

A Messy Food Fight:

Regulating Genetically Modified Food and Products on an International level

Masters Thesis

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My Karlsson

The School of Economics and Commercial Law
Göteborg University
Department of Law
LL.M Program
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Supervisor: Professor Per Cramér

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1. Introduction

The year 2005 marked the tenth planting season since genetically modified crops were first grown in 1996. Since its introduction, thirteen years ago, the debate and controversy over biotechnology has flared around the world. It is a heated debate that in many cases exposes a rift between governments and their people over the potential risks and benefits there are with this technology.

The United States is the largest producer of GM-food in the world¹ and it is also the number one leading biotech crop country, representing 53 per cent of the global transgenic crop area.² This corresponds to about 134.9 million acres. The attitude towards GM-food in the US seems to be quite positive, both from the consumer and government side. Genetically modified food is widely spread over the American market and consumers do not seem to be hesitant to buy it. In the US the attitude towards GM-food seems to be that it is no different from the regular food (non-GM) that we have been consuming for centuries. However, the attitude in the European Union is completely different and stands in sharp contrast with this American view.

When looking at scientific evidence available to us today there are no real indications that GMOs should pose a threat to human health. However the long term effects have not yet been investigated, simply because the technique hasn't been around for long enough. At the moment, the only known health risks that may be caused by GM food are food allergies and increased resistance to antibiotics. However when it comes to environmental risks there are studies showing that wildlife may be harmed by GM crops and that GMOs can cross-pollinate with other plants.³ There is no doubt that GM crops offer great benefits to agriculture and farmers. It also has a number of benefits for human health and the environment, including higher agricultural output, more nutritional food products, and lower utilization of agricultural chemicals, fertilizers, and water in commercial farming. However these benefits are sometimes also debated and as we can see, these potential benefits do not come without risks and uncertainties.

It is in this assessment of the risks and benefits of agro-biotechnology that we begin to see a divergence between the American and the European positions. This divergence goes to the core of the controversy. The United States uses an assessment technique often referred to as a **conventional risk assessment** and the European Union makes use of what is referred to as a **precautionary risk assessment**. In short the conventional assessment is about relevant scientific evidence, meaning that there needs to be sufficient scientific evidence for the perceived risk underlying the measure. This principle also ties in with the **principle of substantial equivalence** which is central to the US regulatory system. This principle is based on the belief that genetic engineering doesn't require a separate regulatory approach, and that GM products should be assessed according to their specific characteristics, just as is done with any other plant or food product.⁴ Conversely the precautionary assessment, which is by

¹ Followed by Argentina, Brazil, Canada, India and China.

² Falkner, p. 101

³ European Union Information Website, <http://www.euractiv.com/en/biotech/genetically-modified-organisms/article-117498>

⁴ Falkner, p. 103

Article 6 of the Treaty on European Union (1992), the basis for European environmental law, is concerned with scientific uncertainty. Under such a precautionary assessment there are three basic conditions that may warrant a protective measure. These are: uncertainty, risk, and lack of proof of direct causal link.⁵ Essentially this means that different GM-foods can be prohibited if they are suspected of being harmful even though this cannot be scientifically proven. This form of risk assessment has created much controversy as it can be interpreted/and has been interpreted as a veiled form of trade protectionism.

As a result of the European Union's adherence to the precautionary risk assessment technique several important pieces of legislation concerning GMOs have been enacted. In 1990 *Directive 90/220/EEC* entered into force introducing an approval system for experimental releases and marketing of GMOs. It was this directive that formed the foundation of the famous *de facto* moratorium on the approval of new GM products that lasted between October 1998 and May 2004. This moratorium spurred a trade war between the European Union and the United States which eventually emanated in a DSU panel decision which will be discussed below. The 1990-directive was later replaced by *Directive 2001/18/EC* on the deliberate release of GMOs into the environment which is currently the main piece of legislation within this area. This later directive introduced rules to ensure that all GM food and crops are subject to strict risk assessments before they can be sold, marketed or planted in the EU. It introduced among other things a mandatory post-marketing monitoring system for GMOs and established a labeling system. A more extensive analysis of this particular directive will follow in section 4.1.1. below.

These directives and regulations from the EC are subject to much controversy. Even though the moratorium has now been lifted very few GM-products are accepted into the European market. There is also the question of the mandatory labeling of GM-food and products established by *Directive 2001/18/EC*. As stated before these regulations are by some countries, mainly potential exporters of GM-food, seen as unnecessary barriers to trade and are considered to be in violation of the EC's obligations under the SPS-agreement, the TBT-agreement and the GATT. It is this controversy that will be the focus of this thesis.

1.1. Research questions, delimitations and purpose

The main purpose of this thesis is to examine whether the rules governing the authorization process and the labeling and traceability requirements that GMOs and GM-products are subject to when imported into the EU are consistent with WTO agreements and how these rules would hold up to a possible challenge under the DSU. As can be seen in the introduction there has, in the past, been much controversy over the *de facto* moratorium on the approval of GM-products that the EC had in place between 1998 and 2004. Now the moratorium has ceased and EC legislation concerning GMOs has changed. We have not since have had another challenge of EC rules under the DSU, but does this necessarily mean that the new legal framework is in conformity with WTO law? As a point of reference I have chosen to use American rules. I hope that by making a comparison with the American legal framework I can illustrate the difference between the two systems, and also highlight the distinctive

⁵ Zarilli 2004, p. 3.

features of the EC regulations and to try to explain why, and in what aspects EC rules may be challenged by the Americans in the future. In order to achieve this purpose I will take a closer look at the legal framework in place and try to present it as clearly as possible for the reader. Having an understanding of the legal framework is fundamental to understanding why there has been so much controversy surrounding the issue of GMOs, and why the U.S. has reacted so violently against these rules.

The abovementioned poses a few questions that I hope to answer during the course of this thesis:

- How does American and European legislation differ in relation to GMOs?
- Do the Americans have good reason for their opinion that EC rules are in violation of the WTO agreements?
- What is the role of the precautionary principle?
- Is there room to argue that the precautionary principle should be used within the WTO system, or is the reliance on science absolute?
- Are there any multilateral agreements governing trade in GMOs other than the WTO agreements? And if so, can these provide justification for the debated EC legislation?

A hugely important and very interesting aspect of the trade in GMOs is the importance of patents and intellectual property law within this area. For example there is a big fear that developing countries will be the losers if patented biotechnology disrupts traditional practices among farmers and makes access to seeds more difficult.⁶ Since I have, in this thesis, chosen to focus on *Directive 2001/18/EC*, *Regulation 1829/2003/EC* and *Regulation 1830/2003/EC* and the framework established by these for the authorization for the placing on the market of GMOs, their labeling and the possibility to trace GMOs through the production chain in order to protect human health and the environment, I have chosen not to discuss this aspect. The reason I made this decision is that it is a very big question and in my opinion worthy of its own thesis and not just a few pages in mine.

I have also restricted my investigation to only include the European and American legal systems since these stand in such sharp contrast to each other. There are of course almost as many legal frameworks for dealing with GMOs as there are countries but I have chosen to limit this presentation to the two abovementioned systems.

1.2. Material and method

In order to best serve the purpose of this thesis, which was to evaluate the current EC legislation on GMOs in light of the WTO agreements, I have worked mainly on the basis of relevant EC Directives and Regulations, Relevant WTO Agreements and also WTO Case Law both from Panels and the Appellate Body. In order to evaluate whether EC legislation on GMOs is indeed in violation of the Communities' obligations under WTO law I took much guidance from WTO Case Law. Even though such case law does not provide precedence in later cases, they were nonetheless very helpful in determining whether a certain practice or aspect of the EC regulations on GMOs were in violation of WTO law. They also provided

⁶ Zarilli, p. 3

excellent clarifications of the provisions of the SPS Agreement and how these are to be interpreted in relation to each other.

Much guidance has also been found in literature discussing the subject of trade in GMOs. The main work here is probably a UN Publication by Simonetta Zarilli, *International Trade in GMOs and GM-products: National and Multilateral legal frameworks*, which provides, as the title suggests, a basic outline of the relevant legal framework and possible problems. This book really helped me get started and gave an indication of what areas needed to be researched further in order for me to answer my research questions.

The method for gathering information when writing has mainly been searching relevant legal databases for legislation and case law as well as gathering literature on relevant subjects. In this aspect the WTO homepage www.wto.org, and also www.worldtradelaw.net have been incredibly helpful and served as the primary source of WTO case law for this thesis. When it comes to EC legislation (Directives and Regulations) www.eurlex.eu has provided a good source for these.

2. General information

2.1. What is a GMO?

A **genetically modified organism** (GMO) is an organism whose “genetic material has been altered in a way that that does not occur naturally by mating or natural recombination”⁷. Contrary to conventional methods of altering genetic material, genetic modification allows for the crossing of natural species barriers, or for the transfer of single or a few genes instead of whole genomes. This is usually achieved by using genetic engineering techniques generally known as recombinant DNA technology⁸. With recombinant DNA technology, DNA molecules from different sources are combined *in vitro* into one molecule to create a new gene. This modified DNA is then transferred into an organism causing the expression of modified or novel traits.⁹

2.2. How is it created?

Both herbicide tolerant and insect resistant characteristics, which are preferred traits in genetically modified crops, are associated with bacteria that can be found in the soil. DNA-sections are extracted from the chromosomal string of these bacteria by so called restriction enzymes which act as scissors separating the required sections. The extracted DNA-section is

⁷ Official EU definition. See European Commission press releases: *Questions and answers on the regulation of GMOs in the EU*. MEMO02/160-REV

⁸ May also be referred to as “modern biotechnology”, “gene technology” or “genetic engineering”.

⁹ http://en.wikipedia.org/wiki/Genetically_modified_organism

then spliced onto a plasmid, which is an extrachromosomal DNA molecule separate from the chromosomal DNA and capable of autonomous replication.¹⁰ The desired characteristic is in this way added to the DNA chain in the plasmid which acts as a host for the extracted DNA. The plasmid is then injected with a marker gene and used to carry the required genetic information for implementation into the target plant cell.¹¹

This transfer is carried out in different ways. For example, when dealing with so-called broad leaved plants one uses bacteria that cause crown gall which is therefore effective at penetrating plant cells. The genes that have been recombined with the DNA holding the desired characteristic will then be separated (by using the marker genes) from the rest and can then be grown into full sized plants. However, not all plants are equally susceptible to this bacterium, and scientists interested in modifying crops such as wheat and corn have turned to other techniques of delivering genes to plant cells. One approach is to use a so called **gene gun** which fires plastic bullets filled with DNA-coated metallic pellets. An explosive blast or burst of gas propels the bullet toward a stop plate. The DNA-coated pellets are directed through an opening in the stop plate, and then penetrate the walls and membranes of their cellular targets. Some projectiles penetrate the nuclei of cells, where occasionally the introduced DNA integrates into the DNA of the plant genome. Transformed cells can then be cloned in culture.¹²

2.3. What are the uses for GMOs?

When it comes to modern biotechnology the development of the so-called GM food and crops is merely a drop in the ocean in comparison to its other uses. However this ability to produce so called transgenic plants and animals is by far its most debated quality. Modern biotechnology “most often means making medicines and drug testing kits using genetic engineering techniques”¹³ and there is “widespread international acceptance”¹⁴ of the benefits biotechnology can bring to these pharmaceuticals products. The treatment of diabetes is just one of the diseases that have been positively affected by the introduction of biotechnology.¹⁵ Transgenic animals are often used in different types of research e.g. testing of cosmetics and biomedical research. Even in the United States, only around 6-10 percent of all biotechnology companies have their main business in agricultural biotechnology.¹⁶

However, this thesis will not focus on this use for biotechnology but that of the modification of plants in order to, among other things, resist pests, herbicides and unfavorable environmental conditions. By introducing different characteristics into crops, for example drought tolerance in crops grown in Africa, we can increase the amount of food produced in the world and thus go a long way towards ending world hunger. Another more recent development is genetic modification for medicinal purposes. There are currently a number of food products being developed as edible vaccines to help improve health in developing

¹⁰ <http://en.wikipedia.org/wiki/Plasmid>

¹¹ Toke, p. 9-10

¹² http://www.learner.org/channel/courses/biology/textbook/gmo/gmo_6.html.

¹³ Toke, p. 6

¹⁴ Zarilli, p. 2

¹⁵ Insulin was one of the first drugs manufactured by using biotechnology.

¹⁶ Toke, p. 6

countries. An example is a strain of genetically altered rice, the so-called golden rice, created by scientists. This rice can be used to combat vitamin A deficiency which is currently the world's leading cause of blindness and affects about 250 million children worldwide.¹⁷

2.4. GMO around the world

In 1996 when the first significant area of crops containing GM traits was planted this covered only about 1.66 million hectares. Ten years later in 2005/2006 the global planted area has increased dramatically and then covered around 87.2 hectares around the world¹⁸, this according to figures presented by the International Service for the Acquisition of Agrobiotech Applications (ISAAA). According to the same study the technology is applied by 8.5 million farmers worldwide.¹⁹ Almost all GM crop area is planted with soybeans, corn, cotton and canola. In 2005, GM soybeans accounted for the largest share (62%), followed by corn (22%), cotton (11%) and canola (5%). In terms of the share of total global plantings to these four crops, GM traits accounted for a majority of soybean plantings (59%) in 2005. For the other three main crops, the GM shares in 2005 were 13% for corn, 27% for cotton and 18% for canola. Lately a number of less common GM-varieties have been developed. These include flaxseed, potato, squash, papaya, rice and melons, all of which are permitted for production in the U.S. but not in the EU. Those crops cultivated within the EU are all hybrids derived from Mon 810, a type of corn modified to be resistant towards corn moth (?).²⁰

As has been previously mentioned the U.S. has the considerably largest share of GM crop plantings, 55 percent amounting to 47.4 million hectares, followed by Argentina with 19 percent of the global crop area. Other countries planting large amounts of GM crops are Canada, Brazil and China.²¹ More recently, significant and increasing areas have been planted to GM crops in newer adopting countries such as Paraguay, South Africa and India (and other countries such as Spain, Romania, the Philippines, Mexico and Uruguay). Within the EU, commercial cultivation exists in Spain, France, Germany, Poland, Portugal, Czech Republic, Slovakia and Romania. However these countries' production only amounts to about 110 000 hectares and accounts for a very small percentage of the world production.²²

According to the ISAAA study there have been many economical benefits by adopting GM technology. In addition to enhanced productivity and efficiency gains there have been several other maybe less obvious benefits. When dealing with herbicide tolerant crops the study mentions for example; reduced harvesting costs since the crop is cleaner, increased management flexibility due to the relative ease in using broad-spectrum herbicides etc.²³ However, this development also raises the concern that more herbicides will be used in growing these GM-crops than with their conventional counterparts. The study also mentions insect resistant crops where the improved health and safety for farmers and workers because of reduced handling of pesticides, and energy conservation due to less aerial spraying is mentioned as positive aspects.²⁴

¹⁷ Zarilli, p. 1

¹⁸ Isaaa briefs, brief 36 *GM Crops: The first ten years-Global Socio-Economic and Environmental impacts*, p. 21

¹⁹ Ibid, p. 14

²⁰ Genteknikens utveckling 2007, p. 21

²¹ Ibid. p. 23

²² Numbers from Gentekniknämnden; Genteknikens Utveckling 2007, p. 21

²³ Isaaa briefs, brief 36 *GM Crops: The first ten years-Global Socio-Economic and Environmental impacts*, p. 54

²⁴ Ibid. p. 55

3. The controversy-background to the EU-U.S. dispute.

To many U.S. Government and industry representatives, the global resistance to genetic engineering and the products generated from this technology is fed by a “potent mixture of scientific irrationalism, economic protectionism, and even anti-US sentiment.”²⁵ When focusing specifically on EU-US relations the dispute surrounding the GMO issue is, according to the U.S, contributing to creating obstacles to free trade between the two blocks. From the EU point of view, the issue is simply a question of legitimate concern about the safety of GM food and not an issue of protectionism.

Since the mid-1990s, there has, as we have seen above, been a rapid adoption of GM crops. As has also been mentioned the majority of the key GM crops, such as corn, soybeans, canola and cotton, are grown in a concentrated group of agricultural-exporting countries. The leading country among these is the United States followed by Argentina and Brazil. In 2006, of the 246 million acres of GM crops planted worldwide, 83 percent was planted in these three countries.²⁶ However the introduction of GM crops and foods have not been a smooth one outside this concentrated group of countries. The debate over the issue has been most intense and vocal in the European Union, where consumer surveys consistently show that the public has a very negative attitude toward GM food.²⁷ In 2006 the European Commission published a poll that found that only 27 percent of EU citizens believe that the technology behind GMOs should be encouraged, the remainder finding it hard to see any clear benefits.²⁸

This skepticism amongst EU consumers served as the background and prompted the actions of EU Member States that led to the moratorium on GM approvals that lasted between October 1998 and May 2004. The roots of this moratorium lie in the Novartis bt-176 corn case²⁹. This particular type of modified corn was initially accepted by France in 1996, but a number of other Member States³⁰ started raising questions about the potentially harmful effects of GMOs on health and the environment. When it came to Novartis bt-176 the particular concern was that the marker gene contained in the corn could be harmful to human health. These Member States also stressed that the EC regulatory framework was inadequate especially in terms of risk assessment, labeling and post-market traceability and monitoring. Austria and Luxembourg lobbied for a temporary ban on the marketing approval of Novartis bt-176 on the grounds that there was new evidence that antibiotic resistance could occur due to the disputed marker gene. Finally, in 1999, Denmark, France, Greece, Italy and Luxembourg declared that they would block future GM crop approvals. This amounted to a moratorium by EU voting rules and as a result no new GMOs were approved under *Directive 90/220/EC*.

Although the moratorium has now been lifted the introduction of *Directive 2001/18/EC* and the requirements contained in it has created other obstacles for exporters of GM-food. As we

²⁵ Falkner, p. 100

²⁶ Sheldon, p. 122

²⁷ Ibid. p. 122

²⁸ Europeans and Biotechnology in 2005: Patterns and Trends - *Eurobarometer 64* (2006):1-85

²⁹ The “bt” in the name refers to a bacteria, bacillus thuringiensis, that provides insect resistance. The way this works is that the crop exudes a toxin in its pollen that kills insects that would otherwise eat the crop.

³⁰ Novartis bt-176 was rejected by Austria, Denmark, Sweden, the United Kingdom and others.

can see from the July 2004 authorization of Monsanto NK603 GM maize³¹ for import and use in animal feed there is no longer a complete stop in approval but still very few GM-products are approved for release onto the European Market. And as a result of Directive 2001/18/EC this particular type of maize, as well as other approved GM products, is also struck by the EU rules on labeling that stipulate that the imports must be labeled as containing GM products.

