THE INITERNATIONAL TRADE

DISPUTE OVER GMOs BEFORE THE WTO: CAUSES AND CONSEQUENCES

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ABSTRACT

The *Biotech* dispute at WTO received a great deal of attention, and reopened a wide-ranging debate over the benefits of genetically modified organisms (GMOs) and their effects on human health and the environment. The dispute was complex and involved a high level of political sensitivity. It brought attention to procedural and substantive issues in which the roles of science and precaution, and the interrelationship between trade law and international law took centre stage. It raised questions as to the degree of risk acceptable to society, as well as questions regarding the regulation of GMOs in the face of continuing uncertainty about the risks they may pose to human health and the environment.

This thesis explores both the conceptual foundations and the legal aspects of this debate. It argues that extending the scope of the SPS Agreement in the manner the *Biotech* decision did is problematic, and overburdens the EU with demonstrating that its GMO authorisation framework is based on scientific risk assessments and not otherwise disguised restrictions on trade.

This thesis also highlights that the conflict surrounding GMOs is not limited to the World Trade Organization. By leaving little room for the application of precautionary approaches and non-scientific factors, the Panel largely failed to recognise the institutional and discursive complexity in which the conflict about GMOs is embedded. The thesis concludes that increased sensitivity of WTO law to environmental and non-scientific factors will reduce the existing tension allowing it to coexist with other international treaties.

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List of Abbreviations

AB	Appellate Body
AIA	Advanced Informed Agreement
APHIS	Animal and Plant Health Inspection Service
BSE	Bovine spongiform encephalopathy
Bt	*Bacillus thuringiensis*
CA	Competent Authority
CBD	Convention on Biological Diversity
CJEU	Court of Justice of the European Union
DNA	Deoxyribonucleic acid
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Communities
VCLT	Vienna Convention on the Law of Treaties
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
GATT	General Agreement on Tariffs and Trade
GM	Genetically modified/ genetic modification
GOMs	Genetically modified organisms
GRAS	Generally- recognised-as- safe
IPPC	International Plant Protection Convention
ISAAA	International Service for Acquisition of Agri-biotech Applications
LMO	Living modified organisms
MEA	Multilateral environmental agreements
NGO	None governmental organisation

OECD	Organisation for Economic Co-operation and Development
OIE	Office International des Epizooties
OSTP	Office of Science and Technology Policy
rDNA	Recombinant deoxyribonucleic acid
SADAC	South African Development Community
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
TFEU	Treaty on the Functioning of the European Union
TRIPs	Trade Related Intellectual Rights
UN	United Nation
ICJ	International Court of Justice
BCH	Biosafety Clearing House
IPR	Intellectual property rights

INTRODUCTION

Genetically modified organisms (GMOs) are organisms, such as plants and animals, whose genetic characteristics are being modified artificially in order to give them a new property.[1] The commercial adoption of GMOs has been growing rapidly, making them increasingly important; genetically modified crops (GM crops) are fast joining agriculture throughout the world.[2]

In this century, more and more of the foods we eat will be produced by organisms that have been genetically altered through modern biotechnology. Food and feed which contain or consist of such GMOs, or are produced from GMOs, are called genetically modified food or feed (GM food or feed).[3] They offer significant potential benefits to society, including increase in crop production, resistance to pests and weeds, and added nutritional value. However, the safety of GMOs is still unknown. Concerns stem from a lack of scientific certainty regarding GMOs and their impact on human health and surrounding environment.[4]

The European Union (EU)[5] and the United States of America ('United States' or 'US') strongly disagree over the EU's regulation of GM food and feed.[6] The disagreement

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[1] GMO technology is an application of modern biotechnology, which is also used for biological and medical research, production of pharmaceutical drugs and experimental medicine. For more on the definition of GMOs, see Chapter 2, section 2.1

[2] Clive James, 'Global Status of Commercialized Biotech/GM Crops' (ISAAA Brief 43, ISAAA 2011) http://www.isaaa.org, accessed June 2012. See also Chapter 2, section 2.6.2

[3] As defined under Art 2(2) of Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms', and Art 2(2) of its predecessor, Directive 90/220/EC, and, under Art. 1(2) (a), 1(2) (b) of EC Regulation (EC) 258/97 concerning Novel Foods and Novel Food Ingredients; Chapter 2, section 2.1- 2.4 addresses the definitional problem of GMOs.

[4] Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Biotechnology Regulation Series, Edward Elgar Publishing, 2008)

[5] On 1 December 2009, the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community (done at Lisbon, 13 December 2007) entered into force. On 29 November 2009, the WTO received a Verbal Note (WT/L/779) from the Council of the European Union and the Commission of the European Communities stating that, by virtue of the Treaty of Lisbon, as of 1 December 2009, the European Union replaces and succeeds the European Community.

[6] Chapter 3 covers the diverging policies of the EU and the US; Jonathan B Wiener and Michael D Rogers, Comparing Precaution in the United States and Europe' (2002) 5(4) Journal of risk Research, 317; Pew Initiative on Food and Biotechnology 'US vs EU: An Examination of the Trade Issues

involves biotechnology companies, governmental regulators, non-governmental organizations and scientists. The debate is most intense in Europe, where public concern about GM foods is higher than in other parts of the world, such as the United States, Argentina, Canada, and Brazil. GM crops are more widely grown in these countries, and the introduction of such products has been less controversial.[7]

The United States has chosen to regulate both GM foods and seeds under existing laws, assuming that GMOs are substantially equivalent to conventional crops, which can be described as reactive legislation.[8] Conversely, the European Union has adopted a distinctive, complex, and specific legislation within which genetically modified foods and crops may be developed, introduced into the environment, and worked into the food supply. This regulatory framework can be described as precautionary.[9]

In the past decade, political tension arose between the leading producers of GMOs, such as the US, Canada, Argentina, and the EU, because the latter put in place a deliberate suspension of its own GMO approval process until it adopt further legislation on labelling and traceability of GMOs, which negatively affected their exports to the EU's market.[10]

This tension has led the GMO issue directly into the World Trade Organizations' (WTO)[11] Dispute Settlement Body (DSB). In August 2003, multiple formal complaints

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Surrounding Genetically Modified Food' (DECEMBER 2005) http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Biotech_USEU1205.pdf. Accessed 03 Feb 2009; David Vogel, 'The Politics of Risk Regulation in Europe and the United States', manuscript for publication in (2003) 3 Yearbook of European Environmental Law.

[7] Clive James, (n 2); See also Chapter 2 section 2.6

[8] A reactive regulation, in which safety or other studies or regulatory restrictions are mandated only on evidence of the substantiality of a health or environmental risk or actual harm. On the US regulations see Maria R Lee Muramoto, 'Reforming the 'uncoordinated' Framework for Regulation of Biotechnology'(2012) 17(2) Drake J Agri L 311; Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' in Luc Bodiguel and Michael Cardwell (eds), *the Regulation of Genetically Modified Organisms: Comparative approaches* (OUP, 2010)

[9] On the EU's regulatory framework, see Maria Lee, *EU Regulation of GMOs Law* (no 4)

[10] See David Vogel, 'The New Politics of Risk Regulation in Europe' (2001) CARR Discussion paper no 3, LSE London, p 3-4 http://eprints.lse.ac.uk/35984/1/Disspaper3.pdf Accessed 4 March 2006; See also Chapter 3 section 2.4

[11] The World Trade Organization was established in 1995 by the Final Act Embodying the results of the Uruguay Round of Multilateral Trade Negotiations, (15 April 1994) 33 I.L.M. 1125. The WTO Agreement establishes the WTO, and all other Agreements are annexed to this agreement. See

were filed by the US, Argentina, and Canada[12] to the WTO against the EU's alleged moratorium on the approval of GMOs during the period of October 1998 to August 2003, as well as against some of the EU Member States' national bans on GMOs and GM foods. The US, Canada, and Argentina argued that the *de facto* EU moratorium (a period of six years in which the EU authorised no genetically modified organisms) was not scientifically justified and amounted to an unfair trade barrier. The complainants also argued that the EU approval system for GM products was not working properly, even though the *de facto* moratorium had been lifted. This complaint became known as the *European Communities - Measures Affecting the Approval and Marketing of Biotech Products* (hereinafter *'EC-Biotech', or 'Biotech'* dispute).[13]

It wasn't until September 2006 that the final ruling became public.[14] In its Report, the WTOs' DSU Panel ('the Panel') addressed the various categories of European Union and EU Member State measures that were challenged, and found inconsistencies with the WTO's Agreement on Sanitary and Phytosanitary Measures (SPS Agreement).[15]

Nevertheless, the Panel emphasised that its Report did not examine the safety of GMOs, and that it did not examine the legitimacy of current EU legislation. Violations found in connection with the approval process relate solely to the procedural requirement not to cause 'undue delay'.[16] The Panel did not find other violations of the SPS Agreement in this context. Thus, the WTO findings were neither a verdict in favour of GMOs, nor a prohibition to regulate the use of GMOs based on precaution. Moreover, the Panel avoided addressing a number of legal issues that many expected

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Marrakesh Agreement Establishing the World Trade Organization, (15 April 1994) 33 I.L.M. 1125 (1994), entered into force Jan. 1, 1995. [Hereinafter 'WTO Agreements'].

[12] Request for Consultations by the United States, *EC-Biotech* (WT/DS291), Request for Consultations by Canada *EC-Biotech* (WT/DS292), and Request for Consultations by Argentina *EC-Biotech (*WT/DS293).

[13] See *European Communities- Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, AND WT/DS293/R (29 September 2006). [hereinafter '*Biotech*']

[14] This ruling was later adopted without appeal by the WTO Dispute Settlement Body on 21 November 2006.

[15] Phytosanitary refers to the health of plants, Agreement on the application of Sanitary and Phytosanitary Measures, (15 April 1994) 1867 UNTS 493.

[16] Panel Reports, *Biotech*, (n 13) pp1081-1087. This high-profile case brought attention to several procedural issues pertaining to the dispute settlement system, such as the role of advisory experts and of *amicus curiae* briefs, as well as the extended time taken in resolving these special cases, which are marked with a high level of complexity and political sensitivity.

would be addressed in this case, such as the role of science, the precaution principle, and the inter-relationship between trade law and public international law.[17] In fact, the Panel explicitly stated that it did not address the question whether EU product-by product approval procedures were consistent with EU obligations under the WTO agreements. If the approval procedures as such were to be challenged, it should be done by filing a new complaint.

The complainants timed the filing of the complaint to fall after their ratification and before the entry into force of The Cartagena Protocol on Biosafety the (Cartagena Protocol).[18] With large base of 164 parties, the Cartagena Protocol is widely considered a multilateral environmental agreement (MEA), and aims to ensure the safe handling, transport, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, while also taking into account risks to human health. Of great importance to the EU position and this thesis is that the Cartagena Protocol allows a precautionary approach in risk assessment.[19]

The WTO *Biotech* dispute reflects a deep disagreement over wide ranging issues concerning the regulation of GMOs affecting the trade of GM crops and GM products. In particular, the *Biotech* case demonstrates great resistance in the EU to allowing unrestricted marketing of GMO products, in contrast with the relaxed approval and marketing of GMOs in the US, Canada, and Argentina. Therefore, the ruling is of key importance not only to the parties of the dispute, but also to a long list of countries registered as third parties to the dispute, as well as to many developing countries considering introducing laws to regulate GM crops and products.

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[17] Such as the definition of 'undue delay', the role of science and precaution, and the inter-relationship between trade law and public international law. There remain, however, several questions on which the panel commented either inconclusively or not at all.

[18]Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted 29 January 2000, 1760 UNTS 9, reprinted in 39 I.L.M. 1027 (2000) UN Doc. UNEP/CBD/ExCOP/1/3, Article 42. [hereinafter 'Cartagena Protocol'] The reference here is to Canada and Argentina; the USA did not sign the Cartagena Protocol. See also Chapter 4 section 3.1.2.

[19] For detailed analysis of the Cartagena Protocol see Christoph Bail, et al (eds), *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment & Development?*(Earthscan Publications 2002)

The debate surrounding the dispute and GM foods and food products, in general, involves moral, environmental, human health, and consumer fears raised by food safety related concerns, the ethical challenges of gene research, unease about corporate control of intellectual property rights in seed varieties, and worry over agriculture.[20] Considering that environmental issues have become increasingly important, this thesis will be limited to human health and environmental aspects (i.e. biosafety aspects)[21] of genetic modification in particular.

