article 18 of the [P]rotocol requires LMOs to be clearly labeled, including separate labeling requirements for LMOs intended for direct use as food or feed or for processing." *Id.* For a discussion of the significance of this labeling requirement, see *infra* Part IV.

71. Schweizer, *supra* note 8, at 600 (footnotes omitted). The Protocol provides that "detailed requirements for th[e] purpose" of labeling LMO food products are to be defined within two years. Protocol, *supra* note 2, at Art. 18(2)(a). The work began at a June 2001 meeting of technical experts. See Saines, *supra* note 20, at 627.

72. See Protocol, *supra* note 2, at Art. 27; see also McCaffrey, *supra* note 7, at 95. The Protocol "postpones entirely the question of liability for harm resulting from the transboundary movement of LMOs." *Id.* (footnote omitted).

III. RISK ASSESSMENT AND A PARTY'S AIA

A basic understanding of the treatment of risk assessments in state decisions to limit international trade is important to an evaluation of the AIA procedure established by the Protocol and an understanding of whether the Protocol seeks to reshape international trade law. International agreements define the current risk assessment and trade regulation regime and provide for the WTO.⁷³ One such agreement is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).⁷⁴ The SPS Agreement's definition of a "[s]anitary or phytosanitary measure" would clearly include an importing nation's decision to exclude LMO's based on the risk posed to biodiversity or to require product labeling.⁷⁵ If the measure conforms to the requirements of the SPS Agreement, then the

73. See General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, 33 I.L.M. 1125 (Apr. 15, 1994) [hereinafter GATT]. Marrakesh Agreement Establishing the World Trade Organization, 33 I.L.M. 81 (1994).

74. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, available at http://www.wto.org/english/tratop-e/sps-e/spsagr_e.htm (last visited Feb. 12, 2002) [hereinafter SPS Agreement].

75. The SPS Agreement provides that such a measure is

[a]ny measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests. Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

SPS Agreement, *supra* note 74, at Annex A: Definitions (1).

measure presumptively conforms to the 1994 General Agreement on Tariffs and Trade (GATT).⁷⁶

The SPS Agreement requires first that members base any sanitary or phytosanitary measure on a risk assessment.⁷⁷ The SPS Agreement requires, moreover, that “each Member shall avoid arbitrary or unjustifiable distinctions in the levels [of sanitary or phytosanitary protection] it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.”⁷⁸

The WTO dispute resolution framework has resolved disputes over the requirements established by the SPS Agreement. The WTO Appellate Body has, in particular, given content to the requirement that nations impose protective measures only on the basis of a sufficient risk assessment.

A risk assessment within the meaning of Article 5.1 must

(1) identify the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;

76. *Id.* at Art. 2(4). “Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).” *Id.*

77. *See id.* at Art. 5(1). “[M]embers shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.” *Id.* The SPS Agreement defines a “[r]isk assessment” as

[t]he evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

Id. at Annex A: Definitions (4).

78. *Id.* at Art. 5(5).

(2) evaluate the likelihood of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and

(3) evaluate the likelihood of entry, establishment or spread of these diseases according to the SPS measures which might be applied.⁷⁹

These components of the risk assessment mean that

[i]t is not sufficient that a risk assessment conclude that there is a possibility of entry, establishment or spread of diseases and associated biological and economic consequences. A proper risk assessment of this type must evaluate the “likelihood”, i.e., the “probability”, of entry, establishment or spread of diseases and associated biological and economic consequences as well as the “likelihood”, i.e., “probability”, of entry, establishment or spread of diseases according to the SPS measures which might be applied.⁸⁰

Evaluation of the “likelihood” need not be quantitative, and the SPS Agreement does not mandate a threshold level of risk. “The likelihood may be expressed either quantitatively or qualitatively. Furthermore, . . . there is no requirement for a risk assessment to establish a certain magnitude or threshold level of degree of risk.”⁸¹

79. Australia—Measures Affecting Importation of Salmon, WTO Appellate Body, WT/DS18/AB/R, ¶ 121 (Oct. 20, 1998) (emphasis in original) [hereinafter Australia-Measures].

80. *Id.* ¶ 123; see de Oliveira Souza, *supra* note 15, at 169-70 (footnotes omitted):

When adopting measures related to technical barriers to trade (e.g., basic standards and labels) the evaluation of the risks justifying the measure must be done based on “available scientific and technical information, related processing technology or intended end-uses of products.” Scientific evidence as such has played an essential role in the adoption of restrictive measures.

The range of acceptable scientific evidence in defining risk is broad. See Victor, *supra* note 11, at 312 (footnotes omitted):

A member country need not rely on ‘mainstream’ scientific opinion to establish sufficient scientific evidence as required by the SPS Agreement, but can rely upon what may be a divergent opinion coming from qualified and respected sources. A panel is given a great deal of discretion in determining what constitutes sufficient scientific evidence.

81. See Australia-Measures, *supra* note 79, at ¶ 124 (footnotes omitted). The Appellate

Finally, the SPS agreement requires an independent evaluation of risk with regard to the effects of the sanitary and phytosanitary (SPS) measures.⁸²

SPS measures that have the effect of limiting international trade must meet a threshold determination that a risk actually exists and that the measures will actually reduce that risk. This requirement should preclude a nation from employing SPS measures for the purpose of limiting imports.⁸³ Moreover, the SPS Agreement requires that SPS measures be applied in a nondiscriminatory manner.⁸⁴ The

Body provided additional elaboration when it stated that "the 'risk' evaluated in a risk assessment must be an ascertainable risk; theoretical uncertainty is 'not the kind of risk which, under Article 5.1, is to be assessed.' This does not mean, however, that a Member cannot determine its own appropriate level of protection to be 'zero risk'." *Id.* ¶ 125 (footnote omitted). *See Victor, supra* note 11, at 311-12:

The Appellate Body's reading of the SPS Agreement gives a member state a much broader ability to raise its standards above the level set by international standards, as long as it possesses sufficient scientific evidence. This more generous authority to raise standards is subject to review by dispute settlement panels and is limited by the requirement that a "rational substantive relationship exist between the risk assessment and the measure adopted."

See also Jacob, *supra* note 46, at 89. "[E]xisting international law allows a country to take action based on any scientific indication of a potential risk, even if there are significant uncertainties associated with it." *Id.*

82. *See* Australia-Measures, *supra* note 79, at ¶ 134.

83. *See* Victor, *supra* note 11, at 307 (footnotes omitted):

The establishment of the [SPS Agreement] allows WTO members to impose stronger measures, but only when there is sufficient "scientific justification" to support a member's determination that there is a need for stricter standards. This requirement is intended to prevent agricultural protectionism by a WTO member who may be seeking to evade its free trade commitments to other member countries. The existence of a verifiable standard removes the ability of a member country to inhibit free trade by a mere assertion unsupported by science.

