The evolution of trade policy on GMOs in Europe

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Abstract

The European Union has a reputation for holding strict genetically modified (GM) safety standards. Yet, there seems to be some dispute about it being a barrier to trade. There are political questions about how public engagement is interconnected with trade negotiations in regards to genetically modified organisms and biosafety standards. The concept of biosafety, as outlined in the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity,* is interpreted as "…the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology". Thus, the question being researched and discussed is: how has EU regulatory and trade policy on biosafety and GMOs evolved in the early 2000s?

Public engagement on genetically modified organisms (GMOs) policies in Europe, is a topic worth researching because GMO biosafety (the prevention of large-scale loss of biological integrity, focusing both on ecology and human health) is a sensitive topic for consumers, government, trade negotiations, transnational corporations and biotech companies. Examining the European Union's stance on GMO regulations and how public engagement has shaped trade negotiations regarding the controversial topic of genetically modified organisms and biosafety standards through the analysis of laws, directives and regulations is imperative. Specifically, the regulatory regime for genetically modified organisms consists of provisions which grant the public formal rights of participation. Participatory approaches both to science policy and regulation so far have been proposed mainly to prevent technocracy, improve democratic accountability, and encourage dialogue between scientists, policymakers, and the public. Growing anti-GM opinions in

Europe have forced a change in the European Union's policy on GMO authorizations and led to a de facto moratorium in late 1998 on new GMO approvals and imports. In fact, public participation in the evolution and implementation of a national biosafety system may be the most significant factor in determining the level of public confidence in risk assessment and management of GMOs. This is important to understand because it has led to the shift in European policy that provoked the first major international trade conflict over GMO safety policies. The relationship between trade and genetically modified organisms is difficult to separate because the biotech industry drives companies to lobby for rules which create strong incentives towards market access. Moreover, the degree of policy freedom attainable to state decision-makers regarding biotechnology tends to be confined by international rules responsive to the needs of GM exporters.

Foreword

My area of concentration focuses on examining the European Union's stance on GMO regulations, and how public engagement has shaped trade negotiations regarding the controversial topic of genetically modified organisms and biosafety standards. The learning objectives that my Major Paper will address are the following:

1.1 To gain a working knowledge of corporate interests in biosafety and politics.

2.1 Acquire an understanding on international (European) legal disputes concerning biosafety negotiations.

2.2 To gain a working knowledge of business and politics (societal concerns and the regulatory frame work on GM crops) in the European Union.

2.3 Gain an understanding of international trade and the European Union.

My Major Paper will fulfill my learning objectives by exploring the relationship between business, European politics and public engagement. This will be accomplished through the examination of journal articles and academic papers on European GMO policy and public engagement.

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Chapter 1: Introduction

Why is this topic important?

The European Union (EU) has a reputation for embracing strict genetically modified organism (GMO) biosafety standards and being a forerunner on this presenting issue. The concept of biosafety, as outlined in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity is interpreted as " … the need to protect human health and the environment from possible adverse effects of the products of modern biotechnology". GM debates have been formed due to the creation of modern food production and distribution, which has promoted a more global outlook on these issues. Because GMOs are traded internationally and have permeated the global food chain, the GM debate has inevitably focused on international trade and global governance issues. During the late 1990s, transatlantic divisions began to emerge that were expected to play significant roles in the international politics of GM food. Consequently, growing anti-GM sentiment in Europe forced a change in the EU's policy on GMO authorization and led to a de facto moratorium in late 1998 on new GMO approvals and imports (Falkner, 2007, p.3). This movement sparked the research question: *How has EU regulatory and trade policy on biosafety and GMOs evolved in the early 2000s?*

This research question has been developed from a personal experience of watching an immediate family member go into an extreme allergic reaction and having to be rushed to the emergency room from eating a fig, which was genetically engineered and doused in pesticides from Turkey. As a young child spending summer vacations in a Greek village where everything is locally grown and organic, the idea of genetically engineered food was unsettling. Becoming older and continuing to have the opportunity to travel back and

forth to Europe, seeing organic certified labels on products was a normal occurrence. However, throughout time on the streets of Greece and other European Union countries, the sight of graffiti stating “No to GMOs” became inescapable. This sparked the beginning of trying to understand what the commotion was about, also, why and how European citizens are against the importation of GMOs and if their opinions are being heard.

The importance of public engagement regarding this topic is based on Hartley and Millar’s argument that science policy development benefits from public participation (Hartley & Millar, 2014, p. 482). Also, allowing diversity in opinion by stakeholders and the public provides a broader range of knowledge and expertise, which challenges and allows for the formation of new scientific values. Public participation is also influenced by context and research available, for example, on risks and hazards due to GMOs. Arguably, risks seem to be more of a concern in today’s society because they include the general public’s vulnerability and its increase in health risks (Battisti, 2009, p.75). Understanding threats to public safety must also be placed at a high priority. In order to mediate societal concerns with biotechnology, threats such as adverse consequences with gene flow, new allergens, market favoritism, and the obstruction and restriction of enterprise exclusively within developing countries must be resolved (Battisti, 2009, p.75). Specific GM risks include

> …the safety, for humans as well as the environment; Gene flow and the introduction of adverse consequences: introduction of new strains like “super weeds” or antibiotic resistant bacteria; introduction of new allergens; threats to organic farming technology; safety in labeling (presently not required in the United States); Societal concern: new techniques and products will advantage the

> rich; Domination of the world's food by only a few companies; Dependence of the developing world on the developed countries.
>
> (Battisti, 2009, p.75)

These stated consequences can have a major affect on the farmers dependency on chemical and biotech-companies, with economic and political effects that are being already felt globally. Farmers whose business is to market crops/plants might now have to rely on chemical companies that supply a market for their genetically engineered herbicides.

The food safety risks associated with chemical residue are prominent in the health of humans. Business and scientific practices made it easy to overlook some of the costs of pesticide technology, but if they are true to their utilitarian principles, researchers and planners must be cognizant of all consequences that can come their way. Some of these consequences include lawsuits and confusing arguments made by large seed companies. For example, Monsanto is currently the second largest company and made $3.9 billion in sales during 1996 from Roundup, the herbicide for which the first two most popular biotech crops (Roundup Ready corn and Roundup Ready soybeans) were designed. For example, Roundup Ready seeds are sold with a "technology use agreement" in place (Dawkins, 2003, p.35). This agreement requires farmers to use only Monsanto's brand of herbicide. They also cannot use the seeds of their crop to sow the next season's crop. Monsanto has hired Pinkerton Detective Agency to find farmers who may have violated this license and also Monsanto's intellectual property right. So far, more than 300 farmers have been sued throughout the US for "illegally" using their own crops. Patenting

crop/plant forms by private companies results in large profits for these companies (Dawkins, 2003, p.35). These companies are taking or "re-modifying" the seeds that were already in the market from farmers and patenting the end result. The new resulting product is then advertised as being more superior and beneficial for the consumers than the old product.

The public's argument is that public funds are being spent in a manner that effectively subsidizes research costs for chemical companies, or that directly benefits corporations by increasing the market for their herbicides. Also the author Paul Thompson argues that chemical corporations are supporting research on herbicide tolerance (both directly and by lobbying public officials) because such research helps them to gain control of the research agenda in agricultural biotechnology (Thompson, 1995, p.39). It has been argued by Monsanto's CEO Robert Shapiro that "New technology is the only alternative to one of two disasters: not feeding people-letting the Malthusian process work its magic on the population-or ecological catastrophe". Subsequently scientists employed by corporations have it even worse. No matter how much the biotechnology industry would like to claim that its only goal is to feed the starving masses of the twenty-first century, corporate research is simply limited to products that will most immediately benefit the company. In the beginning, the focus was on developing plant varieties that would be strong enough to withstand massive doses of a particular company's own herbicide. This meant that as the weeds got stronger a field could be sprayed with even higher amounts of the herbicide without killing off the crop (Thompson, 1995, p.55). This was obviously not good for the health of the farmers and for the consumers who ate these harvested

foods. Unfortunately, despite the decline in yields of rice in places like the Philippines and the adverse affects of pesticide use on the rice paddies and its farmers, fertilizer use continues to increase (Thompson, 1995, p.55).

New technology may at first seem to be good and profitable for private corporations, but what happens when testing is necessary? Many questions, debates and arguments start to arise when private corporations take advantage of their new patents and find loopholes that allow for them to escape public scrutiny about health risks. The companies appear to be focused on gaining a tremendous amount of profit. As of 1992, genetically engineered foods do not require testing or any formal notification before being introduced into the US market, due to the FDA's decision (Isserman, 2001, p. 175).

Recently the EU announced plans for a required "traceability" scheme (Dawkins, 2003, p.49) by which all genetically engineered foods would have to be packaged, shipped, processed and sold in a way that anyone could tell where these foods came from and what genetically engineered ingredients they contained. The US is extremely unhappy with this suggestion because it fears the continued loss of hundreds of millions of dollars in exports each year, and thus it has threatened trade sanctions in the WTO. For many years the US has been arguing that genetically engineered foods are no different than the non-genetically engineered ones.