The US has embraced biotechnology, and is the biggest producer of GMOs.[22] The US was the main driving force behind *Biotech* dispute due to its clash in regulatory and cultural attitudes with the EU over authorisation and access of GMOs.[23] It is therefore not surprising that the United States is also the most frequent complainant, defendant and third party intervener in WTO dispute settlement proceedings.[24] This thesis will focus on the EU and US, which collectively, account for almost half of world trade, because they exhibit striking variations in regulatory outcomes, and because their polices strongly effect what other countries do. It does not explore the Argentina and Canadian arguments or regulatory systems, except where it is part of the general arguments.[25]

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[20] There is no attempt to cover matters of intellectual property law, except in Chapter 2 where it was used as an example of unease about corporate control of intellectual property rights. Similarly, consumer fears raised by food safety related concerns, and the ethical challenges of gene research are used to prove the extent of uncertainty and disagreement surrounding the science behind GMOs.

[21] 'Biosafety' is the prevention of large-scale loss of biological integrity, focusing both on ecology and human health. *Biosafety and the environment: An introduction to the Cartagena Protocol on Biosafety* GE.03-01836/E. UNEP. (undated) p.8 http://www.unep.org/dgef/Portals/43/cpbs-unep-cbd-en.pdf accessed January 2013

[22] See Chapter 2, section 2.6; and Clive James, (n 2)

[23] US government representatives confirmed that the main issue at stake was the EU's GMO regulation, see USTR, '2013 Report on Sanitary and Phytosanitary (SPS) Barriers to Trade' (March 2013) USTR 3-4 http://www.ustr.gov/sites/default/files/2013%20SPS.pdf. Accessed 2 April 13; Petros C Mavroidis, 'The trade disputes Concerning Health Policy Between the EC and the US' in Ernest-Ulrich Petersmann & Mark A Pollack, (eds) *Transatlantic Economic Disputes: The EU, the US, and the WTO* (International Economic Law, OUP, 2003) p 243; Thomas Bernauer; *Genes Trade and Regulations: The Seeds of Conflict in Biotechnology* (Princeton University Press 2003) p 120.

[24] See WTO 'Disputes by country/territory' http://www.wto.org/english/tratop_e/dispu_e/dispu_by_country_e.htm. Accessed 12 December 2012.

[25] Similar to the US, Canada and Argentina applied the conventional scientific risk assessment approach. See Simonetta Zarrilli, *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks*, (UNCTD, Policy Issues in International Trade and Commodities Study Series No.29, UN–New York and Geneva, 2005) p.4.

The focus

Acknowledging that the WTO's central objective is to promote 'trade liberalisation', the *Biotech* dispute challenged the ability of WTO to balance free trade in GMOs with measures that are designed to protect the environment and public health which is protected under the Cartagena Protocol.[26] Tensions between the two regimes are explored, specifically the significant impact that trade has on the environment. Many describe the ruling as a missed opportunity for the WTO to protect the environment and public health.[27]

Bearing this in mind, the conflict about GMOs is not limited to the WTO. The thesis also offers an insight into a variety of legal interactions between the WTO, and the Cartagena Protocol, the EU and the US. This institutional diversity reflects the complex structure of the global economic system, which is governed by multiple legal systems. This expanding network of economic laws is not based on a coherent set of normative or institutional hierarchies. It is an emerging 'disorder of orders' with horizontal and vertical connections between legal systems and other non-legal normative systems.[28]

This thesis will assess whether, in the after math of *Biotech* dispute, the EU will be able to maintain and develop its regulatory system for GMOs that allows for the use of precautionary measures to protect the environment and public health. Whilst the regulation of GMOs over a variety of topics including labelling and traceability, this thesis is primarily concerned with the authorisation framework. This focus is justified because the complaining countries in Biotech only challenged EU's authorisation framework, namely the 'suspension' and 'failure' by the EU to consider applications for approval of GM products.

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[26] *Biosafety and the environment: An introduction to the Cartagena Protocol on Biosafety* GE.03-01836/E. UNEP. (undated) p. 8

[27] For example, Joseph McMahon, 'The EC- Biotech Decision: Another Missed opportunity?' in Luc Bodiguel and Michael Cardwell (eds), *The Regulation Of Geneitically Modified Organisms: Comparative Approaches* (OUP, 2010)

[28] Robert Cryer et al., *Research Methodologies in the EU and International Law* (Hart Publishing, 2011) p. 22.

It is necessary to identify the implications of this ruling for the potential means available to the EU or other WTO members in regulating or taking decisions with effect on the cross-border movement of GMOs. Whether the EU's regulations on GMOs remain ongoing source of trade tension with the US? How wide is the regulatory discretion of WTO members? How should MS balance their obligations, particularly if competing under different treaties? How might WTO Members respond to those uncertain risks?

In answering the above question, the thesis investigates the nexus between institutions and discourse from a legal perspective. It starts by focusing on the WTO, critically analysing the reports of the WTO Panel. This thesis, in particular, analyses the application and scope of the SPS, the lack of consensus in scientific knowledge, and the contentious application of the precautionary principle. In carrying out the analysis, this thesis offers insight into the basics of the science relating to GMOs, benefits versus risks, corporations versus civil society, including their interaction with the WTO, and international environmental agreements and Member States.

Questions of risks to human health and the environment, traditionally a matter over which national governments enjoyed virtually unlimited regulatory control have now become subject to substantial constraint dictated by international legal rules. It is important to clarify that it is not the intention of this thesis to provide full analysis of risk regulation; rather there is a modest analysis of risk regulation in chapter two which explains the competing paradigms of 'sound science' and 'precautionary principle' which have been used throughout the thesis.

Methodology

This thesis will provide an analytical account of the free trade of GMOs under the WTO as they relate to both other obligations under national law and to international treaties. The author approaches the subject in an interdisciplinary perspective approach that allow a more comprehensive understanding in international law. This methodology has

been employed throughout chapters. The analysis will be pitched at a conceptual level, and will draw from, for illustrative purposes, both legal material and social sciences explaining the way the legal systems work and interact with international law.

The methodology used is largely based on a review of relevant primary and secondary sources in the field of trade and environment. The primary and secondary sources includes: a selection of legal texts, Reports of the WTO's Dispute Settlement Body and it's Appellate Body, international treaties, international documents, policy documents academic articles, comments of various authors, NGOs newspapers, and the web.

Value of the research

GMO technology (Agricultural biotechnology) is the fastest growing technology the world has seen. The outcome of the *Biotech* dispute has the potential to shape and steer the direction of the further development of GMO technology, particularly given the fact that once GM crops are released into the environment for cultivation they are hard to contain, borders cannot control their movement, and they may cross-pollinate with relative species.

Concerns about the effects of GMOs are continuously being considered at the national and international levels in a variety of forums. Outcomes of such deliberations include the recent adoption of Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety,[29] and the EU Commission's announcement allowing EU Member States more discretion over where GM crops are grown, reflecting major reversal of opinion.[30] The rules included in different legal instruments remain inconsistent with each other, and may give rise to further conflicts between GMO exporting countries and potential importers.

[29] Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (The Nagoya – Kuala Lumpur Supplementary Protocol) Nagoya, 16.10.2010. http://bch.cbd.int/protocol/supplementary/ accessed 10 Nov 2012

[30] 'GMOs: Member States to be given full responsibility on cultivation in their territories', Commission Press Release, IP/10/921 (Brussels, 13 Jul 2010).

This first GMO case before the WTO's tribunal is of historic importance due to its manifold legal, political, and economic aspects, not to mention its social, developmental, and cultural ramifications and implications. Whether the law can evolve fast enough to provide the right balance to better serve all the parties at stake, we need to, at a minimum, think hard about approaches that can work not just in the US or just in the EU, but rather that make GMOs useful and safer on a global scale. Therefore, this is a timely research with the growing recognition of the need for international cooperation and regulation, as part of the rule of law, being a vital aspect for the future. The thesis will therefore be of practical use to stakeholders and policy makers alike. It pools the findings of a cross section of studies to look at the implications therein, and examine the arising biosafety and trade issues with special reference to developing countries.

This thesis is organized along the following lines:

Chapter 1 focuses on the way the dispute was settled under the WTO regime. It starts with a general overview of the WTO and a critical analysis of the main issues of the WTO's GMO dispute (*EC-Biotech - Measures Affecting the Approval and Marketing of Biotech Products*). This is done by reference to relevant previous disputes brought before the WTO, such as the *EC- Hormones*, and *Australia-Salmon* cases. This chapter highlights the dispute's most important current and prospective legal issues in order to determine to what extent the findings or reasoning of the *Biotech* Dispute might influence the ongoing trade and 'biosafety' debate.

In *Biotech*, the parties used the uncertainty associated with science to justify their positions. At the heart of the dispute was disagreement about the definition and nature of GMOs. Chapter 2) addresses this problem, it explores how the determination of risks to health and the environment has come to be heavily reliant on science, provides a background to the development and science of biotechnology, and explains the complex nature of GMOs. It provides context by way of outlining historical background, current developments, different applications of GMOs, and current

statistics on their use. It also explores arguments for and against cultivation and use of GMOs. It also addresses the difficulty facing regulators conducting risk assessments before authorization and release in the market. It further explains the importance of these new products for the complainants, corporations, civil society, third parties, and how the Ruling of the trade dispute will affect the choices of developing countries with regard to the regulation and adoption of GMOs.

Chapter 3 lays out regulation of GMOs in the EU and the US, outlining attitudes that underpin the differences in regulation. This chapter analyses the conceptual framework with respect to national regulation and its justification. It begins by examining the EU's regulations of GMOs, and underlines its recent legislative changes that led to the dispute. It also briefly illustrates how the attitude of the United States towards GMOs diverges from that of the EU. Additionally, Chapter 3 highlights and contrasts the motives behind the disparate approaches towards GMOs of the EU and the US. It concludes by identifying future layers of complexity related to this debate, as well as crucial issues that require attention such as safety of GMOs, labelling, and coexistence.

Chapter 4 situates the GMO debate within international law. First, it explains the choice of law in the WTO, and the controversial science-based requirements of the WTO Agreement on Sanitary and Phytosanitary Measures in contrast and comparison to the GATT and TBT Agreement. It then provides a critical analysis of the *Biotech* Panel's findings and interpretations on the scope of the SPS Agreement. The chapter also evaluates the Panel's understanding of key concepts and basic definitions on science, such as 'risk assessment', 'uncertainty', and 'precaution', in light of broader institutional questions when the WTO dispute settlement system rules on legal complaints over EU regulatory framework on GMOs. Additionally, the chapter outlines the relevant system of governance applying to GMOs, which involves overlapping and sometimes conflicting regulations promulgated at the national, EU, and international levels. It will focus on controversial science-based requirements of the SPS Agreement, in contrast to the Cartagena protocol and CBD. A broader understanding is an essential tool for scrutinizing EU GMO regulations under current international trade law. Finally, the chapter concludes that increased sensitivity of

WTO law to environmental and non-scientific factors will allow it to coexist with other international treaties.

The final chapter contains summary of the findings of the thesis, as well as the conclusions and highlights drawn therefrom. In general, regards the possible influences that the GMO dispute may have on the trade and environment debate, and in particular, concerning the significant implications of the Panel's ruling on the EU or any other WTO Member's ability to develop and maintain a regulatory system that allows precautionary measure.

The law and cases are current as of 30th November 2012. For the integrity of the discussion, a few materials dated later than 30th February 2013 are included.

CHAPTER 1

THE GMOs AT THE WTO: WHERE DO WE STAND AFTER THE *BIOTECH* DIPUTE?

'In a world dominated by trade, it is the WTO that dominates trade.'[1]

1 Introduction

This chapter presents the GMO dispute before the World Trade Organization. The *European Communities - Measures Affecting the Approval and Marketing of Biotech Products*[2] addresses various EU and EU Member State measures challenged by the US, Canada, and Argentina. The dispute raises a wide range of complex factual, scientific, and legal issues concerning the regulation of GMOs, affecting the international trade of GM crops and GM products.