84. *See* SPS Agreement, *supra* note 74, at Art. 5(5). The nondiscrimination principle would, for example, bar a nation from adopting SPS measures that accept higher levels of risk from domestic products than from similar imported products. *See* Christopher D. Stone, *Is There a Precautionary Principle?*, 31 *Env'tl. L. Rep.* 10,790, 10,799 (2001). The SPS Agreement:

suggests a compromising tactic: a member invoking distinctive national risk concerns as a basis for refusal to import a potentially hazardous agent is allowed leeway in the level of border protection it selects, as long as it applies nondiscriminatorily comparable levels of risk protection across the board, including domestically.

Id. (footnote omitted). For a description of the course of events in Europe, compare Victor, *supra* note 11, at 304.

regime thus ensures that trade limiting SPS measures are grounded in articulable safety concerns and are not motivated by protectionism.⁸⁵

The AIA procedure adopted in the Protocol appears consistent with the requirements of the SPS Agreement. A state's decision to limit the import of LMO's must be based on a risk assessment but may be made notwithstanding uncertain evidence of risk.⁸⁶

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.⁸⁷

On June 25, 1999, the Council recommended that Directive 90/220 be amended to adopt a precautionary approach that prevents the authorization of a GMO until there is positive proof that it does not affect human health or the environment. All the member states of the EU agreed to follow this approach. Despite the member states' assertion that they would enforce the moratorium, seven member states have simultaneously proposed eleven new GMO products for authorization. As a result of the inconsistency in enforcement of GMO regulation between the national governments and the supranational EU government, people have no reliable information on whether these governmental bodies are protecting consumers or industry; thus the European public has little confidence in regulatory authorities.

Id. (footnotes omitted).

85. The requirements defined by the SPS Agreement are analogous to the rules governing trade within the European Communities. In *Commission of the European Communities v. French Republic*, the European Court held that France was not permitted to ban the sale of British beef because of a concern about the risks of bovine spongiform encephalopathy that was not supported by adequate scientific evidence. *Comm'n of the European Cmty. v. French Republic*, Case C-100 (Dec. 13, 2001), available at <http://europa.eu.int> (last visited Feb. 11, 2002). The requirements of the SPS Agreement also appear analogous to the requirement of domestic law that a government not base its decision-making on irrational fears. See *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432 (1985); see also *Dean Milk Co. v. City of Madison*, 340 U.S. 349 (1951); *Brimmer v. Rebman*, 138 U.S. 78 (1891) (holding that dormant commerce clause prevents local limits on trade that are unrelated to health or environmental risks).

86. Protocol, *supra* note 2, at Art. 10(6).

87. *Id.* This provision applies to LMOs intended to be introduced into the environment of the Party of import. *Id.* at Art. 7(1). Identical language is included in the requirements for decision-making regarding LMOs intended for direct use as food or feed or for processing. *Id.*

This language seems consistent with the application of the precautionary principle that now undergirds much of international, as well as domestic, environmental law.⁸⁸ Nevertheless, the Protocol's language has been criticized on the ground that it demands too much scientific evidence of risk before a State may bar the import of LMOs. Professor McCaffrey has written that

[t]he risk management provisions authorize precautionary action only if the scientific uncertainty concerns the "extent" of the potential adverse effects of LMOs. Unless interpreted otherwise by the parties, this requirement would significantly narrow the effectiveness of the provisions on precaution. As one commentator has observed, "[I]n the case of the risks associated with LMOs, it is uncertain[ty] regarding the if and how, rather than the extent, of the risk, that is likely to be primarily at stake."⁸⁹

This concern grows when the final version of the Protocol is contrasted with an earlier draft, which appears to limit the nature of the required scientific evidence.⁹⁰

at Art. 11(8).

88. See Michael P. Healy, *England's Contaminated Land Act of 1995: Perspectives on America's Approach to Hazardous Substance Cleanups And Evolving Principles of International Law*, 13 J. NAT. RESOURCES & ENVTL. L. 289, 291-92 (1997-98) (describing precautionary principle). One commentator has argued that the Protocol's adoption of the principle is especially emphatic. See Stoll, *supra* note 45, at 97:

[T]he Biosafety Protocol, unlike the Basel and PIC Conventions, not only places the precautionary principle in prominent positions in its preamble and objectives provisions (Article 1) but also builds it directly into the operative provisions on risk assessment. The recognition and legal expression of the precautionary principle as highlighted in these provisions can be considered an important and genuine achievement.

89. McCaffrey, *supra* note 7, at 98 (footnote omitted); see also Jacob, *supra* note 46, at 87. "What [the Protocol] says regarding the extent of potential adverse effects is important. By implication, this suggests that we have some scientific information to indicate that there is an adverse effect. Frankly, this suggestion is very much in dispute right now with respect to LMOs, particularly in certain applications." *Id.*; see also Stoll, *supra* note 45, at 116 (according to the Protocol, "precautionary action will only be authorized if the lack of certainty concerns the 'extent' of the adverse effect. The provision thereby implies that all other aspects and especially the source or origin of the adverse effect have to be certain.").

90. Jacob, *supra* note 46, at 88:

The version that appeared in the Pre-Montreal draft text (Article 8.7) read, "[I]lack of

To the extent, however, that a threshold requirement under the WTO regime already compels some evidence of risk before a trade restriction may be imposed,⁹¹ the final Protocol language is less controversial. There will necessarily be an extent of the risk issue, rather than an existence of the risk issue, regarding the basis for a permissible trade restricting decision. For this reason, a different issue regarding the effect of the Protocol seems more significant. How does the agreement address the insufficiency of information for the risk management determination? Indeed, commentators have urged that the question of which party bears the burden of adducing scientific evidence relating to the risks of LMOs is critical.⁹²

With respect to this issue, the Protocol can be read to allocate the burden of coming forward with scientific evidence of safety to the exporting nation based on the preference of the importing nation. Although the Protocol does not include express language authorizing trade restrictions when scientific evidence is not available,⁹³ several

full scientific certainty or scientific consensus regarding the potential adverse effects of a living modified organism shall not prevent the Party of import from prohibiting the import of the living modified organism in question." This was somewhat more direct. The difference in the final result is going to invite challenge and confusion and we would have preferred not to see that difference.

91. For a description of this requirement of the SPS Agreement, see *supra* notes 79-80 and accompanying text.

92. See McCaffrey, *supra* note 7, at 98 (footnote omitted):

[T]he big question in terms of trade in GMOs is who should bear the burden—i.e., the burden of showing whether the GMO in question is dangerous to human health or the environment. Specifically, should the country exporting GMOs have to establish that they are safe or at least that they do not pose unacceptable dangers? Or must the importing country do so before it will be allowed to keep them out? It may be very difficult to carry this burden because the precise risks posed by most GMOs are not fully understood. Allocation of the burden may therefore determine whether the GM goods move across borders or not.

