

THE BIOSAFETY PROTOCOL AND THE WTO

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Abstract: Just a few votes shy of entering into force, the Cartagena Protocol on Biosafety is poised to become the next multilateral environmental agreement that has the potential to pit trade interests against environmental concerns. Nevertheless, concerns over impending conflict with the WTO trade regime may be misplaced. A detailed analysis of the rights and obligations of the parties to the Protocol and the applicable WTO disciplines reveals few instances of probable conflict. The United States, one of the largest exporters of LMOs, has not signed or ratified the Protocol. Thus, the determination that no conflict exists is of particular importance if the Protocol is to be effective in the likely scenario where the exporting country is not a party to the Protocol but both it and the importing country are members of the WTO.

INTRODUCTION

The Cartagena Protocol on Biosafety (Biosafety Protocol or Protocol),¹ adopted in January 2000 as a supplementary agreement to the 1992 United Nations Convention on Biological Diversity (CBD),² could soon become one of the first binding multilateral international agreements dealing specifically and exclusively with some of the challenges created by "modern biotechnology."³ To date, the Biosafety

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¹ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 [hereinafter Biosafety Protocol]. I will use the terms "Biosafety Protocol" and "the Protocol" interchangeably throughout this article to refer to the Cartagena Protocol on Biosafety.

² UN Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 (entered into force Dec. 29, 1993) [hereinafter CBD].

³ According to the Biosafety Protocol:

"Modern biotechnology" means the application of:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

Protocol has been signed by 102 Countries and ratified by forty-six countries.⁴ The Protocol requires fifty ratifications before it can enter into force.⁵

Among the various responsibilities imposed by the Biosafety Protocol on each contracting party, a significant number are affirmative obligations to regulate the transboundary movement of living modified organisms (LMOs).⁶ This incorporation of trade-related obligations has led to an ongoing debate as to whether the Biosafety Protocol will conflict with existing international trade agreements, in particular with the World Trade Organization (WTO)⁷ and its subsidiary agreements. As will be discussed in greater detail in Part I of this article, complicating the negotiation and delaying the adoption of the Biosafety Protocol was the process of agreeing upon the relation between the Protocol and the WTO agreements. The seemingly unsatisfactory way of resolving this question in the Protocol's text, or more specifically in its preamble, has not aided in putting an end to the debate. Many predict impending conflict, while some suggest that the possibility of conflict is perhaps being overstated.⁸

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

See Biosafety Protocol, *supra* note 1, art. 3(i).

⁴ See Cartagena Protocol on Biosafety: Signatures and Ratifications, at <http://www.biodiv.org/biosafety/signinglist.asp> (last visited Apr. 18, 2003).

⁵ Biosafety Protocol, *supra* note 1, art. 37(1).

⁶ For the definition of an LMO see *infra* text accompanying note 51.

⁷ General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT].

⁸ See generally the following in which the authors have analyzed the Biosafety Protocol and have addressed the possibility of conflict: AARON COSBEY & STAS BURGIEL, INTERNATIONAL INSTITUTE FOR SUSTAINABLE DEVELOPMENT, THE CARTAGENA PROTOCOL ON BIOSAFETY: AN ANALYSIS OF RESULTS: AN IISD BRIEFING NOTE (2000), available at <http://iisd1.iisd.ca/pdf/biosafety.pdf> (last visited Feb. 4, 2003); AARTI GUPTA, FRAMING "BIOSAFETY" IN AN INTERNATIONAL CONTEXT: THE BIOSAFETY PROTOCOL NEGOTIATIONS (Harvard Univ., Kennedy Sch. of Gov't Global Envtl. Assessment Project eds., 1999) [hereinafter FRAMING "BIOSAFETY"]; Aarti Gupta, *Creating a Global Biosafety Regime*, 2 INT'L J. BIOTECH. 205 (2000) [hereinafter *Creating a Global Biosafety Regime*]; Thomas J. Schoenbaum, *International Trade in Living Modified Organisms*, in ENVIRONMENT, HUMAN RIGHTS AND INTERNATIONAL TRADE 27 (Francesco Francioni ed., 2001); Thomas A. Cors, *Biosafety and International Trade: Conflict or Convergence?*, 2 INT'L J. BIOTECH. 27 (2000); Nathalie Bernasconi-Osterwalder, *The Cartagena Protocol on Biosafety: A Multilateral Approach to Regulate GMOs*, in RECONCILING ENVIRONMENT AND TRADE 689 (Edith Brown Weiss & John H. Jackson eds., 2001); Simonetta Zarrilli, *International Trade in Genetically Modified Organisms and Multilateral Negotiations*, UNCTAD/DITC/TNCD/1 (July 5, 2000), available at <http://www.unctad.org/en/docs/poditctncdd1.en.pdf>; Paul E. Hagen & John Barlow Weiner, *The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified*

The expectation of conflict is fueled by the ongoing debate about the relationship between multilateral environmental agreements (MEAs) and the WTO.⁹ This debate stems from the more general preoccupation that trade interests are not always compatible with environmental interests and vice versa. From the environmental perspective, the fear is that "the WTO will decide that national (including local) and international measures to protect the environment are inconsistent with the [General Agreement on Tariffs and Trade of 1994 (GATT)]...and other WTO agreements, and will hold them invalid."¹⁰ In 1995, WTO members established a Committee on Trade and the Environment (CTE) charged with the consideration of various issues relating to the WTO and the environment. The first of these issues was, and still is, to address "the relationship between the provisions of the multilateral trading system and trade measures for environmental purposes, including those pursuant to multilateral environmental agreements."¹¹ The CTE meets regularly and, in 1996, issued a report with some very general recommendations. Little progress seems to have been made since then. To date, no measure taken pursuant to an MEA has been brought before the Appellate Body of the WTO.

Organisms, 12 GEO. INT'L L. REV. 697 (2000); Steve Charnovitz, *The Supervision of Health and Biosafety by World Trade Rules*, 13 TUL. ENVTL. L.J. 271 (2000); Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47 (2001); Sabrina Safrin, *Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements*, 96 AM. J. INT'L L. 606 (2002); Gareth W. Schweizer, Note, *The Negotiation of the Cartagena Protocol on Biosafety*, 6 ENVTL. L.J. 577 (2000); Gretchen L. Gaston & Randall S. Abate, *The Biosafety Protocol and the World Trade Organization: Can the Two Coexist?*, 12 PACE INT'L L. REV. 107 (2000); Brett Grosko, *Genetic Engineering and International Law: Conflict or Harmony? An Analysis of the Biosafety Protocol, GATT, and the WTO Sanitary and Phytosanitary Agreement*, 20 VA. ENVTL. L.J. 295 (2001); K. Mulongoy, *Different Perceptions on the International Biosafety Protocol*, 31 BIOTECH. & DEV. MONITOR 16 (1997), available at <http://www.biotech-monitor.nl/3106.htm> (last visited Feb. 4, 2003); Deepa Badrinarayana, *To Trade or Not to Trade . . .*, 32 ENVTL. L. Rep. 10512 (2002).

⁹ On the MEA/WTO debate see generally, Chris Wold, *Multilateral Environmental Agreements and the GATT: Conflict and Resolution?*, 26 ENVTL. L.J. 841 (1996); Edith Brown Weiss & John H. Jackson, *The Framework for Environment and Trade Disputes*, in RECONCILING ENVIRONMENT AND TRADE, *supra* note 8, at 1; P. K. RAO, *THE WORLD TRADE ORGANIZATION AND THE ENVIRONMENT* (2000); KENNETH P. EWING & RICHARD G. TARASOFSKY, *THE "TRADE & ENVIRONMENT" AGENDA: SURVEY OF MAJOR ISSUES AND PROPOSALS: FROM MARRAKESH TO SINGAPORE* (1997); Annick Emmenegger Brunner, *Conflicts Between International Trade and Multilateral Environmental Agreements*, 4 ANN. SURV. INT'L & COMP. L. 74 (1997); Kevin C. Kennedy, *Why Multilateralism Matters in Resolving Trade-Environment Disputes*, 7 WIDENER L. SYMP. J. 31 (2001); Steve Charnovitz, *A Critical Guide to the WTO's Report on Trade and Environment*, 14 ARIZ. J. INT'L & COMP. L. 341 (1997) [hereinafter *Critical Guide to WTO's Report*].

¹⁰ Weiss & Jackson, *supra* note 9, at 2-3.

¹¹ *Id.* at 25.

The Biosafety Protocol is a multilateral environmental agreement, with the following stated objective:

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms [LMOs] resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.¹²

Increased tension among various countries with regard to LMOs and LMO product trade has led some commentators to suggest that a measure instituted under the Biosafety Protocol might be the first case pitting an MEA against the trade disciplines upheld by the WTO and its subsidiary agreements.¹³

Nevertheless, it is important to keep in mind some significant differences between the Biosafety Protocol and other possible MEA measures that have traditionally been the subject of analysis in the MEA/WTO debates. For example:

1. The Biosafety Protocol does not ban trade with non-parties.¹⁴
2. The Protocol does not require countries to ban a product, although admittedly, a country following the procedures laid out by the Protocol might determine the need for one.¹⁵

¹² Biosafety Protocol, *supra* note 1, art. 1.

¹³ See, e.g., Zarrilli, *supra* note 8, para. 75.

¹⁴ Some treaties that ban trade with non-parties include: The Montreal Protocol on Substances That Deplete the Ozone Layer; the Convention on International Trade in Endangered Species; and the Basel Convention on the Transboundary Movement of Hazardous Wastes. Weiss & Jackson, *supra* note 9, at 31. These treaties all include some sort of "escape hatch" which would allow for trade with non-parties under certain circumstances. *Id.*

¹⁵ See Bernasconi-Osterwalder, *supra* note 8, at 698-99.

Unlike the Convention on International Trade in Endangered Species of Fauna and Flora (CITES), the Montreal Protocol on Substances That Deplete the Ozone Layer, and the Basel Convention on the Control of Transboundary Movement of Hazardous Waste and Their Disposal, the Biosafety Protocol does not contain a provision requiring Parties to ban trade with non-parties

Id. (emphasis omitted).

3. The Protocol does not require consideration of extra-jurisdictional environmental concerns; i.e. the Protocol only requires its parties to consider the direct effect an LMO may have on the party of import's environment or ecosystem.
4. Another distinction is that the object of regulation of the Protocol is not the environmental threat that may be caused by the production process of LMOs; its concern is with the effects that the LMO itself may have upon the host or receiving environment.¹⁶
5. And finally, the trade measures required by the Protocol are directly related to the harms being averted. In other words, none of the measures prescribed by the Protocol are using trade measures or restrictions as indirect ways of gaining compliance with the objectives of the Protocol.

These distinctions clarify, at the outset, that the Biosafety Protocol does not contain many of the trade-related environmental measures that are typically viewed as creating conflict with the WTO. But this does not necessarily mean that there is no possibility of conflict between the rights and obligations created by the Biosafety Protocol and those created by the WTO. This possibility of conflict motivates this article. Siding with those commentators who have argued that the Protocol should present no particular conflict with the WTO agreements,¹⁷ this article focuses on some issues that have not been duly addressed, while suggesting a framework for further analysis of this and other MEAs.

Part I of this article will provide an introduction to the origin, negotiation, and approval of the Biosafety Protocol in order to provide a background from which the Protocol can be interpreted. Part II of this article will address the final text of the Protocol. Special attention and interpretative suggestions will be given for those articles that could have an impact on trade. Part III will provide an overview of three WTO agreements and the provisions of those agreements that have been singled-out as being in possible conflict with the Protocol. These agreements are: (1) the GATT;¹⁸ (2) the Technical Barri-

¹⁶ See Gaston & Abate, *supra* note 8, at 142–44 (arguing that what is being regulated by the Biosafety Protocol are the final product's characteristics and not the process and production measures through which the LMO was created).

¹⁷ See generally Charnovitz, *supra* note 8; Bernasconi-Osterwalder, *supra* note 8; Gaston & Abate, *supra* note 8; COSBEY & BURGIEL, *supra* note 8.

¹⁸ GATT, *supra* note 7, at 1154. The GATT 1947 and 1994 are available at the World Trade Organization website, <http://docsonline.wto.org> (last visited Feb. 25, 2003).

ers to Trade Agreement (TBT);¹⁹ and (3) the Sanitary and Phytosanitary Agreement (SPS).²⁰ Part IV introduces the framework for the analysis of conflict between the Biosafety Protocol and the WTO. This framework's point of departure is a detailed analysis of the scope of each of the agreements.²¹ Finally, Part V will examine different actions that a party to the Protocol may take and review them against the rights and obligations of the different WTO agreements that may apply to such a party. Primarily, this analysis will be conducted assuming the importing party is a member of the WTO and a party to the Protocol and the exporting country is only a member of the WTO. Part VI details the scenario in which both countries are parties to both agreements.

I. THE ROAD TO THE BIOSAFETY PROTOCOL²²

The advent of modern biotechnology has been characterized by conflicting images of its implications. Some consider it a source of unbound remedies to our most serious social ills: hunger and diseases.²³ Others believe modern biotechnology advances are steps towards even further hunger and disease.²⁴ Both sides can cite examples to support their views.

¹⁹ Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS--RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 18 I.L.M. 1079 (1979), available at <http://docsonline.wto.org> [hereinafter TBT Agreement].

²⁰ Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS--RESULTS OF THE URUGUAY ROUND vol. 1 (1994), available at <http://docsonline.wto.org> [hereinafter SPS Agreement].

²¹ This framework builds upon the analysis conducted by Professor David Wirth in *Trade Implications of the Basel Convention Amendment Banning North-South Trade in Hazardous Waste*, 7 REV. EUR. COMMUNITY AND INT'L ENVTL. L. 237 (1998).

²² See generally COSBEY & BURGIEL, *supra* note 8; Gaston & Abate, *supra* note 8; Mulongoy, *supra* note 8; Cors, *supra* note 8; FRAMING "BIOSAFETY," *supra* note 8; *Creating a Global Biosafety Regime*, *supra* note 8; Zarrilli, *supra* note 8; Schweizer, *supra* note 8. Most of these sources refer to the *Earth Negotiation Bulletin* produced by the International Institute for Scientific Development (IISD) covering many of the meetings leading to the approval of the Biosafety Protocol. These documents can be found at <http://www.iisd.ca/biodiv/excop/> (last visited Feb. 25, 2003).

²³ See generally Martina McGloughlin, *Ten Reasons Why Biotechnology Will Be Important to the Developing World*, 2 AGBio F. 163 (1999); C.S. Prakash, *Feeding a World of Six Billion*, 2 AGBio F. 223 (1999).

²⁴ See generally Miguel A. Altieri & Peter Rosset, *Ten Reasons Why Biotechnology Will Not Ensure Food Security, Protect the Environment and Reduce Poverty in the Developing World*, 2 AGBio F. 155 (1999); Miguel A. Altieri & Peter Rosset, *Strengthening the Case for Why Biotechnology Will Not Help the Developing World: A Response to McGloughlin*, 2 AGBio F. 226 (1999).

One of the environmental concerns arising from these new technologies was based on the fact that, while many developed countries have regulatory infrastructures that allow them to experiment and produce modified or new organisms under relatively safe conditions, most poor or developing nations—characterized by limited technological and scientific infrastructure—lack national regulations, policies, and procedures to guide their involvement with the new products of biotechnology. This situation, coupled with the fact that many developing countries provide valuable genetic resources and host critical centers of biological diversity, created the fear that products of modern biotechnology could have a negative impact on these resources if left unregulated.²⁵

In 1992, a growing concern for the conservation and sustainable use of biodiversity led to the establishment of the CBD. Many developing countries believed that it was under the auspices of this Convention that these safety concerns with biotechnology should be addressed.