From an international trade perspective, the major concern for GM producing and exporting countries such as the U.S. is to have an easy access to the foreign markets in which they intend to market their products. The international policy conflict concerning GMOs that is taking place around the world today is “creating fragmentation of international markets, decreasing economies of scale”³². This is in turn negative for the exporting countries since they rely on economies of scale in order to recoup the costs spent on research and development. In short, having a unitary approach to GMOs in all corners of the world would benefit international trade and thus GM-exporting countries, but what many countries today are asking themselves is to what expense this will come?

3.1. What are the critics claiming? What risks are there with GMOs?

As stated above many American government and trade representatives have a hard time understanding the global resistance to GM foods. After all GM food has been consumed in the United States for well over a decade now without any documented harm to human health. There have been some GM food-scares over the years but nothing incriminating has really come out of these. The most famous of these scares occurred in 2000 and involved taco shells and other products marketed under the Taco Bell brand in American supermarkets. It was discovered that these taco shells contained the StarLink corn variety, which had not been authorized for human consumption due to concerns over potential allergic reactions. What can be concluded is that, as of today, there is “no conclusive evidence suggesting that consuming authorized GM food ingredients is harmful to the human body”³³. However despite this lack of proof, “the political and regulatory environment of many importing countries gives little confidence that GM crops will simply be accepted as a *fait accompli*”³⁴. So if we have no proof that GM foods are unsafe, then what are the critics of biotechnology claiming is the problem?

The debate around food safety has so far mainly focused on three concerns: allergenicity, toxicity, and antibiotic resistance. Allergenicity can be caused by certain proteins that are artificially inserted in plants through genetic engineering. An example of this is an insecticidal protein derived from a bacterium which is intended to make plants more pest resistant, thereby increasing agricultural yields. StarLink corn, which is mentioned above, contains such a protein and has so far only been authorized for animal consumption. There is also some concern that certain GM plants may contain higher levels of toxins that are harmful to human health than conventional plants. Many naturally occurring plants contain toxins but scientists are worried that genetic engineering can increase their presence beyond acceptable levels. Moreover there are concerns that human pathogens will become resistant to antibiotics. In the process of transferring specific genes, genetic markers are often used to show the successful uptake of the novel genetic material. These markers may inadvertently deactivate, or weaken

³¹ This was the first product to be assessed and approved after the entry into force of Directive 2001/18/EC.

³² Zarilli, p. 7

³³ Falkner, p. 100

³⁴ Sheldon, p. 122

the effect of, antibiotics intended for treating bacterial infections. What should be pointed out here is that the use of antibiotic resistance markers is not necessary for the process of genetic engineering and there are alternatives available to the use of these marker genes.

Another concern or risk, and probably an even more serious one than the health risks, is the effect of GM plants on the environment. The main concern here is that the release of GM plants into the environment would have a negative effect on biological diversity. There are especially three impacts on biological diversity that have been mentioned as being particularly harmful: The first is the fear that non-target species could be harmed by crops modified to produce their own pesticides; the second is the fear of cross pollination. Some critics have raised concerns that conventionally bred crop plants can be cross-pollinated or bred from the pollen of modified plants. Since pollen can be dispersed over large areas by wind, animals and insects it is a real worry that scientists have in recent research with creeping bentgrass found modified genes in normal grass up to 21 km away from the source. They also found modified genes in close relatives of the same genus.³⁵ Similar effects have also been observed in Sweden with rapeseed.³⁶ The third concern is somewhat related to that of cross-pollination and is a fear that certain plants may accidentally transfer harmful traits to other non-target species. This is usually referred to as “gene escape” or “gene transfer”. An example of this situation would be that crops that are modified to be resistant to certain herbicides may transfer this same resistance to weeds growing in their vicinity thus creating so-called “super weeds”. Another related concern is that the use of GMOs might increase one-sided use of crops and lead to increasing use of monocultures in agriculture. This in turn may lead to excessive dependence on a few crop varieties, thereby increasing the vulnerability of crops to diseases.³⁷

Research on the environmental impact of GM crops is still in its infancy and there is a great deal of uncertainty clouding the regulatory debate. Due to the enormous complexity of ecosystems, effects on the environment usually manifest themselves in the long run, and since this technology has not been around for that long it is impossible to say what will be the results. One might therefore say that it is irresponsible when governments authorize the planting of these crops but do not have an adequate framework in place to monitor post-commercialization and contamination. Due to the lack of information on the environmental impact, and the inherent nature of the ecosystem, these concerns may prove to be an even bigger issue, in the future, than the potential risks to human health, to which they have previously taken the back seat in the GMO debate.

4. The root of the controversy-U.S. and EU regulations

At the root of the conflict lies, quite logically, the difference in the approach the U.S. and EU have taken to the regulation of GMOs. As seen in the introduction the US approach is based on the belief that the use of genetic engineering does not require a separate regulatory approach, and that biotech products should be assessed according to their specific characteristics, just like any other plant or food product. On the other hand the EU has taken a much sharper stance against GMOs relying on the precautionary principle which allows for the prohibition of genetically engineered food if it is suspected of being harmful even in cases

³⁵ http://en.wikipedia.org/wiki/Genetically_modified_organism

³⁶ Gustavsson and Falk, p. 1

³⁷ Zarrilli, p. 2

where this cannot be scientifically proven. This approach has, which we will see below, resulted in strict labeling requirements and sometimes even import bans.

4.1. The European Community regulations.

Community legislation on GMOs has been around from the early 1990s and since this first introduction, the regulatory framework has been "further extended and refined"³⁸. In the EU the use of GMOs is very strictly regulated and the legislation is aimed at giving top priority to long-term safety and to ensure that the public has access to information about GMO products on the market. As is almost always the case with EU legislation, the legislation on GMOs has dual purposes. While it is designed to protect its citizen's health and the environment it is simultaneously designed to create a unified market for biotechnology in Europe.

4.1.1. Directive 90/220/EEC and Directive 2001/18/EC

In 1990 the EC introduced *Directive 90/220/EEC* which in turn introduced an approval system for the deliberate release³⁹ into the environment and placing on the market of GMOs for experimental purposes or as commercial products. This was later replaced and updated by *Directive 2001/18/EC*, in October 2001, which is currently the most important European legislation on the authorization of the use of biotechnology. This directive deals with products containing GMOs, however it does not deal with products derived from GMOs, such as ketchup made from a genetically modified tomato. These are instead covered by Regulation *1831/2003/EC on GM food and feed*. In the preamble to *Directive 2001/18/EC* it is stated that the basis for adopting this directive is Article 95 of the Treaty establishing the European Communities i.e. the Treaty of Rome. Thus it is obvious that the regulation of GMOs within the EC system is based on the harmonization of the laws of the Member States in order to aid the establishment and functioning of the internal market.⁴⁰ However, as can be seen from Article 95.3 there are limits to the free movement established by the Treaty. These limits are based on the need for consideration of basic social concerns such as the environment, public health and consumer protection. Article 95.3 reads as follows:

"The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective."

Thus *Directive 2001/18/EC* has two main objectives; to protect human health and the environment from the release of GMOs and, as most EC regulations, to approximate the laws of the Member States pertaining to this area. It is mentioned in Article 1 of the directive that it is based on the precautionary principle and that this principle is to be taken into account when interpreting the directive. The directive puts in place a "step-by-step approval process on a

³⁸ European Commission press releases: *Questions and answers on the regulation of GMOs in the EU*. MEMO02/160-REV

³⁹ "Release" means that the organism is not restricted from contact with the wider environment around it.

⁴⁰ Treaty of Rome, Article 95.1

case by case assessment of the risks to human health and the environment”⁴¹ before a GMO can be released onto the market. In addition to this risk assessment, the directive also contains provisions for a mandatory post marketing monitoring system of GMOs and traceability at all stages of their placing on the market. It also establishes a system for directly informing and consulting the general public in the authorization procedure and finally, it establishes a labeling system.

The objective of the environmental risk assessment carried out under the directive is to identify and evaluate potential adverse effects of the GMO. These include direct or indirect, immediate or delayed effects, taking into account any cumulative and long term effects on human health and the environment which may arise from the deliberate release or placing on the market of that GMO.⁴² The assessment also takes into account how the product was developed, possible toxicity and allergenicity and the possibility of gene transfer. The directive provides for a common methodology to assess the risks associated with the release of GMOs. This is described by the European Commission as being:

- ”• Identification of any characteristics of the GMO(s) which may cause adverse effects
- Evaluation of the potential consequences of each adverse effect
- Evaluation of the likelihood of the occurrence of each identified possible adverse effect
- Estimation of the risk posed by each identified characteristic of the GMO
- Application of management strategies for risks from the deliberate release or placing on the market of GMO
- Determination of the overall risk of the GMO”⁴³

Another important aspect of *Directive 2001/18/EC* is its extensive use of consultations in the approval process. In addition to an extensive system of consultations with the general public it also contains an obligation to consult the European Parliament on the decision to authorize the release of GMOs. To understand the difference between the European and the American regulations and approach towards GMOs it is imperative to understand the approval process. Therefore what will follow below is a closer look at the different steps of the procedure for approval;

When a company wants to market a GMO within the European Union they must first apply to a competent national authority in the Member State where the product will be marketed.⁴⁴ This application should include a technical dossier of information, compiled by the applicant or the notifier, including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labeling and packaging.⁴⁵ The national authority must within a delay of 90 days prepare an”opinion indicating whether the GMO should or should not be placed on the market”⁴⁶. Before issuing this opinion the competent authority has to undertake the environmental and health risk assessment specified in the previous section. If its opinion is favorable the Member State informs the other Member States via the Commission. If the

⁴¹ European Commission press releases: *Questions and answers on the regulation of GMOs in the EU*. MEMO02/160-REV, p. 1

⁴² Ibid, p. 2

⁴³ Ibid. p. 2

⁴⁴ Directive 2001/18/EC note (32)

⁴⁵ Directive 2001/18/EC note (33) and Art 13.2

⁴⁶ Zarilli, p. 10 note 26 and Directive 2001/18/EC Art 6.5

other Member States consent the competent authority of the initial Member State can authorize the release of the GMO onto the European market. The consent to release the GMO is given for a maximum period of ten years, starting from the date on which the consent is issued, after which the producer will have to apply for a renewal of consent according to Article 17 of the Directive.

However, if there are objections to the approval, a decision has to be taken on Community level, thus it can be said that the assessment takes place at two levels and at two stages. At this stage the Commission asks for the opinion of its scientific committees (nowadays the European Food Safety Authority) comprised of independent scientists within different fields. If the scientific opinion is favorable, the Commission then proposes a Decision to the Regulatory Committee composed of representatives of Member States. If the Regulatory Committee gives a favorable opinion, the Commission adopts the Decision. If the Regulatory Committee does not give a favorable opinion the proposal for decision is passed on to the Council of Ministers for adoption (or rejection) by qualified majority. If the Council does not act within three months, the Commission is free to adopt the decision. The competent authority in the Member State where the initial application was filed then authorizes the release of the GMO onto the European Market (just as above). This approval is then valid throughout the European Union. For a Member State that is not satisfied with this decision there is a safeguard clause in the Directive that stipulates that, under certain conditions, this Member State can prohibit provisionally the marketing of the GMO within their territory.⁴⁷ In cases where a member State adopts such a safeguard measure, it must inform other EC member States and the Commission of the action it has taken, and a final decision on whether the safeguard measure can be kept in place must then be taken at Community level.⁴⁸

Following the placing on the market of a GMO as, or in, a product, the person submitting the application for the release of the GMO (referred to as the "notifier" in the Directive) shall ensure that monitoring and reporting is carried out according to the conditions specified in the consent. The reports of this monitoring shall be submitted to the Commission and the competent authorities of the Member States.⁴⁹ If new information about possible adverse effects is discovered as a result of the monitoring the notifier shall take the measures necessary to protect human health and the environment.

4.1.2. Regulation 1829/2003/EC on Genetically Modified Food and Feed

Regulation 1829/2003/EC applies to:

- GMOs for use as food or feed;
- Food or feed containing or consisting of GMOs
- Food/feed produced from GMOs and food containing ingredients produced from GMOs.

The purpose of these rules is to establish a "streamlined, uniform and transparent" EU procedure for all marketing applications.⁵⁰ One of its main achievements is that it introduces a

⁴⁷ Directive 2001/18/EC Article 23

⁴⁸ This section, and the previous, of this thesis draws on information from Zarilli p. 10 note 26, *Questions and answers on the regulation of GMOs in the EU*. MEMO02/160-REV p. 3.

⁴⁹ Directive 2001/18/EC Article 20.1

⁵⁰ O'Rourke, p. 183.

"one door, one key" principle, in that it allows for a possibility to file only one application both for the authorization for the release of a GMO under *Directive 2001/18/EC* and the authorization to use this same GMO in food and/or feed as regulated by *Regulation 1829/2003/EC*. This means that a single risk assessment is carried out and a single authorization is given for a GMO and its possible uses. Thus someone wishing to market a GM crop in the EU need not request separate authorizations for the use of the crop as food or feed. A crop is either authorized for both uses, or for neither. This definitely helps the otherwise quite complicated procedure. If a product is authorized the regulations stipulates that it is to be entered into a public register⁵¹.

Another key component of *Regulation 1829/2003/EC* is that it establishes a labeling requirement for foods delivered to the final consumer or mass caterers in the Community which contain and consist of GMOs.⁵² Feed products are also subject to mandatory labeling according to Articles 24 and 25. The result of this change is that the production process of GM food and feed is now considered a relevant factor that justifies labeling. The labeling requirements are applied irrespective of the ability to detect DNA or protein resulting from the genetic modification in the final product. This was not the case with the novel food regulation (258/97) which *Regulation 1829/2003/EC* has amended.

If it is evident that a product that has been authorized may cause a risk to human health or the environment the Commission may take emergency measures under the procedures outlined in Articles 53 and 54 of *Regulation 178/2002*⁵³. Such measures may include product recalls, or the suspension or modification of the initial authorization of the GMO.

In short *Regulation 1829/2003* can be summarized as providing Community procedures for the authorization and supervision of genetically modified food and feed, and includes specific provisions for their labeling.⁵⁴

4.1.3. Regulation 1830/2003/EC on Traceability and Labeling.⁵⁵

Regulation 1830/2003/EC is considered instrumental to achieving the objects of *Directive 2001/18/EC* since it introduces traceability of the approved product throughout the food chain and also provides a framework for labeling of those products consisting of or containing GMOs and food and feed produced from GMOs. *Regulation 1830/2003* is applicable to GMOs that have received EU authorization for the placing on the market. Thus 1830/2003 is applicable to products once they are placed on the market whilst *Regulation 1929/2003* applies and to and simplifies the actual authorization process. These two regulations work together to fulfill the stringent regulation of GMOs established by *Directive 2001/18/EC*.

⁵¹ Regulation 1829/2003/EC, Article 28

⁵² Regulation 1829/2003/EC, Articles 12 and 13.

⁵³ This regulation has been described as the first piece of EC legislation formally laying down a risk analysis model for Europe.

⁵⁴ Zarilli, p. 11

⁵⁵ Full name: Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Regulation 1830/2003/EC is applicable to the following products:

- products consisting of, or containing, GMOs, placed on the market in accordance with Community legislation;
- food produced from GMOs, also placed on the market in accordance with Community legislation;
- feed produced from GMOs, placed on the market in accordance with Community legislation.

The measures stipulated in the Regulation have two main objectives: to inform consumers of what it is they are buying through a compulsory labeling system, and to create a sort of safety net based on the traceability of these products in case of unforeseen effects on human health or the environment. The traceability requirement is also meant to facilitate monitoring and checking of the nutritional claims made on labels, the surveillance of the potential effects on human health or the environment and ultimately the removal of the product from the market in case any such adverse effects are discovered.

In order to help in the traceability process the Regulation requires operators to submit in writing an indication that the product contains GMO and the unique alphanumeric identifiers assigned to the GMOs which make it possible to know these products' features and characteristics. In particular there is a requirement that operators should have systems and procedures in place in order to identify to whom and from whom products are made available.⁵⁶ If the product is pre-packaged⁵⁷ the operator must at all times, ensure that the words "This product contains genetically modified organisms" or "Product produced from GM (name of organism)" appear on the product label. There is however one exception to the labeling requirements. Traces of GMO in food or feed products, including those intended for processing, that do not exceed 0.9 percent are exempted from the labeling obligation if their presence is adventitious and technically unavoidable.⁵⁸

In line with the general EU rules on labeling, the regulation does not require labeling of products such as meat, milk or eggs obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products.⁵⁹ The labeling of such products is not required by *Regulation 1829/2003* either.

4.2. The U.S. regulations

The principles that lie at the heart of the U.S. regulatory approach are the principle of minimal oversight of food products that are generally regarded as safe (GRAS) and as an extension of this principle the principle of substantial equivalence.⁶⁰ GRAS recognizes that zero tolerance for potentially hazardous ingredients in food would result in very few products ever making it

⁵⁶ O'Rourke, p. 185.

⁵⁷ Meaning any single item offered for sale consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

⁵⁸ Regulation 1830/2003/EC, Article 4.7

⁵⁹ O'Rourke, p. 186.

⁶⁰ Sheldon, p. 124

onto the market. Therefore instead of proving that GM foods are 100 percent risk free, GM foods are judged against the standard of conventional foods that are considered to be safe or GRAS. “The objective of such an approach is not to establish absolute safety, but to consider whether GM food is as safe as its conventional counterpart by finding differences between the types of food”⁶¹.

As a result of the U.S. adherence to these principles the Food and Drug Administration (FDA) has under the Federal Food, Drug and Cosmetic act taken the position that recombinant DNA methods of plant development are not “material information”.⁶² This means that they do not consider GM foods to differ in any substantial way from those developed from traditional plant breeding methods. Genetically modified food is thus considered simply an extension of conventional products and therefore the U.S. has made use of existing laws to ensure the safety of GM food.

The laws that are currently used to regulate biotechnology in the U.S. are; the Plant Protection Act, the Federal Food, Drug and Cosmetics Act, the Federal Insecticide, Fungicide and Rodenticide Act and the Toxic Substances Control Act.⁶³

In addition to these there are a few documents issued by different government agencies impacting the area. Under the 1992 FDA *Statement of Policy: Foods Derived from New Plant Varieties* food manufacturers have a responsibility to make sure that the foods they offer to consumers are safe and comply with all applicable requirements.⁶⁴ In order to do this, manufacturers are encouraged to work cooperatively with the FDA to assess the safety of their bioengineered food. This is done by following a practice of consultations that should allow the FDA to gather the information necessary to address any “safety, nutritional or other regulatory issues before commercialization”⁶⁵. However this practice was not mandatory. This was greatly debated, and public comments indicated support for a more transparent and mandatory process. Eventually the FDA decided to subject bioengineered foods to greater regulatory scrutiny to ensure that they get the best possible information about the product.

