The International Regulation of Genetically Modified Organisms: The Conflicts, Comforts and Limits of the Cartagena Protocol on Biosafety.

Ethicist Roger Straughan (1992) writes:

Deliberately to restrict consumers' freedom of choice by not allowing certain products to reach the market place is, in effect, to make value judgments paternalistically on behalf of those consumers. But the validity of a value judgment cannot be tested or established in the same way as a factual statement; the amount of salt in a tin of tuna, for example, can be measured and this factual information conveyed to consumers, but the judgment that tuna ought not to be offered to the consumer because certain methods of tuna fishing are morally wrong is not factual and cannot be proved or disproved by the experts or authorities. …That is not to say that deliberate restrictions of consumer choice may never be justified, but that any proposed restrictions must be scrutinized carefully and that onus of justification rests upon those wishing to impose the restriction and thereby to make a judgment about what is right for other individuals. [1]

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[1] Susanne L. Huttner, "Government, Researchers, and Activists: The Critical Public Policy Interface" in D Brauer ed, *Biotechnology: Legal, Economic and Ethical Dimensions* (Weinheim: VCH, 1995) 460 at 488.

Table of Contents

Part 1: Introduction

Law is one of the main facets in which modern society can prevent the risks of genetic engineering. Today, biosafety instruments represent the primary source of law on modern biotechnology.[2] Still, legal devices fall short when it comes to the unknown impacts of genetically modified organisms (GMOs) on the environment. As alluded to by Ethicist Roger Straughan above, moral, ethical or non-scientific judgments regarding the use of GMOs in the environment cannot be precisely measured, but they do exist. This paper seeks to explore the various ways in which the dichotomy between science and non-science is embodied in the debate regarding the international regulation of GMOs, and in particular, within the Cartagena Protocol on Biosafety.

Biotechnology is one area where domestic differences in regulation have both prevented a common international approach, and triggered political and trade conflicts between nations. The cultural and socio-economic differences between the European Union and the United States, in particular, have created a Protocol that establishes a framework for the future of transboundary LMO transportation, but embodies many compromises. The disagreements between competing nations are conflated by uncertainty regarding the scientific impacts of GMOs on human and environmental health. Risk regulation, whether precautionary or not, has spilled over into commercial and political conflicts.[3]

At the international level, there is no single comprehensive legal instrument that fulsomely addresses all parts of GMO regulation. Rather, there are at least fifteen instruments that are relevant. While this paper will only examine the Biosafety Protocol, a brief note on other instruments is necessary. Some of the major binding instruments include: the United Nations Convention on the Law of the Sea, The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures, and the Convention of Biological Diversity.

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[2] Sujata Dass, Modern Biotechnology: Trends and Principles (Adarsh Nagar: Isha Books, 2004) at 2.
[3] Robert Falkner & Nico Jaspers, "Environmental Protection, International Trade and the WTO" in Ken Heydon and Steven Woolcock, eds, The Ashgate Research Companion to International Trade Policy (Ashgate, 2012) at 7.

The UN Convention on the Law of the Sea indirectly addresses the use of biotechnology. A state has rights over its territorial sea and rights to exploit, manage and conserve natural resources within the exclusive economic zone; this includes the ability to adopt protective measures over the environment.[4] In the event of transit of a potentially harmful LMO substances through the territorial sea or the exclusive economic zone, there can be conflict between a coastal state that wishes to protect its environment from LMOs, and a state wishing to exercise its right of innocent passage.[5] Part XII of UNCLOS emphasizes protection of the marine environment; this can be understood to include protection from adverse effect of the transit of LMOs.[6] The implications of the transboundary movement of LMOs can be drawn even though LMOs are not directly cited.

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures also affects the international movement of LMOs. The scientific basis for the risk analysis under this agreement conflicts with the precautionary approach embedded in the Biosafety Protocol. The Preamble in the Biosafety Protocol gives little assistance in deciding which approach should take precedence. This conflict will be explored in depth in Section 4.3 of this paper.

The Convention on Biological Diversity is the parent Convention to the Cartagena Protocol on Biosafety.[7] The spirit of the objectives set out in Article 1 of the Convention, the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, are translated into the Biosafety Protocol.[8] Only members of the Convention can sign on to the Biosafety Protocol.

The Cartagena Protocol itself is unique. It is the first international agreement to mandate the need for a party of import to authorize the transboundary movement of LMOs

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[4] The United Nations Convention of the law of the Sea, 10 December 1982, 1833 UNTS 397, Parts V and VI.
[5] Ruth MacKenzie et al, *An Explanatory Guide to the Cartagena Protocol on Biosafety*. IUCN, Gland, Switzerland and Cambridge, UK. xvi + 295pp at 37.
[6] *Ibid*.
[7] The Convention on Biological Diversity, 5 June 1992, 1760 UNTS 79 [CBD].
[8] CBD, supra note 7 at Article 1; Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 29 January 2000, 2226 UNTS 208 [The Biosafety Protocol].

based on areas of scientific uncertainty. This paper will address the main areas of the Cartagena Protocol and examine its limits and conflicts in the international sphere.

There are six parts to this paper. Part One examines relevant contextual information. It looks at the meaning of GMO, LMO, and biotechnology and provides a brief social and political context. Part Two looks specifically at the Biosafety Protocol. It discusses the main political players at the negotiations and addresses the highlights of the Protocol: risk assessment, the Precautionary Principle and the Advanced Informed Assessment Procedure. Part Three seeks to analyze the important implications of the Protocol. This includes socio-economic considerations and looks specifically at the science versus non-science dichotomy. Part Four examines conflicting international themes: the EU perspective versus the North American perspective, conflicts with WTO Agreements and the Protocol, and WTO case law that stems from it. Part Five addresses the positive aspects of the Protocol and particular areas of concern. It also looks to potential solutions for the effectiveness of the Protocol. Ultimately, this paper will argue that the effectiveness of the Protocol is severely limited by the one-dimensional scientific examination of risk.

1.1: What are LMOs, GMOs and Biotechnology

GMOs are scientific entities that have taken on a political and colloquial meaning. In essence, the technology allows scientists to detach specific genes or genetic sequences from one cell and transplant it into another.[9] This allows scientists and researchers to give a plant or animal cell certain desired characteristics that it would not otherwise have. [10]

Under the Cartagena Protocol for Biosafety, "biotechnology" refers to any technical application that uses biological systems, living organisms, or derivatives thereof, to make or modify products of processes for a specific use.[11] "Living modified organisms" refers to living organisms that possess a novel combination of genetic material obtained through the

[9] Jonathan H. Adler, "More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol" (2000) Tex. Int'l L.J 173 at 175.
[10] "Frequently Asked Questions," online: Cartagena Protocol on Biosafety < http://bch.cbd.int/protocol/>.
[11] *Ibid*.

use of modern biotechnology.[12] Specifically, modern biotechnology uses the application of in vitro nucleic acid techniques with fusion of cells beyond the taxonomic family to modify natural breeding and selection.[13]

The use of GMOs is still a relatively new science. Their full potential—whether it is negative or positive—has yet to be fully discovered.[14] There is much that is still unknown.

There are some theoretical benefits to the technology. GMOs have the potential to help heighten production in the agricultural setting. The science could help reduce poverty and enhance food security and nutrition.[15] It could introduce resistance to certain pests and diseases without costly purchase inputs, heighten the tolerance of crops to extreme weather conditions, improve nutritional value of some foods and improve durability of foods for shipping. It could also be used to advance new medical treatments and vaccines.[16]

Likewise, there are perceived risks to GMOs. Potential risks include changes in environmental competitiveness, the possibility of negative impact on a non-targeted species and ecosystems and the potential for a crop to become more invasive than the natural strain.[17]

Despite the incomplete scientific, social and economic implications, the agri-biotech industry is thriving and expanding all across the world. Private industry has dominated the research.[18] According to 2010 FAO research, genetically modified crops are now commercially planted on almost 150 million hectares in about 22 countries.[19] This is mainly in corn, cotton, canola, maize and soybean. Internationally, herbicide resistant soybean, insect-resistant maize and genetically improved cotton account for 85 percent of all plantings.[20]

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[12] The Biosafety Protocol, *supra* note 8 at Article 3.
[13] The Biosafety Protocol, *supra* note 8 at Article 3.
[14] Adler, *supra* note 9 at 174.
[15] Dass, *supra* note 1 at 75.
[16] "Frequently Asked Questions," online: Cartagena Protocol on Biosafety < http://bch.cbd.int/protocol/>.
[17] Ibid.
[18] Dass, *supra* note 1 at 70.
[19] "Genetically Modified Crops" online: Food and Agriculture Organization of the United Nations < http://www.fao.org/docrep/015/i2490e/i2490e04d.pdf>, at 313 [GMO].
[20] Dass, *supra* note 1 at 70.