Accordingly, the shift in European policy provoked the first major international trade conflict over GMO safety policies. However, with the adoption of the Cartagena Protocol

and its employment of the Precautionary Principle as its foundation, on December 29th 1993, by delegates from 170 countries who met in Cartagena, Columbia to draft a protocol on the movement of genetically modified organisms (GMOs) between countries (The Economist, 1999), biosafety regulatory frameworks began to attempt to regulate and manage the risks of GMOs (Traavik & Ching, 2007, p. 21). The relevance of this research topic is to investigate whether and how public engagement has had a substantial impact on the content that has shaped the areas of Directives, Conventions and Protocols on trade agreements on GMOs using document analysis. Using this methodology it is possible to provide a more thorough collection of credible data. This paper is organized as follows. This major research paper explores EU regulatory policies in Chapter 1, such as: Directive 90/220EEC which was intended to harmonize regulation across Europe and took a horizontal and process-based approach (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.129). It addresses the development and significance of the Cartagena Protocol and the Precautionary Principle in Chapter 2, and assesses its ability to be viewed as a potential model for EU regulation. Chapter 3 attempts to provide insight on the formal participation process in the regulatory review throughout the EU. Thereafter, the research will move towards corporate interests in international biosafety and intellectual property rights in Chapter 4. Chapter 4 provides the necessary background to introduce Chapter 5 which outlines how the World Trade Organization (WTO) addresses biosafety and what its purpose is in the larger context of the biosafety platform. Additionally, this chapter will identify EU regulatory labelling policies such as the objectives found in Regulation 1829/2004 on GM food and feed, that is "The scope of the regulation applies to food and feed containing, consisting of, or produced or

containing ingredients from GMOS, irrespective of the existence of transgenic DNA or the expressed protein in the final product" (Traavik & Ching, 2007, p. 362). The research paper concludes with an overview summary of each chapter and revisits the purpose of the paper, which is to examine the importance of public engagement in determining international trade policy related to GMOs.

Chapter 2: Genetically Modified Organisms

2.1 EU regulatory policies

When the first genetically modified (GM) products were commercialized in the late 1980s, the European Union (EU) adopted a more stringent stance than North America towards the application of GM products. The EU has since based its regulatory system on an uncertainty regarding the risks involved in this process (Falkner, 2007, p.118). Since the techniques being used for genetic modification were new, this heightened safety concerns that formed a process-based regulatory supervision of genetically modified organisms (GMOs) in Europe (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.129). In a process-based regulatory regime, author Janus Hansen explains that "the process by which products are produced become the object of regulation" (Hansen, 2010, p.24). This process differs from a products-based regulatory regime and a programmatic-based regulatory regime because it considers whether the GM foods' nutritional characteristics differ from those of conventional foods.

Before EU harmonization, different European countries aligned themselves with different regulatory regimes. For instance, the UK aligned itself with a process-based approach while Germany and Denmark opted for more of a programmatic regulatory regime. Thus, different issues became the objects of regulation, and the overall role of science changed due to the regulatory style of each country. In addition, different social arrangements of various policy areas were created (Hansen, 2010, p. 24). Author Janus Hansen identifies four distinctive configurations that shaped regulation. The first one was "exclusive or elite decision-making (France and UK)". The second one was "co-optation (NL and

Sweden and to some extent Germany)". The third one was "public participation (Denmark)". The final one was "delegation to the European level (mostly southern countries)". Understanding that there were four distinguished configurations shaping regulation sheds some light on the idea of how challenging it was to face harmonization within the EU regarding the legitimization of regulatory principles and their implementation (Hansen, 2010, p. 25). The fact that political systems frequently supported and promoted biotechnology has been instrumental to the decline in public trust towards regulators.

During the 1980s the European Community developed its interest in biotechnology as a potential area for future economic growth (Hanes, 2010, p.25). The European Community acknowledged that this new area of interest would need to be addressed with caution in order to avoid conflicts that had arisen from the damages faced by nuclear power throughout various European countries. Thus, in the 1990s the European Community issued directive 90/219EEC, which was to regulate the contained use of GMOs, and Directive 90/220EEC that regulated "their deliberate release into the environment" (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.129). Directive 90/220EEC was intended to harmonize regulation across Europe and it took a horizontal and process-based approach. A horizontal approach, as explained by Janus Hansen, means that the same legal framework extends throughout different sectors that regulate all applications of GMOs (Hansen, 2010, p.24). It should be noted that even though socioeconomic and ethical concerns did not cease to exist within public debates throughout numerous national contexts, they did not find a way to enter the regulatory

principles in the EU. Alternatively public concerns were addressed by emphasizing the "management of uncertainty and adapting a precautionary approach" (Hansen, 2010, p.25).

Taking a deeper look into the EU's regulatory approach on the two EU directives (90/220/EEC and 90/219EEC) and understanding a brief history behind the revision of the directives is essential for understanding the regulatory approaches behind the EU's comprehensive system towards GMOs. Both of the EU Directives were adopted in 1990 and entered into effect in 1991 (Traavik & Ching, 2007, p. 359). As previously mentioned, Directive 90/220 regulated both experimental and marketing releases of GMOs, however it did not provide EU member states with the opportunity to implement stricter regulations than the ones mentioned in the articles. This was however possible under Directive 90/219 "on contained use of genetically modified microorganisms (GMMs)" (Traavik & Ching, 2007, p.359). Furthermore, Directive 90/220 relied immensely on the cooperation between competent authorities of member countries within the decision making process. Traavik and Ching constructively explain this process: "When an EU country received a notification for commercial marketing release" (Traavik & Ching, 2007, p.359), the appropriate authority receiving the application conducts a risk assessment based on the information in the notification. In addition, scientific characterization encompasses activities that pose a possibility of potential adverse impacts during a risk assessment analysis (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.128). If the country's intention was to approve the notification, it would need to send its positive assessment to the European Commission and other member countries for

review. A decision on whether to approve or not to proceed with an application happens only when a dedicated amount of time, analysis, and voting by the EU committee of competent authorities occurs (Traavik & Ching, 2007, p. 359). Moreover, a final decision is made by the EU council (which is comprised of the heads of government of member states) only if the EU committee is unable to arrive at a final decision in support or against the application. It is interesting to note that the authors indicate that a "major criticism of this approval system" stems from the fact that if the Council fails to arrive at a decision within three months, the European Commission adopts the proposed measures (Traavik & Ching, 2007, p.359). When this happens, the European Commission usually approves the marketing of the GMO product.

A recent increase in criticism has stemmed from the limitations related to the regulatory framework and insufficient attention towards important risk-related issues. The criticism occurred due to the differences between different EU authorities' views on how Directive 90/220/EEC was operated. Such differences were specifically based on the lack of knowledge towards risk assessments. For example, a 'de facto moratorium' against approvals of GMOs became an issue of concern in 1998 (Traavik & Ching, 2007, p. 359). This 'de facto moratorium' obstructed the commercialization of GM agro-food products. However, these products soon gained a presence in supply chains, agricultural fields and on supermarket shelves. This amplified the opposition to GM crops in the EU (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.131). Oppositions, such as non-governmental organizations (NGOs) in 1996, "blockaded shipments" that contained GM soybeans because providers did not want to separate "GM and non GM agro-food

products" (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.131). These events have shed light on public engagement regarding GMOs in Europe, where during the 'de facto moratorium' and with diligent NGO campaigns consumers began to boycott GM agro-food products.

Overall, the 'de facto moratorium' obstructed the commercialization of GM agro-food products throughout the EU. During the 1999 meeting of the Environmental Council, six member states (Austria, Denmark, France, Greece, Italy and Luxemburg) concluded that as long as the existing regulation was not revised they would not accept any new market agreements of new GM crop (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.132). During this meeting, there was a request made for stronger legislation with a focus towards a more rigorous, transparent and precautionary risk assessment criteria. One can argue that this was a necessary step to enable an improved safety assessment of GM agro-food products. After three years of discussion within the European Council and European Parliament, Directive 2001/18/EEC replaced Directive 90/220 on October 17th 2002 (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.133), the objectives of Directive 2001/18/EEC were "the protection of human health and the environment" (Traavik & Ching, 2007, p. 361). It is interesting to note that Directive 2001/18/EEC had a "pre-release authorization procedure" as a mandatory part of its set-up, which was comprised of a case-by-case risk assessment. It also emphasized that the risk assessments required the consideration of "the direct and indirect, immediate and delayed effects of GMOs on the environment and human health" (Traavik & Ching, 2007, p. 361). For that reason, it acknowledged that the future implications of GMOs needed to be taken into

account. In addition, the Directive included "public registers of releases, including cultivation sites" (Traavik & Ching, 2007, p. 361). This introduced the fact that public participation would be mandated in EU regulations, which offered the public the opportunity to comment on sub-legislation and on applications that were "submitted by GMO applicants to the EU countries' authorities" (Traavik & Ching, 2007, p. 361). Furthermore, the directive requested that all unauthorized releases had to be promptly terminated. It also stated that Member States were required to take "remedial action if necessary" and to notify the public, the EU Commission, and other Member States if an unauthorized release occurred (Traavik & Ching, 2007, p. 361).

Correspondingly, authors Traavik and Ching address the differences between directives and regulations in the EU. They also present different regulations within the EU. They explain that "directives have to be implemented via national member states' laws, while regulations are directly applicable" (Traavik & Ching, 2007, p. 359). Examples of the different types of regulations within the EU are: GM Food/Feed Regulation 1892/2003, Traceability Regulation 1830/2003, and Transboundary Movements Regulation 1946/2003 (Traavik & Ching, 2007, p. 359). Overall, the biosafety regulatory framework in the EU has a lot of branches and it is vast. Moreover, it oversees the GMO development process from research in contained use to deliberate release to placing products on the market, labeling, traceability, and transboundary movement that implements obligations under Cartagena Protocol on Biosafety in the EU.