In 2001 the FDA developed a guidance document concerning food developed through biotechnology. This *Pre-market notice concerning bioengineered foods*⁶⁶ required the mandatory submission of data and information regarding these foods that were destined for consumption by humans and animals at least 120 days prior to their commercial distribution. Included in this guidance there is also a part that will assist and guide manufacturers that wish to voluntarily label their products as containing bioengineered ingredients.

Even the Department of Agriculture (USDA) has taken steps towards updating and strengthening their regulations on biotechnology. Currently, companies creating new transgenic plants must submit an application to the USDA. In addition GM crops must undergo field tests to ensure that they do not pose a threat to agriculture or other plants.⁶⁷ Zarilli believes that these updated rules are “more likely to be wider in scope [than those seen

⁶¹ Sheldon, p. 124

⁶² Ibid. p. 123

⁶³ Zarilli, p. 14

⁶⁴ Ibid., p. 14

⁶⁵ Ibid. p. 14

⁶⁶ Available at <http://www.cfsan.fda.gov/~lrd/fr010118.html>

⁶⁷ Zarilli, p. 15

before] and will encompass threats to the environment and public health”⁶⁸.

5. Multilateral Agreements and Frameworks

5.1. Applicable WTO agreements

There are four WTO agreements that could potentially affect the European Communities’ regulatory framework regarding GMOs. These are; the Sanitary and Phytosanitary agreement (SPS) which aims at the protection of human, animal or plant life and health, the Technical Barriers to Trade agreement (TBT), the TRIPS agreement and the General Agreement on Tariffs and Trade (GATT 1994). TRIPS will only affect issues with patents relating to GMOs and is thus not relevant within the scope of this thesis. As far as the relationship between these agreements goes it is important to remember that the SPS and the TBT are mutually exclusive; meaning that once SPS applies, TBT cannot apply and vice versa. If there is a conflict between the SPS or TBT and the GATT the specific agreement will prevail.⁶⁹

The WTO, and the GATT specifically, recognizes the right for individual countries to develop policies to protect human, plant and animal health. Because the WTO is an organization aimed at facilitating international trade it cannot get involved in such national legislation unless the contested regulation has a direct trade component.⁷⁰ This means that the WTO can get involved when it comes to import restrictions, and other practices that lead to a restriction of world trade. Concerning such practices pertaining to GMOs, these are mainly regulated within the WTO framework by the SPS and the TBT agreements. However there is some controversy as to which of these two agreements should be applied to the international trade in GMOs. The Panel’s findings in the *EC-Biotech* case suggest that the SPS agreement should be applied. This view is not shared by all scholars. To some it is uncertain whether the SPS-agreement is applicable, a situation which would leave us to apply the TBT and/or even the GATT. In this section I will go through the different agreements looking at their applicability and what result this would have on the European Union legislation that has been presented above in section 4.1. Later in Chapter 7 I will take a look at the Panel and Appellate Body’s reasoning in several DSU cases, among these the famous *EC-Biotech* and *EC-Hormones* cases.

5.1.1. The Basics

The two main articles of the WTO agreements that could be applied to world trade in GMOs are GATT Articles I and III on non-discrimination and national treatment. Article I GATT is entitled "General Most-Favored Nation Treatment" and deals with the very foundation, or pillar of the WTO system, namely non-discrimination between the organization's different Member States. Article 1.1. prohibits discrimination between "like products", and stipulates

⁶⁸ Zarilli, p. 15

⁶⁹ This according to the General Interpretative Note to Annex 1A to the Marrakesh agreement Establishing the World Trade Organization.

⁷⁰ Sheldon, p. 126

that it is not allowed to grant any "advantage, favor or, privilege or immunity"⁷¹ to a product originating in or destined for any other country without immediately granting this same advantage to like products originating in or destined for all other Members states. The purpose of this regulation is of course to ensure that different countries have an equal opportunity to import from, or export to different WTO Members.

Article I works together with Article III, the national treatment principle. According to this principle a country must accord treatment to imported products that is no less favorable than treatment accorded to "like products" of national origin. The result of these two provisions is that a Member State of the WTO cannot be so inconsistent that they ban imports of GM products from one country and allow them from another, and once the GM product has been imported into the country it should not be treated any differently than like products produced within the country. Whilst it is highly unlikely that a country may blatantly discriminate between the same product produced in different countries it is quite common for countries to be accused of indirect discrimination, i.e. discriminating between "like products". In this context, what constitutes "like products" becomes the key issue. In the debate over GMOs the question becomes, more specifically, whether genetic modification or presence of GM ingredients constitutes sufficient grounds for differentiation from conventional products. The issue of whether the analysis, of what constitutes like products, should be limited to the physical characteristics of the products or should also take into account the production methods and process remains unresolved. According to Zarilli "the relevant jurisprudence is not conclusive, and authoritative authors are deeply divided on the subject"⁷². A side note here could be that as the Cartagena protocol gains wide international acceptance it may eventually provide a basis for determining that genetically modified products are not "like" their conventional counterparts.⁷³ After all, DSB panels are obligated to take into account relevant international law as well as WTO provisions. At present, it has been suggested that there is support for the product/process distinction in Article III GATT and the Note Ad to Article III.

When it comes to the specific issue of GMOs one can conclude that at a minimum, these rules require Members to apply the same or equivalent regulations to domestic GMOs that they are applying to like imported GMOs, and to treat all imported like GMOs in a similar manner that allows those GMOs an equal opportunity for market access.

5.1.2 The SPS Agreement

Measures regulated under the SPS agreement can be put into the more general category of technical barriers to trade. The negotiators of the WTO agreements considered the issue of health protection as an issue that merited special protection and thus created this specialized agreement. According to Peter Van den Bossche there are two reasons for this: first, the measures are closely linked to agricultural trade which is notoriously hard to liberalize. Second, the area of public policy which these measures fall under is particularly sensitive.⁷⁴ However, the most important motivation behind the creation of the agreement was the need for a clarification of the exception for health measures in Article XX(b) of the GATT 1994.

⁷¹ Article 1.1 GATT 1994

⁷² Zarilli, p. 33

⁷³ MacKenzie, Burhenne-Guilmine, La Vina and Werksman, Appendix, paragraph 881.

⁷⁴ Van den Bossche, p. 462

The objective of the SPS agreement is two-fold; while it aims at recognizing the sovereign right of Members to provide the level of health protection they deem appropriate, it also aims at ensuring that SPS measures do not represent unnecessary, arbitrary, scientifically unjustifiable, or disguised restrictions on international trade.⁷⁵ What is regulated by the agreement are so called "SPS measures" which can be broadly defined as being measures that are applied to protect animal or plant life or health from risks arising from the spread of pests and diseases or risks from foods, beverages and feedstuffs. The agreement does not refer to GMOs explicitly but according to Zarilli it can be argued, that even though GMOs are not specifically referred to, "that measures aimed at regulating such trade could reasonably come within the scope of the agreement"⁷⁶.

As can be seen above, the SPS agreement allows countries to set their own policies and standards regarding food safety, animal and plant health. However the agreement requires that such standards are based on science and that they are only applied to the extent necessary to protect health. It also requires that their application is not arbitrary nor should these standards have unnecessary negative effects on international trade and be misused for protectionist purposes. In the agreement countries are encouraged to use international standards, guidelines and recommendations where they exist in order to achieve this objective.

5.1.2. Important provisions

Article 2.2 of the SPS agreement states that:

"Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

Whilst Article 2.1 explicitly acknowledges the sovereign right of WTO members to take SPS measures to achieve their self-determined health protection level, Article 2.2 restricts that right by providing that such measures may only be in place if they are based on "scientific principles", are only applied in the extent necessary to protect human, animal or plant life or health and are not maintained "without sufficient scientific evidence". Members have two options to show that their measures are based on science. These are; to base their measures on international standards, or to base them on scientific risk assessment.

When looking at the "necessity" requirement in Article 2.2, this is a relational concept pertaining to the existence of a logical connection between a measure and a specified objective. What is demanded of this connection under Art. 2.2 is a matter of interpretation, but the requirement has in other cases been understood to imply that the measure does not have to be indispensable, but should rather be capable of making a contribution to the objective in question.⁷⁷

Article 3 of the SPS Agreement encourages members to harmonize their measures around international standards, guidelines and recommendations. The object of this harmonization is

⁷⁵ http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/cls1p1_e.htm

⁷⁶ Zarilli, p. 31

⁷⁷ Scott, p. 85, taken from *Korea-Beef* Appellate Body report, par. 161

to achieve food safety and protection of animal and plant health without unduly restricting international trade.⁷⁸ There are three sister organizations that set these standards; the *Codex Alimentarius Commission* that sets standards for food safety, the *Office Internationale des Epizooties* that deal with animal health and finally the *Secretariat of the International Plant Protection Convention* which sets, as the name suggests, norms for plant protection. If the standards set by these different organizations are followed a measure is presumed to be based on scientific principles and thus consistent with the SPS agreement.

Article 3.3 SPS is important in that it permits Members to refrain from basing their measures on international standards, and consequently apply measures that result in a higher level of protection than would be achieved had the measures been based on international standards. A Member is allowed to apply such a measure if, among other things, there is a scientific justification for doing so.⁷⁹ Such scientific justification exists when a Member, after examination and evaluation of available scientific information in conformity with the relevant provisions of the SPS agreement, determines that the relevant standards are not sufficient to achieve its appropriate level of protection.⁸⁰

Scientific risk assessment is regulated by Article 5 in the SPS-agreement.

Article 5.1 of the SPS Agreement states that:

”Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.”

As can be seen, Article 5.1 requires SPS measures to be ”based on” an assessment of the risks to human, plant and animal life or health. The meaning of this requirement was clarified by the Appellate Body in *EC-Hormones*⁸¹ where they stated that there must be a ”rational relationship” between the measure and the risk assessment and that the risk assessment must ”reasonably support” the measure.⁸² The article does not require the importing country itself to perform this risk assessment, they may rely on risk assessments carried out by another member or an international organization, however they must be able to demonstrate that its measure is based on an ”appropriate” risk assessment. The three sister organizations mentioned above have also prepared and developed risk assessment techniques and members are to take these into account.⁸³ In *Japan-Apples*⁸⁴ the Panel commented on the obligation to take into account risk assessment techniques developed by relevant international organizations. They found that the techniques should be considered ”relevant” but ”a failure to respect each and every aspect of them would not necessarily, per se, signal that the risk assessment is not in conformity with Article 5.1”⁸⁵. The concept of risk assessment is laid out in Annex A, paragraph 4 SPS. This paragraph displays two different definitions whose

⁷⁸ http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c2s2p1_e.htm

⁷⁹ Scott, p. 82

⁸⁰ This is provided in a footnote to Article 3.3

⁸¹ For further discussion of this case, see section 7.2.

⁸² For a more detailed discussion see Section 5 Relevant Case Law below.

⁸³ http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c2s4p1_e.htm

⁸⁴ For further discussion of this case, see section 7.4.

⁸⁵ *Japan-Apples* Panel report, Par. 8.241

application depend on what type of risk is to be assessed:

- When it comes to the risk of entry, establishment or spread of a pest or disease within the territory of the importing Member State, an evaluation of the likelihood of this occurring has to be done.
- However, when it comes to adverse effects on human or animal health, arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages and feedstuffs an evaluation of the potential of these effects is sufficient.

The first definition can, of course, also encompass risks to human health, but only in so far as they arise from the spread etc. of a pest or disease. Thus a proper risk assessment must in relation to the first definition (the risk of spreading pest or disease) comprise three elements; An identification of the disease in question as well as the potential biological and economic consequences associated with the entry, establishment or spread of this disease. An evaluation of the likelihood of entry etc. as well as the potential biological and economic consequences and an evaluation of the entry, establishment or spread of the disease *according to the SPS measures which may be applied*.⁸⁶ When dealing with the requirements for a proper risk assessment under the second definition (food safety etc.) this is more unclear. There are however two identifiable steps; The identification of the adverse effects on human or animal health, and if such effects are found to exist, an evaluation of the potential of the occurrence of those effects. As stated above, Members are, when dealing with the spread of pest and diseases required to evaluate the risk according to the SPS measures which may be applied. No such requirement exists when dealing with issues of food safety. What this difference boils down to is the existence of an obligation to consider alternative policy options before settling on a particular measure. In such cases then, a risk assessment should not be limited to the examination of the measure already in place or favored by the Member but should include a taking into account of alternative measures. However, it is not clear whether a Member is required to consider or identify all possible policy options, however numerous they may be.⁸⁷

The SPS Agreement does not lay down any methodology of risk assessment that is to be followed by its members. However, **Article 5.2 and 5.3** of the SPS Agreement specifies the factors that are to be taken into account in a risk assessment. Article 5.2 lists factors that can be considered scientific or technical such as processes and production methods and of course available scientific evidence. Article 5.3 lists economic factors the cost of control or eradication in the importing member state and the potential damage in terms of loss of production or sales in the case of the entry of a pest or disease. This lack of methodology, or procedural approach is by some authors considered to be the reason for the Panels' preference for "looking less at what Members have done, by way of assessment, and more at what they have found by way of available science, to rationally ground their measure"⁸⁸.

Members are also required to avoid unjustifiable and arbitrary differences in the level of health protection that they consider to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. This is laid down in **Article 5.5**. In addition, SPS measures are not to be more trade restrictive than necessary to achieve the appropriate level of protection, **Article 5.6**.

⁸⁶ Scott, p. 92

⁸⁷ Ibid. p. 96

⁸⁸ Ibid. p. 84

Article 5.7 of the SPS Agreement states that:

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

As Peter Van den Bossche writes the SPS agreement uses science as its touchstone, but it also ”recognizes the fact that science does not always have clear answers to regulatory problems”⁸⁹ Sometimes situations arise where there is insufficient evidence regarding the existence of a risk. As we know, governments are in these situations often prone to act in a precautionary manner without necessarily waiting around for more evidence or more conclusive results i.e. making use of the precautionary principle. Article 5.7 allows members to take such precautionary measures when there is insufficient evidence to permit a final decision on the safety of a process or product. However, such measures are to be provisional in character and members must seek the additional information necessary for a more objective assessment of the risk(s), and review the SPS measure within a reasonable period of time. As can be seen below in section 5, there are four cumulative requirements, developed by the Appellate Body in *EC-Hormones* that must be fulfilled in order for the provision to be legitimately invoked.

5.1.3. The Relationship between the agreements

In case of a dispute, the compatibility of a domestic regulatory measure relating to GMOs is likely to first be examined under the SPS Agreement, then the TBT Agreement and finally the GATT. As mentioned before, the TBT and the SPS are mutually exclusive and can thus never be applied simultaneously. The deciding factor becomes the purpose of the regulation. A more in depth analysis of this will follow below in section 8.1.

Regarding the relationship between the SPS and the GATT the Preamble of the SPS Agreement states that it is intended to "elaborate rules for the application of the provision of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)". In addition, SPS measures that conform with the SPS Agreement are presumed to be consistent with the GATT, although this presumption is understood as being rebuttable (Article 2.4). This suggests that if a measure is found to be inconsistent with the SPS Agreement, it is likely that a panel or the Appellate Body would not carry out an analysis under the GATT.

The relationship between the TBT Agreement and the GATT is less clear since there is no such presumption as is included in the SPS agreement. According to Peter Van den Bossche the TBT and the GATT can both be applicable to the same measure.⁹⁰ In the *EC-Asbestos* case the Appellate Body stated that the TBT Agreement was a specialized legal regime for a limited class of measures that imposed obligations different from, and additional to, the obligations imposed on WTO members under the GATT. This would provide that in such a

⁸⁹ Van den Bossche, p. 465.

⁹⁰ *ibid.* p. 459

case where both the TBT and the GATT appear to apply to the same measure, a panel must first examine whether the measure at issue is consistent with the TBT Agreement, since this agreement deals specifically and in detail, with technical barriers to trade. Should the measure be determined to be TBT consistent, the Panel must then determine whether it is also consistent with the GATT.⁹¹

5.2. The Cartagena Protocol

5.2.1. General information

The Cartagena Protocol, or the Biosafety Protocol as it is also called, was negotiated under the auspices of the Convention on Biological Diversity (CBD) adopted in Rio de Janeiro 1992. After almost four years of complex negotiations the Protocol was adopted in January 2000. To this date, 143 countries⁹² worldwide have ratified it, among them the EC, however the U.S. has not signed on.

Since the negotiations took place under the auspices of the CBD the Protocol became a predominately environmental agreement. During the negotiations, the countries' environmental ministers took charge and this can, according to Zimonetta Zarilli, explain why the Protocol has taken a different approach towards for example the precautionary principle than the WTO negotiations which of course was negotiated by the respective countries' trade ministers.⁹³ The fact that this was the background of the negotiations can also be seen by the fact that the Protocol is primarily concerned with the conservation, and sustainable use, of biological diversity, rather than international trade. The EC considers the Protocol to be based on the understanding that the inherent characteristics of GMOs require them to be subject to rigorous scrutiny so as to ensure that they do not cause harm to the environment or human health, or cause socio-economic disruptions.⁹⁴

5.2.2. What does the Protocol regulate?

The Protocol promotes biosafety by establishing rules and procedures for the safe transfer, handling, and use of Living Modified Organisms (LMOs), with specific focus on their trans-boundary movement. Why the subject of the protocol is LMOs rather than GMOs can be explained by the fervent belief, and expression during the negotiations, of the United States that it is "only the final organism, not the process by which it had been modified, [that poses] a potential risk to biodiversity"⁹⁵. The Biosafety Protocol addresses both parts of the GMO controversy, as opposed to Art XX (b) GATT, namely to protect the biological diversity from threats posed to it but also to take into consideration risks to human life and health.

Living modified organisms are defined in the Protocol as being "any living organism that

⁹¹ *EC-Asbestos* Panel report, par. 8.16.