See also de Oliveira Souza, *supra* note 15, at 173:

[T]he precautionary principle and the principle of 'scientific evidence' would be compatible if the burden of proof shifted. Thus, the new legislation in terms of GMP simply should (a) first, allow any country to take a restrictive measure (label, ban or moratorium, or minimal standard) based on the precautionary principle, and (b) second, allow any country suffering the economic consequences of this measure to challenge the same, and this country would be responsible for proving scientifically that the GMP is absolutely safe to the environment and to human beings, so the change would mean only a shift in the burden of proof.

93. Other international agreements do include explicit provisions allowing regulatory

provisions relating to the risk assessment support this reading. First, the Protocol states that the "[l]ack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."⁹⁴ Such a gap in information is accordingly consistent with any of those conclusions. The Protocol also recognizes that a need for additional information may become

controls in such circumstances. Article 715(4) of the North American Free Trade Agreement provides that:

where a Party conducting a risk assessment determines that available relevant scientific evidence or other information is insufficient to complete the assessment, it may adopt a provisional sanitary or phytosanitary measure on the basis of available relevant information, including from international or North American standardizing organizations and from sanitary or phytosanitary measures of other Parties. The Party shall, within a reasonable period after information sufficient to complete the assessment is presented to it, complete its assessment, review and where appropriate, revise the provisional measure in the light of the assessment.

32 I.L.M. 289, 379 (1993); see also Robert Housman, *The North American Free Trade Agreement's Lessons for Reconciling Trade and the Environment*, 30 STAN. J. INT'L L. 379, 405 (1994) (footnotes omitted), who has written that:

NAFTA also break[s] new ground for the formation of trade policy by explicitly recognizing the precautionary principle of environmental law. [Its provisions] allow the NAFTA parties leeway to adopt environmental, health and safety measures where the scientific evidence is insufficient to determine the actual risk posed by a given product or service. Whereas the other NAFTA standards provisions, discussed above, provide leeway for environmental protections where the science is conflicting, these precautionary provisions provide leeway where the science is incomplete.

Moreover, Article 5.7 of the SPS Agreement includes a similar provision regarding insufficient information:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

SPS Agreement, *supra* note 74, at Art. 5.7. In Japan, the Appellate Body concluded that Japan failed to comply with the provisional measures provision because "Japan did not seek to obtain the additional information necessary for a more objective risk assessment," and "Japan has not reviewed its varietal testing requirement 'within a reasonable period of time.'" *Measures Affecting Agricultural Products*, World Trade Organization Appellate Body, WT/DS76/AB/R ¶¶ 92, 93 (Feb. 22, 1999).

94. 39 I.L.M. 1027, 1045 (2000).

apparent in the consideration of a risk assessment.⁹⁵ It also grants the importing nation authority to request the submission of such information.⁹⁶ Moreover, the Protocol recognizes an important context for additional information, because it realizes the significance of release of LMOs into an environment in which release had not previously occurred.⁹⁷ Finally, the Protocol recognizes the ability of the importing nation to seek additional information in a case of "uncertainty regarding the level of risk" as an alternative to a decision to permit the import of the LMO with a monitoring requirement.⁹⁸

Interpreting the Protocol to permit an importing nation to allocate the burden of adducing scientific evidence to support the release of LMOs to the exporting nation offers several important benefits. First, this allocation creates a strong incentive for the development of relevant scientific evidence,⁹⁹ especially in the United States. Under domestic law, the procedures mandated by the National Environmental Policy Act for government actions that significantly affect the environment help develop information important to public policy making.¹⁰⁰ In a far different context, the formal method of

95. *Id.* "The process of risk assessment may . . . give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process" *Id.*

96. *Id.*

97. *Id.* at 1046 (requiring that risk assessment include "[i]nformation on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment").

98. *Id.* "Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment." *Id.*

99. The clearinghouse mechanism established by the Protocol should further these values as well. See Protocol, *supra* note 2, at Art. 20.

100. See *Foundation on Economic Trends v. Heckler*, in which the court concluded that the National Institutes of Health (NIH) violated the National Environmental Policy Act when it approved the first experimental release of a genetically modified organism into the environment. 756 F.2d 143 (D.C. Cir. 1985). The court concluded that the

NIH must first complete a far more adequate environmental assessment of the possible environmental impact of the deliberate release experiment than it has yet undertaken. That assessment must "provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact," 40 C.F.R. § 1508.9(a)(1). Ignoring possible environmental consequences will not suffice. Nor will a mere conclusory statement that the number of recombinant-

interpreting statutes is defended in part because it induces the disclosure of information.¹⁰¹ Creating new incentives for the development of information about LMOs is important because the United States, as the principal exporter of LMOs, is not obligated by domestic law to develop such information.¹⁰²

DNA-containing organisms will be small and subject to processes limiting survival. Instead, NIH must attempt to evaluate seriously the risk that emigration of such organisms from the test site will create ecological disruption. Second, until NIH completes such an evaluation the question whether the experiment requires an EIS remains open. The University of California experiment clearly presents the possibility of a problem identified by NIH in its EIS as a potential environmental hazard. This fact weighs heavily in support of the view that an EIS should be completed, unless NIH can demonstrate either that the experiment does not pose the previously identified danger, or that its assessment of the previously identified danger has changed through a process of reasoned decision-making. Nor is it sufficient for the agency merely to state that the environmental effects are currently unknown. Indeed, one of the specific criteria for determining whether an EIS is necessary is "[t]he degree to which the possible effects on the human environment as highly uncertain or involve unique or unknown risks." 40 C.F.R. § 1508.27(b)(5).

756 F.2d at 154-55.

101. Professor Sunstein has written that

[i]t seems most straightforward to defend formalism as a massive or global information-eliciting default rule. Perhaps formalism is likely to produce greater clarity from Congress, precisely because it ensures that statutory language will be understood by reference to its terms. Thus the notion that statutes will be taken in their "plain meaning" might be understood as a way of encouraging Congress to speak unambiguously.

Cass R. Sunstein, *Formalism and Statutory Interpretation: Must Formalism Be Defended Empirically?*, 66 U. CHI. L. REV. 636, 655 (1999).

102. See Victor, *supra* note 11, at 304. "The United States has no major laws regulating GMOs." *Id.* (footnote omitted); see also McCaffrey, *supra* note 7, at 93. "[I]t does not appear that the agencies [with regulatory authority relevant to GMOs] have yet succeeded in coordinating their activities in this area, so that what regulation there is of genetically modified organisms (GMOs) is far from seamless." *Id.*

[A]s concerns the United States, based on media reports which suggest a rather passive attitude on the part of U.S. regulatory agencies, I would have to answer that it does not appear that the United States is in fact "tak[ing] all appropriate measures" to prevent or minimize the risk of significant transboundary harm from GMOs.