Over the three year course of the dispute, the parties submitted hundreds of pages of briefs and dozens of factual exhibits. The panel also called upon six independent scientific experts, who submitted hundreds of pages of materials and spent two days with the panel and the parties to opine on scientific issues related to the dispute. The result was a comprehensive Panel Report more than 1,000 pages in length, with hundreds of additional pages of Annexes.[3]

The decision is significant because it affects whether countries have the ability to determine their own approaches on GM crops and food, and whether citizens are

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[1] John Madeley, *Hungry for Trade: How the Poor Pay Free Trade,* (Zed Books, 2000), p. 60.
[2] *European Communities- Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, AND WT/DS293/R (29 September 2006) [hereinafter *EC- Biotech* or *Biotech*].
[3] The Report and all Annexes are publicly available on the WTO website, http://www.wto.org.

able to engage fully in these processes without pressure from large economic interests. This may not affect only European Union countries, but also many other countries, especially developing countries considering how to manage GM crops and foods. In particular, the outcome of the ruling is very important because it could affect whether a precautionary approach to new technological developments is allowable under WTO's 'free trade' rules[4].

Bearing in mind that the aim of the WTO dispute settlement mechanism is to 'secure a positive solution to a dispute',[5] this chapter outlines the contours of the *EC-Biotech* dispute. It will explain the main arguments made by the disputants, as well as explain the outcome of this dispute. The analysis will provide an overview of the main findings in relation to the challenged measures, the alleged 'general *de facto* moratorium' on the approval of biotech products, the related 'product specific measures', and the EU Member States' measures related to the import and/or marketing of specific biotech products.

The objective of the analysis is to highlight the different aspects of issues arising from this GMO dispute. Crosscutting issues such as transparency, public participation, and the relevance of multilateral environmental agreements in the interpretation of WTO agreements will also be considered. The dispute's most important legal issues will be scrutinized in order to see to what extent the dispute might influence the ongoing GMO debate, in general, and its effect of international trade law on domestic health and environmental risk regulatory choices, in particular. Such legal issues include the Panel's finding on the legal nature of the

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[4] The WTO has recognised that regulators commonly adopt a precautionary perspective where risks of irreversible damage to the environment and to human health are concerned. Other international laws, such as the Cartagena Protocol, state that a lack of evidence of harm to human health or the environment shall not prevent governments from taking precautionary measures to avoid harm.

[5]Thus finding a mutually acceptable solution to a problem between members consistent with WTO provisions is encouraged. This may be possible through bilateral consultations between the governments concerned. Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 354(1999), 1869 UNTS 401, 33ILM 1226 (1994) [hereafter DSU] Article 3(7), http://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm. Accessed 12 June 2009.

precautionary principle, and on its relevance for the interpretation of WTO provisions.

The analysis does not cover the entirety of the arguments of the parties or the findings of the panel. Instead, it focuses on the points most relevant for the challenged measures. The plaintiffs' main allegation of EU violations of its commitments as WTO Members under the SPS agreement, and serves as the focus of this analysis.[6]

2 GMOs at the World Trade Organization

2.1 The parties of the dispute

This dispute involves more than the formal parties to the *Biotech* dispute. It also concerns a long list of countries registered as third parties to the dispute, and public interest groups which submitted *amici curiae*, including academics, civil society groups, and NGOs.

On 13 and 14 May 2003 the United States[7], Canada,[8] Argentina,[9] (hereinafter 'the Complainants') requested separate consultations before the World Trade Organisation's Dispute Settlement Body[10] with the European Union in regards to measures affecting the approval and marketing of products that contain or consist of, or are produced from, genetically modified organisms. In brief, the complainants

[6] See Chapter 4 on the applicable law. Several WTO agreements could apply to the topic, including The Agreement on the Application of Sanitary and Phytosanitary Measures [herein after 'SPS agreement'], the Agreement on Technical Barriers to Trade [hereinafter 'TBT Agreement'], Article 19 of the Agreement on Agriculture, and of the General Agreement and Tariffs and Trade 1994 [hereinafter 'GATT' or 'GATT 1994'].
[7] Request for Consultations by the United States, *Biotech*, WT/DS291 (13 May 2003).
[8] Request for Consultations by Canada, *Biotech*, WT/DS292/1 (13 May 2003).
[9] Request for Consultations by Argentina, *Biotech*, WT/DS/293 (13 May 2003).
[10] Pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ('DSU'), Article 11 SPS agreement, Article 14 TBT Agreement, Article 19 of the Agreement on Agriculture and Article XXII of GATT.

claimed that the EU and individual Member State actions regarding GMOs were inconsistent with WTO trade agreements.

The US announced that Egypt would also request consultations with the EU on this issue. The US was counting on support from Egypt in order to back up its claim that EU policies on GMOs have harmed the developing world.[11] In the end, Egypt decided not to request consultation and withdrew from the complaint on May 30, 2003, stating its 'desire to reduce further distortions and impediments to international trade that may result due to the further pursuit of this matter', while also recognizing 'the need to preserve adequate and effective consumer and environmental protection.'[12] A trade source noted that Egypt had no reason to join in as it did not have a significant export interest in GMOs, and had itself banned Thai canned tuna due to concerns that the fish might be canned in GM soy oil.[13] As a result of Egypt's withdrawal from the claim, the US cancelled talks towards a planned free trade agreement (FTA) with Egypt. In a letter to Egypt's Minister of Foreign Affairs, US Senator Chuck Grassley stated that one criterion that ought to be used in determining with whom the United States negotiates future FTAs is whether that country shares the US's vision of the global trading system.[14]

The consultations between the disputants were held in Geneva on 19 June 2003 but they were unable to settle the dispute. Therefore, on 7 August 2003, the United

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[11] For discussion of the 'developing world' argument see Chapter 2, section 3.2.and 3.3.

[12] 'The GMO Dispute: Bush Administration Attack on European Food Safety Policy Latest Challenge to WTO's Legitimacy' Public Citizen- Washington DC, June 2003, http://www.citizen.org/trade/wto/agriculture/ Accessed 13 May 2008; Letter by the Egyptian Ambassador to the EU, Suleiman Awaad, Cited in Al Amrani I.: 'Egypt follows EU line on GM', Middle East Times, 6 June 2003.

[13] Request for consultation, *Egypt — Import Prohibition on Canned Tuna with Soybean Oil* WT/DS205/1(2000) http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds205_e.htm Accessed 4 June 2008.

[14] See 'GMO Update: EU-Egypt; EU; China' 3(10) Bridges Trade BioRes, 2 June 2003. http://ictsd.org/downloads/biores/biores3-10.pdf Accessed 3 July 2008

States[15], Canada[16], and Argentina[17] requested the establishment of a panel to examine the matter.

The three Complaining Parties in this dispute have filed legally separate complaints, but each of the complaints related to the same matter. The DSB, pursuant to the request of the three countries, decided to have them examined by a single Panel in August 2003.[18] However, due to disagreement over the Panel's composition amongst the disputants, it was not constituted until March 2004, when they finally recognised the appointed Panel (consisting of Mr Christian Haeberli (Switzerland) as the chairman, and members Mohan Kumar (India) and Akio Shimizo (Japan)) as being qualified to address disputes involving science.[19]

The European Commission expressed its surprise at the initiation of the dispute as it was in the process of revising its own GMO legislation. The Commission described it as 'legally unwarranted, economically unfounded and politically unhelpful'.[20]

Several WTO Members, including Australia, Brazil, China, Chinese Taipei, Chile, Colombia, El-Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Thailand, and Uruguay, reserved their right to participate as third parties before the Panel.[21] Many of these third parties took active part in the dispute in order to express their views and interests in relation to GMOs. The arguments of Australia, Chile, China, New Zealand, and Norway were clearly set in written submissions and oral statements.[22]

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[15] Request for the Establishment of a Panel by the United States, *Biotech,* WT/DS291/23 (7 August 8, 2003).
[16] Request for the Establishment of a Panel by Canada, *Biotech,* WT/DS292/17 (7 August 2003)
[17] Request the Establishment of a Panel by Argentina, *Biotech*, WT/DS293/17 (8 August 2003)
[18] In accordance with Articles 6 and 9 of the DSU. See Panel Reports, *Biotech*, para. 1.10.
[19] Panel Reports, *Biotech*, paras 1.11-1.12.
[20] Commission 'European Commission Regrets U.S. Decision to File WTO Case on GMOs as Misguided and Unnecessary', Commission Presss Release IP/03/681(13 May 2003).
[21] Panel Reports, *Biotech*, para 1.13.
[22] Panel Reports, *Biotech*, para 1.15, and pp. 228-247.

In addition, the Panel accepted three unsolicited *amicus curiae* briefs, one from a 'group of academics'[23] based at universities in the US and the UK, a second from a 'public interests coalition',[24] and a third from 'a group of five NGOs'.[25] The authors of these *amici* briefs include the major international NGOs aiming largely to protect the environment, wild life, food safety, sustainable development, and organic farming. [26]

This wide interest the dispute generated demonstrates the importance of GMOs as emerging agricultural products. Hence, the outcome of this dispute will have impacts on the development of GMOs worldwide, and affect regulatory choices.[27]

2.2 The challenged measures

According to the Panel, this dispute concerns two distinct matters:

1. The operation and application by the EU of its regime for approval of 'biotech products'; and

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[23] Amicus Curiae Brief, *Biotech*, WT/DS/291,292, and 293 (30 April 2004) authored by Lawrence. Busch (Michigan State University), Robin Grove-White (Lancaster University), Sheila. Jasanoff (Harvard University, David Winickoff (Harvard University), and Brian Wynne (Lancaster University). [hereinafter 'Group of Academics'].

[24] Amicus Coalition, *EC- Biotech*, WT/DS/291,292, and293 (27 May2004) authored by transnational coalition of 15 NGOs (Gene watch, Foundation for international Environmental Law and Development (FIELD), Five Year Freeze, Royal Society for the Protection of Birds (RSPB)(UK), The Centre for Food Safety (USA), Council of Canadians, Polaris Institute (Canada), Group de Reflection Rural Argentina, Centre for Human rights and the Environment (CEDHA)(Argentina), Gene Campaign, Forum for Biotechnology and Food Security (India), Fundacion Sociedades Sustentables (Chile), Green Peace International (Netherlands), Californians for GE Free Agriculture, International Forum on Globalisation); submitted by the FIELD (London). [hereinafter 'Public Interest Coalition'].

[25] Amicus Curiae Brief, *Biotech*, WT/DS/291,292, and293 (1 June 2004) authored by Centre for International Environmental Law (CIEL), Friends of Earth –United Stated (FOE-US), Defenders of wild life, The Institute for Agriculture and trade Policy (IATP), and Organic Consumers Associations- United States (OCA-US) [hereinafter Group of five NGOs].

[26] Panel Reports, *Biotech*, paras. 7.10-7.11.

[27] Steve Suppan, 'US Vs EC Biotech Products Case: WTO Dispute Backgrounder', (2005) ITAP, p.1 http://www.bite-back.org/background/IATPbriefing.pdf, accessed 23 October 2010. See Chapter 3, section 3 for elaboration on the US regulatory position.

2. Certain measures adopted and maintained by the EU Member States prohibiting or restricting the marketing of 'biotech products'. [28]

The panel clarified that '"biotech products" in this dispute refers to plant cultivars that have been developed through recombinant deoxyribonucleic acid ('recombinant DNA') technology'.[29]

The Complainants challenged two EU directives and an EU regulation establishing a pre-marketing approval process for GMOs in the EU. The directives, Directive 2001/18/EC of the European Parliament and of the Council[30] and its predecessor, Directive 90/220/EEC[31] of 17 October 2002, governing the 'deliberate release into the environment of genetically modified organisms', and provided a multi-step process involving Member State and European officials for approval of GMOs before they could be imported or marketed in the EU. Regulation 258/97/EC[32] provided approval procedures relating to 'novel foods and novel food ingredients.'

The EU legislation aimed to protect human health and the environment. It outlined the procedure to be conducted in the event a company seeks to obtain approval to place a biotech product (GM product) on the market, and set the standards by which an application for approval is evaluated. The legislation required a case by case evaluation of potential risks the GM product may pose to human health or the environment.[33]

Directive 2001/18 (and its predecessor, Directive 90/220) and Regulation 258/97, under certain conditions, permit EU Member States to adopt 'safeguard' measures in respect of GM products that have obtained approval for EU wide marketing. The

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[28] Panel Reports, *Biotech*, para 2.19.
[29]. See Panel Reports, *Biotech*, para 2.20. See Chapter 2, section 2 which provides definition of GMOs under EU law, US law, and Cartagena Protocol.
[30] OJ 17.04.2001 L1006/1 [hereinafter 'Directive 2001/18' or Deliberate Release Directive'].
[31] OJ 08.05.1990 L117/15, preamble, as amended by Directive 94/15/EC, OJ 22.041994 L103, and Directive 97/35/EC, OJ 27.061997 L169.
[32] OJ 14.02.1997 L043/1. [hereinafter 'Novel Food Regulation' or Regulation (EC) No 258/97]
[33] The Panel reviewed this process in detail in its Report at paras. 7.103-7.146. See Chapter 3 for analysis of the relevant EU legislation.