The largest producers and exporters of GM crops are the United States, Canada and Argentina.[21] Mainly, the technologies are proprietary, meaning that they are developed privately and released through licensing agreements.[22] The market for GM products is expanding even though the costs for seeds and technology is high. This is because of low labour costs, low production costs and improved economic gain.[23] The vast expansion of the agri-biotech industry worldwide is growing faster than its international regulation.[24]

In essence, GMOs are not inherently good or bad for human health or the environment.[25] The benefits or damage from genetic technology depends on the specific use to which it is put. This is a political decision that is economically driven.

1.2: Social and Political Context

The political and social context for the use and regulation of GMOs is essential to understanding the trajectory of the Cartagena negotiations and outcomes. Despite the continuing scientific uncertainty regarding the health and environmental effects of GMOs, various political and non-political groups take strong positions for or against the use of GMOs.

Greenpeace International exists on one extreme of the spectrum. This NGO organization warns that genetically modified crops seriously threaten biodiversity, wildlife and sustainable forms of agriculture.[26] In the view of some environmentalists, the biotech industry represents an unfortunate culmination of corporate greed and self-regulation at a significant cost.[27] This overlaps with the a major ethical concern that GMOs accelerate the reduction of plants, animals and microorganisms to mere commercial commodities, bereft of any natural or sacred character. The notion that corporations and large industry can, in effect, own entire species of plant food is troublesome.

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[21] GMO, *supra* note 19 at 313.
[22] *Ibid* at 414.
[23] *Ibid*.
[24] Robert Falkner, "Regulating Biotech Trade: The Cartagena Protocol on Biosafety" (2000) 76 International Affairs 299 at 301 [Falkner, "Regulating Biotrade"].
[25] Dass, *supra* note 1 at 78.
[26] Adler, *supra* note 9 at 173.
[27] Falkner, "Regulating Biotrade", *supra* note 24 at 300.

The biotech industry exists at the other extreme of the spectrum. Proponents of the industry often perceive environmentalist sentiment as nothing more than an impediment to business. Some biotech proponents attack environmental groups as being ill-informed alarmists.[28] Under this school of thought, there is simply no evidence that would warrant environmental or health concerns.

The period of Protocol negotiations saw an emergence of social attitude regarding GMOs. The political context changed substantially between the time of the conference in Cartagena and the completion of the Protocol in Montreal.[29] The public response was demonstrated during the Montreal negotiations, where there was a high turnout of individuals marching peacefully through the streets and waiting outside the negotiation venue overnight.[30] Louise Gale, a member of the Environmental NGO Chapter of the Negotiations, said that the Canadian government had underestimated the huge public concern about GMOs in food in agriculture.[31] She also attests that there was a concern over the national governments role in undermining international efforts to ensure high environmental, health and social protection from the possible dangers of GMO releases.[32] These concerns were enhanced by the publication of scientific studies casting doubts on the safety of some GMOs.[33]

Another escalating trend in the intervening months of the sessions in Cartagena and Montreal was multinational food companies, including Gerber Products Co. and McCain Foods, demanding LMO free ingredients.[34] The scientific uncertainty regarding the safety of GMOs blossomed into a full-scale public concern. "GMO" became a buzzword and much of the public divided between the arbitrary lines of pro-GMO or anti-GMO.

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[28] *Ibid*.
[29] Aarti Gupta, "Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety" (2000) 24 Environment 23 at 27.
[30] Louise Gale, "Environmental NGOs" in Christopher Bail et al, eds, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environmental Development?* (London: Earthscan Publications 2002) 251 at 259.
[31] *Ibid*.
[32] *Ibid*.
[33] Peter Andree, "The Cartagena Protocol on Biosafety and Shifts in the Discourse of Precaution" (2005) 5 Global Environmental Politics 25 at 34.
[34] Gupta, *supra* note 29 at 27.

Environmentalists and food advocates tended to focus on the uncertainties in the field. They advocated a careful approach to the release of GMOs into the global market.[35] For them, internationally importing GMOs could be a large source of undesirable, if not dangerous, products.[36]

Part 2: The Cartagena Protocol on Biosafety

2.1: Major Parties and Perspectives at the Conferences in 1999 and in 2000

Part Two of this paper examines the Cartagena Protocol from its conception to its results. While the first subsection addresses the negotiations, there are four subsequent subsections examining the specific results within the Protocol.

The negotiations for the Cartagena Protocol on Biosafety were long and difficult. The parties originally met in Cartagena and completed the negotiations in Montreal. There were five clearly delineated alliances that emerged during the negotiations: The "Miami Group", consisting of certain agricultural exporting countries including The United States, Canada, Australia, Argentina, Chile and Uruguay; The EU; "The Compromise Group" consisting of Japan, Mexcio, Norway, South Korea and Switzerland (and later joined by Singapore and New Zealand); The Central and Eastern European Countries; and the "Like-Minded Group" consisting of developing countries.[37]

During the negotiation process, two distinct perspectives emerged. Some countries, including some NGOs and representatives from the global South, favoured the use of the Precautionary Principle in the Protocol.[38] They regarded the Precautionary Principle as an integral component to the Protocol. For them, a full analysis of a wide range of economic,

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[35] Peter W.B. Phillips & William A. Kerr, "Alternative Paradigms: The WTO Versus the Biosafety Protocol for Trade in Genetically Modified Organisms" (2000) 34(4) J. World Trade 63 at 64.
[36] *Ibid*.
[37] Gupta, *supra* note 29 at 25.
[38] Andree, *supra* note 33 at 26.

social, health and environmental effects should be completed before LMOs were allowed for transboundary trade.[39] The Precautionary Principle was conceptualized beyond only scientific uncertainty, and permeated into other relevant areas of concern as well.

Another perspective was less focused on the impacts of the LMOs but the restrictions that the Precautionary Principle would put in place. Some viewed the Precautionary Principle as a "thinly disguised" barrier to trade, which should have no place in operational sections in an international environmental treaty.[40] GMO industry representatives and LMO-exporting nations (included in the Miami Group) perceived the Precautionary Principle as a means for simply justifying a science-based risk assessment for the GM products in countries that did not have their own regulatory regime. Thus, for them, the Precautionary approach would potentially dominate the international sphere.

The United States is not a member of the Convention of Biological Diversity, and therefore had no chance to join the Cartagena Protocol. Still, the US remained a dominant voice throughout the negotiation process. Their own regulatory understanding of biotechnology influenced their position. At the time of the Protocol negotiations, the United States had domestically approved several varieties of GMOs for use in agriculture.[41] Approval was based on the organisms being "familiar" and "substantially equivalent" to organisms that were already ordinarily used in the United States.[42] The United States was wary that the Precautionary Principle would be used as a justification for what it perceived to be arbitrary and non-science based restrictions on imports.[43]

The so-called Compromise Group was not so different from the Miami Group during the negotiations. The Precautionary Principle approach proposed by this group would allow the operation of the Precautionary Principle where scientific evidence was insufficient, provided only that they would seek to obtain the additional information necessary for a

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[39] *Ibid*.
[40] Andree, *supra* note 33 at 26.
[41] *Ibid* at 30.
[42] *Ibid*.
[43] Gupta, supra note 29 at 25.

more objective assessment of risk.[44] The objective information must be properly measured within a reasonable amount of time.[45]

The EU was the largest proponent for the Precautionary Principle at the negotiations. In the late 1990s, the EU became the world's key advocate on implementing strict rules on the international trade of GMOs.[46] They fought hard to make sure the Principle remained in the text of the Protocol.[47] They sought to include the Precautionary Principle as a legitimate form of implementing restrictive decisions regarding the importation of LMOs, but they did not want any caveats that were presented in earlier formations of the Precautionary Principle such as cost-effectiveness (in the Rio Declaration) or the "reasonable amount of time" that the Compromise Group was advocating.[48] At base, the EU's main objective was to enshrine the Precautionary Principle as a principle of customary international law.[49] With this objective, the EU took on a major leadership role in the negotiations in Cartagena and Montreal.[50]

The perspective of NGOs is also an important one to consider. By the early 1990s, the environmental community was becoming aware that releases of GMOs into the environment could present serious risks to biodiversity and human health.[51] Although there were no specific incidents involving the international movement of LMOs to that point, the concern was how ecosystems would respond to such genetically enhanced organisms.[52] Environmentalists were concerned about the introduction of traits such as herbicide resistance into the wild and the toxic effects the LMOs would introduce into the food chain.[53] For Greenpeace and other NGOs, the Precautionary Principle should not be

