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Genetically modified organisms and the World Trade Organization

The *EC – Biotech* case at the crossroads of genetic engineering, world trade and EU politics

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Malmö, October 30, 2006.

Abstract

Genetically modified organisms (GMOs) are controversial, especially for food and feed products, mainly due to potential benefits and potential risks. Advocates claim substantial yield improvements and reduced pesticide usage, while opponents claim contamination of non-GMO crops and damage to health and the environment. The European Union (EU) has since 2003 used a cautious approach, where GMO products are assessed on a case-by-case basis before being approved for market access or cultivation. However, between the member states opinions differ widely: Some member states are very positive to GMOs, while others have banned specific GMO products. The EU's cautious approach, before 2003 resulting in a *de facto* moratorium on GMOs, and the member state bans have led the United States, Canada and Argentina to start a trade dispute within the World Trade Organization (WTO), challenging EU legislation. This is the so-called *EC - Biotech* case.

In this thesis GMOs are assessed from a sustainability point of view, that is, environmental, social and economic aspects are discussed. Moreover, EU regulations, stakeholder opinions, and relevant WTO agreements are presented, after which the trade dispute is explained, and results from the case are discussed. It is argued that the case has a negative impact on the use of the precautionary principle, and that this is a worrying trend within the WTO. In addition, the implications are discussed of the fact that the dispute panel did not take into account the most relevant multilateral environmental agreement in the field of GMOs, the Convention on Biological Diversity and its Biosafety Protocol. Moreover, it is analyzed whether the dispute will have an impact on the EU's GMO policies, resulting in the conclusion that direct impacts will likely be small, while indirect effects, such as an impact on the strength of a member state in the GMO debate, may lead to a slow change towards a more open attitude on GMOs in the EU.

Executive Summary

Genetically modified organisms (GMOs) are causing controversy within environment and trade. Views differ widely, mainly due to the risks and benefits associated with them. On the one hand, genetic engineering has virtually unlimited technical possibilities. Seeds, crops, plants and animals may theoretically obtain properties that are beneficial (e.g. less water use, less sensitivity for pests, fast growth, etc.). However, the risks of introducing such organisms into the ecosystem have often not been investigated thoroughly, especially long-term risks. Contamination of nearby fields is occurring regularly, and weeds may evolve taking over herbicide resistance properties. Moreover, economic aspects exist such as research and development costs and costs for using patented GMO seeds. Social aspects of GMOs may be, for instance, control of the world food supply, possibilities for farmers to use last year's harvested seeds, and ethical considerations such as patenting of organisms.

The EU has been very restrictive in allowing commercial growth of GMO products. A '*de facto* moratorium' was in place from 1998 to 2003, and currently each GMO product must be approved on a case-by-case basis. Some EU member states have a ban in place, but small-scale test fields have been performed in many member states for a number of years. The political situation in the EU is complicated; the European Commission (EC) is largely in favour of GMOs, while member states have different positions, ranging from extremely restrictive to very positive. The majority of consumers in the EU are opposed to GMOs.

The main objective of this thesis is to assess the interaction of genetically modified organisms, EU GMO policies and the World Trade Organization (WTO). These issues come together in the *EC - Biotech* case, the case brought before a WTO dispute panel by the US, Canada and Argentina challenging parts of the EU's GMO legislation. In order to get a full understanding of the issues related to GMO, sustainability aspects of GMOs are considered, and GMO regulation on the global, EU and national level is reviewed, with focus on the EU member states. Relevant agreements within the WTO are described, in order to first of all understand the trade and environment debate related to GMOs and second to be able to analyze and understand the *EC - Biotech* case. Significant issues of this work are whether a precautionary approach in regulation of GMOs is justified, to what extent trade rules allow the usage of the precautionary principle, how trade agreements and multilateral environmental agreements interact and what the impact of the *EC - Biotech* case is.

Genetically modified organisms

The focus of this thesis is on GMOs for food and feed products, that is, seeds, crops, and food or feed products consisting of, or containing, GMOs. Benefits and drawbacks of genetically modified organisms, compared to products from conventional cultivation, may be seen on an environmental, social and economic scale. The main benefits of GMOs may be the reduction of external inputs, such as herbicides, insecticides or fertilizers. Also, yields may improve. Moreover, enhanced vitamin, mineral or protein content may occur due to changes in the genetic properties of the crops. These benefits may lead to positive factors such as reduced pollution and reduced natural resource consumption, health improvements, or increased profit for the farmer.

However, there are significant disadvantages as well. First, yields may not actually increase, and pesticide use may not decrease, resulting in environmental, social and economic disadvantages rather than positive factors. Moreover, there are specific environmental and health risks associated with GMOs. For example, there is a risk of genetic material spreading to weeds or to non-GMO crops. The contamination of weeds may have consequences for the environment, as more pesticides are needed to control the weeds, and the contamination of non-GMO crops may have economic consequences for organic or conventional farmers. Also,

non-target organisms such as insects or farmland birds may be damaged in various ways due to GMO cultivation, which may have a negative impact on biodiversity. Health issues associated with GMOs may be the occurrence of new proteins, which may have allergenic potential, and the possible impacts on the metabolism of animals or humans consuming GMOs. However, research in this field is limited.

The current genetic engineering industry is based on intellectual property and patenting of GMO traits, and it is promoting a highly technological agriculture based on monoculture. This has significant disadvantages. Inherent disadvantages of monoculture are a reduction in biodiversity and in food security. Moreover, it may lead to wealth concentration amongst farmers instead of wealth distribution. An important drawback is the dominance of companies owning the patents, selling the seeds, and the specific pesticides to go with a certain GMO crop. This situation may lead to dependence and disempowerment of farmers, since GMO seeds are expensive compared to conventional seeds, and a farmer is not allowed to save GMO seeds for next year's cultivation.

The European Union's GMO policies

Due to the issues above, and public concerns about GMOs, the European Union (EU) has implemented GMO legislation based on a cautious approach. Important elements of the legislation are, for instance, an approval procedure for bringing GMOs on the market or releasing them into the environment (i.e. commercial cultivation or field trials), on a case-by-case basis, and with a compulsory risk assessment. In addition, labeling and traceability of products containing or consisting of GMOs is obligatory. Moreover, member states are allowed to install safeguard measures on a national level, thereby blocking GMOs that are approved at the EU level if sufficient concerns exist.

The situation in the EU with respect to GMOs is very diverse. Many member states have field trials, but only some states have commercial cultivation. Moreover, the views of member states on GMOs differ widely. Some states are positive to GMOs, and some are negative. In addition, many stakeholders with different points of view are engaged in the debate, such as the biotechnology industry, consumers, environmental NGOs, and farmers' organizations. Therefore, regulation of GMOs in the EU is a difficult and sensitive issue.

The World Trade Organization

It is crucial to understand important terms used within the World Trade Organization (WTO) that are relevant for the GMO debate. Among them are 'like products', risk assessment, scientific evidence, uncertainty and insufficiency. Under 'like products' it is sometimes argued that GMO- and non-GMO products are inherently similar, that is, they are similar as long as the end products have similar properties. This argument follows the reasoning that process and production methods may not be used as reasons to discriminate one product over another product. However, consumers, especially in the EU, commonly consider GMO- and non-GMO products to be different.

Risk assessment is regulated in the most relevant agreement within the WTO with respect to GMOs, the agreement on Sanitary and Phytosanitary measures (SPS). This agreement concerns protective measures against pests, and it states that such measures must be based on a valid risk assessment and not cause undue delay, something that may be challenging in the case of GMOs since the technology develops fast and new information may come up. The SPS agreement allows for temporary measures with a precautionary notion, as long as there is insufficient scientific evidence. This is a crucial aspect in the *EC - Biotech* case.

There are potential conflicts between trade agreements and the Convention on Biological Diversity (CBD), and more especially its Cartagena Protocol on Biosafety, or Biosafety Protocol, both multilateral environmental agreements. Trade agreements and these environmental agreements are based on different premises. WTO agreements generally proclaim a reduction of trade barriers, also for GMOs, while the CBD proclaims the use of a precautionary approach. With regards to patenting, there are conflicting agreements as well. The WTO's agreement on Trade-Related Intellectual Property Rights (TRIPs) is based more upon protection of intellectual property, while the Biosafety Protocol values traditional knowledge and sharing of benefits.

The EC - Biotech case

The case brought before the WTO on the EU's GMO policy, puts the focus on several aspects of GMOs and world trade, such as the use of the precautionary principle and the tension between multilateral environmental agreements and WTO agreements. Moreover, the outcome of the case may have global effects, with impacts on countries' (real or perceived) possibilities to have strict GMO legislation.

Three main aspects of European GMO legislation were challenged: a perceived *de facto* moratorium on GMOs between 1998 and 2003, 27 product specific measures at EU level, and 9 safeguard measures of six member states. In brief, the panel ruled that the *de facto* moratorium and 24 product specific measures were not SPS measures *per se*, but that they caused undue delay. The member state safeguard measures, however, were deemed incompatible with the SPS agreement, since they were not based on valid risk assessments.

The research questions addressed in this thesis are:

1. *a. Is it justified to invoke the precautionary principle in policies regulating genetically modified organisms (GMOs)?*

1. *b. Is the precautionary principle recognized within the World Trade Organization (WTO)?*

2. *What is the relation between multilateral environmental agreements (MEAs) and the World Trade Organization?*

3. *What are the consequences of the WTO EC-Biotech case on EU GMO policy?*

1. The precautionary principle

With regard to the first research question, whether it is justified to invoke the precautionary principle in GMO policies, this thesis shows that it is justifiable to do so. There are indications that GMOs may cause significant environmental, health and social impacts, but there is a substantial degree of uncertainty. Thus, using the precautionary principle is justified. In EU GMO legislation the principle is invoked, and a case-by-case risk assessment must be made. Also, member states have the right to invoke so-called safeguard measures as an additional precautionary measure if new or additional information justifies this.

A question that was raised in this thesis is what measures are justified as precautionary measures. Is a total ban justified, or is an assessment on a case-by-case basis sufficiently precautious? Moreover, from an EU member state perspective, there seems to be some tension between the single market (i.e. a GMO as a product, to be allowed in all member states) and a precautionary approach (i.e. a GMO as a potential risk for the ecosystem and human, plant or animal life or health, and a member state's desire to set its own appropriate level of protection).

The second part of the first research question was whether the precautionary principle is recognized within the WTO. Formally, a precautionary approach is allowed, although the term is not explicitly mentioned in any agreement. Article 5.7 of the SPS agreement does allow a temporary precautionary measure if there is insufficient scientific evidence. However, jurisprudence from WTO trade disputes has limited the application of this article, mainly by limiting the scope of what insufficient evidence is. The panel in the *EC - Biotech* case follows this trend as well; by, somewhat simplified, stating that article 5.7 is not applicable if a WTO-compatible risk assessment can be made.

2. Multilateral environmental agreements and trade agreements

The second research question was investigating the relation between multilateral environmental agreements (MEAs) and the WTO. Currently, WTO dispute panels have no obligation to take into account relevant multilateral environmental agreements, although these panels may choose to do so. In the *EC - Biotech* case, the panel chose to ignore the only MEA relevant for GMOs, the Convention on Biological Diversity and its Biosafety Protocol, even though more than 130 countries are a party to the convention, amongst them many WTO members. It may be added that one of the parties in the case, the United States, is not a party to the convention. Also, the Biosafety Protocol and the WTO are based on different premises, which may have complicated the situation.

This issue therefore illustrates that within the trade and environment field, agreements may cause tension rather than synergy.

3. The EC - Biotech case and EU GMO policy

The third research question was looking at the consequences of the *EC - Biotech* case on EU GMO policy. First of all, *direct effects* seem to be relatively small. The EU's GMO regulations, as a whole, were not directly challenged, only parts of it, and moreover, parts of previous regulation were challenged. However, for the member states with a safeguard measure the situation is slightly different. They may have to adapt the measure and make it WTO-compatible, or remove it altogether.

It was found that public opinion is unlikely to change due to the case; opinions on GMOs are quite solid in the EU, although slight changes may occur in the coming years, whereas the main factor impacting a member state's position on GMOs is which political party or politician is in power, as was found from interviews with member state representatives.

This thesis showed that there are signs of *indirect effects* of the case on EU GMO policy. Those member states that are negative towards GMOs have become weaker in the debate, versus both the positive member states and the European Commission. This may result in a slow shift towards a more open attitude on GMOs at the EU level.

The *EC - Biotech* case brings together diverse and complicated issues such as genetic engineering, EU policymaking and multilateral trade agreements. The stakes are high, for the biotech industry but also for the environment and for public health. Regulating GMOs, especially those for food and feed products, is a challenging task, and an important question is who reaps the benefits and who suffers the potential risks.

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Abbreviations and acronyms

AB	Appellate Body
AIA	Advanced Informed Agreement
APHIS	Animal and Plant Health Inspection Service
BP	Biosafety Protocol (Cartagena Protocol on Biosafety)
Bt	*Bacillus thuringiensis*
CBD	Convention on Biological Diversity
DEFRA	Department for Environment Food and Rural Affairs (UK)
DNA	Deoxyribonucleic Acid
DSB	Dispute Settlement Body
DSU	Understanding of Dispute Settlement
EC	European Commission
ECJ	European Court of Justice
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
GATT	General Agreement on Tariffs and Trade
GE	Genetic Engineering
GMO	Genetically Modified Organism
IP	Intellectual Property
IPR	Intellectual Property Right
LDC	Least Developed Country
LMO	Living Modified Organism
MEA	Multilateral Environmental Agreement
MFN	Most Favoured Nation
MOP	Meeting of Parties
NGO	Non-Governmental Organization
PPM	Process and Production Method
SDT	Special and Differential Treatment
SPS	Sanitary and Phytosanitary Measures Agreement
TBT	Technical Barriers to Trade Agreement
TRIPs	Agreement on Trade-Related Intellectual Property Rights
UK	United Kingdom
UN	United Nations
US	United States
USDA	United States Department of Agriculture
WIPO	World International Property Organization
WTO	World Trade Organization

"Research so far has identified a number of potential harmful effects resulting either from the very process of genetic modification itself (wrong or unstable insertion) or from the successfully modified end product. Potential harmful effects on human health include toxicity, allergenicity, horizontal gene transfer and antibiotic resistance. Potential harmful effects on the environment, in addition to the above (to the extent they can affect animal or plant life or health) include non-target effects, invasiveness and development of resistance, unintended effects arising through GMO related management practices, and effects on biodiversity. These effects depend on the nature of the specific GMO in question and on the intended use. Where GMOs have been released into the environment, such harmful effects might be irreversible. The need for a pre-marketing case-by-case assessment, thus, is obvious. In addition, research has only started to identify these issues and long term effects are largely unknown."

European Commission, first written submission in the EC - Biotech case before the WTO (EC - Biotech panel, 2006b, par. 4. 338).

1 Introduction

Genetically modified organisms (GMOs) are causing controversy within environment and trade (Zarrilli, 2005; Kerr, 1999, Busch and Howse, 2003). Views differ widely, mainly due to the potential risks and benefits associated with the technology. On the one hand, genetic engineering (GE) has virtually unlimited technical possibilities. Seeds, crops, plants and animals may obtain properties that are beneficial (e.g. less water use, less sensitivity for pests, fast growth, etc.). However, the risks of introducing such organisms into the ecosystem have often not been investigated thoroughly, especially long-term risks (Nottingham, 2002; Shiva, 2000; EC - Biotech panel, 2006b, art. 4.338). Contamination of nearby fields is occurring regularly, and weeds may evolve taking over herbicide resistance properties. Moreover, economic aspects exist, such as research and development costs and costs for using patented GMO seeds. Social aspects of GMOs may be, for instance, control of the world food supply, possibilities for farmers to use last year's harvested seeds, and ethical considerations such as patenting of organisms.

GMOs are grown commercially in countries such as the US, Canada, Argentina, China, and Brazil. Large-scale agricultural crops are so far the most common GMO organisms in use, such as maize, soy, rapeseed (canola), cotton, and wheat. The EU however has been very restrictive in allowing commercial growth of GMO products. A '*de facto* moratorium' was in place from 1998 to 2003, and currently each GMO product must be approved on a case-to-case basis. Some EU member states practically have a ban in place, but small-scale test fields have been performed in many member states for a number of years. The political situation in the EU is complicated; the European Commission (EC) is largely in favour of GMOs, while member states have different positions, ranging from extremely restrictive to very positive. The majority of consumers in the EU are opposed to GMOs.

The careful approach by the EU has caused the US, together with some other countries, to bring a case before the World Trade Organization (WTO), the so-called '*EC - Biotech*' case. Issues at stake are for instance: Is a GMO product equivalent to a non-GMO product? How conclusive is the scientific evidence presented so far? Is it insufficient or uncertain? Further, can the precautionary principle be used according to WTO trade rules? Are some measures to protect health and environment allowed or are they trade barriers? What is undue delay, and what is a reasonable risk assessment? Should Multilateral Environmental Agreements (MEAs) be taken into account in WTO rulings or should international trade rules be in strict isolation from such agreements?

A WTO dispute panel came with a ruling in the *EC - Biotech* case in May 2006. This ruling may have a profound effect on EU policy with respect to GMOs, even though the panel did not deal with many of the more contentious issues, and did not completely rule in favour of the US. The case ties together the field of genetic engineering, world trade rules, and domestic policies on GMOs, more specifically EU policies in this area. Many issues discussed within the trade and environment field are at stake.

1.1 Thesis objective

The main objective of this thesis is to assess the interaction of genetically modified organisms, EU GMO policies and the World Trade Organization. As a case study the *EC - Biotech* case is explored.

The following research questions were analyzed:

1. *a. Is it justified to invoke the precautionary principle in policies regulating genetically modified organisms (GMOs)?*

   As an example, EU policies on GMOs are described.

1. *b. Is the precautionary principle recognized within the World Trade Organization (WTO)?*

   Does the multilateral trade rules system allow for a precautionary approach, and to what extent? As an example, the WTO *EC – Biotech* case is discussed.

2. *What is the relation between multilateral environmental agreements (MEAs) and the World Trade Organization?*

   The Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety – or Biosafety Protocol (BP) – are examples of multilateral environmental agreements that may conflict with trade rules. The thesis evaluates to which extent these agreements are being taken into consideration within the WTO.

3. *What are the consequences of the WTO EC-Biotech case on EU GMO policy?*

   The ruling in the case may have a direct impact on EU GMO policies, for instance if member states' restrictions on GMOs are judged to be violations of trade rules, but the case may also have indirect consequences on EU GMO policies, for instance by supporting and thus strengthening the views of one of the actors in the EU GMO debate.

1.2 Methodology

In order to collect background information, a *literature review* was done, searching with keywords[1], reading previous theses and using references from this material. Also, news articles and websites of relevant organizations, such as e.g. the European Commission, the United States Department of Agriculture, environmental non-governmental organizations (NGOs) such as Friends of the Earth and Greenpeace, and some EU member state governmental agencies, were used as a source of information.

To get information on the points of view of the main actors, the EU member states, as well as stakeholders such as environmental and farmers organizations, the US etc., *interviews* were conducted (see Appendix 1), supplemented by a *questionnaire* to the member state representatives (see Appendix 2). Not all EU member states were interviewed; of the current 25 EU member states, a selection of 10 was made to interview, with the aim of having a diverse representation of all member states. GMO position was taken into account, as well as geographical location, population size and date of EU membership. Thus, the following member states were selected: Austria, Belgium, Denmark, Estonia, Germany, Hungary, Italy, Lithuania, The Netherlands, and The United Kingdom. The representatives were generally working at ministries of environment, competent authorities or permanent representations in Brussels. Based on the goal of this thesis and the research questions, four general categories of interview questions were defined: The country's GMO policy and public attitudes, the

[1] Some of the searches were performed in Lund University's system Elin (http://elin.lub.lu.se), e.g. "all:"world trade organisation" AND all:agriculture", "all:EU AND all:GMO", "all:"world trade organization" AND all:MEA", "all:GM AND all:stakeholder" and "all:"world trade organization" AND all:"trade and environment"". Google Scholar was also used, for instance to search on: "GMO farmer dependent social consequences". Otherwise, specific articles were searched based on references in other articles or data sources.

precautionary principle and multilateral environmental agreements related to GMOs, the effects of the WTO ruling and the future of GMOs in Europe. Within each group a number of questions was then formulated.

These sources of primary and secondary information were then used to answer the research questions posed in the previous section. The research process is represented in Figure 1.

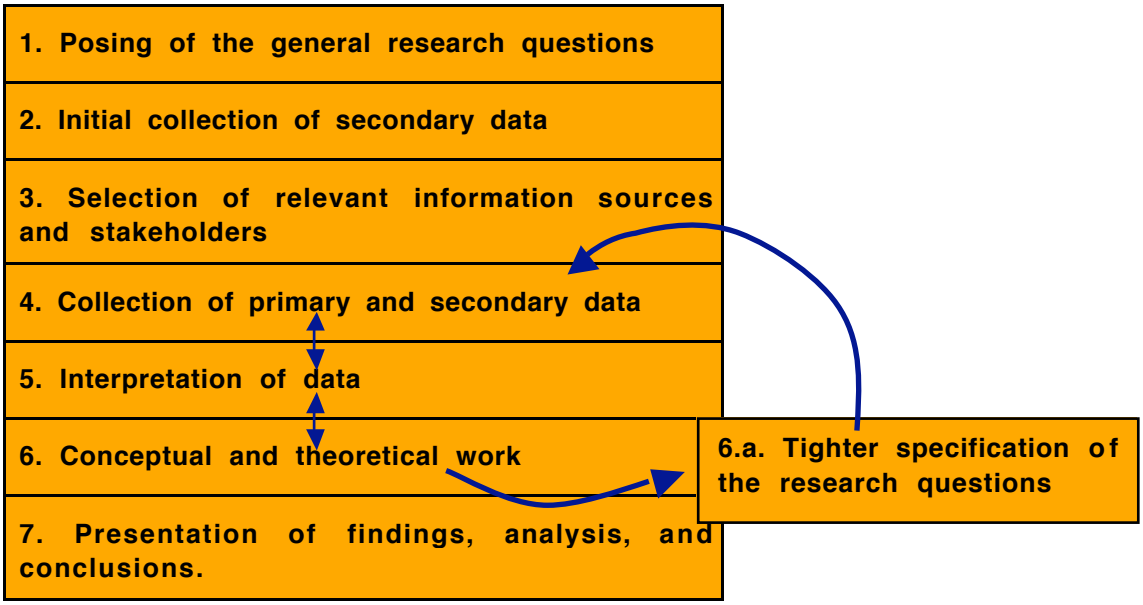

Figure 1. Research process of the thesis work. Adapted from Bryman (2004), p. 269.

In the first step, a general main objective of the thesis was formulated, as well as initial research questions. Then an initial collection of background material was done (step 2), and based on that an inventory of relevant stakeholders was made and relevant information sources, e.g. websites and books, were selected. Based on this work, the interview questions (see Appendix 1) were formulated.

In step 4, interviews were held, giving primary data, and more secondary data was collected. Steps 5 and 6 were done more or less simultaneously, with interaction between the two steps, leading to a tighter specification of the research questions and a reiteration of steps 4, 5 and 6. The process was concluded with the presentation of the (primary) data, and the analysis based on these findings and the secondary data (step 7). Finally, conclusions were presented.

A future outlook is discussed in the final chapter by developing several *scenarios* for GMOs in the EU. After that, recommendations are given on how to reach the most desirable goal.

1.3 Scope

To reiterate from section 1.1, the goal of this thesis is to assess the interaction of genetically modified organisms, EU GMO policies and the World Trade Organization. This is illustrated by looking more specifically at the *EC - Biotech* case. The focus for genetically modified organisms (GMOs) is on food and feed products, consisting of or containing GMOs, and seeds and crops. Thus, GMOs related to agricultural food and feed production and consumption are considered. This is the most controversial aspect of GMOs in view of

resistance of the general population (Eurobarometer, 2006). Applications such as genetically modified microorganisms or GMOs for medical purposes are beyond the scope of this work.

The GMO issue is analyzed in a European context, or more specifically, a European Union (EU) context. The EU has one of the most restrictive and extensive legislations on GMOs, aiming to balance consumer concern and market access for GMOs, taking into account potential risks for human health or the environment (Annerberg, 2003). The EU is engaged in a trade dispute with the United States (US), Canada and Argentina over its legislation. Moreover, within the EU the positions of member states are very diverse, ranging from virtual bans and attempts to stay GMO-free to commercial cultivation of GMOs. To reach consensus on EU's GMO policy is thus very challenging. The above issues make the EU and its member states very interesting and important actors to analyze.

The GMO issue illustrates the debate on trade and environment, considering the tension between environmental protection and global multilateral trade rules. Multilateral environmental agreements (MEAs) may be at odds with World Trade Organization agreements. Thus, in this thesis the most relevant MEAs in the area of GMOs are considered, i.e. the Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety (BP), as well as relevant trade agreements within the WTO.

The *EC - Biotech* case is taken into account including the final ruling of the dispute panel. This ruling was issued in September 2006. The case itself may continue for some time, with a possible appeal or compliance issues, but due to time limits this is beyond the scope of this work.

1.4 Thesis outline

The outline of this thesis is as follows. In *Chapter 2*, sustainability aspects of genetically modified organisms are described, e.g. environmental, social and economic benefits and disadvantages. Moreover, an overview of EU legislation on GMOs and stakeholder viewpoints are presented. In *Chapter 3*, agreements within the World Trade Organization

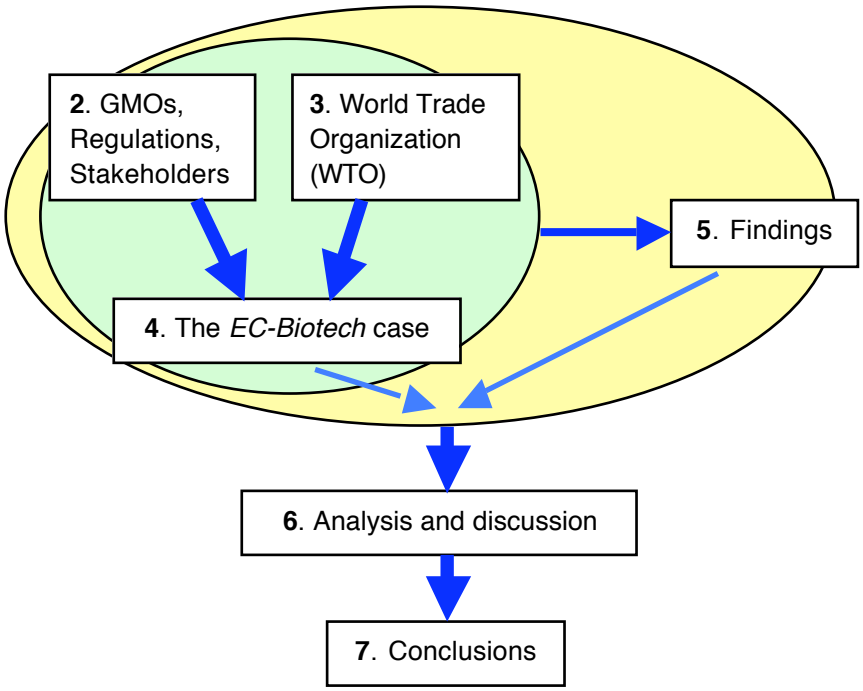

Figure 2. Structure of the thesis.

(WTO) are reviewed that are relevant for GMOs, and potential conflicts between these agreements and the CBD are listed. *Chapter 4* contains an overview of the *EC - Biotech* case, including potential problems related to GMOs and world trade rules and relevant WTO jurisprudence. In *Chapter 5* the findings from interviews with stakeholders are presented, with main focus on the interviews with EU member state representatives, and in *Chapter 6* the research questions stated in section 1.1 are addressed, by analyzing and discussing the findings from the interviews, literature and other background material from previous chapters. Finally, in *Chapter 7* the conclusions are given, as well as a future outlook and recommendations. The structure of the thesis is illustrated in Figure 2.

2 Genetically modified organisms

A genetically modified organism (GMO) can, according to the European Union (EU), be defined as (EU, 2001):

> "... an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".

The altering of genetic material is commonly called genetic engineering (GE). The first GMO was demonstrated in 1973 (NCBE, 2006), and the technology has caught on since the 1980s, with the first commercial product, the FlavrSavr ® tomato, getting market approval in 1994 (Consumers' Research Magazine, 1999). Developments have since then diverged widely, dependent on the world region. In the United States, GE varieties of some crops such as soy, maize, and oilseed rape are forming a substantial part of the market, while in other parts such as Europe the use of GE has been very limited. Especially between the US and Europe, these diverging developments are not only seen at the farm level, but also at the political and consumer level[2]. In other regions such as Latin America and Asia, developments are mixed. Also within the scientific community, the debate on possible advantages and disadvantages has been continuing ever since the early days of GE[3].

In this chapter a brief overview is provided of GMO issues such as GE basics, sustainability aspects of GMOs, and how GMOs are regulated at different levels. The views of stakeholders relevant to this thesis are also given.

2.1 Introduction to genetically modified organisms

The technology used to alter the genetic make-up of an organism by introducing genetic material from other organisms, in order to change the properties of the former, is called genetic engineering (GE), or recombinant DNA technology. GE may be applied to microorganisms, seeds or animals. Biotechnology is a term describing the development of seeds and crops, not necessarily by altering the genetic material. Thus, GE may be considered a subset of biotechnology[4].

Generally, applications of GE are medical, such as the production of a certain vaccine or hormone, or nutritional, such as adding vitamins to or changing properties of seeds or plants. Also pollution clean-up has been investigated, e.g. oil spill clean-up by means of the genetically engineered *pseudomonas* bacteria (Nottingham, 2002, p. 22)[5].

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[2] See for instance Zarrilli (2005), Kerr (1999) and Busch and Howse (2003) for a discussion on different regulatory systems and the underlying reasons.

[3] See for instance http://www.agbioworld.org/biotech-info/articles/agbio-articles/GMfeedsafetypapers.html and Domingo (2000) for an impression of the academic debate on GMOs.

[4] In this thesis the term 'genetic engineering' will be used to describe the process or technology of unnaturally altering genetic material, resulting in a 'genetically modified organism', that is, a product with altered genetic make-up. The term 'biotechnology' is used in some reference material quoted in this thesis, and may be defined as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use' (CBD, 2006). In GMO context, it is commonly used as being equal to genetic engineering, although it is not.

[5] Another example is the breaking down of PCBs (polychlorinated biphenyls) by a different strain of *pseudomonas* bacteria.

2.1.1 Genetic engineering technology

The three main methods of generating recombinant DNA, that is, DNA containing genetic material from different organisms, are the agrobacterium method, the viral vector method and the ballistic impregnation method. With the agrobacterium method, bacteria take up modified plasmid that includes the desired properties as well as an antibiotic-resistance marker gene. Bacteria surviving an antibiotic treatment have taken up the desired genetic material. In the viral vector method, the infecting power of viruses is used to transport genetic material into the target organism's genome. Lastly, the ballistic impregnation or gene-gun method is mostly used for GE plants, such as e.g. cereals. Metal parts coated with DNA material are fired at cells of plants (NCBE, 2006; Nottingham, 2002, p. 3-5; Mendelson in Kimbrell, 2002, p. 150).