⁹² The Cartagena Protocol on Biosafety Online: <http://www.cbd.int/biosafety/signinglist.shtml>

⁹³ Zarilli, p. 24

⁹⁴ *EC-Biotech*, Panel report, note 4.332

⁹⁵ Marquard, in *The Cartagena Protocol on Biosafety-Reconciling Trade in Biotechnology with Environment & Development*, p. 289

possesses a novel combination of genetic material obtained from the use of modern biotechnology." However though a definition of LMOs is provided there is yet no multilaterally agreed definition of GMOs. Living modified organisms resulting from modern biotechnology are broadly equivalent to genetically modified organisms. 'Modern biotechnology' is defined in the Protocol to mean the application of in vitro nucleic acid techniques, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and are not techniques used in traditional breeding and selection.⁹⁶

5.2.3. Human Health

In the Protocol it is stated that in addition to the risk the release of LMOs can pose to biological diversity, risks to human health shall also be taken into account (the exact wording is "taking also into account the risks to human health"). The meaning of this wording is somewhat unclear since there is no additional explanatory provision in either the CBD or the Biosafety Protocol. The phrase becomes even more ambiguous when one learns that its inclusion in the Protocol was contested during the negotiations. Several countries felt that human health should not at all be included in the Protocol since it was dealt with in other contexts. However many countries, especially the developing countries, felt that the potential impact on human health should be given the same weight as the impact on biological diversity.⁹⁷

The practical effect of the absence of unambiguous guidance in the Protocol itself on this issue, along with the lack of consensus on one or the other above mentioned interpretations, appears to be that, under the Protocol at least, Parties will have a certain latitude and flexibility in deciding which human health aspects to cover in their implementation of the Protocol. One possible approach is to see it as risks posed by an LMO to human health can only be taken into account if this same LMO poses a risk to biodiversity. Another approach would be that those risks can be taken into account even without, or separate from potential adverse effects on biodiversity.

5.2.4. The Protocol's relationship with the WTO agreements

As the Biosafety Protocol includes such wide discretion for its signatory countries to adopt measures in order to restrict trade in LMOs and thereby protect biodiversity, there is bound to be conflict with the rules of the WTO with its pronounced goal of liberalizing trade. There are four parts or aspect of the Biosafety Protocol that may overlap with WTO law and cause obvious conflicts. These are: the scope for legitimate government action when there is little conclusive scientific evidence; risk assessment and risk management; whether socio-economic factors can be taken into account in the decision-making process and documentation obligations. As we will see, the relationship between the two legal frameworks is not obvious. The savings clause contained in the preamble to the Cartagena Protocol is still considered to be ambiguous, and therefore uncertainty exists as to which agreement will have more legitimacy in international law in the area of biotechnology. What will follow in this section is first an examination of the four factors that may create conflict and later a

⁹⁶ Cartagena Protocol on Biosafety, Article 3(i) b

⁹⁷ MacKenzie, Burhenne-Guilmine, La Vina and Werksman., p. 27

discussion on what happens in case of conflict between the two regulatory frameworks.

5.2.5. The Precautionary Principle

Art 1 in the Biosafety Protocol singles out the precautionary approach⁹⁸ contained in Principle 15 of the Rio Declaration as the approach that will be used to fulfill the Protocol's objective of protecting biological diversity and human health. As stated before, the essence of the precautionary approach as laid down in Principle 15 is that lack of full scientific certainty is not to be used as a reason for postponing measures to prevent environmental damage, where there is a threat of serious or irreversible damage. The use of the wording "biological diversity" in the context of Article 1 indicates a fairly narrow definition of the object of protection. By contrast, many existing national laws extend the scope of protection to the environment as a whole, including not only biological diversity but also other parts of the environment such as air, water and soils.⁹⁹ However it is accepted that the signatories establish a higher degree of protection than in the Protocol, this according to Article 2 (4) where it is stated that "*Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol*".

The Protocol has its own interpretation of the precautionary approach which can be seen in formulations in Articles 10.6 and 11.8. These articles deal with LMOs for intentional introduction into the environment and LMOs for direct use as food, as feed, or for processing. The language used in both provisions is quite similar:

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

According to *An Explanatory Guide to the Cartagena Protocol on Biosafety* "Article 10.6 represents one of the most explicit examples of the implementation of the precautionary approach in any multilateral environmental agreement"¹⁰⁰. The result of the inclusion of the approach into the Protocol is that a country can ban imports because of lack of scientific certainty. This stands in sharp contrast with the SPS agreement, since "the focus of the SPS is to protect human, plant and animal health from adverse effects, not potential adverse effects"¹⁰¹. What is even more interesting is that, according to the rules in the Protocol, the importing country has complete authority over the review of its decision and exporters have no means to overturn it, no matter what reasoning is used to justify the restrictive measure. The only way an exporter can appeal a decision is if there has been a change of circumstances or additional relevant scientific or technical information has become available. However as said, it is entirely up to the importer to change its decision.¹⁰² In addition to this there is no

⁹⁸ Note how it is not referred to as the precautionary principle, but the "precautionary approach".

⁹⁹ MacKenzie, Burhenne-Guilmine, La Vina and Werksman, p. 46.

¹⁰⁰ Ibid. p. 83

¹⁰¹ Holtby, Kerr and Hobbs, p. 56.

¹⁰² Holtby, Kerr and Hobbs, p. 51

requirement for the importing country to seek the information necessary to reach scientific certainty, so a trade-restrictive measure may be in force without time limits.¹⁰³ Here we can, yet again, see a divergence between the Biosafety Protocol and the WTO agreements. The procedure established in the Protocol can be contrasted with that of Article 5.7 in the SPS agreement where countries are allowed to adopt provisional measures due to lack of scientific certainty, but they also have an obligation to review this decision periodically and also to seek out necessary additional information to make a more objective assessment of the risks involved. No such obligations are explicitly included in the Protocol.

5.2.6. Socio-Economic considerations

The content of Article 26 of the Cartagena Protocol may also be a potential aspect of conflict between the Protocol and the WTO rules. In this article it is stated that, Parties are allowed, in reaching a decision on import, to consider "socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities"¹⁰⁴. The inclusion of political or socio-economic considerations into the Protocol was, during the negotiations, a dividing issue mainly between the developed and developing countries. Most developing countries wished for these concerns to be addressed in the Protocol, however, most developed countries, on the other hand, argued that socio-economic considerations are issues of national domestic concern, are difficult to quantify for purposes of making decisions on imports of LMOs, and that such considerations should therefore not be within the scope of the Protocol. The final result of the negotiations was, as can be seen in Art 26, that socio-economic issues can be taken into consideration as long as this is "consistent with...international obligations". The inclusion of this phrase indicates that where a Party to the Protocol is also a Member of the World Trade Organization that this country is also expected to ensure that its obligations under the WTO Agreements are not violated as a result of any application of socio-economic considerations in making import decisions on LMOs.¹⁰⁵ As Tewolde B. G. Egziabher, one of Ethiopia's representatives during the negotiations writes one can argue that the requirement that such considerations must be consistent with international obligations makes the promises of the article hollow. In his opinion Article 26 does not enable the inclusion of socio-economic considerations in risk assessment; since the reference to international obligations invokes the WTO trade rules under which such considerations are not allowed.¹⁰⁶

The question then becomes; how will measures based on this type of considerations hold up within the WTO? The big concern within the WTO seems to be whether the provision will create ways for countries to restrict imports on the grounds that these products may lead to a loss of cultural traditions, knowledge and practice. This issue has already been treated by a GATT panel in the case *Japanese Measures on Import of Leather*¹⁰⁷ in which the Panel rejected the justification provided by the Japanese in defense of quantitative restrictions put up on the importation of certain leather. In the case Japan claimed that the restrictions on

¹⁰³ Zarilli, p. 27

¹⁰⁴ Cartagena Protocol on Biosafety, Article 26.1

¹⁰⁵ MacKenzie, Burhenne-Guilmine, La Vina and Werksman, p. 164

¹⁰⁶ Egziabher in *The Cartagena Protocol on Biosafety-Reconciling Trade in Biotechnology with Environment & Development?* p. 120

¹⁰⁷ *Japanese Measures on Imports of Leather*, GATT Panel Report BISD 31S/94 (2 March 1984).

import were necessary to protect the Japanese leather industry that was weak and experiencing difficulties due to its small size and the backward character of its enterprises and above all due to the "Dowa problem". The Dowa can be considered as a minority group within the population in Japan that, owing to discrimination based on a class system formed in the process of the historical development of Japanese society, was placed in an inferior position economically, socially and culturally. One of the traditional ways to make a living for the Dowa was in the leather industry. This method of justifying a quantitative restriction was rejected by the panel due to the fact that it was solely based on the effect of cheap imports on the livelihood of a minority group of the population and that such "special historical, cultural and socio-economic circumstances...did not provide such a justification for import restrictions" in light of the GATT.¹⁰⁸ This case obviously gives us an indication as to how socio-economic values are treated under WTO rules; however this case was decided in 1984, long before the Cartagena Protocol had been negotiated, so it doesn't give us such a clear indication as to how this issue would be treated today. It is probably safe to say though that socio-economic justifications are far from a matter of course in WTO proceedings. The issue is further complicated by the call for science as the basis for risk assessment and risk management under the WTO. However, risk assessment under the SPS agreement can involve a mix of scientific and socio-economical factors, at least when it comes to risks to animal and plant life. In these cases economic factors, such as the economical damage to crops etc. a disease can cause when allowed to spread, can be taken into account when assessing the spread of a pest or disease.

Some risks to Biodiversity may not even come within the scope of the SPS agreement but rather fall under the TBT. For example, a mandatory LMO-FFP identification scheme, because it would require a trade-related measure based on product characteristics. This would be considered a technical regulation and therefore fall under the TBT Agreement. According to article 2.2 of the TBT agreement "the preparation, adoption and application of technical regulations cannot have the effect of creating unnecessary obstacles to trade." and these regulations "cannot be more trade restrictive than necessary". It will of course be up to the WTO to decide whether restrictions introduced under the Protocol create unnecessary obstacles to trade or are more restrictive than necessary. A big controversy here will probably be whether measures based on socio-economic concerns can be considered as necessary. As argued by the developing countries in the SPS-negotiations, such connections between socio-economic factors and risks to biodiversity are very hard to prove, and in a science based risk assessment, as used in the SPS, these concerns will certainly not be considered as justified. According to some authors these concerns may however be viable under the TBT. In the TBT there is space for arguing that socio-economic factors may warrant a measure, but due to the difficulty to prove or disprove a connection between a trade restrictive measure and those factors it is unlikely that the necessity of this measure can be proven.¹⁰⁹

5.2.7. What happens in a possible conflict?

Normally what happens in international law is that a later agreement takes precedence over an earlier agreement, except when it is stipulated in the new agreement that this should not take precedence over earlier agreements. Such a specification is called a Savings Clause. As stated earlier there is debate over whether the Cartagena Protocol includes such a clause or not. In

¹⁰⁸ *Measures on Imports of Leather*, GATT Panel Report BISD 31S/94 (2 March 1984, para. 44

¹⁰⁹ Holtby, Kerr and Hobbs, p. 56 f.

the end it all comes down to three paragraphs in the preamble;

1.) *"Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development"*

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

3.) *"Understanding that the above recital is not intended to subordinate this Protocol to other international agreements"*

The combined effect of these three paragraphs certainly is ambiguous and leaves the interpreter little guidance as to how the issue of precedence should be resolved. On the one hand, mutual supportiveness of environmental and trade agreements is emphasized in the first paragraph. This phrasing seems to indicate that the Protocol and WTO rules should be read together. On the other hand, the second paragraph seems to indicate that the Protocol will not change any prior obligations that a signatory may have under other international agreements. The wording of this paragraph suggests that it is a savings clause and that the WTO rules should take precedence since these were negotiated before the Protocol. However, once again, this view is contrasted by the third paragraph that seems to say that the Protocol is not subordinate to other international agreements, thus the WTO rules do not take precedence. According to Holtby, Kerr and Hobbs the EU interprets these paragraphs to mean that there is no savings clause and that the third paragraph simply negates the meaning of the second paragraph. This would in turn mean that the two agreements have equal standing and that they should, in case of a dispute, be interpreted concurrently. The U.S. on the other hand is of the opinion that the second paragraph constitutes a savings clause and that the third paragraph simply confuses its meaning. However they seem to come to the conclusion that the second paragraph only means that the Protocol is not of a lower status than other international agreements¹¹⁰. These views are certainly in line with the respective countries' underlying motives for negotiating the Protocol. One must bear in mind that the negotiations took place simultaneously to the virtual trade war that flared between the EU and the US in the late 1990s-early 2000s where the EU sought to justify their legal framework and import restrictions on biotechnology, whilst the US sought to obliterate these same rules. Since the meaning of the abovementioned paragraphs is so ambiguous, I will now look at some other aspects that may help determine the issue of precedence.

The fact that the WTO has an enforceable dispute settlement mechanism, unlike the Biosafety Protocol, provides one argument that WTO rules should take precedence. At least a dispute between the two legal frameworks will be settled within the WTO. This supports, at least, the assumption that the WTO rules will be the main piece of legislation and that the Protocol, if taken into account at all, will take a supplemental role in the proceedings. It is as Holtby, Kerr and Hobbs write unlikely that the WTO will "ignore its own rules, or take away its own rights in governing one area of trade."¹¹¹

An argument that can be put forward in support of the Protocol is the principle in international law that a more specific agreement takes precedence over a more general agreement. This is known as the law of *generalis specialibus non derogant*. According to this interpretation the

¹¹⁰ Holtby, Kerr and Hobbs, p. 59

¹¹¹ Ibid. p. 59

Protocol would take precedence since it is more specific than the WTO rules in regard to trade in biotechnology. After all, the Protocol is designed specifically for such purposes whilst the WTO agreements are more general in character and cover international trade as such.

However, when both parties to the conflict are parties to the Protocol the interpretation of the savings clause is not that important. In a case where both parties to a conflict have signed the Cartagena Protocol and are also members of the WTO it is likely that a WTO panel or the Appellate Body would take the rules of the Protocol into account. This since a panel must, under the DSU, take into account all relevant international law applicable between the parties.¹¹² The dispute will in such cases revolve around specific domestic regulations that have been constructed bearing in mind both sets of rules. And since the parties have accepted both sets of rules they are unlikely to protest to a ruling that draws on provisions in the Protocol rather on the provisions of the WTO. However, it cannot be ruled out that such a conflict might occur.

The situation gets trickier when the conflict involves a party to the Protocol and a non-party. In such cases non-parties cannot be required to adhere to the obligations of the Protocol. Thus WTO Panels and the Appellate Body are not required to take the Protocol into account since both parties have not accepted the rights and obligations established by the Protocol, i.e. it is not considered to be relevant international law in relation to that particular dispute since it is not applicable between the parties.¹¹³ This would thus be the situation in the event of a dispute between the EC (party) and the US (non-party). It is also largely due to the requirement that such international law must be applicable between the parties that the defense used by the EC in for example EC-Biotech, where it was argued that the precautionary principle should be considered part of customary international law, has been rejected.¹¹⁴

Even though some provisions are not made part of customary law, these provisions may still be compatible with other relevant agreements. An example of such a situation would be that Canada is a party to the Convention of Biological Diversity and still has to adhere to the safety requirements and objectives set forth in this Convention. Thus there is a small possibility for, at least the objectives of the Cartagena Protocol to be considered within a WTO dispute between a party and a non-party to the Protocol.¹¹⁵

5.3. Codex Alimentarius Commission

The Codex Alimentarius Commission was established in 1963 as a joint undertaking of the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The Committee was established to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The Committee has a dual purpose; protecting the health of consumers and ensuring fair trade practices in the food trade. However the Committee has been criticized for allowing public health protection to take a back seat to trade interests.¹¹⁶

¹¹² Article 31(3) of the Vienna Convention

¹¹³ Article 31(3) of the Vienna Convention

¹¹⁴ Alemanno p. 109-110 and *EC-Biotech*, Panel Report, para. 7.71

¹¹⁵ Holtby, Kerr and Hobbs, p. 60

¹¹⁶ Scott, p. 246.

The Codex Alimentarius itself has become "the global reference point for consumers, food producers and processors, national food control agencies and the international food trade"¹¹⁷ When it comes to Biotech assessment, the FAO and WHO provides advice on food safety. However this activity of the parent organizations is not officially part of the Codex Alimentarius Commission structure, instead the organizations provide independent scientific expert advice to the Commission and its specialist Committees and Task Forces. In 1999 the Codex Alimentarius Commission (CAC) established an *ad hoc* intergovernmental task force on foods derived from biotechnology. It was tasked with developing standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology. The scientific basis for this work was provided by the two parent organization, FAO and WHO.

Both FAO and WHO have developed a separate Biotechnology safety assessment. What can be seen from these guidelines is that these organizations are prone to recommend the use of the principle of substantial equivalence, as used by the United States, as a starting point, rather than the precautionary principle for constructing regulatory frameworks regarding Biotechnology. For example, looking at the *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, it clearly states that their approach is based on the principle that GM-food "is assessed relative to the conventional counterpart having a history of safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard associated with a particular food, the intention is to identify new or altered hazards relative to the conventional counterpart."¹¹⁸ However, the standard also includes a footnote stating that "in the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts"¹¹⁹.

The Precautionary principle as such has not been incorporated in International standards, however the Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* adopted in July 2003 include references to precaution, requiring authorities to take into account uncertainties identified in safety assessment and allowing them to implement appropriate risk management measures. In the *Working Principles for Risk Analysis in the Framework of the Codex Alimentarius*, adopted in July 2003 precaution is considered as "an inherent element of risk analysis", however it is important to note that these principles only apply in the framework of the Codex Alimentarius Commission, and is not an outright recommendation for governments. However, in my opinion it can still serve as an indication as to how these two organizations view the complicated issue of the regulation of biotechnology.

¹¹⁷ Understanding the Codex Alimentarius, available at:
ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf , Preface

¹¹⁸ CAC/GL 45-2003 Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. Available at: http://www.who.int/foodsafety/biotech/en/codex_guidelines_plants.pdf

¹¹⁹ *ibid.* footnote 1

6. The role of the Precautionary Principle

6.1. A General Introduction to the Precautionary Principle

The use of the precautionary principle in legal systems around the world reflects the mood of distrust over the introduction of relatively new and risky technologies, processes and products that, at least by its critics, are assumed to be forced on the general public by commercial interests.¹²⁰ At the very core of the principle lies the simple notion that decision makers should act in advance of scientific certainty to protect the environment. Behind it lies also the idea that humans have to hold back from unnecessary and environmentally unsustainable practices that may eventually prove to be excessively costly to our surroundings and to future generations. It is here we can see the clash between the principle and our modern day consumption-society. If we are to follow the principle we can no longer assume that we can continue on the set out track of getting as much of everything that we can possibly get, at any time or at any place. Since its introduction in West German law in the 1970s the principle has moved into other legal and political fora with "remarkable speed and stealth"¹²¹. It appears regularly in national regulations and in texts of International conventions and protocols which can be seen below in section 3.3.1. on the precautionary principle in International Law.