With regards to Directive 2001/18/EEC, it is essential to note that it is based on the 'precautionary principle', which has played a major role in the development of biotechnology regulations and the basis of policy-making in the EU. The philosophy behind the precautionary principle is placing a priority on anticipating and guarding against environmental damages and risks. In addition, the objective of this principle is to guide political and regulatory action (Andrew, 2005, p.185). This principle is founded on preventative action towards protecting ecological space and it places the responsibility of care on those who seek change. This precautionary principle is applicable as an approach towards risk, or where regulation anticipates environmental harm that has not yet happened. However, it does not take into consideration the relative costs and benefits of the regulation with respect to industry and the public (Andrew, 2005, p.186). The precautionary principle is a normative principle, and it seeks to make practical decisions where scientific uncertainty is found. Advocates of the precautionary principle opt for the separation of trade and environmental interests during decision-making and they want an improvement in safety procedures (Traavik & Ching, 2007, p. 458). This principle holds merit by including four strong and central components that do the following: "1) initiate preventative action as a response to scientific uncertainty; 2) shift the burden of proof to the proponents of a potentially harmful activity; 3) explore alternative means to achieve the same goal; and 4) involve stakeholders in the decision making process…" (Traavik & Ching, 2007, p. 458).

Overall, strong versions of the precautionary principle and practical implications of its implementation in policy encompass inherent values of the environment and has come to

be accepted by many national governments as a basis for policy-making. Lastly it has become vital for both the international environmental law and international treaties to play an important role in the Cartagena Protocol on Biosafety, which is an international agreement that regulates the safe transfer, handling or use, and trans-boundary movement of GMOs (Traavik & Ching, 2007, p. 457). In conclusion, the EU regulatory system on GM agro-food objective goal is aimed towards a pragmatic balance between various legal objectives. Regarding the Directive 2001/18/EEC, it was examined that it is based on the Precautionary Principle, which has played a major role in the development of biotechnology regulations and the basis of policy making in the EU.

2.2 Cartagena Protocol on Biosafety: Is this a model for EU regulation?

On December 29th 1993, at the Convention on Biological Diversity, a potential model for EU regulation known as the Cartagena Protocol on Biosafety was implemented (Cartagena Protocol on Biosafety to the Convention on Biological Diversity: texts and annexes, 2000) based on precaution and operationalized on decision-making. (Traavik & Ching, 2007, p. 407) The meeting consisted of delegates from 170 countries who met in Cartagena, Columbia to establish a protocol on the movement of genetically modified organisms (GMOs) between countries (*The Economist*, 1999). This protocol is the first international law to specifically regulate genetic engineering and express concern about the safety, health and environmental risks of GMOs, together with the broader political and socio-economic implications of this controversial technology. Furthermore, it recognizes that GMOs are different from naturally developed organisms and can involve special risks and hazards, hence need for a legally binding international law. The Protocol

has played a significant role in providing an international regulatory framework "to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing global industry, the biotechnology industry" (*Cartagena Protocol on Biosafety to the Convention on Biological Diversity: texts and annexes*, 2000). According to the *Economist*, the United States could not sign the Cartagena Protocol due to its lack of participation in the Convention on Biological Diversity] (The Economist, 1999). Nonetheless, the United States would continue to retain its influence due to its vast quantity of exports of agricultural products (with an increasing portion that is genetically engineered) (*The Economist*, 1999), which presented a huge limitation for the Protocol. However, a small but powerful group of agricultural exporters, led by the United States (US) and also comprised of Canada, Argentina, Chile and Uruguay, opposed the rules outlined in the Protocol, but eventually accepted a compromise agreement in 2000 after hard fought negotiations (Falkner, 2007, p.15). The accepted compromise agreement will be discussed at a later time in the chapter**.**

With the arrival of Europe's first GMO shipment in 1996 and 1997 from the United States, European consumers were introduced to GMO issues and public awareness and engagement became widespread which assisted in creating a European-wide campaign to terminate the import of GM crops and to block additional domestic GMO authorization throughout the EU (Falkner, 2007, p.19). During a time of increased concern over food safety, especially after the admission by the United Kingdom (UK) government "of a link between bovine spongiform encephalopathy (BSE) in adult cattle and Creutzfeld-Jakob's disease in humans and the imposition of an export ban on British beef…" (Falkner, 2007,

p.19), this sort of controversy regarding GMO imports further undermined public confidence in Europe's regulatory authorities. With the increase of anti-GM public opinion, a safeguard clause was put into effect by some EU member states in 1990, which allowed them to impose national GMO bans.

After these bans were imposed, in late 1998, the European Commission was also forced into a de facto moratorium. With this shift in European GMO policy, Faulkner (2007) states there was a significant impact on the direction of the international biosafety dialogue. Amidst accusation of protectionism from the US, the EU bolstered itself for possible legal action at the World Trade Organization (WTO), due to claims of annual losses of up to $300 million in farm exports (Falkner, 2007, p. 20). In 2003, the EU lost the first round of disputes when the WTO ruled in favor of the U.S, towards the EU's regulatory impasse. In 2004, the EU introduced new rules on GMO labeling and traceability and reformed its GMO authorization procedures which weakened its strong stance on the precautionary principle and led to its approval of new GMOs from 2004 and onwards (Falkner, 2007, p.20). Despite these changes, the EU, in its previous confrontational efforts towards GMO-exporting countries, became a significant ally in the creation of an international biosafety regime and was still considered a "critical leader in international biosafety politics: having developed the most comprehensive, precautionary framework of domestic biosafety regulation, it provided a model that many developing countries drew on in their own regulatory efforts…" (Falkner, 2007, p.20). During the 1990s, most developing countries from Latin America, Africa and Asia, were still in progress of developing national biosafety regulations but lacked the capacity to

implement them. However, they persisted with their demands for the creation of an international biosafety instrument and were able to build a broad-based and durable coalition of developing countries (Falkner, 2007, 21). The fact that the developing countries managed to speak with one voice on most of the fundamental demands was to play an important role in the successful conclusion of the Cartagena Protocol (Falkner, 2007, 21). According to Falkner (2007), the strong international leadership provided by the EU played a critical role in countering the US opposition to biosafety rules outlined in the Cartagena Protocol (p.21), which took four years of negotiation between "GMO-exporting and importing nations". The developing countries' concerns about biotechnology, along with the EU's precautionary principle position on GMOs, contributed to the strong momentum towards constructing "stringent international rules that allow importing nations to scrutinize, and potentially reject, international GMO shipments" (Falkner, 2007, p.15). The Cartagena Protocol debates help to clarify these differences on GMO standards and their relevance to trade.

Falkner indicates that a comprehensive, horizontal approach to biotechnological regulation has been introduced throughout the EU, replacing the earlier national regulatory systems, which were "holding back the consolidation and cross-fertilization of the European biotech sector". The European Commission successfully authorized an EU-wide regulatory framework in 1990 (Falkner, 2007, p.19). The EU's GMO regulations became process-based and dependent on using a precautionary system approach. This was successful because it took into account the desire between a "harmonized approach

in the interest of free trade in Europe" (Falkner, 2007, p.19) and public concern regarding environmental protection and food safety (Falkner, 2007).

The US began its first official commercial planting of GM crops in 1995, and in just a couple of years the US had become the largest GMO producer in the world. Falkner thoroughly analyzed the Cartagena Protocol, starting with its negotiation stages and ending with its implementation. This assisted the general public to understand the process of setting an agenda and the various parties involved throughout the process. Most importantly, it was helpful that he captured the tensions that arose during the final stages of the negotiations from 1999 to 2000 which identified the international trade-environment conflict between two groups, the US agricultural exporters (the 'Miami Group') and the EU (the 'Like-Minded Group'), along with other developing countries (Falkner, 2007, p. 26).

With respect to the conditions of the Cartagena Protocol, Falkner's overarching conclusion was that the Protocol should be supported by all parties, as well as other agreements. As a credible source from the London School of Economic and Political Science, Falkner has extensive knowledge on biotechnology regulations, trade policy and risk regulation throughout the political landscape relating to the EU and US and their necessities in biosafety, policies and trade agreements. Tension arose however, when the EU's Like-Minded Group successfully included precautionary language in the protocol and the American Miami Group excluded commodities from the Advance Information Agreement (AIA) procedures which required GMO exporters to provide information

detailing the organism in question, and to seek the importing nations' approval before any transboundary movement occurred (Falkner, 2007, 26). The outlook of the AIA was under intense negotiation during the elaboration of the Cartagena Protocol (Sands & Peels, 2012, p.468). La Vina notes that the AIA is at the heart of the Protocol and its importance should be recognized. Decisions about the acceptance or refusal of an importation are based upon the AIA advisory system, which consists of various assessments and management strategies relating to risk, " …The AIA applies to GMOs intended for international introduction into the environment, such as seeds to be planted for agriculture or genetically modified animals, such as fish" (La Vina, 2003, p.15). GMOs intended for international movement (trans-boundary) such as food or feed (ingredients for processing food, or grain for animal feed) can use a modified procedure which consists of a Biosafety Clearing-House, and its decisions on whether to proceed with importation/exportation are based upon a risk-assessment process (La Vina, 2003, p.15). It is important to understand what a Biosafety Clearing-House is; it is there to establish the implementation of the Protocol's formation and for the formation and cultivation of "scientific, technical, environmental and legal information on GMOs" (La Vina, 2003, p.17). Parties relevant to the implementation of the Protocol are provided access to information by the Biosafety Clearing-House.

La Vina (2003) states it is important to have civil society partners and community organizations such as non-governmental organizations (NGOs), which includes the European Biosafety Association (EBSA) which was founded in June 1996. It is a not for profit organization that aims to provide a forum for its members to discuss and debate

issues of concern and to represent those working in the field of biosafety and associated activities (EBSA, 2015), monitor how respective governments implement AIA requirements to ensure the procedure is properly implemented and allow the activity of public participation to be safeguarded by the Protocol (La Vina, 2003, p.15).