The gene construct inserted in the organism consists not only of the foreign genetic material, but also of a promoter and a marker gene. Often, promoters are viral, and they serve to promote the activity of the foreign genetic material (Mendelson in Kimbrell, 2002, p. 150; Nottingham, 2002, 102-106). A marker gene is used to see if the genetic modification has been successful: If the marker gene is present in the organism, the full gene construct is present. Marker genes are often antibiotic-resistant, so that an antibiotic can be used to select those organisms that have successfully imported the gene construct, since these survive the antibiotic attack - the other, non-successful organisms die (Mendelson in Kimbrell, 2002, p. 150; Nottingham, 2002, p. 106).

GE can be defined as (Walker, 1995, cited in Nottingham, 2002, p. 3):

> "[t]he formation of new combinations of heritable material by the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation".

2.1.2 Some GMO facts and figures

The total area of land used to grow GMO crops has been growing since 1996 (see Figure 3), with a growth of 11% between 2004 and 2005 (ISAAA, 2005). The total area was approximately 90 million hectares by the end of 2005. Twenty-one countries are growing GMOs commercially, but the US, Canada, Argentina and Brazil dominate, with India and China close behind. Four crops represent almost all commercial cultivation: soy, maize, cotton and oilseed rape, with over 50 million hectares of land used for soy, that is, more than 50% of the total area of land with GMO crops.

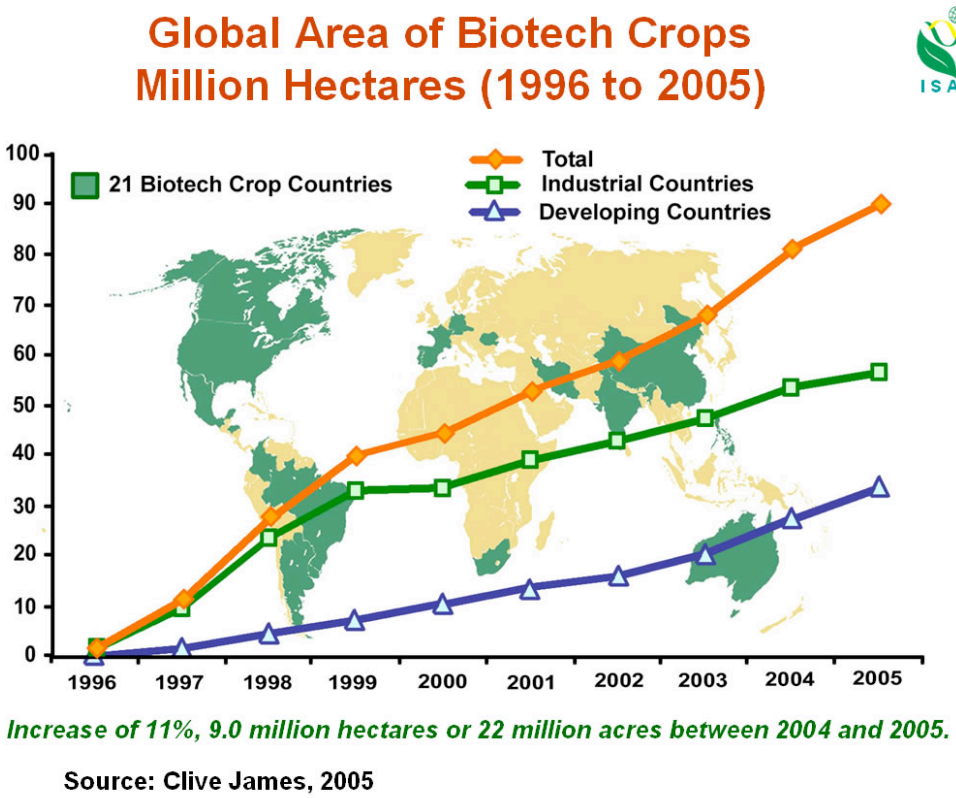

Figure 3.Growth of land area worldwide, used for GMO cultivation. Source: Clive James. (ISAAA, 2005).

2.1.3 The main GMO properties

GMOs in the context of food and feed generally have one or more of five characteristics: They may be herbicide resistant, disease or insect resistant, have improved quality (e.g. flavour, structure, etc.), or contain added nutrients - so-called nutraceuticals (Nottingham, 2002). The three most common properties, herbicide resistance, insect resistance and disease resistance, are discussed below.

The first generation of GMOs mainly had one of these properties; the second generation is developing more towards improved quality and nutraceuticals, that is, they are more consumer oriented[6]. Technically the first generation GMOs were rather simple; they were modified to get one property. For the second generation of GMOs, more complex modifications are needed, often multiple modifications. This may increase the risk of the GMO developing unexpected properties, such as producing allergens or having other unexpected impacts on non-target organisms (Nottingham, 2002, pp. 47-53).

Herbicide resistant GMOs

Herbicide resistant GMOs are crops that tolerate a certain herbicide, so that this herbicide may be used by the farmer to kill weeds present in the field. Usually both the organism and the herbicide are developed and sold by the same company. The herbicides are commonly

[6] A slightly different division into generations was presented by Mooney (1999), where GMOs with improved properties are called 'second generation' and the nutraceuticals 'third generation'.

broad-spectrum, that is, they attack many different weeds. Thus, by applying one herbicide several weeds may be kept away from the crop, this in contrast to the situation where several herbicides must be applied on the same crop in order to keep away different weeds. Thus, the total amount of herbicide may be reduced. In section 2.2.1 some environmental aspects of herbicides are discussed, including whether herbicide use will actually decrease or increase.

The GE-suitable herbicides, such as for instance Monsanto's RoundUp® (a glyphosate), or Aventis' Basta® (a glufosinate), are 'less environmentally damaging than many other herbicides', according to Nottingham (2002, pp. 36-37), even though reports of toxicity to some non-target organisms (Servizi *et al.*, 1987[7]) or contamination of run-off exist (Siimes *et al.*, 2006)[8]. Typical herbicide resistant GMO products include for instance Monsanto's RoundUp Ready™ soybeans and Bayer's Liberty Link™ rice.

Insect resistant GMOs

GMOs that are insect resistant may produce their own insecticide, thus offering the possibility for the farmer to reduce the usage of insecticide. The most common kind of insecticide incorporates genetic material from the soil bacteria *Bacillus thuringiensis* (*Bt*), of which now thousands of varieties are known, where a variety may target a specific insect (Nottingham, 2002, p. 42). Other, more experimental strategies than allowing the GMO to produce *Bt* toxins are to modify the plant to produce lectins, a protein toxic to many insects, or to produce a substance inhibiting an insect's capability of breaking down proteins (Nottingham, 2002, p. 42).

Since the toxins are produced in the plant, insecticide usage is likely reduced. Thus, non-target organisms such as an insect's natural enemy will not suffer as much from the spraying. However, insecticide resistance developing among pests is an issue of concern. A more thorough discussion on advantages and disadvantages is presented in section 2.2, including whether the amount of insecticide that is applied is actually reduced or not. Typical GE insect resistant crops are Monsanto's Yieldgard maize (*Bt*), and Syngenta's maize Bt11.

Disease resistant GMOs

A third, less common, trait for GMO crops is resistance to diseases, especially those caused by viruses. This gives rather special problems, since these GMOs have viral nucleic acid sequences in their genome (Nottingham, 2002, p. 45), which may interfere with any invading virus's replication, since genetic exchange is common for viruses. Thus, these GMOs could facilitate the evolution of viruses, possibly leading to 'the emergence of novel disease-causing viruses' (Nottingham, 2002, p. 46).

2.2 Sustainability aspects of GMOs

Compared to conventional crops, genetically engineered crops may have a different impact on sustainability, i.e. the environmental properties, social aspects or economic factors. In this

[7] This study showed that two components of Roundup, glyphosate and MONO810, showed a higher level of toxicity combined than the sum of toxicity for both components. The impact on salmon, Daphnia and trout in natural waters was investigated.

[8] Three herbicides were compared, Liberty (glufosinate-ammonium), Roundup (glyphosate) and a conventional one (ethofumesate), with respect to their concentration in run-off and in soil of Finnish boreal land, during one year. Even though glufosinate-ammonium degrades rapidly, and was undetectable during winter, residues were found in run-off and soil in spring, sometimes at higher level than the conventional one despite its much longer half-life time. However, overall, the loss of glyphosate and glufosinate-ammonium to the environment was less than that of ethofumesate.

section the focus is on cultivation, but aspects of products consisting of or containing GMOs will be mentioned as well. In each section potential benefits and disadvantages of GMOs will be described; a brief description of relevant differences between GE and conventional industrial agriculture is given. This is important as it illustrates why the issue of GMOs is so controversial, and why some countries or regions are positive to GMOs while some are negative.

2.2.1 Environmental aspects

Ever since the beginning of genetic engineering, there have been concerns about negative impacts on the environment of GE crops. These impacts may be divided into three categories: effects caused by the GMO itself, effects resulting from dispersal of genes from GMOs to other organisms in the environment, and effects due to altered practices in the use of an organism because of the new plant characteristics (Williamson *et al.*, 1990, cited in Myhr and Traavik, 2003). Examples are crops producing their own toxins that may be spread into the environment, the effect of herbicides on non-target organisms such as beneficial insects, or increased use of fertilizer or water, e.g. for GE crops with increased growth rate. However, it has always been argued that GMOs can give substantial environmental benefits, such as a reduction in the use of pesticides and reduced soil erosion due to easier weed management for herbicide-resistant GE crops. Benefits and drawbacks are discussed more thoroughly below.

Environmental benefits

For herbicide resistant GMO crops, potential benefits are first of all a reduction in use of herbicides. This will reduce water pollution through run-off, and the use of resources is decreased. Moreover, less soil cultivation may be needed, especially when using post-emergence broad-spectrum herbicides. This results in less erosion while organisms and moisture are conserved in the soil (Nottingham, 2002, pp. 35-41). Moreover, the herbicides in use for GMOs are less harmful, although it must be noted that also in conventional agriculture there is a clear trend towards less harmful herbicides[9].

Insect resistant GMOs may result in less insecticide being used, since the insecticide is produced in the plant itself. Thus, non-target organisms such as natural pest enemies or other beneficial organisms do not suffer. Moreover, groundwater contamination may be reduced.

If special properties are built into the GMO crops, more environmental benefits may be gained; for instance, plants may need less water in order to reach similar growth or yield, or plants may get nitrogen-fixing abilities. This may bring significant environmental advantages, since in that case the use of artificial fertilizer may be reduced, bringing benefits such as energy savings and reduced run-off pollution.

Environmental disadvantages

In respect to herbicide resistant GMO crops, some environmental disadvantages may be seen as well. One is the impact on plants around farmland; the herbicides used in GMO cultivation are often broad-spectrum, and will thus impact surrounding plants, which may have negative consequences for insects and farm birds that depend on these plants (Nottingham, 2002, pp. 35-41). This could have impacts further up the food chain and

[9] See Benbrook (2001) for a discussion on pesticide trends. The toxicity of herbicides used for GMO crops is generally less, see for instance DEFRA (2005, p.5).

impact biodiversity around the farmland. Moreover, the weed-free fields do not supply food to wildlife, something that has similar consequences.

Increased use of insecticide on cotton in China

Bt cotton, producing insecticide against the cotton bollworm, has grown very fast in China. Initially farmers saved 46% on pesticide use, but the emergence of a secondary pest increased the use of other pesticides with 40%. The secondary pest came up since the bollworm was eradicated in many places. This is an aspect commonly ignored when potential benefits of *Bt* cotton are stated (Wang, 2006). Bollworm refuges may alleviate the problem to some extent.

Box 2-1. An example of weed shift, one of the possible causes for increased use of insecticide for GMOs. Source: Wang, 2006.

Another drawback is that herbicide use may not actually be reduced (Benbrook, 2001; Shiva, 2000, pp. 98-99). One reason is that so-called 'volunteers' may stay behind on the field, that is, GMO herbicide resistant plants that disturb next year's crop. These volunteers are then resistant to the GE herbicide, and thus other herbicides must be used to get rid of them. Another reason is the transfer of the herbicide resistant property from crops to wild relatives through pollen. These wild relatives may then become herbicide resistant weeds, and different herbicides are needed. The consequences of the spread of GMOs depend on how invasive a certain crop is; this is discussed below. A third reason may be weed shift. Due to the suppression of certain weeds, other weeds get the possibility to come up and infest the crop (see Box 2-1 and Wang *et al.*, 2006). A phenomenon called the 'pesticide treadmill' exists: Natural enemies to weeds or pests are suffering from pesticide application, and thus the ecosystem's natural capacity to manage pests is reduced and more artificial pesticides are needed (Nottingham, 2002, p. 87; Benbrook, 2001).

For insect resistant GMOs it must be noted that the built-in insecticide mostly only targets certain insects, so that other insecticides still may have to be used. Another disadvantage is that insecticides continuously present in the plants may promote insecticide resistance[10]. The impact of this resistance depends on the resistance being recessive (i.e. genetically non-dominantly inherited) and on the insects not showing a shift in time in their development. A remedy for the problem of resistance is to use high-dose insecticide plants, so that the insect mortality is about 100% and no resistant insects are left over. Another remedy is to have refuges of non-GMO crops adjacent to or interleaved with GMO crops, so that insects may easily avoid the toxic GMO crops (see also Box 2-1).

Another disadvantage of insect resistant GMOs is that decaying plants may 'release toxins into the soil, where they could be harmful to soil microorganisms' (Nottingham, 2002, p. 45).

When referred to disease (virus) resistant GMOs, one of the most significant risks is virus recombination; Virus-to-virus or plant-to-virus recombinations are not uncommon[11]. In the past specific warnings against viral GMOs have been issued by for instance the US Department of Agriculture (USDA) (New Scientist, 1997).

One of the main issues of GMOs is their spread into the environment, that is, their invasiveness. This is an important issue in the controversies regarding GMOs in e.g. the EU, or the US[12]. First of all, seeds or pollen may be spread into the environment, through insects,

[10] A natural form of *Bt* insecticide is often used by organic farmers, as non-chemical pest management. If insects build up resistance to *Bt*, this may have detrimental effects for these farmers' pest management possibilities (Altieri and Rosset, 1999).

[11] See e.g. Zhou *et al.* (1997).

[12] See e.g. Box 2-2 on the US long-grain rice contaminated with a GMO variety used in field trials in 2001.

birds or mammals, the wind, or during transport or handling. Second, these seeds or pollen may settle in the environment. Factors determining a good invasion (Mack, 1996) are for instance that the seed:

- Germinates in a wide range of conditions;
- Is an adaptable perennial;
- Grows rapidly;
- Flowers early in the season;
- May be self-fertilizing;
- May be able to reproduce asexually;
- Is a good competitor;
- May produce many seeds that disperse widely.

LL601 rice

A recent issue, from August 2006, is the appearance of LL601, a GMO only used in small-scale field trials in the US in 2001, in commercial long-grain rice (US EPA, 2006). This has sparked an EU import ban on long-grain rice until testing can prove if any imported rice contains the GMO that was not approved for human consumption. An appeal to be cautious was issued by some scientists (Pryme *et al.*, 2006). The economic consequences for US rice growers are enormous (ARGA, 2006). In October 2006, the EC proposed mandatory testing of all imported long-grain rice, at the expense of the exporter (EC, 2006d).

Box 2-2. Appearance of GMO rice in US long-grain rice. Source: USDA, 2006; ARGA, 2006; EC, 2006d.

Major invasions are hard to predict, and far from all invasions are successful, but some invasions may cause substantial damage and may be hard if not impossible to eradicate (Mack, 2000). Third, the effect of the invasion may be the persistence of pesticide resistant weeds (see e.g. Box 2-3), or the pollution of conventional or organic crops with GE plants.

The main remedy proposed to deal with the problem of invasiveness of GMOs is to have isolation distances between GE and conventional or organic cultivation. The necessary distance depends on the amount of 'genetic pollution' that is allowed[13], the invasiveness of the crop, and weather conditions. Since the latter are quite unpredictable, isolation distances are hard to determine, also since it is an economic question: Isolation distances are a cost factor. This leads to the issue of risk assessment, taking into account factors such as persistence, reproductive fitness, herbicide resistance, etc. This issue is elaborated on in section 2.3.2.

Glyphosate-resistant Johnsongrass

Johnsongrass, a weed growing in Argentina, amongst others, cannot be controlled by glyphosate anymore in a province in Argentina, apparently having taken over the property of herbicide resistance from other plants. Monsanto is investigating the case; both in field and greenhouse trials glyphosate failed to control Johnsongrass (Farm Futures, 2006).

Box 2-3. An example of the spread of herbicide resistance to wild plants. Source: Farm Futures, 2006.

[13] For instance, in the EU 0.9% genetic pollution is allowed for crops.

Another remedy would be to use so-called Genetic Use Restriction Technology, or Terminator Technology, that is, a GE technology where plants do not produce viable seeds or pollen[14].

Another important issue is seed pollution especially occurring during handling of seed streams that are not properly separated. Thus, conventional or organic seed supplies may be contaminated with GMO seeds. Also this is an economic question; it may be costly to have separate seed streams.

In summary, the main environmental concerns of GMOs are:

- The creation of resistant weeds, through 'volunteers' or cross-contamination of wild relatives;
- The contamination of conventional or organic crops or seeds by spreading GMO plants, seeds or pollen into the environment;
- The impact on non-target organisms such as microorganisms, natural pest enemies, and wildlife such as farmland birds and insects.

Discussion of environmental aspects

Relevant environmental factors of food production systems are for instance the use of external inputs such as fertilizers and pesticides, pollution of water, soil and air, and biodiversity (Kirkpatrick and George, 2005; Pretty, 1995). An indication of possible differences between conventional (industrial) and GE food production in respect to these factors is given in the discussion below.

With regard to the issue of external input use, GE farming has the potential of reducing external inputs, and this is often mentioned as one of the main benefits of herbicide-resistant and insect-resistant GE crops. However, due to for instance genetic pollution, increased resistance of weeds and insects, or effects on non-target species, external inputs must often be increased after some time (Soil Association, 2002; Wang *et al.*, 2006).

The second factor, pollution, does not seem to be very decisive when comparing GE and conventional agriculture. Pollution in farming may be due to the use of external inputs, thus related to the first factor and showing similar possible positive or negative consequences. The herbicides used for GMO crops are generally less toxic than conventional herbicides (DEFRA, 2005, p.5). Otherwise, a specific pollution problem of GE farming may be soil pollution, e.g. by impacted microorganisms suffering from *Bt* toxins transferred from the crop to these microorganisms[15].

[14] Terminator Technology is a highly controversial technology, and within the Convention on Biological Diversity (CBD, see section 2.3.1) a moratorium is placed on it. The main issue is that farmers will not be able to save seeds for next year's cultivation, an agricultural practice that has been around since the beginning of agriculture. An important argument in favour of this technology is that it reduces the risk of spreading GMOs into the environment, since the seeds or pollen are not viable. The main goal of this technology is to prevent unauthorized use of patented material (Nottingham, 2002, p. 112).

[15] See for instance Nottingham (2002), Ch. 3 and 7 for a more thorough discussion on the effects of *Bt* toxins on microorganisms.

For the third factor, biodiversity, field trials generally show that evaluations on a case-by-case basis are necessary to assess the effects of GE crops[16]. However, as GE can be seen as a continuation of industrialized agriculture, it will likely lead to more monocultural farming, at least compared to sustainable agriculture (Pretty, 1995; Shiva, 2000), thus reducing genetic diversity. Moreover, GE research generally focuses on just a few crops and just a few varieties[17].

2.2.2 Social aspects

One of the main differences between GE and conventional food production is the patentability of GE crops. This creates a different relationship between the company owning the seed patent and the farmer, something that has severe social consequences with respect to for instance inequalities but also the capacity for self-sufficiency. Another social aspect is the discussion on ethical aspects of GE, which includes the question of only considering economic costs and benefits or attaching a non-economic value to the environment, as well as the intrinsic value of the environment, something that leads to the consideration of the precautionary principle. Moreover, the ethical argument of helping the poor comes to mind, as well as the debate on whether it is justifiable to manipulate genetic material. When it comes to consumption of GMOs, health impacts are an important social factor. These and other factors are discussed below.

Social benefits

According to the pro-GMO NGO ISAAA (International Service for the Acquisition of Agri-Biotech Applications), GMOs could contribute to fighting poverty, since yields may improve. This could raise the income of many subsistence farmers in developing countries, thus leading to substantial improvements in quality of life (ISAAA, 1998). This argument is part of a moral line of reasoning, according to Myhr and Traavik (2003, pp. 11-12). Similarly, GMOs are often seen as the solution to the problem of feeding a growing world population, often also mentioned in connotation to developing countries. Improved yields are perceived as the most important factor to achieve this[18]. Moreover, farmers in developed countries will benefit from improved yields and reduced external input use, thus improving their quality of life through economic gains.

A second social benefit is improved health related to the potential of decreasing the use of herbicides and insecticides, with farm workers being less exposed to these compounds. Of course second-generation GMOs, containing nutraceuticals, may contribute to improved health. A well-known example is Golden Rice™, now owned by Syngenta, that contains vitamin A. It is claimed that this rice could help solve vitamin-A deficiencies in developing countries[19] (see Box 2-4).

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[16] See e.g. Guardian (2003) for a description of a report on field trials in the UK. The report, focusing on the effects on biodiversity of herbicide tolerant crops, showed positive impacts of some GMOs, and negative impacts of others, thus showing that no general assessment of GMO impacts can be made but that a case-by-case assessment is necessary (DEFRA, 2005).

[17] See e.g. Nottingham (2002, Ch. 12) and Soil Association (2002).

[18] It must be noted that yield improvements are not as significant as originally indicated by the GE industry. Nottingham (2002, p. 170) mentions increases of 5-20%, DEFRA (2005, p.5) mentions similar yields resulting from field trials on certain GMO crops compared to conventional ones, and Shiva (2000, pp. 99-101) lists several examples of equal or less yield of GMOs compared to non-GMOs in practice.

[19] See Beyer *et al.* (2002) and Nestle (2001). See Nottingham (2002, p. 166), for a discussion on GMOs, food supplies and vitamin deficiencies.

Golden Rice

Golden rice is rice containing β-carotene, the chemical precursor of vitamin-A. Vitamin-A deficiency causes the death of about 1 million children annually, also causing blindness. The deficiency problem is mainly seen in developing countries (Nottingham, 2002, p. 51). An average rice serving may contain 10-40% of the required daily intake (Nottingham, 2002, p. 166).

However, in order to transform β-carotene to vitamin-A, 'biological, cultural and dietary factors act as barriers' (Nestle, 2001), and without additional dietary changes the transformation into vitamin-A will be questionable.

Box 2-4. Rice containing β-carotene ("Golden Rice") could help solve vitamin-A deficiencies to some extent. Source: Nestle, 2001; Nottingham, 2002.

Rats and mice eating GMOs

In one experiment, mice were fed with GMO soy and compared to a control group being fed wild soybeans (Malatesta *et al.*, 2002). A significant difference in liver cell nuclei was observed, suggesting a difference in metabolic activities.

In a preliminary publication on an experiment of rats being fed GMO soy, compared to those being fed non-GMO soy and conventional food pellets, it was found that the GMO-fed rats had a significantly higher mortality after 3 weeks (55.6% vs. 9% and 6.8%) and significantly lower weight of newborns. This research was discussed by the UK Advisory Committee on Novel Foods and Processes (ACNFP), which pointed out several uncertainties and unclarities in the study (ACNFP, 2005).

Box 2-5. Impacts of GMO consumption on rats and mice. Source: Malatesta et al., 2002; Regnum, 2005.

Social disadvantages

An important health drawback of GMOs is the risk for the occurrence of allergens. This may happen unexpectedly, as in the recent case of peas[20] (Prescott *et al.*, 2005), or it can be due to the implantation of genetic material from e.g. nuts in other crops such as soy (Nordlee *et al.*, 1996). Moreover, reports have been published on impacts of GMO diets on animals such as mice and rats[21] (see Box 2-5).

If the use of herbicides and pesticides is not decreasing but increasing[22], farm workers may be more exposed to these chemicals, resulting in possible damage to health.

Specific health issues of the process of genetic engineering are related to the incorporation of antibiotic-resistant marker genes and viral promoters in the gene construct (see section 2.1.1). Antibiotic-resistant genetic material may be active in the human or animal gut for a short time, although most of it is broken down. Bacteria present in the gut could thus incorporate the antibiotic-resistance property, and the efficiency of common antibiotics could be reduced (Nottingham, 2002, p. 106).

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[20] It was described how a bean protein imported in peas led to a modified protein, possessing altered antigenic properties leading to increased inflammation and eliciting immunoreactivity (increased immune reaction to other foods) (Prescott *et al.*, 2005; New Scientist, 2005).

[21] For an article on mice, see Malatesta *et al.* (2002), and for rats see Regnum (2005) as well as the somewhat controversial study of Ewen and Pusztai (1999) (see also Shiva, 2000, p. 110). For a list of examples of negative health and other effects of GMOs see Mooney (1999), for an overview of abstracts of scientific papers on animal health effects of GE see http://www.agbioworld.org/biotech-info/articles/agbio-articles/GMfeedsafetypapers.html , and for a general discussion on literature on GE health effects see Domingo (2000).

[22] In section 2.2.1 it was already discussed how herbicide and insecticide usage do not always decrease. See e.g. Benbrook, 2001; Shiva, 2000, pp. 98-99; Wang et al., 2006; Nottingham, 2002, p. 36 and 43.

According to Nottingham (2002, p. 103), viral promoter genes, most commonly based on the Cauliflower Mosaic Virus, may 'integrate into plant genomes, and duplicate repeatedly, become established as latent viruses in plant genomes over several generations, be induced to form infecting viruses at any time, and be spread in pollen'. Contact between the viral material and gut viruses cannot be excluded, so that there is a theoretical possibility for new viruses to emerge.

An important social disadvantage of GE is related to empowerment. Due to the structure of the biotech industry, where patents and corporate ownership of seeds and plants are common – farmers must often sign a gene licensing agreement[23] before using GMO seeds – and pesticides are sold by the same corporation, farmers become more dependent on that corporation (Shand in Kimbrell, 2002, p. 246). The difference in resources between a farmer and a corporation, e.g. in case of a court case related to a supposed violation of patent rights, probably only serves to increase the feeling of disempowerment of the farmer. Also the aforementioned 'Terminator Technology', where seeds cannot be saved for next year's cultivation, would not contribute to farmer empowerment[24].

With regards to ethical and moral aspects, one can say that there is a risk of damaging the environment if GMOs are spread (see previous section). As Karlsson (2003) has quoted, the 'right of humans to utilize nature is linked to the responsibility of managing it well'[25]. The possible risk taking with GMOs may be questioned from this ethical point of view.

Discussion of social aspects

Relevant social factors of food production systems include, for instance, democratic participation and inequalities in society, quality of life, health, and ethical considerations[26]. An indication of possible differences between conventional (industrial) and GE food production in respect to these factors is given in the discussion below.

Percy Schmeizer vs. Monsanto

Canola (oilseed rape) farmer Percy Schmeizer found Roundup Ready canola on his fields, while he had never bought Monsanto's seeds. According to him the seeds could have been spread by the wind or being spread from trucks during transport. He was nevertheless sued by Monsanto, accused of patent infringement, but he countersued, accusing Monsanto of contaminating his crops, trespassing, libel and disregard for the environment.

In a Canadian federal court, it was ruled that Schmeizer had to compensate Monsanto for the Roundup Ready plants that grew on his field.

Box 2-6. Example of a farmer being sued by a patent holding company, while the farmer claims his crop was accidentally contaminated with GMO seeds. Source: Nottingham, 2002, p. 82.

With respect to the first factor, democratic participation and inequalities, GE does not contribute. GMOs are generally patented, and the knowledge is kept with the patent holders, most commonly multinational companies. In addition, democratic participation is not promoted, since most of the research is done by multinationals, not by public research institutes. Therefore, research generally focuses on crops that give high profits, not necessarily on crops that can help most people. An issue that comes to mind when looking at global inequalities is

[23] Such an agreement clarifies the patent situation, e.g. forbids the farmer to save seeds, and in many cases prohibits the farmer to discuss the seeds or crops in public (Soil Association, 2002).

[24] Shand (in Kimbrell, 2002, p. 245) mentions 'bioserfdom', and Swaminathan (2000) mentions 'genetic enslavement'.

[25] This is also addressed by Myhr and Traavik (2003).

[26] These main factors are distilled from Kirkpatrick and George (2005), Pretty (1995), and Myhr and Traavik (2003).

technology transfer. However, due to the nature of GE with patenting and huge monetary resources put into research, this is often not happening. The argument of GMOs reducing poverty and combating hunger are often mentioned, but in practice many GMOs have been developed by private corporations, thus having profit of multinational biotech companies in mind rather than 'saving the world'.

GE may increase the quality of life for society, e.g. for farmers if yields are higher than for conventional crops and less external inputs are used. On the other hand, numerous examples exist of small farmers not being able to deal with debts because of the use of GMOs when the yields are not as high as expected[27]. For farmers, being dependent on a multinational company for seeds and herbicides may not contribute to their quality of life (Peters, 2000; Shand, in Kimbrell, 2002, p. 245; Swaminathan, 2000). Moreover, GE may contribute to wealth polarization rather than redistribution of wealth (Peters, 2000)[28].

Another problem is the spreading of GMOs to neighbouring fields and farms. In case that happens, the multinational company owning the patent may sue the farmer whose crop is infected by the GMO – something that has occurred regularly (see Box 2-6 and Soil Association, 2002; Shand, in Kimbrell, 2002, p. 246), and which may be seen as a symptom for inequality between user and supplier of seeds. More self-reliant farming strategies such as developing own seeds and conventional selective breeding are not promoted by GE, although it can also be questioned whether these strategies are promoted by conventional industrialized agriculture.

When it comes to health, as described above, GMOs may definitely have a positive contribution, e.g. by providing food supplements to consumers. However, GMOs may have adverse health effects as well, such as unexpected allergies, and impacts on organisms eating GMOs. To claim, as a pro-GMO NGO such as the ISAAA (International Service for the Acquisition of Agri-Biotech Applications) is doing, that 'there is no evidence to support the claim that biotech products are unsafe ' (ISAAA, 2000, p. 9) seems somewhat untruthful. Moreover, considering farm workers, if the use of pesticides increases the workers will be exposed more to commonly toxic chemicals. On the other hand, GMOs may also give rise to different agricultural practices compared to conventional agriculture, such as reduction of pesticide spraying by airplane. This could reduce workers' health risks.

2.2.3 Economic aspects

From an economic perspective some of the obvious aspects of GE are the large investment costs for research activities, economic aspects of patenting, costs of GMO seeds for the farmer, and possible profit margins due to increased yields or decreased investments in pesticides. For the consumer, the impact seems to be relatively small, since either GMO products are similar to conventional products or GMOs are just a part of an end product with a rather marginal impact on consumer price. Thus, in this section focus is placed on producer and farmer impacts.