When dealing with the principle there is also the issue of modern day society's reliance on science since the principle challenges the authority of science and the established scientific method. One way of looking at the principle is that it aims at ensuring that, in situations of scientific uncertainty, the ambiguities associated with future or unknown risks are dealt with by democratic authorities rather than only scientists. It is believed that, unlike scientists, persons that can be held politically accountable are in the best position to guarantee a high level of health protection. Thus the principle "expresses a preference for a democratic regulatory response, as opposed to a theocratic one"¹²². The precautionary principle also tests the cost-benefit analysis where it is at its weakest, namely in situations where the environmental damage is irreversible, possibly catastrophic or simply unknown.¹²³ In an analysis where one weighs the potential total expected costs against the total expected benefits it certainly becomes a hard equation to work in situations where the costs are very uncertain and can only be assumed whilst the benefits are usually quite tangible and clear. In such situations the principle is valuable in order to balance the two sides of the equation.

A general definition of the principle can be said to be; if there is a potential for harm from an activity and if there is uncertainty about the impact this activity may cause or the magnitude of this impact, anticipatory action should be taken. However, the precise meaning of the principle is far from clear. There is as of yet no common definition in international law, and the principle is expressed differently in different legal frameworks. According to Andrew Jordan and Timothy O'Riordan there are, however, a number of recurring themes that show up

¹²⁰ Jordan and O'Riordan in *Protecting Public Health and the Environment: Implementing the Precautionary Principle*, p. 18

¹²¹ Ibid. p. 21

¹²² Alemanno, p. 107

¹²³ Jordan and O'Riordan O'Riordan in *Protecting Public Health and the Environment: Implementing the Precautionary Principle*, p. 17.

in the debate over the meaning of precaution, these are;

- "• A willingness to take action in advance of formal justification of proof;
- Proportionality of response;
- A preparedness to provide ecological space and margins for error;
- A recognition of the well-being interests of nonhuman entities;
- A shift in the onus of proof onto those who propose change;
- A greater concern for intergenerational impacts on future generations; and
- A recognition of the need to address ecological debts."¹²⁴

6.2. The precautionary principle in European Community law

Risk assessment goes to the core of the controversy between the two parties in that they apply two very distinct types; conventional risk assessment (US) based on the principle of substantial equivalence, and precautionary risk assessment (EU). In this section I will focus on the precautionary risk assessment or simply the precautionary principle that is used in European Community law.¹²⁵

Since at least the early 1980s, European policy-making on issues of considerable concern and acknowledged scientific uncertainty has progressively adopted precautionary approaches, in order to achieve high levels of public health, environmental protection and consumer safety without compromising science or technological innovation.¹²⁶ During this time the precautionary principle has developed as an aspect of both European and International law, however there are differing opinions as to whether it can be considered a principle in International law as well as in European law.¹²⁷ In European Community law there is only one explicit reference to the precautionary principle in legal text. This reference can be found in Article 174 of the EC Treaty, where it is stated that:

*"2. Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the **precautionary principle** and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay ..."*

¹²⁴ Jordan and O'Riordan in *Protecting Public Health and the Environment: Implementing the Precautionary Principle*, p. 24

¹²⁵ For a more comprehensive look at the US approach see section 3.3.

¹²⁶ WHO Working paper :EUR /04/5046267/11, p.1

¹²⁷ See Panel and Appellate Body reports in *EC-Hormones* and *EC-Biotech*.

As can be seen there is only explicit mention of the principle in legal text relating to the protection of the environment, but according to the Commission its scope is far wider and covers all situations where there is insufficient evidence of, but reasonable grounds for concern over for example human or animal health.¹²⁸ The Commission bases this statement on the horizontal nature of Article 6 EC which provides that:

“Environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities referred to in Article 3¹²⁹, in particular with a view to promoting sustainable development.”

What can also be seen is that the principle is not defined in the legal text. Instead it is for the decision-makers and ultimately the courts to flesh out the principle.¹³⁰ What can be said with certainty however is that the precautionary principle is concerned with scientific uncertainty. It has also been suggested that it has these four central components: taking preventive action in the face of uncertainty; shifting the burden of proof to the proponents of an activity; exploring a wide range of alternatives to possibly harmful actions; and increasing public participation in decision making.¹³¹ When talking about the Precautionary principle in general, it is suggested that “precaution is a culturally framed concept that has evolved along different pathways and at different rates in different countries. Searching for a single, all-encompassing definition is, therefore, likely to be a fruitless endeavor because individuals will never agree upon what is or is not precautionary in a given situation.”¹³² According to this view, one can argue that the introduction of the principle in EC-legal text is an excellent way of spreading a common view of the principle in Europe at least, where it can be argued that we share a somewhat equal cultural base. However if we look at the current status of the principle in light of this statement, it is not strange that the EU way of using the principle is receiving so much critique from other countries around the world.

In its communication on the precautionary principle the Commission makes it clear that when it is deemed necessary to implement a measure based on the principle this should be, *inter alia: proportional to the chosen level of protection, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack thereof, subject to review* meaning that a restrictive measure should only be in place for as long as the scientific information is incomplete or inconclusive and that the measure should be periodically reviewed. The measure should also be *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment. This last characteristic is already a consequence of precautionary measures and refers to the reversed burden of proof that exists when you have a system of prior approval of a product before marketing. In these cases where the products are treated as dangerous unless and until businesses do the scientific work necessary to demonstrate that they are safe, the traditional burden of proof is reversed and placed on the producer, manufacturer or importer instead of on the public authorities.¹³³

¹²⁸ COM(2000)1, Communication from the Commission on the precautionary principle, p.10.

¹²⁹ Where “the attainment of a high level of health protection” is included in point (p)

¹³⁰ COM(2000)1, Communication from the Commission on the precautionary principle, p. 10

¹³¹ Kriebel and Tickner, (Abstract)

¹³² Raffensperger, Carolyn (Editor), p 18

¹³³ COM(2000)1, Communication from the Commission on the precautionary principle, p. 4-5

Although there has been much criticism over the use of the principle, some scholars, especially economists, claim that the precautionary principle has its positive aspects as well. For example, Ian Sheldon sees the principle as “potentially providing guidance about how risk should be managed”¹³⁴. In his article *Food Principles: Regulating Genetically Modified Crops after the 2006 WTO Ruling*¹³⁵ he reasons about how society has to decide on how to trade off the costs and benefits of a new technology across possible future states of the world, and how, in this context, the precautionary principle can be viewed in cases where there is scientific uncertainty about a new technology which can only be resolved over time and through learning. In his article he suggests that there are three ways that the principle can be viewed: First, if preventive measures are not taken today, vulnerability to harm from a new technology may be increased so that there is a precautionary motive for risk-prevention. Second, if the introduction of this new technology is an irreversible decision, this decision then reduces flexibility in the future. Third, due to a process of learning by doing, knowledge may improve through early observance of risk. The impact of great harm today from a new technology makes the prospect of greater harm in the future much worse, which would lead to an increase in preventative efforts today.¹³⁶

6.2.1. The Precautionary Principle in Directive 2001/18/EC

In Article 1 of Directive 2001/18/EC it is stated that the objective of the Directive is to, according to the precautionary principle, to approximate the laws, regulations and provisions of the Member States in order to protect human health and the environment. The Directive can thus be considered to be based on the precautionary principle and its meaning should affect the interpretation of the Directive.

The precautionary principle is mentioned again in Annex II where the objective of an environmental risk assessment and how it is to be achieved is outlined. Here it is mentioned in connection with principles that are to be followed when conducting such a risk assessment and which, according to the text, can be considered to be based directly on the precautionary principle. These are; that identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations; That the risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data; That the risk assessment should be conducted on a case-by-case basis taking into account the type of GMO concerned, its intended use and the potential receiving environment. Finally, the risk assessment may be re-addressed if new information appears in order to determine whether the risk has changed, and whether there is need for amending the chosen risk management accordingly.

¹³⁴ Sheldon, p. 125

¹³⁵ Published in *The Brown Journal of World Affairs*.

¹³⁶ Sheldon, p. 125

6.3. The precautionary principle in International Law

The European Communities claimed, in both the *EC-Hormones*¹³⁷ case and the *EC-Biotech*¹³⁸ case that the precautionary principle is a general customary rule of international law, and cited various International agreements in which the principle has been incorporated to support their claim. In both cases the U.S. opposed their claim since the principle in their view constituted more of an approach.¹³⁹ In the Commission's communication on the precautionary principle from 2000 the Commission bases the official EC position on examples of international agreements where the principle is mentioned suggesting that this shows that the principle "has been progressively consolidated in international environmental law" and has thereby "become a full-fledged and general principle of international law"¹⁴⁰. The Commission even goes as far as suggesting that the preamble to the WTO agreement confirms their observation since it highlights the "ever closer links between international trade and the environment"¹⁴¹ and that the principle should therefore be taken into consideration in applying the WTO agreements, especially the SPS and the TBT. Further discussion on this issue will follow in **Chapter 7** below, where the Panels' and Appellate Body's take on the precautionary principle within the WTO system will be analyzed through case law.

The principle has been mentioned in several agreements within the environmental field such as; the Ministerial Declaration of the Second International Conference on the Protection of the North Sea (1987), the Convention of Biological Diversity (1992), the Paris Convention for the protection of the marine environment of the north-east Atlantic (September 1992) etc. Moreover, the precautionary principle has explicitly been recognized and incorporated into the very high profile Rio Declaration on Environment and Development of 1992 where it is stated that:

*"Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"*¹⁴².

¹³⁷ *EC-Hormones* AB report, para. 121.

¹³⁸ *EC-Biotech* Panel report, para. 7.86

¹³⁹ A more detailed discussion of the question of the precautionary principle as customary international law will follow below in Chapter 7 regarding case law, and 9.2.

¹⁴⁰ COM(2000)1, Communication from the Commission on the precautionary principle, p. 11

¹⁴¹ The Commission makes reference to this wording in the preamble to explain their reasoning: *"The parties to this agreement ...recognising that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing to in a manner consistent with their respective needs and concerns at different levels of economic development ..."*

¹⁴² Principle 15 of the Rio Declaration

In addition to the Rio Declaration the principle has also been included into the more specific 2000 Cartagena Protocol on Biosafety (or the Biosafety Protocol) where it is stated in article 10, paragraph 6 that:

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

To reference the Cartagena Protocol as support for the notion that the principle is customary international law may however be tricky when it comes to dealings with the U.S. since they are not a party to this particular agreement.

6.4. The Precautionary Principle in U.S. Law

Whilst in the EC the precautionary principle has been the basis for Community policy on the environment since its inclusion in the Treaty of the European Union in 1993, the principle is not mentioned in national laws or policies in the U.S. However, there are some laws that are of a precautionary nature, such as the *Clean Air Act*, the *National Environmental Policy Act*, the *Federal Food, Drug and Cosmetics Act* and the *Clean Water Act*. While the US believes firmly in a context-specific precautionary approach to protect human health and the environment, it has generally opposed references to the precautionary principle at the international level.¹⁴³ For example the U.S. does not agree with the EC that the principle has become part of international law. This position is expressed in for example *EC-Biotech* where the U.S. states that the precautionary principle cannot be considered a general principle or norm of international law because it does not have a single, agreed formulation.¹⁴⁴ The principle is therefore considered more of an approach than a principle in the U.S. Instead as we can see from recent disputes before the WTO the U.S. clearly emphasizes that domestic regulations must be science-based and that there are certain other deficiencies in the principle, for example that it does not allow for considering the risks of alternative technologies.

7. Relevant Case Law

Several recent WTO disputes have raised the question of whether or not WTO rules allow governments to take trade-related measures based on precaution, and if so to what extent. All of these disputes have focused on the principle in relation to the SPS agreement, probably since it puts such a strong emphasis on science. No disputes concerning the TBT or the GATT have explicitly addressed the principle. There have, to this date been five cases that have addressed the question of how Article 5.7. SPS, and the whole Agreement, relates to the precautionary principle. These cases may be important in determining how a potential future dispute regarding GMOs and biotechnology may be viewed by the WTO dispute settlement body. These cases are; *Australia-Salmon*, *EC-Hormones*, *Japan-Varietals*, *Japan-Apples* and of course *EC-Biotech* which bears the most relevance to the issue of this thesis. Each of these

¹⁴³ Baumüller, p. 31

¹⁴⁴ *EC-Biotech*, Panel report, para. 7.81

five cases will be discussed in detail below.

7.1. Australia-Measures Affecting Importation of Salmon

In this case the Appellate Body considered the relationship between Article 2.2, that states that SPS measures are to be applied only to the extent necessary and should not be maintained without sufficient scientific evidence, and Articles 5.1 and 5.2 relating more specifically to risk assessment. The case concerned a prohibition of imports of salmon based on a quarantine regulation put in place by Australia. The AB came to the conclusion that if a measure is found to be in violation of the more specific Articles 5.1 and 5.2 then one can presume that the more general provision 2.2 has also been violated. However, the AB found that Art 2.2 establishes a much broader obligation than do Art 5.1 and 5.2 and thus there is a possibility that a measure can be found to violate 2.2 but not 5.1. and 5.2. However, despite this ruling there have been no such situations in case law to this date.

Which will be seen from this case and those discussed below, there is an overlap between Art 2.2 and Art 5.1 as construed by the AB. One element of both seems to be the rational relationship between available science and the measure.

The AB also made an important remark about what can be considered as a proper risk assessment:

”... it is not sufficient that a risk assessment conclude that there is a possibility of entry, establishment or spread A proper risk assessment ... must evaluate the "likelihood", i.e., the "probability", of entry, establishment or spread ... ^{145,}”

They also note that such a evaluation of the "likelihood" can be expressed either quantitatively or qualitatively.¹⁴⁶ However, one should remember that the SPS agreement contains two definitions for risk assessment, one for food-related risks to human or animal health and one for the risk of pest or disease. *Australia-Salmon* concerned the risk of pest or disease and in such cases the Member State must evaluate the likelihood of entry etc. When it comes to food related risks, it is sufficient to evaluate the potential for adverse effects.¹⁴⁷ What can be seen from these two definitions is that we are dealing with two different levels of evaluation. "Likelihood" which is required in the first definition is stricter than "potential", which is required for the second definition, and can be equated with "probability" whilst the other is associated with the mere "possibility". The distinction between the two definitions came to a head in *EC-Biotech* where Austria had based its safeguard measure on T25 maize on a report known as the Hoppicher study. Austria suggested that this study constituted a risk assessment, but were rejected by the Panel since the study "[did not] indicate relative probability of the potential risks it [identified], but rather [made] references to the possibilities of risks or simply to the inability to determine possibilities."¹⁴⁸ Thus in this case, the Panel, found that for the purpose of the first definition in Annex A.4 the mere possibility of risk was not enough to ground protective measures.

¹⁴⁵ *Australia-Salmon*, AB report, par. 123.

¹⁴⁶ *Ibid.* para. 124.

¹⁴⁷ http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c2s4p1_e.htm

¹⁴⁸ *EC-Biotech*, Panel report, par. 7.3044 and Scott, p. 93

7.2. European Communities-Measures Concerning Meat and Meat Products (Hormones)

7.2.1. Background

This case concerned a series of EC Council Directives covering the ban on the administration of certain hormones (among others progesterone and testosterone) for growth promoting purposes in livestock and the marketing and import of meat and meat products derived from cattle treated with such hormones. The legislation was challenged by the U.S. since it allegedly restricted and prohibited the import of meat and meat products from the U.S. and thus violated Articles III (National Treatment) or XI (elimination of Quantitative restrictions) GATT, Articles 2, 3 and 5 (on risk assessment) SPS etc.

A panel was formed by U.S. request and it found that the disputed measures were not in conformity with **Articles 3.1** since the EC had maintained sanitary measures which were not based on existing international standards, **5.1.** since the EC had maintained sanitary measures which were not based on a risk assessment, and **5.5.** since the EC had adopted arbitrary or unjustifiable distinctions in the levels of sanitary protection it considered to be appropriate in different situations which resulted in discrimination or a disguised restriction on international trade, **of the SPS agreement.** The Panel therefore requested that the EC bring their measures into conformity with the SPS agreement. However the EC appealed the Panel's decision and the case was submitted for review by the Appellate Body.

Throughout the dispute, the EC argued that the precautionary principle had developed into a fully fledged rule of customary international law, therefore constituting a relevant rule of international law applicable in the relations between the parties under Article 31(3)(c) of the Vienna Convention on the Law of Treaties. The U.S. however, argued that it should not be considered a principle but rather an approach that had little relevance to the interpretation of WTO provisions.

The Appellate Body found that the studies that the EC had provided as basis for their measures were "general" and that even though they were relevant, they were not "sufficiently specific to the case at hand".¹⁴⁹ The AB therefore upheld the Panel's finding that the EC import prohibition was inconsistent with Articles 3.3 and 5.1 of the SPS Agreement. However they reversed the Panel's finding that the EC import prohibition was inconsistent with Articles 3.1 and 5.5 of the SPS Agreement.

7.2.2. Relevance

In this case the question of the precautionary principle in the framework of the SPS agreement, like in EC-Biotech, was addressed. The Appellate Body deals, in this case, with the EC's view that the precautionary principle is a part of customary international law. Whilst the AB finds it "possibly imprudent" to take a position on the status of the precautionary principle in international law, it does note some aspects of the relationship between the

¹⁴⁹ *EC-Hormones*, AB report, par. 200.

principle and the SPS agreement.

i) That the reason why the precautionary principle has been incorporated in Article 5.7¹⁵⁰ is not to create a situation where Members can justify measures otherwise prohibited under specific provisions in the agreement.

ii) The incorporation of the principle into Article 5.7. does not exhaust the relevance of the precautionary principle for the whole SPS.

iii) A Panel in charge with proving "sufficient scientific evidence" may, and should bear in mind that responsible governments often act from a perspective of prudence and precaution where risks are irreversible.

iv) The precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement.¹⁵¹

These aspects that are presented by the AB leads up to, and ties in with, their conclusion that even in a situation where the precautionary principle is found to be customary international law it does not "override the explicit wording of Articles 5.1. and 5.2."¹⁵² this then mainly because the principle has been incorporated and been given a special meaning in Article 5.7 SPS.¹⁵³ Thus, one of the most important things that can be seen from this case is that one of the requirements for risk assessment is that the risk evaluated in a risk assessment must be an ascertainable risk and there is no room under Article 5.1. to assess theoretical uncertainty.¹⁵⁴ In addition to this requirement the argumentation in the case also provides a few more requirements or aspects important to the concept of risk assessment under the SPS agreement. First, the Appellate Body recognized that a risk assessment may go beyond controlled laboratory conditions and take account of actual potential for adverse effects in the "real world where people live and work and die".¹⁵⁵ Secondly, as we can see above the risk assessment has to be specific to the particular risk at issue in the case and not merely show a general risk of harm.¹⁵⁶ This last conclusion has also been discussed in later cases where it has been found that the risk assessment must evaluate risk on a disease-specific basis, and not simply address the overall risk related to a combination of different diseases.¹⁵⁷ Likewise, Members should identify the risk on a product specific basis, rather than a general assessment relating to a variety of different products.¹⁵⁸

¹⁵⁰ 5.7. deals with measures taken when scientific information is insufficient. Under the article Members are permitted to take measures, however they must be provisional and based on pertinent information.