The Economist published a report on January 27th 2000, which reported on the Biosafety Protocol. It brought to light how commendable such a protocol was (The Economist, 2000). One strong point of this article was that it provided some clarification as to who is part of the Miami Group (America, Argentina, Australia, Canada, Chile and Uruguay). The article also successfully pointed out that the Miami Group contributed to the failure of the first attempt at the agreement that was held in Cartagena, Columbia in 1999. The failed attempt resulted from these countries holding a lot of power (as six major food-exporting nations) and deciding to oppose the agreement (*The Economist*, 2000). Both Falkner and *The Economist* articles have adequately emphasized the differences in the stances held by the Miami group and the Like-Minded group. *The Economist* article attempted to identify and discuss the viewpoint of the Miami group in respect to why it would agree to put commodity crops into the protocol through only an Internet-based "information clearing house", since this is a reputable and less rigorous process than the AIA agreement (*The Economist*, 2000). Other sources such as *The New York Times,* presented its stance on how Washington feared upcoming negotiations and proposed provisions would "cripple world food trade and endanger billions of dollars a year in farm exports" (*The New York Times*, 2000). This article highlighted the effectiveness of various countries in integrating the concerns of biotechnology companies with the treaty

that regulates trade with respect to GM products (*The New York Times*, 2000). The overarching conclusion of this article seems to be that the treaty represents a successful step towards finding a balance between environmental protection and free trade. However, it should be noted that these interests are frequently difficult to reconcile (*The New York Times*, 2000). There seems to be an error in the article, where the author states that federal officials indicated that the US government would honour the treaty, however, the US never ratified the Convention on Biological Diversity in Rio de Janeiro in 1992, as it was previously stated in the article by *The Economist*. By having the US not ratify the treaty it allowed them to defend their position in the later compromise, which allowed them to counter the Like-Minded groups objectives of the Convention. This did not present the US in a positive light because they are resistant to following the precautionary principle which is the foundation and is embedded in the Convention, which portrays them as only focusing on economic wealth rather than environmental health.

The Economist has also indicated that the US wants to soften the precautionary principle advanced by the EU and embraces an "Internet-based information clearing house" instead of the rigorous AIA agreement (*The Economist*, 2000). This information may be perplexing due to important details being weakened with vague statements made by US government officials. *The Economist* published an article titled "Trade: Caution Needed" on February 2000, which has provided further discussion on the concerns over loopholes for protectionists that the Biosafety Protocol presents (*The Economist*, 2000). This particular article provided helpful examples of why the World Trade Organization (WTO) plays a major role in setting standards that restrict trade. Introducing the WTO as

a major player has led to many more questions that further research can assist in answering. The overarching conclusion of this article is that due to the existing trade agreements, the WTO's ability to maintain free trade may be weakened (*The Economist*, 2000).

Due to a compromise on the treatment of commodity trade between the EU and the Like-Minded Group, precautionary language was inserted in the protocol. However, a less "trade-invasive" procedure was implemented by The Miami Group, which also "succeeded in excluding commodities from the AIA procedure" (Falkner, 2007, p.26). Parties are encouraged to inform other parties of decisions made towards the "domestic use of GMOs that may be subject to transboundary movement", and thus the Biosafety Clearing-House is the instrument used to communicate this information (Falkner, 2007, p.26). The EU and the Like Minded Group wanted to ensure extensive information was supplied on GM products by their exporters, contrary to the objectives of The Miami Group, which wanted to adopt a more generalized regulation, ie, "without specifying the type of GMO and the level of GMO presence" (Falkner, 2007, p.27).

On October 17, 2002, the EU Environment Council reached a political agreement on the cross-border movement of GMOs (EurActiv, 2002). This EurActiv article outlined how the implementation of the Cartagena Protocol should be carried out. The strong point of the article was providing the Environment Ministers' requirements, and the information for transboundary movement of GMOs (EurActiv, 2002). A possible weakness of the article was that it reminded the readers that there were currently only 40 parties to the

Protocol, while 50 are required to enter into force; yet a political agreement has already come into effect. As of June 14th 2003, *The New York Times* stated that Palau, the 50th nation, signed onto the agreement and thus it would go into effect in 90 days (September 11th, 2003) (Pollack, 2003). This article provided some support to previous information gathered regarding the dispute over agricultural biotechnology, where the US indicated that the EU's existing moratorium on approval of new GM crops was not based on sound science (Pollack, 2003).

In conclusion, it can be argued that the Cartagena Protocol on Biosafety can be a model for EU regulation. However, it can also be argued that strong versions of the precautionary principle, EU Directives, the Cartagena Protocol and practical implications of their implementation in policy issues can together work as a different model. This is because it has become vital for both the international environmental law and international treaties to play an important role in the Cartagena Protocol on Biosafety. Individually these instruments are moderately adequate, but in combination they can provide a more robust environmental framework. As previously stated in this Chapter, the EU regulatory system on GM agro-food objective is aimed towards a pragmatic balance between various legal objectives. Regarding the Directive 2001/18/EEC, it was stated that it is based on the Precautionary Principle, which has played a major role in the development of biotechnology regulations and is the basis of policy making in the EU. The Cartagena Protocol as an international binding law, has set its mark holding strong to precaution being operationalized in the decision-making procedures. However, as an negotiated text,

there have been opportunities where there has been room for interpretation and compromises to be made (Traavik & Ching, 2007, p. 424).

Chapter 3: Public participation in the regulation of GMOs

Formal participation in regulatory review process

Appropriate and effective policies are shaped and formed with the support of public participation within decision-making. Multilateral environmental agreements are important because they place governments with the responsibility of involving awareness and the enhancement of public participation. The reasoning is that regulatory framework requires public involvement in order to be effective. One such example was the Rio Declaration on Environment and Development (from the 'Earth Summit' 1992), which focused on the "rights and responsibilities of states in the area of environment and development" (Traavik & Ching, 2007, p. 556). Therefore, an appropriate link to the principles of this declaration would be 'Principle 10', which associates environmental issues with public participation through key elements such as "appropriate access to information, facilitating awareness and participating in decision-making process, and access to judicial and administrative proceedings" (Traavik & Ching, 2007, p. 556). The Principle 10 of the Rio Declaration states:

> Environmental issues are best handled with participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities.
>
> In their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.
>
> (UNEP, 1992)

In October 2001, the Aarhus Convention, the second major multilateral environmental agreement, which includes provisions on public participation, was made effective. It is also known as The UN Economic Commission for Europe Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters. This convention covers Parties from the "Pan-European region, including Europe, Caucasus and Central Asia region (EECCA) and has been ratified in 39 countries, including the European Community" (Traavik & Ching, 2007, p. 556). To promote principles within international organizations related to international environmental decision-making, Principle 10 recommended that parties guarantee public rights to access of information as well as requiring public participation in decision-making and access to justice in environmental matters (Sands and Peels, 2012, p.91).

There were several times between the entry into force of both the Aarhus Convention and the Cartagena Protocol where the Conference of the Parties (COP) served as the meeting of the Parties to the Protocol (COP-MOP) (Convention on Biological Diversity, 2010). It is evident that in 2005, the second Meeting of the Parties played a more crucial role in identifying the importance of how public participation continues to adapt and to suggest a necessary amendment to improve existing applications designed to permit decisions on the deliberate environmental release of GMOs. In this amendment, a new Article 6 was introduced which now requires "parties to provide for early and effective information and public participation prior to making decisions on whether to permit the deliberate release into the environment and placing on the market of genetically modified organisms" (Sands and Peels, 2012, p.654). This amendment is the first treaty to establish "a right

and modalities for public participation prior to making of such decisions" (Sands and Peels, 2012, p.654) as opposed to the original Article 6 which states that: " ...Parties must ensure that a member of the public having a sufficient interest or maintaining impairment of a right has access to a review procedure or a court of law or other independent and impartial body established by law to challenge its substantive and procedural legality" (Sands and Peels, 2012, p.654).

To provide 'effective information and public participation', specific measures must be followed and implemented into the regulatory framework of participating parties. These measures are detailed in Annex I under the new Article 6. It states that there must be "...a reasonable timeframe for public comment and submissions on proposed decisions, making available relevant documentation including any environmental risk assessment, ensuring transparency of decision-making processes and providing reason for decisions, and provisions of access to procedural information to the public" (Sands and Peels, 2012, p.654). Lastly, despite these measures, parties are not obligated to strictly 'endeavour to ensure' that public views reflect the decisions made towards the environmental release of GMOs and also, parties are allowed to have rules within their regulatory framework that can potentially exclude and jeopardize public participation due to the ability to apply "confidentiality requirements" which can inhibit participatory rights (Sands and Peels, 2012, p.655).

The Cartagena Protocol on Biosafety outlines an explicit obligation in Article 23 relating to public awareness and participation, stating:

> 1. The Parties shall:
> (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
>
> (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.
>
> 2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.
>
> 3. Each Party shall endeavor to inform its public about the means of public access to the Biosafety Clearing-House.
>
> (Convention on Biological Diversity, 2010)

The Cartagena Protocol on Biosafety provides a distinct obligation in Article 23 towards Parties to encourage and expedite public awareness. Among others, it requires mandatory public consultation along with disclosure of results to the public in the decision-making process (Traavik & Ching, 2007, p. 557).

Among the three different multilateral instruments, there have been some common elements. However, it is evident that they all refer to the "active" provision of information and the right for the public to receive information, while obligations are placed on governments to ensure transparency and accountability (Traavik & Ching, 2007, p. 557).