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[27] See e.g. Bloomberg (2006) for an article on Indian farmers suicide and GMO crops. It is suggested that suicide rates amongst Indian farmers have increased significantly since the introduction of GMO cotton and its failure to live up to its promise of high yield and high returns on investments. Many small farmers, having taken a substantial risk by changing to GMO cotton, may thus see no other end to their financial trouble than suicide. See also Shiva (2000, p. 101).

[28] According to Peters (2000), modern agriculture, which is based on technology, monoculture, and farmers' economy of scale, has led to a concentration of wealth, that is, a few large farmers become larger. Current genetic engineering is based on the same premises, and does not focus on small farmers, or hunger or poverty relief. Therefore, genetic engineering in its current form is likely to lead to a larger concentration of wealth.

Economic benefits

For seed producers, economic benefits of GMOs lie in the higher price that can be charged for GMO seeds. Moreover, the patents that are granted on GE products or processes are an asset to the company, and may provide income.

For farmers, the potential yield improvements may provide a larger income to the farmer[29]. Also, if the use of external inputs such as herbicides and pesticides is reduced, costs for cultivation will be reduced.

Economic disadvantages

As has been stated in section 2.2.2, large investments need to be made for GE research. This is an economic drawback for seed producers[30]. Moreover, patent applications are costly.

For the farmers, costs for GE seeds are relatively high. Also, seeds may not be saved by the farmer for next year, so this investment must be made every year.

Discussion of economic aspects

Relevant economic factors of food production systems are for instance profit margins, employment, and income[31]. Also, long-term economic stability and reinvestment in society[32] may be considered. An indication of possible differences between conventional (industrial) and GE food production in respect to these factors is provided in the discussion below.

When looking at the GMO suppliers, that is, the biotech companies, the profit margin depends on a number of factors: Investment costs for research, patent costs, seed prices, and sales of other items such as specialized herbicides. Costs for GE research are high, compared to conventional agricultural research (Zarrilli, 2005, p. 7), as are costs for patent applications – something that is not usual for conventional research. These investments have as a consequence that focus for GE research is on crops that can be used on a large scale, i.e. monocultures, for large markets. On the sales side, seed prices charged to farmers tend to be high (see e.g. Shiva, 2000, p. 101). Moreover, the specialized herbicides needed for GE seeds that are herbicide resistant (the most common treat of GE crops) are commonly produced by the same company, thus generating more revenue.

For farmers, the profit margin depends on factors such as seed prices, pesticide prices, use of external inputs, yields, and sales and prices of GMO products. As mentioned above, GE seeds tend to be more expensive than conventional seeds, and specialized pesticides associated with a certain type of GMO crop are expensive as well. On the other hand, fewer pesticides may be used, especially in the initial phase of growing a GMO crop, thus decreasing costs. Also, yields may be higher than for conventional crops, thus bringing in more profit. However, as

[29] However, Pimentel et al. (1989) argue that a 1% yield increase actually results in a 4.5% reduction in market price received by farmers. This is beneficial for consumers, since prices are reduced, but is not beneficial for farmers.

[30] In the current GMO market situation, it is not unlikely that seed producers will be able to transfer some of the costs to farmers, while the food market is such that farmers may have difficulties transferring their increased costs to consumers.

[31] It is hotly debated if the most common indicator of economic progress – a country's gross domestic product – does justice to sustainable development, see e.g. Hamilton (1999).

[32] See e.g. Sustain (2002) for a discussion of local reinvestment in sustainable local food systems. The money spent in a local food system generates more money locally than that spent in for instance a large chain supermarket or other components of a large-scale industrial food system. The GE and conventional food system are both exponents of a large-scale industrial system and will not differ much in this respect.

mentioned before, yield predictions have not always been fulfilled. Thus, together with the possibility of increased use of pesticides necessary to combat upcoming secondary pests or 'volunteers' there will be no guarantee for an increase of the farmers' profit margin (see e.g. Shiva, 2000, p. 101).

With regards to employment, the increased concentration of biotech companies, where the top 10 biotech companies increased their market share from 'just over half to nearly three quarters' in two years time (ETC group, 2005), may point at job loss, a common phenomenon associated with companies being bought up or merged (Schweiger and DeNisi, 1991). It is not unlikely that due to the increased financial risks of GE compared to conventional seed production, this phenomenon is more prominent in the former[33]. For the industrial agriculture farmer, there is likely to be no difference in this respect between GE and conventional.

Income is of special interest to farmers, since their margins are not always large, and often dependent on world commodity prices. Assuming the amount of GE produce sold is equal to the amount of conventional produce sold, the income of the farmer will roughly fluctuate with the profit margin, which is discussed above. Also, increased yields will contribute to increased sales. However, in some cases the market for GE produce is much smaller than the market for conventional produce, e.g. in the EU. Thus, sales could plummet, diminishing the income of the farmer. Of course it must be noted that sales will depend on many factors such as consumer interest and producer competition[34]. A discussion on this aspect is beyond the scope of this thesis.

The mergers and take-overs can be seen as a negative impact on long-term economic stability, especially for smaller actors in the market. The few remaining actors however, may see increased stability due to market dominance.

2.3 Regulation of genetically modified organisms

GMOs are regulated at the international, national and sometimes local level. For this thesis relevant treaties and regulations are the Convention on Biological Diversity, EU legislation such as Directive 2001/18/EC and Regulations (EC) 1829/2003, (EC) 1830/2003 and (EC) 1946/2003. Moreover, EU member states have their own implementation of Directive 2001/18/EC. An overview will be given in the following sections. The treaties within the World Trade Organization (WTO) that touch upon GMOs are discussed in Chapter 3.

2.3.1 The Convention on Biological Diversity and the Cartagena Protocol on Biosafety

The only international treaty considering genetically modified organisms is the Convention on Biological Diversity, under auspices of the United Nations (UN). Within the convention, the Cartagena Protocol on Biosafety has been signed regulating cross-border trade in living modified organisms.

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[33] See e.g. Lesser (1998) for a discussion on the relationship between IPR and corporate merging.

[34] It is often argued that the decrease in soy exports from the US to the EU was due to the EU's GMO legislation. However, SoyLine (USB, 1999) describes how other factors, such as competition from countries such as Argentina and Brazil, play a significant role.

The Convention on Biological Diversity

In 1992 the Convention on Biological Diversity (CBD) was signed by 150 government leaders at the Earth Summit in Rio de Janeiro. To date, the convention has 188 parties, of which 158 have ratified it (CBD, 2006). It entered into force on December 29th, 1993.

The treaty has as its goals (CBD, 2006):

> "The conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding".

By ratifying the convention, governments commit to (CBD, 2006):

- Conserve and sustainably use biodiversity;
- Develop national biodiversity strategies and action plans, and to integrate these into broader national plans for environment and development;
- Identify and monitor the important components of biological diversity that need to be conserved and used sustainably;
- Establish protected areas to conserve biological diversity while promoting environmentally sound development around these areas;
- Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species in collaboration with local residents;
- Respect, preserve and maintain traditional knowledge of the sustainable use of biological diversity with the involvement of indigenous peoples and local communities;
- Prevent the introduction of, control, and eradicate alien species that could threaten ecosystems, habitats or species;
- Control the risks posed by organisms modified by biotechnology;
- Promote public participation, particularly when it comes to assessing the environmental impacts of development projects that threaten biological diversity;
- Educate people and raise awareness about the importance of biological diversity and the need to conserve it;
- Report on how each country is meeting its biodiversity goals.

From these commitments the importance of biodiversity for ecosystems can be sensed, as well as the value of traditional knowledge, and the importance of sustainable development and public participation.

The Biosafety Protocol

Within the Convention on Biological Diversity (CBD), on January 29th 2000 a protocol has been agreed upon that is crucial for transboundary movements of GMOs: the Cartagena Protocol on Biosafety, or Biosafety Protocol (BP). It 'seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology' (BP, 2006), and its main components are an Advance Informed Agreement procedure and a Biosafety Clearing House. It refers to a precautionary approach and confirms the notion of precaution established in the Rio Declaration on Environment and Development (UN, 1992). On September 11th, 2003, it entered into force, and as of this date it had been ratified or accessed by 134 countries. Notably, the United States, Argentina and Canada are not amongst the countries that have ratified or accessed the protocol; the US has not signed it, while Argentina and Canada have signed it (BP, 2006).

According to Phillips and Kerr (2000), the BP – which they describe as a *de facto* trade agreement - has three possible ways to positively impact international trade in GMOs:

- Using the Advanced Informed Agreement (AIA) procedure may increase transparency in GMO trade and reduce tensions in the market;
- Trade fairness should be increased by scientific risk assessment procedures so that both domestic and imported GMO products are assessed consistently for risks to biodiversity;
- The BP may overcome weak or non-existent GMO regulation in countries that have no prior experience with such regulation.

They see as a global benefit of the protocol the 'overall conservation and protection of biodiversity', while industry may benefit from a more predictable market through the protocol. However, they recognize that the protocol only deals with cross-border trade, not with 'research and development, transfer, handling, testing, use and disposal of all [GMO] products' (Phillips and Kerr, 2000).

In section 3.6 the CBD and the BP will be analyzed further, mainly with respect to conflicting issues between these MEAs and the World Trade Organization (WTO).

2.3.2 EU legislation

In the mid-1980s the first EC Communication related to GMOs was issued. At that time, genetic engineering (GE) was an emerging technology, still many years away from the first GE food product to be placed on the market. The Directive 90/220/EC, approved in 1990, was the first binding document on this topic (Sindico, 2005)[35]. This directive dealt with 'deliberate release into the environment of genetically modified organisms' (EU, 1990), and its main procedures and properties were:

- An application must be submitted to the competent authority of the member state where the deliberate release or placing on the market is planned;
- A full risk assessment must be included in the application;

[35] Simultaneously, Directive 90/219/EC was approved, on the contained use of genetically modified micro-organisms.

- The member state informed the other member states, and if no objections were raised the product was allowed in all member states. Otherwise, an opinion was asked of a scientific committee at EU level;

- The next decision-making bodies were the regulatory committee, and then the European Council of ministers;

- There is a safeguard clause for member states to invoke if they have serious concerns about a specific GMO.

In 1997, EU regulation (EC) 258/97 on novel food and novel food ingredients was approved. This regulation mainly deals with the food safety aspect. Also, labeling is regulated: All 'foods and food ingredients which contain or consist of a GMO' must be labeled, as are additives, flavourings and seeds (EC, 2001)[36].

Under these directives and regulations, 10 GMO food and feed products were allowed on the EU market (see Appendix 5). But in the late 1990s concerns in member states and public opinion became more vocal, and dissatisfaction with the current legislation was expressed (Annerberg, 2003; Vogel, 2002). This resulted in a temporary standstill in GMO approvals, the beginning of the so-called '*de facto* moratorium' (see section 4.1). Thus, new legislation was prepared, and in 2001, Directive 90/220/EC was replaced by Directive 2001/18/EC, which is still in place. According to Annerberg, the new directive differed in several important points from the old one, such as special attention being paid to antibiotic resistant marker genes, to cumulative long-term effects, to traceability and labeling, and information on cultivation sites becoming available and time limited first time approval for a GMO (Annerberg, 2003).

Moreover, in 2003 two regulations were approved: (EC) 1829/2003 on genetically modified food and feed, and (EC) 1830/2003 on labeling and traceability of GMOs. Moreover, (EC) 1946/2003 was approved, basically implementing the Biosafety Protocol (see section 2.3.1). Issues that are still to be regulated are coexistence and liability[37].

Current EU legislation on GMOs (EC, 2006c) thus consists of:

- Directive 2001/18/EC - on the deliberate release into the environment of genetically modified organisms. Part B focuses on deliberate release for experimental purposes, for example field testing; Part C regulates the placing on the market of GMOs, that is, cultivation, import or processing into industrial products.

- Regulation (EC) 1829/2003 – on genetically modified food and feed, that is, the placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs[38].

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[36] Feed must now be labeled as well, although not the meat from animals fed with GMO feed. Moreover, for foods derived from but no longer containing GMOs the labeling is dependent on 'equivalence'; if the food is not equivalent anymore due to genetic engineering, the food must be labeled (EC, 2001, p. 5).

[37] Coexistence is the cultivation of GMO- and non-GMO crops on adjacent or nearby fields. The question of liability addresses who is responsible in case of contamination by GMOs, e.g. the farmer, the GMO manufacturer, or the authorities who permitted cultivation.

[38] According to EC (2006c), " where a food product contains or consists of GMOs, the applicant has a choice: either the application as a whole is subject solely to Regulation (EC) 1829/2003, in application of the principle of "one door, one key", in order to obtain authorisation for the deliberate release of a GMO into the environment - in accordance with the criteria laid down by Directive 2001/18/EC - and for the use of this GMO in food products - in accordance with the criteria laid down by Regulation (EC) 1829/2003; or the application - or part of it - is subject both to

- Regulation (EC) 1946/2003 - on transboundary movements of genetically modified organisms. This regulation thus implements the Biosafety Protocol (BP).

- Regulation (EC) 1830/2003 - concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. This regulation amends a part of Directive 2001/18/EC.

- Regulation (EC) 258/97 – on food safety aspects of novel foods and novel food ingredients.

Moreover, several communications have been issued by the EC, for instance on coexistence. According to a communication on strategic vision on life sciences and biotechnology (EC, 2006b), the following broad goals in this field may be distilled:

- To 'best attract the human, industrial and financial resources necessary to develop and apply life sciences and biotechnology in order to meet society's needs and increase its competitiveness';

- To 'deliver effective, credible and responsible policies which enjoy the confidence and support of its citizens';

- To 'best respond to global challenges, develop its domestic policies with a clear international perspective, and act internationally to pursue its interests'.[39]

The EU GMO legislation may be summarized by listing the key points of directive 2001/18/EC (EC, 2005):

- "Principles for environmental risk assessment;

- Mandatory post-market monitoring requirements, including on long-term effects associated with the interaction with other GMOs and the environment;

- Mandatory information to the public;

- A requirement for Member States to ensure labelling and traceability at all stages of the placing on the market […];

- Information to allow the identification and detection of GMOs to facilitate post-market inspection and control;

- First approvals for the release of GMOs to be limited to a maximum of ten years;

Directive 2001/18/EC and to Regulation (EC) 1829/2003". There should thus be no difference in end result; However, it must be noted that for a decision according to Directive 2001/18/EC the EU council of ministers of the environment is involved, while for Regulation (EC) 1829/2003 the council of ministers of Employment, Social Policy, Health and Consumer Affairs is involved. It was indicated by one of the interviewed member state representatives that this may make a difference. However, it was indicated by others that an inter-ministerial case-by-case assessment was done, which would prevent the occurrence of such difference.

[39] It must be noted that concerns for the environment and health are absent from the main goals of this strategy paper, although according to Sindico (2005) the main objective of Directive 2001/18/EC is to 'protect human health and the environment from possible adverse effects arising from GMOs'.

- The consultation of the Scientific Committee(s)/European Food Safety Authority (EFSA) to be obligatory;

- An obligation to consult the European Parliament on decisions to authorise the release of GMOs and

- The possibility for the Council of Ministers to adopt or reject a Commission proposal for authorisation of a GMO by qualified majority."

2.3.3 The EU member states

Within the EU regulatory system, regulations must be followed in all member states, while member states have some freedom to implement directives nationally as long as it achieves the stated goal. In the context of GMOs and this thesis, Directive 2001/18/EC may thus be different per member state, while all regulations are the same.

In Table 2-1 an overview is given of GMO cultivation, field trials and safeguard measures invoked under Directive 2001/18/EC. The majority of these safeguards is subject to the WTO *EC – Biotech* case (see section 4.1).

Table 2-1. GMO cultivation, field trials and safeguard measures of the EU member states.

Member state	**Cultivation in 2005**[40]	**Field trials, total, 1992-2006**[41]	**Safeguard measures under Dir. 2001/18/EC**[42]
Austria		3 plants, 0 other GMOs[43]	3
Belgium		121 plants, 9 other	
Cyprus		0	
Czech Republic	Commercial cultivation	5 plants, 0 other	
Denmark		41 plants, 1 other	
Estonia		0	
Finland		22 plants, 2 other	
France	Commercial cultivation	563 plants, 10 other	2
Germany	Commercial cultivation	157 plants, 2 other	1
Greece		19 plants, 0 other	1
Hungary		17 plants, 0 other	1
Ireland		5 plants, 1 other	
Italy		279 plants, 16 other	

[40] Source: http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/191.eu_growing_area.html . For the time being, the only type of GMO grown in the EU is *Bt* maize.

[41] Source: *Deliberate releases of GMOs into the environment for field trails*. Available: http://www.gmo-compass.org/eng/agri_biotechnology/field_trials/228.summary_gmo_field_trials_eu_year_crop_trait.html

[42] Source: *Questions and Answers on the Regulation of GMOs in the European Union*. Memo/05/104. Available: http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/104&format=HTML&aged=0&language=EN&guiLanguage=en

[43] 'Other GMOs' are mainly viruses and bacteria, e.g. varieties of E. coli and salmonella. Source: *Breakdown of summary notifications by Organisms other than higher plants*. Available: http://biotech.jrc.it/deliberate/dbother.asp

Member state	**Cultivation in 2005**[40]	**Field trials, total, 1992-2006**[41]	**Safeguard measures under Dir. 2001/18/EC**[42]
Latvia		0	
Lithuania		0	
Luxembourg		0	1
Malta		0	
Netherlands		147 plants, 12 other	
Poland		5 plants, 0 other	[44]
Portugal	Commercial cultivation	21 plants, 0 other	
Slovakia		0	
Slovenia		0	
Spain	Commercial cultivation	317 plants, 27 other	
Sweden		85 plants, 2 other	
UK		216 plants, 16 other	

The table shows a diverse landscape of GMO presence across the EU, with non-existent GMO presence in many countries – commonly small and relatively new member states – and significant presence in other countries. Moreover, it is clear that the majority of field trials is with GMO plants, and only a small part with other GMOs.

2.4 Stakeholders in the GMO issue

A stakeholder analysis may identify a stakeholder map as shown in Figure 4. Key stakeholders are, for instance, the biotech industry, GMO [illegible] GMO farmers, media,

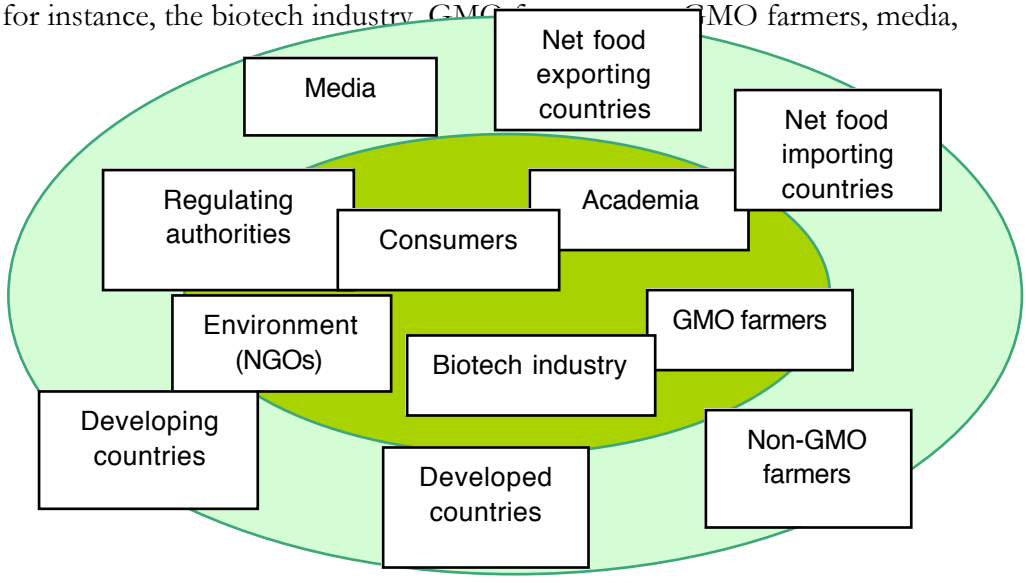

Figure 4. Stakeholder map for the GMO issue. The stakeholders in the center may be considered to be the ones that either have a large impact or are heavily impacted by GMOs.

[44] Poland is using the safeguard clause of another Directive, 2002/53/EC on seeds, to have a safeguard against a GMO maize variety (EC, 2006a).

regulating institutions, consumers, and the environment. GMO- and non-GMO farmers have opposite interests, so they are labeled as separate stakeholders. Regulators could be situated in food importing countries, such as the EU, or exporting countries, such as Argentina, or the US. They may have different interests depending on whether GMOs are cultivated or not.

Also, organizations such as the World Trade Organization (WTO) and the Convention on Biological Diversity (CBD) may resort under regulators. The environment is represented by environmental non-governmental organizations (NGOs) such as Greenpeace or Friends of the Earth[45].

Some of the stakeholders may overlap or interact, such as biotech industry and developed countries, academia and biotech industry, or farmers and developing countries[46]. Moreover, countries may be net food exporters and developing, or net food exporters and developed.

The positions of some of the stakeholders will be addressed in the sections below. The United States and developing countries get special attention in this matter.

2.4.1 Key stakeholders in the European GMO debate

If the stakeholder map is projected on the European GMO debate, one can be more specific and for instance divide 'regulating authorities' into EU member states, the European Commission (EC), and the European Food Safety Authority (EFSA). Thus, key stakeholders may be identified as the member states, the European Commission, EFSA, EU citizens as consumers, GMO farmers, non-GMO farmers, environmental NGOs representing the environment, and biotech industry. The US can be taken as a representative for developed, net food exporting countries, and developing countries may be considered. The media is neglected, since it is not directly impacted by the GMO debate or by actions related to GMO regulation, although the media can exert significant influence on the GMO debate by its way of reporting on the issue. The positions of some of the main stakeholders are provided below.

EU citizens

Generally, consumers in the EU are quite sceptical to GMO food and food products containing GMOs. According to the Eurobarometer 2005 on biotechnology, the average support for GM food in the EU is only 27% (Eurobarometer, 2006, p. 19)[47]. Table 2-2 lists the level of support per member state.

It has been suggested that one of the reasons for consumer scepticism is that the benefits of GE technology predominantly go to the industry, not really to consumers (Wu, 2004; Walker and Lonsdale, 2000), while the risk of the technology is borne by the consumers. This inequality may cause a reluctance to accept GMO food products. This was also confirmed by the Eurobarometer (2006, pp. 17-18).

[45] Most of the large environmental NGOs are opposed to or at least are critical to GMOs.

[46] In fact, a country cannot be assumed to be so homogeneous as to be able to be a single stakeholder, let alone the group of developed/developing countries. However, since the interests and resources of these countries may be quite different, the author of this thesis chose to mention them specifically.

[47] According to the Eurobarometer, 'the introduction of the new regulations on the commercialization of GM crops and the labelling of GM food (2001/18/EC) appears to have done little to allay the European public's anxieties about agri-food biotechnology' (Eurobarometer, 2006, p. 19).

Table 2-2 EU member state consumer support for GM food in 2005. Source: Eurobarometer, 2006.

Member state	**Support for GMO food (%)**	**Member state**	**Support for GMO food (%)**
Austria	21	Latvia	15
Belgium	27	Lithuania	23
Cyprus	15	Luxembourg	13
Czech Republic	46	Malta	36
Denmark	28	Netherlands	25
Estonia	18	Poland	23
Finland	35	Portugal	38
France	20	Slovakia	30
Germany	21	Slovenia	20
Greece	14	Spain	34
Hungary	23	Sweden	22
Ireland	29	UK	30
Italy	34		

GMO farmers

Farmers growing GMO crops have concerns such as regulatory limitations on GMO crops, for instance compulsory buffer zones, seed separation requirements or liability for contamination of non-GMO crops. Also, opposition from neigboring farmers or environmental groups may be of concern. Moreover, being dependent on one supplier for both seeds and herbicides and being bound by a gene licensing agreement may be a concern to farmers, as was described in section 2.2.2. The economic aspects of disappointing yields and increased herbicide use are not to be underestimated, especially for small farmers. In addition, concerns over the market for GMO products may play a role.

Non-GMO farmers

The main concern of non-GMO farmers, that is, conventional farmers and organic farmers, is the risk for contamination. Related to this is the question of liability in case such a farmer's crop is contaminated; is it then the GE industry that is liable, or the GMO farmer? Or does the government pay the bill, or the non-GMO farmer? Especially for organic farmers this is an important issue, since there is additional value to be received for organic crops, which is lost if they are contaminated. Moreover, organic certification could be at risk if organic crops are contaminated[48]. For conventional farmers, the risk of contamination is also substantial, especially if there is no market for GMO products. Thus, coexistence of non-GMO and GMO farms or crops is a controversial issue, especially in the light of the risk of contamination and the examples discussed in section 2.2.

[48] There are ongoing discussions about the contamination level allowed for organic crops (so that even with some contamination they may still be called organic).

Environmental NGOs

Environmental NGOs are generally concerned about the risk of genes spreading to the environment, e.g. to wild relatives, which likely is irrevocable, and about health effects of GMOs when they enter the food chain. They are commonly strong supporters of the precautionary principle (see sections 4.2.2 and 4.4), and see GE as a risky technology in that respect. Moreover, possible environmental benefits of GMOs are often not delivered in their viewpoint.

Biotech industry

The GE industry, commonly referred to as the biotech industry, has large economic interests in a growing market for GMOs. They have made and are still making large investments in research and development of seeds and crops, as well as other products. Limitations for GMO farming are therefore not desirable, and consumer interest is an important factor, since this has a significant impact on the market.

2.4.2 The United States

In the US the approach to GE and GMOs has been different from the start of GMO development[49]. The underlying thought is that GMOs are 'like' non-GMOs: GMOs producing insecticide must undergo the same regulation process as other insecticides, food products containing GMOs are subject to the same rules as non-GMO food products. Three agencies are responsible for different aspects of the permission: the US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), the US Environmental Protection Agency (EPA) and the US Department of Health and Human Services' Food and Drug Administration (FDA). Depending on a product's properties, one or more of these agencies is involved in the approval process (NBII, 2006).

In recent years several proposals have circulated to tighten the US's GMO regulation (Zarrilli, 2005, pp. 14-15): Pre-market notice, voluntary labeling, and pre-cultivation field trials have been proposed, as well as a multi-tiered, risk-based authorization process.

The GE industry in the US is large: In farming, the US is responsible for approximately 55% of the total area used for GMO crops worldwide (ISAAA, 2005). Many of the multinational corporations providing seeds are US-based, such as Monsanto and Syngenta. These two branches – agricultural and biotechnology business – are both significant actors due to their size, and they have a large impact on US policy. Moreover, by lobbying European and other governments they also have an impact on GMO or trade policies worldwide.

2.4.3 Developing countries

Some specific issues exist for developing countries, more specifically for those countries that do not produce GMOs. First, they have a technological and regulatory disadvantage compared to developed countries. The regulatory system with control and enforcement may be underdeveloped, especially for a high-level technology such as genetic engineering. Also, detection of GMOs present in e.g. imported food products would require significant technological equipment, if at all possible.

[49] The US and European developments in this area were thoroughly discussed in Vogel (2002), where a parallel is drawn between US regulation of chemicals in the 1980s and current European GMO regulation.

This leads to the issue of separate processing systems for GMO and non-GMO seeds or crops, something that requires significant resources. Developing countries may consider this to be economically unsustainable. Moreover, the risk for contamination of non-GMO seeds or crops jeopardizes the export to for instance the EU, since the GMO food market is virtually non-existent there. This was one of the reasons why some African developing countries refused to accept food aid consisting of GMOs (Zarrilli, 2005, p. 7).

Another issue is the number of small farmers, which is generally large - family farming may be very crucial for the survival of a large number of people. Many of these farmers use a traditional way of farming, that is, they save seeds for next year's cultivation (Downes, 2004), and they may have a diverse cultivation (polyculture) in order to be less vulnerable for pests or other natural disasters. GMO agriculture on the other hand is more directed towards monoculture, and requires substantial investments and thus risk-taking for small farmers. Moreover, patenting and gene licensing agreements may make them very dependent on a single supplier (see section 2.2.2) and traditional knowledge may be lost.

According to Downes (2004), many of the patented plants are based on plant material found in developing countries, where it has been used with e.g. medicinal purpose, or where farmers have created certain species through selective breeding. For these existing varieties generally no compensation is given. This discussion is reflected in the CBD (see section 2.3.1). The number of patents on plant material has grown significantly since the TRIPs agreement (an agreement within the World Trade Organization on trade-related intellectual property rights, see section 3.6) came into being (Downes, 2004).

2.5 Conclusions

Genetic engineering has opened up a new area in agriculture; through the insertion of foreign genetic material, the number of potential new crop properties is enormous. Environmental benefits such as nitrogen fixation may be built into a crop, or the use of external inputs such as pesticides, fertilizers or other energy demanding and potentially environmentally damaging substances, may decrease as a result of the most common traits, herbicide resistance and insect resistance, or yields may be increased. Moreover, health benefits may occur, e.g. if a GMO contains extra vitamins or minerals.

However, there are some risks and disadvantages as well. Herbicide resistance may spread to weeds or wild relatives, and conventional or organic crops or seeds may be contaminated, and non-target organisms may suffer, e.g. because of loss of food resources or the insecticides being broad-spectrum. Moreover, the yield improvements may not be as large as expected, or the use of external inputs may increase instead of decrease. Indications exist for potential health problems related to consumption of some GMOs. A case-by-case approach is necessary, since each GMO behaves differently and may have unexpected effects to some extent. Another aspect of the current GE technology is intellectual property rights and dominance by multinational corporations over seeds and external inputs. This may lead to economic dependence and disempowerment of the farmer, especially in developing countries.

GMOs are regulated at the global level, at the European level - by regulations and directives - and in the EU to some extent at the national level, by the EU member states. The Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety are the only multilateral environmental agreements focusing on GMOs.

Genetic engineering is a field with stakeholders such as consumers, GMO- and non-GMO farmers, the environment and biotech industry. The stakes are high, and the interests diverse. All aspects combined, show that the field of GMOs is a difficult and sensitive issue to

regulate. The potential negative consequences must be anticipated and prevented, while benefiting from the potential positive attributes must be facilitated.

In the next chapter, agreements within the World Trade organization are discussed that are relevant for the area of genetically modified organisms.

3 The World Trade Organization

Now that sustainability issues connected to GMOs have been addressed, world trade issues that are relevant to GMOs are addressed in this chapter. Since the main arena where world trade is regulated is the World Trade Organization (WTO), some of the agreements within the WTO such as the General Agreement on Tariffs and Trade (GATT), the Agreement on Agriculture (AoA), the Sanitary and Phytosanitary Measures Agreement (SPS), the Technical Barriers to Trade Agreement (TBT) and the Agreement on Trade-Related Intellectual Property Rights (TRIPs) are discussed. Moreover, special attention is paid to possible conflicts between WTO agreements and the Convention on Biological Diversity (CBD), since both forums are international and have a large number of countries that are party to respective treaty.