¹⁵¹ *EC-Hormones*, AB report, par. 124.

¹⁵² *EC-Hormones*, AB report, par. 120 and 125

¹⁵³ *EC-Hormones*, AB report, par. 120.

¹⁵⁴ Zarilli, p. 32.

¹⁵⁵ Van den Bossche, p. 465 and *EC Hormones*, AB report, par. 187.

¹⁵⁶ Van den Bossche, p. 465 and *EC Hormones*, AB report, par. 200.

¹⁵⁷ *Australia-Salmon* (Panel) par. 8.74 and *Japan-Apples*, Panel report, par. 8.257

¹⁵⁸ *Japan-Apples*, AB report, par. 203

7.3. Japan-Measures Affecting Agricultural Products¹⁵⁹

In this case the U.S. questioned a Japanese prohibition, under quarantine measures, of certain agricultural products. They claimed that Japan prohibited the importation of each variety of a product by testing and confirming the efficacy of the quarantine treatment for each variety of certain agricultural products, even when the treatment had proved to be effective for other varieties of the same product. In this case the Appellate Body gives guidance on how to interpret two of the essential articles of the SPS agreement, namely Article 2.2 and Article 5.7.

Japan invoked Article 5.7. SPS as support of their testing requirements, so that article was therefore specifically addressed. According to the Appellate Body there are four cumulative requirements for adopting and maintaining provisional SPS measures. Such measures may be imposed; i) in a situation where relevant scientific evidence is insufficient and, ii) if it is adopted on the basis of available pertinent information. However, the measure may not be maintained unless the country that adopted it: i) seeks to obtain the additional information necessary for a more objective assessment of risk; and ii) reviews the measure within a reasonable period of time.¹⁶⁰

When it comes to Article 2.2 and the phrase "sufficient scientific evidence" the AB affirmed that it must be interpreted in the context of Articles 3.3, 5.1 and 5.7 SPS.¹⁶¹ When it comes to the relationship with Art. 5.7 the AB recognizes that 5.7 is a qualified exemption to the obligation under Art. 2.2. to not maintain measures without sufficient scientific evidence, and comes to the conclusion that an "overly broad and flexible interpretation" of Art 2.2. would render Art 5.7 meaningless.¹⁶² According to the AB Art. 2.2 should therefore be interpreted restrictively and exceptions from the general rule should instead be treated and justified under Art. 5.7.

When addressing the meaning of "sufficient", the AB concluded that it is a "relational concept" that "requires the existence of a sufficient or adequate relationship between two elements, *in casu*, between the SPS measure and the scientific evidence".¹⁶³ It further noted that the determination of whether such a relationship exists must be made on a case-by-case basis and will depend on the particular circumstances of the case, including the characteristics of the measure and the quality and quantity of the scientific evidence.¹⁶⁴ In addition to the above the AB offered, in this case, another relevant statement, namely that "sufficient scientific evidence" under Art 2.2. should not be confined to mean mainstream scientific evidence but could include qualified and respected divergent scientific opinion. This conclusion was also drawn in the *EC-Hormones* case to which the AB refers.¹⁶⁵ It is especially acceptable for governments to rely on minority opinion when the risk involved is "life-threatening in character, and is perceived to constitute a clear and immanent threat to public health and safety". Thus the more serious the threat to public health and safety is the further governments can rely on minority opinion in trying to contain or prevent this risk. This

¹⁵⁹ More commonly known as *Japan-Varietals*.

¹⁶⁰ Zarilli, p. 32.

¹⁶¹ *Japan-Varietals*, AB report, para. 74.

¹⁶² *Ibid.* para. 80.

¹⁶³ *Ibid.* para. 73.

¹⁶⁴ Bernasconi-Osterwalder, Magraw, Oliva, Orellana, and Tuerk, p. 283

¹⁶⁵ *Japan-Varietals*, AB report, para. 77.

relationship was tried in *EC-Biotech* where the Panel did not consider the circumstances surrounding the Member States' safeguard measures to be life-threatening, nor did they consider them to constitute a clear and immanent threat.¹⁶⁶

7.4. Japan-Measures Affecting the Importation of Apples

In this case the U.S. challenged certain requirements and prohibitions imposed by Japan with respect to the importation of apples from the United States. The restrictions were caused by the problem of fire blight, a contagious disease affecting apples and pears etc. causing affected fruit to appear blackened, shrunken and cracked, as if scorched by fire.¹⁶⁷ The Panel applied a test, referred to as the "rational or objective relationship test", that was developed in *Japan Varietals*¹⁶⁸ in order to determine whether there was sufficient evidence for Japan to keep its measures in place. What the Panel found was that that the measure seemed "clearly disproportionate" to the negligible risk identified by the available scientific evidence and has therefore been maintained without sufficient evidence.¹⁶⁹ This ruling was later upheld by the Appellate Body. When looking at the argumentation in this ruling it seems to introduce a proportionality dimension to the rational relationship test. However, it seems unclear what type of proportionality the Panel was advocating.¹⁷⁰ Thus this case gives us additional guidance on the issue of the rational relationship needed in order to establish that there has been sufficient scientific evidence. But why this case is specifically important in the context of this thesis will be shown below where some interesting observations and statements made about Art. 5.7 SPS are presented.

In this case the four cumulative requirements, set forth in *Japan-Varietals* (see above), were again addressed and the AB confirmed the need for the requirements to be met in order for WTO members to adopt and maintain provisional SPS measures under Art. 5.7. The AB's argumentation in this case is very important in explaining and clarifying the first of these criteria, namely the situation where "relevant scientific information is insufficient". Here the AB states that "relevant scientific evidence will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*"¹⁷¹.

The AB goes on to state that "the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence."¹⁷² It goes on to say that according to the Appellate Body, the text of the Article is "clear", it refers to cases where relevant scientific evidence is insufficient, not to scientific uncertainty as such and that these two concepts are not interchangeable. This ruling can be considered as clear indication that there is little room for arguing that the present inconclusiveness that can be seen regarding the actual or potential impact on GMOs on human and animal health should warrant

¹⁶⁶ *EC-Biotech*, Panel report, para. 7.3059

¹⁶⁷ http://en.wikipedia.org/wiki/Fire_Blight

¹⁶⁸ Bernasconi-Osterwalder, Magraw, Oliva, Orellana, and Tuerk, p. 260

¹⁶⁹ *Japan-Apples*, AB-report, para. 147

¹⁷⁰ Scott, p. 90 f.

¹⁷¹ *Japan-Apples*, AB report, para. 179.

¹⁷² *ibid.* para. 184.

a precautionary measure under article 5.7 SPS.¹⁷³ In this case there is ample scientific evidence suggesting that GMOs are harmless, but much uncertainty as to whether they can be considered as harmful i.e. there is scientific uncertainty, but not insufficient scientific evidence. This availability of information about GMOs thus prevents governments from taking action against the possible threat of GMOs based on Art 5.7. Here we can see a difference between the SPS agreement and the Cartagena Protocol. Whilst Article 5.7 SPS talks about "insufficiency of scientific evidence", Article 10.6 of the Cartagena Protocol refers to the "lack of scientific certainty due to insufficient relevant scientific information and knowledge" as a basis for taking precautionary action. The Protocol advocates the view that the insufficiency of the relevant scientific evidence would lead to scientific uncertainty and thus justifying a precautionary measure. As the Article in the Protocol is worded, it addresses two different situations; first the situation where after carrying out the risk assessment there is still lack of certainty as to whether the product is safe or whether it poses a risk of potential adverse effects. Secondly, the situation where there simply isn't enough evidence to carry out a risk assessment. Thus the room for precautionary action for governments under the Cartagena Protocol is wider than under the SPS agreement. As we can see in many of the cases discussed in this thesis, the contested measures would have been accepted had they been judged under the Biosafety protocol instead of under the SPS agreement.

7.5. EC-Biotech

7.5.1. Background

According to the complainant, the U.S., the European Communities (EC) had before October 1998 established a system for approval of agricultural products and through the implementation of these procedures approved more than ten different products produced by biotechnology. However, in October 1998, the EC suspended its approval procedures which in turn led to that whilst new applications for approval were accepted, no new biotech products had moved to final approval.¹⁷⁴ This reluctance to approve new biotech products amounted to a moratorium according to the Americans. Such a moratorium, they argued, was against the EC's obligations under WTO law, especially the SPS agreement. According to their first written submission the U.S. had no objections to the EC system of approvals itself, but argued that procedures under that system must be undertaken and completed without undue delay and went on to state that "it is hard to think of a situation that involves "undue delay" more than a complete moratorium on approvals"¹⁷⁵. The EC denied the existence of a general moratorium on the approval of biotech products and submitted that the alleged practice alone, not based on a formal or informal instrument, would not constitute a measure under WTO agreements. As a response to the issue of "undue delay" the EC replied that failing to deal with applications in a timely manner could not be considered to be a "measure" under the SPS agreement and could therefore not be challenged. In their submission the U.S. also criticized the marketing and import bans placed on previously approved Biotech products by six EC Member States¹⁷⁶ and claimed that these bans were not based on science (and

¹⁷³ Zarilli, p. 33

¹⁷⁴ *EC-Biotech*, Panel report, para. 4.130 and 4.131

¹⁷⁵ *Ibid.* para. 4.133

¹⁷⁶ France, Germany, Austria, Italy and Luxembourg had marketing bans in place while Greece had an import

neither was the moratorium) and were thus inconsistent with WTO regulations. The EC, on its part, claimed these measures, given their provisional nature, were in full compliance with relevant WTO disciplines citing art 5.7 SPS as support for their claim.

7.5.2. Impact on EC regulations on Biotechnology

Particularly important is how the panelists ruled on the relation of “insufficient scientific information” to “scientific uncertainty”, i.e. the use of the precautionary principle as a basis for regulations. According to some writers the EC sees the precautionary principle as a risk management tool which is part of a risk analysis framework rather than the overall guide to its implementation. According to this argument, precautionary action should only be taken after experts prepare an “objective” quantitative risk assessment. Precaution is seen as a temporary measure pending further risk assessment. These same writers consider the commission’s interpretation of the precautionary principle in the EC Biotech case as a clear attempt to make its application conform to the provisions of the SPS agreement.¹⁷⁷ What was argued from the EC side was that the safeguard measures implemented by some Members States were in accordance with Article 5.7 SPS since they were only in place on a provisional basis.

As can be seen from several cases above, a minority scientific opinion can be used as a base for a measure under the SPS agreement as long as this diverging minority opinion is derived from qualified and respected sources. In the absence of such a qualified minority opinion, it will be open for the Member State to depart from the risk assessment only to the extent that they can explain, with reference to the relevant risk assessment, how and why they assess the risk differently and of course also provide a supplemental or revised assessment of the risk.¹⁷⁸ What is established in *EC-Biotech* is that an unequivocally positive risk assessment cannot in general be referred to as a rational basis for a measure establishing a prohibition on a product or substance. However, the Panel acknowledges that there may be situations where there are “factors which affect scientists’ level of confidence in the risk assessment they have carried out”,¹⁷⁹ that a Member is entitled to take this lack of confidence into account in determining what protective measure that should be applied. Thus there seems to be an opening in the Panel’s reasoning for using a precautionary approach, resulting in a measure not otherwise warranted, when a risk assessment identifies uncertainties and constraints. However, in order to make use of these uncertainties it is not enough for a Member to simply identify these, but they also need to explain why their measure is warranted in the light of the uncertainties.¹⁸⁰

The EC standpoint that there is sufficient support in the SPS agreement for states to apply a precautionary approach when dealing with GMOs was vehemently denied by the U.S. As said in earlier sections, the EC cited articles 10(6) and 11(8) of the Cartagena Protocol on Biosafety in support of their view.¹⁸¹ They argued that the precautionary principle was

ban in accordance with the safeguard option in Directive 90/220/EC.

¹⁷⁷ Suppan, p. 4

¹⁷⁸ Scott, p. 107

¹⁷⁹ *EC-Biotech*, Panel report, para. 7.3065-7.3066

¹⁸⁰ Scott, p. 107

¹⁸¹ These provisions, as has been showed above, are similar in their wording: “Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question...in order to avoid or minimize such

recognized in international law and should therefore be seen as an international standard thus used in the interpretation of the SPS, in particular Article 5.7 of the agreement. However as we will see, the standard interpretation of the SPS agreement, that an import ban on a GM product would have to meet the risk assessment criteria of the agreement, prevailed in this case. As the precautionary principle was rejected as an international standard, the only way to justify a measure found to be affecting international trade was by providing scientific justification.

7.5.3. What agreement is applicable to GM-products?

Throughout the dispute the claimants used the SPS agreement as a base for their case. The EC however argued that their measures should not be assessed under the SPS but rather under the TBT agreement. This because the objective was "environmental protection" which they argued was a much broader notion and would be best analyzed under the TBT. In its 2006 ruling the Panel favored the claimants' line of argumentation and found that that all three categories of measures challenged (the de facto moratorium, product-specific EC measures, and EC member State safeguard measures) were SPS measures within the meaning of the SPS Agreement. This decision has been criticized by some authors.

Christine Conrad, from the Institute of European and International Economic Law at the University of Bern, criticizes the Panels arguments for using the SPS agreement as the base of its ruling in the EC-Biotech case in her article *PPMs, the EC-Biotech Dispute and Applicability of the SPS Agreement: Are the Panel's Findings Built on Shaky Ground?* and argues that there are great doubts regarding the applicability of the SPS Agreement to the EC measures on biotech products. In this article she points to the fact that such a decision by the Panel is most likely to pre-determine the lines of reasoning along which future disputes on national regulations of biotech products will be decided, and because the Panel report is silent on the issue of the striking similarities between genetic engineering and many processes and production methods, or PPMs, we may experience some problems with this classification in the future.

She expresses three fundamental concerns about the Panel's reasoning; the first being that the Panel interprets the SPS agreement in an overly broad manner, the second being that the Panels fails to point out that the contested measures differ considerably from those in previous SPS disputes i.e. that they are not classic SPS measures, and the third being the Panel's failure too explore the full meaning of environmental protection and biodiversity. She also suggests that a "cautious and normative approach" should be applied to measures concerning biotech products, this since the SPS agreement is a specialized agreement designed for a specific purpose and one must be careful in determining whether there is enough objective evidence to warrant their application and whether these rules are even suitable for regulating products of biotechnology.¹⁸² What Conrad concludes in the end is that given the ambiguity of the scope of the SPS Agreement with respect to measures on biotech products, the rule of minimal obligations, also referred to as *in dubio mitius*, could be of use. This would require the Panel to take into account the substantive provisions of alternatively applicable agreements when

potential adverse effects."

¹⁸² Conrad, Christiane p. 7

determining the legal basis for a review.¹⁸³

7.5.4. What the Panel found

In its report, circulated on 29 September 2006, the Panel found that the actions of the European Communities did indeed amount to a de facto moratorium, a fact which the EC had categorically denied during the process, and that the EC had thereby violated its obligations under Annex C(1)(a), first clause, and Article 8 of the SPS Agreement since the de facto moratorium led to undue delays in the completion of EC approval procedures.

With respect to the product specific measures, or the approval process of some products, the Panel found that the EC had, as in the case of the moratorium, acted inconsistently with its obligations under Annex C(1)(a), first clause, and Article 8 SPS and caused undue delay in the approval of 24 out of 27 biotech products identified by the complaining parties.

Finally, when it came to the EC member State safeguard measures the Panel found substantial violations of the SPS agreement. In this case the Panel found that the EC had acted inconsistently with its obligations under Article 5.1 SPS, which requires that a measure be based on a risk assessment, and Article 2.2 SPS, which requires that a measure be based on scientific principles and not maintained without sufficient scientific evidence. The Panel's argumentation here mirrors that of the cases presented above. Even though GMOs can be considered as somewhat special in the sense that there is no real way to measure their harmfulness over a longer period of time, since the technology has not been around for long enough, the Panel still ruled that the risk assessment undertaken did not satisfy the requirements of the SPS agreement. The ruling ultimately goes back to the Appellate Body's argumentation in *Japan-Apples* concerning Art 5.7 and the distinction between "scientific uncertainty" and "insufficient scientific evidence". In this case they found that there was enough scientific evidence to adequately perform a risk assessment, thus the EC could not use Art 5.7 to justify their measures. In the end the Panel's ruling was that the safeguard measures were not based on risk assessments satisfying the definition of the SPS agreement and were therefore presumed to be maintained without sufficient scientific evidence.¹⁸⁴

7.5.5. Relevance

Formally previous Panel or Appellate body reports do not have precedent value in WTO law, however it can be expected to shape the reasoning of subsequent panels dealing with similar regulations. The Panel's ruling in EC-biotech is considered by many as "a narrow legal ruling"¹⁸⁵ since it mainly focuses on the EC moratorium, a question that could almost be considered as moot since the EC had already taken action lifting the moratorium before the U.S. even filed its complaint. However there are certain indications as to how subsequent rulings on similar issues would be dealt with that can be seen from the case. One thing that can be seen from the ruling is that it is definitely the SPS agreement that should cover regulatory frameworks put in place on GMOs and not the TBT agreement.¹⁸⁶ Another very

¹⁸³ Conrad, Christiane (Abstract) Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=920742

¹⁸⁴ http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm

¹⁸⁵ Sheldon, p. 128.

¹⁸⁶ However there are obviously some parts of the EC regulations that might fall under this agreement, such as

important aspect of the ruling is the rejection of the safeguard measures put in place by some member states. These measures were found both to violate Article 5.1. SPS which requires that a measure be based on a risk assessment, Article 2.2. which requires that a measure be based on scientific principles and not maintained without sufficient scientific evidence and finally it was also found to violate Article 5.7 since there was enough evidence to conduct a risk assessment and this provision only applies when such evidence is lacking. This part of the ruling obviously reflects upon the precautionary principle in WTO law and suggests that Panels are unwilling to accept the principle's standing as accepted international law and thus this line of reasoning cannot, in the future, be used as a defense for introducing potentially trade distorting legislation on GMOs. This is a conclusion which is also supported by the Panel's ruling in the EC-Hormones case.

8. Analysis

As (I hope) can be seen consistently throughout this thesis, the lack of conclusive scientific evidence on the actual or potential adverse effects on human and animal health and the environment caused by biotechnology, fuels the already very heated and emotional debate surrounding this technology. As pointed out before, the suspicion towards products derived from such technology has produced legislation that reflects the uncertainty seen today. Among these legislators the European Communities has been, to date, the strongest advocate for taking a precautionary approach in the face of these potential risks. It is however; quite clear that the EC's legislation also hampers international trade in those products, and it has also been suggested that it has a negative impact on the transboundary movement of conventional agricultural products as well.