More specifically, returning to the public participation scope of the European Community, in European Governance a *White Paper* was introduced in 2001, which is

identified as the main principle in good governance. The essence of the *White Paper* is explained by EUR-Lex as: "The Commission has launched a vast reform of governance in order to drive forward a wide-ranging democratic process in the Union, and proposes four major changes: more involvement of citizens, more effective definition of policies and legislation, engagement in the debate on global governance, and finally the refocusing of policies and institutions on clear objectives" (EUR-Lex, 2008). This connects with the Council Directive 90/220/EEC when it was replaced by Directive 2001/18/EC, allowing greater access by the public towards the regulatory process. However, Cardwell (2010) reports that limitations remain. Directive 2001/18/EC expresses that member states should consult the public and where appropriate, non governmental organizations (NGO) and when they do, they must "lay down arrangements for this consultation, including a reasonable time period, in order to give the public or groups the opportunity to express an opinion" (Cardwell, 2010, p.19). Cardwell identifies that there seems to be an obligation to consult and it is also communicated that "comments by the public should be taken into consideration in the drafts of measures submitted to the Regulatory Committee" (Cardwell, 2010, p.19). It is evident that based on Cardwell's (2010) analysis, groups are only to be consulted when it seems to be considered appropriate by Member states. Furthermore, the obligation is subject to overriding provisions. He explains that this occurs "first, where the GMO enjoys a different procedure as a result of prior release; and secondly in respect of confidentiality" (Cardwell, 2010, p.19).

Public engagement in scientific policy making continuously remains a topic of significance. With declining levels of public trust in food safety, the European Food Safety Authority (EFSA) has stepped in to try and enhance scientific independence and expand risk decision-making using public consultations (Hartley & Millar, 2014, p.481). This however, revealed tensions between … "balancing the goals of scientific excellence and transparency, protecting science from interests, addressing judgments, and limited opportunities to debate ethical and social issues (Hartley & Millar, 2014, p.481). In 2002, the EFSA was established as an innovative example of transnational regulatory framework. Scientific advice, policies, the decisions of risk managers and all associated risks within a food chain are all managed by the EFSA. Besides this, specific requests for scientific assessments are received from the European Commission, the European Parliament and EU Member States (*European Food Safety Authority*, 2000). By adopting or revising food and feed safety, which includes "deciding whether to approve regulated substances such as pesticides and food additives, or, developing new regulatory frameworks and policies for instance in the field of nutrition" within the European Legislation, the EFSA encourages the risk management and policy-making processes. Although the EFSA is not involved with the management of these processes, it provides consultation and bolsters the scientific foundation. Stakeholders and the public are top priorities for the EFSA, which strives to provide appropriate, consistent, accurate and timely communication on food safety issues through risk communication and raising awareness (*European Food Safety Authority*, 2000).

With the establishment of the EFSA, certainly there have been implications for the institutional balance throughout the multi-level system regarding the authorization of GM foods (Kesim & Ayirtman, Unknown, p. 20). From the *White Paper*, an outcome that came about was the General Food Law Regulation (EC Regulation No 178, 2002), which in 2002 prepared the EFSA to contribute scientific advice to the European Commission on a variety of food safety concerns and to take responsibility for the risk assessment and the overall communication functions of the risk analysis (Hartley & Millar, 2014, p. 482). The EFSA has played an important role in developing European risk assessment policy through its "Guidance" documents. In these documents, the principles behind the procedures and approaches to risk assessment are explained, and they also indicate the information and data required for risk assessors, risk managers and the applicant (Hartley & Millar, 2014, p.482). Overall, the EFSA embedded this notion of 'good governance' with a specific focus on strengthening the independence of scientific advice and opening-up risk assessment policy to the public through consultations. On the other hand, the EFSA has faced great scrutiny for this, based on Hartley and Millar's (2014) account, there are four identified tensions arising from opening up science policy, and in particular risk assessment policy to the public or stakeholder involvement. They include: (1) Scientific excellence and openness and transparency, especially when public consultations are used to achieve these goals. Extending scientific policy making to public and stakeholder involvement can allow for a "…broader range of knowledge that may challenge traditional notions of scientific excellence and expertise, potentially allowing values to shape scientific outputs and therefore undermine these notions of scientific excellence" (Hartley & Millar, 2014, p.482). Current management approaches

favour scientific excellence over broader inclusiveness and such processes are not responsive to public and stakeholder expectations, therefore they limit the possible expansion of policy making. (2) Opening up scientific policy to the public and stakeholder can challenge the independence of scientific advice. This presents tension, due to management only opening-up the process and facilitating technological input, however they fail to facilitate insights from stakeholders (Hartley & Millar, 2014, p.482). (3) Risk assessment can be challenged through an open consultation process, which may include traditional notions of science as a value-free enterprise (Hartley & Millar, 2014, p.483). (4) How risk is managed through scientific characterization within a governing framework may seem to be questionable and therefore disputed (Hartley & Millar, 2014, p.483).

On the other hand, Hansen (2010) further expresses that the over-confidence in scientific practices combined with a misreading of public concerns suggests that valuable knowledge is excluded from policy-making and risk assessments, simply because it is disqualified as "public knowledge" (Hansen, 2010, p,40). Risk assessment is one of three components under risk analysis. Under risk assessment, potential adverse impacts associated with a specific activity are scientifically characterized. Under risk management policy alternatives to accept, minimize or reduce the characterized risks are weighed and, if needed, appropriate prevention and control option are selected. And under risk communication, there is interactive exchange of information and opinions on risk throughout analysis, running between risk assessors, risk managers and other interested parties (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.128).

Technology Assessment bodies maintain the involvement of *Ad hoc* committees and participatory initiatives, therefore the protection of scientific integrity and reduction in conflict of interest towards risk assessment, functional and temporal separation must exist between risk assessment and risk management (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.128). After a risk assessment has been completed, two things occur First, the resulting risk management is directly correlated with societal concerns. Second, to omit values, using risk assessment to assess the safety of GMOs is an objective and sound science-based approach (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.128). Under Directive 2001/18/EEC, mandatory consultation of the public and other actors during an authorizing procedure is necessary to accurately distinguish varying understandings of uncertainties and the fundamental principles expressed by various actors, therefore, an assumption must be made based on the fact that public consultation allows risk managers to make better informed decisions, "since they will better understand divergent interpretations of uncertainties and the underlying values held by different actors" (Devos, Reheul, De Waele & Van Speybroeck, 2006, p.138).

In conclusion, it is evident that public concern to become more involved and to portray a more active role has been intertwined in Directives, Protocols and Conventions. What has been identified is that closer cooperation on public consultation is required to enable the public to provide input on the full range of issues related to risk governance. The EFSA public consultation policy tool presents a valuable and innovative opportunity to

exchange and identify the value judgments embedded in risk assessment (Hartley & Millar, 2014, p.498).

From the European Commission, a report to the European Commission's Directorate-General Research, which examines the outcomes of the Eurobarometer on Biotechnology and Life Science, this survey provided a representation of public voices. A section from "Support for GM Food" provides a possible explanation on whether EU citizens are concerned about GM foods and whether they want to know if they are beneficial, safe and inequitable (European Commission, 2010, p.37). With GMO decision-making becoming more of a transparent topic that involves the European citizens opinions and concerns, the *White Paper*, in 2002 prepared the EFSA to contribute scientific advice to the European Commission on a variety of food safety concerns and to take responsibility for the risk assessment and the overall communication functions of risk analysis (Hartley & Millar, 2014, p. 482). The EFSA has played an important role in developing European risk assessment policy through its "Guidance" documents. In these documents, the principles behind the procedures and approaches to risk assessment are explained, and they also indicate the information and data required for risk assessors, risk managers and the applicant (Hartley & Millar, 2014, p.482). Overall, the EFSA embedded this notion of 'good governance' with a specific focus on strengthening the independence of scientific advice and opening-up risk assessment policy to the public through consultations.

Chapter 4: Corporate Power and effects on public participation and regulation

4.1 Corporate interests in international biosafety

Corporations played a crucial role in the negotiation of the Cartagena Protocol on Biosafety. Industry players – individual corporations as well as international and domestic industry associates – strongly resisted strict regulations on the trade of GMOs (Falkner, 2007, p. 34). Hence, in the private sector, partnerships of the International Chamber of Commerce (ICC) and the World Business Council for Sustainable Development (WBCSD) have sought to secure that the interests of the business community are taken into account (Sands & Peels, 2012, p.89). For instance, they have made suggestions for the development of international environmental law, such as "the Business Charter on Sustainable Development, the Declaration of the World Industry Conference on Environmental Management (WICEM II) and the Valdez Principles (in the US)" (Sands & Peels, 2012, p.89). They also hold regular dialogues with intergovernmental environmental organizations, such as the ICC-UNEP Business and Industry Global Dialogue (Sands & Peels, 2012, p.89).