In brief, the GATT regulates issues such as non-discrimination between domestic and imported products. The AoA deals with agricultural cultivated products, but does not have special measures for GE crops. Thus, for the current *EC – Biotech* trade dispute, this agreement is not relevant. The SPS on the other hand is highly relevant, since it allows countries to install sanitary or phytosanitary measures as protection against pest contamination and such. Thus, GMO regulation is generally seen as an SPS measure. Under the TBT agreement it is basically checked if policy measures or (voluntary) standards have legitimate justification, or if they cause illegal barriers to trade. The TRIPs agreement addresses patenting, a partial but potentially important aspect of GMOs that is also addressed within the CBD. TRIPs is not an issue in the *EC – Biotech* case, since this case does not concern patenting of GMOs.

3.1 Introduction to the World Trade Organization

The World Trade Organisation (WTO) originates from the beginning of the 20th century[50]. After the economic crisis of the 1930s and World War II, negotiations were held to increase worldwide trade in goods and reduce trade barriers. The opinion that tariffs and other barriers to trade had contributed to the 1930s crisis as well as to World War II is seen as a motivation for this. The negotiations initially resulted in the foundation of the International Trade Organisation (ITO), which in 1948 was replaced by the General Agreement on Tariffs and Trade (GATT) (Lowenfeld, 2003). Around that time even the so-called Bretton Woods institutions (the International Monetary Fund and the World Bank) were founded.

In the decades to follow, several trade negotiating rounds were held, mainly focused on the reduction of customs tariffs and the accession of new members. Topics such as non-tariff barriers, subsidies, dumping, public procurement and special treatment of developing nations (also known as special and differential treatment, or SDT) were formally discussed for the first time in 1973.

In the so-called Uruguay Round, lasting from 1986 to 1993, cross-border trade in services and intellectual property rights were included, and an umbrella organisation, the World Trade Organisation, was founded, which formally became operational in 1994[51]. In all, the influence of the GATT and WTO has moved from tariffs on goods to many aspects of society, amongst others protection of health and the environment.

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[50] This section is mainly based on Wohlmeyer and Quendler (eds), 2002, Ch. 2.

[51] The Uruguay Round was the first 'single undertaking' round, meaning that all WTO members must accept all multilateral agreements. such as GATT 1994, SPS, TBT, AoA, TRIPs *et al.* (Lowenfeld, 2003).

In the Marrakesh Agreement Establishing the World Trade Organization, a kind of mission statement is given in its preamble (WTO Agreement, 1994):

> " ... 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 so in a manner consistent with their respective needs and concerns at different levels of economic development ...".

The passage on sustainable development as well as on protection and preservation of the environment is new in comparison to GATT 1947 (GATT, 1947).

The main goals of the WTO can be summarized as follows: A reduction of tariffs, abolition of non-tariff barriers to trade, and increased access to markets through increased liberalization (Wohlmeyer and Quendler (eds.), 2002, Ch. 2; Jawara and Kwa, 2003, Ch. 1).

3.1.1 Structure of the WTO

The WTO deals with three main areas: international trade in goods, international trade in services and trade-related aspects of intellectual property rights. The three key agreements are thus:

- The General Agreement on Tariffs and Trade (GATT), for trade in goods
- The General Agreement on Trade in Services (GATS)
- The Agreement on Trade-Related Intellectual Property Rights (TRIPs).

Under the GATT, several agreements for specific sectors reside, such as the Agreement on Agriculture (AoA), Trade in Textiles and Clothing, and Trade-Related Investment Measures (TRIMs). Separate agreements are the Sanitary and Phytosanitary Measures Agreement (SPS) and the Technical Barriers to Trade Agreement (TBT). The organizational structure of the WTO is illustrated in Figure 5. Member countries are obliged to adhere to most agreements; only a few are so-called plurilateral agreements, i.e. voluntary agreements. One of these is GATS, where countries negotiate what services they open for liberalization.

Special mention must be made of the Committee on Trade and Environment (CTE). It was established in 1994, with the establishment of the WTO itself. Its mandate includes identifying the relationship between trade measures and environmental measures (WTO, 2004a, p. 5). Within the CTE discussions have been held on the relationship between MEAs and trade rules, and more specifically, on the relationship between TRIPs and the Convention on Biological Diversity (CBD). However, the CTE's effectiveness has been questioned (Bernasconi-Osterwalder, 2006, p. 312; Esty, 2001; UNEP and IISD, 2005; Phillips and Kerr, 2000).

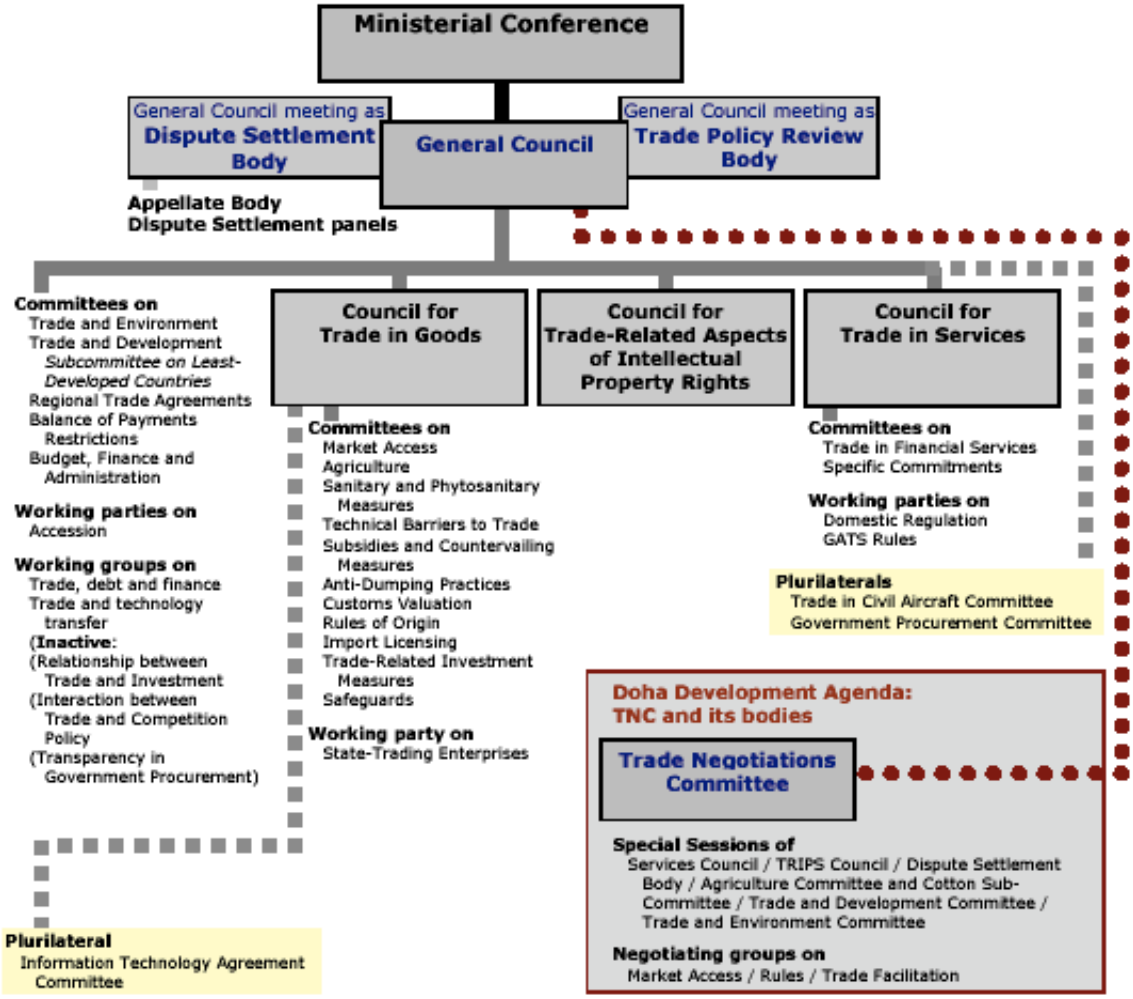

Figure 5. The organizational structure of the World Trade Organisation (WTO). Source: Understanding the WTO (WTO 2006c).

"Common" WTO principles

Some principles are common for all WTO agreements, such as *national treatment*, *most favoured nation*, *reciprocity* and *special and differential treatment* of developing nations[52]. National treatment means that 'internal taxes and regulations must treat imported products no less favourably than like domestic products'[53]. According to the principle of most favoured nation (MFN), WTO members must 'extend any advantage granted to a product from one WTO Member to 'like products' from all other Members'[54]. The key concept of 'like product' is explicitly mentioned in WTO agreements such as TBT and GATS. However, there is no definition of it, and it can be interpreted slightly differently depending on which agreement is considered. 'Like products' ties to the discussion on process and production methods (PPM) and is crucial for environmental discussions, since oftentimes the question whether a product is

[52] See e.g. Wohlmeyer and Quendler (eds.) (2002), Bernasconi-Osterwalder *et al.* (2006), and Lowenfeld (2003).

[53] Bernasconi-Osterwalder *et al.* (2006), describing GATT 1994 Article III (GATT, 1994).

[54] Bernasconi-Osterwalder *et al.* (2006), describing GATT 1994 Article I (GATT, 1994).

environmentally friendly is related to the way it is produced, e.g. organic food[55]. With respect to GMOs it is important whether GMO products are considered to be like non-GMO products. This is discussed more thoroughly in Chapter 4.

The principle of special and differential treatment (SDT), another 'cross-cutting' issue, may give developing countries special rights, trade preferences or assistance (WTO, 2006b). Examples are longer time periods for implementing agreements, special tariff cuts, and assistance in dispute settlement.

3.1.2 How does the WTO work?

Important practical aspects of the WTO are its decision-making structure as well as its dispute settlement procedure. The latter is described in the Understanding of Dispute Settlement (DSU, 1994).

Decision-making

Currently the WTO has 149 member countries (WTO, 2006a). Each member has one vote, and consensus is strived for in most decisions concerning agreements, administrative measures, etc. Majority voting has not been used yet by the WTO. The Ministerial Conference is the highest decision-making body, meeting biannually. The General Council, that is, ambassadors and heads of delegation to the WTO in Geneva, carries out the tasks in between ministerial conferences, directed by the decisions made at the ministerial conference. Other meetings occurring between ministerial conferences are working group meetings, committee meetings, and so-called 'mini-ministerial' meetings, informal gatherings with a selection of members (Jawara and Kwa, 2003, Ch. 1).

Trade negotiating rounds generally run for a number of years; current negotiations go under the name of Doha Development Agenda (WTO, 2006a). The negotiations were started in 2001, and were basically suspended in July 2006, due to difficulties in coming to an agreement. They covered issues such as trade in services, agriculture and implementation issues.

Dispute settlement[56]

One of the strengths of the WTO is its possibility to allow the issuing of monetary fines upon member countries that are breaching WTO rules. If a member country does not adhere to WTO rules, while another member country is suffering from the non-compliance, consultations with the non-complying member may be requested. If no solution to the dispute is found within 60 days, the member may then request a dispute panel to be installed. Within six months[57] this panel must present a final report with recommendations to the Dispute Settlement Body (DSB), which resides under the General Council[58]. The DSB may then make its decision. During this time, the parties may provide written and oral

[55] According to Lowenfeld (2003, 298-299), interest in environmental regulations started off as regulations on e.g. hazardous products, while there has been a shift towards also considering a (non-hazardous) product's production method and its impacts on the environment.

[56] This section is based on Lowenfeld (2003), section 8.1.

[57] As a side note, in the *EC – Biotech* case the panel was composed in August 2003. The final panel report was issued on September 29, 2006. The parties to the case may appeal this decision.

[58] The DSB is in practice equal to the general council of the WTO, see Figure 5.

submissions to the panel; Third parties (other WTO members) may do so as well to a certain extent.

Appeals only based on issues of law or legal interpretations – no new facts may be submitted - may be filed to the standing appellate body (AB), which then must give recommendations within 60 days and notify the DSB. The DSB must then decide, after which the members have 30 days to adhere to the decision. If the non-complying member does not adhere, the complainant may contact the DSB with the request to install retaliating measures against the non-complying member. Measures have been taken to ensure that no party has a veto at the crucial points in the process of establishing a panel, adoption of the panel report, and granting of retaliation.

Case law within the WTO is thus developed by the panels and the appellate body. Since the AB is a standing body, it is seen as a controlling organization of panel decisions and argumentations. Moreover, the AB is supposed to provide consistent development of WTO case law. Decisions issued by the AB carry therefore more weight than panel decisions.

3.2 The General Agreement on Tariffs and Trade

The General Agreement on Tariffs and Trade (GATT) was first agreed upon in 1947. The current version was updated in 1994 and is therefore called GATT 1994. The agreement has four parts and some annexes. Part 1 describes the most favoured nation principle (MFN) as was addressed in the previous section, while part II (article III – XXIII) starts out with the national treatment principle, also addressed in the previous section, and contains articles on anti-dumping, elimination of quantitative restrictions, subsidies and general and security exceptions, amongst others. In part III more practical issues are treated, such as entry into force and withdrawal. Finally in part IV (article XXXVI – XXXVIII and annex A – I) the central issue is trade and development. This part can be seen as the start of special and differential treatment (SDT), a WTO expression for developed countries providing special measures to promote trade of least developed countries (LDCs)[59].

Articles I and III have already been mentioned as being significant, since these mention 'like products'[60]. Article XX is a key article for the trade and environment discussion: it is a general exceptions clause, under certain conditions allowing members to adapt measures that are inconsistent with GATT obligations (Bernasconi-Osterwalder *et al.*, 2006, Ch. 2), presuming the measures

GATT article XX

General Exceptions

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

[...]

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

[...]

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

[...]

Box 3-1. General Agreement on Tariffs and Trade (GATT), article XX. Source: GATT (1994).

[59] Part IV of GATT was established in 1965, see Keck and Low (2004). The SDT became more formalized in 1979. Jawara and kwa (2003, pp. 46-47) question whether SDT is actually implemented or if it is more of a public relations term.

[60] According to Bernasconi-Osterwalder *et al.* (2006, pp. 9-17) 'like products' is mentioned in nine GATT articles, one TBT article and one article of the Agreement on Subsidies and Countervailing Measures.

are no 'disguised restriction on international trade' (GATT, 1994). The possible conditions are listed in subclauses (a) to (j), where subclauses (b) and (g) are relevant for environmental measures. The text of these subclauses is given in Box 3-1.

WTO jurisprudence in judging violations of article XX has evolved into a two-step testing of a measure: First, to see if a measure fulfils one of the subclauses, and second to check if the measure then is consistent with the chapeau. Thus, the architecture of the article itself, with a chapeau and discrete exceptions, has influenced jurisprudence (Bernasconi-Osterwalder *et al.*, 2006, p. 78)[61].

Of exception (b), 'necessary' must be tested. The Appellate Body has considered least-trade-restrictiveness and the extent of reasonably available alternatives in this matter. Important tests coming from the chapeau are arbitrary discrimination, unjustifiable discrimination and disguised restrictions on trade.

Moreover, the AB has taken into account issues such as sustainable development and efforts to solve issues through multilateral negotiations[62]. Also, flexibility is appreciated, e.g. when a WTO member prescribes a certain goal in turtle protection without prescribing the use of a certain turtle protection device[63].

3.3 The Agreement on Agriculture

Even though the Agreement on Agriculture (AoA) is not relevant for the discussion of GMOs in the WTO or for the *EC – Biotech* case, the agreement is very important for food issues and world trade, not the least since food can be seen as a basic necessity of life while food supply may be impacted heavily by trade issues.

In the AoA, signed in 1994, four areas are in focus (Wohlmeyer and Quendler (eds.), 2002, Ch. 2): the creation of a 'fair and market-oriented trade system', the initiation and introduction of a reform process, 'reduction of agricultural levies' as well as 'reduction of supportive and protective measures', and as an add-on special treatment for developing countries. Thus, the three pillars of the AoA are market access, domestic support and export subsidies (WTO, 2004), while non-trade concerns and special and differential treatment are considered important aspects as well[64].

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[61] Bernasconi-Osterwalder *et al.* (2006, p. 78). It is common that article architecture as well as exact content and wording play a role in panel or appellate body jurisprudence, as do subtle differences between different articles.

[62] From the *US – Shrimp/Turtle I* ruling, see Bernasconi-Osterwalder *et al.* (2006, pp. 251-252). A US measure to ban the import of shrimp caught with turtle-damaging equipment was challenged by India, Malaysia, Pakistan and Thailand under GATT article XX. The US was condemned by a panel and the appellate body (AB), since the measure was too unflexible, and no attempt had been made to reach a multilateral solution. The AB did not go so far as stating that such 'extraterritorial' measures (e.g. bans dictating other countries' environmental protection measures) are forbidden *per se*.

[63] From the *US – Shrimp/Turtle I* ruling, see Bernasconi-Osterwalder *et al.* (2006, p. 84). This is an important aspect in discussions on environmental protection and developing countries. Developing countries often do not have the same technical, regulatory or monetary possibilities as developed countries; Thus, imposing an unflexible environmental protection demand on certain products may be seen as a trade barrier by developing countries.

[64] Negotiations on percentage-wise reduction of tariffs and countrywise implementation were to be concluded during the Doha Development Round (see section 3.1.2), originally supposed to end by January 1st, 2005 (WTO, 2004), but now suspended.

Export subsidies

Currently 25 member countries are allowed to subsidize their export products, on the condition that these subsidies are reduced (WTO, 2004, pp. 19-30). Many of these countries are developed countries, such as the EU and the US, who historically have subsidized their export. Negotiations have focused on four categories: export credit, guarantee and insurance; food aid; exporting state trading enterprises; and export restrictions and taxes (WTO, 2004, p. 19).

Market access

Generally market access for agricultural products is only limited by tariffs, since with the birth of the AoA, members have agreed to convert non-tariff barriers to tariffs (WTO, 2004, 31-49). Exceptions regulated in other WTO agreements may be allowed and have an impact on market access. Now a complex system of tariffs and tariff quota exists. Negotiations have focused on six categories: tariffs; tariff quotas; tariff quota administration; special safeguards; importing state trading enterprises; and other issues (WTO, 2004, p. 31).

Domestic support

Many member countries have monetary support or subsidies to domestic production. Within the AoA, three types of such support are defined: 'green box' support, that is, allowed support, 'amber box' support, that is, support with a commitment from member states to reduce the total sum, and 'blue box' support, i.e. support aimed at limiting production of an agricultural product. A fourth subject of discussion is special and differential treatment, sometimes called the 'S&D box' (WTO, 2004, pp. 50-60). Some member states are making moves to change their subsidies e.g. from the amber to the green box.

One of the compromises reached during the Uruguay Round was the instalment of a 'peace clause', Article 13. This article protected certain agricultural subsidies from being challenged within the WTO (Morgan and Goh, 2003). Formally the peace clause ended in 2003; however, proposals to keep or alter the clause have been made (WTO, 2004, p. 73). Subsidies and other agricultural support mechanisms have been debated extensively at the different ministerial conferences and meetings, and are thus continuously negotiated.

3.4 The Agreement on Sanitary and Phytosanitary Measures

As mentioned before, the Agreement on Sanitary and Phytosanitary Measures (SPS) allows for measures to prevent spread of pests, spread of diseases carried by plants or animals, contaminants or poisons in foodstuff, etc (SPS, 1994). However, some obligations and principles must be obeyed when implementing SPS measures. As expressed in the preamble,

> "... no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade".

In brief, the measure must be grounded on scientific principles, and the measures should not be 'maintained without sufficient scientific evidence, except as provided for in paragraph 7 of article 5' (i.e. article 5.7) (SPS, 1994, article 2.2). Risk assessment is necessary (SPS, 1994, article 5.1). Relevant articles of the agreement are 2.2, 5.1 and 5.7 (see Box 3-2).

Through jurisprudence it has been established that the following principles must be applied[65]:

- Members have the right to determine their own appropriate level of protection.
- While risks to human, animal or plant life or health must be assessed, this assessment can be either qualitative or quantitative.
- Members are not obliged to rely on majority scientific opinions, but may base measures to protect human, animal or plant life or health on respected sources of divergent scientific opinion.

These principles are all crucial for the GMO debate, as is explained in the next chapter.

Articles 2.2, 5.1 and 5.7 of the SPS agreement

Article 2.2. 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.

Article 5.1. 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.

Article 5.7. 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.

Box 3-2. Articles 2.2, 5.1 and 5.7 of the Agreement on Sanitary and Phytosanitary measures (SPS). Source: SPS (1994).

Besides prescribing that measures are based on scientific principles, article 2.2 also states that measures '*only* to the extent necessary' (emphasis added) may protect human, animal or plant life or health. This implies that the measures may not be more trade-restrictive than necessary (also stated in article 5.6), although member states may determine their own level of protection.

Article 5.1 states that measures must be based on a risk assessment. Risk assessment is defined in the SPS agreement in annex A (see Box 3-3), and this definition is quite specific (Bernasconi-Osterwalder *et al.*, 2006, p. 261). Thus, not all forms of risk assessments are compliant with the SPS agreement, even though some flexibility is allowed through the passage 'appropriate to the circumstances'. The AB has ruled that article 5.1 is a specific application of the scientific principles requirement of article 2.2, and that risks to be taken into account may be risks in human society or laboratory risks. However, the extent to which e.g. socio-economic risks may be taken into account remains unclear (Bernasconi-Osterwalder *et al.*, 2006, p. 262). Moreover, an important issue is who will bear the costs for the risk assessment; does a member state have to prove that the risks with a certain GMO are too large, that is, perform its own risk assessment, or does the importer or supplier need to fulfil risk assessment requirements? The impact of WTO dispute rulings remains unclear in this context, as the *EC – Biotech* case indicates.

A precautionary approach may be justified through article 5.7 of the SPS agreement. It states that (SPS, 1994, article 5.7):

[65] Bernasconi-Osterwalder *et al.* (2006, p. 257), describing results from the *EC – Asbestos* case (see note 71).

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures ..."

However, members are obliged to seek completing information – a clear indication of who is responsible. Moreover, the article describes 'insufficient' information, that is, 'little or no reliable information'[66]. It was specifically stated that scientific uncertainty is not included in this. Jurisprudence has resulted in a four-step procedure to be followed (Bernasconi-Osterwalder *et al.*, 2006, p. 263):

Article 4 of Annex A of the SPS Agreement

Article 4*. Risk assessment* - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

Box 3-3. Annex A, article 4, of the Agreement on Sanitary and Phytosanitary measures (SPS), defining risk assessment. Source: SPS (1994).

- The measure may be imposed only if 'relevant scientific information is insufficient';
- The measure must be adopted 'on the basis of available pertinent information';
- The member must 'seek to obtain the additional information necessary for a more objective assessment of risk';
- The member must review the measure accordingly within a reasonable period of time.

Thus, a measure according to this article (the one article possibly allowing a precautionary approach[67]) is always temporary if it is to be WTO compliant.

Annex A of the SPS agreement defines what measures are covered by the agreement, and thus determines much of the scope of the agreement, and annex B describes transparency issues, e.g. notification and publication of measures. Lastly, annex C concerns the issue of control, inspection and approval procedures. Article 1(a) for instance states that '... such procedures are undertaken and completed without undue delay ...' (SPS, 1994, annex C).

3.5 The Agreement on Technical Barriers to Trade

The Agreement on Technical Barriers to Trade (TBT) has as its goal to ensure that requirements or (voluntary) standards issued by member states do not pose unnecessary barriers to trade (article 2.2), or result in unequal treatment of imported products compared to domestic ones (article 2.1) (TBT, 1994; Lowenfeld, 2003, p. 79). The agreement applies to

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[66] Bernasconi-Osterwalder *et al.* (2006), p. 263, describing the *Japan – Apples* case. The US challenged Japan for its measures to restrict import of American apples to try and prevent the introduction of fire blight, a disease targeting apples and other fruits. The measures were challenged under the SPS agreement. A panel and the appellate body ruled that Japan's measures violated SPS article 2.2, since according to the panel and AB there was ample evidence that the risk for spread of the disease is negligible, and thus the measure was judged to be disproportionate (Bernasconi-Osterwalder *et al.*, p. 288). Moreover, the 'precautionary' article 5.7 was not valid since the evidence in case was not insufficient. Also, article 5.1 was violated, since no valid risk assessment was performed.

[67] The appellate body has in the *EU – Hormones* case (see note 72) noted that article 5.7 is the 'most direct reflection of the precautionary principle' (Bernasconi-Osterwalder *et al.*, 2006, p. 268), even though a precautionary notion is also reflected in aricle 3.3 and the preamble of the SPS agreement.

Articles 2.1, 2.2 and 3.1 of the TBT agreement

Article 2.1. Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

Article 2.2. Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such 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. In assessing such risks, relevant elements of consideration are, *inter alia:* available scientific and technical information, related processing technology or intended end-uses of products.

Article 3.1. Members shall take such reasonable measures as may be available to them to ensure compliance by such bodies [Local Government Bodies and Non-Governmental Bodies] with the provisions of Article 2, with the exception of the obligation to notify as referred to in paragraphs 9.2 and 10.1 of Article 2.

Box 3-4. Relevant articles of the agreement on Technical Barriers to Trade (TBT). Source: TBT (1994).

all regulations that are not covered by the SPS Agreement (Wohlmeyer and Quendler (eds.), 2002, Ch. 3).

Since the agreement recognizes the need of members to protect human, animal and plant life or health, or the environment, amongst others, it can be seen as an attempt to balance trade requirements such as non-discrimination and not allowing barriers to trade, with concerns for health and the environment. In the preamble, similar language as in GATT article XX (see Box 3-1) is used.

The agreement promotes the use of international standards and harmonization, and obligates members to 'take such reasonable measures as available to them' to make sure that local governments and non-governmental bodies abide by the agreement's rules on preparation, adoption and application of technical regulations as well (article 3.1). It is not difficult to imagine that this may create tensions between the national government and the local government or non-governmental body.

Processes and production methods (PPMs) are mentioned in the agreement (annex 1, where 'technical regulations' and 'standards' are defined). Article 2.1 suggests that a similar 'like products' test as for GATT article III may be necessary.

Comparing the 'necessity' requirement in GATT, SPS and TBT, there are some differences (Bernasconi-Osterwalder *et al.*, 2006, pp. 152-153). One of them is the burden of proof: For GATT, the *responding* party in a trade dispute must prove that no alternative was available, while for SPS it is the *complaining* party that apparently must prove that an alternative is available. The language and status of the TBT necessity test is as yet unclear (Bernasconi-Osterwalder *et al.*, 2006, pp. 152-153). Moreover, when comparing the three agreements, SPS is the only one requiring measures to depend on scientific principles and risk assessment. Thus, it can be argued that the SPS agreement is the most stringent in this respect.

3.6 The Agreement on Trade-Related Intellectual Property Rights

As mentioned previously, the Agreement on Trade-Related Intellectual Property Rights (TRIPs) protects intellectual property (IP) in the area of computer programs, artistic works,

integrated circuits, geographical indications, *et al.*, but also patented foodstuff and pharmaceuticals. The agreement basically obliges members to adhere to the WIPO system (World International Property Organization), even if the WTO member is not a party to WIPO (Lowenfeld, 2003, p. 102). It contains articles on most favoured nation and national treatment, and obliges members to put in place enforcement procedures against IP infringements (TRIPs, 1994, article 41). These procedures must be 'fair and equitable', not 'unnecessarily complicated or costly', and not entail 'unreasonable time limits or unwarranted delay' (Lowenfeld, 2003, 102-103).

Articles 1.1, 8.1 and 27.3 of the TRIPs agreement

Article 1.1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

Article 8.1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Article 27.3. Members may also exclude from patentability:

[...]

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Box 3-5. Relevant articles of the Agreement on Trade-Related Intellectual Property Rights (TRIPs). Source: TRIPs (1994).

In Chapter 2 the issue of patentability of GMOs was already addressed; as may be seen from article 27.3(b) (see Box 3-5), some plants and animals and 'essentially biological processes' may be exempted from patentability according to TRIPs. However, the number of patents on plant material has grown significantly since TRIPs came into being (Downes, 2004).

TRIPs and the Convention on Biological Diversity (CBD)

As TRIPs focuses on patenting and intellectual property rights (IPRs), and the CBD (see section 2.3.1) describes aspects of genetic resources in terms of equal sharing of resources and access to technology, there is a conflict to be seen in the area of patenting genetic material or processes – something very crucial for genetic engineering.

The TRIPs agreement within the WTO came into force six months after the CBD. TRIPs was commented as 'universali[zing] the level of intellectual property protection of industrialized countries' (Bernasconi-Osterwalder *et al.*, 2006, 307-308), while CBD promotes traditional knowledge of indigenous and local communities. Article 16.5 of the CBD reads: patents and IPRs 'are supportive of and do not run counter to [the CBDs] objectives' (CBD, 2006). Another crucial point is the focus on private rights in TRIPs and the mentioning of state sovereign rights over natural resources. The question thus comes up whether these two agreements are in synergy or in conflict. A more thorough analysis (Bernasconi-Osterwalder *et al.*, 2006, Ch. 7) singles out the following main issues:

- Patenting of life forms – even though article 27.3(b) of TRIPs says that plants, animals and some essentially biological processes may be excluded from patentability (TRIPs, 1994) if an equally effective *sui generis* system is in place;

- Access to and fair and equitable sharing of benefits – within the CBD, prior informed consent is a key concept to facilitate fair sharing of benefits and to prevent misuse of e.g. genetic resources or traditional knowledge. This is not present in TRIPs;

- Preservation and respect for the knowledge, innovation and practices of indigenous and local communities – protection of traditional knowledge is not present in TRIPs;

- Transfer of technology – although it is mentioned as one of the objectives of TRIPs, it has not been promoted, and it is questionable whether the conventional IPR regime will do this at all.

However, it must be noted that TRIPs sets a minimum standard, and that more protective measures are allowed as long as they do not 'contravene the provisions' of TRIPs (1994, article 1.1). According to Zarrilli (2005), some issues of tension between the CBD and the WTO agreements are:

- If scientific evidence is not sufficient or not conclusive, what action may be undertaken by governments? This is an issue in the SPS agreement;

- What risk assessment and risk management measures are allowed? The CBD has no obligation to seek missing scientific information, while SPS has;

- Can socio-economic factors be taken in consideration in the decision making process? The CBD seems to allow trade-restrictive measures because of a 'loss of cultural traditions, knowledge and practices' (Zarrilli, 2005, p. 29), something that has been rejected in pre-WTO GATT jurisprudence;

- What kind of documentation is needed? The CBD does not have the obligation to review a sanitary or phytosanitary measure within a certain time, but the SPS agreement has.

Phillips and Kerr (2000) see some conflicting issues between the Biosafety Protocol and WTO principles:

- According to the BP, production and processing methods (PPM) may justify trade restrictions;

- The precautionary principle may be used to invoke import bans;

- Socio-economic factors may be considered;

- Labeling of some commodities that may potentially contain GMOs is mandatory.

From literature or expert comments it is not clear which treaty would prevail in case of a conflict[68]. This is illustrative for the issue of multilateral environmental agreements (MEAs) in the WTO.