A. *The Convention on Biological Diversity*

The CBD was negotiated during the 1992 Earth Summit in Rio de Janeiro.²⁶ Biodiversity was defined by the Convention as “the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.”²⁷

The CBD was agreed upon by almost every country in the world and currently, 186 countries are parties to the Convention.²⁸ A notable exception is the United States which, although a signatory and

²⁵ For a list of some of the concerns that have been voiced regarding the risks that biotechnology products could present to biodiversity, see Vicente Paolo B. Yu III, *Compatibility of GMO Import Regulations with WTO Rules*, in RECONCILING ENVIRONMENT AND TRADE, *supra* note 8, at 575, 582-85. See also SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, GLOBAL BIODIVERSITY OUTLOOK 67 (2001), available at <http://www.biodiv.org/doc/publications/gbo/gbo-ch-01-en.pdf>.

²⁶ SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, SUSTAINING LIFE ON EARTH: HOW THE CONVENTION ON BIOLOGICAL DIVERSITY PROMOTES NATURE AND HUMAN WELL-BEING 2 (2000), available at <http://www.biodiv.org/doc/publications/cbd-sustain-en.pdf>.

²⁷ CBD, *supra* note 2, art. 2.

²⁸ See Secretariat of the Convention on Biological Diversity, *Parties to the Convention on Biological Diversity/Cartagena Protocol on Biosafety*, at <http://www.biodiv.org/world/parties.asp> (last visited Feb. 4, 2003).

active participant in its creation, has yet to ratify it.²⁹ Although in Rio de Janeiro there was no consensus on the need for a Biosafety Protocol, the CBD did achieve the inclusion of Article 19(3), directing the parties to contemplate the need for such a protocol.³⁰ Article 19(3) specifically provides that:

[t]he parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advanced informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

The specific language used in Article 19(3) reflects the preliminary compromises made by the participants to the CBD regarding three main issues. One commentator has referred to these issues and their impact on framing the ensuing negotiations:

These three issues were, first and foremost, the primary and highly contested question about whether GMO's posed unique risks at all, and thus needed to be singled out for attention; second, whether "prior informed consent" was the appropriate transnational governance mechanism in this realm, and third, whether the Convention on Biological Diversity was the appropriate transnational forum within which to pursue this discussion, and if so, which aspects of GMO risks were appropriate to address within this forum.³¹

Regarding the first of these issues, the United States attempted to convince other nations that there was nothing unique in genetically modified organisms (GMOs) that merited singling them out for special treatment as opposed to organisms modified through more traditional breeding methods.³² U.S. delegates insisted that there was no

²⁹ There are no signs this fact will change any time soon. It is also interesting to note that the commitment to promulgate a Biosafety Protocol is one of the reasons put forth for the United States not signing the CBD. See HENRY I. MILLER, *IS THE BIODIVERSITY TREATY A BUREAUCRATIC TIME BOMB?* 2-6 (1995).

³⁰ See Zarrilli, *supra* note 8, para. 60 (stating that the proposal for provisions dealing with the safe transfer, handling, and use of LMOs was already being discussed during the negotiations of the CBD but "there was neither time nor a wholehearted willingness to . . . include them into the Convention . . ."); see also Cors, *supra* note 8, at 29.

³¹ FRAMING "BIOSAFETY," *supra* note 8, at 4.

³² *Creating a Global Biosafety Regime*, *supra* note 8, at 208.

scientifically-based evidence to support the proposition that GMOs represented exceptional ecological or health-related dangers.³³ Yet, an increasing number of European nations were legislating protective measures regarding GMOs.³⁴ In an attempt to reach middle ground, the United States introduced the concept "LMOs" as a substitute for GMOs. This was an effort to divert the focus away from the genetically engineered aspect of the organisms and toward the fact that they were *living* organisms.³⁵

The second issue addressed during the Rio de Janeiro meeting had to do with the concept of "prior informed consent" (PIC), a term already in use in the Basel Convention on hazardous wastes and chemicals. Events like the one in 1986, where a U.S.-manufactured, genetically altered, rabies vaccine was tested on a farm in Argentina without knowledge or consent of the government, prompted developing countries to demand PIC on this type of activity.³⁶ Not being able to garner support against this demand for informed consent and to at least play down the association between PIC and the management of hazardous waste, the United States proposed the alternative language of "advanced informed agreement" (AIA).³⁷

The third issue had to do with the reasons that justified placing "biosafety"³⁸ concerns within the scope of the CBD, which would define the scope of a Biosafety Protocol under its auspices. Participants in the Rio de Janeiro meeting seemed to agree that certain transboundary transfers of LMOs could result in adverse effects on biodiversity. The issue was thus whether to limit the scope or to broaden it to include other potential adverse impacts, such as those to human health, through the use of LMOs in foods and medications.³⁹ Most developed countries argued that concerns outside the concept of biodiversity, such as those of human health, were already addressed by other international organizations such as the Codex Alimentarius Commission and, from the trade perspective, by the SPS.⁴⁰ Significantly, the resulting mandate in Article 19(3) refers to the "ad-

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ FRAMING "BIOSAFETY," *supra* note 8, at 6.

³⁷ *Id.*; *Creating a Global Biosafety Regime*, *supra* note 8, at 208–09.

³⁸ Biosafety has been commonly defined as the "safe use of biotechnology." *Creating a Global Biosafety Regime*, *supra* note 8, at 206.

³⁹ FRAMING "BIOSAFETY," *supra* note 8, at 7.

⁴⁰ *Id.*

verse effect on the conservation and sustainable use of biological diversity” and nothing more.

Thus, having defined the issues from GMOs to LMOs, from PIC to AIA, and from a broader scope of biosafety to a biodiversity scope of biosafety, the developed countries, led by the United States, were able to frame the next round of dialogues leading to the Biosafety Protocol.

B. *Negotiating the Biosafety Protocol*

The Second Conference of the Parties (2nd COP) to the CBD, held in November 1995, agreed on the need for a Biosafety Protocol.⁴¹ The 2nd COP designated an Open-Ended Ad Hoc Working Group on Biosafety (BSWG) entrusted with drafting and negotiating a Biosafety Protocol.⁴² Throughout the years of negotiations there were three dominant groups: the *Miami Group* (Argentina, Australia, Canada, Chile, Uruguay, and the United States, all of them producers of bioengineered products); the *Like-Minded Group* (the majority of developing countries, coming from the G-77/China sector); and the *European Union* countries.⁴³ At the Extraordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity (Ex-COP), held in Cartagena in February 1999, significant divisions among the negotiating parties prevented consensus and blocked the adoption of a protocol. The persistent points of contention were: the scope of the Protocol, the relationships between the Protocol and other international agreements, and the issue of liability in the event that LMOs caused environmental damage.⁴⁴

Almost a year later, on January 29, 2000 in Montreal, 133 countries agreed to the Biosafety Protocol. Some analysts have suggested that governments and industry participants had been more willing to compromise this time in order to avoid another embarrassing failure like the WTO Ministerial Conference held in Seattle.⁴⁵ In addition, during the months between Cartagena and Montreal there was grow-

⁴¹ Second Conference of the Parties to the Convention on Biological Diversity, Decision II/5: Consideration of a Need for Modalities of a Protocol for the Safe Transfer, Handling and Use of Living Modified Organisms, UNEP/CBD/COP/2/19 (Nov. 1995), available at <http://www.biodiv.org/decisions/default.asp?lg=0&m=cop-02&d=05> (last visited Feb. 4, 2003).

⁴² *Id.*

⁴³ FRAMING “BIOSAFETY,” *supra* note 8, at 9.

⁴⁴ Schweizer, *supra* note 8, at 585–86.

⁴⁵ Charnovitz, *supra* note 8, at 298; COSBEY & BURGIEL, *supra* note 8, at 2.

ing concern in various countries regarding the risks of LMOs in agriculture, concerns that were also being heard in the United States.⁴⁶ National legislatures considered or implemented responses to these concerns.⁴⁷ Some large multinational food companies also started to state their intention to use only non-genetically modified ingredients in their products.⁴⁸ Thus, the idea of a harmonized procedure might have begun to sound more appealing to some exporting countries.

II. A Close-Up Look at the Protocol

The Biosafety Protocol has been referred to as a “compromise text,”⁴⁹ and indeed this seems a fitting description of a text that took more than four years of intense negotiations to finalize. But how were the conflicts resolved, and what does the final compromise look like? In particular, what is the scope of the Protocol, and which of its obligations have an impact on trade?

In Article 4, the Protocol states: “This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.”⁵⁰ This Article reflects the different compromises made in the negotiation of the Biosafety Protocol. Therefore, a review of each relevant element will be briefly addressed.

The first significant aspect of the Article is its reference to LMOs. The Protocol describes LMOs as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.”⁵¹ This definition is further narrowed in the Biosafety Protocol by the definition given to the concepts “living organism” and “modern biotechnology.”⁵² The first is defined as “any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.”⁵³ Modern biotechnology is also restricted to the application of specific scientific procedures that have the purpose of overcoming “natural physiologi-

⁴⁶ *Creating a Global Biosafety Regime*, *supra* note 8, at 217-18.

⁴⁷ *Id.* at 218.

⁴⁸ *Id.*

⁴⁹ Zarrilli, *supra* note 8, para. 64.

⁵⁰ Biosafety Protocol, *supra* note 1, art. 4.

⁵¹ *Id.* art. 3(g).

⁵² *Id.* art. 3(h)-3(i).

⁵³ *Id.* art. 3(h).

cal reproductive or recombination barriers and that are not techniques used in traditional breeding.”⁵⁴

An additional element to note is the exclusion from the scope of the Protocol of products derived from LMOs, or what was described during the negotiating process as “products thereof.” Products made of, or derived from, LMOs include commodities, such as clothing made from genetically modified cotton, and many processed foods, such as tomato paste, cereals, and soybean oil. The fact that these products will not fall under the scope of the Protocol is important for several reasons: first, these commodities conform a significant percentage of the trade in LMO products, and second, many of the controversies relating to the safety of LMOs and the desirability of them being labeled for consumer interest reasons, have revolved around these types of products.⁵⁵

The second element in Article 4 that is significant to the Protocol’s scope is the phrase: “may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.” Although it is evident that the overall purpose of the Protocol is the protection of biological diversity, it is debatable whether the phrase, “taking also into account risks to human health,” broadens its scope.

The question, in other words, is whether a risk to human health can be referred to as an independent ground on which to base a measure under the Protocol. On one hand, it appears that nothing on its face would exclude this possibility, except perhaps for the modifying word, “also.”⁵⁶ Additionally, Article 2(5) makes a stand-alone reference to the risks of human health.⁵⁷ On the other hand, the Protocol excluded from its scope—or, in certain cases, limited from its

⁵⁴ *Id.* art. 3(i).

⁵⁵ On the ongoing controversy of GMO product labeling see generally Mathew Franken, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 MINN. INTELL. PROP. REV. 153, 158–59 (2000); Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT’L ENVTL. L. REV. 717 (2000); Diane Thue-Vasquez, *Genetic Engineering and Food Labeling: A Continuing Controversy*, 10 SAN JOAQUIN AGRIC. L. REV. 77 (2000); Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?*, 54 FOOD & DRUG L.J. 667 (1999).

⁵⁶ Biosafety Protocol, *supra* note 1, art. 4.

⁵⁷ *Id.* art. 2(5). Article 2(5) indicates that “the parties are encouraged to take into account, as appropriate, available expertise, instruments, and work undertaken in international forums with competence in the area of risks to human health.” *Id.* It is important to note that this might also be a recognition of the fact that there are other international forums with particular expertise and competence in the issue of human health. *See id.*

reach—those products that could not pose a direct risk to biodiversity. Thus, it could be persuasively argued that any coherent reading should interpret the phrase, “human health,” within the context of the general scope of the Protocol, i.e. only human health risks incidental to an identifiable risk to biodiversity.⁵⁸ But, perhaps a third interpretation could also be consistent with both limiting the scope to only those LMOs being introduced into the environment as well as giving independent meaning to the “human health” provisions.⁵⁹ This interpretation would permit consideration of human health risks which were incidental to the release of an organism into the environment, *i.e.* from coming in contact with the LMO seed or from harvesting LMO plants, but would not cover human health risks related to the consumption of LMO food and food products.

Few analyses have been put forward on the significance of this phrase. However, one commentator has stated that most of the negotiating countries insisted that the phrase, “taking also into account risks to human health,” should include only “*indirect* human health impacts that could arise as a result of direct impacts on biodiversity.”⁶⁰ For the purpose of this article, the phrase will be interpreted in the limited sense suggested by this commentator.⁶¹ As will be discussed in another section, the interpretation given to this phrase will have a significant impact in determining the Biosafety Protocol’s relation to the WTO agreements.

There are three other limitations on the scope of the Protocol that must be considered. These are found in Articles 5, 6, and 7. Article 5 states:

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals *for hu-*

⁵⁸ *Id.* art. 2(5).

⁵⁹ *Id.*

⁶⁰ *Creating a Global Biosafety Regime*, *supra* note 8, at 211.

⁶¹ It must be pointed out that the fact that a risk to human health could or could not be addressed as an independent ground for a measure under the Biosafety Protocol would not impede a country from limiting the entrance of a product that in fact poses such a risk.

*mans that are addressed by other relevant international agreements or organisations.*⁶²

Although by some accounts of the negotiation's outcome, LMO pharmaceuticals were excluded from the application of the Protocol, their absolute exclusion is anything but clear.⁶³ Article 5 could be reasonably understood as excluding application of the Protocol only when other relevant international agreements or organizations cover the specific pharmaceutical.⁶⁴ Other commentators have also noted that the Article refers solely to human pharmaceuticals.⁶⁵ Thus, it would seem that veterinary pharmaceuticals, which satisfy the definition of LMOs,⁶⁶ do fall under the Protocol's scope.⁶⁷ Notwithstanding the possibility of some pharmaceuticals falling under the scope of the Protocol, it is possible that they would still be excluded from the AIA procedure, which will be discussed below, under either Article 6(2) (intended for contained use) or Article 7(2) (intended for use as food, feed, or for processing).

Articles 6 and 7 place certain limitations not on the scope of the Protocol itself, but on the application of certain features, particularly the AIA. These Articles basically state that: LMOs in transit,⁶⁸ LMOs intended for "contained use"⁶⁹ "undertaken in accordance with the standards of the Party of import,"⁷⁰ LMOs "intended for direct use as food or feed or for processing" (LMO-FFPs),⁷¹ and "intentional trans-

⁶² Biosafety Protocol, *supra* note 1, art. 5 (emphasis added).

⁶³ Murphy, *supra* note 8, at 77.

⁶⁴ See *id.* The significance of this interpretation might be limited. But one can imagine, for example, an imported seed for a medicinally enhanced fruit, which, for its hybrid nature (pharmaceutical/fruit), were not addressed by other international agreements. In this case, these seeds' impact on biodiversity should be analyzed under the Protocol's provision.

⁶⁵ Hagen & Weiner, *supra* note 8, at 702.