In 2000, the United Nations (UN) established a Global Compact, which requested that its corporate participants comply with ten principles and shared values. Three of the principles relate to the environment and commit businesses to: "supporting a precautionary approach to environmental challenges; undertaking initiatives to promote greater environmental responsibility; and encouraging the development and diffusion of environmentally friendly technologies" (Sands & Peels, 2012, p.89). International legal negotiations to be legislated are observed by the corporate sector, primarily when these

negotiations involve their interests. Active participation from various interest groups such as individual companies, trade associations and other industry groups reflects a growing interest in public international law and the business community, in conjunction with the international regulatory measures transnational corporations have been subjected to in order to minimize possible "activities which may entail harmful consequences" (Sands & Peels, 2012, p.89). Until recently, "the first internationally agreed framework for co-operation in the field of international direct investment and multinational enterprises" had not been updated since it was first introduced in 1976 (Sands & Peels, 2012, p.89). Taking into consideration the extensive guidelines that Part V of the 2000 Guidelines on the environment provides, it is crucial to note that:

> Enterprises should, within the framework of laws, regulations and administrative practices in the countries in which they operate, and in consideration of relevant international agreements, principles, objectives, and standards, take due account of the need to protect the environment, public health and safety, and generally to conduct their activities in a manner contributing to the wider goal of sustainable development.
>
> (Sands & Peels, 2012, p.89)

Based on Falkner's (2007) research, the area of international political economy has included a focus on the structural power of transnational corporations (TNCs) and their role as sources of 'private authority' in the global realm. These players have a strong presence in global environmental negotiations, which allows them to have an immense influence towards the outcome of international environmental treaties (Falkner, 2007, p.35). This becomes evident when there is an increase in the number of these actors attending global environmental negotiations, starting with the 1992 Earth Summit, held in Rio de Janeiro. For transnational corporate actors, it is not sufficient to simply react to international environmental agreement outcomes. Currently, they have become more

directly engaged in public debates over global environmental issues (Falkner, 2007, p.35). For instance, one way that firms have sought to restrict the scope of systems of public regulation for GM crops is by invoking international trade rules (Newell & Glover, 2003, p. 9). This becomes more apparent regarding global environmental issues with clear economic implications for industry, such as the politics surrounding the trade of GMOs (Falkner, 2007, p.35).

Once concern over the trade of GMOs became the central focus of the negotiations on the Cartagena Protocol on Biosafety, during its negotiation state in 1996, corporate influence and interest in biosafety became evident. Conflict began between the Miami Group and the Like-Minded Group due to their opposing perspectives on which GMO products were to be covered by the protocol "including whether and how to identify and label GMOs in agricultural commodity shipments, the use of the precautionary principle and the relationship of the protocol to international trade rules under the WTO" (Falkner, 2007, p.37). Accordingly, during negotiations, industry groups acted as observers and as it became clear that the treaty would significantly impact them, their involvement in the negotiations became increasingly evident over the course of the conference (Falkner, 2007, p.37). In 1996, eight industry groups represented the first round of negotiations and in 1999, there were over twenty present at the meeting in Cartagena. By the late 1990s, representatives from various individual and industry corporations were present such as Monsanto, DuPont and Syngenta, Biotech Industry (BIO), BioteCanada, Japan BioIndustry Organization, the International Chamber of Commerce, the US Grains Council and the International Association of Plant Breeders for the Protection of Plant

Varieties (Falkner, 2007, p.37). Although there was a wide range of industries present with varying objectives, they all remained opposed to the "adoption to strict rules to limit the production and trade in genetically engineered seeds and crops" (Falkner, 2007, p.38).

In accordance with the precautionary principle, international trade had the potential to decelerate once industry groups started identifying and labelling agricultural commodities. The identification and labeling of agricultural commodities such as animal feed not intended for direct human consumption would pose an unnecessary strain on international trade due to the processes involved in labeling a product as genetically modified. Risk assessment posed a higher priority for industry groups over the precautionary principle, the former of which was based on "weight of science as a requirement" (Falkner, 2007, p.38), prior to the refusal of GMO imports into countries. Subsequently, these industry groups believed that WTO rules should not be outweighed by biosafety protocols and in the event of a conflict, WTO rules should prevail (Falkner, 2007, p.38). As a result of these beliefs, industry groups "tended to favor the positions taken by the Miami Group" (Falkner, 2007, p.38). As previously mentioned above, the Like Minded Group, the Miami Group and various industry groups came to a compromise over the final agreement, which some have "characterized as being vague and somewhat obscure". Concerning the classification of GMOs being covered in the treaty, there are multiple categories with varying rules that apply to each. During the first international transboundary movement of a Living Modified Organism (LMO) intended for release into the environment (ie. seeds), the explicit AIA procedure is exempted and instead, there should be identification requirements on a separate document stating that

the commodity shipment 'may contain' LMOs, while domestic shipments of GMOs require the approval of an internet-based Biosafety-Clearing House (Falkner, 2007, p.39). In cases of inadequate scientific information, both parties (importer and exporter) are allowed the right to make a decision on imports.

Despite this, the publication by *EurActiv* in 2013 entitiled "Monsanto to drop requests for GM approvals in EU" highlights the fact that Monsanto withdrew all pending requests to grow new classes of genetically modified crops in the EU. EurActiv reports the frustration still experienced by biotech companies in relation to the EU's approval system for GMOs. However, an alarming factor presented in this article, which requires further research, is the notion that although EU citizens portray extreme hostility towards genetically modified foods, Europe continues to be one of the world's leading "buyers of biotech grain, importing more than 30 million tonnes" (*EurActiv*, 2013). This vast importing mainly concerns the GM feed for Europe's livestock industry. Approximately a year later, in June, *EurActiv* reported that the EU had reached an agreement granting its member states the right "to restrict or ban GMO crops in their territory" (*EurActiv*, 2014). There are "two key rules which govern GMOs in the EU: a directive used for the authorization of GMO products in EU and regulation used on food and feed made from GMO products that have been authorized" (*EurActiv*, 2014). Overall, this article states that companies such as Monsanto would be against a "community authorization system" which gives member states the freedom to decide whether or not to cultivate GM crops on their territory, because these companies would not want a government body assessing the cultivation of GM crops. The overarching conclusion based on the abovementioned

sources is that the June agreements will most likely not repress any controversy encompassing GMO approvals (EurActiv, 2014). This is due to Tonio Borg's (the Commissioner for Health) statement suggesting that the Environment Council has reached a political agreement moving towards a "new legal basis" that provides member states with the option to "restrict or prohibit the cultivation of GMOs on their territory" (EurActiv, 2014).

EurActiv reported in the article "EU agreement opens door for new GMO cultivation in 2015" that the European Commission has already validated new GMOs and they will "be put on the market in the EU as soon as the adoption of the text is finalized" By examining the sequence of media events, it is questionable as to why the Commission would validate new GMOs despite the numerous conflicts occurring throughout the EU regarding banning GMOs. This is a gap which still remains to be addressed. The entire article emphasizes that different member states are "welcoming the agreement", yet the agreement seems to be authorizing the entry of new GMOs into the EU market. At the same time, the agreement allows the member states to ban the GMOs. Thus, this begs the question: *Why would the EU allow GMOs into the market if most member states will only proceed to ban them?*

To identify key actors in global biotechnology politics, it is important to first understand the dynamics amidst intra- and inter-firm decision-making (inter-firm is between two companies and intra-firm is within one company). The endeavours of agri-biotech companies have powerful effects on the research and "development of GM crops, the

tests that are undertaken to assess their safety, and the means by which they are distributed" (Falkner, 2007, p.71). Risks correlating with the advancement and release of GMOs are reviewed and scrutinized by governments and international organizations with differing corporate strategies. Lastly, it is also prudent to understand that policy is an influencing factor, capable of generating change in a commercial environment from where investment decisions are taken and that the policy space available to state managers is due to technological innovations and investment practices among leading firms (Falkner, 2007, p.71). To remain conducive to commercial interests, biotechnology firms must ensure a regulatory environment and maintain market dominance through their use of corporate strategies (Falkner, 2007, 72). Thus, fluctuating market opportunities and political landscape changes endorse the continuous reconstruction of corporate strategy in the biotechnology sector (Falkner, 2007, p.72).

In conclusion, the position of agricultural biotech corporations on the Cartagena Protocol on Biosafety is a direct result of developments in both the agricultural biotech and the chemical sector. Corporate mergers between the two sectors and the industry's positions on biosafety communication showcase the recent changes taking place related to the profitability of genetically modified seeds and agricultural chemicals (Falkner, 2007, p.41). As a result, three of the top global seed firms, DuPont, Monsanto and Syngenta, are also among the top four global agro-chemical firms today. Therefore, changes in the profitability of these sectors is tied to the transnational corporate strategy on global environmental treaties such as the Cartagena Protocol on Biosafety, which is

consecutively conditioned by both the status of scientific understanding with respect to health and environmental safety (Falkner, 2007, p.41).

4.2 Intellectual property rights

Trade principles such as the equal treatment of member states and non-discrimination against imports, have only recently been incorporated by the WTO, which was originally established in 1994 by the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in conjunction with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). These principles paved the way for strengthened global expectations of property rights for genetic modifications and limitations on the "amount of national variation on intellectual property rights" (Falkner, 2007, p.161). Member states of the WTO continuously developed competing norms and procedures to consider them opposing the WTO's norm for trade promotion. GM products are subject to two important agreements, the first one, the Sanitary and Phytosanitary (SPS) Agreement which allows "national regulation to protect human, animal and plant life or health" (Falkner, 2007, p.161) and the second one, the Technical Barriers to Trade (TBT) Agreement, which provides guidelines for packing, marketing and labeling. It is evident that the TBT agreement "stresses that any guideline under its purview must not present barriers to trade" while the SPS agreement "insists on the use of scientific standards for risk assessment" (Falkner, 2007, p.161).