[68] See for instance Phillips and Kerr (2000), Zarrilli (2005), and Bernasconi-Osterwalder *et al.* (2006) for a discussion on the balance between the WTO and the Convention on Biological Diversity (CBD).

3.7 Conclusions

In this chapter, agreements within the World Trade Organization (WTO) have been described that are relevant for GMOs and GMO policy. Examples are the General Agreement on Tariffs and Trade (GATT), the Sanitary and Phytosanitary Measures Agreement (SPS), the Technical Barriers to Trade Agreement (TBT) and the Agreement on Trade-Related Intellectual Property Rights (TRIPs).

Important trade terms for the GMO debate are 'likeness' of GMO- and non-GMO products, and whether a distinction can be made between them based on process and production methods (PPMs), something highly controversial in WTO circuits. Risk assessment is a challenging issue, since this may be difficult for a rather young and fast-evolving technology such as genetic engineering, but it is required through the SPS agreement.

The precautionary principle or approach is not explicitly mentioned in WTO agreements, but it seems to be allowed to use such an approach temporarily under certain limiting conditions. One of these conditions is *insufficient* scientific knowledge - while scientific *uncertainty* is not enough to allow the use of a precautionary approach.

There is a potential conflict between two agreements regulating trade with GMOs: the Agreement on Trade-Related Intellectual Property Rights (TRIPs) and the Biosafety protocol of the Convention on Biological Diversity. The former is more based on free trade of products, also GMOs, and protection of intellectual property, while the latter is based on a precautionary approach, valuation of traditional knowledge and sharing of benefits.

In the next chapter, the *EC - Biotech* case is discussed, as this case brings together the issues of genetic engineering, GMO policy and world trade rules, and illustrates the stakes of the debate.

4 The *EC - Biotech* case

One of the most publicized cases brought before a WTO dispute panel is the case "European Communities – Measures affecting the approval and marketing of Biotech Products" (WTO, 2006d), or *EC – Biotech* in brief. The US, together with Canada and Argentina, accused the EU of having breached WTO regulations in the case of GMOs, since the EU has been restrictive in allowing commercial GMO seeds on the EU market. The main focus of the complainants was on a perceived moratorium on GMOs, but also the refusal by the EU as well as some member states to allow some specific GMOs on the market was targeted. The request to establish a panel was filed in 2003, and the case thus mainly targets EU GMO policy from before 2002.

This case forces an intersection of trade and environment. Many aspects described in the previous chapters are present: GMO policy in the EU and its member states, environmental and other aspects of GMOs, trade rules and their impact on environmental protection, and multilateral environmental agreements in the world trade system. In this chapter the *EC – Biotech* case is introduced, and issues at stake are addressed. Moreover, the preliminary outcome of the WTO trade dispute is described.

4.1 Introduction to the case

As was stated in the introduction of this chapter, three main elements of EU GMO policy are targeted in the case: The EU '*de facto*' moratorium, EU product specific measures and member states safeguard measures.

Between 1998 and 2003 the EU did not approve any GMO application. This was perceived as being a '*de facto* general moratorium', and as such questioned by the complainants. Moreover, the refusal to approve specific GMO products was targeted in 27 cases, being EU product-specific measures (CIEL, 2006). Subject to the case are also several EU member states' bans on certain GMO products, so-called safeguard measures in EU language, in accordance with Directive 2001/18/EC. Nine such safeguards were concerned, of six member states: Austria, France, Germany, Greece, Italy and Luxembourg.

The *de facto* moratorium ended in 2004[69] with the approval on EU level of a GMO crop, and the assessment for approval is made on a case-to-case basis in accordance with EU Directive 2001/18/EC[70]. However, several member states have issued safeguard measures on specific GMO products, and an EC proposal put forward in June 2005 to end these national bans (the safeguard measures) was 'rejected overwhelmingly' by member states (FOEI, 2006).

The US, Canada and Argentina started the consultation process in May 2003, and a panel was established in August of that year and finalized in March 2004 (WTO, 2006d). In February 2006 the panel issued a preliminary ruling, officially only submitted to the parties of the dispute but leaked to the NGO Friends of the Earth. Section 4.4 is based on this preliminary report. A final ruling has been issued in May 2006, and this report became public in September 2006.

[69] It is argued that this approval was given e.g. due to pressure from the WTO case (FOEI, 2006), or in an attempt to make EU GMO legislation compatible with WTO rules (see e.g. Euractiv, 2006).

[70] Since then 4 products have been approved by the EU, and 8 transferred to Regulation 1829/2003, see Appendix 5.

The panel has not only looked at the situation of EU GMO legislation before 2003, but has taken the current legislation into account as well (*EC – Biotech* panel, 2006), for instance to assess the intent of where EU legislation pre-2003 was heading.

4.2 Issues potentially at stake

A trade dispute may have an impact on a number of levels. For example, as was stated in Chapter 3, WTO jurisprudence develops interpretation of trade laws, and of course the defending country's targeted legislation may have to be changed. So what is potentially at stake in the *EC – Biotech* case?

According to Kerr (1999) a GMO trade dispute has certain distinct characteristics. First of all, major regulatory differences exist between the major players in this case, the EU and the US (see Chapter 3 and Zarrilli (2005)). Therefore, US GMO farmers perceive their exports to be unjustly limited, so they will push for a trade dispute. Second, technological developments may go so fast in this highly technological area that regulations cannot keep up with developments, and will be perceived to be unfair.

Third, it is unlikely that a scientific consensus on the pros and cons of GMOs will evolve in the near future. Thus, other bodies to which the WTO refers, such as the Codex Alimentarius (Mbengue and Thomas, 2005), are not likely to publish a harmonized standard on GMOs. Fourth, as has been noted in section 2.3.2, each GMO product, if allowed at all, is commonly assessed on a case-by-case basis. Each of these assessments could potentially produce a conflict. Fifth, there is considerable debate regarding the 'long-run effects [of GMOs] on human health and the environment' (Kerr, 1999). Since these long-term effects cannot be ascertained with scientific certainty, but indications of possible effects exist, can the precautionary principle then be invoked?

The issues at stake are first of all the EU GMO legislation, especially from before 2003, and the question whether it is WTO compliant or not. Moreover, interpretation of WTO agreements and terms may be due, such as like products, scientific evidence, risk assessment and undue delay. These are terms from WTO agreements such as GATT, SPS and TBT and are relevant for this case. Third, broader 'trade and environment' principles are at stake such as the status of the precautionary principle in trade agreements, and the coexistence of multilateral environmental agreements (MEAs) and trade agreements. Last, issues such as the reputation of the WTO and transatlantic trade relationships may be impacted by this case. Also, third parties such as developing countries may be impacted, e.g. with respect to GMO legislation or trade relations. These issues will be addressed in the sections below.

4.2.1 Relevant WTO terms

Like products

As described in section 3.2, one of the issues related to GMOs and world trade is the concept of 'like products'. Proponents of free trade in GMOs often state that there is no inherent difference between e.g. a GMO and a non-GMO tomato. As was addressed in Chapter 2, this simplification may not always be true, since for instance health impacts may differ. Moreover, according to Busch and Howse, one of the factors taken into account by WTO dispute bodies is consumer perception of the likeness of products[71]. The case may be made that consumers,

[71] This is WTO jurisprudence from the *EC – Asbestos* case (Busch and Howse, 2003). Canada challenged the EU for a French ban on the manufacturing, sale and import of asbestos fibres under GATT articles III and XX. The appellate body ruled that asbestos fibres are not 'like' non-carcinogene fibres, with a reference to consumer perception, and that article III(4) was thus not violated. The EU's defense that the ban was necessary for protection of human life and

especially in the EU, consider GMO products to be different from non-GMO products (Busch and Howse, 2003, p. 6).

Risk assessment

Several SPS issues and terms may play a significant role in this case, of which one is risk assessment (see section 3.4). As was addressed in Chapter 2, uncertainties exist about the long-term consequences of GMOs as well as their sometimes unpredictable behaviour. Kerr (1999) argues that such uncertainty makes it impossible to perform a risk assessment, as risk assessments are generally based on statistical probabilities, not uncertainties. Moreover, within the SPS agreement risk assessment is interpreted as evaluating the probability of a risk, not the possibility (Bernasconi-Osterwalder *et al.*, 2006, p. 263; Lowenfeld, 2003, p. 329).

WTO jurisprudence states that 'all matters not susceptible of quantitative analysis are excluded' from the scope of a risk assessment (Oliva, 2005)[72]. However, article 5.1 of the SPS agreement says that a risk assessment must be 'appropriate to the circumstances' (see section 3.4). In the case of GMO legislation this may provide some flexibility to e.g. take into account local or regional circumstances. Moreover, the risk should be the 'risk in human societies as they actually exist' (*EC – Hormones* Appellate Body report, as cited in Oliva (2003)). According to Oliva and Bernasconi-Osterwalder *et al.* the interpretation of risk assessment is rather broad, even though there are some limiting interpretations as well, as mentioned above.

An important aspect in the case of GMOs is that from WTO jurisprudence, minority scientific opinions may also validate the scientific basis for a risk assessment. Since scepticism towards the effects of GMOs seems to be a minority opinion, this is crucial.

Within the Biosafety Protocol (BP) the scope of a risk assessment is broader (see section 2.3.1), for instance, socio-economic factors are allowed to be considered. Thus, if the dispute panel would take the BP (a multilateral environmental agreement) into account, this could broaden the scope of risk assessments for GMO applications (Olivera, 2005).

Scientific evidence

A protective measure in accordance with the SPS agreement must be based on scientific principles and not maintained without 'sufficient scientific evidence' (see article 2.2 of the SPS agreement in section 3.4). As was stated in this section, also minority science may be taken into account according to WTO jurisprudence.

A second issue is the difference between insufficient and inconclusive scientific evidence. To reiterate from section 3.4, insufficient evidence justifies the use of article 5.7 – and have an

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health (article XX(b)) was accepted, and Canada had according to the AB not shown that a reasonable alternative measure was available (Bernasconi-Osterwalder, 2006, p. 175).

[72] WTO jurisprudence from the *EC – Hormones* case (Oliva, 2005). This case focused on the SPS agreement as well – in fact, it was the first case to consider this agreement. Canada and the US challenged EU measures to ban the import of meat from cattle treated with bovine growth hormones (BGH). The EU invoked the precautionary principle, since there does not seem to be conclusive evidence that BGH meat is damaging for human health. The appellate body ruled that the EU violated article 5.1 of the SPS agreement, since the measure 'was not sufficiently based on a risk assessment' (Bernasconi-Osterwalder *et al.*, 2006, p. 268). The EU has chosen to keep the ban, and paying trade sanctions to the US and Canada, something the EU in its turn is challenging, since it claims that it has made sufficient changes to its import restricting measures.

SPS compliant measure – while inconclusive evidence does not[73]. In the case of GMOs there is generally an abundance of evidence, and thus, as indicated by Oliva (2005), article 5.7 may be problematic to invoke, even though the evidence may not be relevant for a specific region (Kerr, 1999).

Undue delay and provisional measures

Two time-related terms of the SPS agreement are 'undue delay' and 'provisional' measures. In section 3.4 it was already pointed out that the SPS agreement requires WTO members to undertake and complete SPS procedures without 'undue delay'. Since the EU allegedly had a *de facto* moratorium in place (see section 2.3.2), causing long delays in approving GMO products, and is still having product specific bans in place, this may be an important aspect of the case.

The second time aspect, that is, measures being temporary, is provided by SPS article 5.7, as this article only allows provisional measures, with the obligation for the WTO member to seek for more information. In the case of GMOs, waiting for more conclusive evidence – or scientific consensus – may be causing undue delay.

4.2.2 The precautionary principle

In environmental issues the precautionary principle was first implemented in the 1970s in Germany. The approach calls for public policy action when there are strong indications of 'potentially serious or irreversible threats to the environment', before there is strong proof (EEA 2001). Often the economic dimension of protective measures is considered as well (see for instance Box 4-1 on the UN Rio Declaration). It is referred to in many environmental and health public policies and multilateral environmental agreements, such as the European Union Communication on the precautionary principle (see Box 4-2), the Montreal protocol on substances that deplete the ozone layer, the Framework convention on climate change and the Biosafety Protocol (see section 2.3.1). However, it is not clearly defined, and different terms are in use such as the precautionary principle, approach or measures. Partly due to this ambiguity – and the principle's implications - the principle and its use is hotly debated within the trade and environment area (Lowenfeld, 2003; Bernasconi-Osterwalder *et al.*, 2006; Kerr, 1999; Busch and Howse, 2003; Sindico, 2005).

The Rio Declaration on environment and development, principle 15

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

Box 4-1. The precautionary approach according to the Rio Declaration. Source: UN (1992).

In the area of GMOs, the discussion in Chapter 2, as well as the preamble of EU directive 2001/18/EC and the Convention on Biological Diversity (CBD), show that a precautionary approach may be needed (EU 2001/18/EC, 2001; CBD, 2006; Sindico, 2005). With regard to the precautionary principle in WTO agreements it has been stated previously that the SPS

[73] Here it is interesting to consider how the 'inconclusiveness' of evidence and minority science interact. From a common sense point of view one may think that a significant, diverging, minority scientific opinion may lead to the total body of evidence being inconclusive. WTO jurisprudence does not seem to have addressed this.

The EU and the precautionary principle

In its Communication on the precautionary principle (EC, 2000), the European Commission (EC) puts the principle in both an EU perspective and an international law perspective, illustrating its use within international environmental treaties and discussing its presence in WTO agreements. However, the principle is not defined. "Whether or not to invoke the precautionary principle is a decision exercised where scientific information is insufficient, inconclusive or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection" (EC, 2000, p. 8).

Box 4-2. The EU on the precautionary approach. Source: EEA (2001); EC (2000).

agreement is basically the only agreement containing a precautionary notion[74], more specifically in article 5.7. Thus, discussions on the principle in relation to the WTO tend to focus on the SPS agreement. Briefly reiterating from section 3.4, a WTO-compatible precautionary measure – based on insufficient scientific evidence – may only be a provisional measure, and completing data must be gathered by the member state.

In WTO jurisprudence, four cases have played a significant role in the discussions on the precautionary principle: The *EC – Hormones, Australia – Salmon, Japan – Varietals* and the *Japan - Apples* case (Mbengue and Thomas, 2005)[75]. The *EC – Asbestos* case touched upon the precautionary principle within GATT 1994, but neither the panel nor the appellate body report, shed much light on the issue of the principle.

From the *EC – Hormones* case stem the four requirements as mentioned in section 3.4, but also a first recognition of the precautionary principle in WTO jurisprudence, according to Mbengue and Thomas (2005). On the other hand, jurisprudence in this case and in the *Australia – Salmon* case[76] limits the scope of the SPS agreement's risk assessment to risks with a certain probability, excluding possible (i.e. theoretical) risks. These results point to the situation where *preventive* measures will be allowed, but not *precautionary* measures[77].

In *Japan – Varietals*[78] the panel and AB allegedly limited further the scope of article 5.7 (Mbengue and Thomas, 2005; Bernasconi-Osterwalder, 2006), while in *Japan – Apples* the AB made the statement that article 5.7 of the SPS agreement is not triggered by scientific uncertainty, but by insufficient evidence. However, when describing the precautionary principle, scientific uncertainty is often mentioned as one of the causes for precaution. Thus, the AB hereby also limited the precautionary notion in article 5.7.

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[74] Neither precaution nor science is explicitly mentioned in GATT 1994 or the TBT agreement, according to Bernasconi-Osterwalder *et al.* (2006, p. 256).

[75] The *EC – Hormones* case is briefly explained in note 72, the *Japan – Apples* case in note 66, and the *EC – Asbestos* case in note 71.

[76] In the *Australia – Salmon* case, Canada challenged Australia's import prohibition of certain kinds of (uncooked) salmon, out of concerns for the spread of a disease from North-American salmons to Australian ones. Canada claimed that the prohibition was more trade restrictive than necessary, thus breaching article 5.6 of the SPS agreement. The panel agreed, and the appellate body as well, although it based its ruling on different arguments. The AB also established the right of a WTO member to choose its own appropriate level of protection (Bernasconi-Osterwalder *et al.*, 2006, p. 185).

[77] See Mbengue and Thomas (2005) for a more extensive discussion on the topic of precautionary vs. preventive measures.

[78] In the *Japan – Varietals* case, the US challenged Japan's import prohibition of certain fruits under the SPS agreement. The measure was issued in 1950 to prevent the establishment of the codling moth. If an efficient quarantine progam was guaranteed by the exporting country, Japan would lift the prohibition. The appellate body ruled that the measure violated article 2.2 of the SPS agreeemnt, due to lack of scientific evidence. Moreover, article 5.7 was not applicable since no additional information had been sought by Japan, and the measure was not reviewed within a reasonable time (Bernasconi-Osterwalder *et al.*, 2006, pp. 282-283).

It is clear that a ruling in the *EC - Biotech* case may have a significant impact on the interpretation of the precautionary principle in the WTO and its agreements. In section 4.3 details of this case will be discussed, and in section 4.4 the interim ruling of the panel will be described.

4.2.3 Multilateral environmental agreements in the WTO

The issue of multilateral environmental agreements (MEAs) in coexistence with trade rules has been debated fiercely, both within trade and environmental circuits[79]. Simplified, free trade proponents sometimes argue that environmental protection measures (and MEAs) are protectionist and may be barriers to trade, while environmentalists say that unlimited trade is sometimes harmful to the environment. Of the approximately 200 MEAs, about 20 have trade provisions (WTO, 2004a). However, Eckersley (2004) noted that

> "... [T]he expanding reach of the WTO's trade agreements does serve to cramp the scope and operation of MEAs ..."

In theory the two sets of rules may coexist in accordance with the principles of public international law. On the other hand, more clarity could be helpful, something which was reiterated at the Doha Ministerial Conference and which guides the WTO Commission on Trade and Environment (CTE) in its work (see also section 3.1.1). Also, formal negotiations were mandated on the relationship between 'WTO rules and specific trade obligations set out in MEAs', as long as other WTO rights and provisions will not be altered (WTO, 2004a, p. 10). Generally, it is often stated that trade rules and MEAs should be 'mutually supportive' to achieve sustainable development, a goal that is also mentioned in the agreement establishing the WTO.

An important move in trade dispute positions has occurred since the pre-WTO times. Panels and the appellate body have opened up for taking into account 'public international law' when interpreting trade rules (UNEP and IISD, 2005, p. 67). This would include MEAs as well. More specifically, in the *US – Shrimp/Turtle I* case[80], the appellate body took several other treaties into account, even treaties to which not all dispute parties were a member (CIEL, 2006, 47-48), although it also noted that this was no obligation.

As was discussed in section 2.3.1, the only multilateral environmental agreement dealing with GMOs is the Convention on Biological Diversity (CBD). Except for the conflicting measures in TRIPs vs. the CBD, which is not at issue in the *EC – Biotech* case, some remarks may be made on the impact of the CBD. A possibility is that this specialized MEA will be used by the panel to interpret some parts of WTO legislation, such as risk assessment or scientific uncertainty. As mentioned before, the *US – Shrimp/Turtle I* case has opened up for taking into account MEAs in this respect. Moreover, the CBD can be used as a relevant source of information (Oliva, 2005).

Also for the status of MEAs in the WTO, the *EC – Biotech* case could prove to have an impact. In section 4.3 details of this case will be discussed, and in section 4.4 the interim ruling of the panel will be described.

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[79] See for instance Lowenfeld (2003), Bernasconi-Osterwalder *et al.* (2006), UNEP and IISD (2005) and WTO (2004a).

[80] See note 63.

4.2.4 Effects of the case on EU GMO policy

When it comes to the possible impact of the *EC – Biotech* case on EU legislation, the direct issue is of course whether EU GMO legislation is WTO-compatible. For instance, can member states keep their safeguard measures? Is it allowed to ban a GMO product at all, and is the risk assessment procedure in accordance with WTO rules?

Moreover, there may be indirect effects within the EU. Will there be a push for more harmonized legislation, or a renewed attempt to remove the national bans? The literature suggests that the case may have an impact. Similarly, news articles expressed such concerns (Planet Ark, 2005):

> "Fearing a new trade war, the Commission is keen to show the three complainants that Europe is ready to push GMO applications through the EU system, diplomats say. [...] "The WTO outcome will clarify things and inject some reality into the GMO debate, which at the moment is dominated by the idea that the EU can do whatever it likes," one said. "The ruling is the only thing that can bring any kind of political movement."

According to the International Herald Tribune (IHT, 2006):

> "Facing international pressure and a lawsuit at the World Trade Organization, the EU said this year that all member states must open their doors to GMOs".

Moreover, Euractiv wrote (Euractiv, 2006)[81]:

> "The final ruling will not have immediate effects, because it concerns the EU GMO moratorium, which ended in April 2004. It may however affect the way that the EU deals with GMOs in the future. New, more permissive rules on GMOs were introduced in 2004 partly to address concerns brought forward by the EU's adversaries in the trade dispute."

Some members of the EC (European Commission) proclaimed a more open stance towards GMOs after the ruling had come out (Seedquest, 2006):

> "Where a product has been shown not to be harmful, in principle the rules of the free internal EU market apply. So, also, do WTO rules, as we have seen. The debate on co-existence must be about ensuring co-existence, not preventing it."[82]

The direct consequences of the interim ruling are discussed in section 4.4, while both the long-term and the more indirect consequences of the ruling are discussed in Chapter 6.

4.2.5 Other issues

It has been argued[83] that taking the case to the stage of establishing a panel was more damaging than helpful, for example with regard to the case's potential negative impact on consumer attitudes, transatlantic diplomatic and trade tensions, or the impact of the WTO ruling on a sovereign state's (or in this case the EU's) domestic policy, including 'democratic regulation of risk and its scientific basis' (Busch and Howse, 2003). Moreover, the reputation

[81] Euractiv is an independent media portal fully dedicated to EU affairs, see www.euractiv.com.

[82] EC Commissioner of Agriculture Fischer Boell, quoted in Seedquest (2006).

[83] See for instance Busch and Howse (2003).

of the WTO itself could be damaged, as 'there is a very real risk that even a modest victory [of the complainants] in the GM products case could turn the political tide against the World Trade Organization' (Busch and Howse, 2003). The impossibility for the panel to base their decision on sufficient information and scientific consensus at this stage could also damage the WTO's reputation (Kerr, 1999). Also, tensions between EU member states could rise, tensions that will 'prove untimely' (Busch and Howse, 2003) considering the animosity already occurring between member states on a range of topics.

Another consequence of the case could be the precedent-setting rule for or against strong GMO legislation. If the EU loses the case, this gives a strong signal to other countries not to pursue similar legislation. On the other hand, if the EU wins the case, a signal is given that WTO-compatible regulation of GMOs is possible, and other countries may follow a similar path. According to Zarrilli (2005, p. 6), many developing or LDC countries are in the process of establishing regulation of GMOs. Having them establish a certain kind of legislation may have a large impact on future markets for GMO exporters such as the US, Canada and Argentina.

4.3 The case

4.3.1 Alleged violations of agreements

The complainants claimed that the EU violated three agreements (EC - Biotech panel, 2006): The agreement on Sanitary and Phytosanitary measures (SPS)[84], on Technical Barriers to Trade (TBT)[85], and the General Agreement on Trade and Tariffs (GATT 1994)[86]. Most focus has been on the SPS rules. According to IATP the complaining parties claimed (IATP, 2005):

1. The existence of the alleged moratorium is a violation of the SPS rules against 'undue delay' in SPS agreement approval procedures;

2. Failure to notify the moratorium as an SPS measure is a violation of SPS agreement rules on transparency of rule making and notification of domestic SPS measures to the WTO SPS committee;

3. The EC [European Commission] and EC [EU] member states failed to publish risk assessments on the likelihood of harm resulting from biotech products as required by article 5.1;

4. The alleged moratoria are maintained without 'sufficient scientific evidence' in violation of article 2.2;

5. By regulating biotech products, such as genetically engineered seeds, more strictly than biotech processing agents, such as enzymes used in food manufacturing, the EC violates article 5.5, which seeks to ensure that WTO agreements apply SPS measures indiscriminately to domestic and imported products 'in comparable situations'.

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[84] For the *de facto* moratorium: articles 2.2, 2.3, 5.1, 5.5, 5.6, 7, 8, 10.1 and Annexes B(1), C(1)(a) and (b). For the product-specific measures: articles 2.2, 2.3, 5.1, 5.5, 5.6, 7, 8 and Annexes B(1), C(1)(a), (b), (c) and (e). For the member state safeguard measures: articles 2.2, 2.3, 5.1, 5.5 and 5.6 of the SPS Agreement.

[85] For the product-specific measures: articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12. For the member state safeguard measures: articles 2.1, 2.3, and 2.9 of the TBT Agreement.

[86] For the *de facto* moratorium: article III:4. For the product-specific measures: article III:4. For the member state safeguard measures: articles III:4 and XI:1 of GATT 1994.

A full overview of all alleged violations is given in Appendix 6[87]. The complainants were not challenging the GMO legislation itself, e.g. they did not challenge the right to demand a risk assessment before market approval or the right *per se* of member states to impose safeguard measures. However, they did question the legality of the *de facto* moratorium, of the EU product-specific measures and of the national safeguard measures, along with some other challenges.

4.3.2 EU Defense

With regards to the product-specific measures, the EU defended itself by stating that the SPS rules do not apply since the 'alleged delay in completing the approval procedures [...] does not, itself, constitute a sanitary or phytosanitary measure'[88]. But even if they are considered such measures, the delays are not undue but caused by 'legitimate requests for information' and the 'implementation of [EU] Directive 2001/18' (IATP, 2005). Moreover, according to the EU the SPS Agreement was not intended to address the prevention of risks to the environment (EC - Biotech panel, 2006b, art. 4.355) – it encourages the panel to take into account the Cartagena Protocol on Biosafety (EC - Biotech panel, 2006b, art. 4.358).

The *de facto* moratorium, according to the EU, was first of all non-existent, but if the panel would judge that it existed, it was not an SPS measure either, only an application of such a measure (EC - Biotech panel, 2006b, art. 4.368-4.372).

When it comes to the member state safeguard measures, the EU admitted that these are SPS measures, allowed under article 5.7 (see Box 3-2), since they are temporary. Moreover, with regard to other claims of the complainants, the EU mentions the consideration of different circumstances (SPS, 1994, art. 5.1), and member states' appropriate level of protection (EC - Biotech panel, 2006b, art. 4.373-4.378).

4.4 A preliminary outcome: the ruling

In February 2006 the panel came with an interim ruling, submitted only to the parties of the dispute, but leaked to an environmental NGO (EC - Biotech panel, 2006). Based on this version, several analyses have been made[89].

The panel focused mainly on the SPS agreement, not as much on the GATT or TBT challenges. SPS is generally considered to be stricter than relevant GATT and TBT articles (CIEL, 2006). First of all, the panel ruled that the purpose and targeted concerns of the EU measures could be seen as residing under the SPS agreement. However, the panel also concluded that the EU measures *per se* (the moratorium and the EU product-specific measures) were not to be seen as SPS measures as defined in the SPS agreement. It noted that the complaining parties 'had not challenged these procedures as such, but rather the application of these procedures' (CIEL, 2006, p.9). Thus the panel avoided having to consider the WTO-compliance of EU GMO legislation *per se*.

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[87] For more extensive coverage of the dispute see FOEI (2006), IATP (2005) and the official WTO webite for this case, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm.

[88] EC Biotech products: "First written submission by the European Communities." (May 17th, 2004, paragraph 469, cited in IATP (2005).

[89] See e.g. FOEI (2006), CIEL (2006) and IATP (2006). These analyses as well as the text of the interim report itself are the basis for this section.

Other initial findings of the panel were that a *de facto* moratorium existed, but not a *de jure* (expressed in policy or legislation). Thus, the moratorium is an implementation, not a measure in itself. The panel then went on to check if the moratorium as implementation violated the SPS, and found that it violated Annex C(1)(a) and thus article 8. Annex C(1)(a) contains the 'undue delay' clause, meaning that an SPS measure should not cause undue delay[90], something which the moratorium did. It was not established that the EU moratorium violated articles 2.2, 2.3, 5.1, 5.5, 5.6, 7, 10.1 and Annexes B(1), and C(1)(b).

It seems to have been crucial that the moratorium was *de facto*, not *de jure*, and that the complainants had focused on the moratorium, not the EU legislation itself. Thus, many SPS clauses did not apply. The panel followed the EU arguments in this part.

The product-specific measures were also not judged to be SPS measures, but implementations. Thus, they were not subject to the requirement of science-based decision making. According to the panel, 24 out of 27 measures were causing undue delay, violating Annex C(1)(a) and thus article 8 (EC - Biotech panel, 2006b, art. 8.18, 8.38 and 8.53).

With respect to several member states' safeguard measures, the panel ruled that these are SPS measures, while not based on risk assessment, and that all of them breached article 5.1, which says that a measure must be based on such an assessment. Moreover, these national safeguards 'did not fall within the scope of article 5.7', the clause with precautionary intent. In WTO jurisprudence it thus automatically follows that these national safeguards also violate SPS article 2.2. The panel did not rule that import bans *per se* are illegal. The EU member states are therefore prompted to bring their safeguard measures in line with the SPS agreement.

The panel in its initial findings broadened the scope of the SPS agreement, by arguing that relevant terms such as pests, substances, food and feed, additives, toxins and contaminants should be interpreted quite broadly (CIEL, 2006, pp. 15-18). Since the SPS is arguably stricter than other agreements, this makes it harder for sanitary or phytosanitary measures to be WTO compliant. On the other hand, the panel recognized article 5.7 to be an autonomous right, not just an exception clause. Moreover, according to WTO jurisprudence, countries do have their own right to set their own acceptable risk level. But as mentioned earlier in this section, the panel ruled that the safeguard measures did not fall under article 5.7. In their reasoning they significantly narrowed the application of article 5.7; When analyzing the claim of the EU, that a risk assessment must be adequate for the member state's appropriate level of protection, they interpreted 'adequate' as 'having a sufficient amount of information' to perform a risk assessment in agreement with the risk assessment definition in SPS. Considerations regarding adequacy in respect to a country's chosen level of protection (i.e. the quality of information rather than the quantity) were dismissed by the panel (CIEL, 2006, p. 43). This leads to the conclusion that as soon as an SPS-compatible risk assessment is possible, article 5.7 no longer applies and a precautionary approach cannot be invoked. This severely limits the scope of article 5.7. As concluded by CIEL (2006, p. 45):

> "The interim report, by excluding all cases where a risk assessment has been conducted from the scope of article 5.7, regardless of the uncertainty or inconclusiveness of its results, raises serious concerns for the right of WTO members to adopt and maintain their chosen level of SPS protection".

One of the considerations used by the panel was that all products banned by a national safeguard measure had been approved by a scientific body at EU level (the European Food

[90] While deliberating on Annex C(1)(a) and the term undue delay, the panel consulted dictionaries and previous cases, since the term 'undue delay' is not defined in SPS. Neither did the panel give a definition now, but it said that it must be assessed on a case-by-case basis whether a measure causes undue delay (EC – Biotech panel, 2006).