⁶⁶ See *id.* One could conceive, for example, feed in the form of seeds or grain engineered to deliver medicinal benefits to animals falling under this category as long as the seeds are "living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." *Id.* art. 3(g). But if the seed in this example is grown elsewhere and intended to be used directly as seed the AIA procedure would still not apply. See *id.*

⁶⁷ Hagen & Weiner, *supra* note 8, at 702 n.28.

⁶⁸ Biosafety Protocol, *supra* note 1, art. 6(1).

⁶⁹ *Id.* art. 6(2). "Contained use" means any operation, which undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment." *Id.* art. 3(b).

⁷⁰ *Id.* art. 6(2).

⁷¹ *Id.* art. 7(2).

boundary movement of living modified organisms identified in a decision of the Conference of Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health,"⁷² do not need to comply with the AIA procedure.

Each of these exceptions to the AIA procedure does not entail exclusion from other aspects of the Biosafety Protocol. However, since the AIA procedure is the feature in this agreement that interacts with trade more pervasively, it is significant that LMO-FFPs, which compose the majority of the actual trade in LMOs with products such as "modified corn, soya, wheat, rapeseeds, tomatoes and cotton,"⁷³ are not included.

Having examined the limitations upon the scope of the Protocol, this article will now analyze the obligations created by the Biosafety Protocol.

The Biosafety Protocol imposes various obligations on its parties. Some of them are trade-related, but many of them are not. Some of the non-trade-related obligations are those found in Article 20, regarding information-sharing and the Biosafety Clearing-House, and Article 22, regarding capacity building.⁷⁴ Other non-trade-related obligations imposed by the Protocol include: the obligation to provide notice when an unintentional transboundary movement of LMOs has taken place,⁷⁵ the obligation to protect confidential information,⁷⁶ the obligation to promote public awareness and participation with regard to LMOs,⁷⁷ and the obligation to adopt appropriate measures to prevent and handle illegal transboundary movement of LMOs.⁷⁸

⁷² *Id.* art. 7(4). This provision would seem to have been included to attract LMO exporting countries which could arguably manage exclusions for several of their products.

⁷³ Zarrilli, *supra* note 8, para. 69.

⁷⁴ Biosafety Protocol, *supra* note 1, arts. 20, 22. The Biosafety Clearing-House offers a mechanism for information sharing between countries providing the opportunity for exchange of scientific technical and environmental information that will aid an importing Country in its decision-making processes. *Id.* Capacity building, on the other hand, aims at more directly improving a developing country's capacity to assess the desirability or potential hazards of importing an LMO, taking into consideration its own environmental and ecological realities. Both of these efforts by the Protocol should be seen as important contribution primarily to developing countries if they are adequately carried out. *Id.*

⁷⁵ *Id.* art. 17.

⁷⁶ *Id.* art. 21.

⁷⁷ *Id.* art. 23.

⁷⁸ *Id.* art. 25.

Another set of obligations that merit particular attention are those found in Article 11, which refers to the procedures that must be followed with regard to LMO-FFPs.⁷⁹ This Article permits each party to conduct its regulation with regard to both the *import* and *domestic use* of these products under its domestic regulatory framework. Article 11 does not offer much in terms of the criteria on which a country must base its decision regarding domestic use. However, Article 2 of the Protocol is arguably applicable. This Article states that “[p]arties shall ensure that the *development*, handling, transport, *use*, transfer and *release*, of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.”⁸⁰ Article 16, on risk management, should also apply. This Article requires parties to “establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use [and] handling . . . of living modified organisms.”⁸¹ Article 16 also states that each party should endeavor to ensure that LMOs that are locally developed undergo an appropriate period of observation before they are put to their intended uses.⁸² These two Articles (Articles 2 and 16) seem to provide the only guidelines in the Protocol for the domestic *development*, *use*, and *release* of LMO-FFPs.

There are, however, specific requirements on a party to the Protocol that makes a decision regarding domestic use of an LMO as an FFP. The party must inform the Biosafety Clearing-House of its decision, accompanying such notification with a minimum of information as set out in Annex II of the Protocol.⁸³ The information provided to the Clearing-House is of central importance. Based on this information, the rest of the parties to the Protocol must proactively announce their determination as to the import of such products. Article 11(4) does specify that the determination by the potential importing country must be consistent with the objective of the Protocol, adding in Article 11(8) the first expressed reference to the controversial precautionary principle, aside for the general reference in Article 1 relating to the objective of the Protocol.

⁷⁹ Biosafety Protocol, *supra* note 1, art. 11.

⁸⁰ *Id.* art. 2(2) (emphasis added).

⁸¹ *Id.* art. 16(1).

⁸² *Id.* art. 16(4).

⁸³ *Id.* Annex II(j). Annex II(j) of the Protocol specifically requires a risk assessment report consistent with Annex III. *Id.* Annex II(j).

Article 11(8) states:

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 that living modified organism intended for direct use as food or feed or for processing, in order to avoid or minimize such potential adverse effects.⁸⁴

Thus, this Article could have an effect on trade insofar as it requires that the decision to permit an import of LMO-FFPs be consistent with the objectives of the Protocol and in accordance with the precautionary principle. In fact, the only distinguishing aspect of this procedure from those required for other LMOs under the AIA is that it "lays first responsibility on potential importers to develop and announce [its] regulations proactively."⁸⁵ Consistent with its preoccupation concerning the lack of regulatory mechanisms in developing countries, Article 11 establishes a procedure for those countries that lack a domestic framework under which to make a decision regarding the import of LMO-FFPs. The procedure requires developing countries 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 . . . [to the Clearing-House] . . . will be taken according to . . . a risk assessment undertaken in accordance with Annex III; and . . . a decision made within a predictable time frame not exceeding two hundred and seventy days.⁸⁶

It seems clear that Article 11 does its best not to interfere with the local regulatory frameworks, typically present in developed countries, which already deal with the sanitary standards applicable to both the local production and the importation of food and feed. At the same

⁸⁴ Biosafety Protocol, *supra* note 1, art. 11(8).

⁸⁵ COSBEY & BURGIEL, *supra* note 8, at 8; *see also* David J. Schnier, *Genetically Modified Organisms & The Cartagena Protocol*, 12 FORDHAM ENVTL. L.J. 377, 410 (2001).

⁸⁶ Biosafety Protocol, *supra* note 1, art. 11(6).

time, and being that LMOs intended for FFP are still living and thus without proper handling could be introduced into the environment, the Article provides a framework for those countries that do not have a regulatory system in place to deal with these novel products.

Moving on to those obligations with a direct impact on the trade of LMOs, the AIA procedure has been referred to as the "backbone"⁸⁷ or the "cornerstone"⁸⁸ of the Protocol. Still, it appears that the procedure is considerably restricted in its application to various LMOs.⁸⁹ Specifically, the AIA procedure is required only for those LMOs which are destined for direct introduction to the environment and which have not been excluded by any of the exceptions mentioned before.⁹⁰ Examples of such LMOs would be seeds for planting or fish for release into streams, among others.⁹¹ Compliance with the AIA procedure is also only required for the first intentional transboundary movement of an LMO.⁹²

The first thing the AIA procedure requires is for the party of export to notify, in writing, the competent national authority of the party of import prior to the intentional transboundary movement of an LMO.⁹³ This notification must, at a minimum, include the information stated in Annex I of the Protocol, which includes information such as: the "[t]axonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety";⁹⁴ the "[c]enters of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate";⁹⁵ the "[t]axonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety";⁹⁶ the "[d]escription of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism";⁹⁷ the "[i]ntended use of the living modified organism or prod-

⁸⁷ COSBEY & BURGIEL, *supra* note 8, at 7.

⁸⁸ Bernasconi-Osterwalder, *supra* note 8, at 693.

⁸⁹ Biosafety Protocol, *supra* note 1, art. 7.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.* art. 7(3).

⁹³ *Id.* art. 8(1).

⁹⁴ Biosafety Protocol, *supra* note 1, Annex I(e).

⁹⁵ *Id.* Annex I(f).

⁹⁶ *Id.* Annex I(g).

⁹⁷ *Id.* Annex I(h).

ucts thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology,"⁹⁸ and the "[r]egulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban."⁹⁹

After the notification is received by the importing party, Article 9 requires acknowledgment of receipt of the notification.¹⁰⁰ Article 10, in turn, establishes the decision procedure the importing state must follow, including certain limitations on the time a party may take before informing its decision which can be: (a) "approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism"; (b) "prohibiting the import"; (c) "requesting additional relevant information in accordance with its domestic regulatory framework or Annex I"; or (d) "informing the notifier that the period specified [in Article 10(3)] is extended by a defined period of time."¹⁰¹ In all cases, except when consent is unconditional, the decision must "set out the reasons on which it is based."¹⁰²

A party taking a decision under Article 10 must ensure that a risk assessment pursuant to Article 15 has been carried out.¹⁰³ The party of import may require the exporter either to carry out the risk assessment or, alternatively, to cover the costs of a risk assessment.¹⁰⁴ The risk assessment must be carried out in a "scientifically sound manner, in accordance with Annex III, and taking into account recognized risk assessment techniques."¹⁰⁵ The minimum amount of information on which a risk assessment can be based is that provided in

⁹⁸ *Id.* Annex I(i).

⁹⁹ Biosafety Protocol, *supra* note 1, Annex I(m).

¹⁰⁰ *Id.* art. 9. It is interesting to note that among the information that the acknowledgment of receipt must include is whether to proceed according to the domestic regulatory framework of import or according to the AIA procedure as specified in Article 10. *See id.* art. 10. This presents another opportunity for the scope of the AIA procedure to be limited.

¹⁰¹ *Id.* art. 10(4).

¹⁰² *Id.*

¹⁰³ *Id.* art. 15(2).

¹⁰⁴ Biosafety Protocol, *supra* note 1, art. 15(2), (3).

¹⁰⁵ *Id.* art. 15(1).

accordance with Article 8, which, in turn, refers to Annex I. Annex III, in turn, details the methodology, identifies points to consider when carrying out a risk assessment, and states that "[r]isk assessment is . . . used by competent authorities to make informed decisions regarding living modified organisms."¹⁰⁶ Finally, Article 10(6) also specifies that:

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.¹⁰⁷

The inclusion of a precautionary principle into the Protocol was a point of contention, especially between the European Union and the United States.¹⁰⁸ The precautionary principle is in itself a contentious term. It has been defined in a variety of ways¹⁰⁹ and it is said to

¹⁰⁶ *Id.* Annex III(2), (9).

¹⁰⁷ *Id.* art. 10(6).

¹⁰⁸ Although the *Miami Group* as a whole also resisted the inclusion of the precautionary principle, at least one member to that group, Australia, presently invokes the precautionary principle in its regulation relating to GMO labeling. See generally Denise M. Lietz, *A Precautionary Tale: The International Trade Implications of Regulating Genetically Modified Foods in Australia and New Zealand*, 10 PAC. RIM L. & POL'Y J. 411 (2001).

¹⁰⁹ James Cameron refers to the debate surrounding the principle's meaning in the following way:

Much of the confusion surrounding the principle's interpretation stems from a failure to distinguish between precautionary and preventative measures. Preventive standards may be precautionary or non-precautionary in certain degrees, but precautionary standards, while able to vary the degree of prevention, cannot be non-preventative. This is because, regardless of the particular language used by an instrument, a key element in defining the core of precaution is a lack of certainty about the cause and effect relationships or the possible extent of a particular environmental harm. If there is no uncertainty about the environmental risks of a situation, then the measure is preventive, not precautionary. In the face of uncertainty, however, the precautionary principle, like the *Vorsorgeprinzip*, allows for the state to act in effort to mitigate the risks. Put best, "the precautionary principle stipulates that where the environmental risks being run by regulatory inaction are in some way uncertain but non-negligible, regulatory inaction is unjustified."

occur in varying degrees of force, from weak to strong formulations.¹¹⁰

Principle 15 of the Rio Declaration, cited both in Article 1 and in the Preamble of the Protocol, has been catalogued among the weaker formulations of the Principle.¹¹¹ It states:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.¹¹²

Although commentators Cosbey and Burgiel have considered Articles 10(6) and 11(8) as strong formulations of the principle,¹¹³ commentators Cameron and Gupta, offering alternative interpretations that could place it towards the weaker end of the spectrum, have put that contention in doubt.¹¹⁴ These last authors have brought attention to specific aspects of the language used in these Articles.¹¹⁵

(2001) (emphasis added). Various books and articles have been written on the subject of the precautionary principle. Some of these are: *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION* (David Freestone & Ellen Hey eds., 1994); *INTERPRETING THE PRECAUTIONARY PRINCIPLE* (Timothy O'Riordan & James Cameron eds., 1994).

¹¹⁰ Timothy O'Riordan & James Cameron, *The History and Contemporary Significance of the Precautionary Principle*, in *INTERPRETING THE PRECAUTIONARY PRINCIPLE*, *supra* note 109, at 12, 20–22; UNITED NATIONS DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 2001: MAKING NEW TECHNOLOGIES WORK FOR HUMAN DEVELOPMENT: CH. 3 MANAGING THE RISKS OF TECHNOLOGICAL CHANGE 70 (Box. 3.3) (2001), available at <http://www.undp.org/hdr2001/> (last visited Feb. 4, 2003) [hereinafter UN HUMAN DEVELOPMENT REPORT].

¹¹¹ UN HUMAN DEVELOPMENT REPORT, *supra* note 110, at 70 (Box. 3.3).

¹¹² *Report of the United Nations Conference on Environment and Development*, U.N. GAOR, 47th Sess., Annex I, Agenda Item 21, at Principle 15, U.N. Doc. A/CONF.151/26 (vol. I) (1992) [hereinafter Rio Declaration].

¹¹³ COSBEY & BURGIEL, *supra* note 8.

¹¹⁴ James Cameron, *The Precautionary Principle in International Law*, in *REINTERPRETING THE PRECAUTIONARY PRINCIPLE*, *supra* note 109, at 113, 141; *Creating a Global Biosafety Regime*, *supra* note 8, 221–23. Admittedly the precautionary principle as formulated in Articles 10(6) and 11(8) could be interpreted as a stronger formulation of the Principle if compared to the Rio Declaration Principle 15, because it does not seem to require a threat of serious or irreversible damage, or impose a cost-benefit analysis. See Biosafety Protocol, *supra* note 1, arts. 10(6), 11(8); Rio Declaration, *supra* note 112, Principle 15. Additionally, it is not contingent on the capabilities of the State. See Biosafety Protocol, *supra* note 1, arts. 10(6), 11(8); Rio Declaration, *supra* note 112, Principle 15.

¹¹⁵ Cameron, *supra* note 114, at 141; *Creating a Global Biosafety Regime*, *supra* note 8, at 221–23.