On January 1, 1995 in Marrakesh, GATT was officially replaced by the WTO, in which 123 member countries signed a definitive agreement created by Arthur Dunkel, director-

general of GATT (Robin, 2010, p.313). This founding document of the WTO contains twenty-nine sectoral agreements which allow for trade in most goods or services that was originally under the area of public policy to be subjugated to private sector control (beyond the reach of government and citizens). The Intellectual Property Committee (IPC) was a coalition of companies along with "major players in the area of biotechnology" (Robin, 2010, p.314) that gathered to design the TRIPs agreement and in March 1986, brought together thirteen multinational corporations from the chemical, pharmaceutical and computer industries: Bristol-Myers, DuPont, FMC Corporation, General Electric, General Motors, Hewlett-Packard, IBM, Johnson and Johnson, Merck, Pfizer, Rockwell International, Warner Communications and Monsanto. The document titled "Basic Framework of GATT Provisions on International Property: Statement of Views of the European, Japanese, and United States Business Communities", that formed the basis of the TRIPs agreement, was created by the Union of Industrial and Employers' Confederations of Europe (UNICE) and the Keidanren, the Japanese employers' confederation and was submitted to GATT in June 1998, its aim was to extend a patent system to the rest of the world like that which already existed in industrialized countries (Robin, 2010, p.314). The document presented the issue in this way: "Disparities among systems for the protection of intellectual property result in excessive loss of time and resource in the acquisition of those rights. Holders find that the exercise of their rights is hindered by laws and regulations limiting market access and the repatriation of profits" (Robin, 2010, p.314). Controversy swirls around Article 27, paragraph 3(b):

> plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any

> combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.
>
> (World Trade Organization, 2015)

Once paragraph 3(b) under Article 27 is understood, "animals and plants but not microorganisms may be excluded from the patent system", however, it also states "plant varieties" shall be protected "either by patents or by an effective *sui generis* system." The underlying intent of this section of the document was to enable manufacturers to collect royalties on transgenic seeds, which are currently supported by sanctions and are "protected" by the International Union for the Protection of New Varieties (UPOV) agreements system (Robin, 2010, p.316). Foods deriving from seeds may now also need protection. For this reason, countries such as South Africa, India and Brazil are demanding that Article 27, paragraph 3(b), be revised (Robin, 2010, p.316).

In conclusion, intellectual property rights have become giant corporations' weapon of choice to monopolize products, regardless of their value to society. It is unsurprising that biotech companies whose products are the subject of regulation, are heavily involved in the international governance of crop biotechnologies. Systems of governance constructed to address trade concerns nevertheless have important implications for national-level policy choices around biotechnology (such as TRIPS). With the arrival of TRIPs, all products must be patentable with very narrow exceptions. Overall, practically anything that can be genetically manipulated can be patented and monopolized as private property of giant transnational agricultural corporations. With patent legislation by the WTO in place in every country now, these companies can eventually in the future easily have the power to take over national industries and call the whole world their market.

Chapter 5: International trade and Biosafety Standards

5.1 WTO – Biosafety

Trade, environment and biosafety are international matters in which the WTO (153 member states and the EU) is continuously engaged in. There are various interests that facilitated the development of the WTO. These include the WTO's responsibility for administering dozens of international trade agreements and declarations that are specific to certain areas of commerce from agriculture to copyright and protection. In addition, the WTO operates as a forum for trade negotiations, monitors national trade policies and handles trade disputes (Cline, 2010). Internationally, countries benefit from having membership in the WTO because it provides accessibility to the markets of other WTO members, the option of invoking dispute resolution to enforce that right, and the opportunity to influence the course of future trade negotiations.

From its inception, the WTO had intentions to eliminate tariffs for a better flow of goods. However, as the years went by, the WTO evolved and adapted to the needs of its members and multiple corporate interests. Part of this adaptation involved copyrights, updating trade policies, piracy, and intellectual properties. Thus, by conveniently attaching the term "trade-related" as a prefix to its title, the WTO agreement transforms an entire domain of domestic policy and law into one apparently suited to WTO regulations. The Trade-Related Intellectual Property Rights (TRIPs) agreement urges all WTO member nations to adopt and implement U.S style patent protection regimes (Shrybman, 2001, p.45-56). The effect is to provide both U.S and European transnational corporations with global patent rights enforceable by retaliative trade sanctions. Yet, the

commonly held rights of domestic communities to genetic and biological resources are ignored. Moreover, one of the key achievements of the WTO has been to institute a system of dispute resolution, by which trading disputes between member states can be resolved by a tribunal of trade lawyers, thus ostensibly preventing such disputes from becoming too political or controversial (McLean & Wood, 2010, p. 336).

Correlating to the previous chapter, based on Traavik and Ching (2007), there are controversial relationships between the GATT, SPS, and TBT Agreements. This is evident under Article 1.4 of the SPS Agreement, which states:

> Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.
>
> (World Trade Organization, 2015)

and Article 1.5 of the TBT Agreement which states:

> The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures**.**
>
> (World Trade Organization, 2015)

Phytosanitary and sanitary measures are regulated under the SPS Agreement and measures that are compatible under this agreement are presumed in Article 2.4 of said agreement which conform to GATT 1994:

> Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).
>
> (World Trade Organization, 2015)

GATT-compatible measures may violate the SPS Agreement (although not necessarily true in reverse). Specific agreements relating to biosafety are given a higher priority within the WTO and thus, a hierarchy is established. For example, the SPS Agreement is more specific than the TBT Agreement and addresses plant, animal and human health protection, while the latter is less specific and regulates measures that affect trade which are technical and industrial standards, including packing, marking and labelling requirements, although they do not fall under the SPS Agreement (Traavik & Ching, 2007, p. 431). Looking at GATT 1994, it is a noticeably more generalized and broader agreement which "applies to all measures affecting any product in international trade, including GMOs and GM products" (Traavik & Ching, 2007, p. 432). Depending on the objective of a measure, an agreement may be suitable to its correlating biosafety measure. For example, restricting GM food with a policy objective to protect human health would be an SPS measure and would therefore, fall under the bounds of the SPS Agreement. If the policy objective of the GM food policy in question was to prevent deceptive practices by informing the consumer, it would then fall under a TBT measure and therefore, within the bounds of a TBT Agreement (Traavik & Ching, 2007, p. 432). GATT, Article XX which states: "(policies) necessary to protect human, animal or plant life or health" (World Trade Organization, 2015) held no weight with regard to GMO regulation since "necessity" was an uncommon concept and could not be evidently decided on, therefore, there was no official method for settling disagreements in such circumstances (Patterson & Josling, 2005, p. 14).

Dispute Settlement Understanding (DSU) oversees disputes between WTO members concerning environmental measures, agreements and trade obligations. Dispute settlement procedures, formerly supervised by the GATT have seen significant changes, after 1995, the most significant change was that the panels reports become binding unless a party decides to appeal it or if the Dispute Settlement Body (DSB) decides not to adopt it. (Sands & Peels, 2012, p.812). This is what Article 1.1 outlines as the dispute settlement procedures:

> The rules and procedures of this Understanding shall apply to disputes brought pursuant to the consultation and dispute settlement provisions of the agreements listed in Appendix 1 to this Understanding (referred to in this Understanding as the "covered agreements"). The rules and procedures of this Understanding shall also apply to consultations and the settlement of disputes between Members concerning their rights and obligations under the provisions of the Agreement Establishing the World Trade Organization (referred to in this Understanding as the "WTO Agreement") and of this Understanding taken in isolation or in combination with any other covered agreement.
>
> (World Trade Organization, 2015)

Established under the WTO, The Dispute Settlement Body (DSB) is responsible for administering the rules and procedures governing dispute settlement (Sands & Peels, 2012, p.812).

As dictated by the Vienna Convention on the Law of Treaties (adopted in May 1969 and came into force January 1980) and understood by International law, a later agreement supercedes an earlier one and an agreement on a specific subject prevails over a general one, though, "it should be emphasized that the WTO agreements were adopted before the Cartagena Protocol on Biosafety was adopted and entered into force" (Traavik & Ching, 2007, p. 439). It could also be argued that the Cartagena Protocol overrules the WTO

Agreements due to the fact that the Cartagena Protocol on Biosafety was enacted after the WTO Agreements, addresses biosafety, and is therefore, "a more specific agreement and more recent law" (Traavik & Ching, 2007, p. 439). The Protocol's relationship with other international agreements is ambiguous due to the compromises made during the Protocol's negotiations and yet, the Preamble of the Protocol realizes that trade and multilateral environmental agreements should be mutually supportive. For this reason, "agreements between the same States and covering the same subject matter should be interpreted in such a way that promotes their compatibility" (Traavik & Ching, 2007, p. 439).

In addition, failing to apply for an authorization system for GMOs may lead to having a complaint filed against a country by the WTO, as was in the case with the EU. If a particular product is unsafe to import, the importing country must scientifically prove why and issue a legal ban on the import of that food (if there is a lack of scientific evidence, temporary precautionary measures may be applied) (Traavik & Ching, 2007, p. 465). Therefore, there is room for conflict between the WTO's requirements and the Precautionary Principle in the Cartagena Protocol with regards to the degree of scientific evidence required to provoke action (Traavik & Ching, 2007, p. 465).

In conclusion, establishing an internationally accepted regulatory framework for GMOs has been highly controversial. Factors conducive to a harmonious trade-environment relationship are not present with respect to the two multilateral paradigms for regulating biotechnology products such as, produce that are herbicide tolerant or disease resistant.

(Falkner, 2007, p.210). According to Traavik and Ching (2007), certain agreements that relate to biosafety are given a higher priority within the WTO, which forms a hierarchy. In addition, it is important to remember that a later agreement supercedes an earlier one and an agreement on a specific subject prevails over a general one, which in this case means the Cartagena Protocol should overrule the WTO Agreements due to the fact that the Cartagena Protocol on Biosafety was enacted after the WTO Agreements. A possible explanation as to why this has not happened yet is, that the US has not ratified the Cartagena Protocol therefore provisions cannot be invoked against them.