The EU's import- and market regime relating to GMOs is the most stringent in the world. As has been illustrated above, applications for the release of GMOs into the environment and onto the common market must be accompanied by a full risk assessment which should identify and evaluate potential negative effects of the product, either direct or indirect, immediate or delayed, also taking into account the cumulative and long-term effects on human health and the environment. The process was further strengthened by the introduction of *Directive 2001/18/EC* which established mandatory information to the public, including information on notifications, assessments and releases of GMOs, and general rules on mandatory labeling and traceability at all steps of the placing on the market.

Domestic regulations should be scrutinized in the light of multilaterally agreed trade rules, if they are suspected of having an impact on international trade. The two legal frameworks relevant to the regulation of Biotechnology are presented above, namely the WTO framework and the Cartagena Protocol which we have concluded in this thesis are inconsistent with each other on many issues. Since the Cartagena Protocol provides quite a large space in which a government can maneuver when it comes to protecting themselves against potential risks from biotechnology it is unlikely that the EC's legislation will be found inconsistent with the provisions in the Protocol. However, the same cannot be said for the WTO agreements. As far as the WTO agreements go, it is the SPS and the TBT agreements that are especially applicable to GMO import regulations. The SPS agreement applies, if we are dealing with a so called SPS-measure, i.e. one that is aimed at the protection from food safety risks or from damage caused by pests or diseases. As can be seen above, any such measures should be

based on international standards or on risk assessment. The TBT agreement applies to products requirements that are mandatory (technical regulations) as well as voluntary (standards) and to conformity assessment not covered by the SPS agreement. Also certain provisions of the GATT are applicable, however since the SPS and TBT agreements are *lex specialis* in relation to the GATT this section will mainly focus on the conformity of the EC's regulations to these agreements. In light of the above, this part will provide an analysis of the European Union legislation in light of the WTO agreements and try to come to a conclusion as to whether the EU legislation can be considered to be in conformity with these agreements.

8.1. The purpose behind the legislation and how this affects the analysis

The trouble with the EC regulations on GMOs is that the legal framework is designed to serve three different purposes; health protection, environmental protection and consumer interests. It is as EC Health and Consumer Commissioner Byrne described it that he, as one of the Commissioners responsible for the authorization of GMOs, "wears three hats: the consumer protection hat, the food safety one and the public health one"¹⁸⁷ The purpose behind the legislation is instrumental in deciding under which WTO agreement a measure should be assessed, and a measure impacting on GMOs might imaginably fall within the GATT, the TBT agreement, or the SPS agreement, depending on its nature and formulation. As mentioned before, the TBT and the SPS Agreements are mutually exclusive and can thus never be applied simultaneously. To complicate things even further, there is the fact that a single measure can fall under more than one agreement insofar as they serve multiple purposes – e.g., they may be SPS insofar as they protect health, and TBT insofar as they protect the consumer.

As we have seen, the SPS applies to sanitary and phytosanitary measures aimed at the protection against food safety risks or damage caused by pests. These would thus cover such GMO related regulations as; risks associated with using antibiotic marker genes and environment-related measures that are aimed at addressing pest risks such as the accidental creation of "super weeds". The TBT however deals with technical regulations and standards necessary to meet legitimate objectives and are not covered by the SPS agreement. Such regulations may include: Non-pest related environmental concerns e.g. measures to avoid adverse effects of pest-resistant GM crops on non-target species.

In light of the above we must first examine what the motivation behind each aspect of the regulation is in order to determine under which WTO agreement a certain part of the EC regulation should be assessed. During the course of this thesis I've identified three specific aspects of the EC legislation that can be considered as trade restrictive and therefore possibly be in violation with WTO law. These three aspects are firstly the mandatory labeling system, secondly the traceability requirement and thirdly the authorization process and then mainly the part of the application process that requires the producer, manufacturer or importer to provide a risk assessment in order to prove that their product is safe. As we have seen above, the EC risk assessment only becomes a problem under WTO rules when we look at the EC reaction to the evidence generated through the assessment, and when the precautionary principle is used in risk management.

¹⁸⁷ EP Committee on the Environment, *Public Health and Consumer Policy - Orientation debate on GMOs with Commissioners Byrne and Wallström*, Tuesday 24 October

If we start by looking at the labeling system this seems to be motivated by the right for the general public to know that they are consuming genetically modified food i.e. consumer interests. It also allows the consumers to make a choice between conventional food and GM-food, and it gives the consumer reassurance should they choose GM-food that the product they are consuming has been assessed strictly for their safety. Since the labeling requirement is motivated by consumer interests this part of the legislation must be assessed according to the TBT agreement.

When looking at the traceability requirement this entails the ability to trace a product through the production and distribution chains and facilitates the monitoring of any effects on human health and the environment. Thus the traceability requirement can be divided up into two parts. Since one of the purposes of the legislation is to monitor effects on human health, this portion of the legislation and measures taken under it falls within the definition of an SPS measure, and should therefore be assessed under the SPS Agreement. However, since the SPS agreement only regulates threats to human and animal life and health the portion of the legislation that aims towards monitoring the effects on the environment has to be assessed according to the TBT agreement.

Finally, when it comes to the authorization process and the motivation behind this procedure the purpose can again be considered as twofold; to protect human health but also to protect the environment. This thesis will however mainly focus on the food safety, and human health issue, and how the reversed burden of proof that is placed on the producer/importer/manufacture by requiring them to submit a risk assessment with their application which essentially boils down to them having to prove that their product is safe in order for it to be approved is consistent with the provisions in the SPS agreement.

8.2. Trade restrictive elements

Regarding the European traceability and labeling regulations, the US, Canada, Australia and Argentina and other countries have argued that they are unnecessarily trade restrictive, and that less trade restrictive measures could be taken instead in order to achieve the desired objects. Their argument refers particularly to products derived from but no longer containing GMOs and GM feed both of which before 2003 had been excluded from the labeling requirements.

The trade restrictive element consists of the additional costs put on producers, manufacturers and importers of GM-products in order to comply with the requirements. These costs put the producers of GM food in a less favorable position than those producing conventional products since they must in order to make profit recoup these costs in some way. The US alone estimated before the amendment that US companies would lose up to 4 billion USD a year.¹⁸⁸ Often cited in this context are the costs of segregating modified from non-modified products, of monitoring a particular crop throughout the food chain, and of testing for the presence of GM materials to comply with the labeling threshold of 0.9% and the threshold of 0.5% for the accidental presence of GMOs as set up by the regulations.¹⁸⁹

¹⁸⁸ Baumüller, p. 27

¹⁸⁹ *ibid.* p. 27.

8.2. Risk Assessment and Risk Management

When looking at the risk assessment carried out by the EC Member States during the authorization procedure this should probably not pose any problems in relation to WTO rules. There are "no independent procedural requirements as such"¹⁹⁰ for such an assessment, and the factors taken into account in the assessment made by the EC seem reasonable. Annex II of *Directive 2001/18/EC* lays down the objective to be achieved, the elements to be considered and the general principles and methodology to be followed in an environmental risk assessment. It involves both an evaluation of the potential consequences of each adverse effect and an evaluation of the likelihood of the occurrence of each identified possible adverse effect¹⁹¹, thus it evaluates likelihood and makes a quantitative estimation of the risk, just as we will see is required under the SPS agreement. Instead, as can be seen from the case law presented above, this risk assessment becomes a problem in the reaction to the results it generates. Thus it is in risk management that problems occur. It is by using the precautionary principle as a basis for taking different measures against GMOs, like for instance banning them even though there is no evidence suggesting that this is necessary. Thus it is not in what they know States are disagreeing, but rather the proper reaction to not knowing. Below I will start by taking a look at the difference between risk assessment and risk management, thereafter I will continue by examining the requirements for the risk assessment and try to evaluate whether the European procedure lives up to these, and finally I will discuss risk management and the problems related to it.

8.2.1. Differentiating between risk assessment and risk management

Diagram 1: Structure of Risk Analysis (Source: *Risk Management and Food Safety, a Joint FAO/WHO Consultation, Rome, Italy, 27 - 31 Jan 1997*)



Risk assessment is typically seen as a method for organizing and analyzing scientific information. Thus it has a clear scientific component. This means that such a process relies on scientific research, "both in the establishment of general procedures and in the production of

¹⁹⁰ Scott, p. 91

¹⁹¹ MEMO02/160-REV, *Questions and answers on the regulation of GMOs in the EU*, p. 2

data for particular assessment”¹⁹².

Risk management on the other hand comes in after having performed a risk assessment, and once we have verified that there actually is a risk at hand and what the nature of this risk is. Risk management is thus a process, separate from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors and if needed the selection of appropriate prevention and control options.¹⁹³ It is defined within the OECD as ”a decision-making process that takes into account political, social, economic and engineering information on the one hand and risk assessment information...associated with a hazard, in order to weigh policy alternatives in response to it”¹⁹⁴.

It can thus be said that while risk assessment is seen as the technical or scientific phase in which experts analyze information, risk management can be seen as a more political phase where decisions are made on how to handle the risk at hand. During such a process one has to make a decision on whether such a risk should be accepted or not, and if not, what to do in order to prevent it from materializing.

8.2.2. The requirements of a risk assessment

First, there is a requirement that a risk assessment must evaluate either the *likelihood* of the entry etc. of a disease or pest, or the *potential for* adverse effects on humans and animals caused by a lapse in food safety. As we can see from the Commission's statements about the common methodology for the risk assessment procedure established by *Directive 2001/18/EC*, the likelihood of each potential adverse is to be evaluated, both for pest-related issues and those concerning food safety. This is a more stringent evaluation than is required under the SPS agreement since it is harder, and requires more evidence to prove the likelihood of something happening than proving the mere possibility. As can be concluded from this, if the methodology is followed, the EC should not have any problems fulfilling this requirement.

The next requirement that the risk assessment has to fulfill is that of *specificity*. There has been heavy emphasis on this requirement, and the need for a risk assessment to be sufficiently specific to the issue at hand in case law. However, this requirement is not, according to the Appellate Body, meant to constrain Members in the risk assessment methodology that they want to use. It is simply that regardless of what methodology is used, the risk assessment must generate results that are sufficiently specific to the issue at hand in order to be accepted under the SPS.¹⁹⁵ Thus as can be seen, this is not an issue where the specific procedure, and its inherent qualities, established by the EC is lacking since a Member can use whatever methodology they choose. However there may of course be, and has been for example in *EC-Hormones*, occasions where the risk assessment and its findings fail to be sufficiently specific.

¹⁹² Alemanno, p. 85.

¹⁹³ Ibid. p. 86

¹⁹⁴ ENV/JM/MONO(2003)15- *Descriptions of selected key Generic Terms Used in Chemical Hazard/Risk Assessment*, p. 86

¹⁹⁵ *Japan-Apples*, AB report, para. 204-205

When it comes to those factors that are to be taken into account when conducting a risk assessment, these are mainly laid down in Articles 5.1 to 5.3 in the SPS agreement. According to Art 5.2. Members shall "take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases and pests; existence of pest-or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment". Important to note here is that there is a difference between the obligation to take something into account, and to actually base a measure upon that something. Thus a failure to respect every aspect of for example risk assessment techniques developed by international organizations probably does not constitute a breach of the SPS agreement. Again, I can see no breaches in the format of the EC risk assessment. Of course there may be isolated cases, as with specificity, where the assessment will be considered insufficient in this respect. However looking at WTO case law this seems quite rare.

8.2.3. Risk Management

As stated above, the problem with the EC risk assessment lies not in the format of the assessment, but rather in how the results of the assessment are interpreted and used as a basis for risk management. As we have seen throughout this thesis, the EC risk assessment should be carried out in accordance with the precautionary principle. A problem arises when the European Communities' risk assessment does not bring forward anything conclusive on the actual risk posed by GMOs, and a decision is nonetheless made to base measures upon this assessment restricting trade in GMOs. This has been seen in *EC-Biotech* where the EC's various measures, such as the moratorium on GMOs, was found to be inconsistent with the SPS Agreement. As has been shown in the case law presented above, there is very little room to argue that a precautionary measure is justifiable under the SPS agreement. In *EC-Hormones* the Appellate Body did not reach a conclusion concerning the EC's claim that the precautionary principle should be considered a principle of international law and therefore be used when interpreting the SPS Agreement. However what the AB did find was that even if the precautionary principle was to be recognized as a principle of international law it does not "override the explicit wording of Articles 5.1. and 5.2."¹⁹⁶ This led to the conclusion that the risk evaluated in a risk assessment must be an ascertainable risk and that there is no room under Article 5.1. to assess theoretical uncertainty. Thus from this we can conclude that a risk assessment will never be able to rationally ground an SPS measure in so far as it merely yields evidence of theoretical uncertainty.

The use of the precautionary principle as a basis for risk management also comes into conflict with the rational relationship that the AB has stated, in for example *Japan-Varietals*, that there has to be between the scientific evidence generated by the risk assessment and the measure in question. It is very hard to motivate that there is a rational relationship between a risk assessment that comes to the conclusion that there are no real dangers with consuming products containing GMOs, however that it can't be ruled out that there might be adverse effects in the future, and a measure that restricts international trade in such products.

The EC has argued in relevant case law that their measures could be justifiable under article 5.7 SPS which allows for the adoption of provisional SPS measures as a precautionary step when the relevant scientific evidence is insufficient. However, this comes with the

¹⁹⁶ *EC-Hormones*, AB report, para. 120

requirement that the Member shall seek to obtain the additional information necessary in order to make a more objective assessment of the risk. However, in cases concerning GMOs there is little chance for the EC to justify any measures under 5.7 since the article deals with cases where there is not enough scientific evidence available to carry out a risk assessment. This is not the case with GMOs where there seem to be many studies indicating that GMOs in general are not harmful to human health. For the purposes of Art 5.7. it doesn't really matter that there are uncertainties as to whether these results are conclusive or not, what matters is that there is enough information available.

8.3. The EC Approval Regime

One of the aspects of the European Communities legislation that can be considered as trade restrictive, and thus may be in violation of WTO rules, lies in the actual approval regime for the placing of GMOs on the market as introduced by *Directive 2001/18/EC*. As discussed before, one aspect of the approval regime is that the manufacturer or importer of a product must submit a notification or application with an accompanying dossier to the competent authority of the Member state where the GMO will be placed on the market. The dossier shall contain specified information, such as information about the applicant, the nature of the GMO, the commercial names to be used, the intended uses of the product, proposals for labeling or for restrictions on use, and an assessment of any risks for human health and the environment related to the GMO. I.e. what is to be provided is a full risk assessment. What is interesting here is that the information should be compiled by the applicant (notifier). This procedure constitutes a reversal of the burden of proof, since the applicant must prove that its product is not harmful before it is allowed to be marketed instead of the other way around, that the Member State has to show reasons as to why the product should not be allowed to be marketed. It is whether this reversal of the burden of proof can be considered as a violation of the WTO agreements that I will examine in this section.

Placing a requirement on the applicant to prove that their product is harmless can certainly be seen as trade restrictive. The applicant is thus required to compile, or conduct a probably more strenuous risk assessment of their product than a manufacturer or an importer of the corresponding conventional product would have had to do. This procedure is expensive, and adds to the cost of the product since the company must recoup these costs by selling their product at a higher price should it gain access to the Community market. This can then be considered to put the manufacturers or importers of GM-products at a disadvantage in relation to manufacturers of conventional products. Thus this part of the EC legislation can be considered as trade restrictive and may thus be found to violate WTO rules.

The purpose of *Directive 2001/18/EC* is said to be to protect human health and the environment when placing on the market genetically modified organisms as or in products. Article 4 further clarifies that the purpose of *Directive 2001/18/EC* is to "avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs." Thus here we find ourselves in the, abovementioned, situation where we are dealing with a piece of legislation that serves multiple purposes and may thus be found to fall under two different WTO agreements. As mentioned above, when the purpose of a legislation is said to be to protect the environment it is to fall under the TBT agreement instead of the SPS which only regulates measures designed to protect human and animal health. The issue of whether the provisions of the Directive fall under the SPS or the TBT agreements is discussed by the Panel in *EC-Biotech* where the discussion focuses on

those adverse effects that the directive should guard against and that are identified in Annex II. The Panel comes to the conclusion that all of these risks or adverse effects are covered by one or more of the sub-paragraphs of Annex A (1) a-d in the SPS Agreement, and that they therefore meet the purpose element of the definition of the term SPS measure.¹⁹⁷ This ruling has however been criticized by for example Conrad, but for the purpose of this discussion I will base it on the view expressed by the Panel.

Although a piece of legislation is not what one traditionally associates with being an SPS measure, it is stated in the definitions in Annex A that:

"Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety."

Thus *Directive 2001/18/EC* can be considered to fall under the SPS agreement in this aspect as well. Below will therefore follow a discussion of whether the requirement to present the specified information in the dossier, or the reversed burden of proof established in the Directive can be considered to be a violation of the SPS agreement.

According to scholars a reversed burden of proof to the proponents of an activity has been suggested to be one of the four central components of the precautionary principle.¹⁹⁸ The European Commission has also stated that when it is deemed necessary to implement a measure based on the precautionary principle this should be capable of assigning responsibility for producing the scientific evidence. According to the European Commission this is a thus a consequence of the precautionary measure and refers to the reversed burden of proof that exist when you have a system of prior approval of a product before marketing. In these cases where the products are treated as dangerous unless and until businesses do the scientific work necessary to demonstrate that they are safe, the traditional burden of proof is reversed and placed on the producer, manufacturer or importer instead of on the public authorities.¹⁹⁹ The decision to place the burden of proof upon the producer, manufacturer or importer should, according to this communication, be considered as a "specific precautionary measure"²⁰⁰. This situation illustrates just what have been done in *Directive 2001/18/EC*, where much of the burden of showing that the product that is to be imported is harmless lies on the applicant. This measure might therefore be in violation of the SPS agreement since it can probably be considered to be based on the precautionary principle. Such measures are, as we have seen above, not allowed unless they fall under Article 5.7 SPS meaning that they are provisional. This can hardly be said for the Directive which is probably here to stay.

¹⁹⁷ *EC-Biotech*, Panel report, para. 7.393

¹⁹⁸ See section 3.3.

¹⁹⁹ COM(2000)1, Communication from the Commission on the precautionary principle, p. 4-5

²⁰⁰ *Ibid.* p. 5

8.4. Labeling and Traceability

Labeling and documentation requirements related to food, nutrition claims and concerns, quality and packaging regulations are normally subject to the TBT agreement.²⁰¹ Thus for the purpose of this discussion it might be beneficial to separate the two requirements of mandatory labeling and of traceability established in EC legislation.