Member States may provisionally restrict or prohibit the use and/or sale of an approved GM product in their own territory if they have detailed grounds for considering, based on new or additional information or scientific knowledge, that the particular product poses a risk to human health or the environment.[34]

2.2.1 The allegations

The complaining parties alleged that the operation of the EU legislation amounted to a general moratorium on the approval of GMOs and biotech products. The Complainants further alleged that the moratorium posed an unjustified trade barrier in violation of various WTO Agreements.[35] They also complained about failures to approve specific GMOs and biotech products. Finally, they asserted that safeguard measures taken by individual EU Member States to prohibit or restrict GMOs and biotech products in their territory were inconsistent with WTO rules.

The Complainants focused on the benefits and safety of modern biotechnology. Both the US and Canada also emphasised that there was no inherent difference between GMOs and their conventional counterparts in terms of health and environmental risk. Moreover, Argentina looked to the impact on developing countries to support the moral argument, claiming that the European Union measures hindered developing countries' agricultural and economic development by blocking exports of biotech products, and by discouraging imports and cultivation of biotech seeds.[36]

The US argued that EU's position on GMOs violated WTO rules and was a barrier to trade. It also contended that American export markets had been significantly

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[34] The Panel reviewed this process in detail in its Report at paras. 7.103-7.146. See Chapter 3 for analysis of the relevant EU legislation.
[35] Panel Reports, *Biotech*, paras. 4.160-4.359 (part 1 – arguments of the parties) violations mainly under GATT, TBT, and SPS Agreement.
[36] See US Request for Consultations,(n 7). See also Canada Request for Consultations, (n 8); and Argentina Request for Consultations, (n 9)

harmed by the moratorium as US farmers grow crops that are not approved in the EU.

The Complainants based their claims on numerous provisions of four WTO covered agreements: the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement); the Agreement on Technical Barriers to Trade (TBT agreement), the General Agreement on Tariffs and Trade (GATT); and the Agreement on Agriculture in an alternative to the SPS Agreement. [37]

The US maintained that the objective of the challenged measures was the protection of human health, hence the applicable law must be found in the Agreement on Sanitary and Phytosanitary Measures.[38] The Complainants declared that the EU general moratoria, the product specific moratoria, and the national bans breached several SPS provisions. These provisions can be divided into two groups: those containing procedural requirements (Article 8 and Annex C, Article 7 and Annex C), and those entailing substantive obligations (Article 5.1 and Article 2.2).

According to the Complainants, the EU measures (the general moratorium, product specific moratorium, and the national bans) did not comply with the obligation to undertake approval procedures without 'undue delay'[39] (Art 8 and annex C of the SPS Agreement), and that they did not comply with the obligation to promptly publish sanitary measures (Article 7 and Annex B of the SPS Agreement).[40] They also argued that the EU measures did not comply with substantive obligations of the SPS Agreement. Specifically, the measures did not comply with the obligation

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[37] For detailed discussion of the applicable WTO law see Chapter 4, section 2.1.
[38] The first US submission to the dispute panel largely compromises a statement of facts followed by legal discussion that focuses on the SPS agreement. However, it reserved the right to also make claims under TBT Agreement. See First Written submission of the United States, *Biotech,* paras. 71-80.
[39] **Article 8** requiring Members to observe the requirements of Annex C in the operation of control, inspection and approval procedures; **Annex C(1)(a)** – requiring that Members undertake procedures related to SPS measures 'without undue delay'; **Annex C(1)(B)** – requiring that Members publish SPS procedures and communicate with applicants promptly and openly based on certain guidelines.
[40] **Article 7** requiring Members provide notification of changes in SPS measures in accordance with Annex B; **Annex B(1)** – requiring publication of SPS measures.

to carry out a risk assessment (Article 5.1 of the SPS Agreement) and with the obligation to base measures on scientific principles (Article 2.2 of the SPS Agreement).[41] Furthermore, the Complainants asserted that the EU measures were a disguised restriction on international trade because, on the one hand, they violated Article 5.5 of the SPS Agreement, which obliges members to be consistent in the application of sanitary measures, and, on the other hand, because they also violated Article 2.3 of the SPS Agreement, which obliges members not to discriminate in the application of sanitary measures.[42]

While the US only presented claims under the SPS Agreement, Canada and Argentina further challenged the EU measures as being inconsistent with Article 2.1 of the TBT Agreement, which obliges Members, in relation to technical regulation, not to discriminate imported like products, and Article 2.2, which allows members to establish technical regulations for the protection of human health or the environment, but to do so without creating 'unnecessary obstacles to international trade'. Both countries maintained that the objective of the EU measures was neither human health, nor environmental protection, and that their application was unnecessarily restrictive to trade.[43] Both countries also considered the moratoria and the national bans to violate Article III.4 of the GATT. This provision enshrines the national treatment principle, according to which a country cannot accord an imported product different treatment than a domestic like product.

Additionally, Argentina claimed that the EU moratorium negatively affected exports to the EU from developing countries that have adopted GMOs techniques in their agriculture practices. Argentina held that the moratorium violated Article

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[41] First written submission of the US, *Biotech,* pp. 109-111; First written submission of Canada, *Biotech,* pp. 177-179.
[42] **Article 2.2** – permitting SPS measures only based on 'sufficient scientific evidence'; **Article 2.3** – prohibiting discrimination between WTO members through SPS measures; **Article 5.1** – requiring that SPS measures be based on risk assessments; **Article 5.5** – prohibiting 'arbitrary or unjustifiable distinctions in the levels' of SPS measures in different situations; **Article 5.6** – requiring Members to employ the least restrictive means to achieve the desired SPS protections.
[43] See First Written Submission of Canada, *Biotech,* paras. 486-499; First Written Submission of Argentina, *Biotech,* paras. 571-583.

10.1 of the SPS Agreement and Article 12.3 of the TBT agreement, which embody the special and deferential treatment principle.[44]

The Panel, in its ruling, assessed three main issues for their compliance with WTO rules:

- The alleged general EU moratorium on approvals of biotech products (referred to as 'general EU moratorium');
- The EU's failure to approve a number of specific biotech products (referred to as 'product-specific EC measures');
- Failure to take action to stop EU Member States banning GM products (national-level bans in several EU Member States on the marketing and import of specific biotech products after the products had been approved at the EU level).[45]

It is important to stress that the Complainants did not challenge the right of a WTO Member to regulate or maintain pre-marketing approval procedures for agricultural products. Rather, the complaint is based on the EU's failure to implement those regulations and procedures in a manner consistent with WTO rules, which in turn resulted in a violation of the EU's WTO commitments.

2.2.2 EU's defence

The EU countered the Complainants' allegations by highlighting the potential and proven risks of biotech products, as well as drawing attention to the widespread

[44] **Article 10.1** – requiring that Members 'take account of the special needs of developing country Members' in establishment of SPS measures. See First Written Submission of Argentina, *Biotech,* para. 5.
[45] Interim Panel Reports, *Biotech,* WT/DS291-293/Interim (7 February 2006) p.1032.

recognition among the international community regarding the differing risks of genetically modified and conventional organisms.[46]

It also pointed to trade statistics in order to show that their policies did not restrict exports of developing countries to the EU.[47] In its defence, the EU further argued that determination of the applicable law must be made by reference to the objective of its GMO related legislation, which was protection of the environment.[48]

In response to claims against it, the EU asserted that the general moratorium did not exist, and argued that the lack of approvals did not qualify as a formal or informal measure under the SPS Agreement regulations on how measures can be applied.[49] It stated that 'the alleged delay in completing the approval procedures for certain applications does not, itself, constitute a sanitary or phytosanitary measure'[50], But even if delays in regulatory review of applications of the commercialization of GMOs were considered to be measures, the EU argued that they are not 'undue' but that the delays are due to legitimate requests for information from applicants and due to the implementation process for Directive 2001/18.[51] Most of the delays, the EU contends, resulted from lack of applicant response or incomplete response to provide further information regards GMOs, therefore failure to complete product-specific applications did not qualify as measures SPS Agreement either.[52]

As to the EU's Member State bans, the EU argued that because they were temporary, they did not violate WTO obligations.[53] Firstly, as provisional measures

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[46] First Written Submission of the European Communities, *Biotech,* pp. 15-24.
[47] Ibid, p. 64.
[48] Ibid, para. 416.
[49] Ibid, p. 64.
[50] Ibid, para. 469.
[51] Ibid.
[52]Ibid para.48; see also Second Written Submission by the European Communities, *Biotech*, para. 172, for example, regarding an application to commercialize genetically modified oilseed rape (canola), the EC points to delays in receiving information requested of the applicant, including information related to 'the impact of herbicide regimes associated with the cultivation of GM herbicide tolerant oilseed rape, on farmland biodiversity, and population dynamics and life cycles in the farming ecosystem.'
[53] First Written Submission by the European Communities, *Biotech*, p.595-599.

based on the 'precautionary principle' they were justified under Article 5.7 of the SPS Agreement. Secondly, as provisional measures, they could not be challenged under the TBT Agreement because there were not technical regulations.[54] Thirdly, they did not violate Article III.4 of the GATT because they do not treat domestic like products differently.

Additionally, the EU claimed that the contested moratoria and bans primarily addressed environmental, not health concerns, and consequently fell outside of the SPS Agreement.[55] While the SPS Agreement does not deal with environmental concerns, the TBT and the GATT do have environmental related provisions. Therefore, the EU concluded that the SPS Agreement was applicable only to the extent that it protected human health. As the EU's main interest was environmental protection, the applicable law must be found in the other two WTO agreements.

The EU stressed that it strongly disagreed with the complainants and considered its measures to not breach the different WTO Agreements. However, it maintained that, if the Panel should decide otherwise, the challenged measures (the general moratoria, the product specific moratoria, and the national bans) were justified under Article XX (b), (d), or (g) of the GATT, and that they did not constitute an arbitrary or unjustified discrimination resulting in disguised restriction on international trade.[56]

The EU emphasised the issue of regulatory autonomy in the face of uncertain risks and differences in levels of 'acceptable risks' between countries.[57] It argued that its regulatory approach was not unique, and was supported by international instruments including the Cartagena Protocol. Furthermore, according to the EU,

[54] Ibid, paras. 649-650.
[55] Ibid, para 433.
[56] Ibid, paras. 673-674.
[57] Ibid, paras. 71-75.

the Cartagena Protocol on Biosafety applied instead.[58] It further contended that even if WTO agreements were applicable, they should be interpreted in conjunction with, rather than separate from, other sources of international law.