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[44] Andree, *supra* note 33 at 31.
[45] *Ibid*.
[46] Robert Falker, "The Political Economy of 'Normative Power' Europe: EU Environmental Leadership in International Biotechnology Regulation" (2007) 14:4 JEPP 507 at 514 [Falkner, "Political Economy"].
[47] Andree, *supra* note 33 at 32.
[48] Andree, *supra* note 33 at 32.
[49] *Ibid* at 32.
[50] Falkner, "Political Economy", *supra* note 46 at 514.
[51] Gale, supra note 30 at 251.
[52] Kate Cook, "Liability: 'No Liability, No Protocol'" in Christopher Bail et al, eds, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environmental Development?* (London: Earthscan Publications 2002) 371 at 371.
[53] *Ibid*.

subordinate to international trade rules.[54] These parties ultimately decided to support the similar initiatives of the EU.[55]

2.2: Highlights of the Protocol

The Biosafety Protocol was signed in January 2000 and entered into force on September 11th 2003.[56] The ultimate result of the Protocol is to assert that certain classes of LMOs should be assessed for their potential to do harm to the environment and biodiversity before they are imported internationally. Decisions to restrict their import may be taken in cases of scientific uncertainty.[57] The Protocol establishes international rules for trade in LMOs and solidifies the right of importing nations to refuse GMO imports from other nations on environmental or health grounds.[58] Specific organisms that it will govern include seeds for planting, fish for release, or microorganisms for bioremediation.[59]

The Precautionary Principle is a defining feature of the Protocol (discussed more below). It appears in five different areas: the preamble, Articles 1, 10.6, 11.8 and Annex III. Discussed at length below, the Precautionary Principle is the crux of the ideological, cultural and scientific perspectives that the Protocol embodies. To the disappointment of certain southern states and NGOs, however, the Protocol's use of Precaution does not include potential impacts of socio-economic considerations.[60] The relevant risks to be considered in making decisions are environmental and human health related, but not social or economic.

The Protocol also establishes an Advanced Informed Agreement mechanism that requires parties to submit relevant information regarding LMO products they are exporting, ensuring that the importing country has all the necessary information they need to make an informed decision about importation.

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[54] Gale, *supra* note 30 at 251.
[55] *Ibid* at 255.
[56] Thomas Bernauer, *Genes, Trade and Regulation: The Seeds of Conflict in Food Biotechnology* (Princeton: Princeton University Press, 2003) at 144.
[57] The Biosafety Protocol, *supra* note 8.
[58] Falkner, "Regulating Biotrade", supra note 24 at 299.
[59] Bernauer, *supra* note 56 at 144.
[60] Andree, *supra* note 33 at 27.

What Greenpeace International representative Louise Gale describes as "bullying tactics" of the Miami Group at the negotiations helped ensure that a distinction was drawn between LMOs intended for direct use in food, feed or processing, and LMOs meant for the intentional release into the environment. This "compromise" affects labeling. Exporting countries are required only to label shipments of LMOs intended for direct use in food, feed or processing with the declaration that they "may contain" LMOs.[61] The countries do not have to specify which ones may contain the LMOs or which ones may not.[62] For much of the NGO community, the distinction was illogical because agricultural commodities such as grain can be used interchangeably, for seed or for food, feed and processing.[63] The non-labeled commodities could be just as harmful. For many NGO representatives, the distinction signaled the Miami Group's desire to ensure the fewest possible controls on its agricultural exports.[64]

The Biosafety Clearing House mechanism established in the Protocol is another highlight. Article 20 of the Protocol lays out its basic function. Essentially, it facilitates the exchange of information related to LMOs. This includes scientific, technical, environmental and legal information that may be relevant to the Protocol.[65] Its purpose is also to assist parties with Protocol implementation. It acts as an information-sharing forum for the parties of the Protocol. For example, in Article 11, the Protocol states that a party that makes a decision regarding domestic use of an LMO that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the parties through the Biosafety Clearing House.[66] While the Clearing House is an important mechanism for sharing information, it does not include powers for regulation and monitoring.[67]

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[61] Gale, *supra* note 30 at 257.
[62] Gupta, *supra* 29 at 29.
[63] Gale, *supra* note 30 at 255.
[64] *Ibid*.
[65] The Biosafety Protocol, *supra* note 8 at Article 20.
[66] *Ibid* at Article 11.
[67] Thomas Cottier, "Implications for Trade Law and Policy: Toward Convergence and Integration" in Christopher Bail et al, eds, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environmental Development?* (London: Earthscan Publications 2002) 467 at 468.

2.3 Risk Assessment

Risk Assessments are a crucial tool within the Protocol. They can help determine which LMOs will likely cause harm to human health and the environment and which will not. The risk assessment is used in order to analyze the effect the LMO will have on the conservation and sustainable use of biological diversity, taking into account risks to human health.[68] The underlying principle of risk assessment is to prevent harm by identifying the probability that particular hazards will occur.[69]

The approach to risk assessment taken under the Protocol is conservative. According to Article 15, risk assessments must be carried out in a "scientifically sound manner."[70] The scientifically sound manner must be in accordance with Annex II of the Protocol and take into account "recognized risk assessment techniques."[71] In effect, the Protocol seeks actual scientific damage in order to prohibit transboundary movement.

The Biosafety Clearing House released a "Guidance" on risk assessment for LMOs. The Guidance covers a wide range of risk assessment procedures including planning and conducting risk assessment to specific guidance with particular LMOs such as living modified plants with stacked genes or traits and LM plants with tolerance to abiotic stress. In the Guidance document, in the "Overarching Issues in Risk Assessment," the criteria for the quality of scientific information are included. In essence, it says that information of "acceptable scientific quality" should be used. "Data quality should be consistent with the accepted practices of scientific evidence-gathering and reporting and may include independent review of the methods and designs of studies."

2.4: Precautionary Principle

As Falkner and Jaspers note, various governments have responded to systemic uncertainty in different ways. On one hand, regulatory authorities have been reluctant to implement direct action; they follow a "wait and see" approach that delays regulation until

[68] The Biosafety Protocol, *supra* note 8 at Article 15.
[69] Dass, *supra* note 1 at 44.
[70] *The Biosafety Protocol*, supra note 8 at Article 15.
[71] *Ibid*.

sufficient knowledge about risk has become available.[72] Here, scientific research is promoted in order to reduce the uncertainty and accelerate science-based decision-making.[73] On the flip side, authorities can initiate new technologies and regulations despite the uncertainty.[74] This is especially so when the potential harm is perceived as likely to be severe.

The use of the Precautionary Principle in the Cartagena Protocol represents the latter strategy. In some ways, the Precautionary Principle serves as a remedy between the objective and subjective dichotomy: it embraces the uncertainty and advocates actions despite of that uncertainty. Today, the Precautionary Principle is reflected in well over fifty multilateral instruments.[75] It is practically universally accepted as one of the most important principles in international environmental law.[76]

Yet, the Precautionary Approach is still a somewhat contested norm.[77] Some countries, such as the United States, deny that the Precautionary Principle has attained the status as a full-fledged principle of international law. Other countries in the developing world have expressed concerns that the Precautionary Principle could give rise to trade protectionism in environmental disguise.[78]

There are several major areas where the Precautionary Principle has arisen. Most notably is Principle 15 of the 1992 Rio Declaration that states: "where there are threats of serious or irreversible damages, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation."[79] Article 5.7 of the Agreement on the Application of Sanitary and Phytosanitary Measures also embodies the Protocol. The wording is slightly different. It states that in cases where relevant scientific information is not sufficient, a member may provisionally adopt measures based on the available information. In these situations, parties will seek to obtain the additional

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[72] Falkner & Jaspers, *supra* note 2 at 6.
[73] *Ibid*.
[74] *Ibid*.
[75] *Ibid* at 7.
[76] Arie Trouwborst, "The Precautionary Principle in General International Law: Combating the Babylonian Confusion" (2007) 16 RECIEL 185 at 187.
[77] Falkner & Jaspers, *supra* note 2 at 8.
[78] *Ibid*.
[79] CBD, *supra* note 7.

information necessary for a more objective assessment of risk and review the measure within a reasonable period of time.[80]

The Cartagena Protocol includes precaution not only in the preamble, but in the operational parts of the treaty.[81] Rather than simply using the Precautionary Principle as an umbrella principle to be loosely followed, the Protocol sets out a specific framework and operational guidance.[82] As previously mentioned, The Cartagena Protocol mentions the Precautionary Principle in five different areas: the preamble, Articles 1, 10.6 and 11.8 and Annex III. Articles 10.6 and 11.8 state that lack of scientific certainty due to insufficient relevant scientific information and knowledge as to the extent of the possible adverse effects of an LMO on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks of human health, shall not prevent the Party from making a decision, as appropriate, with regard to the import of the LMO.[83] The use of the Precautionary Principle in the Cartagena Protocol, however, is not necessarily a grand acceptance of the Principle into the vast area of biotechnology. It represents an amalgamation and compromise of previous existing formulations and other international agreements.[84]