Safety Authority, EFSA), and thus, adequate information had been available. This leaves open several questions: What if the EU scientific body and a national competent authority come to a different conclusion on a risk assessment? What if the EFSA is not taking into account national or regional considerations or specific ecosystem sensitivities? It turns out that the role of EFSA has been debated fiercely, also by EC members (IHT, 2006):

> "The European Food Safety Advisory, or EFSA, commission of the European Union provides scientific judgments on such matters. But this agency's core mandate concerns food safety and even the EU environment commissioner, Stavros Dimas, said recently that it had not looked adequately at long-term effects of GMOs on issues like biodiversity".

An EFSA official was cited by Reuters (2006a):

> "Another EFSA official said recently that it was natural that the agency was using short-term data from the industry in its assessments because GMOs were fairly young as a scientific subject and the assessment would become longer-term as science accumulates more material."

Moreover, EFSA received a different task description from the EC in April 2006[91], both on scientific evaluation and on the decision making process, basically having to take member state opinion more into account (EC, 2006).

In the ruling the panel deliberated on whether the CBD – being a multilateral environmental agreement (MEA) – should be taken into account. According to the panel's interpretation of the Vienna Convention on the Law of Treaties, if not all parties in a dispute are party to the MEA then there is no obligation to take it into account (CIEL, 2006, p. 47). Thus, the panel did not take into account the CBD or the Biosafety Protocol (CIEL, 2006, pp. 47-49), thereby deviating from the practice of the *US – Shrimp/Turtle I* panel, that did take into account relevant MEAs, but also registered that this is not mandatory (see section 4.2.3). This has quite serious implications, as the CBD is the only MEA on GMOs and a large majority of WTO members is party to the CBD as well. This multilateral work is thus simply dismissed by the panel.

With regards to the precautionary principle, the panel continued the reasoning of the *EC - Hormones* appellate body report, stating that the status of the principle is unclear and that it is unclear if it is a widely accepted general principle of law (CIEL, 2006).

The WTO dispute panel did not rule on GMOs being safe or not, the 'like products' issue of GMO and non-GMO products, or the right of the EU to have an authorization system and its risk assessment process. These elements were not part of the complaints of the US, Canada and Argentina (see section 4.3.1).

As was indicated by the Washington Post (Washington Post, 2006), the first impression from the interim ruling was that the EU had lost the case. This was used by the US government to put pressure on developing countries in particular, not to create limiting GMO legislation:

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[91] "The measures proposed aim to bring about practical improvements which will reassure Member States, stakeholders and the general public that Community decisions are based on high quality scientific assessments which deliver a high level of protection of human health and the environment. These improvements will be made within the existing legal framework, in compliance with EC and WTO law, and avoiding any undue delays in authorisation procedures" (EC, 2006).

> "US officials claim the ruling stands as a warning for other nations, especially those in Africa and Asia, not to follow the EU in implementing even partial bans on biotech foods."

However, as shown above, the interim ruling was much more nuanced than that. The panel did not forbid bans *per se*, but ruled that the member state safeguard measures (bans) were not in compliance with the SPS agreement with respect to risk assessment. And essentially, the main problem with the EU's *de facto* moratorium and product-specific measures was that they caused undue delay.

The final ruling came in September 2006. Compared to the interim version, the differences were quite small[92], although one change was that the panel agreed to issue a recommendation to the EU to bring the *de facto* moratorium 'in conformity with its obligations under the SPS agreement' (EC - Biotech panel, 2006b, p. 261). This is slightly controversial, since it was implicitly agreed that the moratorium had ended. The panel, therefore, initially did not issue a recommendation. Another issue that received considerable attention of the panel in the final ruling was the leaking of the interim version, and thus, the breach of confidentiality (EC - Biotech panel, 2006b, pp. 280-282 and Annex K).

Reports in the media were somewhat different from when the interim report first came out: For instance, UPI (2006) now stated that 'the World Trade Organization said European countries were within their rights to ban genetically modified foods on health and environmental grounds'.

4.5 Conclusions

In this chapter, the *EC - Biotech* case was described, including the matters that are potentially at stake, and a discussion of the interim and final report of the dispute panel. Important considerations are that there is some tension between multilateral environmental agreements (MEAs) and WTO agreements, and that the most relevant MEA, the Convention on Biological Diversity and its Biosafety Protocol, were not taken into account in the case. Moreover, the use of the precautionary principle within the WTO, and more specifically in the SPS agreement, seems to be further limited through this case, due to considerations such as insufficient versus inconclusive or uncertain evidence and risk assessments.

More fundamental issues related to GMOs were not considered by the panel, for instance whether GMO products are to be considered 'like' non-GMO products.

Three main aspects of EU GMO legislation were challenged by the US, Canada and Argentina: the *de facto* moratorium (from 1998 to 2003), 27 product-specific measures at the EU level, and 9 safeguard measures of six member states. In brief, the *de facto* moratorium and 24 product-specific measures were ruled to have caused undue delay but no other infringements of WTO agreements, while the safeguard measures were ruled to be incompatible with several articles of the SPS agreement.

Other issues considered in this chapter were the role of the European Food Safety Authority (EFSA), related to the case and more specifically to risk assessment, and media reporting on the case. Especially this last factor may have an impact on GMO policies of countries globally.

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[92] One of the issues addressed by the panel in the so-called 'interim review' was labeling (EC - Biotech panel, 2006b, art. 6.52-6.68), or more specifically, EU's intention with labeling in Directive 2001/18/EC. This may be a warming-up to a new WTO case, e.g. on EU's labeling and traceability legislation.

The *EC - Biotech* case may not be solved any time soon; the final ruling became public on September 30th, 2006, and basically confirmed the draft ruling from February 2006. This ruling may be appealed. But even if this specific case is resolved, it is likely that the issue of GMOs and trade rules will be contentious for a long time.

In the next chapter, findings are presented from interviews with stakeholders such as EU member states, environmental NGOs, and biotech industry, on issues such as EU's and member states' GMO policies and public attitudes, the precautionary principle and multilateral environmental agreements, effects of the WTO *EC – Biotech* ruling and the future of GMOs in Europe.

5 Findings

Now that background information on GMOs, the WTO, and the *EC – Biotech* case has been presented, it is relevant to analyze the effects of the case on some of the issues discussed in the previous chapters, such as EU GMO policy, the precautionary principle in relation to the WTO, and the status of multilateral agreements (MEAs), specifically the Convention on Biological Diversity (CBD).

In order to collect first-hand data to answer the research questions, interviews were held. A selection of the stakeholders presented in section 2.4 was made, and representatives of EU member states, environmental NGO representatives, the US Department of Agriculture, and representatives for the biotech industry were interviewed, mostly by phone. Moreover, a questionnaire was sent to the representatives of the EU member states. Also, a representative for a trade and environment law NGO was interviewed, as an expert on the WTO and environmental issues. In this chapter the findings resulting from these interviews and questionnaire are given. The analyses, discussions and answers to the research questions are presented in Chapter 6.

5.1 Interviews with member state representatives

Of the current 25 EU member states, a selection of 10 was made to interview, based on their voting record on GMO approvals (see Appendix 4): Five states positive to GMOs and five negative to GMOs were chosen. Moreover, geographical diversity was strived for, and thus some north/western European countries were chosen and some south/eastern. Also country size was taken into account. Consequently, the following member states were selected: Austria, Belgium, Denmark, Estonia, Germany, Hungary, Italy, Lithuania, The Netherlands, and The United Kingdom. The representatives were generally working at ministries of environment, competent authorities or permanent representations in Brussels.

Four blocks of questions were posed (see Appendix 2):

- The country's GMO policies and public attitudes;
- The precautionary principle and multilateral environmental agreements;
- Effects of the WTO *EC – Biotech* ruling;
- The future of GMOs in Europe.

The interview results for each of these blocks are reviewed below. In Appendix 8 the full results of the interviews with member states are given, based on coding (Bryman, 2004, Ch. 13) of the answers from the semi-structured interviews with member state representatives.

5.1.1 The countries' GMO policies and public attitudes

The main results on the first block of questions may be summarized as follows:

- The main points of European GMO regulation come forward; many member state representatives mentioned 'no general ban' (mentioned 4 times), and 'case-by-case assessment' (6 times). Also, safeguard measures were mentioned. Many member states have field trials, and one representative mentioned commercial cultivation.

- Which GMO products are allowed is regulated at the EU level.
- Some member states were very late in implementing EU Directive 2001/18/EC[93].
- An inter-ministerial decision-making process is mentioned by some (3 times).
- A member state's position on GMOs may be very dependent on the politician or political party in power (mentioned 5 times).
- Most member state representatives acknowledge the low support for GMOs from the public (mentioned 6 times).
- There is a large diversity in governments' activities, that is, some governments have activities, e.g. research, while some governments do not.

Apart from these general results from the interviews with the member state representatives, other interesting remarks and observations were brought forward, sometimes by one representative, sometimes by several. On the aspect of consumer opinions and stakeholder interaction, it was mentioned by two representatives that for consumers, risks do not outweigh the benefits, and by another that it is important to work with stakeholders. As an example, two representatives mentioned that they work with regions proclaiming themselves GMO-free. A representative from a more positive member state mentioned that farmers' organizations in that member state prefer farmers to have a choice between growing GMO- and non-GMO crops.

Having a negative attitude towards GMOs was defended by one relatively new member state with both economic and environmental arguments. Economically, the consumer interest in the EU is too low to make GMO crops interesting for cultivation. This was also confirmed by an older EU member state, which generally is more positive towards GMOs. Moreover, according to the new member state, it would be costly to maintain separate systems for GMO and non-GMO crops. It is interesting to note that this argument is similar to arguments heard from developing countries, namely that it is costly to implement a fully separate GMO- and non-GMO food, feed and seeds processing system, and that it is thus economically sensible to try and stay GMO free (see section 2.4.3).

From an environmental point of view, it was pointed out that the risk assessments provided by the biotech industry sometimes were quite poor, especially with respect to taking into account the local environment. More research on environmental risks of GMOs is necessary. Moreover, the aspect of risks and benefits was confirmed (this was also addressed in section 2.4.1).

A representative from a more GMO-positive member state expressed that a balance must be found between GMO- and organic agriculture. This opinion is supported by the member states' and the European Commission's work on coexistence (see also section 5.1.4).

A difference in resources came forward between new EU member states (e.g., Hungary and Lithuania), and old member states, such as the UK; this concerned issues such as government support for research, and the economic burden of coexistence and the separation of GMO- and non-GMO crops, as was addressed in this section.

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[93] Actually, 11 member states were taken to court by the EC for this on July 15, 2003: France, Luxembourg, Belgium, The Netherlands, Germany, Italy, Ireland, Greece, Spain, Austria and Finland. Source: http://www.seedquest.com/News/releases/2003/july/6197.htm .

5.1.2 The precautionary principle and multilateral environmental agreements

The main results of questions 7 and 8 of the interviews with member state representatives are:

- The precautionary principle is in many countries explicitly written into the legislation, and especially risk assessment legislation was mentioned in this context by a few countries.

- Most representatives think that the principle is taken into account at the EU level sufficiently; one member state government thinks it is not.

- Many member states are party to the CBD and BP, and it is taken into account at the country and EU level. Some member states mention having a national Biosafety Clearing House (an instrument of the Biosafety Protocol) (mentioned twice).

It was noted by one representative that in order to stop the authorization process, there should be 'reliable signs that there might be a risk for health or environment'. It must be noted that this representative's member state has recently changed from being quite negative towards GMOs to being more positive.

One interviewee mentioned that the precautionary principle can be interpreted in many different ways.

5.1.3 Effects of the WTO *EC – Biotech* ruling

The main results of this block of questions are:

- The application of EU legislation may change (mentioned twice), but otherwise no changes are expected in the legislation itself.

- The safeguard measures of some member states are likely to be affected (mentioned twice); otherwise, maybe a slight shift will occur for some member states towards a more open attitude on GMOs. There will not be very profound changes in attitudes of the EC or member states due to the ruling.

- However, several member states indicate that the EC is strengthened and may want to apply EU legislation more strictly (e.g., to speed up authorization, or lift the safeguard measures) (mentioned twice). This weakens the position of those member states that argue against GMOs (3 times).

Other opinions and thoughts that were expressed were that due to this case, the ministry of economy may be stronger in the inter-ministerial discussions. Also, pressure of environmental NGOs on the minister of environment, to refuse GMOs, was mentioned. Thus, one can say that this minister experiences pressure from opposite sides in the debate. It must be noted that in the previous section, stakeholder interaction was mentioned as a positive asset, while stakeholder involvement has a slightly negative notion in this section. This may of course depend on the fact that it was mentioned by different member state representatives, where the member state positive to stakeholder involvement is a large, older EU member state, and was not more specific during the interview than just mentioning 'stakeholder involvement'. The other two member states, more negative towards stakeholder involvement, mentioned specific examples of stakeholders, where the stakeholder acted in opposition to their own interest.

Another aspect that was mentioned was that each country can set its own level of protection (an argument used in the case), but that each country should make a proper risk assessment, not just issue opinions. This would mean that WTO jurisprudence is also applied at the European level. On the other hand, another representative mentioned that national legislation largely responds to the Meeting of Parties (MOP) of the Biosafety Protocol.

5.1.4 The future of GMOs in Europe

The main results of this block of questions are:

- By far the most significant barrier is the negative public opinion (mentioned 6 times). Also, NGO opposition, politics and contamination by non-approved GMOs were mentioned.

- As drivers, the following factors were mentioned: GMOs that may show obvious advantages to people (mentioned 5 times), GMOs that are used in specialized or non-food applications (4 times), GMOs are on the market in any case (3 times), technology progress (twice), the good economic possibilities (twice), biotech companies' lobby, and the large number of small biotech firms.

- On consumer interest, the results are mixed: Some expect no changes, some expect an even stronger opposition, but a significant number of member state representatives see a more positive public opinion (mentioned 5 times).

- On member state policies, it was pointed out by several member state representatives that there have been changes already (mainly due to changes in government, but also the EU legislation being in place and sufficient). The influence of public opinion on member states' policies was pointed out by a few interviewees.

- On EU policies, the common agreement was that no changes in legislation will occur, since the process is extremely difficult. However, several more or less open issues were mentioned, such as coexistence, liability, and cultivation. One interviewee mentioned possible changes in application of the legislation.

- On coexistence, the consensus was that this is under development. The principle of subsidiarity[94] was indicated by three of the interviewees in this context.

- On risk assessment, views were diverging. Some member states expected no future changes, while some appealed for stronger standards. The developments within EFSA were mentioned by some interviewees.

- On a new case in the WTO, no strong viewpoints were expressed, and responses rated from 'would be surprised' to 'don't know' to 'would not be surprised'.

Other results from this part of the interviews are for instance that the European Food Safety Authority (EFSA) has changed for the better, that is, more towards subsidiarity. This was expressed by two representatives of GMO-negative member states. On risk assessment, one member state representative mentioned that 'public opinion, technical and scientific data and options for risk management must be balanced'. Moreover, two representatives said that

[94] EU's subsidiarity principle implies that decisions should be made at the most appropriate level, e.g. at local, national or EU level, depending on the policy area.

environmental effects should be taken into account more: One from a GMO-positive and one from a GMO-negative member state.

The economic aspects of strict legislation were indicated by one member state, namely that 'labeling, traceability and low seed contamination threshold is an economic loss for industry'[95]. On the other hand, practical difficulties with coexistence were mentioned by two representatives, one from a GMO-positive and one from a GMO-negative member state, namely that due to the small-scale agriculture and the 'patchy mosaic' of European landscape, coexistence may be difficult. One representative from a country that is GMO-free now, expressed that they probably would not be able to stay GMO free for a long time.

Finally, on the issue of the possibilities for having a new GMO dispute within the WTO, one member state said that the US may wait with a new case, as the EU is working on lifting the bans, and may become more positive to GMOs. The US will take other measures, such as diplomacy, e.g. exert influence through the ministry of economy[96].

5.2 Questionnaire on the *EC – Biotech* case

To be able to analyze the impact of the *EC – Biotech* case more specifically and to be able to compare the importance of different impacts to each other, a questionnaire on this topic was sent to the member state representatives who were interviewed (see Appendix 3). The results are presented in Table 5-1.

Table 5-1 Results of the questionnaire 'Effects of the WTO Biotech case ruling' (see Appendix 3).

Option	**Number of responses**
Increased public acceptance of GMOs	1
Decreased public acceptance of GMOs	2
Increase in GMO applications/field tests/products/cultivations	7
Decrease in GMO applications/field tests/products/cultivations	0
Increased conflict of your government with organic farmers	1
Decreased conflict of your government with organic farmers	1
Increased conflict of your government with environmental NGOs	4
Decreased conflict of your government with environmental NGOs	0
Increased contact between your government and biotech industry	6
Decreased contact between your government and biotech industry	0
Increased public resistance to the WTO	5
Decreased public resistance to the WTO	0
Increased public scepticism to the EU	4

[95] This was also expressed, but then for organic producers, by European Commissioner Fischer Boell, according to GMO Compass (2006): 'EU Agriculture Commissioner Mariann Fischer Boel, however, continued to warn that lowering the threshold below 0.9 percent would be a burden and would place unneeded added costs on organic producers'. See also note 48 on the allowed GMO content in organic produce.

[96] This was confirmed by an article in the International Herald Tribune (IHT, 2006), where the former greek deputy environment minister was quoted saying that 'the first visit any new minister in Greece gets is from the U.S. ambassador saying you need to have GMOs. The pressure is incredible'.

Option	Number of responses
Decreased public scepticism to the EU	2
No effect/hardly any effect	3
Other: 1. The thing is how the issue was reflected in mass media. There was much false information, a la WTO made decision that all GMOs are safe for use. This kind of false information has increased public scepticism in regard of EU, WTO, USA, biotech industry, govermnent, even scientists. 2. The WTO did not state that the recent EC legislation is not in line with the WTO rules or that Member States do not have the right to ban a particular GMO product if they have sufficient scientific evidence. However, according to my opinion, the European Commission will take all measures to lift all Member States' prohibitions because of the EFSA opinions (=lack of scientific evidence) much more intensive than before. If the Commission lifts our ban as well, the cultivation of GMOs will be possible and this will increase the conflict among the government, organic farmers, conventional farmers and environmental and agricultural NGOs. This will – according to our estimations – decrease the public acceptance of GMOs.	

The response rate was 100%[97].

From this table it can be seen that the representatives believe that an '*increase* in GMO applications/test fields/products/cultivations' is a likely effect of the WTO ruling, mentioned by 7 out of 10 respondents. Moreover, comparing interactions with stakeholders such as organic farmers, environmental NGOs and biotech industry, two kinds of interactions seem significant: '*increased conflict* with environmental NGOs' (4 out of 10) and '*increased contact* with biotech industry' (6 out of 10). When it comes to the public's attitude towards institutions, both an '*increased* resistance to the WTO' and an '*increased* scepticism to the EU' was expected as a result of the case. It may be significant that the scores for either increased or decreased public acceptance of GMOs were relatively low, indicating that the expected impact of the case on public opinion is quite low. Moreover, three respondents chose 'no or hardly any effect' of the case.

5.3 Other stakeholders

Other stakeholders that were interviewed were environmental NGOs, farmers' organizations and biotech industry representatives (see Appendix 1).

Environmental NGOs

Some of the results of the *EC – Biotech* case were, according to representatives from an environmental NGO, that the panel 'did not take into account the Cartagena Protocol [on Biosafety]', but that the case 'had a surprisingly positive result. According to standard WTO logic, the EU would lose'. It was also noted that the WTO is 'very nervous about the case', and the panel seemed to be careful not to damage the WTO's reputation.

[97] Not all respondents interpreted the assignment of the questionnaire correctly; Some selected more than 3 alternatives, one less. However, all responses have been taken into account. Thus, the total number of responses is not 30 as would be expected.

With regard to the impact of the ruling, it was judged that there 'will likely be more polarization between member states'. Also, the 'European Commission is strengthened' vs. the member states, and it is likely that tighter cooperation with industry and increased pressure on member states will occur. The case will have a big effect on the safeguard measures.

The publication of the leaked interim report was helpful 'to counter US press that they had won the case'. On a possible difference between interim and final report, something unusual, it was said that 'apparently there have been considerable changes between the interim and final version, so an appeal may be more likely. An appeal could change the outcome of the dispute considerably'[98].

As an example of politicians' influence on GMO attitude of a member state Germany was mentioned, having a ban [safeguard measure] but now voting more positively. It was noted that since the start of the *EC – Biotech* case, 'more bans have come into place in the EU', e.g. product-specific bans in Greece and Hungary and a more general ban in Poland (see also Table 2-1).

Farmers' organizations

According to the organic farmers representatives, an obvious outcome of the case is that different parties in the case interpret it differently. The EU stated that the case will not have an effect on current GMO legislation, while the US 'creates the impression that legislation with a high level of security is not compatible with WTO agreements'. This was more seen as a political goal than a result from legal aspects of the case. The national safeguard measures 'are a different story'; they are clearly questioned by the panel.

On the impact of the ruling on EU policy, one of the representatives noted that there was an interesting contrast of the European Commission normally being pro-GMO, while in this case they had to argue against. This argumentation, prepared by consultants, had to be released by the EC after a court order. This was seen as rather embarrassing for the commission. Further, it was stated that some member states with a safeguard measure actually may refuse to change it, and that the EC cannot do very much against this. There is the option that the EC will 'just accept to pay compensation', as they have done in other cases.

They saw a 'growing interest for GMO crops', which is perceived as a barrier for organic food. A possibility for countering this trend would be to inform consumers, as increased consciousness on GMOs is perceived to lead to increased resistance.

Biotech industry

Representatives from the biotech industry said that the main outcome of the case is that 'the EU institutions are not implementing their legislation'. The European legislation itself is good, it is just not applied well. The approval on EU level was too slow [undue delay], and member state bans [safeguard measures] are only allowed if there are serious safety concerns and new evidence can be presented. The member states 'claim that they presented new evidence, but the scientific panels [under EFSA] say that no new evidence was presented'. It would be interesting for them if the member states [that have a ban] would be taken to court by the European Commission (EC). On the voting behaviour of member states in scientific committees and the European Council of environment ministers it was said that

[98] The interview was held before the final version of the panel report was published. The final version was not leaked, since it was made electronically traceable by the WTO after the interim report was leaked (EC – Biotech panel, 2006b, Annex K).

> "... many countries vote with political motives, that is, the politicians are influenced by e.g. public attitudes or by activism. Some ministers themselves, especially green ministers, are opposed to GMOs."

The biotech industry representatives see a 'huge growth potential [for GMOs] in Europe'[99]. However, the ruling will likely not have an impact on public opinion in Europe. With respect to the probability of a possible new case in the WTO, for instance on labeling and traceability, the representatives did not know, and said that they were not sure whether the US government is interested in a new case at this moment. 'Probably some interest groups, such as farmers, want to have such a case'.

One of the representatives sees some problems with the Biosafety Protocol if it is implemented fully. It 'could be very restrictive and block [poor] people who have a problem to meet their own needs. As it looks now, I think it is not helpful'. Originally the Convention on Biological Diversity (CBD) 'mentioned biotechnology several times, implying that 'biotech can help sustaining biodiversity'. The Biosafety Protocol, however, 'only refers to biotech once'.

Other stakeholders

Other stakeholders, such as the US Department of Agriculture (USDA) and the US Trade Representative (USTR) office, published press releases (USDA, 2006b)[100]. They stated that the 'WTO has ruled in favor of the United States, Argentina and Canada' on the two most important aspects of the case, the EU *de facto* moratorium and the member state safeguard measures. Moreover, they said that 'although the EU approved a handful of biotech applications following the initiation of the case in 2003, the EU has yet to lift the moratorium in its entirety' and that 'farmers who grow biotechnology crops in 21 countries around the world, including 5 in the EU, stand to benefit from today's decision'[101].

5.4 Expert interview

A representative for an NGO working on the legal aspects of the trade and environment debate was interviewed (see Appendix 1).

The main result of the case, according to the expert, is that the EU does not have to change its legislation, and that the member state bans were found to be inconsistent with WTO rules since they are not based on risk assessment. The fact that the panel did not look at the EU legislation itself, but mainly at its application, ' watered down the significance of the case'.

As a possible impact of the case it was mentioned that the impact on EU legislation would likely be small, although the EU may look at risk assessment more carefully. The positions on GMOs in member states were deemed to be 'solid'.

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[99] The representatives referred to the ISAAA (International Service for the Acquisition of Agri-Biotech Applications, see e.g. ISAAA (2005)), who presented figures of double digit growth, and fast acceptance of GMOs in other parts of the world.

[100] The person from USDA that was interviewed would not comment except for what was stated in the press releases.

[101] Additionally, the USDA gave the following description of genetic engineering: 'Agricultural biotechnology promotes economic development, and has delivered on its promise to feed a hungry world, increase product yields, reduce pesticide use, improve nutrition and disease prevention, enhance food security, and increase incomes of farmers—most of whom are in the developing world' (USDA, 2006b).

The expert opinionated that the European Commission is 'definitely strengthened [by this ruling] vis-a-vis member states'.

On the precautionary principle in the WTO, the expert said that the ruling did not add much, with the panel referring to the *EC – Hormones* case (see note 72). Thus, the interpretation of the SPS agreement with regards to the precautionary principle is 'still unclear'. It was said that 'even if you can do a risk assessment you still may need to use the precautionary principle'.

The expert ruled very harshly on the aspect of MEAs in this case, with the panel refusing to take into account the CBP, especially since more than 130 WTO members are a party to the CBD. The WTO panel could take into account the MEA in different ways, 'they don't have to take into account all rules [in the MEA], but at least take into account that it is there'.

Other aspects that were noted were that an appeal may damage the EC in either way; the appellate body may decide to look at EU's GMO legislation itself, or – if the ruling is weakened on the safeguard measures – the EC could be weakened versus the member states. Moreover, some questions were raised on whether the EC can represent the member states, due to diverging opinions, and whether the member states safeguard measures violate EU law.

5.5 Conclusions

In this chapter, findings were presented from interviews held with EU member state representatives, experts and other stakeholders such as environmental and farmers' organizations and biotech industry representatives. Results from a questionnaire sent to the member state representatives were included as well.

The member state representatives have converging views on some issues, for instance that EU legislation is more or less fixed, except for issues such as coexistence and liability. Also, public opinion was identified as the main barrier for an increasing market for GMOs. Some slight changes in member states' attitudes towards GMOs might occur; however, these attitudes are mainly dependent on which political party or politician is in power.

A difference in resources came forward between new EU member states (e.g., Hungary and Lithuania), and old member states, such as the UK; this concerned issues such as government support for research, and the economic burden of coexistence and the separation of GMO- and non-GMO crops.

The main result of the *EC - Biotech* case, identified by some member states, the environmental and organic farmer NGOs, the biotech industry representatives and the expert, is that the EU does not have to change its legislation, but that the safeguard measures of some member states will have to change. The representatives of the organic farmer NGO suggested that some member states may refuse to change the safeguard measures. Some member states, the environmental and organic farmer NGOs representatives as well as the expert confirmed a strengthening of the European Commission and a weakening of the member states negative to GMOs as a result of the case.

In the next chapter these findings, along with the material from the previous chapters, are used to analyze and discuss the research questions posed in Chapter 1.

6 Analysis and discussion

In this chapter the research questions as listed in Chapter 1 are addressed. To do this, the material presented in the previous chapters is drawn upon, both the literature review based material and the interview and questionnaire findings. In doing so, the issues of GMOs, trade rules and EU policies are tied together.

Issues to be discussed are, for instance, whether it is justified to use a precautionary approach in GMO policies, and how it is used within the World Trade Organization (WTO). Moreover, the relationship between multilateral environmental agreements (MEAs) and trade agreements is discussed. Lastly, the impact of the *EC – Biotech* case on EU GMO policies is addressed.

6.1 The precautionary principle in GMO policies

Part a of the first research question addressed in this chapter is:

Is it justified to invoke the precautionary principle in policies regulating genetically modified organisms (GMOs)?

In section 4.2.2 the precautionary principle and its origin were described: The approach calls for public policy action when there are strong indications of 'potentially serious or irreversible threats to the environment', before there is strong proof (EEA 2001). Taking this description of the principle, is it then justified to invoke it in the case of GMO legislation? The examples given in section 2.2 point to several issues. First, spreading of genetic material into the environment occurs, sometimes with negative consequences for the ecosystem, biodiversity or use of external inputs. This is not inherent only to genetic engineering (GE); also non-GE organisms introduced in the environment may cause such damage. A difference between GE and non-GE organisms, however, is that GMOs may have received specific properties to e.g. out-compete native organisms, and that unexpected properties may occur due to the introduction of foreign genetic material in an organism.

Second, the development of current GE technology facilitates an industrial agriculture based on more monoculture. This generally leads to a decrease in biodiversity and to an insecure food supply that is sensitive to pests (Pretty, 1995).

Third, there are indications of possible negative health effects of GMO consumption. Reports of intestinal damage on rats and mice have been published, as well as of allergic reactions due to unforeseen protein production. Some of these health effects are included in risk assessments (see Appendix 7), but some more long-term effects are not.

Fourth, there are significant negative social effects of the current GE technology. For instance, GMO farmers become more dependent on a single company that supplies both seeds and pesticides, and owns the patent on the seeds. This may lead to disempowerment amongst farmers. Especially in combination with disappointing yields, increased pesticide use and thus lower return on investment – all factors that occur regularly – farmers may suffer, as was exemplified in section 2.2.2.

All facets that were reiterated here may be reason to invoke the precautionary principle. The question is then what precautionary measures should be taken: Is it justified to have a general moratorium on GE and GMOs, or should each application, field trial and cultivation be assessed case-by-case, and the risks and benefits of each case be taken into account? This is the issue of GMO policies in the EU, where some member states take the former and some –

including the European Commission (EC) – the latter position[102]. All member state representatives said that the precautionary principle or approach is included in EU legislation (see section 5.1.2), but the interpretations of the principle seem to differ, expressed for instance in the member states' attitude towards GMOs (see Appendix 4.).

In EU GMO legislation a precautionary approach is used, as is stated in Directive 2001/18/EC, for instance (EU, 2001). In this case it implies that GMOs are assessed on a case-by-case basis. The legislation is meant to be compatible with the WTO Agreement on Sanitary and Phytosanitary measures (SPS), where measures to prevent the establishment of pests etc. generally must be scientifically justified (see section 3.4). However, it is slightly unclear what a member state can decide, e.g. on which areas of the legislation the subsidiarity principle applies (see section 5.1). If a GMO product, or a product containing GMOs, is put on the market, the EU principle of the single market applies, that is, if the product is allowed in one member state it must be allowed in all member states. If on the other hand GMO seeds or crops are to be cultivated, the member states have more autonomy to implement Directive 2001/18/EC. The member state safeguard measures, allowed under this directive, are examples of member state autonomy. Thus, if a member state has a somewhat different interpretation of a precautionary approach, or a different appropriate level of protection, or seeing different risks and benefits, in theory they may impose different measures - but in practice there may be a conflict within the EU. As was addressed in section 4.4, there has been tension within the EU on the member state safeguard measures, and they have been ruled WTO-incompatible in their curent form by the *EC – Biotech* dispute panel. This was due to the risk assessment and approval at EU level of the respective products. Thus, one may wonder, at least from a member state perspective, whether the precautionary approach and the single market principle are incompatible with each other in the case of GMOs[103].