Finally, the EU argued that determination of the applicable law must be made on the basis of the objective of its GMO related legislation, which was to protect the environment.[59] Therefore, the appropriate WTO agreement was the TBT Agreement, not the SPS Agreement.[60]

2.2.3 The institutional and legal context:

The majority of international trade is now subject to the rule-based system of the World Trade Organisation,[61] of which almost all major trading nations can be found among its 153 Members.[62] The WTO's adjudication system for the dispute settlement process 'serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law.'[63]

To date, the only other GMO dispute to come before the WTO is *Egypt — Import Prohibition on Canned Tuna with Soy Bean Oil*[64] on 22 September 2000, in which Thailand put forth a request for consultation with Egypt regarding prohibitions that

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[58] First Written Submission by the European Communities, *Biotech*, paras. 453-459. See also Chapter 4, section 3 for the applicability of The Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 1760 UNTS 9 (2000) [herinafter 'Cartagena Protocol'].
[59] First Written Submission by the European Communities, *Biotech,* para. 416.
[60] Panel Reports, *Biotech* dispute, pp. 140-142.
[61] The World Trade Organization was established in 1995 by the founding act – Final Act Embodying the results of the Uruguay Round of Multilateral Trade Negotiations, (15 April 1994) 33 I.L.M. 1125. The WTO Agreement establishes the WTO, and all other Agreements are annexed to this agreement. See Marrakesh Agreement Establishing the World Trade Organization, (15 April 1994) 33 I.L.M. 1125 (1994), entered into force Jan. 1, 1995. [Hereinafter 'WTO Agreement'].
[62] 153 members on 10 February 2011, Members and Observers, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm accessed 10 February 2011.
[63] DSU, Article 3.2.
[64] Request for Consultation, *Egypt — Import Prohibition on Canned Tuna with Soybean Oil* WT/DS205/1 (2000).

the latter imposed on the import of canned tuna with soybean oil from Thailand.[65] In this case Thailand claimed that Egypt had failed to carry out its obligations under Articles I and XI of the Marrakech Agreement, Article XII of the GATT, and Articles 2, 3, 5 and Annex B, paragraphs 2 and 5, of the SPS Agreement. Thailand argued that tuna exported to Egypt did not contain soybean oil produced from genetically modified plants. Moreover, Thailand claimed it was not possible to identify the origin of soybean oil because the final processing stages destroyed genetic material. Thailand therefore found restrictions on its canned tuna discriminatory, and asked the Egyptian government to lift them. Egypt's argument was based on the claim that Thailand's export of tuna contained genetically modified soybeans, and thus could represent a potential risk to Egyptian consumers. During the framework of the consultations, Egypt had to withdraw its violating measures.

Egypt — Import Prohibition on Canned Tuna with Soy Bean Oil is considered to be a straight forward trade dispute which was quickly resolved. In comparison, the challenged measures in the *EC- Biotech* dispute are considered to be non-tariff barriers to trade.[66] The *EC-Biotech* dispute has proved a big challenge to the WTO dispute settlement mechanism, placing very complex issues, mostly non trade issues, in the spotlight. It was the first indication of the tension surrounding international trade of GMOs.

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[65] In this case Thailand claimed that Egypt had failed to carry out its obligations under articles I, XI of the Marrakech Agreement, and XII of the GATT, and Articles 2, and 3 and 5, and annex B, Paragraph 2 and paragraph 5, of the SPS Agreement.

[66] Francesco Sindico, 'The GMO Dispute before the WTO: Legal Implications for the Trade and Environment Debate' (January 2005), FEEM Working Paper No. 11.05. http://ssrn.com/abstract=655061. Accessed 9 November 2010.

3 Reports of the Panel

The Panel was unsuccessful in concluding its task within the usual six month period for WTO procedures. It repeatedly postponed the circulation of the Reports[67] until 7 February 2006, when the Panel issued a confidential preliminary ruling, released only to the parties to the dispute.[68] In May 2006, a WTO dispute panel issued its final ruling 'Reports' of the Panel on the complaint brought by the US, Canada and Argentina against the alleged EU 'moratorium' on the approval of new biotech products. At that stage, the substance of the Report was confidential, and was only released to the parties to the dispute.

Three years after the Panel was established, on 29 September 2006, the Reports of the Panel were finally circulated to the parties of the dispute. [69] Subsequently, at its meeting on 21 November 2006, the DSB adopted the official **'Reports' of the Panel**.[70] The findings in the final Panel Report unsurprisingly correspond, to a large extent, to the February Interim Report, except for a critical change in the Panel's position on remedies (recommendations), which will be discussed in section 4.2 below. The reasoning of the Panel is long and complex. Its Reports comprise more than 1,000 pages and several annexes.

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[67] For example, Communication from the Chairman of the Panel, *Biotech*, WT/DS291/30, (21 Dec 2005).
[68] Interim Panel Reports, (n 45).
[69] *Biotech*, Panel Reports circulated on 29 September 2006. The WTO Secretariat divided the Panel Report into eight parts: **Part I** (pp. 1-108, covering I. Introduction, II. Factual Aspects, III. Complaining Parties' Requests for Findings and Recommendations, and IV. Arguments of Parties); **Part II** (pp. 109-247, covering IV. Arguments of Parties and V. Arguments of Third Parties); **Part III** (pp. 248-342, covering VI. Interim Review and VII. Findings [A. Procedural Issues and General Matters]); **Part IV** (pp. 343-423, covering VII. Findings [B. Overview of Measures at Issue and C. Relevant EC Approval Procedures]); **Part V** (pp. 424-691, covering VII. Findings [D. General EC Moratorium]); **Part VI** (pp. 692-866, covering VII. Findings [D. General EC Moratorium and E. Product-Specific Measures]); **Part VII** (pp. 867-1066, covering VII. Findings [E. Product-Specific Measures and F. EC Member State Safeguard Measures]); **Part VIII** (pp. 1067-1087, covering VIII. Conclusions and Recommendations).
[70] Reports of the WTO Panel, *Biotech*, p. 1.

3.1 The main findings

After three years of consideration, the Panel concluded that the EU acted inconsistently with its obligations under specific articles of the SPS Agreement, and dismissed the charges under other WTO trade agreements.[71]

In its Report, the Panel recognised the existence of a general moratorium, as well as 'product-specific ones', which created unnecessary delays inconsistent with the SPS Agreement. It focused on three issues.[72] First, it noted 'undue delay' in the EU's GMO approval procedure resulting from the moratoria, in violation of Article 8 and Annex C of the SPS Agreement. Second, the Panel struck down national bans (safeguards) established by some EU Member States on certain EU-approved GMOs on ground specifying that these Member States failed to conduct risk assessments, and thus violated SPS Article 5.1 and Annex A. Third, the Panel found that the sufficiency of available scientific evidence, such as earlier conclusions rendered by relevant EU scientific committees, precluded these Member States from invoking provisional measures (national bans or safeguards) under SPS Article 5.7 without having conducted a risk assessment under Article 5.1. The Panel requested that the EU correct the inconsistencies with the WTO in relation to the implementation of its pre-market approval system for GM products.[73]

The next section provides critical overview of the main findings of the 'Reports of the Panel' in relation to the challenged measures. The analysis does not cover the entirety of the parties' arguments or the findings of the Panel. Instead, it focuses on the points most relevant for the challenged measures.

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[71] The Panel considered only one of the GATT claims by Canada and Argentina None of the TBT claims was successful. See Panel Reports, *Biotech*, p. 866.
[72] Interim Panel Reports, *Biotech*, (n 45) paras. 8.4-8.64.
[73] Panel Reports, *Biotech*, paras. 8.16, 8.20, and 8.32 (US); 8.36, 8.40, and 8.48 (Canada); 8.55 and 8.64 (Argentina).

3.2 The applicability of SPS Agreement [74]

With the launch of the *EC-Biotech* dispute, the EU and many academics reviewed the measures presented by the Complainants, and hotly contested the applicability of WTO law to it.[75] As a preliminary matter, the Panel had to consider whether the EU approval procedures themselves constituted SPS measures, thus triggering the application of the Agreement on Sanitary and Phytosanitary Measures.[76]

The underlying objective of the SPS Agreement is to ensure that Members do not use food safety, animal and plant health regulations as unjustified trade restrictive measures or barriers to protect their domestic agricultural industries from competitive imports.[77] The SPS Agreement and disputes under it are of relatively recent origin. To date 41 cases were brought in a request for consultation to the Dispute Settlement system, and which cite the SPS Agreement, domestic food safety laws, and quarantine requirements that affect international trade.[78] Key

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[74] The SPS Committee has not discussed GMOs in any detail. However, the United States circulated a paper in June 2000 which pointed out the lack of consistency in notifications. Some countries notified GMO-related regulations under SPS, others under TBT, and sometimes under both. WTO, see 'Genetically Modified Organisms (GMOs)' (Current issues in SPS Agreement Training Module) http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s1p1_e.htm accessed 3 April 2012.

[75] See, Francessco Sindico, 'The GMO Dispute before the WTO: Legal Implications for the Trade and Environment Debate' (January 2005), FEEM Working Paper No. 11.05. http://ssrn.com/abstract=655061. Accessed 9 November 2010, see Chapter 4, section 2.1.

[76] If a measure falls within the SPS Agreement, the measure is already presumed to be a trade barrier. See, SPS Agreement, preamble and Article 1.1.

[77] SPS Agreement, preamble, Article 1.

[78] World Trade Organisation - Disputes by Agreements: Sanitary and Phytosanitary Measures (SPS) http://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A19 accessed 12 April 2014. Those cases show that there are a number of legal problems in relation to the interpretation and application of the provisions of the SPS Agreement, and that the jurisprudence still at a very early stage. See Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (OUP, Oxford, 2007).

disputes are *EC-Hormones*[79] ; *Australia — Salmon*[80]; *Japan — Agricultural Products*[81]; *Japan — Apples,* [82] *United States-Poultry (China)*[83].

According to Article 1.1 of the SPS Agreement two requirements need to be fulfilled for it to apply: first, the measure in dispute is a sanitary or phytosanitary measure; and second, 'the measure in dispute may, directly or indirectly, affect international trade.'[84]

To start with, the scope of the SPS agreement is set in Annex A, which defines an SPS measure as:

> Any measure applied:
>
> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
>
> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
>
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests, or

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[79] Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998. [hereinafter '*Hormones*'] In this case the EU banned the import of meat and meat products from cattle which had been treated with certain hormones for growth production purposes.

[80] Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998. [hereinafter '*Australia- Salmon*']

[81] Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999. [hereinafter' *Japan — Agricultural Products*']

[82] Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003. [hereinafter' *Japan — Apples*']

[83] Panel Report, *United States –Certain Measures Affecting Imports of Poultry from China* WT/DS392/R adopted 25 October 2010 [hereinafter *United States-Poultry (China)*]

[84] Panel Reports, *Biotech*, para. 7.254.

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

These measures can be laws, decrees, regulations, requirements and procedures applied to achieve protection against specific risk.[85]

The Complainants argued that the EUs regulatory framework is an SPS measure, and that the acts in question, as components of this structure, are by extension SPS measures. The US, in particular claimed that the EUs regulatory framework was an SPS measure because it aimed to address the SPS objectives of protecting animal or plant life or health, or the environment, from risks arising from disease-causing organisms, contaminants, toxins, or the spread of pests.[86]

In defence, the EU argued its approval procedures were SPS measures only in part, which also partly fell outside the scope of the SPS Agreement. The reasoning was that some measures could incorporate both SPS and other measures simultaneously because they were aimed at protecting the environment in general, rather than in preventing the spread of disease amongst plants, animals, and humans.[87] For example, the EU argued that GM seeds intended to be planted in the ground were not 'foods, beverages or feedstuffs' under Annex A (1) (b), and that GMOs were not 'diseases' or 'pests' as defined by Annex A (1). The EU also argued that one of the express purposes of Directives 90/229 and 2001/18 was protection of 'the environment', which it argued was distinct from protection of human, animal and plant life as defined by the SPS.[88]

The Panel rejected these arguments, giving a broad reading to the definition of an SPS measure, and thus a broad applicability to the scientific justification

[85] SPS Agreement, Annex A, Article 1.
[86] First submission of the US, *Biotech*, paras. 82-3; First submission of Canada, *Biotech*, para 155.
[87] Panel Reports, *Biotech,* paras. 7.150-7.173.
[88] Ibid, para 7.198.

requirements of the SPS agreement. The Panel adopted an expansive understanding of the concept of an SPS measure, seeming to bring an unexpectedly wide range of EU's regulations (approval procedure) that may be considered environmental within the ambit of the SPS Agreement. It did so by looking at the ordinary meaning of every word used in Annex A in their broader context, frequently referring the 'Shorter Oxford English Dictionary' and other dictionaries.[89]

First, the Panel identified the types of risks covered by Directives 90/220 and 2001/18. The Panel noted that the central objective of the EU's legislation was to protect human health and the environment when placing GMOs on the market, by themselves or in products, and to avoid adverse effects on human health and the environment which may arise from the deliberate release of GMOs.