Since the Principle takes on operational significance in the Protocol, some scholars have argued that the adoption of the Principle here may be the moment where the Precautionary Principle crossed the threshold and became regarded as a principle capable of practical application.[85] For others, the Protocol does not embody a new operational framework, it is still merely a loose general guidance with major implementation issues.[86] Although the principle can be refined, and limits and boundaries can be put around the decision making process, the Precautionary Principle cannot provide a decision-making rule.[87] The debate is an important one because as scholar Robert Faulkner notes: "The

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[80] *Agreement on the Application of Sanitary and Phytosanitary Measures*, 15 April 1994, being part of Annex IA to the *Agreement Establishing the World Trade Organization*, 15 April 1994, 33 ILM 1144 [SPS Agreement].
[81] Falker & Jaspers, *supra* note 2.
[82] MacKenzie, supra note 5 at 462.
[83] The Biosafety Protocol, *supra* note 8.
[84] Gupta, *supra* 29 at 30.
[85] MacKenzie, *supra* note 5 at 463.
[86] Phillips & Kerr, *supra* note 35 at 72.
[87] *Ibid*.

distinction between uncertainty and risk is analytically important in that it demarcates the realm of calculable and controllable risk from the murkier field of uncertain knowledge about risk."[88]

2.5: Advanced Informed Agreement

Prior to the shipment of LMOs, there must be an Advanced Informed Agreement (AIA) between the party of import and the party of export. This is the centerpiece of the Cartagena Protocol.[89] Articles 8, 10 and 12 set out the Advanced Informed Agreement. It must be carried out before the "intentional introduction" of LMOs into the environment of the importing country.[90]

The choice of language is notable. Instead of the often-used "prior informed consent," the Protocol uses the language "Advance Informed Agreement." The United States was the driving force behind this change. "Prior Informed Consent" was objectionable to the United States because it had become associated in the international realm with trade in hazardous and restricted substance.[91] It was important for one of the world's largest exporters of LMOs to create a semantic distinction between hazardous materials and "safe" LMOs. They were attempting to avoid imputing language with specific institutional history and baggage.[92]

There are several exceptions to the AIA procedure. There are four categories of exceptions: LMOs in transit (Art 6(1)); LMOs for contained use (Art. 6(2)); LMOs identified in a decision of the Conference of Parties/Meeting of Parties (COP-MOP) as not likely to have adverse effects on biodiversity conservation and sustainable use (Art. 7(4)); and LMOs intended for direct use as food, feed or for processing (Art. 11).[93]

This means that there are many imports of LMOs that will not be subject to the strict

[88] Falkner & Jaspers, *supra* note 2 at 5.
[89] Gupta, *supra* note 29 at 25.
[90] *Ibid*.
[91] *Ibid*.
[92] *Ibid*.
[93] Anna Milena Zivian, Alessandra Sensi & Carmen Bullon Caro, *Biosafety Resource Book: Legal Aspects* (Rome: FAO, 2011) at 16.

AIA procedure, the so-called "centerpiece" of the Protocol. These exceptions will limit the over all effectiveness of the Protocol because large quantities of LMOs will be imported without strict regulation. Bulk shipments of LMOs such as corn or soybean that are intended for food, feed or processing will not be subject o the AIA procedure. Although such shipments must still be documented, the labeling will only say that the shipment may contain GE organisms that are not intended for intentional release into the environment.[94] For these shipments, importing countries have the responsibility to follow up on risk assessment information provided by exporters to a web-based clearing house, in order to decide whether or not to accept shipments.

Part 3: Analyzing Important Implications

3.1: Shift towards a presumption of harm rather than harmlessness

When the Biosafety Working Group commenced work and negotiations, many observers questioned why biosafety was the first issue that the parties to the convention had chosen to address through a legally binding instrument. Notwithstanding that the mandate for the negotiations lay within the convention, many working in the field did not see LMOs as the most pressing threat to biodiversity.[95] LMOs do represent, however, a substantial profit for many large industrial companies and exporting countries. The "pre-emptive strike" represents a broader grapple for power in an area with unlimited potential.

The Protocol's focus on harm prevention represents a major ideological stance in the governing of GMOs. It also reflects the societal perception of GMOs in a more general way. The Protocol recognizes that GMOs are substantially different than non-LMOs, and they require a higher degree of regulation and control.[96] If the LMOs are introduced directly into the environment, according to the Protocol, they require even more regulation via the Advanced Informed Agreement and labeling. This reflects a major shift in the international understanding of GMOs because it implicitly takes a stance on the public perception of the

[94] Bernauer, *supra* note 56 at 144.
[95] MacKenzie, *supra* note 4 at 457.
[96] Andree, *supra* note 33 at 36.

effects of genetic engineering. It embodies a presumption of potential harm rather than a presumption of harmlessness.[97]

In this sense, the Protocol is pre-emptive. It was negotiated and drafted before any known incidents of damage due to the transboundary movement of LMOs occurred.[98] This can lead to a notion that the Protocol is liberal, proactive or environmentally positive. The Protocol, then, has the retrospective appearance of a proactive precautionary initiative for addressing the possible risks associated with a developing science.[99]

3.2: Socio-Economic Considerations

During the Protocol negotiations, there was debate about the place of socio-economic considerations in the risk assessment process.[100] The result is Article 26 of the Protocol, which gives parties to the Protocol narrow latitude to consider socio-economic factors in importing decisions. Parties can take socio-economic considerations into account only insofar as they arise from the impact of LMOs on the conservation and sustainable use of biological diversity.[101] Essentially, decision-making in this area can only account for the socio-economics related to potential biodiversity loss; it cannot be considered more broadly.[102] The Protocol implies that socio-economic considerations not be used in the identifications of harm or hazards.[103]

The Protocol legitimizes scientific and ecological issues, yet does not fully include social and economic concerns. The scope of what exactly socio-economic considerations can be applied to is vague. This is despite the wide recognition that policies that are aimed at achieving sustainable development, in this case sustainable biodiversity, and can only be measured on a triple bottom line.[104] The World Commission on Environment and Development defines sustainability as: "development that meets the needs of the present

[97] *Ibid*.
[98] Cook, supra note 52 and 372.
[99] MacKenzie, *supra* note 5 at 457.
[100] Dass, *supra* note 1 at 61.
[101] The Biofsafety Protocol, *supra* note 8 at Article 26.
[102] Dass, *supra* note 1 at 61.
[103] *Ibid*.
[104] Andree, supra note 33 at 38.

without compromising the ability of future generations to meet their needs."[105] It is widely recognized that this broad definition integrates social, environmental, and economic issues.[106]

In effect, the precautionary biosafety regulations, then, focus on uncertainty, complexity and only hypothetical risks.[107] The Protocol will not address immediate concerns that fall outside the realm of the objective scientific method. This means that immediate social and economic concerns related to the introduction of LMOs into the environment, which are often readily apparent, are not considered.[108]

Even within the Parties of the Protocol, the precise use of socio-economic considerations is ambiguous. At the sixth meeting of the Parties to the Cartagena Protocol on Biosafety, the members adopted decision BS-VI/13, which includes a request for the Executive Secretary to commence a series of activities with the aim to "contribute to the development of conceptual clarity on socio-economic considerations."[109] To this effect, the Executive Secretary initiated online discussion groups and conferences to encourage discussion on various information, views and experiences regarding socio-economic considerations. During this process, some participants addressed the need to clarify the relationship between risk assessment and socio-economic considerations.[110] Some participants also addressed the importance of looking at provisions from other international agreements that were applicable to socio-economic considerations in decision-making on LMOs[111]. Examples of such agreements include the Covenant on Economic, Social and Cultural Rights, the International Convention Concerning Indigenous and Tribal Peoples and the International Treaty on Plant Genetic Resources for Food and Agriculture.[112]

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[105] *Report of the World Commission on Environment and Development: Our Common Future*, UNWCED, UN doc A/42/427 (1987).

[106] Cristina Gimenez, "Sustinable Operations: Their Impact on the Triple Bottom Line: (2012) 140 Int J Production Economics 149 at 150.
[107] Andree, *supra* note 33 at 38.
[108] *Ibid*.
[109] Report of the Ad Hoc Technical Expert Group on socioeconomic considerations; UNEP, UNEP/CBD/BS/AHTEG-SEC/1/3 (2014) at para 1 [Socioeconomic Considerations].
[110] *Ibid* at para 17.
[111] *Ibid* at para 18.
[112] *Ibid*.