Id. at 100.

Professor McCaffrey provides the following example of the very limited regulatory requirements in the United States.

The USDA admitted that its system for evaluating applications for genetically engineered plants was still "evolving." It accepted studies by the proponent of the new plant, and those studies are often—even in the most critical cases—sub-par. For example, in the crookneck squash case, only fourteen of the weeds related to the

The allocation of the burden to produce information permitted by the Protocol is also defensible because the Protocol so far lacks a liability regime. In a context in which harm may not be remedied if it occurs to an importing nation, that nation should have greater opportunity to ensure the safety of LMO imports.¹⁰³

Finally, the Protocol's discretionary allocation of the burden to produce information responds to the national differences among importing states regarding risk concerns.¹⁰⁴ A state with greater

proposed squash were actually studied to determine whether its population would be kept in check by the virus that the new plant would be immune to—an immunity that could spread from the new, supersquash to the weeds, making them superweeds. As one scientist observed, the fact that none of the weeds studied had the virus could just as well be due to the virus having wiped out all the weeds it had encountered. If so, the spread of the immunity from the new squash to the weedy cousin would be a real problem. In fact, the National Academy of Sciences (NAS) found that the USDA did not have an adequate scientific basis for its approval of the squash. In what some would consider to be an understatement, one member of the NAS panel opined that: "There needs to be some caution here."

Id. at 98 (footnotes omitted); *cf.* GAO, Environmental Information: EPA Is Taking Steps to Improve Information Management, but Challenges Remain, at 5 (Sept. 1999 GAO/RCED-99-261) (describing how EPA regulates despite "extensive data gaps [that] are a result both of a lack of fundamental scientific knowledge and of inadequate data collection"). *But cf.* Kupchella, *supra* note 12, at 730-31. "No statutes exist in the United States that address biotechnology specifically. However, there is a very comprehensive process to evaluate genetically modified products for risks to human, animal, and plant health and for environmental safety." *Id.* (footnotes omitted).

103. *See* Stone, *supra* note 84, at 10,798 (footnotes omitted):

One can conjure circumstances in which uncompensated risk-shifting could be defended. Nonetheless, the presumptions against it find support on grounds both of economic efficiency and intuitive fairness. The impact of uncompensated harms can and of course should be reduced by fortifying the law's compensation mechanisms. But as long as the prospect of settling up *ex post* are limited, there is all the more warrant to foster precautionary mechanisms *ex ante*. How far, is hard to say. Mechanisms that stifle externalities find favor, as do those that build on information-forcing and consent. For example, when the risk accompanies a commodity in transit, boundary crossing can be conditioned on the risk receiver's consent, as under the prior informed consent provisions of the Basel Convention and Cartagena Protocol.

104. Professor Stone has written that:

There remains, however, a set of cases in which more risk information, alone, will not reduce and reconcile conflicting evaluations of the uneliminated risks. In the tumult over LGMOs, for example, the opposition arises not merely from diverging interpretations of the limited empirical data. Conflicting national and cultural values are involved, including control over what we eat, and attitudes toward science, sovereignty, and capitalism. And different evaluations—different risk targets, with differing willingness to "take the risk"—can arise out of differences in wealth. As one

concerns should have the ability to withhold a final decision until information about risks and benefits is available. Of course, a state that is risk averse and requires more information must apply that same approach to domestic products under the principle of nondiscrimination.

In sum, the Protocol appears consistent with the regime of international trade regulation by requiring that scientific evidence show a risk posed by LMOs before an importing nation is authorized to bar their import. The Protocol, however, arguably permits the importing nation to allocate the burden to demonstrate a lack of risks to the exporting nation.¹⁰⁵

commentator has said of the Bergen Declaration: "One person's unacceptable consequence' is another's regrettable necessity."

Stone, *supra* note 84, at 10,798 (footnotes omitted).

Stone also noted that

sometimes the intuition that we ought to be cautious reflects an awareness that different people (and in the international context, nations), react to risks differently. Sometimes the risks are objectively different. . . . In other circumstances, variations in risk assessment may largely reflect differences in the degree to which the available data and recommendations of experts (ordinarily Western) are trusted.

Id. at 10,798 (emphasis omitted).

Commentators have noted the significant differences in the perception of risks associated with LMOs in the United States as compared to Europe. *See de Oliveira Souza, supra* note 15, at 142-43 (footnotes omitted):

In the USA, GMP will be considered safe, unless there is actual proof against this assumption, and if the GMP is safe, the food is also safe and there is no need for special label indicating that the food originated from GMP. On the other hand, the position in EU is that the GMP and its products are considered unsafe, unless there is clear proof against this assumption, and if the food is not safe 'a priori' the consumer must be protected through a special label.

Cf. Victor, supra note 11, at 309. "In a statement to EU officials last fall, U.S. Commerce Undersecretary David Aaron claimed that because the EU did not have the scientific grounds to reject products containing GMOs, it had resorted to 'a variety of ploys and political maneuvers to delay and deny' the product's approval." *Id.* (footnote omitted).

105. The consistency of this aspect of the Protocol with the GATT's regime may depend on whether the importing country is seen as having adopted a provisional measure pending the receipt of additional information. *See supra* note 93. One commentator has written that

a conflict in which the respective parties belong to both instruments will most likely be resolved in favor of the Biosafety Protocol, as it is the more specific (*lex specialis*) and the most recent agreement (*lex posterior*). In the case of a non-party to the protocol, the SPS Agreement will prevail.

Stoll, *supra* note 45, at 117.

IV. INFORMATION DISCLOSURE AND INFORMED CONSENT OF PRODUCT PURCHASERS

The Protocol's regulatory approach to LMOs intended for food, feed, or processing differs from the AIA approach that applies to LMOs intended for release into the environment. The importing country has authority to bar the initial import of genetically modified food products¹⁰⁶ and there must be "documentation accompanying" the LMOs stating that the product "may contain" LMOs.¹⁰⁷ By imposing this requirement, the Protocol accepts the need for a disclosure requirement despite the fact that the importing nation has not found a product risk that warrants a prohibition against import. This Article considers whether this requirement is consistent with the international trade regime and whether the requirement yields important policy benefits.

The Protocol is ambiguous about who will have a chance to review the required documentation. Details of the requirement, which will be discussed as a "labeling requirement," are to be identified within two years.¹⁰⁸ The Article assumes that the purchaser to whom the product information is disclosed includes the ultimate consumer.¹⁰⁹ To the extent only retailers receive the product information, the requirement will be seen as more or less defensible depending on the nature of the risks of the LMOs.