The Panel then analysed whether the aim of protecting 'human health and the environment' in the relevant EU Directives fell within the scope of the SPS Agreement.[90] The Panel understood environmental protection as being the protection of animal and plant health, and held that 'to the extent directives 90/220[91] and 2001/18[92] are applied to protect animals and plants as a part of their purpose of protecting the environment, they are not a *priori* excluded from the scope of application of the [SPS Agreement].'[93]

The Panel recalled in this regard that the purpose of directive 2001/18/EC is to avoid adverse effects arising from 'deliberate release' into the environment of GMOs. The term deliberate release is defined as 'any international *introduction* into the environment of a GMO'.[94] Annex II.C.2.1 to Directive 2001/18/EC specifies that potential adverse effects of GMOs may include disease to animals and plants. It

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[89] Many examples available, Panel Reports, *Biotech,* paras. 7.212-7.437. On the scope of SPS see, Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (OUP, 2007) p 21.
[90] Panel Reports, *Biotech,* para. 7.196.
[91] For discussion of the Directive. See Chapter 3, section 2
[92] Ibid.
[93] Panel Reports, *Biotech,* para. 7.207.
[94] Deliberate Release Directive, Article 2(3).

was clear to the Panel that the purpose of avoiding disease in general includes the purpose of avoiding, more specifically, the 'entry, establishment or spread' of 'disease'. Furthermore, Annex C.2.1 designates effects to the dynamics of populations of species and genetic diversity of populations as relevant adverse effects. These effects relate to potential 'pest effects' of GMOs, which could occur, *inter alia,* through the spread of pollen from genetically modified plants to other plants 'out crossing', or through the development of persistence or 'invasiveness' of the GMO or GM plant due to selective advantage. The purpose of avoiding 'pest effects' of GMOs includes the purpose of avoiding the 'entry, establishment or spread' of GMOs as 'pests'.[95]

The panel, then, went on to analyse whether the Directives to protect the environment fell within the definition in Annex A(1)(a)-(d) of the SPS Agreement.[96] The most noticeable interpretation of the Annex was the broad interpretation of 'pests', which was understood to cover plants in addition to animals. The Panel analysed whether the *specific* threats posed by GMOs to the environment could be characterized as 'pests' under Annex A(1)(a). The first threat was that GMO plants could grow where they are undesired (i.e. the issue of invasive alien species).[97] The next issue was whether a cross-bred plant could be considered as a pest within Annex A(1)(a).[98] The third issue was whether 'pesticide-producing GM plants increase the potential for the development of pesticide-resistance in target and non-target organism…could be considered a "pest" within the meaning of Annex A(1)(a).'[99] In these three situations the Panel gave broad interpretations as to what could be considered a pest within the meaning of the Annex A(1)(a).[100] Therefore, the Panel 'consider[ed] that the directives can be viewed as measures

[95] Panel Reports, *Biotech,* para. 7.231 (footnotes omitted).
[96] Ibid*,* para. 7.212.
[97] Ibid, para. 7.243-7.
[98] Ibid, paras. 7.248- 7.258.
[99] Ibid, paras. 7.259- 7.263.
[100] Ibid, para. 7.263.

applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds as "pests".'[101]

The Panel then went on to assess whether Directives 90/220 and 2001/18 fell within the scope of Annex A(1)(b) of the SPS Agreement, where covers measures 'to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminates, toxins or disease- causing organisms in foods, beverages or feedstuffs.' The Panel adopted a similarly broad interpretation while analysing the specific terms and phrases used in the Annex, for example, those relating to pollen of the GM crop consumed by insects, and GM plants consumed by non-target insects, deer, rabbits or other wild fauna.

The Panel also took a very broad view of what was included in Annex A(1)(c), which covers measures to 'protect human life or health within the territory of the Member From risks arising from disease carried by animal, plants or products thereof, or from the entry, establishment or spread of pests.' [102]

Finally, as regards Annex A(1)(d), which covers measures to prevent or limit other damage within the territory of a Member from the entry, establishment or spread of pests, the Panel noted that the damage to biodiversity implied damage to living organisms that would more likely qualify as the type of risks referred to in Annex(1)(a) and (b).[103]

Afterwards, the Panel turned to examine the application of the SPS Agreement to Regulation 258/97, concerning novel foods and food ingredients. It first, had to identify the purpose of the Regulation. To do so, it pointed to Article 3(1) of the Regulation, which states that foods and food ingredients falling within the scope of the Regulation must not present a danger for the consumer, mislead the consumer, and differ from foods or food ingredients which they are intended to replace to such

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[101] Panel Reports, *Biotech,* para. 7.275 (emphasis added).
[102] Panel Reports, *Biotech,* paras. 7.361-7.362.
[103] Panel Reports, *Biotech,* paras. 7.379-7.380.

an extent that their normal consumption would be nutritionally disadvantageous for the consumers.[104]

The Panel concluded that, to the extent the Regulation seeks to achieve the first purpose, it could be considered as a measure which is applied for the purpose identified in Annex A(1)(b), thus qualifying as an SPS measure. [105] It also added, that to the extent where the Regulation is applied to achieve the second and third purposes, the Regulation was not a measure applied for one of the purposes mentioned in Annex A(1), and thus did not qualify as an SPS measure. [106]

Following the detailed analysis of Annex A of the SPS Agreement, the Panel held that **many** of the potential effects at which the EU measures were aimed fell within the scope of the SPS Agreement. The Panel held that Directives 90/220 and 2001/18 as well as Regulation 258/97 were, for the most part, SPS measures which may, directly or indirectly, affect international trade within the meaning of the SPS Agreement.[107]

The applicability of the SPS Agreement was also analysed in relation to the **national bans (safeguard measures)**. The Panel examined the purpose, form and nature, as well as the effect on international trade, of each of the nine challenged measures individually to determine if they were SPS measures as described in the SPS Agreement. To a large degree, the legal reasoning described above in relation to the EU approval regulations was applied in the analysis of the safeguard measures. In each instance, safeguard measures were found to constitute SPS measures. While the Panel's decision that the EU's approval procedures are SPS measures required that the Panel analyse the complaints under the SPS Agreement, the complaining parties did not challenge the EU approval procedures themselves,

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[104] Panel Reports, *Biotech,* paras. 7.394-7.414.
[105] Panel Reports, *Biotech,* para. 7.415.
[106] Panel Reports, *Biotech,* para. 7.416.
[107] Panel Reports, *Biotech,* paras. 7.432-7.437. The panel noted that Regulation (No) 258/97 was not an SPS measure to the extent it applied to ensure either that novel foods do not mislead the consumer or that they are not nutritionally disadvantageous.

but rather the EU moratorium on approval of applications and the Member State safeguard measures.

The Panel widely interpreted key terms of the SPS measure definition of the SPS Agreement, and concluded that the EU approval procedures were, in fact, SPS measures. It found that a broad range of measures to protect biodiversity fell within its scope, including cross contamination plants by GM plants, reduction of the economic value of crop, and effects of non-target insects and plants.[108]

The Panel's interpretations of key terms of EU's approval system, and of the national bans, qualified as purposes covered by the SPS Agreement. Some believe this will broaden the scope of the scientifically strict SPS Agreement,[109] which is used to cover environmentally related measures rather than the TBT and/or the GATT agreements, unless the Panel or Appellate Body choose to overturn these holdings in the future.[110] The issue of the applicability and its effect on trade and cultivation of GMOs of remains highly debated. Chapter 4 examines this issue further, and situates it in the context of international law.

The Panel also had to decide whether, consequently the general and specific product moratoria constituted SPS measure, and whether, consequently, the obligations of the SPS Agreement requiring scientific justification applied to them. The next sections closely examine the findings of the Panel on the nature of the moratorium.

3.3 The delay in concluding the ruling

The WTO provides a strict timeframe for the completion of a dispute. A case should not take more than a year before the Panel; the *Biotech* dispute took three times

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[108] The Panel's findings suggests that one measure incorporating different purposes could fall within the scope of application of more than one WTO agreement, but what should apply when there is overlap remains open question. See Panel Reports, *Biotech,* paras. 7.147- 437.
[109] Christiane R Conrad, 'PPMs, the *EC Biotech* dispute and the Applicability of SPS Agreement' (2007) 6(2) World Trade Review. 243.
[110] This also means that very few measures will fall under the TBT Agreement. See discussion in section 3.2 below.

longer. There were a number of reasons. The parties requested several postponements and extensions in relation to the submissions and responses. There were a huge number of documents submitted to the Panel, which is reflected in the large number of Annexes to the case. The Panel sought additional scientific and technical expert advice. There were also a large number of issues addressed by the parties. Some understood this long delay as reflecting 'the acute awareness of the panel of the repercussions of its ruling on this controversial and high-profile case', and not only as just a product of the inherit complexity of the case itself, and the various uncertainties surrounding several of the issues of the dispute.[111]

3.4 The legal nature of the 'moratorium'.

The complaining parties alleged that from October 1998 until the establishment of the Panel in August 2003, the EU applied an effective, 'general *de facto* moratorium' on all GMOs/Biotech products so that applications for such products were not allowed to obtain final approval. This constituted a sanitary or phytosanitary measure that failed to observe several requirements for SPS measures under the SPS Agreement.[112]

The parties did not dispute that during this period the EU did not approve any biotech product applications. The Complainants pointed to statements by several EU officials declaring a 'moratorium' on the approval of applications until the EU had updated its labelling and traceability regulations. The Complainants alleged that the moratorium posed an unjustified trade barrier in violation of various WTO Agreements. [113]

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[111] Archana Negi 'World Trade Organization and the EC Biotech Case: Procedural and Substantive Issues' (2007) 44(1) International Studies. p15.

[112] In relation to the general *de facto* moratorium the parties alleged the following violations under the SPS Agreement: Annex C(1)(a)-(b), and consequently, Article 8; Annex B(1) and, consequently Articles 7, 5.1, and 5.6; and consequently Articles 2.2; Article 5.5 and, consequently Articles 2.3 and 10.1.

[113] Panel Reports, *Biotech,* paras 4.31-4.66 Part 1 – arguments of the parties- claim mainly under GATT, TBT, and SPS agreement.

EU denied of the existence of a moratorium. The EU claimed that even if there was a moratorium between June 1999 to August 2003, this case was 'moot' if the moratorium 'ceased to exist' after the establishment of the Panel. The EU submitted that under these circumstances the Panel should not rule on the moratorium.[114]

Relying on previous cases, the Panel rejected the EU's claim. The Panel noted that two biotech products were approved in 2004, after it was established.[115] These new developments might have terminated the 'across-the-board' moratorium which the Complainants claimed to have existed between the relevant dates.[116] The Panel ruled that it 'had the authority' to rule on measures within the terms of reference, even if the measure subsequently ceased to exist. [117]

The Panel did not address the legality of the EU's approval legislation itself since this issue was not raised by complainants, although it construed the EU's suspension of its approval procedure on GMOs from June 1999 to August 2003 as a general *'*de facto*'* moratorium.[118]

The EU also argued that Annex A(1) of the SPS Agreement presupposed the existence of an act. The complaining parties' allegations about the general moratorium were in reality complaints about delay in the completion of the approval procedure. The EU asserted that a delay of this kind is not an SPS measure since it only concerned the application of an SPS measure within the meaning of Annex A(1), and therefore was not subject to Article 5.1 of the SPS Agreement.

The Panel began its analysis of the general moratorium with an examination of whether the EU acted inconsistently with Article 5.1 of the SPS Agreement, which requires SPS measures to be based on risk assessment. Although Directives 90/220 and 2001/18, as well as Regulation 258/97, were found to be SPS measures, the

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[114] Panel Reports, *Biotech,* paras.7.1286 and 7.1297.
[115] Panel Reports, *Biotech,* paras. 7.1303 and 7.1305.
[116] Panel Reports, *Biotech,* para. 7.1304.
[117] Panel Reports, *Biotech,* paras. 7.1306-8.
[118] Panel Reports, *Biotech,* para. 8.3.

Panel in the *Biotech* dispute did not find the EU moratorium on GMO products to be an SPS measure according to the definition contained in Annex A(1) of the SPS Agreement; rather it amounted to a procedural decision to delay the final positive approval until certain conditions were met. This affected the operation and application of the EU's approval procedures.[119] The Panel held that the moratorium was not a 'requirement' or 'procedure', as identified by Article 5.1 and Annex A(1), because they were procedural decisions that neither approved nor rejected applications.[120] Alleged violations under Articles 2.2, 2.3, 5.5, 5.6, 7, and Annex B(1) were also dismissed on similar grounds.