In summary, it is the opinion of the author of this thesis that the question posed in the beginning of this section can be answered positively: *It is justified to invoke the precautionary principle* – there are significant indications of environmental uncertainties, health uncertainties, but also undesirable social consequences.

From a member state perspective, one can see a conflict between the precautionary principle and EU's single market requirement. The question remains if assessing case-by-case is precautionary enough, or if there should be a moratorium on GMOs. On the EU level, the former approach is taken.

6.2 The precautionary principle in the World Trade Organization

Part b of the first research question is:

Is the precautionary principle recognized within the World Trade organization (WTO)?

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[102] Although views on GMOs may differ within the European Commission (see e.g. commissioner Dimas quoted on p. 54, and commissioner Fischer Boell on p. 50), the commission acts as a single body. On, the whole, it is the opinion of the author of this thesis that the EC is more in favour than against GMO cultivation. Supporting this view is for instance the Communication on strategic vision on life sciences and biotechnology (EC, 2006b), the commission's push to remove member state safeguard measures, and work on coexistence and allowed GMO content in non-GMO food (see also footnote 12).

[103] The EC stated that a review of the safeguard clause in Directive 2001/18/EC may be done, leading 'either to a modification of the Community-wide authorization or the termination of the national safeguard measures' (EC - Biotech panel, 2006b, art. 4.373). The former action may be seen as a deviation from the single market principle, while the latter action may be interpreted as an infringement of the precautionary approach for member states.

When it comes to the WTO, protection of human, animal or plant life or health is written into several agreements, such as the GATT, the TBT and the SPS agreement. The SPS agreement, especially applicable to GMO issues, determines, however, that protective measures must be based on science and a risk assessment unless they qualify for article 5.7, the article most allowing a precautionary approach (see section 3.4). In summary, when there is insufficient evidence, a temporary protective measure may be allowed. WTO jurisprudence, developed by dispute panels and the appellate body, has addressed this article and its application a number of times (see section 4.2.2).

The issue of insufficient scientific evidence versus scientific uncertainty has been discussed, with the outcome that article 5.7 is only triggered by insufficient evidence, not by scientific uncertainty. However, on the other hand, in environmental common understanding the precautionary principle may be triggered by scientific uncertainty (see section 4.2.2). Thus, this is a crucial issue, also reiterated in the *EC – Biotech* case. It leads to the question of when scientific evidence is insufficient. In the ruling of the *EC – Biotech* panel, regarding the EU member states safeguard measures, the answer was that there was sufficient evidence to perform a risk assessment, and thus article 5.7 did not apply. Consequently, it seems that the precautionary principle cannot be invoked based on minority science, but a risk assessment can be based on minority science, as has been established in earlier WTO jurisprudence. [104].

It can thus be concluded that the use of the precautionary principle is limited within the WTO, although there may be leniency if a science-based risk assessment takes into account the precautionary principle, e.g. resulting in a low appropriate level of protection.

Current EU GMO legislation seems to be compatible with WTO rules, but the challenge is to make the member state safeguard measures compatible with these rules. However, this does not seem impossible.

From the interviews with experts (see section 5.4) as well as from literature (see sections 4.2.2 and 4.4) it became clear that there is a worrying trend within WTO jurisprudence to continually limit the application of article 5.7, and thus, to more and more limit the use of a precautionary approach. However, as was shown in the previous section, in the case of GMO legislation having a precautionary approach is justified. Thus, it seems that the limiting approach taken within the WTO is at odds with GE reality. No panel or appellate body has yet assessed GE technology *per se*.

In summary, the question posed in the beginning of this section can be answered as follows: A precautionary approach or notion *is expressed* in the SPS agreement of the WTO. In practice, however, the application has been *limited by jurisprudence*, also in the *EC – Biotech* case: If a risk assessment can be done, the article most expressing a precautionary notion cannot be invoked.

6.3 The relation between multilateral environmental agreements and the World Trade Organization

The second research question is:

How is the relation between multilateral environmental agreements (MEAs) and the World Trade Organization?

[104]Moreover, a nation has the right to set its own appropriate level of protection according to WTO jurisprudence. How this is interpreted in practice by dispute panels and the Appellate Body is unclear.

The Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety – or Biosafety Protocol (BP) – are examples of multilateral environmental agreements that may conflict with trade rules. It is discussed to what extent these agreements are being taken into consideration within the WTO.

An important aspect of the trade and environment debate is the question of tension or synergy between multilateral environmental agreements (MEAs) and trade agreements. Environmental protection rules are sometimes judged as being protectionist, while trade rules are sometimes seen as preventing environmental protection. As stated in section 3.6, it is sometimes said, however, that both types of agreement may be in synergy to promote sustainable development.

The WTO has a mixed history when it comes to MEAs. It has been established in jurisprudence that the panels and appellate body have no obligation to take into account relevant MEAs, although there is no prohibition to do so either. As a result, in some environment related cases MEAs have been taken into consideration, in others not (see section 4.2.3).

Looking more specifically at the issue of GMOs, there is one relevant MEA: the Convention on Biological Diversity (CBD). Within it the Biosafety Protocol has been agreed upon, on transboundary movements of living modified organisms (LMOs). As was described in sections 2.3.1 and 3.6, the underlying principles of the CBD are quite different from those of the SPS and TRIPs agreement (see sections 3.4 and 3.6). Where the CBD aims to protect traditional knowledge, requires prior informed consent for trade with GMOs, and a fair sharing of benefits, the main goal of TRIPs seems to be protection of patent holders. And while the CBD advocates the precautionary principle quite strongly, within the SPS agreement it is not mentioned explicitly, and, as was shown in the previous section, its use is limited. Thus, one may say that the CBD and WTO agreements are built on different premises and thus difficult to use in synergy.

In the *EC – Biotech* case, the panel chose to ignore the CBD, mainly because one of the complainants – the US – is not a party to the CBD. As a result, the multilateral effort to specifically address the issue of GMOs, with more than 130 countries being a party to it, is dismissed in this case. Trade and environment experts are very concerned about this development (see section 5.4).

From the interviews with member state representatives it was found that all member states are parties to the CBD, and that the CBD plays an important role for some member states in formulating their GMO policies. However, in general the member states did not see many difficulties in taking the CBD and WTO into account (see section 5.1.2).

A different position was indicated by a biotech industry representative: If the CBD and the Biosafety Protocol were strictly implemented as they were written in their current shape, they could hinder trade in GMOs. Thus, different stakeholders have different views on this issue.

In summary, the answer to the second research question is that there are *potential conflicts* between the CBD and Biosafety Protocol on one side and WTO agreements such as the SPS and TRIPs agreement on the other. They are based on quite different premises.

WTO dispute panels have no obligation to take into account MEAs, and the *EC – Biotech* panel chose to ignore the CBD and Biosafety Protocol, even though many WTO members – and almost all dispute parties – are party to the CBD as well. This is a worrying development.

6.4 Effects of the case on EU GMO policy

The third research question is:

What are the consequences of the WTO EC-Biotech case on EU GMO policy?

The ruling in the case may have a direct impact on EU GMO policies, for instance, if member state restrictions on GMOs are judged to be violations of trade rules. But the case may also have indirect consequences on EU GMO policies, for instance, by supporting and thus strengthening the views of one of the actors in the EU GMO debate.

In section 4.4 the preliminary results of the *EC – Biotech* case were presented. The case dealt with three aspects of previous and current EU GMO legislation: The EU *de facto* moratorium on GMO products from 1998 to 2003, EU product specific measures, and member state safeguard measures. In brief, the results were that 'undue delay' in GMO approval procedures had been caused by the moratorium and the product specific measures, while the member state safeguard measures were violating the SPS agreement by not being based on a risk assessment.

Therefore, the direct consequences will likely be that the member states in question (Austria, France, Germany, Greece, Italy and Luxembourg, see section 4.1) will adapt or abolish their safeguard measures, while the direct impact on EU regulations will be negligible. This was also stated by many interviewees, and by the EC (see e.g. Financial Times, 2006).

On the other hand, it is unlikely that member states or the EC[105] will change their position on GMOs immediately – this was also an outcome of the interviews with member state representatives (see section 5.1).

The indirect consequences for EU GMO policies of the case are difficult to assess. It is likely that the EC will put more pressure on member states with a safeguard measure. The EC has tried before to force these member states to lift their bans, but not succeeded. These member states are generally the same states that block a qualified majority approval decision on GMO. Will they be weakened in the discussions more generally? This is not unlikely (see section 5.3), and it may have an impact on the application of EU GMO policy, e.g. approval may be sped up. Moreover, if decisions on new legislation are made, such as on coexistence or liability, this may have an impact[106]. Generally, a slight shift towards a more positive attitude on GMOs could thus result from the case.

It must be mentioned that many interviewees indicated that member state attitudes to a large extent depend on the political parties or politicians in power. However, also within the member state, politicians' attitudes towards GMOs may be impacted by the *EC – Biotech* case, as was indicated by one interviewee:[107]

> "We may see the impact in the next few years. The ministry of economy had serious concerns about our ban on MON810, and there was a big lobby going on. They [the ministry of economy] will be stronger in such discussions. It's not the table of the ministry of economy, but we will hear their voices more."

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[105] See note 102.

[106] The current legislation seems fixed, without much space for changes, due to the issue being so contentious within the EU, and the difficulty in reaching consensus with 25 member states on such an issue. This was also mentioned by several member state representatives.

[107] From an interview with one of the member state representatives.

Such a change could also be facilitated by increased contact between governments and biotech industry. This 'increased contact' was an expected result from the *EC - biotech* case, as was shown by the outcome of the questionnaire (see section 5.2 and Table 5-1).

Environmental NGOs' representatives see a risk for increased polarization between member states, as well as tightened cooperation between industry and governments. They generally support the precautionary principle, and the safeguard measures, and see a large effect of the case on these measures.

This latter thought was shared by the biotech industry representatives. According to one of them, the WTO [dispute panel] said that 'the EU legislation *per se* is good, it's just the application that is not, e.g. the safeguard measures'[108], thereby implying that, according to the dispute panel, the safeguard measures as they are now are not in accordance with EU legislation.

In summary, the third research question may be answered as follows: The *direct effects* of the *EC – Biotech* case will likely be *small*. EU legislation is fixed, with very little space for changes. Moreover, the case was partly about old legislation. However, member state safeguard measures will probably change: they may be adapted to WTO rules or abolished. Member state and EC positions on GMOs will probably not change immediately due to the case.

Indirectly, some changes may occur: It can be argued that member states negative to GMOs (e.g. with a safeguard measure in place) will be *weakened* in the debate with both the EC and GMO-positive member states. This may result in a *slow change towards a more open stance* overall on GMOs within the EU.

6.5 Other issues

Issues that fall outside the scope of the research questions, but are nevertheless interesting to address, are for instance EFSA's role in connection with risk analysis, and the question whether member states with a safeguard measure will be taken to court.

EFSA's role

In section 6.4 the effects on EU GMO policy were discussed. One aspect not discussed there is the role of EFSA (European Food Safety Authority), the main competent authority at EU level, and the impact of the *EC - Biotech* panel ruling. For a GMO product to be placed on the EU market, EFSA has to give its approval after a risk assessment (see Appendix 7 for an EFSA GMO application form), but a member state may evoke the safeguard clause 'on the basis of new or additional information [... or ...] scientific knowledge' (EU, 2001, art. 23). It is then up to EFSA to judge if the information or scientific knowledge is relevant.

The fact that EFSA judged that in none of the safeguard cases the information was new or additional, was the main reason for the *EC - Biotech* panel to rule that the safeguards were not based on a risk analysis, and that they were thus incompatible with the SPS agreement (EC - Biotech panel, 2006b, art. 8.9).[109]. In the author's opinion, the ruling thus gives substantial power to EFSA: In the initial risk assessment they decide to what extent member states

[108] From an interview with one of the biotech industry representatives.

[109] The EC - Biotech panel also 'examined whether the risk assessments undertaken by [EFSA] could provide reasonable support for a prohibition of the biotech products at issue, but considered that this was not the case' (EC - Biotech panel, 2006b, art. 8.10).

opinions and information are taken into account in the risk assessment, and in second occasion they decide whether (additional or new) information is relevant. As may be reiterated from section 4.4, the role of EFSA has been debated fiercely and they have received new instructions.

It is not clear from the ruling whether minority scientific opinion may be taken into account by the member states when imposing a safeguard measure, e.g. if this opinion is not sufficiently taken into account by EFSA.

Will member states be taken to court by the EC?

The panel ruled that the member state safeguard measures are not WTO compatible, but they are allowed according to Directive 2001/18/EC. On the other hand, Directive 2001/18/EC is considered WTO-compatible (as was indicated by one member state representative). The question is thus raised how these two positions may be resolved. Will the member states that have safeguard measures installed, be taken to the European Court of Justice (ECJ) by the European Commission? As was stated in section 4.1, the EC has so far not succeeded in forcing member states to abandon their safeguard measures. One option for member states with a safeguard measure is to make sure this measure is WTO compatible; In that case it may be less likely that they will be taken to court. On the other hand, it was indicated by a representative of a farmers' organization that member states with a safeguard measure may not be inclined to change these measures. The question is what the effect would be of a ruling of the ECJ in this case.

6.6 Conclusions

In this chapter, the areas of GMOs, world trade and EU policies were tied together by addressing the research questions posed in Chapter 1. First, is it justified to invoke the precautionary principle in GMO polices? It was shown that there are indications to justify this. Second, it is questioned to what extent the precautionary principle is recognized within the WTO. Formally, precautionary measures are allowed temporarily and under certain conditions, but in practice this is limited, and the *EC – Biotech* case contributes to this limitation. Third, what is the relationship between MEAs and the WTO? It was discussed that a WTO dispute panel is not obliged to take relevant MEAs into account, and indeed the panel in the *EC – Biotech* case chose not to do so.

Finally, direct and indirect effects of the *EC – Biotech* case were discussed, such as the impact on member state safeguard measures and a possible shift in either member state or EU attitudes towards GMO.

In the next chapter the conclusions are presented, a future outlook on GMOs in Europe is given, and recommendations are made.

7 Conclusions and future outlook

The main objective of this thesis was to assess the interaction of genetically modified organisms, EU policies and the World Trade Organization (WTO). These issues come together in the *EC - Biotech* case, the case brought before a WTO dispute panel by the US, Canada and Argentina challenging parts of the EU's GMO legislation. In order to get a full understanding of the issues related to GMO, sustainability aspects of GMOs were considered, and GMO regulation on the global, EU and national level was reviewed, with focus on the EU member states. Relevant agreements within the WTO were described, in order to first of all understand the trade and environment debate related to GMOs and second, to be able to analyze and understand the *EC - Biotech* case. Significant issues of this work are whether a precautionary approach in regulation of GMOs is justified; to what extent trade rules allow the usage of the precautionary principle, how trade agreements and multilateral environmental agreements interact, and what the impact is of the *EC - Biotech* case.

Genetically modified organisms

The focus of this thesis is on GMOs for food and feed products, that is, seeds, crops, and food or feed products consisting of, or containing, GMOs. Benefits and drawbacks of genetically modified organisms, compared to products from conventional cultivation, may be seen on an environmental, social and economic scale. The main benefits of GMOs may be the reduction of external inputs, such as herbicides, insecticides or fertilizers. Also, yields may improve. Moreover, enhanced vitamin, mineral or protein content may occur due to changes in the genetic properties of the crops. These benefits may lead to positive factors such as reduced pollution and reduced natural resource consumption, health improvements, or increased profit for the farmer.

However, there are significant disadvantages as well. First, yields may not actually increase, and pesticide use may not decrease, resulting in environmental, social and economic disadvantages rather than positive factors. Moreover, there are specific environmental and health risks associated with GMOs. For example, there is a risk of genetic material spreading to weeds or to non-GMO crops. The contamination of weeds may have consequences for the environment, as more pesticides are needed to control modified weeds, and the contamination of non-GMO crops may have economic consequences for organic or conventional farmers. Also, non-target organisms such as insects or farmland birds may be damaged in various ways due to GMO cultivation, which may have a negative impact on biodiversity. Health issues associated with GMOs may be the occurrence of new proteins, which may have allergenic potential, and the possible impacts on the metabolism of animals or humans consuming GMOs. However, research in this field is limited.

The current genetic engineering industry is based on intellectual property and patenting of GMO traits, and it is promoting a highly technological agriculture based on monoculture. This has significant disadvantages. Inherent disadvantages of monoculture are a reduction in biodiversity and in food security. Moreover, it may lead to wealth concentration amongst farmers instead of wealth distribution. An important drawback is the dominance of companies owning the patents, selling the seeds, and the specific pesticides to go with a certain GMO crop. This situation may lead to dependence and disempowerment of farmers, since GMO seeds are expensive compared to conventional seeds, and a farmer is not allowed to save GMO seeds for next year's cultivation.

The European Union's GMO policies

Due to the issues addressed above, and public concerns about GMOs, the European Union (EU) has implemented GMO legislation based on a cautious approach. Important elements of the legislation are, for instance, an approval procedure for bringing GMOs on the market or releasing them into the environment (i.e. commercial cultivation or field trials), on a case-by-case basis, and with a compulsory risk assessment. In addition, labeling and traceability of products containing or consisting of GMOs is obligatory. Moreover, member states are allowed to install safeguard measures on a national level, thereby blocking GMOs that are approved at the EU level if sufficient concerns exist.

The situation in the EU with respect to GMOs is very diverse. Many member states have field trials, but only some states have commercial cultivation. Moreover, the views of member states on GMOs differ widely. Some states are positive to GMOs, and some are negative. In addition, many stakeholders with different points of view are engaged in the debate, such as the biotechnology industry, consumers, environmental NGOs, and farmers' organizations. Therefore, regulation of GMOs in the EU is a difficult and sensitive issue.

The World Trade Organization

It is crucial to understand important terms used within the World Trade Organization (WTO) that are relevant for the GMO debate. Among them are 'like products', risk assessment, scientific evidence, uncertainty and insufficiency. Under like products it is sometimes argued that GMO- and non-GMO products are inherently similar, that is, they are similar as long as the end products have similar properties. This argument follows the reasoning that process and production methods may not be used as reasons to discriminate one product over another product. However, consumers, especially in the EU, generally consider GMO- and non-GMO products to be different.

Risk assessment is regulated in the most relevant agreement within the WTO with respect to GMOs, the agreement on Sanitary and Phytosanitary measures (SPS). This agreement concerns protective measures against pests, and it states that such measures must be based on a valid risk assessment and not cause undue delay, something that may be challenging for GMOs since the technology develops fast and new information may come up. The SPS agreement allows for temporary measures with a precautionary notion, as long as there is insufficient scientific evidence. This is a crucial aspect in the *EC - Biotech* case.

There are potential conflicts between trade agreements and the Convention on Biological Diversity (CBD), and more especially its Cartagena Protocol on Biosafety, or Biosafety Protocol, both multilateral environmental agreements. Trade agreements and these environmental agreements are based on different premises. WTO agreements generally proclaim a reduction of trade barriers, also for GMOs, while the CBD proclaims the use of a precautionary approach. With regards to patenting, there are conflicting agreements as well. The WTO's agreement on Trade-Related Intellectual Property Rights (TRIPs) is based more upon protection of intellectual property, while the Biosafety Protocol values traditional knowledge and sharing of benefits.

The EC - Biotech case

The case brought before the WTO on the EU's GMO policy, puts the focus on several aspects of GMOs and world trade, such as the use of the precautionary principle and the tension between multilateral environmental agreements and WTO agreements. Moreover, the result of the case may have global effects, with impacts on countries' - real or perceived - possibilities to have strict GMO legislation.

Three main aspects of European GMO legislation were challenged: a perceived *de facto* moratorium on GMOs between 1998 and 2003, 27 product specific measures at EU level, and 9 safeguard measures of six member states. In brief, the panel ruled that the *de facto* moratorium and 24 product specific measures were not SPS measures *per se*, but that they caused undue delay. The member state safeguard measures, however, were deemed incompatible with the SPS agreement, since they were not based on valid risk assessments.

1. The precautionary principle

With regard to the first research question, whether it is justified to invoke the precautionary principle in GMO policies, this thesis shows that it is justifiable to do so. There are indications that GMOs may cause significant negative environmental, health and social impacts; however, there is a substantial degree of uncertainty. Thus, using the precautionary principle is justified. In EU GMO legislation the principle is invoked, and a case-by-case risk assessment must be made. Also, member states have the right to invoke so-called safeguard measures as an additional precautionary measure if new or additional information justifies this.

A question that was raised in this thesis is what measures are justified as precautionary measures. Is a total ban justified, or is an assessment on a case-by-case basis sufficiently precautious? Moreover, from an EU member state perspective, there seems to be some tension between the single market (i.e. a GMO as a product, to be allowed in all member states) and a precautionary approach (i.e. a GMO as a potential risk for the ecosystem and human, plant or animal life or health, and a member state's desire to set its own appropriate level of protection).

The second part of the first research question was whether the precautionary principle is recognized within the WTO. Formally, a precautionary approach is allowed, although the term is not explicitly mentioned in any agreement. Article 5.7 of the SPS agreement does allow a temporary precautionary measure if there is insufficient scientific evidence. However, jurisprudence from WTO trade disputes has limited the application of this article, mainly by limiting the scope of what insufficient evidence is. The panel in the *EC - Biotech* case also follows this trend; by, somewhat simplified, stating that article 5.7 is not applicable if a WTO-compatible risk assessment can be made.

2. Multilateral environmental agreements and trade agreements

The second research question was concerning the relation between multilateral environmental agreements (MEAs) and the WTO. Currently, WTO dispute panels have no obligation to take into account relevant multilateral environmental agreements, although those panels may choose to do so. In the *EC - Biotech* case, the panel chose to ignore the only MEA relevant for GMOs, the Convention on Biological Diversity and its Biosafety Protocol, even though more than 130 countries are a party to the convention, amongst them many WTO members. It may be added that one of the parties in the case, the United States, is not a party to the convention. Also, the Biosafety Protocol and the WTO are based on different premises, which may have complicated the situation.

This issue therefore illustrates that within the trade and environment field, agreements may cause tension rather than synergy.

3. The EC - Biotech case and EU GMO policy

The third research question was looking at the consequences of the *EC - Biotech* case on EU GMO policy. First of all, *direct effects* seem to be relatively small. The EU's GMO regulations,

as a whole, were not directly challenged, only parts of it, and moreover, parts of previous regulation were challenged. However, for the member states with a safeguard measure the situation is slightly different. They may have to adapt the measure and make it WTO-compatible, or remove it altogether.

It was found that public opinion is unlikely to change due to the case; opinions on GMOs are quite solid in the EU, although slight changes may occur in the coming years, whereas the main factor impacting a member state's position on GMOs is which political party or politician is in power, as was found from interviews with member state representatives.

This thesis showed that there are signs of *indirect effects* of the case on EU GMO policy. Those member states that are negative towards GMOs have become weaker in the debate, versus both the positive member states and the European Commission[110]. This may result in a slow shift towards a more open attitude on GMOs at the EU level.

The *EC - Biotech* case ties together diverse and complicated issues such as genetic engineering, EU policy making and multilateral trade agreements. The stakes are high, for the biotech industry but also for the environment and for public health. Regulating GMOs, especially those for food and feed products, is a challenging task, and an important question is who reaps the benefits and who suffers the potential risks.

7.1 Future outlook

Based on an understanding of the situation regarding GMOs in Europe, and the interviews with ten EU member state representatives, three *scenarios for GMOs in the EU* can be distinguished: a continuation of the current status quo, an increase of GMOs on the EU market, and a decrease. The causes and consequences of these scenarios will be illustrated by describing the situation for a consumer in an EU member state.

If a time scale of 10 years from now is considered, that is, the year 2016, some assumptions can be made, such as that EU's GMO legislation still will be in place, that the WTO still exists, as well as the Convention on Biological Diversity (CBD).

1. A continuation of the current status quo

In 10 years from now, ms. Larsson from Sweden will still not know if the meat she buys is from animals being fed with GMO feed. Products containing GMOs are hardly on the market, since they have to be labeled, and consumer interest is still quite modest. Products with nutraceuticals are available in other parts of the world, but not in the EU. In ms. Larsson's municipality there have been some small-scale field trials, she has heard, but there is no large-scale commercial cultivation. Scientists still disagree on the environmental risks of GMOs, and as far as the debate comes through in the media, the positions of for instance NGOs, politicians and biotech industry seem locked.

From a sustainability point of view, there will likely have occurred quite a few cases of contamination of nearby non-GMO crops and wild relatives. Biodiversity impacts in the EU will be low, since there are mainly small field trials. The health impacts of GMOs are still not clear. A slight increase of tension between farmers has occurred, as some have shown interest for cultivating GMO crops, while others are concerned about contamination and are strongly opposed.

[110] See note 102.

Internationally, the cultivation of GMOs has increased also in the years 2006-2016, but not half as much as in the years 1996-2005. Consequences for small farmers in developing countries are mixed: Some achieve a better standard of living, but others do not.

The process of corporate mergers and acquisitions has continued, but mainly by the big players buying smaller companies. New small companies still emerge, since the field is still evolving with new niche products.

The US has finally lost its patience, and started a new trade dispute in the WTO, on EU's labeling and traceability legislation. They are now joined by Argentina, Canada, Brazil and China.

2. An increase of GMOs on the EU market

Mr. Lopez from Spain will see many products in his favorite supermarket labeled with 'may contain genetically modified organisms'. As most of his neighbors, he does not see any danger in consuming GMOs, and he has positive associations to the environmental benefits of GMOs, such as decreased pesticide and water use, two problems in Spain. Moreover, the products containing nutraceuticals benefit his health.

Spain, which was one of the first EU member states to have commercial cultivation of GMOs, has lost the first place to Germany, which now has the largest area of GMO cultivation. Applications for GMO seeds and products are now approved much faster in the EU, and the requirements for risk assessments have become less stringent. A few years ago, scientists found a new method to significantly reduce the risk for contamination of the environment, and isolation distances for coexistence were reduced. Moreover, the scientific consensus is now that GMOs are not damaging for human health and the environment.

For the agricultural landscape in the EU, this development has led to more monoculture, now also with GMO crops. This has a negative impact on biodiversity, not only considering crop diversity but also with respect to non-target organisms.

Moreover, multinational corporations have extended their grip on EU agriculture, and in many countries such as Austria, Italy, Belgium, Hungary, etc., the number of small farmers has been reduced significantly. This in turn has led to reduced liveability on the countryside, and the urbanization of the EU has continued.

Internationally, the growth of GMO cultivation has continued. Many countries have decided not to implement stringent GMO legislation, and there has been no new trade dispute on GMOs in the WTO.

3. A decrease of GMOs on the EU market

Mr. Sekulov from Bulgaria will see virtually no GMO-labeled products in his supermarket. Moreover, his region has declared itself GMO-free, so there are no cultivations of GMO crops either. As many people in this region, Mr. Sekulov is very concerned about possible negative environmental and health impacts of GMOs. A number of cases have been described in the media, and scientific evidence that GMOs are not that safe seems to be growing.

EU legislation has become stricter compared to ten years ago. Coexistence is limited, and GMO producers and importers are liable for negative impacts. Moreover, meat from animals fed with GMO feed must now be labeled as well. As a consequence, the market for GMO food and feed products has plummeted, and many small countries exporting these products to

the EU have stopped growing GMO crops, since the costs for having separate GMO- and non-GMO systems are too high.

The biotech industry has basically withdrawn from the agricultural GMO food and feed market, and is now focusing on other applications such as medical and pollution clean-up applications.

Environmental damage due to contamination is limited, and the impacts of GMOs on biodiversity are small. Due to more stringent testing requirements and smarter genetic engineering technologies, the industry has managed to limit some negative health effects of GMOs, e.g., insecticide is no longer expressed in al parts of the plant, however, without much impact on consumer attitudes towards GMOs.

The US, joined by China, has started a new dispute in the WTO, but this case has not been resolved yet. Parallel to that, the work within the CBD has evolved rapidly towards worldwide minimum safety standards for GMO agriculture, taking into account environmental, social and economic aspects.

7.2 Recommendations

From an overall sustainability viewpoint, it is my opinion that current GMO development and cultivation is unsustainable. It is based on monoculture, including the food security risks associated with it, and based on intellectual property rights, having large impacts especially on small farmers in developing countries. Moreover, there are strong indications of GMOs spreading into the environment, possibly having a negative impact on biodiversity, and of GMOs having undesired and unexpected side effects such as the production of allergenic proteins. Also, GMO crops have often not lived up to the promise of substantial yield increase and reduction of pesticide usage.

However, the potentials of GMOs are plentiful: They may have beneficial effects on the environment such as nitrogen fixation, or requiring fewer pesticides, or less water. The inclusion of genetic material that stimulates the organisms to produce or incorporate higher concentrations of vitamins and minerals in basic food crops may help combat deficiencies, and thus, could lead to health improvements.

Thus, my recommendations, directed at policy makers, build on three main tracks: First, having stringent control of environmental, social and economic effects of GMOs, taking a precautionary approach. Second, strengthening research on GMOs for the public interest. And finally, taking into account alternative food supply strategies that may be more sustainable than genetic engineering.

I recommend policy makers in the EU and member states to:

- Strengthen EU GMO legislation, taking a precautionary approach especially as long as long-term environmental or health effects are not known. Important issues are coexistence and liability;

- Demand a sustainability impact assessment of producers and importers of GMOs, where environmental, social and economic aspects are taken into account, both upstream (the producers or farmers) and downstream (the consumers);

- Have a capacity-building program for developing countries' regulators and competent authorities, so that they can receive support if they desire to have a strict and arguably complicated and high-tech regulatory system;

- Support research on long-term environmental and health impacts of GMOs;
- Support research on how to minimize risks to the environment associated to GMOs, such as contamination, herbicide resistance, etc.;
- Respect and act upon the values behind the Convention on Biological Diversity, such as valuing biodiversity, traditional knowledge, sustainable development and public participation;
- Try to balance public interest and private intellectual property rights, and consider a form of public property rights, to be used for public benefit;
- Support research on pest management in organic farming;
- Work on reforming the EU's agricultural policy, e.g. remove export subsidies on agricultural products, let domestic subsidies promote sustainable agriculture such as organic agriculture, local food production and consumption, a liveable countryside, and nature and biodiversity conservation, instead of focusing on units of production.
- Have a capacity building and technology transfer program for small-scale farmers in developing countries, based on their needs, their community, their local environment, and sustainability.

Many of these recommendations are already implemented to some extent, but continuing work on these issues, in accordance with values such as sustainability, precaution and global awareness, is a necessity.