5.2 EU labeling policies

According to authors Legge and Durant (2010), any nation undergoes a five-step decision-making process regarding GM foods. First, the nation must decide how much institutional protection of intellectual property they will allow multinational corporations which are investing in the research and development of GMOs within the said nation (Legge & Durant, 2010, p.61). Second, they must decide "to what extent regulatory regimes will screen for biosafety risks when GMOs are involved (i.e., will GMO seeds and products be screened differently)" (Legge & Durant, 2010, p.61). Thirdly, nations are required to agree on the amount that regulators can encourage or discourage the import or export of GMO products (Legge & Durant, 2010, p.61). Fourth, if GMOs in food trigger labelling of products, then they must allow consumers the choice over whether to purchase them or not. Finally, unilateral or partnership research investments of GMOs must hold a connection with public opinion (Legge & Durant, 2010, p.61).

Accordingly, since 2004, the objectives of Regulation 1829/2004 on GM food and feed have been the protection of human and animal health, and the environment and ensuring transparency of the GMO content of a product. The objective of the regulations is that it "…applies to food and feed containing, consisting of, or produced or containing ingredients from GMOS, irrespective of the existence of transgenic DNA or the expressed protein in the final product" (Traavik & Ching, 2007, p. 362). Therefore, an extensive authorization procedure (with a time limit of 10 years) is required, consisting of a mandatory pre-marketing authorization procedure. If the food and or feed contains GMOs, an environmental risk assessment in line with Directive 2001/18 and its annexes is carried out and conducted at the EU level by the EFSA. However, "…if a GMO is likely to have dual purposes, i.e it is likely to be used for both food and feed, it cannot be released onto the market without approval for both purposes" (Traavik & Ching, 2007, p. 362).

Since November 7, 2003, the traceability and labelling of GMOs and traceability of food and feed products (including undetectable products) purchased from GMOs have been in force amidst Regulation 1830/2003 and extended to regulation 1829/2004. Furthermore, non-compliance of this regulation qualifies said products for withdrawal (Traavik & Ching, 2007, p. 363). Record keeping and documentation is required for five years and the identification of GMOs is based on unique codes. For example, GM plants are assigned codes by the Organization for Economic Co-operation and Development (OECD) (established in 1961) Unique Identifiers system.

In February 2002, the OECD published the Guidance for the Designation of a Unique Identifier for Transgenic Plants. A Unique Identifier is a nine-digit alphanumeric code

that is given to each transgenic (or genetically engineered) plant that is approved for commercial use, including planting and food/feed use. This guidance was developed because confusion can arise when different national authorities are sharing information on the same genetically engineered crop if different names or descriptions can be used for the same product. This is particularly important as more and more information on the safety of approved products becomes available through websites.

(OECD, 2015)

Based on Traavik and Ching's (2007) notion, commodities that contain a range of GMOs are exempt and therefore a list of unique codes is given in order to constitute this. Furthermore, they are required by the EU to provide documentation demonstrating the kind of GMOs that were used to constitute the shipment. Additionally, various solutions regarding documentation accompanying shipments of GMOs being used for food, feed or for processing, as stated in Article 18.2(a) of the Cartagena Protocol (Traavik & Ching, 2007, p. 363).

As a result of the activities of the International Labour Organization (ILO), United Nations Environment Program (UNEP), World Health Organization (WHO), Food and Agriculture Organization (FAO), OECD and the EU, international rules and practices for the registration and classification of hazardous substances are extensive (Sands & Peels, 2012, p.522). Concerning production, the FAO has developed a range of guidelines on various aspects of pesticide production and use, including registration and control; packing and storage; labelling; retail distribution; national legislation; and obsolete stocks. In 1962, the Codex Alimentarius Commission was established to implement the joint FAO/WHO Food Standards Programme. This programme was developed to protect the health of consumers; promote the co-ordination of food standards work undertaken by

international governmental and non-governmental organizations, and prepare and finalize regional or global standards (Sands & Peels, 2012, p.522-523). Maximum limits for pesticide residue have been established by the Alimentarius Commission's 180 members. Products "whose consumption and/or sale has been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by government" (Sands & Peels, 2012, p.522-523) are now overseen by the Consolidated List of Products, which has since replaced the Codex Alimentarius Commission (Sands & Peels, 2012, p.523).

An Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology was formed by Codex and held its first meeting in March 2000 (Patterson & Josling, 2005, p.16). The meeting was attended by a broad array of public officials from over 33 countries, five international governmental organizations, and about 14 international non governmental organizations and its purpose was to "identify the work priorities and key concepts and definitions to be developed by the task force" (Patterson & Josling, 2005, p.16) in which "the task force decided it would proceed with the elaboration of two major texts" (Patterson & Josling, 2005, p.16). The first text would focus on expansive general principles towards risk analysis of foods derived from biotechnology and would incorporate matters of science-based decision-making, pre-market assessment, transparency, and post-market monitoring (Patterson & Josling, 2005, p.16). In the second text, the focus would be towards providing specific guidance on the risk assessment of foods such as food safety and nutrition, "substantial equivalence" (Patterson & Josling, 2005, p.16) potential long-term health effects, and non-intentional effects. It is crucial to note that the task force required a "list of available analytical

methods for the detection and identification of foods or food ingredients derived from biotechnology should be prepared" (Patterson & Josling, 2005, p.16). A committee that has identified a set of "proposed draft guidelines for labeling food and food ingredients obtained through genetic modification" (Patterson & Josling, 2005, p.16) is the Committee of Food Labelling, which has become involved in the debate over biotech policy (Patterson & Josling, 2005, p.17). This committee defends "labeling when food and food ingredients are no longer equivalent to their conventional counterparts, and/or when they are composed of or contain a GMO or protein or DNA resulting from gene technology, and/or when they are produced from but do not contain GMO, protein or DNA resulting from gene technology" (Patterson & Josling, 2005, p.17).

In conclusion, the EU has taken steps towards addressing their labelling policy. Since November 7, 2003, the traceability and labelling of GMOs and traceability of food and feed products (including undetectable products) purchased from GMOs have been in force amidst Regulation 1830/2003 and extended to regulation 1829/2004. There has also been the creation of the Codex Alimentarius Commission in 1962, to implement the joint FAO/WHO Food Standards Programme. This programme was developed to protect the health of consumers; promote the co-ordination of food standards work undertaken by international governmental and non-governmental organizations, and prepare and finalize regional or global standards (Sands & Peels, 2012, p.522-523).

Chapter 6: Conclusion

To conclude this research paper, first, it can be argued that the Cartagena Protocol on Biosafety can be a model for EU regulation and also represent a strong version of the precautionary principle and EU Directives. Therefore, once practically implemented, these regulations in policy issues begin to collectively work as a comprehensive framework. This is because they have become vital for both international environmental law and international treaties, as they play an important role in the Cartagena Protocol on Biosafety. Individually, these instruments are moderately adequate, but in combination they can provide a more robust environmental framework. As previously stated in Chapter 2 of the EU the regulatory system on GM agro-food, the objective is aimed towards a pragmatic balance between various legal objectives regarding the Directive 2001/18/EEC which is based on the Precautionary Principle and has played a central role in the development of biotechnology regulations and forms the basis of policy making in the EU. This is only the beginning of a long and difficult road towards effective international regulation of genetic engineering, which requires ongoing work and effort. Sovereign countries must act collectively to ensure that biosafety becomes a reality.

The Cartagena Protocol, as an international binding law, has set its mark by holding strongly to precaution (which is operationalized) during decision-making procedures and negotiated text, which have created the space for interpretation and compromises. Overall, one can argue that strong versions of the precautionary principle and practical implications of its implementation in policy issues are constructive because the principle encompasses inherent values of the environment and has been accepted by many national

governments as a basis for policy-making. The principle has become vital for both the international environmental law and international treaties to play an important role in the Cartagena Protocol on Biosafety, which is an international agreement that regulates the safe transfer, handling or use, and trans-boundary movement of GMOs. It is evident that public concerns about GMOs and public desires for a more active role, has been intertwined in Directives, Protocols and Conventions. What has been identified is that closer cooperation on public consultation is required to enable the public to provide input on the full range of issues related to GMO risk governance. Attempts to establish an internationally accepted regulatory framework for GMOs has been highly controversial. Factors conducive to a harmonious trade-environment relationship are not present with respect to the two multilateral paradigms for regulating biotechnology products (Falkner, 2007, p.210).

According to Traavik and Ching, certain agreements that relate to biosafety are given a higher priority within the WTO, which forms a hierarchy. In addition, it is important to remember that a later agreement supercedes an earlier one and an agreement on a specific subject prevails over a general one. However, the intellectual property rights have become giant corporations' weapon of choice to monopolize products, regardless of their value to society. It is unsurprising that biotech companies whose products are the subject of regulation are heavily involved in the international governance of crop biotechnologies. Systems of governance constructed to address trade concerns (such as TRIPS) nevertheless have important implications for national-level policy choices around biotechnology and the EU has taken steps towards addressing a legitimacy crisis in their

adoption of Regulation 1829/2003 on GM Food and Feed, and Regulation 1830/2203 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs (Traavik & Ching, 2007, p. 363). To date, opt-out measures have been created to allow EU member states the ability to restrict or prohibit a GMO relating to food or feed (European Commission, 2015). The European Commission proposed this measure to allow individual member states the opportunity to accept or to ban the importation of a GM product. In order to "opt-out" member states would have to apply "principles of proportionality and non-discrimination between national and non-national products" (European Commission, 2015) and they would have to make sure they are in accordance with EU Law.

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