For example, the phrasing in Articles 10(6) and 11(8) refers to insufficient scientific information and knowledge with regard to *the extent* of the potential adverse effect.¹¹⁶ This wording may limit the possibility of basing a decision on this principle to those cases when the uncertainty relates to the extent or severity of an adverse effect and not when the uncertainty relates to the nature of a possible adverse effect.¹¹⁷ This interpretation is consistent with the Protocol's requirement of basing determinations with regard to the import of an LMO on a risk assessment.¹¹⁸ Under this interpretation, only after a risk assessment has identified a possible risk to biodiversity would reference to the precautionary principle be allowed.¹¹⁹

Other aspects of these Articles are worth pointing out, such as the fact that no specific action, such as a ban, is required except that necessary to "avoid or minimize the potential adverse effects."¹²⁰ Articles 10(6) and 11(8) also use the phrase "taking a decision *as appropriate*."¹²¹ On the aspect of what would be an appropriate measure regarding a decision of a party to the Protocol in reference to Articles 10(6) and 11(8), reference to Article 16(2) on risk management may be necessary. This Article states that:

Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.¹²²

At least one commentator, analyzing the impact the Biosafety Protocol may have on trade, has pointed to the use of the word "necessary" in this Article as a potential limit on the rights of the party to impose certain measures.¹²³

There are two more articles that have the potential of further limiting the use of the AIA procedure. Article 13 establishes a simplified procedure through which an importing party may specify in advance to the Biosafety-Clearing-House: (a) that the importing party

¹¹⁶ Biosafety Protocol, *supra* note 1, arts. 10(6), 11(8).

¹¹⁷ *Id.*; Cameron, *supra* note 114, at 141.

¹¹⁸ Biosafety Protocol, *supra* note 1, art. 15(2); *see also* Cameron, *supra* note 114, at 141.

¹¹⁹ Cameron, *supra* note 114, at 141.

¹²⁰ Biosafety Protocol, *supra* note 1, art. 10(6).

¹²¹ *See* Charnovitz, *supra* note 8, at 301.

¹²² Biosafety Protocol, *supra* note 1, art. 16(2).

¹²³ Charnovitz, *supra* note 8, at 299; *see also infra* text accompanying note 276–280.

wishes to permit the transboundary movement to it with regard to an LMO at the same time the movement is notified (doing away with the requirement of prior notification), or (b) that an LMO will be exempt from the entire AIA procedure, thus allowing imports of an LMO with no further restrictions.¹²⁴ Article 14, on the other hand, establishes that parties may enter into bilateral, regional, and multilateral agreements and arrangements regarding intentional transboundary movements of LMOs as long as such arrangements do not result in a lower level of protection than that provided by the Protocol's procedures.¹²⁵ This Article further states that when such an agreement is in place the provisions of the Protocol shall not apply.¹²⁶

Another obligation which has an impact on the way trade in LMOs is carried out is found in Article 18.¹²⁷ Article 18 requires each party to take the necessary measures to make sure that LMOs which are subject to intentional transboundary movement are handled, packaged, and transported safely.¹²⁸ The Article also indicates that towards this end parties should take into account relevant international rules and standards.¹²⁹ The Protocol then lays out the required documentation that should accompany LMOs depending on their intended use.¹³⁰

Article 18(2)(a) requires documentation accompanying LMOs intended for direct use as food or feed or for processing to indicate clearly that it "may contain" LMOs and is not intended for introduction into the environment.¹³¹ Article 18(2)(b) requires documentation accompanying LMOs intended for contained use to be identified clearly as LMOs and to specify any requirement for their safe handling, storage, transport, and use, and the contact point for further information.¹³²

Although some have suggested that these provisions are somehow related to consumer choice,¹³³ nothing in the Protocol's lan-

¹²⁴ The notification must include the information specified in Annex I. Biosafety Protocol, *supra* note 1, art. 13(2-3).

¹²⁵ Biosafety Protocol, *supra* note 1, art. 14(1).

¹²⁶ *Id.* art. 14(3).

¹²⁷ *Id.* art. 18.

¹²⁸ *Id.* art. 18(1).

¹²⁹ *Id.* arts. 18(1-10).

¹³⁰ Biosafety Protocol, *supra* note 1, art. 18(2).

¹³¹ *Id.* art. 18(2)(a).

¹³² *Id.* art. 18(2)(b).

¹³³ See Badrinarayana, *supra* note 8, at n. 85.

guage suggests that this is an adequate interpretation.¹³⁴ It seems more appropriate, to interpret this provision in light of the objective of the Protocol, the protection of biodiversity.¹³⁵ Indeed, if a particular LMO is going to be allowed into the country without an AIA because it is not meant to be introduced into that country's environment, there must be some way for the importing country to identify said shipments and ensure they are not accidentally or purposely introduced into the environment. Also, there must be a way for that country to know what should be done or whom to contact in case of an accidental introduction into the environment.

Article 18(2) (c) requires documentation, accompanying all other LMOs falling within the scope of the Protocol, to be identified clearly as LMOs; to specify their identity and relevant traits and/or characteristics; to specify any requirements for their safe handling, storage transportation, and use; and to identify a contact point for further information.¹³⁶ The Article also requires a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.¹³⁷

The last paragraph of Article 18 indicates that the Conference of the Parties serving as the meeting of the parties to the Protocol shall consider the need for establishing additional "standards with regards to the identification, handling, packaging and transport practices, in consultation with other relevant international bodies."¹³⁸ This Article opens the door for more requirements in these areas but also reflects what some commentators have referred to as a determination that will allow for market driven requirements to emerge.¹³⁹ For example, in order to appease the Miami Group, the requirement for shipments of LMO-FFPs is simply that they are identified with the term "may contain."¹⁴⁰ This decision avoided requiring segregation of non-LMO crops from LMO crops, a procedure that the Miami Group qualified as impossible or extremely costly.¹⁴¹ Some argue, however, that in-

¹³⁴ Similarly, see Bernasconi-Osterwalder, *supra* note 8, at 698, stating that "[i]t should be noted that these labeling requirements do not concern consumer product labeling but shipping documentation only."

¹³⁵ Biosafety Protocol, *supra* note 1, art. 1.

¹³⁶ *Id.* art. 18(2) (c).

¹³⁷ *Id.*

¹³⁸ *Id.* art. 18(3).

¹³⁹ See Rafe Pomerance, *The Biosafety Protocol: Cartagena and Beyond*, 8 N.Y.U. ENVTL. L.J. 614, 620 (2000).

¹⁴⁰ Biosafety Protocol, *supra* note 1, art. 18(2) (a).

¹⁴¹ See Hagen & Barlow, *supra* note 8, at 705; Schweizer, *supra* note 8, at 594.

creasing market demands for non-GMO products is, in fact, already requiring the segregation so resisted by the exporting countries.¹⁴²

But aside from the AIA procedure, and the limited requirements of Article 18, attention must also be given to two other aspects of the Protocol before concluding a review of its trade-related obligations. It is important to note that Article 24 on non-parties does not ban trade with non-parties but it does require that the transboundary movement between parties and non-parties “be consistent with the objectives of the Protocol.”¹⁴³ This Article also states that a party may enter into bilateral, regional, and multilateral agreements or other arrangements with non-parties regarding such transboundary movements.¹⁴⁴ This Article could lessen the fear that non-parties would be discriminated against with regard to trade in LMOs covered by this protocol, although it does not limit the rights of a party to demand compliance with certain of the Protocol’s obligations.¹⁴⁵

Finally, we must refer to the way in which the Protocol resolved the impasse relating to the inclusion of a savings clause. Included in the Preamble—and not in the operative language of the protocol—are the following phrases:

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

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

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements.¹⁴⁶

Commentators Cosbey and Burgiel described the emergence of this preambular trio in the following manner:

¹⁴² Stephen Tomans, *Promise, Peril, Precaution: The Environmental Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 187, 203 (2001); Thomas P. Redick & Christina G. Bernstein, *Nuisance Law and the Prevention of “Genetic Pollution”: Declining a Dinner Date with Damocles*, 30 ENVTL. L. REP. 10328, ¶ 1 (2000).

¹⁴³ Biosafety Protocol, *supra* note 1, art. 24(1). The fact that the specific obligations of the protocol relating to transboundary movements of LMOs are only applicable as between parties to the protocol is also affirmed by Article 3(k) which states: “Transboundary movement” means the movement of a living modified organism from one Party to another Party, save that for the purposes of Article 17 and 25 transboundary movement extends to movement between Parties and non-Parties.” *Id.* art. 3(k).

¹⁴⁴ *Id.* art. 24(1).

¹⁴⁵ *Id.*

¹⁴⁶ *Id.* pmbi.

The Miami Group got what it wanted. The text states that "this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreement." The EU also got what it wanted. The next paragraph of text states that, "the above recital is not intended to subordinate this Protocol to other international agreements." And the Like-Minded Group got what it wanted: both statements appear in the preamble, not in the main text. It is not clear where this compromise leaves the Protocol relative to the WTO.¹⁴⁷

It is precisely this relation that will be examined in the rest of this article. This article will evaluate if it is even necessary to resort to the preambular language, by examining if there is any conflict between the rights and obligations of the Biosafety Protocol and the rights and obligations of the WTO that would require an answer as to the question of which treaty prevails. The next section begins by laying out what are the rights and obligations of the WTO agreements.

III. WTO AGREEMENTS: THE NEGATIVE OBLIGATIONS

The WTO is the institutional framework of the international multilateral trading system.¹⁴⁸ Every member of the WTO has entered into commitments related to its trade policy regime and measures with relation to its trade in goods among other things.¹⁴⁹ The rights and obligations of the WTO members can be enforced through a dispute settlement system.¹⁵⁰

WTO obligations constitute limits, or what has been termed "negative obligations," upon its members to refrain from enacting certain governmental regulations. The following agreements, and their negative obligations, have been selected for review because of their potential to conflict with the positive obligations that the Biosafety Protocol places upon its parties.

¹⁴⁷ COSBEY & BURGIEL, *supra* note 8.

¹⁴⁸ WTO, *World Trade Organization: A Training Package*, available at http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited Feb. 25, 2003).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

A. The GATT

The GATT covers all international trade in goods.¹⁵¹ Within the WTO, three GATT 1947 “principles” or “disciplines” continue to be the framework upon which the ideal of “free trade” is built. These are as follows: Article I, prohibiting discrimination between the products imported by member states, also referred to as the most favored nation principle; Article III, prohibiting discrimination between imported and domestic goods, also referred to as national treatment; and Article XI, prohibiting quantitative restrictions on trade.¹⁵²

Articles I and III embody the principle of non-discrimination among “like products.”¹⁵³ Under Article I, like products from different countries should receive the same treatment by the importing country. Under Article III, like products from foreign member countries must be treated no differently than the like domestic products. Thus, determining if products are alike is central to any claim that there has been a violation of these Articles.

The most recent expression of the Appellate Body with regard to like products can be found in *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products (Asbestos Case)*.¹⁵⁴ It stated that a finding that two products are alike must be made on a case-by-case basis¹⁵⁵ by examining four general characteristics that the products might share: (1) “the physical properties of the products”; (2) “the extent to which the products are capable of serving the same or similar end-uses”; (3) “the extent to which consumers perceive and treat the product as alternative means of performing particular functions in order to satisfy a particular want or demand”; and (4) “the international classification of the products for tariff purposes.”¹⁵⁶

The Appellate Body, in the *Asbestos Case*, also rejects the WTO Panel’s determination that if two products could be used towards the same end, their physical properties should be considered equivalent, if not identical.¹⁵⁷ It further determined that characteristics such as

¹⁵¹ GATT, *supra* note 7, art. I; WTO, *GATT and the Goods Council*, available at http://www.wto.org/english/tratop_e/gatt_e/gatt_e.htm (last visited Feb. 25, 2003).

¹⁵² GATT, *supra* note 7, arts. I, II, XI.

¹⁵³ *Id.* arts. I, III.

¹⁵⁴ WTO Appellate Body Report on *European Communities—Measures Affecting Asbestos and Asbestos-containing Products*, WT/DS135/AB/R (Mar. 12, 2001), 40 I.L.M. 1193 (2001), available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm#1998 [hereinafter *Asbestos Appellate Body Report*].

¹⁵⁵ *Id.* ¶ 101.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* ¶ 112.

the products' risks to human health should be considered as physical properties and may also be considered under the category of consumers' taste and habits.¹⁵⁸ When examining the third criterion, the Appellate Body indicated the importance of determining the extent to which consumers would be willing to use the products to perform similar end uses.¹⁵⁹

GATT's prohibition of quantitative restrictions on imports and exports must be read in conjunction with the principle of non-discrimination and, thus, also requires a determination of like products. It is also of interest to the objective of this article that Article XI, although normally referred to as applying to quotas or bans on foreign products, at least in one instance has been interpreted broadly by the WTO "to apply to any border measure imposing any burden on international trade."¹⁶⁰

A country can, nonetheless, undertake trade measures that result in violation of any of these three disciplines if it satisfies the exceptions present in Article XX of GATT. Article XX states, in pertinent part:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

....

(b) necessary to protect human, animal or plant life or health;

....

¹⁵⁸ *Id.* ¶ 113. In the *Asbestos* case, the particular health threat was the known carcinogenic nature of the chrysotile asbestos fibers. *Id.* ¶ 114. Interestingly, the Appellate Body also established that the use of health risks in determining the physical properties of a product does not nullify the effect of article XX(b). *Id.* ¶ 113.

¹⁵⁹ Asbestos Appellate Body Report, *supra* note 154, ¶ 121.

¹⁶⁰ David M. Driesen, *What Is Free Trade?: The Real Issue Lurking Behind the Trade and Environment Debate*, 41 VA. J. INT'L L. 279, 293 (2001) (citing WTO Dispute Settlement Panel Report on India—Quantitative Restrictions on Imports of Agricultural, Textile, and Industrial Products, 1999 WTO DS Lexis 5, para. 5.142 (Apr. 6, 1999)).

(g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.¹⁶¹

Although these exceptions have been interpreted by a number of WTO Panel and Appellate Body decisions, these exceptions actually have never been applied to exempt a member country from its general GATT obligations.¹⁶² In both *United States—Standards for Reformulated and Conventional Gasoline*,¹⁶³ and in *United States—Import Prohibition of Certain Shrimp and Shrimp Products*,¹⁶⁴ the WTO Appellate Body concluded that there was a distinction between the standards for Article XX(b) and XX(g). In what has been termed a more “environmentally friendly reading for Article XX(g),”¹⁶⁵ the Appellate Body consistently recognized that a measure does not need to be “necessary” to be “related to” the conservation of an exhaustible natural resource.¹⁶⁶ It is important to note that “necessary” in Article XX(b) is not a determination of whether *protection* is necessary, but whether the *measure* is necessary—*i.e.*, are there other less trade-restrictive ways of pursuing the same goal?¹⁶⁷

But even if a measure is found to satisfy the requirements of either Article XX(b) or XX(g), it must still meet the requirements of the introductory paragraphs of Article XX.¹⁶⁸ Thus, a measure must also meet the requirement of not being an arbitrary or unjustifiable discrimination between countries where the same conditions prevail, nor can it constitute a disguised restriction on trade.

¹⁶¹ GATT, *supra* note 7, art. XX. The phrase “exhaustible natural resources” has been interpreted to include dolphins, salmon fisheries and clean air. DAVID HUNTER ET AL., *INTERNATIONAL ENVIRONMENTAL LAW AND POLICY* 1166 (2002).

¹⁶² See HUNTER ET AL., *supra* note 161, at 1163–65. Only one WTO Panel report actually determined that a measure that violated GATT disciplines was permissible under Article XX(b), but the WTO Panel decision was reversed by the Appellate Body. See *generally* Asbestos Appellate Body Report, *supra* note 154.

¹⁶³ WTO Appellate Body Report on *United States—Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (May 20, 1996), 35 I.L.M. 603 (1996).

¹⁶⁴ WTO Appellate Body Report on *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (Oct. 12, 1998), 38 I.L.M. 118 (1999).