In the Annex of the Report, the Ad Hoc Expert Group decided to adopt a descriptive approach to socio-economic considerations in recognition that there is no one single agreed upon definition. Of specific importance in this new description is: "Planning and conducting risk assessments and taking socio-economic considerations into account may be complementary in the decision-making process."[113] This language is vague and non-comitial, but it suggests a progression towards integration in risk assessment and socio-economic considerations. The result of such integration would, like the FAO code of conduct, represent a more complete analysis of our current historical juncture with the evolution of GMOs.

However, this glimmer of progress was quickly diminished. In March of 2015, the United States released a report that responded to the Ad Hoc Group. The United States (not a party to the Biosafety Protocol), criticized the Group for going well beyond the parameters of the Protocol.[114] For the United States, the Framework for Conceptual Clarity simply fails to provide any clarity whatsoever to the context of Article 26 of the Protocol. Barbara M. De Rosa-Joynt, the US Chief for Biodiversity, said that most of the discussions centered around national decisions of whether to allow or not to allow cultivation of genetically engineered crops, not specifically related to import.[115] Based upon this, the United States thought it was clear that the discussions were moving toward including socio-economic considerations beyond the mere impacts of biodiversity, and they do not support it. The United States does not support broadening the use of socio-economic considerations. In the letter, the United States emphasizes that Article 26 is not mandatory and it is within purview of each participant to do more than is explicitly set out in the Protocol.[116]

3.3: Science Versus Non-science

[113] *Ibid* at Annex.
[114] Barbara M. De Rosa-Joynt, U.S. National Focal Point for the Convention on Biological Diversity, to Braulio Ferreira de Souza Dias, Executive Secretary, Convention on Biological Diversity (13 March 2015) online: < http://bch.cbd.int/protocol>.
[115] *Ibid*.
[116] *Ibid*.

The objective nature of the risk assessment process is often contrasted with the subjective analysis of socio-economic considerations. This dichotomy could be classified as science versus "non-science."

The reference to science may simply be an attempt to ensure that an assessment is objective in order to minimize arbitrary assessment approaches.[117] Science can be reinforced with evidence whereas non-science evidence, such as public will, economic trends, impact on income and impact on exchange practices may not always be able to be objectively assessed and weighed. The concept of science-based risk assessment is often referred to in international agreements. The UNDO Voluntary Code of Conduct asserts that risk assessment be based on "sound scientific principles" including various experts from relevant disciplines. International trade law also offers the guiding principle that risk assessment should be science based.[118]

Risk assessment may not be able to be divorced from its political under pinning.[119] Although scientists and researchers are at the forefront in creating knowledge regarding potential harm to humans and the environment through risk assessments, they are not working in isolation. Political and social values can permeate the so-called objective surface and serve to guide and motivate the outcomes of science. The same is true with financial incentives. Thus, the dichotomy between science and non-science may not be as stark and near as originally conceived. As Falkner and Jaspers argue, even though scientists play an integral role in creating knowledge about potential harm, their scientific judgment alone is not sufficient for the basis of risk assessment and management.[120]

The "objective" parameters of scientific risk assessment are far from clear. There are rarely concrete answers as to how much sound science is enough, or when uncertainty no longer exists.[121] There is also a separation between deciding up on the "acceptability" of an issue versus the "severity." If there is no clarity on these issues, the basis for international and political decisions on the scientific information could be unknown.[122] The distinction

[117] Dass, *supra* note 1 at 47.
[118] *Ibid*.
[119] Falker & Jaspers, *supra* note 2 at 5.
[120] *Ibid*.
[121] Plillips & Kerr, *supra* note 35 at 72.
[122] *Ibid*.

between these two extremes is analytically important because it demarcates the division between foreseeable and manageable risk from relatively fluid uncertain knowledge.[123]

Part 4: Conflicting Themes: International Trade Versus Environmental Protection

4.1: EU Perspective Versus North American Perspective

Section Four focuses on the various conflicts that arise between international trade and environmental protection through the lens of the Cartagena Protocol. First, the European Union ("EU") standpoint will be discussed in relation to the United States perspective. Then, the conflict between WTO Agreements and Cartagena will be analyzed. The nature of the conflict, its implications, and the WTO case law that has stemmed from these issues will be discussed in the latter part of this section.

The United States is not a party to the UN Convention on Biodiversity, a prerequisite for joining the Biosafety Protocol. It does not intend to ratify either the Convention or the Protocol in the future.[124] Canada is also not a member of the Agreement.[125] The EU, however, has ratified both the Convention of Biodiversity and the Biosafety Protocol and has already passed implementing legislation.[126] The leadership of the EU has been essential in creating the international biosafety regime.[127]

The political positions of the two regions exemplify the conflict. The dispute revolves around a major disjunction in socio-economic, cultural, and ideological perspectives. The EU's position insists on a Precautionary Approach to the international regulation of GMOs, which takes into account uncertain risk, and the United States promotes a "science-based" method of risk assessment.[128] The EU was central in establishing the

[123] Falker & Jaspers, *supra* note 2 at 5.
[124] Bernauer, *supra* note 56 at 144.
[125] Gupta, *supra* note 29 at 32.
[126] Bernauer, *supra* note 56 at 144.
[127] Falkner, "Political Economy", *supra* note 46 at 508.
[128] Falkner, "Regulating Biotrade", supra 24 at 31.

Precautionary Principle in the Cartagena Protocol.[129] This was significant because the Precautionary Principle was only an emerging model at the time of the time. It stood in sharp contrast to the traditional principles and norms of international trade.[130] While the United States has repeatedly maintained that regulatory trade restrictions should be established on "sound science" that are in compliance with WTO law, the EU has pressed for the international expansion of precautionary standards and a re-shaping of the connection between WTO rules and environmental procedures, in favor of the latter.[131]

The purpose and nature of the Protocol is another area of contention between the two sides. Whether the Biosafety Protocol was intended to facilitate trade in biotechnology by establishing uniform biosafety standards, or to strengthen the regulatory interests of GMO importing nations against the financial interest of the biotech industry remains a debate. The EU maintains that its GMO regulations are designed to enhance consumer safety and the wider social acceptance of GE food, to enable consumers to make informed choices and to keep track of environmental and health effects.[132] The market drives the United States. It is the world's largest exporter of biotechnological products.[133]

4.2: Conflict Among International Regimes

The conflict among international regimes is not aided by the wording of the Cartagena Protocol itself. During the negotiations, the Miami Group argued that the text of the Protocol should contain a type of savings clause that would state that nothing under the Protocol should affect a country's obligations under other international agreements.[134] Most of the other groups strongly opposed such a savings clause because, they argued, it would defeat the very nature of the Protocol.[135]

[129] Falkner, "Political Economy", *supra* note 46 at 508.
[130] *Ibid*.
[131] Falkner & Jaspers, *supra* note 2 at 7.
[132] Bernauer, *supra* note 56 at 156.
[133] Falkner, "Regulating Biotrade", *supra* note 24 at 299.
[134] Gupta, *supra* note 29 at 30.
[135] *Ibid*.

The Preamble to the Biosafety Protocol was the result. The compromise was to leave out the savings clause in the body of the Protocol and include a statement regarding the relationship between the Protocol and trade agreements in the Preamble.[136] It addresses the relationship of the parties to the Protocol with other international obligations and agreements. The last two paragraphs of the Protocol state:

> 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.[137]

The Preamble fails to clarify the relationship between the Biosafety Protocol and other international agreements.[138] The paragraphs cited above appear to be in direct contradiction. The first of the two paragraphs implies that a country can refer to existing WTO obligations regarding rules for international trade in GMOs. The second of the two paragraphs suggests that any rules that the Biosafety Protocol makes regarding GMOs do not have to defer to WTO rules.[139] For the Miami Group, this statement provides a clear savings clause to ensure that obligations under the WTO, in particular, will not be undermined by the Protocol.[140]

The Preamble and the Cartagena Protocol more generally create problems with WTO Agreements. As will be explored in the next part, The Protocol does not appear to be mutually supportive with the WTO.[141]

4.3: WTO and Cartagena

The most direct conflict arising from the Biosafety Protocol is the conflict with the Agreements of the WTO. The Cartagena Protocol is as much a trade agreement as it is an

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[136] *Ibid*.
[137] Biosafety Protocol, *supra* note 8.
[138] Phillips & Kerr, *supra* note 35 at 66.
[139] *Ibid*.
[140] Gupta, *supra* note 29 at 31.
[141] Phillips & Kerr, *supra* note 35 at 66.

environmental agreement.[142] It is not surprising, then, that it's trade implications clash with WTO Agreements.