In order to evaluate the legality and the advisability of the labeling requirement, this Article sets forth three hypothetical contexts in which the requirement would apply. First, an importing nation may decide that the import of LMO food products results in definite articulable risks. The importing nation may nevertheless decide to

106. See Protocol, *supra* note 2, at Art. 7(3).

107. *Id.* at Art. 18(2)(a). LMOs that are intended for release into the environment must meet more definitive labeling requirements. Such items must be "clearly identifie[d]" as LMOs. *Id.* at Art. 18(2)(c).

108. See *supra* note 71 and accompanying text.

109. In describing the implementation of Article 18, the Intergovernmental Committee for the Cartagena Protocol on Biosafety has plainly considered the issue of product labeling for use by consumers. See *Intergovernmental Committee for the Cartagena Protocol on Biosafety, Handing, Transport, Packaging and Identification* (Article 18), at 8-14 (UNEP/CBD/ICCP/1/6) (Sept. 25, 2000) (reviewing international and national requirements relating to labeling of LMO food products).

permit import of the products because it does not pursue a zero risk policy regarding LMOs. Second, the importing nation may be quite uncertain about the risks of LMO food products after analyzing the risk assessments for the products, which may lack probative scientific studies of effects. The importing nation may decide to permit the import of the products, notwithstanding its uncertainty about product risks. Third, the importing nation may allow import of the LMO products based on its conclusions that the risk assessment shows that the product does not cause any risks.¹¹⁰ With these different scenarios in mind, this Article now considers the legality of the labeling requirement.

Because labeling is a type of SPS measure,¹¹¹ its consistency with the international trade regime is assessed by reference to the requirements of the SPS Agreement. As previously discussed,¹¹² that agreement imposes two requirements for SPS measures. First, there must be a reasonable, articulable risk of harm associated with the fact that the food product is genetically modified for the label to be acceptable. Second, the importing state has to apply the requirement in a nondiscriminatory manner by requiring such labeling of genetically modified domestic food products. Under the first hypothetical scenario, the importing nation concludes that an identifiable risk is present and allows the import nonetheless. As long as that nation conforms to the nondiscrimination requirement, its labeling requirement is permissible and is less restrictive than a ban on importation. Under the second hypothetical scenario, again assuming nondiscrimination, the labeling requirement arguably conforms to the SPS Agreement. Allowing the import of labeled LMO products seems less restrictive than barring import until more certain scientific studies are available. In the previous part, the article explains how the Protocol arguably permits such an action by the

110. There are, of course, significant uncertainties relating to the risks of LMOs. The risks that the release of LMOs poses to genetically-rich ecosystems may not have been tested. *See supra* note 37. Also, risks to human health posed to human health are quite difficult to identify and necessarily uncertain. *See supra* notes 39-42. This third, zero-risk category may accordingly be nonexistent.

111. *See supra* note 75 and accompanying text.

112. *See supra* notes 77-81 and accompanying text.

importing nation in conformity with the SPS Agreement.¹¹³ Indeed, the Protocol's labeling requirement appears to reflect a generic decision by its Parties that the uncertainties associated with LMOs establish at least a minimum level of articulable risk. Under the third scenario, however, the labeling requirement would undoubtedly violate the SPS Agreement. If an importing nation decides that an LMO food product poses no articulable risk, a label identifying the product as genetically modified would be unwarranted as an SPS measure.

There are also several public policy bases for the labeling requirement that merit consideration. By mandating labeling of LMO food products, the Protocol imposes an information disclosure requirement that is independent of, but has the effect of supplementing, the regulatory scheme for consent to importation—a type of command and control regulation.¹¹⁴ This supplementary role of information disclosure is consistent with the increasingly important role of information disclosure in environmental regulation. Regarding the import of LMOs, the governmental regulation related to permitted imports in the first two hypothetical scenarios does not entirely eliminate the risks associated with importation: The decision of the importing state in the first two scenarios does not reflect a zero risk standard, either because there is an established, known risk associated with the LMOs or because the uncertainties of the risk mean that use of the product imposes a risk of an uncertain extent on consumers. The label in these two circumstances accordingly gives individual consumers an opportunity to make their own decisions about voluntary exposure to the residual, nonzero product risks. In

113. See *supra* notes 94-98 and accompanying text.

114. See de Oliveira Souza, *supra* note 15, at 163-64 (footnotes omitted):

Labels . . . do not impose any internal requirement on the product. They only impose an external requirement in terms of information: some information about the product must be attached to the product. So, labeling has three basic functions: (a) it informs the consumer that some product is more or less dangerous to the consumer's health (making consumers more aware of the risks of the product), or to the environment (e.g., the voluntary European Eco-Label); (b) it protects consumers through a clear and honest exposure to the existing risks relating to the product; and (c) it allows consumers to make intentional choices, so if a similar product exists (in terms of characteristics, performance, taste, price and so on) it will enable the consumer to choose among them or opt for a substitute product.

the third, very rare circumstance, in which the importing nation determines that no articulable risk is present, there is no reason for a label since there would be no risk for the consumer to consider.

In the United States, the government requires regulated entities to provide the government with information that will be disclosed to the public as an alternative or supplement to traditional command and control regulatory requirements. The government first took this approach in the required annual Toxics Release Inventory (TRI).¹¹⁵ Another important example is California's Proposition 65, which requires warnings by companies of exposure to identified toxic substances.¹¹⁶ A final example is the federal mandate, included in the 1996 Amendments to the Safe Drinking Water Act,¹¹⁷ that "each community water system [] mail to each customer of the system at least once annually a report on the level of contaminants in the drinking water purveyed by that system."¹¹⁸

Among the required contents for these "consumer confidence reports" is the following information.

If any regulated contaminant is detected in the water purveyed by the public water system, a statement setting forth (I) the maximum contaminant level goal, (II) the maximum contaminant level, (III) the level of such contaminant in such water system, and (IV) for any regulated contaminant for which there has been a violation of the maximum contaminant level during the year concerned, the brief statement in plain language regarding the health concerns that resulted in regulation of such contaminant¹¹⁹

All three of these regulatory regimes require companies to report releases of, or exposure to, pollutants, regardless of whether the release or exposure is permitted under the command and control regulations of polluting activities. Other nations have begun to

115. The reporting requirement is prescribed in 42 U.S.C. § 11023 (Supp. 1999). See generally Bradley C. Karkainen, *Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a New Paradigm?*, 89 GEO. L.J. 257, 289 (2001).

116. See *id.* at 345-47.

117. Safe Drinking Water Acts Amendments, Pub. L. No. 104-182, 110 Stat. 1613 (1996).

118. *Id.* § 114(a) (codified at 42 U.S.C. 300g-3(c)(4)(A) (2000)).