¹⁶⁵ HUNTER ET AL., *supra* note 161, at 1168.

¹⁶⁶ *Id.*

¹⁶⁷ See Thomas J. Schoenbaum, *International Trade and Protection of the Environment: The Continuing Search for Reconciliation*, 91 AM. J. INT’L L. 268, 276 (1997).

¹⁶⁸ GATT, *supra* note 7, art. XX.

B. *The TBT Agreement*

There are measures that can also fall into the categories covered by another WTO agreement, the TBT. The TBT's purpose is ensuring that WTO members do not use technical regulations and standards in a way that creates unnecessary obstacles to international trade.¹⁶⁹ To date, no case has been decided under the TBT.

The TBT covers all technical regulations, standards, and conformity assessment procedures that may bear upon all imported products including "industrial and agricultural products."¹⁷⁰ A technical regulation is defined by the TBT as:

[A] [d]ocument which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.¹⁷¹

The following analysis of the TBT will be limited to the interpretation of the obligations imposed as to technical regulations because of their pertinence to this article's objective. It is interesting to point out that the Appellate Body in the *Asbestos Case* stated that, contrary to the WTO Panel's reasoning, a ban could be a technical regulation falling under the scope of the TBT.¹⁷²

Technical regulations are governed primarily by Article 2 of the TBT, which establishes the following requirements for member countries. First, members shall make sure that their technical regulations do not result in discriminatory treatment of products imported from other member countries, by requiring they be treated no less favorably than like products of domestic origin or from other countries.¹⁷³ This obligation is a clear reference back to the already-analyzed requirements of GATT Articles I and III.

Second, technical regulations should not create unnecessary obstacles to international trade. Towards this end, technical regulations

¹⁶⁹ Kristina Kloiber, *Removing Technical Barriers to Trade: The Next Step Toward Freer Trade*, 9 TUL. J. INT'L & COMP. L. 511, 517 (2001).

¹⁷⁰ TBT Agreement, *supra* note 19, art. 1.3.

¹⁷¹ *Id.* annex 1(1).

¹⁷² *Asbestos Appellate Body Report*, *supra* note 154, ¶ 76.

¹⁷³ TBT Agreement, *supra* note 19, art. 2.1.

“shall not be more trade-restrictive than necessary to fulfill [sic] a legitimate objective, taking account of the risks non-fulfillment would create.”¹⁷⁴ Among the legitimate objectives, the TBT recognizes protection to human health or safety; protection to animal or plant life or health; and protection to the environment. The TBT also describes some relevant elements to be considered when assessing the risks that non-fulfillment would create. These are: “available scientific and technical information, related processing technology or intended end-uses of products.”¹⁷⁵

Third, the TBT requires that technical regulations be eliminated if the circumstances or objectives giving rise to their adoption no longer exist or if an alternative less trade-restrictive measure is presently available.¹⁷⁶

These second and third requirements of the TBT are commonly referred to as the “necessity test.”¹⁷⁷ This test, also present in the SPS, has been described as “the means by which an effort is made to balance between two potentially conflicting priorities: promoting trade expansion versus protecting the regulatory rights of governments.”¹⁷⁸

Fourth, the TBT pursues harmonization by requiring that technical regulations be based on available and relevant standards formulated by an international body unless those standards would be ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued¹⁷⁹ The TBT defines an “international body” as one whose membership is open to the relevant bodies of all members.¹⁸⁰

Another significant requirement is that members must consider accepting equivalent technical regulations of other members that, although different from their own, adequately fulfill the objectives of their regulations.

Finally, it must be noted that the scope of the TBT is also limited by its own Article 1.5, which states: “The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in

¹⁷⁴ *Id.* art. 2.2.

¹⁷⁵ *Id.* art.

¹⁷⁶ *Id.* art. 2.3.

¹⁷⁷ WTO, *Application of the Necessity Test: Issues for Consideration* (Oct. 8, 1999), at http://www.wto.org/english/tratop_e/serv_e/serv_reg_secretariatnot_e.htm.

¹⁷⁸ *Id.*

¹⁷⁹ TBT Agreement, *supra* note 19, art. 2.4. This article gives examples of reasons why a certain international standard could be ineffective or inappropriate because of “fundamental climatic or geographical factors or fundamental technological problems.” *Id.*

¹⁸⁰ TBT Agreement, *supra* note 19, Annex 1 (4).

Annex 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures.”

C. *The SPS Agreement*

The SPS's stated purpose is to limit the use of SPS measures as disguised barriers to trade.¹⁸¹ Three cases have already been resolved by the Appellate Body under the SPS: *EC Measures Concerning Meat and Meat Products (Beef Hormones Case)*;¹⁸² *Australia—Measures Affecting Importation of Salmon (Australian Salmon Case)*; and¹⁸³ *Japan—Measures Affecting Agricultural Products (Japan Agricultural Products Case)*.¹⁸⁴ Significantly, in each of the cases, the measure has been deemed inconsistent with the members' SPS obligations. Interestingly, these cases all involved disputes between highly developed countries with intricate regulatory frameworks and were decided prior to the WTO Ministerial Conference in Seattle.

All measures enacted by members of the WTO that come under the scope of the SPS must be in accordance with the provisions of the Agreement.¹⁸⁵ A sanitary or phytosanitary measure is defined in Annex A, paragraph 1 of the SPS as any 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 ani-

¹⁸¹ SPS Agreement, *supra* note 20, pmb1.

¹⁸² WTO Appellate Body Report on European Community Measures Concerning Meat and Meat Products, WT/DS26/AB/R; WT/DS48/AB/R (Jan. 16, 1998) [hereinafter *Beef Hormones Appellate Body Report*].

¹⁸³ WTO Appellate Body Report on Australia—Measures Affecting Importation of Salmon, WT/DS18/AB/R (Oct. 20, 1998) [hereinafter *Australian Salmon Appellate Body Report*].

¹⁸⁴ WTO Appellate Body Report on Japan—Measures Affecting Agricultural Products, WT/DS76/AB/R (Feb 22, 1999) [hereinafter *Japan Agricultural Products Appellate Body Report*].

¹⁸⁵ SPS Agreement, *supra* note 20, art. 1, ¶ 1.

mals, 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.¹⁸⁶

According to the SPS, a measure must be applied only to the extent necessary to protect human, animal, or plant life or health. The measure should be based on scientific principles and should not be maintained without sufficient scientific evidence.¹⁸⁷ An exception to this requirement is provided by Article 5, paragraph 7 of the Agreement. In language reminiscent of Article XX of GATT, the Agreement requires that SPS measures not discriminate between members “where identical or similar conditions prevail including between their own territory and that of other Members” and that measures not be applied in a manner that constitutes a disguised restriction on international trade.¹⁸⁸

Article 3 of the SPS requires members to base their SPS measures on international standards, guidelines, or recommendations where they exist.¹⁸⁹ It provides that measures which conform to international standards, guidelines, or recommendations will be deemed as necessary and presumed consistent with both the SPS and GATT in general.¹⁹⁰

The international standards are defined in Annex A, paragraph 3(a), (b), and (c).¹⁹¹ In matters of food safety, the Agreement refers to the work of the Codex Alimentarius Commission (Codex).¹⁹² For animal health and zoonoses, the Agreement refers to the work of the International Office of Epizootics (IOE).¹⁹³ And finally, for plant health, the Agreement refers to the work of the Secretariat of the International Plant Protection Convention (IPPC).¹⁹⁴ In the case of matters not covered by those organizations, the relevant standards can be those promulgated by “other relevant international organizations

¹⁸⁶ *Id.* Annex A, ¶ 1.

¹⁸⁷ *Id.* art. 2, ¶ 2.

¹⁸⁸ *Id.* art. 2, ¶ 3.

¹⁸⁹ *Id.* art. 3, ¶ 1.

¹⁹⁰ SPS Agreement, *supra* note 20, art. 3, ¶ 2.

¹⁹¹ *Id.* Annex A, ¶ 3(a)–(c).

¹⁹² *Id.* Annex A, ¶ 3(a).

¹⁹³ *Id.* Annex A, ¶ 3(b).

¹⁹⁴ *Id.* Annex A, ¶ 3(c).

open for membership to all Members, as identified by the Committee [on Sanitary and Phytosanitary Measures of the WTO]."¹⁹⁵

Notwithstanding the SPS's aim of harmonization, a member country maintains the right to implement SPS measures that are neither based on, nor exceed, international standards.¹⁹⁶ But in these cases, the measure must be based on a "scientific justification"¹⁹⁷ or "as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.2."¹⁹⁸

Article 5, paragraph 1 states: "Members shall ensure that their sanitary or phytosanitary measures are based on a risk assessment, as appropriate to the circumstances of the risk to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."¹⁹⁹

The SPS provides a list of elements that shall be taken into account in the process of assessing risks: "available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest—or disease—free areas; relevant ecological and environmental conditions; and quarantine or other treatment."²⁰⁰

In the context of risks to human health, the Appellate Body in the *Beef Hormones Case* asserted, regarding this listing:

Some of the kinds of factors listed in Article 5.2 such as "relevant processes and production methods" and "relevant inspection, sampling and testing methods" are not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry or pharmacology. Furthermore, there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list. It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascer-

¹⁹⁵ SPS Agreement, *supra* note 20, Annex A, ¶ 3(d).

¹⁹⁶ *Id.* art. 3, ¶ 3.

¹⁹⁷ *Id.* In paragraphs 174 to 176 of the *Beef Hormones Case* the Appellate Body concluded that the disjunctive "or" created a distinction that may be more apparent than real, basically equating both requirements as entailing a risk assessment. *Beef Hormones Appellate Body Report*, *supra* note 182, ¶¶ 174–76.

¹⁹⁸ SPS Agreement, *supra* note 20, art. 3, ¶ 3.

¹⁹⁹ *Id.* art. 5, ¶ 1.

²⁰⁰ *Id.* art. 5, ¶ 2.

tainable in a science laboratory operating under strictly controlled conditions, but also risks in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.²⁰¹

According to the SPS, the risk assessment must identify: (1) a likelihood of entry, establishment or spread of a pest or disease within a territory or (2) a 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.²⁰²

Aside from these indications, the SPS offers little guidance as to what constitutes an adequate risk assessment. However, in the *Australian Salmon Case*, the Appellate Body established a three-pronged test for satisfactory risk assessment in the context of the first part of Annex A, paragraph 4, referring to measures designed to protect animal life or health from risks arising from pest or disease. The test developed requires that the risk assessment:

(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; (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*.²⁰³

It is significant to note that in both the *Australian Salmon Case* and the *Beef Hormones Case* the Appellate Body has insisted that the risk assessment need not be carried out by the member adopting the sanitary measure and that the SPS measure “might well find its objective justification in a risk assessment carried out by another member, or an international organization.”²⁰⁴

A member can establish a “measure” based on the findings of the risk assessment. But first, the member must determine the level of

²⁰¹ Beef Hormones Appellate Body Report, *supra* note 182, ¶ 187.

²⁰² SPS Agreement, *supra* note 20, Annex A, ¶ 4.

²⁰³ Australian Salmon Appellate Body Report, *supra* note 183, ¶ 121 (emphasis added).

²⁰⁴ Beef Hormones Appellate Body Report, *supra* note 182, ¶ 190; Australian Salmon Appellate Body Report, *supra* note 183, ¶ 122 n.68.

protection it desires against the identified risk, and then the measure that it chooses in order to achieve the level of protection desired.²⁰⁵ The Agreement establishes different requirements for each of these determinations. With regard to the level of protection, the member appears to have significant discretion, but is constrained by at least two provisions of the Agreement.²⁰⁶ First, Article 5.4 states that members should take into account the objective of minimizing negative effects on trade when determining the appropriate level of sanitary and phytosanitary protection.²⁰⁷ Second, Article 5.5 requires a member to be consistent, avoiding arbitrary or unjustifiable distinctions in the levels of sanitary and phytosanitary protection it considers appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on trade.²⁰⁸

The measure that a member imposes in order to achieve its desired level of protection is also subject to various requirements aside from having to be based on a risk assessment. Article 5.6 requires that members ensure that a measure is not more trade-restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection, taking into account the economic and technical feasibility

²⁰⁵ Australian Salmon Appellate Body Report, *supra* note 183, ¶ 200. "The 'appropriate level of protection' established by a Member and the 'SPS measure' have to be clearly distinguished. They are not one and the same thing. The first is an *objective*, the second is an *instrument* chosen to attain or implement that objective." *Id.* (referring to Beef Hormones Appellate Body Report, *supra* note 182, ¶ 214).

²⁰⁶ *Id.* ¶ 125. In the *Australian Salmon Case* the Appellate Body clarified some expressions made by the WTO Panel with regard to a country's determination on level of protection by stating in ¶ 125:

The statement by the Panel quoted above is not appealed, and we merely note that it is important to distinguish—perhaps more carefully than the Panel did—between the evaluation of "risk" in a risk assessment and the determination of the appropriate level of protection. As stated in our Report in *European Communities-Hormones*, 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. (emphasis added).

²⁰⁷ At least one commentator has drawn attention to the fact that the language in this article through the use of the word "should" instead of "shall" seems to "denote a lesser degree of obligatory force." Robert Howse, *Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization*, 98 MICH. L. REV. 2329, 2356 (2000).

²⁰⁸ Beef Hormones Appellate Body Report, *supra* note 182, ¶ 211. Two of the cases examined have referred to this last requirement: The *Beef Hormones Case* at ¶¶ 210–46, where no violation was found; and the *Australian Salmon Case* at ¶¶ 139–78, where the Appellate Body found a violation of Article 5.5. Beef Hormones Appellate Body Report, *supra* note 182, ¶¶ 210–26; Australian Salmon Appellate Body Report, *supra* note 183, ¶¶ 139–78.

of the alternatives. Article 4 of the SPS imposes the obligation upon WTO members to accept the SPS measures of other members as equivalent to their own, if such measures are demonstrated to achieve the appropriate level of sanitary or phytosanitary protection pursued by the importing member's measure. Finally, the *Japan Agricultural Products Case* seems to add an additional requirement with regard to the measure and its relationship to the general obligation in Article 2.2. Seeming to take a stricter stand than that reflected in the *Beef Hormones Case*,²⁰⁹ the Appellate Body determined that, in addition to requiring a rational relationship between the measure and the risk assessment, there must be a rational or objective relationship between the measure and the scientific evidence.²¹⁰ It is important to note that, according to the Appellate Body, all of the requirements mentioned in this paragraph are to be determined on a case-by-case basis.

Up to this point, we have seen two ways in which a WTO member can legitimately establish an SPS measure. The first is by basing its measure on an international standard. The second is by basing its measure on a risk assessment. But there is a third way in which a party can establish a legitimate SPS measure under the agreement, albeit a temporary one. Article 5, paragraph 7 states:

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.²¹¹

In the *Beef Hormones Case*, the Appellate Body was faced with having to determine the relevance of the precautionary principle in the context of the SPS.²¹² The Appellate Body determined that the precautionary principle was reflected in Article 5.7, but at the same time recognized that there was no need to assume that Article 5.7 ex-

²⁰⁹ See *Beef Hormones Appellate Body Report*, *supra* note 182, ¶¶ 192–94.

²¹⁰ See *Japan Agricultural Products Appellate Body Report*, *supra* note 184, ¶ 84.