4.3.1: WTO Tradition versus Cartagena

The WTO and the Biosafety Protocol emerge from two very different traditions. Considering the origin of the WTO is helpful in identifying the precise nature of the conflict. The WTO emerged from the traditions of the General Agreement on Tariffs and Trade (GATT) and inter-war period in the twentieth century.[143] Based upon difficult experiences of the period, the main purpose of the WTO was to dismantle significant barriers to trade in goods.[144] The WTO emerged to control and contain national sovereignty in order to monitor forms of "protectionism" that tended to decrease economic activity and flow.[145] It took a period of about 50 years for the comprehensive framework that exists now within the WTO to emerge.[146]

WTO agreements are essentially contracts binding governments to keep their trade policies within agreed limits. As of June 2014, the WTO has 160 members.[147] All members to the WTO automatically accede to all multilateral WTO agreements and consent to using the WTO dispute resolution process.[148] The WTO also has its own form of legal proceedings and multilateral authorization to impose sanctions in situations of non-compliance.[149] Thus, the WTO has a very prominent role within international law. It may, as Thomas Cottier of the World Trade Institute phrased it, be the nucleus of what, in the future, may be deemed the global law of integration.[150]

The WTO's ultimate aim is to liberalize trade.[151] Its over-arching purpose is to help trade flow as freely as possible, as long as there are no undesirable side effects. It is

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[142] Cottier, *supra* note 67 at 470.
[143] *Ibid* at 467.
[144] *Ibid*.
[145] *Ibid* at 469.
[146] *Ibid* at 467.
[147] "WTO Membership" online: World Trade Organization < https://www.wto.org/>.
[148] Zivian, *supra* note 93 at 21.
[149] Cottier, *supra* note 67 at 468.
[150] *Ibid*.
[151] Bernauer, *supra* note 56 at 150.

important for economic well-being to remove impediments to trade that are not grounded in a legitimate purpose. The WTO has a committee on Trade and the Environment, but it has continuously maintained that it simply does not have the expertise to form environmental policy.[152] It suggests, instead, that the proper forum for such policy is Multinational Environmental Agreements (MEAs).

The Cartagena Protocol is much different than the WTO. It is of a much newer tradition than trade regulation, even though environmental agreements have existed for some time in international law. Thus, the Protocol operates wholly within the traditional concepts of environmental law. In contrast to the WTO, the Protocol can be seen as an "enabling agreement."[153] It is an effort to counter disciplines imposed on governments by the liberal trading order.[154] Significantly, the Protocol does not operate within a larger framework of multilateral decision-making or authorization within a comprehensive organization, as does the WTO.[155]

4.3.2: Nature of Conflict

Two distinct views arise from the juxtaposition of the two regimes. The EU emphasizes the importance of Protocol application independent from and unaffected by WTO rules. Second, advocates of producer interests (the United States) support unrestricted application of WTO rules on market access.[156] They fear that the Protocol could allow parties to enact extensive trade restrictions that may ultimate lead to a moratorium on trade.

Under Article XX of the General Agreement on Tariffs and Trade (GATT, 1947), it appears that the Precautionary Principle and the WTO mandate can rightly co-exist. WTO countries could still establish domestic regulations that constitute trade barriers but only under certain circumstances. The Article states:

> "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable

[152] Phillips & Kerr, *supra* note 35 at 150.
[153] Cottier, *supra* note 67 at 469.
[154] *Ibid*.
[155] *Ibid* at 468.
[156] *Ibid* at 469.

> 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…
> (*g*) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption."[157]

At face, the Precautionary Approach could co-exist without conflict because, given the burgeoning acceptance of the Principle as a principle of customary international law, it could equally apply in cases affecting parties to the Protocol and non-parties alike.[158] There would be no discrimination. But, as Cottier notes, the Precautionary Principle remains under continuous scrutiny by the WTO, especially because of subsection (g). The broad effect of Article XX is to prohibit measures that are taken arbitrarily, or as disguised restrictions to trade.[159] What the WTO may consider "disguised protectionism" could be differently classified under the Cartagena Protocol as legitimate Precautionary concern.

A similar analysis can be undertaken with regard to socio-economic considerations. In the 2014 Report on Socio-Economic considerations, it was "suggested" that taking socio-economic considerations into account within the context of Article 26 of the Protocol may not conflict with the rules of the WTO.[160] However, this was presupposing that the socioeconomic considerations must be formulated with justifications, and be defendable under available information and not lead to arbitrary distinctions. The trend of referring to non-science distinction is once again classified as "arbitrary." Furthermore, the AHTEG did not even decide on this matter. They said that this was an issue that would benefit from further examination.[161]

Another consideration is the production methods of the WTO and Cartagena. The WTO does not permit trade barriers to be put in place based on production and processing methods. Only the final characteristics of the product may be used.[162] However, in some

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[157] General Agreement on Tariffs and Trade, 30 October 1947, 58 UNTS (entered into force 1 January 1948) at Article XX.
[158] Cottier, *supra* note 67 at 474.
[159] *Ibid* at 475.
[160] Socioeconomic considerations, *supra* note 109.
[161] *Ibid*.
[162] Phillips & Kerr, *supra* note 35 at 70.

processed food products, the process of refining and production removes all traces of the GMO from the final product.[163] For example, processed canola oil does not have any detectable proteins, and in the result, does not contain any GMO materials.[164] Effectively, there would be no change in the characteristics of the product imported. The result is that any restriction on such a product could not be justified under the WTO, but since the GE process was used in the original production of the crop, regulation could be warranted under the Biosafety Protocol.

4.3.3: Implications

The implications of these conflicts are somewhat uncertain. Some scholars suggest an extreme: that the Protocol has made an all-out transatlantic trade war with the WTO more likely because its Precautionary Approach encourages the EU to pursue its coveted GMO regulation.[165] Others claim that the Biosafety Protocol has made trade war less likely because it legitimizes the EU's position. It could deter the US from heightening the dispute.[166] It is uncertain to what extent the WTO will tolerate provisions justified by the Precautionary Principle, and an ongoing process of risk assessment. It also remains uncertain to what basis, if any, the WTO will tolerate restrictions based on "arbitrary" exclusions based on ethical, religious or economic concerns.[167]

4.4: SPS Agreement

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) broadly established a framework for the protection of food safety, animal and plant health.[168] The SPS Agreement allows trade barriers to be enacted for health, sanitary or phytosanitary reasons if there is a scientific justification for keeping the products out of the market and if a risk assessment had been completed. Unlike the highly contested Cartagena Protocol, The SPS Agreement is a very widely accepted international

[163] *Ibid* at 71.
[164] *Ibid*.
[165] Bernauer, *supra* note 56 at 145.
[166] *Ibid*.
[167] *Ibid* at 156.
[168] Zivian, *supra* note 93 at 22.

agreement.[169] It entered into force on January 1 1995 and is binding on all WTO member states.

The text of the SPS Agreement does not specifically mention GMOs. Still, it could seriously affect the transboundary trade of GMOs. When GMOs are involved in international trade, and could potentially pose a risk to human, animal or plant life or health to an importing country, the SPS Agreement would apply to national sanitary or phytosanitary measures (SPMs) designed to address the threats prior to import. WTO member countries must ensure that sanitary and phytosanitary measures are based on an assessment of risks to human, animal or plant life or health.[170]

The issue arises with the purpose of the SPS Agreement. One of its objectives is to encourage the harmonization of SPMs purely on the basis of internationally accepted scientific standards.[171] Any SPMs that may directly or even indirectly affect international trade are included in the Agreement. Like the GATT, the SPMs cannot arbitrarily or unjustifiably discriminate between Member States, and cannot be applied in a manner that would constitute a disguised restriction on international trade. The particular measure used must also not be more trade restrictive than necessary for reaching the SPS protection a country envisages.[172] Members that want to implement new standards and SPMs that would result in a greater level of protection than is already offered, can only do so if there is a scientific basis to justify the measure.[173] It is clear that the science-based mechanism in the Agreement can come into conflict with the Precautionary Approach in the Biosafety Protocol.