119. 42 U.S.C. § 300g-3(c)(4)(B).

impose similar information disclosure obligations¹²⁰ and have already proposed or adopted labeling requirements for LMO food products.¹²¹ The United States, which arguably began this regulatory approach when it imposed the TRI requirement, so far has imposed no such labeling requirements for LMOs.¹²²

An important consequence of this regulatory approach is that the required disclosure of information may change the behavior of the regulated entity even in the absence of command and control regulatory requirements. For example, in the view of many observers, the success of the TRI has been great, yielding reductions in reported emissions of almost fifty percent that go beyond reductions mandated by the EPA's command and control requirements.¹²³ These beneficial environmental results have been accomplished, moreover, at costs to the agency and regulated entities that appear to be much lower than the administrative and compliance costs associated with command and control regulations.¹²⁴ Similarly, consumer attitudes about the safety of GMOs might change if the government required labeling for LMO products.¹²⁵ The reduced level of demand for and production of

120. See generally Karkainen, *supra* note 115, at 347-50.

121. See Mike Kepp, *Cardoso Inks Brazilian GM Labeling Decree; Green Consumer Groups Seek Revocation*, 24 Int'l Env'tl. Rep. (BNA) 661 (2001); Joe Kirwin, *EU Proposes Strict GMO Labeling Rule; Action Likely to Aggravate U.S. Concerns*, 24 Int'l Env'tl. Rep. (BNA) 639 (2001); Shai Oster, *China Issues New Rules to Ensure Safety, Labeling, Licensing of GMO Crop Activities*, 24 Int'l Env'tl. Rep. (BNA) 519 (2001).

122. See Victor, *supra* note 11, at 306 (footnotes omitted):

The FDA only requires labeling of genetically-modified foods if the composition of the food differs significantly from the food from which it was derived or if it may pose a health threat. The U.S. Congress may consider a bill for the mandatory labeling of foods containing GMOs, similar to the EU's "Novel Food Regulation." However, the U.S. Secretary of Agriculture has stated that federal requirements for labeling are unlikely.

The lack of a labeling requirement does not reflect a lack of consumer interest in such information. See de Oliveira Souza, *supra* note 15, at 144. "[Eighty-five percent] of Americans considered the labeling of GMF very important, according to the United States Department of Agriculture, and 99% desire a clear identification in the label indicating that the product is a GMF." *Id.* (footnote omitted).

123. See Karkainen, *supra* note 115, at 287-88.

124. See *id.* at 291-92. The costs of TRI for reporting entities are hardly trivial, however, as can be seen by the EPA's estimates of the significant costs associated with expanding the scope of TRI reporting. See William F. Pedersen, *Regulation and Information Disclosure: Parallel Universes and Beyond*, 25 HARV. ENVTL. L. REV. 151, 189 (2001).

125. A recent poll made the following findings.

these products would then presumably last until producers are able to demonstrate product safety to consumers.¹²⁶ In this respect, the labeling requirement creates an incentive for interested companies or nations to develop information that will convince consumers that their products pose no risk.¹²⁷ If this incentive generates substantial new information about the risks associated with LMO food products, then that information could lead to a confident determination that risks are not posed by the products. In this manner, the labeling requirement for the second category of decisions to allow importation could come to be inconsistent with the theory of supplementary

Consumers' attitudes and purchasing behavior would be affected by GE food labels. About 30% of consumers stated that GE-labeled foods were "not as safe" as or were "worse" than identical foods without such label information. In addition, 40% to 43% of those surveyed would buy products labeled "genetically engineered," while 52% of consumers would choose a product labeled "does not contain genetically engineered ingredients" over a product labeled that it does "contain" such ingredients. In other words, the poll indicates that many consumers would favor non-GE foods because straightforward label statements about GE or non-GE implies to them that non-GE foods are better and safer than comparable GE foods

Center for Science in the Public Interest, National Opinion Poll on Labeling of Genetically Engineered Foods 1 (May 15, 2001), available at http://www.cspinet.org/reports/op_poll_labeling.html (last visited Feb. 10, 2002); see also Schweizer, *supra* note 8, at 582 n.29.

Consumers have shied away from purchasing these products because of environmental and health concerns, making it difficult for farmers to market their genetically altered products. As a result, a recent poll of 400 farmers conducted at the annual meeting of the American Farm Bureau Federation indicated that there might be a 24 percent decline in plantings of Bt corn compared with last year.

Id. (citations and internal quotations omitted); see also de Oliveira Souza, *supra* note 15, at 158. "[A] recent survey [in Brazil] supported by the newspaper 'O GLOBO' concerning GMF showed that: 44% believe that GMF is not healthy, 38% had no opinion about the subject, and 18% considered GMF not harmful to health." *Id.* (footnote omitted); see also Victor, *supra* note 11, at 296.

The concomitant effect of a lack of faith in science upon the acceptance of science is especially evident in the backlash against genetically altered foods in Europe. In reaction to the fear generated by the outbreak of madcow disease in the early 1990s, European consumers have a great lack of trust for additives, modern livestock-feeding techniques, and biotechnology in general.

Id. (footnotes omitted).

126. Lost sales resulting from consumer preferences are not the only costs of a labeling requirement. The labeling requirement could force food suppliers to develop supply methods that separate LMO from non-LMO products. See Kupchella, *supra* note 12, at 736.

127. This incentive would reinforce another incentive already created by the AIA procedure discussed in *supra* Part III.

information based regulation, as there would not be any residual risk for the consumer to consider.

A second reason to impose the labeling requirement for LMO food products is that the Protocol provides for a differential regime for individual, as opposed to governmental, decision-making. A requirement that LMO food products be labeled, even though the importing state decides that they are sufficiently safe to import, reflects an important and coherent difference between the quality of information required for the government's food safety determinations and the quality of information required for a consumer's food safety decision-making. For example, if domestic policy relating to tobacco is coherent, it is because our polity has concluded that the government need not ban sales of tobacco because the public is well advised of the risks associated with product use, based at least in part on product labeling. Adult individuals are given the power and responsibility to choose whether to expose themselves to the product's risks. Government can reduce the need for paternalistic regulations by requiring disclosure of product risks and by allowing individuals to decide for themselves whether risks are too high. This approach may also result in more rational government decision-making about risk prevention.¹²⁸

The extent to which this rationale supports the Protocol's labeling requirement is less certain than the first rationale. With respect to both the first and second hypothetical scenarios, a risk is either known to be present or is presumptively present due to uncertain scientific evidence. To allow individual decision-making in these contexts would be consistent with the reason for the differential regime for decision-making. The Protocol requirement is, however, flawed with respect to this rationale. To the extent that the LMO food product does impose risks, the Protocol's watered down label requirement, the "may contain" language, impedes the individual's ability to make an informed choice about purchasing the product.

128. If a state opts for the zero risk approach, then the issue of risk based labeling does not arise because the products may not be imported. This has occurred under the European regulatory regime. That regime provides for labeling of genetically modified products, but such products have not been approved for sale because of safety concerns. See Kupchella, *supra* note 12, at 732-33.