²¹¹ SPS Agreement, *supra* note 20, art. 5, ¶ 7.

²¹² *Beef Hormones Appellate Body Report*, *supra* note 182, ¶¶ 120–25.

hausted the relevance of the precautionary principle to the SPS. The Appellate Body stated:

We agree, at the same time, with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e., more cautious) than that implied in existing international standards, guidelines and recommendations. Thirdly, a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS Measure may, of course and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risk of irreversible, *e.g.* life terminating, damage to human health are concerned.²¹³

Notwithstanding this explicit recognition of the precautionary principle as embodied in various provisions of the SPS, the Appellate Body was clear in stating that the Principle did not override the provisions of Articles 5.1 and 5.2.²¹⁴ In this context, the Appellate Body seems to recognize that a member country may invoke the precautionary principle when determining its level of protection, as long as a risk has been identified pursuant to Articles 5.1 and 5.2. Furthermore, in the context of the *Japan Agricultural Products Case* and its requirement that a reasonable link exists between the scientific evidence and the measure being employed, the apparent inclusion of the precautionary principle by the Appellate Body in determining whether "sufficient scientific evidence" exists might become increasingly relevant. However, the most important assertion is the recognition that Article 5.7 does not exhaust the applicability of the precautionary principle in the context of the SPS.

But when can Article 5.7 be invoked as sufficient ground for a measure? In the *Japan Agricultural Products Case*, the Appellate Body described four requirements of a measure under Article 5.7 that must

²¹³ *Id.* ¶ 124.

²¹⁴ *Id.* ¶ 125.

be met in order to adopt and maintain a provisional SPS measure. The Appellate Body stated:

Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure if this measure is: (1) imposed in respect of a situation where “relevant scientific information is insufficient”; and (2) adopted “on the basis of available pertinent information.” Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the member which adopted the measure: (1) “seek[s] to obtain the additional information necessary for a more objective assessment of risk”; and (2) “review[s] the . . . measure accordingly within a reasonable period of time.”²¹⁵

The Appellate Body made the following important comments with regard to these requirements. First, it established that the four requirements were cumulative in nature; thus, if one of the requirements was not met, the measure would be inconsistent with Article 5.7.²¹⁶ Second, with regard to the information that a member “shall seek to obtain,” it was determined that this requirement referred to the pursuit of information that would aid in conducting an adequate risk assessment.²¹⁷ And finally, with regard to what constitutes a reasonable period of time, the Appellate Body found that this determination has “to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure.”²¹⁸

IV. DETERMINING SCOPE

An important part of any analysis that aims to identify or resolve conflict among international agreements is determining whether the subject matter—or more specifically, the scope of the treaties—coincide before further determining if the rights and obligations created by the treaties are in any way incompatible. In the context of determining the existence of a conflict between any MEA and the WTO, this analysis is important because it could reveal that there is no

²¹⁵ Japan Agricultural Products Appellate Body Report, *supra* note 184, ¶ 89.

²¹⁶ *Id.*

²¹⁷ *Id.* ¶ 92.

²¹⁸ *Id.* ¶ 93.

shared scope and therefore, no potential for conflict. In the case of the Biosafety Protocol and the WTO trade regime, this analysis is particularly significant because the rights and obligations of the parties and the rigors of the disciplines will vary depending on which WTO subsidiary agreement is used to analyze a measure.

The first and most obvious distinction between the WTO and the Biosafety Protocol is that the former is a trade agreement and the latter is an environmental agreement. The Protocol requires affirmative regulatory action from the parties' governments to ensure that trade in LMOs is adequately regulated in order to protect biodiversity. The WTO requires members to practice restraint from imposing measures that will have an impact on the movement of goods from one member state to another.

Another interesting distinction between trade regimes and environmental regimes is pointed out by authors Brown and Jackson:

The environmental culture contrasts sharply with that prevalent in the trade field. The environmental community is generally an open one that relies on public access to information and is accustomed to demanding public participation (especially by NGOs) in decision-making. Because the public views the environment as "their" issue, governments in the democratic tradition necessarily operate to varying degrees in a transparent fish bowl.²¹⁹

....

By contrast, the trade culture is more closed. Trade matters have been viewed by many governments as being within the exclusive competence of governments The culture surrounding much of trade law, especially negotiations, neither promotes public access to information nor invites public participation by NGOs and individuals in its processes.²²⁰

Indeed, the WTO's lack of transparency and of public participation has been a point of constant criticism by many in environmental and other fields. This is one of the characteristics of the WTO that was at issue in the protests at the 1999 Ministerial Conference in Seattle.²²¹ This lack of transparency and public participation, when coupled with

²¹⁹ Weiss & Jackson, *supra* note 9, at 14.

²²⁰ *Id.* at 16.

²²¹ See Gregory C. Shaffer, *The World Trade Organization Under Challenge: Democracy and the Law and Politics of the WTO's Treatment Of Trade And Environment Matters*, 25 HARV. ENVTL. L. REV. 1, 1-2 (2001).

decisions that impact the environment or health measures, lends itself to even harsher criticism and public mistrust.²²² It is hard to imagine that the WTO will ignore this criticism, which could undermine the credibility and strength of the WTO. These issues should play at least a background role in the task of predicting the outcome of future conflicts that posit multilateral environmental concerns against "free trade."

Although this distinction of general subject matter is important, the fact is that trade and environmental agreements are cognizant of the impact of each regime upon the other. This recognition of "interconnection"²²³ is clearly present in both the WTO's and the Biosafety Protocol's Preambles.²²⁴ This recognized interconnectedness requires moving beyond the general distinction between a trade and an environmental agreement in order to resolve the question of whether these agreements share—at least with regards to some provisions—the same scope.

The Biosafety Protocol's scope—with reference to trade—comprises certain LMOs as they are introduced into international trade. The one undisputed objective of all measures required under the Protocol is to ensure the conservation and sustainable use of biological diversity. As discussed in Part II of this article, whether other objectives such as protecting human health or certain socioeconomic concerns can also be considered stand-alone objectives of a measure under the Protocol is doubtful. Still, this possibility will be considered in the analysis that follows.

The scope of the SPS encompasses a wide array of measures; but two factors limit the scope. First, the measures have to have the objective of protecting either a member's territory, the life or health of an animal or plant, or human life or health.²²⁵ Second, the SPS limits the sources of the threats. For example, the threat to a member's territory is limited to having pests enter, establish, or spread. In the case of human life or health, the threat must arise either from additives, contaminants, toxins, or disease-causing organisms in foods and beverages; from disease carried by animals, plants, or products thereof; or

²²² See Charnovitz, *supra* note 8, at 271.

²²³ Philippe Sands, *Treaty, Custom and the Cross-Fertilization of International Law*, 1 YALE HUM. RTS. & DEV. L.J. 85, 90 (1998).

²²⁴ See GATT, *supra* note 18, pmbl.; Biosafety Protocol, *supra* note 1, pmbl.

²²⁵ SPS Agreement, *supra* note 20, Annex A, ¶ 1.

from the establishment or spread of pests.²²⁶ In the case of animal health, the threat must arise from the entry, establishment, or spread of pests, disease, disease-carrying organisms, or disease-causing organisms; from additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuff.²²⁷ With regard to plants, the risk must also arise from the entry, establishment, or spread of pests, disease, disease-carrying organisms, or disease-causing organisms.²²⁸ This list of measures is most appropriately viewed as a closed list given that the TBT applies only to measures excluded from this list.

Technical regulations affecting “[a]ll products, including industrial and agricultural products” fall within the scope of the TBT.²²⁹ Under the TBT there are no further limitations, except that the measures must not be SPS measures. All other measures relating to traded goods that do not fall into either the TBT or the SPS would fall under the scope of GATT and its three disciplines.

With what WTO agreement does the Biosafety Protocol’s scope overlap? Let us first examine several examples of measures that could be enacted by parties to the Protocol.

Example 1

A country, following the AIA procedure, announces its decision to ban the seeds of a particular strain of LMO-corn. The measure—a product of the Protocol’s procedures—will probably set out as its objective the conservation of biodiversity. Notwithstanding this objective, a closer look at the reasons for the ban might reveal that the risk assessment identified a risk that this particular strain of LMO-corn would accelerate the process by which certain insects create resistance to existing pesticides. This, in turn, could create a pest problem for the country, threatening the local crops.²³⁰

This is one of the best examples that could be given to support the proposition that measures taken under the Protocol would fall

²²⁶ *Id.* Thus, for example, threats to human health or life from a pharmaceutical or from toxins and contaminants not contained in food, beverages, plants, or animals are not included under the scope of the SPS.

²²⁷ *Id.*

²²⁸ *Id.*

²²⁹ TBT Agreement, *supra* note 19, art. 1.3.

²³⁰ See, e.g., ENVIRONMENTAL PROTECTION AGENCY, BT PLANT-PESTICIDES BIOPESTICIDES REGISTRATION ACTION DOCUMENT § IID1, ¶ 1 (recognizing the possibility of certain Bt Crops increasing insect resistance to pesticides), available at http://www.epa.gov/oscpmont/sap/2000/october/brad4_irm.pdf (last visited Mar. 26, 2003).

under the scope of the SPS. This measure would seem to fit nicely into the definition of an SPS measure under the objective of “protecting plant health” from “pests.” But fitting this measure under the scope of the SPS would require substituting the country’s stated objective for one which fits the SPS’s, ignoring the true purpose of the measure as an environmental and ecological one.

The WTO Secretariat, in a booklet describing the different Uruguay Round Agreements, states that measures for environmental protection other than those specifically defined in the SPS are not covered by the agreement and are more appropriately addressed under the TBT or Article XX of GATT 1994.²³¹ A review of the examples given of measures protecting plants against pests also reveals a more direct association between the pest and the measure under the scope of the SPS, *i.e.*, the measure’s traditional intent is not to let pests that may be “hitching a ride” on foreign products into the country.²³²

Example 2

A party to the Protocol bans a particular LMO-cotton crop that is found—by a risk assessment—to present a threat to the health of microorganisms in the soil, such as bacteria and fungi. These microorganisms are not only helpful to the local plant life, but are also in themselves valuable for their genetic characteristics and as part of a delicate ecosystem.²³³

Should a measure banning this particular LMO-cotton with the objective of protecting biodiversity be considered an SPS measure? One alternative would be to consider it a measure to protect plant life, but if the real threat identified in the risk assessment was to the microorganism itself, could the microorganism be considered an animal as defined in the SPS? The word animal in the SPS is footnoted to clarify that it includes fish and wild fauna, but does it include microorganisms?²³⁴ Finally, from what SPS-recognized threat would

²³¹ WTO, THE WTO AGREEMENTS SERIES 4 SANITARY AND PHYTOSANITARY MEASURES 9 (1998).

²³² *Id.* at 13-15. The examples given of measures include: “plant . . . quarantine”; “regulation on treatment of imported fruit to prevent pests spreading.” *Id.*

²³³ See generally Soil Association, *Soil Biodiversity: Briefing Paper*, (Jan. 2002), at <http://www.soilassociation.org/web/sa/saweb.nsf/home/index.html> (discussing the importance of biodiversity for soil organisms) (last visited Apr. 4, 2003).

²³⁴ It is significant to note that the International Animal Health Code prepared by the IOE—referred to in the SPS as the recognized international standard-setting body with regard to animal health—applies only to mammals, birds and bees. A separate IOE code refers to aquatic animals. See David G. Victor, *The Sanitary and Phytosanitary Agreement of the*

the measure be protecting the microorganism: disease-carrying organisms, or contaminants and toxins in the microorganism's "food"?

Example 3

In compliance with Article 18 of the Protocol, an importing party requires that certain documentation accompany shipments of LMOs whether they be LMO-FFPs, LMOs for contained use, or LMOs for introduction into the environment.

As stated in Part II of this article, these requirements, which refer primarily to information that must accompany the shipments of LMOs, are not akin to product labeling requirements. These requirements are limited to that information which an importing party would need to know in order to meet the objectives of the Protocol. For example, a party would need to know information relating to the nature of the product or shipment including whether they are LMOs or whether the shipment may contain LMOs. These documents must also dictate whether particular precautions should be taken to ensure the safe handling and transport of the LMO before it reaches its intended destination, *i.e.*, a supermarket, processing plant, laboratory, or farm.²³⁵ These requirements could fall under the scope of the TBT and its definition of technical regulations described as "administrative provisions, with which compliance is mandatory,"²³⁶ and which include provisions that deal with the terminology, marking, and labeling requirements applicable to products.²³⁷ Unless, of course, these requirements form a part of a measure whose objective is covered by the SPS. We then return to the debate of examples 1 and 2. Still, in this example, there is an additional consideration (that the Protocol does not require a particularized risk assessment for these measures) which will apply equally to all LMOs according to their intended uses. Absent this risk assessment, it is less feasible to locate an alternate objective and threat that will fit the SPS other than the stated objective of avoiding "adverse effects on the conservation and sustainable use of biodiversity."²³⁸

World Trade Organization: An Assessment After Five Years, N.Y.U. J. INT'L & POL. 865, 892 (2000). Since none of the IOE standards seem to apply to microorganisms, or insects for that matter, a situation like the one mentioned in this example would have no recourse to a set international standard.

²³⁵ Biosafety Protocol, *supra* note 1, Annex II.

²³⁶ TBT Agreement, *supra* note 19, Annex I.

²³⁷ *Id.*

²³⁸ Biosafety Protocol, *supra* note 1, art. 1.

These examples illustrate the fact that biosafety matters regarding biodiversity are not part of the affirmed scope of the SPS.²³⁹ Biodiversity is a distinct environmental concern that transcends typical sanitary and phytosanitary concerns. According to the definition of biodiversity in the CBD, this term focuses on the diversity among genes, the diversity among and within species, and the diversity among and within ecosystems.²⁴⁰ This last concept of ecosystem biodiversity is significant because it is not necessarily concerned with quantity, but instead with interconnections. In other words, ecosystem biodiversity is not solely centered around the extinction of one genetically unique organism, but around the effects that extinction (or increase or decline) of an organism can have on the remaining environment. Thus, the question of whether a ban undertaken by a party to the Protocol with the objective of conserving biodiversity should be considered an SPS measure must be addressed seriously.

It is unclear how the WTO will classify measures whose objective is biodiversity conservation. Is the objective of conserving biological diversity analogous to protecting human, plant or animal life; or is it more akin to the objective of conserving limited natural resources (GATT XX(g)); or is it similar to the objective of protecting the environment expressly stated in Article 2.2 of the TBT?

This analysis does not lead to the conclusion that a ban under the Protocol would escape WTO rights and obligations, but it does indicate the need to consider that these measures may be more appropriately situated under the scope of the TBT or the general GATT disciplines. The following analysis is necessary in the event that, under an alternative interpretation of the Biosafety Protocols' scope, a ban could be based on only the objectives of protecting human health or protecting certain socioeconomic considerations of developing countries.

In the case of a ban based on a human health risk identified by a risk assessment, various questions also arise with regard to the scope of the SPS. In order to come within the scope of the SPS, the LMO itself—or the change introduced by modern biotechnology into an

²³⁹ In fact, whether the SPS is the agreement that applies or should apply to measures concerning LMOs in general is also a disputed matter. See Charnovitz, *supra* note 8, at 276–77 (citing U.S. Statute, Trade and Development Act of 2000, Pub. L. No. 106–200, which contains a provision in section 409(b)(4) establishing as one of the U.S. objectives in WTO trade negotiations to affirm that SPS applies to new technology, including biotechnology); see also Cors, *supra* note 8, at 30.