The Panel next examined the allegation by the Complainants that the general moratorium had led to failure by the EU to comply with the requirements of Article 8 and Annex C(1)(a), which require that the EU's approval procedure for GMOs had to be undertaken and completed **'without undue delay'**.[121] The US considers undue delay to be 'the unjustifiable' and 'excessive' and 'hindrance' in undertaking or completing an approval procedure.[122]

The Panel found the meaning of 'undertake and complete' to cover 'all stages of approval procedures and should be taken as meaning that, once an application has been received, approval procedures must be started and then carried out from beginning to end.'[123] It also found the ordinary meaning of the phrase 'without undue delay' to be completed with no unjustifiable loss of time.[124]

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[119] Panel Reports, *Biotech,* paras. 8.6 - 8.8.
[120] Panel Reports, *Biotech,* para. 7.1382. As a result, the requirements of risk assessment and scientific basis for SPS measures did not apply to the moratorium.
[121] Art. 8 of the SPS Agreement: Members shall observe the provisions in Annex C in the operation of control, inspection and approval procedures, including national system for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this agreement; Annex C(1)(a) Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: such measures are undertaken and completed without undue delay..
[122] First Written Submission by the United States, *Biotech*. para. 89. And Report of the Panel paras. 7.1469-7.1471.
[123] Panel Reports, *Biotech,* paras. 7.1491-7.1492.
[124] Panel Reports, *Biotech*, para 7.1494.

The determination of whether there was 'undue delay' had to be made on case by case basis. The Panel found that both the reason for a delay and its duration were relevant factors. The Panel noted that a 'lengthy delay for which no adequate explanation is provided might in some circumstances permit the inference that the delay is "undue".'[125]

The Panel proceeded with its analysis to determine the reason behind the application of the general *de facto* moratorium on the approval of biotech products between October 1998 and August 2003. The Panel found especially persuasive a June 1999 declaration of the 'Group of Five countries' – Denmark, Italy, France, Greece, and Luxembourg – according to which they would take steps to suspend new approvals, pending the adoption of EU legislation on labelling and traceability of GMOs. The Panel held that the Commission, while not necessarily in favour of the Group of Five countries' declaration, did in fact fail to take steps necessary to move applications through the approval process, perhaps due to an awareness of the lack of political support for such approvals.[126] The Panel concluded, that the lack of EU legislation ensuring labelling and traceability of GMOs and GMO-derived products did not provide a justification for delays in the completion of approval procedures.[127]

The Panel also examined the perceived inadequacy of then-existing EU approval legislation. The Panel held that the moratoria affecting the 'operation and applications of the EU approval procedures' constituted 'procedures to check and ensure the fulfilment of SPS measures', resulting in 'undue delay' under the procedures, and therefore violated Article 8 and Annex C of the SPS Agreement.[128] Additionally, the Panel held that neither the perceived inadequacies of the EU regulatory system on GMOs, nor the evolving science and application of a

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[125] Panel Reports *Biotech*, paras. 7.1497-7.1498.
[126] Panel Reports, *Biotech,* paras. 7.1508, 7.1564-5, 7.1569.
[127] Panel Reports, *Biotech,* para. 7.1518.
[128] Panel Reports, *Biotech,* para. 8.6.

precautionary approach justified the lengthy delay in approval of applications in the EU from June 1999 to August 2003.

According to the Panel, Annex C(1)(a), together with Article 8, were intended to prevent Members from using procedural delays to avoid establishing or revising substantive SPS rules indefinitely.[129] The Panel also held that a Member could take a precautionary approach in compliance with Annex C(1)(a) by adopting substantive rules that provided for provisional approvals or approvals subject to other conditions. [130]

The Panel observed that not all moratoria would necessarily violate the 'undue delay' standard of Annex C(1)(A). For instance, a general delay might be justifiable if new scientific evidence were brought to light that conflicted with available scientific evidence and affected the approval of all application.[131] The Panel held:

> [I]f new scientific evidence comes to light which conflicts with available scientific evidence and which directly relevant to all biotech products subject to a pre-marketing approval requirement, we think it might, depending on the circumstances, be justifiable to suspend all final approvals pending an appropriate assessment of the new evidence.[132]

All other claims by the complainants that the *de facto* moratorium resulted in various inconsistencies with obligations under the SPS Agreement were dismissed.[133]

In its recommendation, the Panel stated that the EU should bring the general moratorium into conformity with relevant WTO obligations 'if, and to the extent

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[129] Panel Reports, *Biotech,* para. 7.1518.
[130] Panel Reports, *Biotech,* para. 7.1527.
[131] Panel Reports, *Biotech,* para. 7.1532.
[132] Panel Reports, *Biotech,* paras. 7.1530-7.1532.
[133] Panel Reports, *Biotech,* para. 8.14

that' it still exists.[134] The Panel found that it did not have to determine whether the general moratorium had ceased any time after the establishment of the Panel.[135]

In sum, the Panel characterised the general moratorium as a procedural decision not to make the final decision which did not constitute an SPS measure. In doing so, the panel avoided ruling on its consistency with the substantive requirements of risk assessment according to Article 5.1 of the SPS Agreement. The moratorium was only in breach of procedural requirements under Article 8 and Annex C(1)(a) of the SPS Agreement.

3.5 Product-specific EU Measure

The complaining parties argued that the EU had failed to consider for final approval applications concerning certain specified biotech products for which the EU had commenced approval procedures ('product–specific measures'). They alleged that these so called 'product specific measures' resulted in various breaches of the EU's WTO obligations.[136] The Complainants also alleged that 'product–specific measures', which is the moratorium as applied to specific product approval applications of GMOs/biotechnology products, failed to observe several requirements of WTO rules[137]

Following the same reasoning outlined in the previous section, the Panel determined that, like the 'general moratorium', the 'product-specific delays' were

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[134] Panel Reports, *Biotech,* para 7.1317. In comparison, the Interim Report refrained from making recommendations to the EU to bring this into conformity with its obligations as the general *de facto* moratorium had ended, and given that the EU had approved a relevant biotech product subsequent to the constitution of the Panel. See, Interim Panel Reports, *Biotech*, (n 45) Conclusions, paras. 8.15-8.16.

[135] Panel Reports, *Biotech,* paras. 7.1318-19.

[136] Panel Reports, *Biotech,* paras. 7.1629-7.1631.

[137] In relation to product specific measures the parties alleged the following violations of the WTO rules: Annex C(1)(a)-(c)&(e), and consequently, Article 8 of the SPS agreement; Annex B(1) and, consequently Article 7 of the SPS agreement; Article 5.1 & 5.6 and, consequently Article 2.2 of the SPS agreement; Article 5.5 and, consequently Article 2.3 of the SPS agreement; Article III:4 of the GATT 1994; and in the alternative, alternative, Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2, and 12 of the TBT Agreement.

not themselves SPS measures within the meaning of the SPS Agreement, but rather affected the operation and application of the EU approval legislation for the approval of GM products, which the panel found to be an SPS measure.[138] The Panel found the product-specific measures would not, themselves, have been measures applied for achieving the EU's appropriate level of SPS protection, and thus could not be considered SPS measures within the meaning of Article 5.1.[139] In other words, it declined to make any finding as to the consistency of the moratorium, or product specific measures, with the provisions of Articles 2.2 and 5.1 of the SPS Agreement. The Panel found that the EU breached its obligations in only one matter.[140] It established that there was 'undue delay' in the completion of the approval procedures with respect to 24 of 27 specified biotech products, and therefore the EU had breached its obligations to ensure that procedures were undertaken and completed without 'undue delay', as required under Article 8 of the SPS Agreement.[141] All other claims by the Complainants that the relevant product specific measures were inconsistent with the SPS Agreement were dismissed.

With respect to Directives 90/220 and 2001/18, the Panel concluded that the general *de facto* moratorium resulted in a failure to complete individual approval procedures without undue delay, and hence inconsistent with Article 8 and Annex C of the SPS Agreement. With respect to Regulation 258/97, the Panel provided similar a finding, noting that to the extent the approval procedure addressed safety aspects within the scope of the SPS agreement, the general *de facto* moratorium resulted in a failure to complete individual approval procedures without undue delay, also giving rise to an inconsistency with Article 8 and Annex C of the SPS Agreement.

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[138] Panel Reports, *Biotech,* paras. 7.1393 and 7.1491-general moratorium; paras. 7.1695- 7.1697-product specific.
[139] Panel Reports, *Biotech,* para. 7.1713.
[140] All other claims by the Complainants that the *de facto* moratorium resulted in various inconsistencies with obligations under the SPS Agreement were dismissed.
[141] Panel Reports, *Biotech*, paras. 8.18 and 8.19.

In sum, the Panel found that the EU's failure to complete its approval procedures without 'undue delay' was inconsistent with the Agreement's provisions on control, inspection and approval procedure (Article 8 and Annex C). These articles do not refer to SPS measures, instead referring to procedures to fulfil SPS measures. The Panel recommended that the EU bring the relevant product specific measures into conformity with its obligations under the SPS Agreement, effectively recommending that the EU ensure approval procedures for any pending application are undertaken and completed without undue delay.[142]

The next section analyses the Panel's ruling on 'safeguard measures' against the importation, marketing, or sale of a number of GMOs and Biotech products which had already been approved at a community level by a number of EU Member States.

3.6 National bans are not 'based' on 'risk assessment'

The Complainant's third allegation concerned 'certain Measures adopted and maintained by EU Member States prohibiting or restricting the marketing of biotech products.'[143] Under the 'Deliberate Release Directive' and the 'Novel Food Regulation' some EU Member States (Austria, France, Germany, Greece, Italy and Luxembourg) continued to maintain safeguard measures in respect of Biotech products or GMOs that had obtained approval for EU wide marketing under the EU law because they considered them too risky. In their view, GMO risks should be scientifically determined and assessed, such that an absence of sound science supporting regulation is fatal to its legitimacy.[144]

The complaining parties alleged that the safeguard measures violated Article 5.1 of the SPS Agreement,[145] which provides:

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[142] Panel Reports, *Biotech*, paras. 8.20.
[143] Panel Reports, *Biotech,* para. 7.2529.
[144] Panel Reports, *Biotech,* paras. 7.2530- 7.2533; US First Submission, *Biotech,* p. 109-111, Canadian Submission, *Biotech,* p. 192-94;
[145] It should be read with Article 2.2 of the SPS Agreement. Article 2.2 of the SPS Agreement states that 'any sanitary or phytosanitary measure is applied only to the extent necessary to protect human,

> 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 organization.

The Panel determined, step by step, whether the SPS Agreement applied, whether the safeguard measures were SPS measures for the purpose of the SPS Agreement. First, the Panel had to establish that the SPS Agreement was applicable to the measures. The Panel analysed the documents submitted by these Member States to justify their adoption of safeguard measures, as well as text and structural features of the measures, in order to ascertain their purposes.[146] Taking into account the evidence pertinent to each individual safeguard measure, the Panel held that the Member State safeguard measures (the national bans) were SPS measures in their purpose, form and nature, and in their effect on international trade.[147]

The Panel concluded that they were all SPS measures, so they were subject to the substantive requirements of the SPS Agreement. The SPS measure should have been 'based on scientific principles and ... not maintained without sufficient evidence', and 'based on' an acceptable form of risk assessment.[148]

Risk assessment is defined in Annex A(4) of the SPS Agreement. The definition differentiates two types of risks. The first is risk assessment made on 'the evaluation of the likelihood of entry, establishment or spread of pest or disease within the territory of an importing Member'. The second is related to measures adopted to limit or avoid the 'presence of additives, contaminants, toxins or disease-causing

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animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.'

[146] Panel Reports, *Biotech*, para. 7.2546.

[147] Panel Reports, *Biotech*, paras. 7.2610, 7.2662, and 7.2702 (Austria), 7.2749 and 7.2774 (France), 7.2813 (Germany), 7.2854 (Greece), 7.2891 (Italy), and 7.2922 (Luxembourg).

[148] Articles 2.2 and 5.1 of the SPS Agreement.

organisms in food, beverages or feedstuffs'. In this case the risk assessment should focus on the potential adverse effect on human or animal health.

In defence, the EU argued that the extent of scientific uncertainty surrounding GMOs triggers the SPS provision, allowing precautionary 'provisional measures' which render risk assessment unnecessary as a basis for national safeguard provisions. Additionally the EU argued that the safeguard measures were based on other risk assessments.[149] The EU's view of the role of risk assessment was supported by amicus curiae submission from a group of academics. [150]

The Panel did not question the right of EU Member States to ban GMOs, which was recognised in its main Directive 2001/18, and under Article 5.7 of the SPS Agreement, which permits Members to adopt temporary SPS measures 'where relevant scientific evidence is insufficient'.