The SPS Agreement does not specifically mention issues pertaining to environmental safety. The science-based process was established in order to prevent trade protections from being spread to domestic producers through the abuse of technical regulations.[174] Within the Agreement, there is an assumption that there will be sufficient information to make an appropriate scientific decision. This is not the case with GMOs. It is

[169] Falker & Jaspers, *supra* note 2 at 26.
[170] The Biosafety Protocol, *supra* note 8 at Article 5(1).
[171] Zivian, *supra* note 93 at 22.
[172] Bernauer, supra note 56 at 153.
[173] Zivian, *supra* note 93 at 23.
[174] Phillips & Kerr, *supra* note 35 at 71.

a situation of uncertainty.[175] Thus, the dilemma rears its head again: an objective and certain science that promotes liberal trade and international access versus cautious and uncertain regulation that promotes environmental well-being. As a result, certain proponents of legal action claim that regulations adopted by the EU and implemented into the Protocol violate the SPS Agreement.[176]

4.5: WTO Case Law

Disputes regarding trade at the international level are dealt with by the WTO. The WTO has a standing appellate body that is the ultimate arbiter in member disputes. It can also specify certain measures to be used to enforce panel decisions.[177] WTO dispute settlement panels can effect decisions against the will of the Defendant country.[178] Enforcement of these decisions is usually decentralized, meaning that when the WTO finds a state guilty and approves an economic punishment on the member, the execution of the punishment is usually in the hands of the Plaintiff.[179] The punishment is usually more of an incentive for the Defendant to change its regulation to comply with its international legal commitments.[180] One of the most awaited cases in WTO history has been the Biotech dispute.[181]

In 2000, the same year the Cartagena Protocol was negotiated, the first agri-biotech case was entered the WTO system.[182] Thailand challenged an import ban that was imposed on canned Thai tuna by Egypt.[183] Thailand argued that there was no legal basis for the ban; it was arbitrary and discriminatory. Egypt claimed that the tuna was packaged in genetically modified soybean oil. For Thailand, there was a lack of scientific evidence regarding the health risks of genetically modified soybeans, or whether the oil was even produced from

[175] *Ibid*.
[176] Bernauer, *supra* note 56 at 152.
[177] *Ibid* at 151.
[178] Bernauer, *supra* note 56 at 148.
[179] Bernauer, *supra* note 56 at 148.
[180] *Ibid* at 149.
[181] Zivian, *supra* note 93 at 47.
[182] Bernauer, *supra* note 56 at 151.
[183] *Ibid*.

genetically enhanced soybeans. Thailand also asserted that a strict ban on tuna alone was discriminatory.[184] After much negotiation between Thailand and Egypt, the case was ultimately withdrawn.[185]

The United States then launched a case in mid-May 2003. Supported by Canada and Argentina, all large exporters of GMOs, it attacked the EU's agri-biotech regulations in two different ways. First, The United States claimed that the EU's 1998 moratorium on approvals of new GE crops was illegal under WTO rules.[186] The moratorium had restricted imports of agricultural and food products from the United States. The EU, on the other hand, denied the existence of such a moratorium. Second, the United States asserted that certain EU member states, such as Austria, France, Germany, Greece, Italy and Luxembourg upheld refusals to allow certain GE crops on their markets, despite the fact that they and already been approved for import and marketing.[187]

The WTO established a single panel to address the United States dispute, as well as similar claims from Canada and Argentina. After two years of delay, in which experts were sought and the parties requested more time to prepare rebuttals, the final panel report was circulated.[188] The panel found that the EU had, indeed, applied a de facto moratorium on the approval of biotech products between June 1999 and August 2003.[189] The panel also found the EU to be in violation of several clauses in the SPS Agreement because their moratorium had led to undue delays in the completion of EU approval procedures. But, the panel found that the EU was not in violation of the particular clauses that the US, Canada and Argentina raised in the original complaint.

Most importantly, the panel found that the EU was in contravention of Articles 5.1 and 2.2 of the SPS Agreement.[190] Article 5.1 says that Members to the SPS Agreement shall ensure that SPMs are based on risk assessment techniques developed by the relevant

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[184] *Ibid*
[185] *Ibid*
[186] WTO, online: The World Trade Organization < https://www.wto.org/>.
[187] *Ibid*.
[188] *Ibid.*
[189] *Ibid.*
[190] *Ibid.*

international organizations.[191] Article 2.2 says that Members shall ensure that any SPMs are only applied to the extent necessary to protect human, animal, or plant life or health. They are based on scientific principles and are not maintained without sufficient scientific evidence.[192] On January 14, 2008, both parties notified the panel that they had reached an agreement under the WTO Dispute Settlement Understanding (DSU). After the United States requested authorization to suspend concessions and other obligations, the EU referred the matter to an arbitration. The arbiter suspended the arbitration proceedings from February 18th, 2008 until the United States requests their resumption under the original circumstances agreed by the parties.[193]

The fundamental issues between the parties were not resolved. The WTO proceedings are simply a temporary solution to much more deep-seeded cultural and ethical differences. Some scholars even believe that there is a high probability that the bio-trade conflict could turn into a larger and more fundamental conflict over correct regulatory frameworks for both consumer and environmental risks.[194] At the very least, it appears that the EU and the United States will hold firm in their positions on the international stage.

Part 5: Looking Forward

5.1: Positives of the Protocol

While the bio-trade issues between the United States and the EU are ongoing, the Cartagena Protocol has made positive strides in the environmental community. Environmentalists celebrated the inclusion of the Precautionary Principle in the Protocol.[195] It established an international obligation on certain exporting countries to share information and obtain consent from an importing country before the release of LMOs into

[191] SPS Agreement, *supra* note 80.
[192] *Ibid*.
[193] WTO, online: World Trade Organization < https://www.wto.org/>.
[194] Bernauer, *supra* note 56 at 167.
[195] Falkner, "Regulating Biotrade", supra note 24 at 311.

the environment.[196] Certain business representatives were also satisfied with the Protocol's provisions; they hoped that the Protocol would synchronize international rules in biosafety and legitimize trade in GMOs.[197] The Protocol will also potentially strengthen existing market pressures on farmers, major agricultural exporters and food retailers to begin to identify GM foods and crops.[198]

The use of the Precautionary Principle within the Protocol's AIA procedure works to challenge the United State's assertion that risk assessment must be based solely on objective scientific proof.[199] As demonstrated by the WTO dispute, the United States has not responded in a large-scale way to changing their domestic regulation. Still, some United State's exporters have made some concerted efforts to accommodate changes in accordance with consumer preferences.[200] There are many small examples: some United States corn processors have established IP systems that maintain separation between corn varieties not approved by the EU and those that are; soybean producers have worked with biotech firms and farmers to implement the same system with GE soybeans, and have restricted the farming of soybean varieties not approved by the EU. For fear of losing export markets, some U.S. sugar refineries have asked farmers not to grow GE sugar beets.[201] Since the U.S. only exports roughly 10-15% of its agricultural products to the EU, the small-scale measures are somewhat constrained.[202]

The Protocol also promotes increased transparency in trade. Labeling LMOs that are intended for direct release into the environment is a step in the right direction towards full disclosure of all GMOs. Also, the Protocol has the potential to overcome the lack of domestic regulation in developing countries where GMOs are bring imported, where there is little experience with regulating GM products.[203] For these LMO-importing countries, the Protocol ensures that there is a framework in place to minimize potential adverse affects to biodiversity from the release of GMOs into the environment.

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[196] Gupta, *supra* 29 at 25.
[197] Falkner, "Regulating Biotrade", supra note 24 at 311.
[198] *Ibid* at 312.
[199] *Ibid*.
[200] Berauer, *supra* 56 at 146.
[201] *Ibid* at 147.
[202] *Ibid*.
[203] Phillip & Kerr, *supra* note 35 at 67.

5.2: Challenges and Areas of Concern

There are many challenges with the Biosafety Protocol. It serves as only an initial framework for enabling future international aid and bio-tech trade. There is still considerable room for interpretation in the Protocol regarding the precise application of the Precautionary Principle, the place the Protocol occupies with regard to other international agreements, and how much potential risk is enough risk to justify the use of Precaution. The Protocol contains many exemptions and compromises that could work to defeat its original purpose of protecting biodiversity.

The Protocol does not address the obvious conflicts with the WTO and the SPS Agreement. Similarly, the Protocol has not relieved any over-arching tensions between the two competing parties: the United States and the EU. Lack of direct acknowledgment of the conflict serves only to weaken the Protocol because the WTO is a much more established organization with many more signatories.

Genetic engineering is a rapidly advancing field. The Protocol certainly marks a significant step toward integrating that technology with legal regulation, but it is questionable whether the Protocol can keep up with technology. As Falkner mentions, the effectiveness of the Protocol may depend on its ability to adapt to, and catch up with, rapid change in biotechnology research and commercialization.[204]

5.3: Enforcement of the Protocol

Enforcement is another weak link in the Protocol. As with many other multilateral environmental agreements, enforcement is almost non-existent.[205] Some developing countries and NGOs argued for the inclusion of a liability and compensation clause early in the negotiations, but the Protocol originally only provided for future discussions on the

[204] Falker, "Regulating Biotrade", supra note24 at 300.
[205] Gupta, *supra* note 29 at 32.

issue, which are to be concluded within four years.[206] This was a necessary compromise in the negotiations.