Starting with the European Communities' use of a mandatory labeling scheme, this can be challenged under both the SPS and the TBT agreements. The TBT agreement is somewhat less restrictive on the legitimacy of technical regulations than is the SPS Agreement, which follows from the fact that it does not require a risk assessment of any regulation and it does not require scientific evidence to support any regulation.²⁰² Also, unlike the SPS Agreement, the TBT agreement allows members to introduce TBT regulations when necessary to meet a number of legitimate objectives, including national security, the prevention of deceptive practices, the protection of human and animal health and safety, the environment and consumer preferences. On the other hand, as can be seen from the Panels' reasoning in *EC-Biotech*, the mandatory labeling scheme should, in their opinion, be evaluated under the SPS Agreement, as should the rest of the EC legislation put in place to regulate GMOs. This since it does not serve a purpose "different from, or additional to, the purpose *Directive 2001/18/EC* says it seeks to achieve, i.e. the protection of human health, and the environment."²⁰³ However, further discussion of the labeling requirement leaves an opening for argumentation that the TBT Agreement should be applicable since it recognizes that labeling may be required in order to ensure that consumers who have preferences for non-GM food are not misled into buying GM food.²⁰⁴

The key clauses in the TBT Agreement, Articles 2.1. and 2.2., stipulate that Members are not allowed to give less favorable treatment to products "than that accorded to *like* products of national origin, and to *like* products originating in any other country"²⁰⁵. This is simply a restatement of Art III in the GATT. Some, among them the United States, argue that import regulations that impose special risk assessment, labeling and traceability requirements for substantially equivalent products might violate this provision since it discriminates between like products. The important question is thus the issue of what constitutes "like" products. Some authors suggest that the relevant benchmark for deciding which products can be considered as "like" is the chemical composition of that product.²⁰⁶ Using this as a benchmark would probably undermine domestic regulation regarding GMOs since the chemical composition of a GM-product, which is simply an expression of the relative number of each type of atom in it, would be the same as that of its conventional counterpart. However, according to cases settled under the GATT, likeness is determined on a case-by-case basis and according to four criteria; the products' physical properties, end-uses, tariff classification and consumer tastes and habits.²⁰⁷ There has yet to be an examination under the DSU of the

²⁰¹ Zarilli, p. 33

²⁰² Sheldon 2002, p. 169.

²⁰³ *EC-Biotech*, Panel report, para. 7.389.

²⁰⁴ Sheldon, p. 131.

²⁰⁵ Art. 2.1. Emphasis added.

²⁰⁶ Heumueller and Josling as described in Sheldon 2002, p. 169

²⁰⁷ Baumüller, p. 28.

likeness between GM-products and their conventional counterparts. Essentially it comes down to the product/process distinction. This refers to the isolation of information pertaining to the consumer good as such (its proximate attributes) such as price, quality, and safety, from that information pertaining to the means by which it is made (its peripheral attributes) such as the working conditions under which it comes into being, as well as the treatment of animals involved in its production chain etc.²⁰⁸ There has been much debate under the WTO system, and in literature, over this issue and the "relevant jurisprudence is not conclusive"²⁰⁹ and authors are also deeply divided. However, it might be so that one can take guidance from *EC-Asbestos*, and *US-Shrimp* in which this differentiation between product and process has been discussed. Another organization whose view is highly regarded is that of the World Health Organization, and as can be seen above in sec. ? their opinion seems to be that GM products should be judged according to the principle of substantial equivalence. However, in their *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* a footnote is included stating that "in the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts"²¹⁰ which definitely leaves room for argument. However, in spite of this, due to the physical similarities between GM-products and their conventional counterparts, it is likely that a WTO Panel will also consider them to be "like" in the sense of the TBT agreement. In order for the EC to be able to succeed with a defense against this perception that the products are "like" it would have to show e.g. how consumers' perception and behavior affect the degree of substitutability and competitiveness on the market.²¹¹ If GMOs and GM products are considered "like" products in relation to conventional products, then there are no grounds for applying any special treatment to them, including mandatory labeling schemes. However, if the labeling is aimed at health protection and not consumer information it must be assessed under the SPS agreement which does not include a "like" product provision. Although, in such a case the Member State is instead struck by the restrictions in using the precautionary principle as justification for its measure, an approach which has proved futile in the past.

If the argumentation that GM-products should not be considered to be "like" their conventional counterparts should prove to be successful there is an additional requirement for technical regulations laid down in the TBT agreement that the contested labeling scheme has to fulfill. This is that the measure imposed should not create unnecessary obstacles to international trade or be more trade restrictive than is necessary to fulfill a legitimate objective. These legitimate objectives are *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.²¹² Consequently, in such a case where labeling of GM foods could be justified in terms of consumer interests, a case brought under the TBT Agreement would revolve around the question of which label is the least trade-distorting for of labeling. Members must design the labeling requirement (or any technical regulation) in the way that is the least trade restrictive, making it proportional to the objectives which it is trying to fulfill.

Even though there are possible arguments that the EC can put forward in defense of its labeling requirements, the outcome of a possible challenge to a country's labeling or traceability legislation for GMOs is difficult to predict since so far no mandatory labeling

²⁰⁸ http://en.wikipedia.org/wiki/Product/process_distinction

²⁰⁹ Zarilli, p. 33.

²¹⁰ Footnote 2, p. 2

²¹¹ Baumüller, p. 28

²¹² Article 2.2 TBT

scheme has been formally challenged at the WTO, let alone one related to GMOs.

To conclude, it might be a good idea for the European Communities to isolate those provisions of *Directive 2001/18/EC* relating to labeling from the others and when doing so make it clear that these provisions are warranted by consumer interests. While these provisions remain under the Directive there is always the chance that a WTO Panel or Appellate Body will determine these to have the same purpose as the rest of the Directive, i.e. to protect human health and the environment. Such a ruling would warrant an assessment of the labeling scheme under the SPS agreement, and the outcome would probably not be favorable for the EC since there is, as said before, little room for using the precautionary principle under this agreement. If however, the labeling scheme is said to be motivated by consumer interests it will have to be assessed under the TBT Agreement. In such a case there is at least a possibility, or room to argue, that the scheme could be kept in place since the jurisprudence on whether the product/process distinction should be relevant under WTO law, and ultimately whether GM products can be considered as "like" in relation to their conventional counterparts is inconclusive. Since there are no previous rulings from the WTO on the issue of the likeness between GM and conventional products the field seems to be considerably more open than if the EC would attempt to justify their labeling scheme under the SPS agreement where the issue of precautionary measures has been dealt with in several cases before, and then always to the detriment of the European Communities. Should the EC be successful in their argumentation, a possible WTO dispute brought under this agreement would then, as stated above, instead revolve around the question of which label is the least trade-distorting form of labeling.

Concerning the traceability requirements these are most likely to be divided into two parts. Since one of the purposes of the legislation is to monitor effects on human health, this portion of the legislation and measures taken under it falls within the definition of an SPS measure, and should therefore be assessed under the SPS Agreement. However, since the SPS agreement only regulates threats to human and animal life and health the portion of the legislation that aims towards monitoring the effects on the environment has to be assessed according to the TBT agreement. In all essential parts, the traceability requirement would face the same difficulties described above for the labeling scheme. For the part that falls under the SPS agreement the EC would have to prove that it is not a precautionary measure and that there is actual scientific justification for requiring that the products should be traced. For the part falling under the TBT agreement, it cannot be found to discriminate between "like" products, nor create unnecessary obstacles to international trade or be more trade restrictive than necessary to achieve the objective of protecting the environment.

8.5. Free Trade vs. Democracy

It is the opinion of many that it is unsettling to see the relatively undemocratic and commerce-related rules of world trade forcing a population to admit products that they genuinely do not wish to have on their market. The question then becomes whether it is reasonable to demand of a reluctant population to accept GMOs to exist freely in their market? This issue is one of the most common critiques of globalization, in that it affects countries' abilities to make independent choices about policies that affect the immediate welfare of their people, whether this is on a health protection level, environment protection or simply on a consumer protection level.²¹³

One can of course definitely see an attitude difference in the American consumers and the European population. As we all know, genetically modified food is widely spread over the American market and consumers do not seem to be hesitant to buy it. However this is definitely the case in Europe. Are we as Europeans "spooked by anti-biotechnology activists" as some GM-advocates claim, and are we in reality scared of something that is in fact completely harmless? And if we are, does it really matter? Whether or not the majority of the population can provide a rational and defensible explanation for their opinion should not be the issue since "contemporary deference to democracy suggests that they should be able to decide for themselves what is made and sold within their jurisdiction."²¹⁴

Many argue, however, that an adherence to every Members State's democratic views does not work if we are to have a global system of trade rules. It is exactly this idea of being bound to act in a certain way even if you don't necessarily want to that provides predictability for your partners.²¹⁵ Thus one can say that arguments of democracy are incompatible with binding agreements because they put the predictability that such agreements are designed to create out of play. An agreement that contains a provision that allows Members to derogate when the majority of their population wishes to do so "barely deserves to be discussed in terms of law, or even called an argument at all"²¹⁶ Since we are dealing with representative governments in most WTO Member States these governments should definitely take the attitude of the population into account when making decisions within the WTO, however the WTO cannot be asked to do so if these views derogate from the majority view within the organization. However, if the population in a country feels very strongly about one issue, there is always the option to leave the organization entirely or to renegotiate the terms of their membership.

Some authors, like Robert Howse, believe that the democratic challenge to the SPS agreement that the GMO issue poses is over exaggerated and that the SPS provisions should be "understood not as usurping legitimate democratic choices for stricter regulations, but as enhancing the quality of rational democratic deliberation about risk and its control."²¹⁷ This since the wording in the SPS Agreement, "based on" and "taking into account", brings in science as one necessary component of the regulatory process, however it does not make it the only decisive factor. He believes that allowing some role for scientific principles and evidence in the regulatory control will enhance democratic control of risk, however he also sees the

²¹³ Howse, p. 1

²¹⁴ Davies, p. 6

²¹⁵ Ibid. p. 6

²¹⁶ Ibid. p. 6

²¹⁷ Howse, p. 2

democratic importance of taking into account "popular choices" that are based on facts etc.²¹⁸

In my personal opinion I believe that the inability to take into account domestic democratic issues is a deficiency in the SPS agreement, and the WTO as a whole. This since it reinforces the critique that there is a democratic deficiency within the system. Such a blatant ignorance about public opinion on issues such as food safety relating to GMOs will ultimately hurt the WTO since public dismay will grow if the organization continues to block measures taken by for example the European Communities to protect their population from perceived health, and environmental risks. The deciding factor being that this strict legal framework is very much warranted by public opinion, and there is a risk that the people of Europe (and other countries as well) will eventually feel set aside and lose confidence in the WTO system. At the very least, I feel, together with many Europeans that consumers have a right to know whether the foods that they are purchasing and consuming are either genetically modified or contain genetically modified ingredients, and hopefully the labeling system will not be considered to be a violation of trade rules. To me it seems unfair that I should be unable to make the choice to completely avoid GM-food in my diet just because labeling is prohibited. A labeling system is, as agricultural economist Ian Sheldon suggests, the solution to this problem of asymmetric information where one party of the transaction, i.e. the consumer, knows less than the other party to the transaction, i.e. the producer. He also argues that since GM foods have the characteristic of credence goods²¹⁹, some sort of labeling system would in fact be the optimal solution. With using a system of labelling, "informed customers can maximize their utility, relative prices will reflect their choices, and the gains from trade will be maximized"²²⁰.

9. Final Conclusions

9.1. *The relationship between EC-US regulations and WTO-Cartagena*

As has been seen throughout this thesis, the US applies what is referred to as a conventional risk assessment which is based on the occurrence of an actual risk and also relies heavily on scientific evidence. The European Communities however, apply what is referred to as a precautionary risk assessment. As we have seen, this type of risk assessment deals with uncertainties and how to handle these. These two different approaches have generated domestic legislation that is very different within the two trading blocks. In the US genetically modified food is not regulated separately from "regular" food, since the idea is that GM-food should be assessed according to its characteristics just as any other food that is approved for consumption would. The EC on the other hand applies a separate regulatory approach for GM-food and has thus put in place strict regulations in order to control and regulate the import and marketing of GM-food within their market. Thus what we have are two very different approaches to this relatively new technology.

²¹⁸ Ibid. p. 2

²¹⁹ A Credence good is a good whose utility impact is difficult or impossible for the consumer to ascertain. This is true even after consumption. The seller of the good however knows its utility impact, creating a situation of asymmetric information.

²²⁰ Sheldon 2002, p. 174

This same difference can be observed when looking at the two main multilateral frameworks governing GMOs that exist. Here we have two very different and opposing legal frameworks as well. Risk assessment and risk management within the WTO system, and the SPS agreement in particular, mirrors the American reasoning and as we have seen throughout this thesis the risk assessment within this agreement is heavily reliant on science. Case law tells us that there is almost no room for applying a precautionary approach under this agreement except for in situations where there really is no scientific evidence at all and an assessment is impossible to make.²²¹ However, there exists yet another multilateral agreement regulating GMOs on the international scene, and that is the Cartagena Protocol. Here we can see many similarities between the Protocol and the risk assessment and risk management applied by the European Communities, the main similarity being that the precautionary principle is considered to be of fundamental importance within both frameworks. What can be concluded is thus that the two large trading blocks can find support for their regulations within a multilateral agreement, it's just that they cannot rely on the same multilateral framework.

What we see today is not just a power struggle between two large actors on the international arena for trade, but also a power struggle between different agreements within international law that regulate the same area. To go even further one can say that ultimately it is a power struggle between different values. In the end it all comes down to the question of what value should be considered more important in today's society; trade liberalization or the protection of the environment.

9.2. Common international law

The question that we then have to answer is which multilateral agreement, and ultimately what value, should take precedence. At the moment everything seems to indicate that this would be the WTO framework which as is commonly known tends to favor the liberalization of trade. In the case of EC-US relations this is mainly because the United States have not signed and ratified the Cartagena Protocol and therefore its provisions cannot be invoked against them according to Article 31(3) of the Vienna Convention. This conclusion is also supported by WTO case law presented above. However, there is still the possibility that certain principles, such as the precautionary principle, contained in the Cartagena Protocol could eventually be considered to be principles of common international law. In such a situation, WTO panels and the Appellate Body would be obliged to apply these when interpreting the WTO agreements. This defense has, as we have seen, been used so far on two occasions by the EC in order to defend precautionary actions but has still not been successful.

Even if certain provisions are not made part of customary international law, these provisions might still be compatible with other relevant international agreements. This means that certain provisions contained in the Cartagena Protocol could be applied indirectly in disputes involving countries that have ratified this other agreement. An example of this is Canada, that has not ratified the Cartagena Protocol but is a party to the Convention of Biological Diversity. This means that they have to adhere to the objectives and safety requirements set forth in this convention which correspond to many of those objectives set forth in the Cartagena Protocol.

²²¹ Article 5.7. SPS Agreement

9.3. Reflections on the future

What will happen in the future remains to be seen. What is certain is that as the Cartagena Protocol gains more recognition, it will also gain weight in international relations, maybe even in relation to the WTO. It might as has been discussed above morph into "common international law" and thereby be a force to reckon with. It has already been suggested within the Codex Alimentarius Commission that foods derived from modern biotechnology and their conventional counterparts will not be considered to be "like" in the foreseeable future²²², and the strengthening of the Cartagena Protocol and its differentiation between GM products and Non-GM products might definitely help speed this process along. Such a development is also supported in literature where it seems to be the belief of some authors that as the Cartagena Protocol gains wide international acceptance that it may eventually provide a basis for determining that genetically modified products are not like their conventional counterparts.²²³

One question that will be relevant for the future of GMOs in Europe, and as has been suggested above for the interest of democracy as well, is whether or not the EC labeling system will be challenged and possibly abolished under the WTO. It is my firm belief that such a ruling would be seen as undermining the democratic right for a country's population to decide in matters concerning them, and that denying people the right to decide what they put into their own body, regardless of on what grounds they make this decision, will ultimately harm the image of free trade and the World Trade Organization as such.

However, another issue that may also play a huge role in the future of GMOs is the ongoing food crisis that is currently affecting the world. Already we are hearing reports that there is not enough food at acceptable prices to feed the population of the world and faced with such an enormous problem it is likely that governments will turn to the use of GMOs as a way of handling this crisis. In doing so it would be possible to increase agricultural yields which might be crucial should the crisis continue or escalate even further. It is possible that in such a situation the potential benefits will simply outweigh the potential drawbacks of GMOs and that even its harshest critics will eventually come to accept the technology.

A different issue of the future relates to the WTO's reliance on science. According to Alberto Alemanno it has been proposed to develop a procedural, intensity-variable standard of review within the WTO in order to mitigate partly the tendency within the Organization to prioritize the scientific and technical evidence over other legitimate interests.²²⁴ This would complete the WTO risk analysis framework, by structuring it in small and simpler concepts for each stage and component of risk and the review would take place at different levels of intensity depending on the level of normative constraints present within each stage. It would also enable the courts to vary their intensity of review depending on the rights and obligations of the Member States.²²⁵ Implementing such an approach might contribute to breaking the current monopoly that the scientific requirements enjoy in the review of a contested measure. By varying the intensity of the review depending on the rights and obligations of the Member States within each step of the risk analysis, such a standard of review would lead the judges to focus more on the risk management component of the contested measure rather than on the risk assessment. This would in turn mean greater governmental discretion in the SPS areas. According to Alemanno it is "predicted that it is only by integrating such a presumption of

²²² Codex Alimentarius, Guidelines, footnote 1

²²³ MacKenzie, Burhenne-Guilmine, La Vina, and Werksman, para. 881

²²⁴ Alemanno, p. 449 f.

²²⁵ Ibid. p. 450

bona fide into their standard that the WTO judicial bodies will be able to produce not only legally valid but also socially acceptable rulings, by thus acquiring legitimacy vis-à-vis the public.”²²⁶

If such a result could be achieved it would certainly be beneficial, not only for those countries wishing to exercise precaution in their regulation of foods, but also for the WTO since one of the biggest questions they have had to struggle with in recent years has been the legitimacy of the Organization. Such a standard of review would open up for a larger tolerance regarding difference of opinions between the countries involved in the Organization. That there are differing opinions within the Organization is inevitable when so many countries have to cooperate within a large structure such as the WTO. Ultimately it will prove untenable for the WTO to continue making decisions that go so fundamentally against the beliefs of the citizens in many of their Member States. After the rulings in the Shrimp/Turtle case we saw violent protests against the Organization from the public, and as polls taken by the European Commission²²⁷ show, we can expect to see similar protests should the WTO contribute to GM-products being let loose freely on the European market.

²²⁶ Ibid. p. 451

²²⁷ Europeans and Biotechnology in 2005: Patterns and Trends - *Eurobarometer 64* (2006):1-85

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