²⁴⁰ CBD, *supra* note 2, art. 2.

organism—would need to be considered an additive, contaminant, toxin, or disease-causing organism. In the *Beef-Hormones Case*, the Appellate Body seemed to accept that a hormone (be it natural or synthetic) introduced into an animal destined to become food fell into one of these categories. But this situation is still distinguishable from a determination that an introduced gene can also be considered under one of these categories. In a case such as this, in which the clear objective of a measure is the protection of human health and not the conservation of biodiversity, it will be more difficult to argue that such a measure does not fall under the scope of SPS disciplines. Still, it is important to note that if the risk identified came from the handling of, or certain contact with, an LMO not related to its use as feed, beverage, or feedstuff, the measure would not come under the SPS's scope.

A measure that bans an LMO with the objective of preventing an adverse socioeconomic impact is clearly not an SPS measure. The possibility of a measure such as this emerging from the Protocol without a prior finding of a threat to biological diversity is improbable.²⁴¹ Furthermore, the text of the Protocol specifically states that consideration of socioeconomic impacts may be taken into account but only in a manner "consistent with their international obligations."²⁴² Therefore, this will definitely not be a situation for which the Biosafety Protocol could be credited with creating a right or obligation that conflicts with its parties' other international obligations.²⁴³

But, given the fact that there are instances in which measures taken pursuant to the Biosafety Protocol could arguably come under the scope of the SPS or the TBT and GATT disciplines, further analysis is required to identify the possibility of conflict. It is important to note that two treaties may share the same scope yet not result in a conflict. For a conflict to exist, the rights and obligations of the parties to both international agreements must be in contradiction. Indeed, in the scenario of a conflict among rights and obligations of the parties to both international agreements, the controversial preambular language requires consideration.

²⁴¹ See discussion *supra* Part II.

²⁴² Biosafety Protocol, *supra* note 1, art. 26.

²⁴³ But see Article 12.4 of the TBT, which appears to provide an alternative to some developing countries concerned with the economic dependence that could arise from the introduction of certain types of LMOs into their existing agricultural arrangements. TBT Agreement, *supra* note 19, art. 12.4.

Before dealing with this scenario, it is helpful to begin with the analysis of a situation in which a transboundary movement of LMOs will take place between an importing country that is a member of the WTO and a party to the Biosafety Protocol, and an exporting country that is a member of the WTO but not a party to the protocol. The reasons for beginning with this scenario are twofold. First, the WTO rights and obligations of both parties with regard to one another undoubtedly remain intact. Thus, if under this analysis there appears to be no conflict among the rights and obligations of the agreements, the analysis of the same situation but among parties to the Protocol is practically unnecessary and is an interpretation of the preambular language. Second, this scenario is most likely to give rise to a confrontation, given the fact that many LMO exporting countries seem reluctant to sign or ratify the Protocol.

V. COMPARING RIGHTS AND OBLIGATIONS AMONG MEMBERS OF THE WTO, ONE OF WHICH IS NOT A PARTY TO THE BIOSAFETY PROTOCOL

The only obligation that affects trade in LMOs between parties to the Protocol and non-parties is that transboundary movement among the two be conducted in accordance with the objective of the Protocol, as stated in Article 24.²⁴⁴ Complying with the Article 1 objectives²⁴⁵ would mean establishing a set of measures that would ensure an adequate level of protection to the conservation and sustainable use of biodiversity from adverse effects resulting from the introduction of LMOs into the environment of the importing country, in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration. The Protocol provides ample room for negotiating an agreement between a party and a non-party that would satisfy both sides and thus, avoid any confrontation under the WTO.²⁴⁶ But, notwithstanding this situation, it would also be possible for an importing country to determine that the simplest way to ensure compliance with the objectives of the Protocol is to conform all transboundary movement of LMOs to the Biosafety Protocol's specific pro-

²⁴⁴ Article 24(1) of the Protocol, referring to non-parties, states: "Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements." Biosafety Protocol, *supra* note 1, art. 24(1).

²⁴⁵ See *supra* text accompanying note 12.

²⁴⁶ Biosafety Protocol, *supra* note 1, art. 24(1).

visions.²⁴⁷ As an importing country, this could mean that the party to the Protocol may require both parties and non-parties: (1) to conform to the provisions on notification and approval prior to a transboundary movement; (2) to prohibit the entrance of a certain LMO under Article 10; and (3) to establish measures to comply with Article 18 on identification of imported LMOs. These examples adequately represent the range of measures that could require analysis under the WTO disciplines.

A. *Requiring an AIA*

The AIA procedure is a requirement that previous authorization be obtained from the importing party prior to the export of certain LMOs. As detailed in Part II of this article, the AIA procedure provides certain time constraints in order to reduce the effects such a measure could have on trade. The procedure, as set out in the Protocol, is also restricted to the first introduction of any particular LMO into the importing country, which further limits its effect on trade. The AIA procedure is also similar to the prior informed consent procedure found in other environmental treaties. It is significant that this procedure has not found its way into the ongoing debate of MEA measures and their compatibility with trade disciplines.

Nevertheless, at least one commentator has suggested that the AIA procedure itself might be subject to WTO discipline, particularly the SPS. Still, most commentators simply do not consider the AIA procedure to be worrisome with regards to WTO trade disciplines.²⁴⁸ One of them suggests that this type of measure would not be subject to the same rigors as other more trade-restrictive measures.²⁴⁹

It is interesting to note that the SPS itself asserts in the last paragraph of Annex C(1):

²⁴⁷ It would be hard for a party to argue that compliance with the specific provisions of the Protocol is the only way to comply with the Protocol's objective because this interpretation would render Article 24, an operative provision of the Protocol, superfluous. In fact, the recognition of alternative ways of achieving the objectives of the protocol can be found in various provisions of the Protocol allowing parties to agree to or inform that an alternative procedure than that provided by the protocol will be used. *See id.* arts. 2(4), 9(2)(c), 9(3), 11(4), 13, 14.

²⁴⁸ Schoenbaum, *supra* note 8, at 37.

²⁴⁹ Bernasconi-Osterwalder, *supra* note 8, at 712 (pointing out that she had found no evidence that the negotiating parties to the Protocol expressed any concern that the AIA procedure as such was WTO inconsistent).

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feed stuffs which prohibits or restricts access to its domestic market for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.²⁵⁰

This provision would seem to recognize, albeit in the context of food, beverages, or feed stuffs, the right of member countries to establish mechanisms such as the AIA before reaching a final determination on the product's entry. Significantly, the Article merely suggests that a member could consider referring to relevant international standards as a basis for access while the final determination is being made.

This analysis leads me to conclude that the AIA procedure should more adequately be considered as the background procedure upon which certain measures are taken. This is not to say that the procedure could not be abused and lead, for example, to a *de facto* ban of certain LMOs. But this sort of situation would not be created as a result of the obligations imposed by the Biosafety Protocol on its parties and thus, any violation of WTO disciplines would not be the result of a conflict between the Protocol's rights and obligations and those of the WTO.

B. *Imposing a Ban on an LMO*

The second measure to be analyzed is a determination, by a party to the Protocol, to prohibit or ban a certain LMO from being imported. It is important to remember the following aspects of a ban pursuant to the Biosafety Protocol: first, that a ban, although permitted by the Protocol, is not specifically required; second, that any determination regarding the import of an LMO, including a ban, must be preceded by a risk assessment carried out in a scientifically sound manner;²⁵¹ third, that a determination to ban a product must set out the reasons on which this decision is based;²⁵² fourth, that although a ban could be a result of the application of the precautionary principle, as established in Article 10(8), this Article requires a prior deter-

²⁵⁰ Biosafety Protocol, *supra* note 1, Annex C(1).

²⁵¹ *Id.* art. 10(1), 15(1).

²⁵² *Id.* art. 10(4).

mination of a potential adverse effect; finally, that the measure banning a LMO must also be consistent with Article 16(2) of the Protocol which states that such measures should be applied to the extent necessary to prevent adverse effects on biodiversity.

This article will first discuss a ban under the more rigorous SPS discipline. Although, as was indicated previously, scope must be carefully contemplated before reaching the conclusion that any measure under the Biosafety Protocol should be considered as falling under the scope of the SPS.

1. A Ban and SPS Disciplines

The simplest and most desirable way of ensuring compliance with the SPS disciplines is to compel a member to base its measure on international standards. Thus, if the banning of a certain LMO was based on an international standard, guideline, or recommendation, no incompatibility should exist between the ban and the SPS obligations. However, in the case of the SPS, only three international organizations have been recognized as providers of standards: the Codex, the IOE, and the IPPC.²⁵³ The Codex establishes standards with relation to the quality and safety of food.²⁵⁴ The IOE establishes veterinary regulations designed to prevent the spread of transmissible diseases to animals and to human beings.²⁵⁵ The IPPC aims to provide standards for measures to protect plant resources from harmful pests.²⁵⁶ Commentator Cors, citing documentation prepared by the BSWG, has pointed out that none of these organizations have specific coverage of biosafety concerns and their dealings with LMOs is, at best, incidental to their objectives.²⁵⁷ If WTO members are intent on

²⁵³ SPS Agreement, *supra* note 20, art. 12(3).

²⁵⁴ It is interesting to note that with regard to food derived from biotechnology, a task force of the Codex has recently agreed on a final draft of principles for the risk analysis of foods derived from biotechnology. The agreement is also said to mark a breakthrough in international negotiations concerning the use of tracing systems in relation to food in international trade. Joint Press Release, Food and Agriculture Organization of the United Nations, *Codex Task Force Agrees on Final Draft of Principles for the Evaluation of GM Foods* (Mar. 8, 2002), available at http://www.fao.org/WAICENT/OIS/PRESS_NE/english/2002/3060-en.html.

²⁵⁵ See Office International des Epizooties, *To Guarantee the Sanitary Safety of World Trade by Developing Sanitary Rules for International Trade in Animals and Animal Products* (last updated Apr. 22, 2002), at http://www.oie.int/eng/OIE/en_securite.htm.

²⁵⁶ See International Plant Protection Convention, Apr. 3, 1952, 23 U.S.T. 2767, 150 U.N.T.S. 67, art. 1, ¶ 1 (as amended Nov. 17, 1997) [hereinafter IPPC].

dealing with Biosafety measures under the SPS, it might be wise for the SPS Committee to recognize the Biosafety Protocol as the standard-setting body in this area. Still, given that the SPS Committee's determinations require consensus,²⁵⁸ and given the controversies surrounding trade in LMOs, it is difficult to envision the United States allowing for such consensus to form.

Moreover, at least one of these organizations, the IPPC, has been actively coordinating its work with the Convention of Biodiversity and, in particular, with the Biosafety Protocol.²⁵⁹ Thus, another possibility is that, to the degree in which these organizations could overlap with the Protocol, their standards will reflect those considered appropriate by the Protocol. Such organization could, in some circumstances, justify measures taken pursuant to the Protocol based on the recognized international standards.

In the short run, however, if a party to the Protocol establishes a ban, it would likely need to satisfy the requirements of Article 3.3 of the SPS which, as was discussed previously, requires compliance with Articles 5.1 and 5.2 on risk assessment.²⁶⁰ With regard to risk assessment, the strictest requirements appear to accompany risks from pests or disease that can affect plants or animals. Thus, this article will analyze the ban under these requirements, as stated in the *Australian Salmon Case*.²⁶¹ The requirements for a risk assessment under this case find their equivalents in the risk assessment procedure of the Protocol as laid out by its Annex III. For example, Annex III requires: (1) "identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse

²⁵⁷ Cors, *supra* note 8, at 34–35. This limited scope of the international organizations referred to in the SPS could also be significant in the analysis about scope carried out in Part IV of this article.

²⁵⁸ SPS Agreement, *supra* note 20, art. 12.1.

²⁵⁹ See Food & Agricultural Organization of the UN (FAO), *FAO Helping the Consumer and Protecting the Environment Through Food Quality Control and Plant Protection: Codex Alimentarius/ International Plant Protection Convention*, at <http://www.fao.org/WorldFoodSummit/sideevents/papers/Y6823e.htm> (last visited Apr. 18, 2003) ("Many components of the IPPC are directly related to elements of the Convention on Biological Diversity (CBD) and the Cartagena Protocol, including work on invasive species and genetically modified organisms. As a consequence, the CBD and IPPC are establishing a close collaborative relationship to ensure consistency."); see also International Centre for Trade & Sustainable Development (ICTSD), *FAO Plant Health Commission to Build Bridges Between WTO and CBO*, ICTSD BRIDGES: WEEKLY TRADE NEWS DIGEST, Apr. 10, 2001, at <http://www.ictsd.org/html/weekly/10-04-01/story5.htm> (last visited Apr. 18, 2003).

²⁶⁰ SPS Agreement, *supra* note 20, art. 3.3.

²⁶¹ See *supra* text accompanying note 203.

effects on biological diversity in the likely potential receiving environment";²⁶² (2) "evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism";²⁶³ (3) "evaluation of the consequences should these adverse effects be realized";²⁶⁴ and (4) "recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks."²⁶⁵

Thus, it would be difficult to argue that a risk assessment carried out pursuant to the Biosafety Protocol would not satisfy the requirements of an "adequate" risk assessment by the SPS. Once the risk assessment procedure has determined the likelihood of a risk, then the importing country must determine its adequate level of protection and it may determine, pursuant to the precautionary approach, that it should set its level of protection at "zero risk."²⁶⁶ This result would not violate any of the party's obligations under the SPS. The importing party can prohibit the import of a particular LMO in order to achieve its desired level of protection. The measure, in this case the ban, would need to comply with the party's other SPS obligations. Such obligations include not being more trade restrictive than necessary—taking into account the technical and economic feasibility of the alternatives—and accepting other members' measures as equivalent. Again, there appears to be no evident conflict between these obligations and those of the Protocol, if the desired level of protection is met.

Still, absent adequate information on which to base a risk assessment, a determination to ban might also be a result of a country wanting to extend protection of biodiversity beyond what is specified in the Protocol. This action, although recognized as a right under Article 2(4) of the Protocol, is restricted by this same Article to actions consistent with the party's other obligations under international law. Thus, the importing party, which under this scenario is also a member of the WTO, could exercise its right under Article 5.7 of the SPS in order to ban a product when relevant scientific information is insufficient to carry out a proper risk assessment.

²⁶² Biosafety Protocol, *supra* note 1, Annex III(8) (a).

²⁶³ *Id.* Annex III(8) (b).

²⁶⁴ *Id.* Annex III(8) (c).

²⁶⁵ *Id.* Annex III(8) (e).

²⁶⁶ See *supra* note 206.

In this case, once more, no conflict would arise between the importing party's rights and obligations under the Protocol and its obligations under the SPS. A ban imposed pursuant to Article 5.7 would need to satisfy the requirements of this Article as expressly laid out in the *Japan Agricultural Products Case*.²⁶⁷ With regard to these requirements, one commentator has stated:

To adopt such a provisional measure, a Member has the obligation to seek additional information and to review the measure within a reasonable period of time. The latter requirement leaves much room for interpretation. In the young field of biotechnology, the "reasonableness" of duration should be longer than in the context of older methods and technologies where long term effects are better known.²⁶⁸

Due to the fact that some cases of present and future LMOs could conceivably lack sufficient scientific information on which to base an adequate risk assessment, this Article could be useful.