Moreover, a paradox emerges regarding LMOs. The risks that are likely to motivate the consumer's decisions about risk exposure, such as risks to the health of the consumer and the consumer's family, may not be the risks that the products pose from the perspective of the importing nation, such as risks to biodiversity.¹²⁹ Moreover, the significant ecosystem risks that LMOs may pose arise principally in the nation in which the LMO food products were grown, rather than in the importing nation.¹³⁰ This latter point may not foreclose a nation from imposing SPS requirements,¹³¹ but consumers are unlikely to

129. The risks associated with LMOs are described in *supra* Part I.

130. *But cf. supra* note 22 and accompanying text (describing situation in Mexico, in which native corn may have been contaminated by LMOs distributed as food products).

131. In *United States-Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Appellate Body, WT/DS58/AB/R (Oct. 12, 1998), the Appellate Body discussed whether GATT permitted a nation to adopt trade restrictions based on impacts on "exhaustible resources," endangered sea turtles in that case, located outside of the importing nation's jurisdiction. Its conclusion in that case did not definitively resolve the issue.

The sea turtle species here at stake . . . are all known to occur in waters over which the United States exercises jurisdiction. Of course, it is not claimed that all populations of these species migrate to, or traverse, at one time or another, waters subject to United States jurisdiction. Neither the appellate nor any of the appellees claims any rights of exclusive ownership over the sea turtles, at least not while they are swimming freely in their natural habitat—the oceans. We do not pass upon the question of whether there is an implied jurisdictional limitation in Article XX(g), and if so, the nature or extent of that limitation. We note only that in the specific circumstances of the case before us, there is a sufficient nexus between the migratory and endangered marine populations involved and the United States for purposes of Article XX(g).

Id. ¶ 133 (footnote omitted).

An earlier GATT Panel, applying the terms of GATT 1947, considered *inter alia*, the permissibility of a "Dolphin Safe" label requirement based on the tuna fishing practices of the exporting nation. *See Report of the GATT Panel, United States-Restrictions on Imports of Tuna DS21/R-39S/155* (Sept. 3, 1991):

5.42 The Panel proceeded to examine the subsidiary argument by Mexico that the labelling provisions of the [Dolphin Protection Consumer Information Act (DPCIA)] were inconsistent with Article I:1 because they discriminated against Mexico as a country fishing in the [Eastern Tropical Pacific Ocean (ETP)]. The Panel noted that the labelling provisions of the DPCIA do not restrict the sale of tuna products; tuna products can be sold freely both with and without the "Dolphin Safe" label. Nor do these provisions establish requirements that have to be met in order to obtain an advantage from the government. Any advantage which might possibly result from access to this label depends on the free choice by consumers to give preference to tuna carrying the "Dolphin Safe" label. The labelling provisions therefore did not make the right to sell tuna or tuna products, nor the access to a government-conferred advantage affecting the sale of tuna or tuna products, conditional upon the use of tuna harvesting methods. The only issue before the Panel was therefore whether the provisions of the

contemplate such risks when making decisions about whether to purchase the products. In sum, under the first two scenarios, the labeling requirement arguably reflects a proper distinction between the consideration of risk at the national and individual levels. The requirement would be even more defensible if the public more clearly understood the nature of the risks posed by LMOs as food products. The watered down label prescribed by the Protocol is, however, contrary to the second rationale.

With respect to the third scenario that requires a label despite a decision to allow product imports based on a finding of no risk, the rationale of differential regimes for decision-making is inapplicable. Once the government has determined that a product poses no risks, it is incoherent to require a label that would allow individual decision-making based on concerns about the product that have no basis in

DPCIA governing the right of access to the label met the requirements of Article I:1.

5.43 The Panel noted that the DPCIA is based inter alia on a finding that dolphins are frequently killed in the course of tuna-fishing operations in the ETP through the use of purse-seine nets intentionally deployed to encircle dolphins. The DPCIA therefore accords the right to use the label "Dolphin Safe" for tuna harvested in the ETP only if such tuna is accompanied by documentary evidence showing that it was not harvested with purse-seine nets intentionally deployed to encircle dolphins. The Panel examined whether this requirement applied to tuna from the ETP was consistent with Article I:1. According to the information presented to the Panel, the harvesting of tuna by intentionally encircling dolphins with purse-seine nets was practised only in the ETP because of the particular nature of the association between dolphins and tuna observed only in that area. By imposing the requirement to provide evidence that this fishing technique had not been used in respect of tuna caught in the ETP the United States therefore did not discriminate against countries fishing in this area The labelling regulations governing tuna caught in the ETP thus applied to all countries whose vessels fished in this geographical area and thus did not distinguish between products originating in Mexico and products originating in other countries.

The Panel accordingly concluded that the labeling requirement was not barred by GATT. See *id.* ¶ 7.3.

It is important to recognize that, as the concerns about the risks inhering in the product being labeled become less connected to the jurisdiction of the nation imposing the label requirement, the labeling arguably relates solely to the product's process and production methods, rather than risks to the safety of the importing nation. The legality of such eco-labeling is determined by reference to the GATT's Agreement on Technical Barriers to Trade (TBT Agreement). See http://www.wto.org/english/docs_e/legal_e/fina_e.htm (last visited Feb. 7, 2002) for the text of the TBT Agreement. The issue of the permissibility of such labeling under the TBT Agreement is a controversial one. See, e.g., DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 1182-84 (2d ed. 2002). That issue is beyond the scope of this Article.

fact.¹³² A regulatory regime that bars a nation from limiting the import of a product that imposes no risks should not require product labeling that would allow, if not encourage, product decisions by consumers that are irrational given the lack of a showing of product risk.¹³³ An analogy to the circumstances of the *City of Cleburne*¹³⁴ case may illustrate this point. There, the U.S. Supreme Court held that a local government acted unlawfully when its zoning discriminated against a group home for the retarded on the basis of concerns about the residents of such a home that were shown to have no basis in fact.¹³⁵ In such a circumstance, it would be similarly unacceptable to force the home to label itself as a home for the retarded with the result that neighborhood residents would act upon their baseless concerns about the home's residents.

A third and final context for assessing the advisability of the labeling requirement is to compare it to another labeling requirement that is accepted by the international trade regime. The terms of GATT expressly permit country of origin labeling.¹³⁶ Country of origin labeling allows consumers to preferentially select products of domestic origin.¹³⁷ Interestingly, the United States requires country of

132. Few, if any, LMOs, of course, will fall within this third category. See *supra* note 110. Labeling of zero-risk LMOs may arguably be defended as an indicator of the product's process and production methods. See *supra* note 131.

133. Cf. Center for Science in the Public Interest, *supra* note 125. "The survey found that approximately 40% of consumers believe that GE-related labeling reflects upon the quality and safety of the food, even though many scientists and regulatory agencies have found no such differences for current products." *Id.* "[A] percentage of consumers who think GE foods are the same as or better than unlabeled foods still would not buy a labeled GE food." *Id.*

134. 473 U.S. 432 (1985).