In furtherance to the open-ended liability regime, there were subsequently five meetings of the Working Ad-Hoc Group on Liability and Redress followed by four meetings of the group of the Friends of the Co-Chairs. In October 11, 2011, in Nagoya, Japan, the Group of the Friends of the Co-Chairs on Liability and Redress for the Protocol concluded the supplementary Protocol for Liability and Redress. The Group then submitted the Supplementary Protocol to COP-MOP 5, which opened the next day.[207]

In Article 3 of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, the scope is defined as any damage resulting from LMOs that find their origin in a transboundary movement. It includes any authorized use of LMOs, damage resulting from unintentional transboundary movements as well as illegal transboundary movements, and includes damage resulting from a trans-boundary movement only after the Protocol comes into force.[208] Article 11 states that the Supplementary Protocol shall not affect the rights and obligations of States under general international law.[209] Parties may use criteria set out in their domestic law to address damage that occurs inside their national jurisdiction, or develop civil liability rules and procedures specifically for this purpose.[210] Article 5 also lays out the Response Measures that should be taken in the event of damage.

In essence, the Protocol provides a regulatory liability regime that relies heavily on the domestic protocols that are, or will be, implemented by its party states. It fails to make large strides as a binding liability instrument. This is probably not what the proponents for liability during the original negotiations had in mind when they were arguing for a liability regime. However, it may prove to be an impetus for member states to implement their own liability regimes.

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[206] *Ibid*.

[207] "What Has Been Done Since Liability and Redress" online: Convention on Biological Diversity < https://bch.cbd.int/protocol/cpb_art27_info.shtml>.

[208] The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, October 15, 2010, 50 ILM 108 (2011) Decision BS-V/11, available at https://bch.cbd.int/protocol/NKL_text.shtml, at Article 3.

[209] *Ibid* at Article 11.

[210] *Ibid* at Article 12.

The Protocol does not have its own dispute settlement mechanism. It refers to its parent convention, the Convention on Biological Diversity, for its dispute settlement provisions.[211] But, the CBD contains no mandatory binding dispute settlement procedure. Instead, it has an optional acceptance of arbitral of judicial settlement, with a mandatory, but not binding, negotiation procedure unless the Parties agree otherwise.[212]

Article 25 of the Biosafety Protocol states that in the event of an illegal transboundary movement, the country affected may request the party of origin to dispose, at its own expense, of the LMO in question by repatriation by reparation or destruction, as appropriate.[213] This is a very minimal punishment for illegal transboundary movement that may be ineffective in deterrence.

As noted in the WTO section, the WTO does have a mandatory and binding dispute settlement mechanism. Even though the Protocol has been ratified, the WTO may take up a default role in accordance with the WTO DSU, regarding its member's complaints about LMO import prohibitions or restrictions.[214] This has already been seen with the dispute between the United States and the EU.

Enforcement and Protocol implementation suffers from unpredictability. In working to ensure that international rules minimize national differences and bring unity to global LMO regulation, the Protocol falls short. Importantly, though, enforcement must still allow room for legitimate national differences and priorities regarding complex new technologies such as genetic engineering.[215] In this way, the Protocol certainly succeeds.

5.4: The Possibility of Negotiating a More Comprehensive LMO Agreement

[211] MacKenzie, *supra* note 5 at 463.
[212] *Ibid*.
[213] The Biosafety Protocol, *supra* note 8.
[214] MacKenzie, *supra* note 5 at 463.
[215] Gupta, *supra* note 29 at 32.

Even though the international climate is not necessarily conducive to large scale and binding implementation of the Precautionary Principle, there are several possible solutions that could aid the Biosafety Protocol in its acceptance and successful implementation.

One strategy could be to simply amend the wording in the Preamble to clarify the hierarchy between the Protocol and the WTO. This would help to clarify the exact scope of the Protocol and its place on the international sphere. The disputes between the United States and the EU show, however, that transboundary trade with GMOs will inevitably be anchored to the heavy and historical weight of the WTO. While the SPS Agreement remains one of the most well accepted international agreements, and certain basic principles of the Biosafety Protocol remain contested by major GMO-exporters, the political climate is extremely difficult to work within. Even a simple amendment will be difficult.

There are also many proponents who suggest that increased liability within the Liability Protocol could be strengthened. If members knew that they could be held responsible for illegal transboundary trade in LMOs, they could be more likely to exercise caution and adhere to the Protocol.[216] This could have positive implications for importing countries; they would be reassured that they would not have to absorb the risks associated with illegal LMO movement, and would, therefore, be more willing to import more LMO products[217] Also, scholars and environmentalists who are in favour of increased liability identify a growing trend for specific treaty based civil liability regimes that cover areas that are potentially hazardous to the environment. This includes such agreements that address oil pollution, carriage of hazardous waste and noxious substances by sea and the transboundary movement of hazardous waste.[218]

Perhaps a better model to follow in risk assessment is the Food and Agriculture Organization of the United Nations Code of Conduct on Responsible Fisheries. It specifically applies to genetically altered stocks used in aquaculture. Its more general provisions do not specifically refer to GMOs but they could be interpreted to apply.[219] The Code states that conservation should be based on the best scientific evidence, taking into account traditional

[216] Cook, *supra* note 52 at 372.
[217] *Ibid* at 373.
[218] *Ibid* at 374.
[219] Dass, supra note 1 at 62.

knowledge, as well as environmental, economic and social factors.[220] This method would allow for a fulsome analysis into the potential risks of GMOs without the guise of objectivity that the Protocol currently projects. It would also promote discussion of the underlying socio-economic and ethical considerations that divide the two schools of thought in order to directly address the issue. The Protocol could be broadened to apply not only a purely scientific risk assessment, with a more extensive analysis into important societal considerations that extend beyond precaution in biodiversity.

At a minimum, a realistic solution for the Biosafety Protocol would be to eliminate the AIA exceptions for LMOs for direct use in food or feed, LMOs in transit, and LMOs for contained use. The Protocol would more wholly address the issues surrounding the cultural and non-scientific adversity towards LMOs if it's regulation was a total one. Given the confined nature of the Protocol to harm to biodiversity, though, even this may be difficult.

Finally, perhaps the best solution would come from abandoning the purely trade restrictive nature of the Protocol and aiming for a broader, more comprehensive regulation of LMOs. Such an approach could look at targeting the privatized GMO industry as well as international states. Such a regulation could work backwards: instead of relying on scientific risk assessment to reveal that certain LMOs are not dangerous, the regime could mandate the private industry to produce and trade only LMOs that are proven safe. Thus, the standard is much higher for industry to be able to produce. However, given the extensive negotiations with the Liability Protocol (only ending in 2011), and other live discussions with areas of the Cartagena Protocol (like socio-economic considerations), a wholly new regime is very unlikely. Working within the existing Biosafety Protocol is a much more likely solution moving forward.

5.4.1 The Strategic Plan for the Cartagena Protocol of Biosafety 2011- 2020

The relatively recent Strategic Plan for the Cartagena Protocol on Biosafety addresses some obvious concerns with the Protocol and presents useful ideas. Strategic

[220] Fisheries and Aquacultural Department, *Code of Conduct for Responsible Fisheries* ([Rome]: Fisheries and Aquacultural Department, 2002), Article 6.4.

Objective 2.7 calls for Biosafety education and training.[221] This is especially necessary given the evolving and uncertain nature of genetic engineering and its effect on human health and the environment. This Objective also calls for greater collaboration among academic institutions and relevant organizations. Again, this is key to achieve any semblance of unity between conflicting international views.

Strategic Objective 5.1 addresses the ratification of the Protocol. The large goal is to achieve global recognition of the Protocol itself.[222] This is an ambitious goal. Given the financial incentives of many exporting nations, global recognition seems unlikely, especially since the WTO disputes in 2008. Overall, while the sentiments in the strategic plan are good, the individual objectives are vague and lack a clear proactive direction.

Part 6: Conclusion

The Cartagena Protocol on Biosafety does not reconcile the distinct international interests of trade and the environment. The Strategic Plan for the Cartagena Protocol of Biosafety 2011- 2020 addressed some of the issues with the Protocol. Still, addressing issues on a theoretical level and addressing these issues in practice are distinct. Given the snail-like pace with which international law moves, it may be some time before we see the objective of the Protocol realized.

Since its inception, the Protocol has been the crux of political, cultural and scientific debate. Fifteen years after its formation, little has changed. The lack of connection between WTO Agreements and the Protocol is a problem. Both fail to sufficiently address the challenge of creating an operational connection to bring about a more coherent overall biosafety instrument that can deal with both systems in a coordinated and consistent manner. Given the legal resistance to the Precautionary Principle in WTO Agreements, a more fulsome analysis of Precaution is needed to adequately address the issues facing the transboundary movement of GMOs. Although the Biosafety Protocol was a significant step

[221] Cartagena Protocol, COP-MOP 5, BS- V/16, "Strategic Plan for the Cartagena Protocol on Biosafety 2011-2020, decision BS- V/16" (2010).
[222] *Ibid*.

in the right direction for the regulation of LMOs, we are left with many questions and frustrations in its wake.

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