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Appendix 1. List of interviews

Member states representatives

Of the current 25 EU member states, a selection of 10 was made to interview, based on their voting record on GMO approvals (see Appendix 4): Five states positive to GMOs and five negative to GMOs were taken. Moreover, geographical diversity was strived for, and thus some north/western European countries were chosen and some south/eastern. Also country size was taken into account, and a mix between 'old' and 'new' EU member states was aimed for. Thus, the following member states were selected: Austria, Belgium, Denmark, Estonia, Germany, Hungary, Italy, Lithuania, The Netherlands, and The United Kingdom. The representatives were generally working at ministries of environment, competent authorities or permanent representations in Brussels.

Environmental NGOs

Two representatives of the environmental organization Friends of the Earth Europe were interviewed.

Farmers' organizations

Two representatives of the swedish organization Ekologiska Lantbrukarna [The Organic Farmers] were interviewed.

Biotech industry

Two representatives of the biotech industry organization Europa-Bio were interviewed.

USDA

One representative of the US Department of Agriculture (USDA) was interviewed.

Experts

One expert from the organization Center for International Environmental Law (CIEL) was interviewed.

Note on the interviews

The interviewees were granted confidentiality. Most of the interviews, especially with government or competent authority's representatives, must be seen as given on a personal capacity. Some interviewees especially stated this, for the full interview or parts of it. If the reader is interested in more details on the interviews, the author of this thesis can be contacted at ellie.cijvat@gmail.com.

Appendix 2. Interview with member state representatives

Background

Based on the goal of this thesis and the research questions, four general categories of questions were defined: The country's GMO policy and public attitudes, the precautionary principle and multilateral environmental agreements related to GMO, the effects of the ruling and the future of GMOs in Europe. Within each group a number of questions was then formulated, with the additional goal of having diverse questions (see Bryman, 2004, p 324) and providing a good opportunity for the member state representatives to give their opinion. The framework for each of the interviews with member state representatives is provided below.[111]

GMO/WTO biotech products (BP) case

Phone interview with **??** (country, function)

July ??th, 2006.

****

A. The country's GMO policy + attitudes

1. *Could you describe your country's GMO policy (e.g. ban, test fields, cultivation, etc.)?*

2. *What GMO products (plants and seeds, or food and feed) do you currently allow? On what scale?*

3. *When did your country adapt legislation to EU directive 2001/18/EC? (Can you send me a copy of the legislation?)*

4. *Can you describe how you generally vote in GMO questions in the EU council of environment ministers?*

[111] The questiosn for interviews with other stakeholders and experts were based on these categories and questions, but fewer questions were asked and the most relevant were chosen based on which stakeholder was interviewed.

5. *What is the public's attitude towards GMO? Farmers' attitudes? (consumer polls, investigations etc?)*

6. *Is your government (or governmental organization/competent authority) doing its own tests on buffer zones, spreading, superweeds etc? Risk assessments?*

B. GMO and precautionary, biosafety/biodiversity (MEAs)

7. *Do you apply the precautionary principle in your GMO policy? Explain how?*

8. *How do you take into account the Cartagena protocol on biosafety/Convention on Biological Diversity?*

    - *Can you balance WTO and Cartagena/CBD, or do they conflict?*
    - *Are the Cartagena protocol on biosafety and the Convention on Biological Diversity taken into account at EU level?*

C. Effects of the WTO ruling

9. *How, in your estimation, is your country's GMO policy affected by the WTO ruling in the biotech products case?*

10. *How, in your estimation, will EU GMO policy be affected by the ruling?*

11. *Does the ruling strengthen the European Commission (EC) or member states? (e.g. does the ruling facilitate future harmonization within EU? Or will there be more polarization between members?)*

12. *Please fill out the questionnaire on effects of the ruling in your country.*

D. Future of GMOs in Europe

13. *How do you see the future of GMOs in Europe?*

- *Main barriers for GMOs (cultivation and products) catching on?*
- *Main drivers for GMOs (cultivation and products) catching on?*

- *Some specific issues:*
  - *consumer interest?*
  - *member states' policies?*
  - *common EU policy?*
  - *coexistence, risk assessment?*
  - *new WTO case?*

Appendix 3. Questionnaire to member state representatives

This questionnaire aimed at getting more specific information on the effects of the *EC - Biotech* case in the member states. It was distributed by e-mail to the representatives of the ten EU member states who were interviewed as well.

Questionnaire to member states

Please select the three most likely effects of the WTO Biotech Case ruling in your country, in your estimation.

__ increased public acceptance of GMOs

__ decreased public acceptance of GMOs

__ increase in GMO applications/field tests/products/cultivations

__ decrease in GMO applications/field tests/products/cultivations

__ increased conflict of your government with organic farmers

__ decreased conflict of your government with organic farmers

__ increased conflict of your government with environmental NGOs

__ decreased conflict of your government with environmental NGOs

__ increased contact between your government and biotech industry

__ decreased contact between your government and biotech industry

__ increased public resistance to the WTO

__ decreased public resistance to the WTO

__ increased public scepticism to the EU

__ decreased public scepticism to the EU

__ no effect/hardly any effect

__ other, namely .....

Appendix 4. Voting record of EU member states on GMO applications

Table A4-1. EU member states voting results on GMO products or cultivations (June 2004 – October 2005).

Member state	**Voting results, total 15 votes [112] (for/against/abstentions or absent)**	**Overall attitude [113]**
Austria	0/15/0	negative
Belgium	9/3/3	positive
Cyprus	0/13/2	negative
Czech Republic	10/0/5	positive
Denmark	1/10/4	negative
Estonia	10/2/3	positive
Finland	15/0/0	positive
France	12/3/0	positive
Germany	4/0/11	positive
Greece	0/12/3	negative
Hungary	0/10/5	negative
Ireland	6/0/9	positive
Italy	1/12/2	negative
Latvia	4/8/3	negative
Lithuania	0/13/2	negative
Luxembourg	0/14/1	negative
Malta	0/11/4	negative
Netherlands	15/0/0	positive
Poland	3/7/5	negative
Portugal	5/8/2	negative
Slovakia	2/6/7	negative
Slovenia	0/6/9	negative
Spain	0/1/14	negative
Sweden	15/0/0	positive
UK	13/1/1	positive

Source: http://www.foeeurope.org/GMOs/pending/votes_results.htm .

[112] Source: http://www.foeeurope.org/GMOs/pending/votes_results.htm

[113] The overall attitude is only based on the voting results; the situation is more complex in reality, see e.g. Spain, where commercial cultivation is present while the voting record shows a negative attitude towards GMOs, or Germany, which is being reprimanded by the WTO panel for its ban but showing a somewhat positive voting record.

Appendix 5. Overview of allowed GMO products in the EU

A5.1. Authorized before 1998

18 GMOs were approved before 1998, of which 10 were food or feed products; the rest was medicine, tobacco, etc.

Source: http://ec.europa.eu/environment/biotechnology/index_en.htm

A5.2. Pending during 1998 - 2003

14 product applications were pending.

Source: http://ec.europa.eu/environment/biotechnology/index_en.htm

A5.3. Placing on the market of GMOs as or in products (under directive 2001/18/EC, part C) from October 2003.

Source: http://gmoinfo.jrc.it/gmc_browse.aspx?DossClass=0 [2006, October 16].

Pending: [114]

Dianthus caryophyllus L. (carnation) with modified flower colour (NL) [115]

Genetically modified maize NK603 Å~MON 810 (for import and use, including cultivation) (ES)

Insect resistant Bt11 maize (FR)

Lepidopteran resistant and glufosinate tolerant 1507 Maize (ES)

Oilseed rape Ms8xRf3 (BE)

Potato variety EH92-527-1 with modified starch content (SE)

Genetically modified maize NK603 Å~MON 810 (for import and use, NOT including cultivation) (UK)

---

[114] These products are pending as of March 14th, 2006.

[115] The country codes for the countries mentioned here are: Belgium=BE, Denmark=DK, Germany=GE, Italy=IT, The Netherlands,=NL, Spain=ES, Sweden=SE and The United Kingdom=UK.

Authorized:

Insect-protected maize line MON 863 and maize hybrid MON 863 x MON 810 (GE)

Lepidopteran resistant and glufosinate tolerant 1507 Maize (NL)

Roundup Ready (glyphosate tolerant) oilseed rape, event GT73 (NL)

Roundup Ready (glyphosate tolerant) maize, event NK603 (ES)

Withdrawn:

Insect resistant cotton events 281-24-236 and 3006-210-23 (NL)

Glufosinate-tolerant Rice, LLRICE62 (UK)

Roundup Ready maize line NK603 for cultivation in the EU (ES)

Genetically modified BROMBXNNIL-tolerant cotton (ES)

MaisGard/Roundup Ready maize GA21 x MON810

Roundup Ready maize line GA21

Glufosinate Tolerant oilseed rape T45 (UK)

Glufosinate tolerant soybeans A 2704-12 and A5547-127 (BE)

Roundup Ready sugar beet (BE)

Transferred to regulation 1829/2003:

Glufosinate Tolerant oilseed rape T45 (UK)

Glufosinate tolerant Cotton Transformation event LLCotton25 (ES)

Roundup Ready fodder beet derived from line A5/15 (DK)

Glufosinate tolerant Oilseed Rape Liberator pHoe6/Ac (GE)

Roundup Ready Sugar Beet (Beta Vulgaris) Derived from Event H7-1 (GE)

Glufosinate tolerant Oilseed Rape Falcon, GS40/90pHoe6/Ac (GE)

Insect-Protected cotton line derived from Event 531 (ES)

Roundup Ready cotton line derived from Event 1445 (ES)

Appendix 6. Overview of alleged violations in the *EC – Biotech* case.

Source: EC - Biotech panel, 2006b.

Alleged violations by the EU of the SPS Agreement:

For the *de facto* moratorium: articles 2.2, 2.3, 5.1, 5.5, 5.6, 7, 8, 10.1 and Annexes B(1), C(1)(a) and (b). For the product-specific measures: articles 2.2, 2.3, 5.1, 5.5, 5.6, 7, 8 and Annexes B(1), C(1)(a), (b), (c) and (e). For the member state safeguard measures: articles 2.2, 2.3, 5.1, 5.5 and 5.6.

Alleged violations by the EU of the TBT Agreement:

For the product-specific measures: articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12. For the member state safeguard measures: articles 2.1, 2.3, and 2.9.

Alleged violations by the EU of the GATT 1994:

For the *de facto* moratorium: article III:4. For the product-specific measures: article III:4. For the member state safeguard measures: articles III:4 and XI:1.

It was not established by the dispute panel that the EU moratorium violated articles 2.2, 2.3, 5.1, 5.5, 5.6, 7, 10.1 and Annexes B(1), and C(1)(b) of the SPS agreement, nor was it established that the EU product specific measures violated articles 2.2, 2.3, 5.1, 5.5, 5.6, and 7, and Annexes B(1), and C(1)(b), (c) and (e) of the SPS agreement. With respect to the member state safeguard measures, it was established that they breach articles 2.2 and 5.1. Considering violation of articles 5.5 and 5.6 was thus deemed not to be needed.

The panel did not see the need of considering most of the alleged GATT and TBT violations.

Appendix 7. European Food Safety Authority GMO risk assessment – Annex IV of the EFSA guidance document

Source: EFSA (2006), un-edited.

Annex IV

Format[116] of the Summary of applications for genetically modified plants and/or derived food and feed

According to Articles 5(3)(l) and 17(3)(l) of Regulation (EC) 1829/2003, the application shall be accompanied by a summary of the dossier in a standardised form. This annex specifies the format of such summary for genetically modified plants and/or derived food and feed. Depending on the scope of the application, some of the specifications may not be applicable. The summary shall be presented in an easily comprehensible and legible form. It shall not contain parts which are considered to be confidential.

A. GENERAL INFORMATION

1. Details of application

a) Member State of application
b) Application number
c) Name of the product (commercial and other names)
d) Date of acknowledgement of valid application

2. Applicant

a) Name of applicant
b) Address of applicant
c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii))

[116] This format of summary is based on Part II of Council Decision 2002/812/EC of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products (Official Journal of the European Communities L280: 37-61), and is adapted according to the current guidance document.

3. Scope of the application

o GM plants for food use

o Food containing or consisting of GM plants

o Food produced from GM plants or containing ingredients produced from GM plants

o GM plants for feed use

o Feed containing or consisting of GM plants

o Feed produced from GM plants

o Import and processing (Part C of Directive 2001/18/EC)

o Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

4. Is the product being simultaneously notified within the framework of another regulation (*e.g.* Seed legislation)?

Yes o	No o
If *yes*, specify	

5. Has the GM plant been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?

Yes o	No o
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC or Regulation (EC) 258/97?

Yes o	No o
If *yes*, specify	

7. Has the product been notified in a third country either previously or simultaneously?

Yes o	No o
If *yes*, specify	

8. General description of the product

a) Name of the recipient or parental plant and the intended function of the genetic modification
b) Types of products planned to be placed on the market according to the authorisation applied for
c) Intended use of the product and types of users
d) Specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for
e) Any proposed packaging requirements
f) A proposal for labelling in accordance with Articles 13 and Articles 25 of Regulation ((EC) 1829/2003. In the case of GMOs, food and/or feed containing or consisting of GMOs, a proposal for labelling has to be included complying with the requirements of Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC
g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants)
h) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for. Any type of environment to which the product is unsuited

9. Measures suggested by the applicant to take in case of unintended release or misuse as well as measures for disposal and treatment

B. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name

a) Family name
b) Genus
c) Species
d) Subspecies
e) Cultivar/breeding line or strain
f) Common name

2 a. Information concerning reproduction

(i) Mode(s) of reproduction
(ii) Specific factors affecting reproduction
(iii) Generation time

2 b. Sexual compatibility with other cultivated or wild plant species

3. Survivability

a) Ability to form structures for survival or dormancy
b) Specific factors affecting survivability

4. Dissemination

a) Ways and extent of dissemination
b) Specific factors affecting dissemination

5. Geographical distribution and cultivation of the plant, including the distribution in Europe of the compatible species

6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

7. Other potential interactions, relevant to the GM plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

2. Nature and source of the vector used

3. Source of donor DNA, size and intended function of each constituent fragment of the region intended for insertion

D. INFORMATION RELATING TO THE GM PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified

2. Information on the sequences actually inserted or deleted

a) The copy number of all detectable inserts, both complete and partial
b) In case of deletion(s), size and function of the deleted region(s)
c) Chromosomal location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination
d) The organisation of the inserted genetic material at the insertion site

3. Information on the expression of the insert

a) Information on developmental expression of the insert during the life cycle of the plant
b) Parts of the plant where the insert is expressed

4. Information on how the GM plant differs from the recipient plant in

a) Reproduction
b) Dissemination
c) Survivability
d) Other differences

5. Genetic stability of the insert and phenotypic stability of the GM plant

6. Any change to the ability of the GM plant to transfer genetic material to other organisms

a) Plant to bacteria gene transfer
b) Plant to plant gene transfer

7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

7.1 Comparative assessment

Choice of the comparator

7.2 Production of material for comparative assessment

a) Number of locations, growing seasons, geographical spread and replicates
b) The baseline used for consideration of natural variations

7.3 Selection of material and compounds for analysis

7.4 Agronomic traits

7.5 Product specification

7.6 Effect of processing

7.7 Anticipated intake/extent of use

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins
7.8.2 Testing of new constituents other than proteins
7.8.3 Information on natural food and feed constituents
7.8.4 Testing of the whole GM food/feed

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein
7.9.2 Assessment of allergenicity of the whole GM plant or crop

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food
7.10.2 Nutritional assessment of GM feed

7.11 Post-market monitoring of GM food/feed

8. Mechanism of interaction between the GM plant and target organisms (if applicable)

9. Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification

9.1 Persistence and invasiveness
9.2 Selective advantage or disadvantage
9.3 Potential for gene transfer
9.4 Interactions between the GM plant and target organisms
9.5 Interactions of the GM plant with non-target organisms
9.6 Effects on human health
9.7 Effects on animal health
9.8 Effects on biogeochemical processes
9.9 Impacts of the specific cultivation, management and harvesting techniques

10. Potential interactions with the abiotic environment

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants and if the applicant has clearly shown that environmental exposure is absent or will be at

levels or in a form that does not present a risk to other living organisms or the abiotic environment)

11.1 General (risk assessment, background information)
11.2 Interplay between environmental risk assessment and monitoring
11.3 Case-specific GM plant monitoring (approach, strategy, method and analysis)
11.4 General surveillance of the impact of the GM plant (approach, strategy, method and analysis)
11.5 Reporting the results of monitoring

12. Detection and event-specific identification techniques for the GM plant

E. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT AND/OR DERIVED PRODUCTS

1. History of previous releases of the GM plant notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier

a) Notification number
b) Conclusions of post-release monitoring
c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)

2. History of previous releases of the GM plant carried out outside the Community by the same notifier

a) Release country
b) Authority overseeing the release
c) Release site
d) Aim of the release
e) Duration of the release
f) Aim of post-releases monitoring
g) Duration of post-releases monitoring
h) Conclusions of post-release monitoring
i) Results of the release in respect to any risk to human health and the environment

3. Links (some of these links may be accessible only to the competent authorities of the Member States, to the Commission and to EFSA):

a) Status/process of approval
b) Assessment Report of the Competent Authority (Directive 2001/18/EC)
c) EFSA opinion

d) Commission Register (Commission Decision 2004/204/EC[117])
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre
f) Biosafety Clearing-House (Council Decision 2002/628/EC[118])
g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC)

[117] Commission Decision of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council. Official Journal of the European Communities L 65: 20 – 22.

[118] Council Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety. Official Journal of the European Communities L 201: 48 – 49.

Appendix 8. Results from the interviews with member state representatives

A8.1. The country's GMO policies and public attitudes

Question 1, 2

1. *Could you describe your country's GMO policy (e.g. ban, test fields, cultivation, etc.)?*
2. *What GMO products (plants and seeds, or food and feed) do you currently allow? On what scale?*

The results of the coding of the replies (Bryman, 2004) are:

AU	No general ban, safeguard measures. Maybe test fields. Contamination special concern Austria.
BE	Case-by-case. No test fields, no cultivation right now. EU regulated. Few food products, more feed.
DK	No ban. No cultivation. Case-by-case. Coexistence. GM animal feed.
EE	Case-by-case. No request yet.
GE	Test fields, commercial growing. EU regulated.
HU	No general ban. Field trials. EU regulated.
IT	No ban. Test fields after authorization. See EU level.
LT	Case-by-case, precautionary. Little experience. No test fields. -
NL	Case-by-case. EU regulated.
UK	Case-by-case, precaution, science. EU level, See website.

Results:

- Main points of European GMO regulation come forward; Many MS mention 'no general ban', case-by-case. Also, safeguard measures. Many MS have field trials, one mentions commercial cultivation.
- Allowed GMO products are regulated at the EU level.

Question 3, 4

3. *When did your country adapt legislation to EU directive 2001/18/EC?*

4. *Can you describe how you generally vote in GMO questions in the EU council of environment ministers?*

AU	2004? little too late. Against.
BE	February 24th 2005 Case-by-case, 2 ministries, set of criteria.
DK	Dec. 3rd 2002 Previously against, now case-by-case.
EE	2004? Mixed.
GE	March 2006 (too late). Import and use: now positive. Cultivation: ?
HU	Last decree in 2004. Case-by-case, 4 ministries. Generally against. Research and contained use: generally supportive.
IT	8 july, 2003. Case-by-case, inter-ministerial. Careful on specific issues.
LT	May 1st, 2004 Generally against.
NL	Don't know. case-by-case.
UK	2002? Case-by-case assessment.

Results:

- Some MS were too late implementing EU Directive 2001/18/EC.
- Most MS mention case-by-case assessment. Inter-ministerial decision-making process is mentioned by some.

Question 5, 6

5. *What is the public's attitude towards GMO? Farmers' attitudes? (consumer polls, investigations etc?)*

6. *Is your government (or governmental organization/competent authority) doing its own tests on buffer zones, spreading, superweeds etc? Risk assessments?*

AU	60-80% of population against, all political parties

	Maybe fund research projects.
BE	Eurobarometer: european middle. no tests, but research.
DK	Food: majority against GMOs. Farmers divided. Some research.
EE	General public negative, politicians follow. No research.
GE	Population against GM food (75%). Farmers similar. Coexistence field studies.
HU	Majority against GMO food. Farmers complicated, many against. No research.
IT	No good data; number of regions 'GMO-free'. Protocols on test fields, risk assessment.
LT	- -
NL	- -
UK	See website. Substantial research.

Results:

- Most MS acknowledge the low support for GMOs of the public.
- Large spread in government's activities: substantial research to no research. This can be related to development of the country (e.g. GDP or development of biotech sector?)

Other findings from question 1-6:

- position on GMO depending on persons/political situation
- GM food: risks don't outweigh the benefits
- GM feed is imported
- Consumer interest too low to make GMO interesting for cultivation
- find balance between GMO & organic farming
- keep country GM free: economic, environmental reasons
- not GM free for a long time
- risk assessment studies are poor, especially with respect to local environment

- informing the audience impacts public attitudes
- stakeholder involvement
- GM free regions
- farmer organizations support coexistence, free choice of farmer
- national competent authority gives recommendation, besides EFSA

A8.2. The precautionary principle and multilateral environmental agreements

Question 7, 8

7. *Do you apply the precautionary principle in your GMO policy? Explain how?*
8. *How do you take into account the Cartagena protocol on biosafety/Convention on Biological Diversity?*
    - *Can you balance WTO and Cartagena/CBD, or do they conflict?*
    - *Are the Cartagena protocol on biosafety and the Convention on Biological Diversity taken into account at EU level?*

AU	PP: EU: PP not sufficiently, AU thinks.
BE	PP. EU level. BP: EU level.
DK	PP: yes, especially in risk assessment legislation. BP: we have a clearinghouse
EE	PP: not explicit, but from EU leg. BP: Also from EU leg.
GE	PP: yes, both GE and EU. BP: at EU level.
HU	PP yes, in risk assessment legislation BP: yes, clearinghouse.
IT	PP: yes, both IT and EU. BP: yes, both IT and EU.
LT	PP: yes BP: yes, EU.
NL	PP: EU level. BP: EU level.
UK	PP: UK: precautionary approach. BP: yes, EU and UK.

Results:

- The precautionary principle is in many countries explicitly written into the legislation, and especially risk assessment legislation was mentioned in this context by a few countries.

- Most countries think that the principle is taken into account at the EU level sufficiently; one MS thinks it is not.

- Many MS are party to the CBD and BP, and it is taken into account at the country and EU level. Some MS mention a national Biosafety Clearing House (a goal of the BP).

Other findings from question 7-8:

- On the PP: there should be reliable signs that there might be a risk for health or environment to stop the authorization process

- On conflict WTO/BP: ban of *Bt*-176 maize was based on concerns about antibiotics resistance and *Bt*-toxin; this ban was condemned in the *EC - biotech* case

- On the PP: it can be interpreted in many ways

A8.3. Effects of the WTO *EC – Biotech* ruling

Question 9, 10

9. *How, in your estimation, is your country's GMO policy affected by the WTO ruling in the biotech products case?*

10. *How, in your estimation, will EU GMO policy be affected by the ruling?*

AU	AU: safeguard measures are likely affected. EU: no effect.
BE	BE: no effect. EU: little effect except safeguard measures
DK	DK: no effect. EU: no effect.
EE	EE: hopefully yes (towards more open attitude on GMOs) EU: moratoria will change, legislation not.
GE	GE: safeguard measures are likely affected. EU: legislation applied more strictly.
HU	HU: some effects in next few years (more open attitude on GMOs) EU: speed up the process, try to lift bans.
IT	IT: no real effects. EU: no real effects.

LT	LT: no effects. EU: maybe some effects on risk assessment or on scientists.
NL	NL: no effect. EU: -
UK	UK: no effect. EU: no effect.

Results:

- Safeguard measures of some member states are likely affected, otherwise no changes expected but a slight shift in some MS towards a more open attitude on GMOs.

- Application of EU legislation may change, but otherwise no changes are expected in legislation.

Question 11

11. *Does the ruling strengthen the European Commission (EC) or member states? (e.g. does the ruling facilitate future harmonization within EU? Or will there be more polarization between members?)*

AU	-
BE	The whole EU is strengthened. The MS with safeguard measures will likely become weaker.
DK	In theory strengthen the EC (since the application of the legislation was the problem).
EE	No changes.
GE	EC will want to apply rules more strictly, question MS arguments against GMOs.
HU	EC will try to speed up authorization, lift bans.
IT	Not much effect, no real polarization.
LT	-
NL	MS negative to GMOs will be weakened.
UK	-

Results:

- There will not be very profound changes in attitudes of EC or MS due to the ruling.

- However, several MS indicate that the EC is strengthened and may want to apply EU legislation more strictly (speed up authorization, lift the safeguard measures). This weakens the position of MS that argue against GMOs.

Other findings from question 9-11:

- Within the EC there are also diverging opinions on GMOs
- Each country can set its own level of risk, but countries should make proper risk assessments, not just opinions
- Pressure of NGOs on the minister to refuse GMOs
- Liability would need better legislation
- Coexistence will likely be set at the national level
- Negative or extremely positive countries are not taken seriously
- Ministry of economy will be stronger in the national [inter-ministerial] discussions
- MS are likely to change their position in the next few years due to changes in politicians and governments
- National legislation responds to the MOP to the BP
- Outcome of the ruling: EU should not be so 'stiff'

A8.4. The future of GMOs in Europe

Question 13, part 1.

13. How do you see the future of GMOs in Europe?

- *Main barriers for GMOs (cultivation and products) catching on?*
- *Main drivers for GMOs (cultivation and products) catching on?*

AU	- Driver: Maybe we will have more food stuff with GMOs.
BE	Barrier: negative image by NGOs, contamination of the market by not-allowed GMOs. Driver: economic possibilities, progress in technology, new GMOs with more benefit for industry and consumers.
DK	Barrier: consumer attitudes, env. NGO opposition. Driver: large number of small biotech firms, medical applications, contained use.
EE	Barrier: public opinion. Driver: economic aspects, GMOs are there,
GE	Barrier: opposition of the population.

	Driver: GM plants showing obvious advantages to people.
HU	Barrier: political. Driver: biotech companies' lobby, GMOs in animal feed, possible benefits of GMOs becoming clear.
IT	-
LT	Barrier: none. Driver: GM is growing, will be mostly GM on the market.
NL	Barrier. consumer sees no benefit. Driver: GMOs showing advantages to consumer
UK	Barrier: public attitudes Driver: possible benefits of GMOs are shown, GM product can fill niche.

Results:

- By far the most significant barrier is public attitudes (6 times). Also, NGO opposition, politics and contamination by non-approved GMOs were mentioned.

- As drivers were mentioned: GMOs showing obvious advantages to people (5 times), GMOs used in specialized or non-food applications (4 times), GMOs are on the market (3 times), technology progress (2 times), economic possibilities (2 times), biotech companies' lobby, and the large number of small biotech firms.

Question 13, part 2.

- *Some specific issues:*
  - *consumer interest? (CI)*
  - *member states' policies? (MS)*
  - *common EU policy? (EU)*
  - *coexistence, risk assessment? (C), (RA)*
  - *new WTO case? (WTO)*

AU	CI: will stay low MS: seen changes already EU: no changes in near future. C: maybe become subject to subsidiarity RA: EFSA has changed to more subsidiarity.
BE	CI: will depend on the image of GMOs. MS: depends on consumers' opinion and pressure from NGOs. EU: depends on MS attitudes C: could work in MS with larger surface, but not easy in BE (small-scale agriculture)

	RA: will stay as strict as now. WTO:
DK	CI: no change, maybe some consumers even stronger against. MS: maybe, with new legislation in place no arguments left to say no. EU: no new legislation, maybe changes in application. C: getting in place now. RA: no changes. risk communication may develop. WTO: maybe.
EE	CI: might change [more positive]. MS: seen changes already. EU: no changes. C: [under development, subsidiarity struggle]. RA: need to find consensus. WTO: don't know.
GE	CI: could change (more positive) in future. MS: try to bring law and public opinion in harmony. EU: try to bring law and public opinion in harmony. C: in development. RA: check the schemes.
HU	CI: Europe will produce and eat GMOs. MS: no major changes. EU: no major changes, maybe softened a little [on GMOs]. C: under development. Hope for subsidiarity. RA: hope it will be more based on science, and more info requirements. WTO: don't know.
IT	-
LT	CI: will increase. MS: follows public opinion, thus more positive. EU: no changes, very difficult. C: difficult. RA: stronger standards are needed. WTO: difficult.
NL	CI: a slow shift going on [to more positive] MS: negative MS might change a little. EU: - C: - RA: - WTO: -
UK	EU: no changes, very difficult. GMO products no change, cultivation has more subsidiarity. C: under development. RA: no changes. WTO: would be surprised.

Results:

- On consumer interest, the results are mixed: some see no changes, some see an even stronger opposition, but a significant number of MS representatives see a more positive public opinion.

- On member state policies, it was pointed out by several MS that there have been changes already (mainly due to changes in government, but also the EU legislation being in place and sufficient). The influence of public opinion on MS policies was pointed out by a few interviewees.

- On EU policies, the common agreement was that no changes in legislation will occur, since the process is extremely difficult. However, several more or less open issues were mentioned, such as coexistence, liability, and cultivation. One interviewee mentioned possible changes in application of the legislation.

- On coexistence, the consensus was that this is under development. The principle of subsidiarity was indicated by many of the interviewees in this context.

- On risk assessment, views were divergent. Some member states saw no future changes, some appealed for stronger standards. The developments within EFSA were mentioned by some interviewees.

- On a new case in the WTO, no strong viewpoints were expressed, and responses rated from 'would be surprised' to 'don't know' to 'would not be surprised'.

Other findings from question 13:

- Cultivation may be more subject to the subsidiarity principle

- Changes in MS GMO policies are due to changes in government, e.g. Spain, Slovenia

- EFSA has changed towards more subsidiarity, it is getting better.

- Now that labelling legislation is in place, MS may feel that there are no logical arguments left to say no

- Public opinion does not have to do with real risks or benefits, but more with panic and misinformation.

- Reasons for people to buy more GMO food may be that they now don't have enough information, or that they will buy the cheapest food.

- The UN is working on getting countries to write down a policy, so it becomes less dependent on the person.

- Our government tries to work with voluntary agreements with farmers on GMO free regions; but each farmer has the right to veto this process.

- Risk analysis is very open, e.g. the environmental effects.

- Seed contamination threshold value is a big issue. A low threshold is costly for seed producers.

- The US will take other measures such as diplomacy (e.g. exert influence through the ministries of economy) and maybe other trade agreements.

- The US may wait with a new case, since the EU is working on lifting the bans and is more and more in favour of GMOs.

- Labelling and traceability is an economic loss for industry.

- On risk assessment: public opinion, technical and scientific data and options for risk management must be balanced.

- Risk assessment should take an ecosystem approach instead of the present focus on strict biomolecular studies.

- The patchy mosaic of European landscape and small scale agriculture seems not really to guarantee for a safe coexistence or make enforcement easy

- Europe will not easily give way in the area of food safety and public health

- First GMOs on the market should have shown benefits to consumers, not profit for Monsanto

- Traceability of GMOs is very difficult, especially if they are not registered

- Contamination happens, but the consequences will likely be not that severe