The second scenario that will be examined is the compatibility of a ban of an LMO pursuant to the Protocol with the obligations of the TBT.

2. A Ban and TBT Disciplines

The TBT also pursues the goal of harmonization through the use of relevant international standards, but unlike the SPS, it does not provide for any particular international organization as the recognised standard-setting body in any field. Thus, a ban established pursuant to the procedures set out in the Protocol possibly could benefit from the presumption in Article 2.5 of the TBT that it is not an unnecessary obstacle to international trade. Different from the case under the SPS, the only apparent requisite for an international organization or agreement to be considered a standard-setting body is that its membership be open to the relevant bodies of all WTO members.²⁶⁹ Therefore, there appears to be no impediment, under the TBT, for the Biosafety Protocol to become the standard-setting body with regards to technical regulations referring to LMOs that may have an impact on biodiversity.

²⁶⁷ See *supra* text accompanying note 215.

²⁶⁸ Bernasconi-Osterwalder, *supra* note 8, at 720.

²⁶⁹ TBT Agreement, *supra* note 19, Annex 1 (4).

Aside from this possibility, a ban pursuant to the Protocol simply would not appear to conflict with any of the obligations of the TBT. First, the ban's objective would probably best be catalogued as that of protection of the environment, an objective expressly recognized in TBT's Article 2.2. Nevertheless, the conservation and sustainable use of biodiversity, an objective not only of the Protocol but also present in the CBD—which actually has more parties than the WTO—could also be considered a separate legitimate objective in the open ended listing of the TBT. Second, the risk assessment procedure provided in the Protocol would, in all probability, be considered adequate under the TBT. The TBT has very few indications as to what needs to be considered in an adequate risk assessment; but, for example, two of its mentioned considerations, *scientific information* and a *products' end uses*, are integral parts of the Protocol's risk assessment.²⁷⁰

Still, particular attention should be given to the requirement in Article 2.1 with regard to like products. As Parts I and II of this article demonstrate, the first major obstacle the Biosafety Protocol faced was certain countries objecting to distinguishing LMOs from other organisms modified through more traditional methods. This debate, although arguably resolved with the approval of the Biosafety Protocol, could potentially resurface in the context of the WTO.

The *Asbestos Case* requires examination of four characteristics of the product to determine if two products are alike in the context of the WTO non-discrimination disciplines.²⁷¹ At least two of these characteristics could strongly support a finding that they are not alike. The first characteristic is the physical properties of the products. In the case of most LMOs, it is precisely a change in a physical property that is purposely created to make the product more attractive to certain needs of farmers or consumers. Additionally, the fact that, for example, both an LMO cotton seed and its non-LMO counterpart can be used for the same end-uses has been termed irrelevant in the analysis of this first criterion by the *Asbestos Case*.²⁷² The Appellate Body also determined that health risks related to the physical properties of the product were appropriately considered under this criterion. Arguably, the same could be said about environmental risks. Thus, it would be difficult to imagine an LMO that would not be considered as distinguishable from its non-LMO counterparts based on its physical prop-

²⁷⁰ Biosafety Protocol, *supra* note 1, Annex 3.

²⁷¹ See *supra* text accompanying note 156.

²⁷² Asbestos Appellate Body Report, *supra* note 154, ¶23.

erties. The second characteristic is the characteristic of consumer tastes and habits; this characteristic could be particularly significant in the case of LMOs in that they have created such a polemic among consumers. In most cases, an analysis of this criterion should also render sufficient reason not to consider the products alike.

The TBT would also require that a ban be eliminated if the circumstances or objectives that gave rise to its adoption no longer existed. Again, this obligation does not conflict with a party's obligations under the Protocol. In fact Article 12(2) of the Protocol specifically provides for the review of decisions, such as a ban of an LMO, in light of additional relevant scientific information that had not previously been considered in the risk assessment, or due to a change in the circumstances, that led to the imposition of such a measure. Finally, and as was the case with a similar requirement by the SPS, the requirement that equivalent measures by other members be considered as sufficient, if adequate to meet the desired level of protection, is not in conflict with any Protocol obligation.

Lastly, this article will examine the possibility that a ban may be considered under the general GATT discipline.

3. A Ban and GATT Disciplines

None of the obligations of the Biosafety Protocol require a party to establish measures that discriminate among local and foreign LMOs or LMOs exported by different countries. Thus, again, there is no conflict between the Article I and Article III obligations of an importing party and the obligations under the Protocol of such parties.

But even if the ban were considered a violation of Article XI, which prohibits quantitative restrictions to trade, it could likely find refuge under Article XX(g). In this hypothetical situation, a ban has been placed on a specific LMO after a risk assessment had identified the likelihood of it having an adverse effect on the conservation or sustainable use of biodiversity. Therefore, the ban is a measure "related to the conservation of exhaustible natural resources."²⁷³ Admittedly, fitting a ban, pursuant to the Protocol, under the exception of Article XX(g), would require interpreting biodiversity as an exhaustible resource. The WTO has already determined that dolphins, salmon and clean air are examples of natural resources.²⁷⁴ These determinations, coupled with the fact that there exists an international recogni-

²⁷³ GATT, *supra* note 7, art. XX(g).

²⁷⁴ See *supra* note 161.

tion by the CBD that biodiversity is an exhaustible resource (hence the need to conserve it), make it difficult to imagine the WTO reaching any other conclusion. Still, after fitting under the exception of Article XX(g), a party to the Protocol (who is a member of the WTO) is still under the obligation of the "Chapeau" to ensure that its measure is not an arbitrary or unjustifiable discrimination between countries where the same conditions prevail, nor that it constitutes a disguised restriction on trade.²⁷⁵ Commentators Gaston and Abate have provided a persuasive analysis of why a determination to implement a ban, or any other measure, pursuant to the Protocol would satisfy these obligations. Regarding the obligation against arbitrary and unjustifiable discrimination, they have signaled various Protocol provisions that guard against it. For example, Articles 24 and 14 of the Protocol guard against the possibility of a party to the Protocol establishing an agreement with less restrictive terms towards one country, and more restrictive terms towards another.²⁷⁶ Furthermore, there are various provisions throughout the AIA procedure²⁷⁷, and in the Clearing-House mechanism, that provide transparency to all measures instituted pursuant to the Protocol, and guard against a determination that any such measure is arbitrary.²⁷⁸

The Biosafety Protocol also guards against "disguising restrictions on trade" by requiring the disclosure of information regarding the importing party's laws, regulations, and decisions relating to its imports of LMOs, to exporting countries through the Biosafety Clearing-House.²⁷⁹ Gaston and Abate state, provided countries adopt measures pursuant to the Protocol, the Clearing-House mechanism—and the requirement that all measures necessitate prior risk assessment, as

²⁷⁵ GATT, *supra* note 7, art. XX.

²⁷⁶ Gaston & Abate, *supra* note 8, at 145.

²⁷⁷ Gaston & Abate state:

[T]he Biosafety Protocol, through its AIA process, not only requires notification from the exporting countries of certain LMO transactions, but also requires "acknowledgement of receipt of notification" from the importing country. Moreover, the Biosafety Protocol establishes a "decision procedure," which lays out a structure for accepting or denying imports. Once a decision is made, or anytime thereafter, an importing country may change its decision "in light of new scientific information on potential adverse effects on . . . biodiversity" and an exporting country may, at any time, request that the importer review its prior decision.

Id. at 146.

²⁷⁸ *Id.* at 145-46.

²⁷⁹ Biosafety Protocol, *supra* note 1, art. 20.

well as the required notification to the exporting country of the reasons behind a decision—make it hard to argue that the Protocol would allow disguised restrictions on trade.²⁸⁰

Based on this analysis, it is again difficult to find that a conflict exists between the rights and obligations of the GATT and those of the Biosafety Protocol.

C. Handling, Transport, Packaging, and Identification Requirements

Per the analysis conducted in Part IV of this article, it is hard to envision the measures required under Article 18 of the Protocol as coming within the scope of the SPS. Still these requirements do seem to fall comfortably within the scope of the TBT. As discussed previously, there would seem to be no obstacles for the requirements of Article 18, and any subsequent standards agreed to by the “COP serving as the meeting of the Parties to the Protocol,” to become the applicable international standard with regard to the handling, transport, packaging, and identification requirements of transboundary movements of LMOs. The possibility of conflict with TBT obligations would therefore be substantially reduced. Nevertheless, an analysis of the requirements of Article 18—as they were discussed in Part II—reflect that they are directly related to the objectives of the Protocol, which, as stated before, should be considered a legitimate objective under the TBT.

VI. CONFLICT BETWEEN MEMBERS OF THE WTO BOTH OF WHICH ARE PARTIES TO THE BIOSAFETY PROTOCOL

The Vienna Convention on the Law of Treaties²⁸¹ (VCLT) states, (in Article 30 paragraph 3) with regard to successive treaties relating to the same subject matter, that “[w]hen all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under Article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the latter treaty.”

Regarding the interpretation of this Article Professor David Wirth has stated:

²⁸⁰ Gaston & Abate, *supra* note 8, 147-48.

²⁸¹ Vienna Convention on the Law of Treaties, May 22, 1969, 1155 U.N.T.S. 332, 81 I.L.M. 679.

In other words, the obligations in international agreements ought to be harmonized where possible to give effect to all commitments simultaneously, an approach that counsels reconciling agreements with each other whenever possible. The obligations stemming from multiple agreements among the same Parties ought to be interpreted against the background of a presumption that gives life to them all, except to the extent that, in the words of the Vienna Convention, those obligations are not "compatible" with each other.²⁸²

The previous sections have exposed a true lack of incompatibility among the rights and obligations of the Biosafety Protocol and the WTO regime. Thus, there would seem to be no need to resort to the specific instructions of Article 30 of the VCLT with regard to conflict. It could also be considered unnecessary to refer to the preambular phrases of the Biosafety Protocol to resolve a conflict that does not exist.

Most preambles are a restatement of the intentions of the parties who have agreed to a particular operative text, and constitute the context in which an agreement should be interpreted. It is in this sense that the three controversial phrases should be analyzed. However, one commentator has argued for a weightier reading of the preamble indicating that the preamble is in effect calling off the effects of Article 30 of the VCLT and referring to Article 31.3. He states:

These two statements appear to cancel one another out to some degree. The matter may be resolved with reference to the Vienna Convention on the Law of Treaties. Article 30 on the application of successive treaties relating to the same subject matter, would not seem to apply in the light of the Preamble which clearly intends both agreements to be regarded on the same level; neither is intended to be superior to the other. Thus, the applicable rule of interpretation would be Article 31.3 of the Vienna Convention, which provides that "[t]here shall be taken into account, together with the context, any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions."²⁸³

²⁸² Wirth, *supra* note 21, at 242.

²⁸³ Schoenbaum, *supra* note 8, at 36.

This interpretation is necessary for the commentator because he finds that the approach required by the precautionary principle in the Protocol is incompatible with SPS's interpreted in the *Beef Hormones Case*. Interestingly, through this interpretation of the preambular language, he arrives at the conclusion that the precautionary principle included in the protocol is supplementing the requirements of the SPS. Cosbey & Burgiel reach a similar conclusion but they do not seem to identify a conflict to begin with.²⁸⁴ They interpret that all rights and obligations of the SPS are in force against a party of the Protocol and that various provisions of the Protocol simply "fill in some of the gaps of the SPS Agreement."²⁸⁵ This interpretation, they believe, "gives real meaning to the preambular recognition that trade and environment agreements should be mutually supportive."²⁸⁶

In fact, it is in tune with this last interpretation that true meaning can be given to the controversial phrases. They are the manifestation of a desire to harmonize and a call to give life to all the agreements. The previous interpretations of the Protocol and the WTO Agreements manage just that. Therefore, it no longer seems like a contradiction to state that the Protocol: recognizes that trade and environmental agreements should be mutually supportive; emphasizes that the Agreement should not be interpreted as changing the rights and obligations of the parties under other international agreements; and understands that the veracity of the previous statements in no way subordinates the Protocol to existing international agreements.

CONCLUSION

The Protocol's negotiators were primarily concerned with filling in regulatory gaps in international law that could allow for biodiversity-related biosafety preoccupations to remain unattended. The BSWG's documentation reflects the fact that the interaction and overlapping of the Protocol's scope with other existing international obligations was constantly being avoided.²⁸⁷ It is also of importance to note that the driving forces behind much of the negotiations were

²⁸⁴ COSBEY & BURGIEL, *supra* note 8, at 11-12.

²⁸⁵ *Id.*

²⁸⁶ *Id.*

²⁸⁷ See, e.g., Documento de Antecedentes sobre Acuerdos Internacionales Existentes sobre Seguridad de la Biotecnología (revisión del documento UNEP/CBD/BSWG/2/3) (*Background Document on Existing International Agreements Related to Biosafety* (revision of UNEP/CBD/BSWG/2/3)), UNEP/CBD/BSWG/3/Inf.2 (June 28, 1997).

developing countries. This fact is relevant because traditionally, developing countries have been suspicious of environmental measures, viewing them as a way of limiting their developmental possibilities and their products' market access. Thus, it seems consistent that an environmental treaty pushed forward by concerns from developing countries would not substantially alter aspects of the existing trade regime which could benefit them.

The 1996 CTE report approved by the Singapore Ministerial Conference, as summarized by Charnovitz, included the following recommendations with regards to the relationship between MEAs and the WTO:

1. The CTE endorses and supports multilateral solutions based on international co-operation and consensus as the best and most effective way for governments to tackle environmental problems of a transboundary or global nature.

. . . .

2. Due respect must be afforded to both WTO Agreements and MEAs.

3. Adequate international co-operation provisions, including among them financial and technological transfers and capacity building, as part of a policy package in MEAs are important to facilitate the ability of governments, particularly of developing countries, to become parties to an MEA

. . . .

4. Trade measures based on specifically agreed-upon provisions can also be needed in certain cases to achieve the environmental objectives of an MEA, *particularly where trade is related directly to the source of an environmental problem*. They have played an important role in some MEAs in the past, and they may be needed to play a similarly important role in certain cases in the future.²⁸⁸

It would seem clear that, consistent with these few recommendations that have emerged from the CTE, the Biosafety Protocol is an example of a treaty that has aimed to create an environmental agreement that is cognizant and supportive of existing trade obligations. Under these circumstances, it truly would be surprising if the WTO, through its Appellate Panel, were to interpret that a measure required by the Protocol violates WTO disciplines.

²⁸⁸ *Critical Guide to WTO's Report*, *supra* note 9, at 351 (emphasis supplied).

The truth is that it is also highly speculative and premature to predict how the WTO will deal with products of modern biotechnology. The LMO or GMO issues are highly divisive and involve concerns, which the WTO is not yet equipped to handle, such as ethical and moral concerns and consumer interests. This uncertainty could, in part, explain why the United States has yet to pursue an action in the WTO against members, such as the European Union, which are enforcing strict restrictions on the trade of LMOs and LMO products.

Finally, although the Biosafety Protocol may not be the treaty that will pit MEAs against the WTO regime, the value of this debate is not necessarily diminished. Any proposal that attempts to make the WTO more MEA-friendly could be beneficial. Particularly because it would prevent the "chilling effect" this type of debate could have on the advancement of multilateral environmental agreements.