135. See *id.* at 448 (holding "mere negative attitudes, or fear, unsubstantiated by factors which are properly cognizable in a zoning proceeding, are not permissible bases for treating a home for the mentally retarded differently from apartment houses, multiple dwellings, and the like").

136. GATT, *supra* note 73, at Art. IX; see also Terence P. Stewart et al., *Trade and Cattle: How the System Is Failing an Industry in Crisis*, 9 MINN. J. GLOBAL TRADE 449, 508 (2000). "The [WTO] Technical Committee's work makes clear . . . that mandatory country of origin labeling is consistent with WTO obligations . . ." *Id.*

137. It is evident that many consumers consciously prefer to purchase domestic products. One recent example was the reaction of consumers to a proposal by the Federal Trade Commission (FTC) to change the requirements for the "Made in USA" label. In December 1997, the FTC published a notice in the Federal Register recounting its "comprehensive review of 'Made in USA' and other U.S. origin claims in product advertising and labeling." "Made in USA" and Other U.S. Origin Claims, 62 Fed. Reg. 63,756 (Dec. 2, 1997). The FTC had historically required "that a product must be *wholly domestic* or *all or virtually all* made in the

origin labeling for imported products,¹³⁸ while it does not require labeling of LMOs.¹³⁹

To compare the Protocol labeling requirement to the country of origin labeling under GATT, it is necessary to return to the three scenarios under which the Protocol requires LMO labeling. In the first two scenarios, risks related to LMO food products have either been found to exist or to presumptively exist due to a lack of sufficient probative information. Under these circumstances the product label permits an individual consumer to make purchasing decisions based on individual considerations of product risks. LMO labeling thus allows consumers to make choices based on the quality, including the safety, of available products. The country of origin labeling permitted by GATT, however, bears no relation to the quality of the product. It merely provides domestic consumers with a basis for discriminating against out of state products.¹⁴⁰ In sum, the

United States to substantiate an unqualified "Made in USA" claim." *Id.* In May 1997, the FTC issued Proposed Guides for the Use of U.S. Origin Claims, under which a marketer could make an unqualified U.S. origin claim if there was a reasonable basis substantiating that the product was substantially all made in the United States. Request for Public Comment on Proposed Guide for the Use of U.S. Origin Claims, 62 Fed. Reg. 25,020 (May 7, 1997). The Proposed Guides also included two "safe harbors" under which an unqualified U.S. origin claim would not be considered deceptive. *Id.* The FTC received 1,057 comments representing 1,165 commenters, including 963 individual commenters, 24 members of Congress, and two consumer organizations. *Id.* at 63,757. The consumer commenters

overwhelmingly opposed the Proposed Guides and generally supported an "all or virtually all" standard or advocated a specific percentage, usually 90% or, more often, 100%. Many commenters stated that "'Made in USA' means what it says" or expressed similar sentiments. Several commenters asserted that changing the current standard would confuse consumers wishing to buy American products, leaving them unable to determine whether a product was truly made in the United States.

Individual consumers also stated that they buy American products to support fellow Americans and expressed concern that lowering the standard would lead to a loss in American jobs.

Id. at 63,758.

138. 19 U.S.C. § 1304(a) (1994):

[E]very article of foreign origin . . . imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article . . . will permit in such manner as to indicate to an ultimate purchaser in the United States . . . the country of origin of the article.

139. See *supra* note 122 and accompanying text.

140. Compare *Hunt v. Washington State Apple Advertising Comm'n*, in which the Supreme Court held that North Carolina violated the requirements of the dormant commerce

Protocol's labeling requirement in these two circumstances is more defensible than the labeling permitted by GATT.

Under the third scenario, the Protocol's labeling requirement does not fare as well. In this situation the state has concluded that the LMO food products do not pose a risk. The label, although factually true, is likely to have the effect of prompting a product choice that is unrelated to the quality of the product, because although the LMO is safe, consumers could still avoid any product that bears an LMO label. In this context, the Protocol's required label interacts with the attitudes of the purchaser in ways that are similar to the country of origin labels, which also have no relation to the quality of the product. The Protocol's labeling requirement in this context is defensible only on the ground that it appears no worse than country of origin labeling.¹⁴¹

In sum, the labeling requirement adopted by the Protocol, while flawed, is defensible under some circumstances. It does, however, appear to apply too broadly and may, for that reason, be inconsistent with the international trade regime.

V. CONCLUSION

The Protocol establishes a two pronged approach regarding the international trade of genetically modified agricultural products. With

clause when it imposed a statutory bar against the labeling of Washington state apples regarding their origin and state rating.

[T]he statute has the effect of stripping away from the Washington apple industry the competitive and economic advantages it has earned for itself through its expensive inspection and grading system. The record demonstrates that the Washington apple-grading system has gained nationwide acceptance in the apple trade. Indeed, it contains numerous affidavits from apple brokers and dealers located both inside and outside of North Carolina who state their preference, and that of their customers, for apples graded under the Washington, as opposed to the USDA system because of the former's greater consistency, its emphasis on color, and its supporting mandatory inspections. Once again, the statute had no similar impact on the North Carolina apple industry and thus operated to its benefit.

432 U.S. 333, 351 (1977).

141. Indeed, the Protocol requirement may not be as bad as country of origin labeling because the nondiscrimination principle would require that domestic LMO food products also bear the required label. In this manner, there would not be discrimination against imported products, only discrimination against all LMO food products.

respect to the AIA regime for products that are released into the environment, the Protocol properly requires the providing of information to importing states. The Protocol creates strong incentives for the development of adequate scientific information to form the basis for risk management decisions.

Regarding the labeling required for LMOs intended as food products, the Protocol's regime is more problematic. Its requirement is overinclusive in some respects and underinclusive in others. Underinclusiveness results from the fact that, when residual risks are present as a result of the decision to allow imports, the required label states only that the product "may contain," rather than "does contain," genetically modified materials. Overinclusiveness results from the fact that the label requirement hypothetically applies even when the importing nation has allowed the import of genetically modified food products based on a conclusion that the product poses no risks. It may be most sensible to view the Protocol's regulatory regime as providing a transitional rule until a firmer basis for risk management decisions develops through better scientific studies.¹⁴²

142. This assessment of the modest accomplishment that the Protocol represents is consistent with the views of other commentators. See Jacob, *supra* note 46, at 89. Cf. McCaffrey, *supra* note 7, at 102:

We know there are potential problems; we need more knowledge; we should proceed cautiously; we should develop a tighter regulatory scheme; international trade law should, and apparently does, permit countries to exclude GM food as to which they can make a prima facie showing that it may be dangerous. Let us hope that commercial considerations do not blind us to a proper, far-sighted approach to managing the risks associated with biotechnology.