The Panel detailed that for each of the products in question, the EU's relevant scientific committee conducted risk assessment, evaluated the potential risks to human health and/or the environment and the supporting arguments presented by the relevant Member States. The Panel also noted that some EU Member States did provide additional reports and scientific studies to support their national product-specific bans. The Panel asserted that a risk assessment must determine the likelihood or the probability of a risk. In contrast, scientific studies demonstrating a mere possibility of risk were not sufficient to justify the imposition of SPS measures. The Panel argued that many of the studies on which the national governments based their measures did not contain all of the elements it considered necessary to qualify as proper risk assessment. The Panel identified that most studies were missing the likelihood element, i.e. 'the probability of entry, establishment or spread of diseases and associated biological and economic consequences'. The Panel considered that this was not a risk assessment that meets

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[149] EU First Written Submission. *Biotech*, paras. 574, 590-1, 610.
[150] Group of Academics (n 23).

the requirements of the SPS Agreement.[151] In the case of all safeguard measures, the Panel therefore found that the failure to base the safeguard measures (national bans) on risk assessment violated Article 5.1 of the SPS Agreement. By implication, the Panel also found a violation of Article 2.2, which requires SPS measures to be based on scientific principles.[152]

While Article 5.7 permits Members to adopt SPS measures 'where relevant scientific evidence is insufficient', the Panel held that the safeguard measures fell outside the scope of Article 5.7, which would, according to the Panel, only apply in cases where there was insufficient evidence to conduct such risk assessment. The Panel found that the EU Member States imposing the safeguard measures had not conducted separate risk assessments, and the risk assessments conducted by the EU did not support the imposition of SPS measures.[153]

In order to provide a scientific justification, Members must follow the principle laid down in Article 5 of the SPS Agreement. The general rule is that full risk assessment must be presented, with the only exception being if it is a provisional application for precautionary measures as specified in Article 5(7). In order to invoke Article 5(7) there has to be not only 'insufficient' scientific evidence, but also has to be some kind of qualified risk present. The phrase 'on the basis of available pertinent information' clarifies that the risk present cannot merely be a hypothetical risk. The measure has to be temporary. The Panel in *Biotech* dispute explained: [154]

> a Member may provisionally adopt an SPS measure on the basis of available pertinent information in situations where the scientific evidence is insufficient for an adequate risk assessment, as required by Article 5(1) and as defined in Annex A(4), it makes sense to require, as the second sentence of Article 5(7) does, that that Member seek to obtain 'the additional

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[151] Panel Reports, *Biotech,* paras. 8.22-30.
[152] Panel Reports, *Biotech,* pp. 958-1007, and paras. 8.22- 8.31.
[153] Panel Reports, *Biotech,* pp.1008-1055, and paras. 8.22- 8.31.
[154] Panel Reports, *Biotech,* para. 7.2990.

> information necessary' for such a risk assessment. Once a Member has obtained the additional information necessary for risk assessment which meets definition of Annex A(4), it will be in a position to comply with its obligation in Article 5(1) to base its SPS measure on a risk assessment which satisfies the definition of Annex A(4).

With regard to risk assessment, the Panel admitted that it may include diverse and divergent scientific opinions. Moreover, the Panel asserted that this did not prevent states from adopting a precautionary approach where there were scientific uncertainties. However, in these cases, the individual Member States of the EU had not carried out risk assessments which supported a precautionary approach.[155] When a measure has a higher level of protection than laid down in international standards, this higher level needs to be scientifically justified, and if no international standard exists, an SPS measure equally needs to be scientifically justified.[156]

A risk assessment is described in Article 5.2 as:

> In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest or disease free areas; relevant ecological and environmental conditions; and quarantine or other treatment

In *Hormones,* the Appellate Body (AB) has interpreted Article 5.2 with a view to real life situations:

> …there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed

[155] Panel Reports, *Biotech,* para 7.3219.
[156] See SPS Agreement, Article 3.3.

> list. It is essential to bear in mind that the risk is to be evaluated in risk assessment under Article 5.1 is not only risk ascertainable in science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.[157]

In *EC-Hormones* the Appellate Body declared that what constitutes a sufficient risk assessment is not defined in the SPS Agreement, either substantially or procedurally. A Member, therefore, is free to consider both Article 5(2) ('available scientific evidence') and Article 5(3) ('relevant economic factors'), but there must be a 'rational relationship between the trade measure and the risk assessment'.[158] Notably, the Panel in *Biotech* held that the decision in the *EC – Hormones* case, which permitted the imposition of SPS measures based on divergent scientific views, applied only to cases where the divergent views were expressed within the same risk assessment.[159]

Furthermore, based on *Japan – Apples* case[160], the Panel stated that SPS measures may be imposed when there is insufficient scientific evidence to perform an 'adequate' assessment of risks. The Panel instead held that a risk assessment is 'adequate' if it meets the definition of a risk assessment in Annex A(4), which only requires an 'evaluation' of likelihood of entry of a pest or disease and its potential adverse effects without reference to any qualitative standard determined by the Member.[161]

In the *Biotech* case, the Panel recommended that the DSB request the EU bring the relevant Member States' safeguard measures into conformity with its obligation

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[157] See *Hormones,* (n 79) para. 187.
[158] See *Hormones*, (n 79) para.193.
[159] Panel Reports, *Biotech,* para. 7.3024.
[160] The Panel found that the risk assessment report submitted by Japan was not 'sufficiently specific' to qualify as a risk assessment under the SPS Agreement*,* See *Japan- of Apples*, (n 82) para. 8.270.
[161] Panel Reports *Biotech,* paras 7.1075 and 7.286.

under the SPS Agreement, either by revoking or justifying them based on an SPS-compliant risk assessment.[162]

The Panel found most of the challenged measures fell under the scope of the SPS Agreement, whose assessment is more risk and science-based relative to the GATT or TBT Agreement, which could also have been found applicable.

This restrictive interpretation raises concerns as to the leeway for WTO Members to protect their environment and public health. The Panel ruling ignores the relevance of the precautionary principle in determining the scope of risk assessments by not addressing the issue of insufficiency of scientific evidence. It reveals the real issue, which is the broader division on the international level over the use of science-based and precaution-based models for risk regulation in conditions of uncertainty. Chapter 4 expands on this issue.

4 Procedural issues

This *Biotech* dispute brought attention to several procedural issues pertaining to the dispute settlement system, such as the extended delays and time taken in resolving this special case marked by a high level of complexity and political sensitivity.[163]

4.1 Leaked Interim Reports, and Transparency of WTO,

In the WTO, the dispute settlement procedures still maintain restrictions on documents until the circulation of the final report. The arguments of the parties

[162] Panel Reports, *Biotech*, para. 8.64.
[163] And other procedural issues such as the role of advisory experts and of *amicus curiae* briefs will be considered below in section 4.2. and 4.3. Chapter 3 tackles the causes of disagreement over GMOs and the different regulatory attitude.

submitted to the Panels are restricted, in effect closing the process to public scrutiny until a decision is rendered.[164]

On 7 February 2006, the WTO dispute Panel issued its Interim Report to the parties. Such reports are not made public. They are considered preliminary until parties have a chance to review or challenge the findings, after which a final report is issued, adopted by the WTO Panel and made public.[165] In the *Biotech* dispute, Friends of the Earth published most of the Report after receiving a leaked copy. On legal advice, it deleted limited company-specific information from the interim report to avoid legal action.[166]

The legal reasoning in the final Report mirrored to large extent the Interim Reports,[167] but surprisingly the findings on the moratorium were changed in the Panel 'Reports' from the original finding in the 'Interim' ruling.[168]

In the Interim Reports, the EU had, notwithstanding its own rules and regulations, applied a general *de facto* moratorium on approvals of biotech products between June 1999 and August 2003. The general *de facto* moratorium resulted in a failure by the EU to 'complete individual approval procedures without undue delay', thereby violating Article 8 and Annex C of the Agreement on the Application of Sanitary and Phytosanitary Measures, which state, amongst other things, that a

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[164] Article 9.2 DSU; WTO 'The Process- Stages in Typical Dispute Settlement Case' http://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c6s3p4_e.htm accessed 1 May 2007.

[165] Appendix III of the DSU.

[166] FoE International, 'Looking behind the US spin: WTO ruling does not prevent countries from restricting or banning GMOs' FoE International, Briefing Paper, February 2006, available www.foeeurope.org/publications/2005/alternatives-wto.pdf. Accessed November 2006. FoEE, 'World Trade Organisation GM Dispute- Secret Report Leaked' FoEE http://www.foeeurope.org/biteback /WTO_decision.htm. accessed 4 March 2009.

[167] 'WTO Panel Provisionally Rules Against EU Moratorium on Biotech Approvals', 6(3) Bridges Trade BioRess, 17 February 2006, available on http://www.ictsd.org. However, some may argue that the significance of the Interim Report as a barometer of the Panel's eventual Ruling is diminishing, for example, Korea's and Indonesia's dispute over anti-dumping duties on certain Indonesian paper imports, where the final ruling differed substantially from the interim report.

[168] Interim Panel Reports, *Biotech*, (n 45) Conclusions and Recommendations, pp.1029-1050.

WTO Member should ensure that its approval procedures 'are undertaken and completed without undue delay'.

The Panel's Interim Ruling originally rendered no recommendation as to the EU's general moratorium as it ended in 2004 with the first GMO approval since 1998.[169] This was in accordance with WTO jurisprudence according to which a Panel refrains from making a recommendation regarding a WTO-inconsistent measure if such measure is no longer in force after the establishment of the Panel.[170] Effectively, the Panel ruled that the EU had already remedied the inconsistency of its *de facto* moratorium, and needed to take no further action on this front. Nevertheless, in the final Report the Panel accepted the Complainants' request,[171] and rendered a 'qualified' recommendation that the EU should bring the general moratorium into conformity with relevant WTO obligations 'if and to the extent that' it still exists.[172]

The Panel justified such a conditional remedy in its recommendation by observing that due to its 'murky and complex' nature the moratorium might be re-imposed in the future; thus, deciding this issue here and now would 'secure a positive solution' to the dispute.[173] This reasoning did not sit well with some commentators. For example, Cho wrote 'one might speculate that under this logic, decisions could always be rendered measures no longer in force, since all violations could potentially be reintroduced.'[174]

The Panel's final Ruling changed from the Interim Ruling, exposing the EU to possible further litigation over EU's authorisation regulatory regime for agricultural biotechnology.[175] In other words, the Panel left open the possibility that parts of the

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[169] Panel Reports, *Biotech*, para. 6.74.
[170] Interim Panel Reports, *Biotech*, (n 45) Conclusions and Recommendations, pp. 1029-1050.
[171] Panel Reports, *Biotech*, para. 6.79.
[172] Panel Reports, *Biotech*, para. 7.1317.
[173] Panel Reports, *Biotech*, paras. 7.1310-7.1311.
[174] Sungjoon Cho, 'The WTO Panel on the EC-Biotech Dispute Releases its final Ruling' (2006) 10(2) ASIL http://www.asil.org/insights/2006/10/insights061026.html Accessed 8 November 2008.
[175] Panel Reports *Biotech*, at Conclusions, para 8.16, p.1070.

EU's authorisation regulatory system for agricultural biotechnology might violate WTO rules. For example, doubt as to whether the Directive and Regulation are in compliance with SPS Agreement? Or whether there is breach of the national treatment principle, will require assessment of whether GMOs are like products ?[176]

The Interim Ruling also raised concerns in relation to the transparency and institutional integrity of the WTO. It is important to note that the Interim ruling was made public on non-governmental organisations websites, including Institute for Agriculture and Trade Policy, and Friends of Earth Europe.[177] Hence, the Interim ruling raised concerns in relation to the transparency and institutional integrity of the WTO. Advocates for transparency in WTO Dispute Settlement system call not just for public release of documentation but also for public access to WTO hearings before Panels and Appellate Body.[178]

In Appendix (k) to the final ruling, the Panel expressed 'grave concern' that the publication of the confidential Interim ruling had led to misinterpretation of its findings, particularly concerning the right of WTO Members to take a precautionary approach.[179] The Panel warned that such a leak 'could damage the integrity of the WTO dispute settlement system as a whole.'[180] While the parties concerned denied any involvement in the breaches of confidentiality, and condemned these breaches, the Panel emphasized that 'these statements cannot easily be reconciled with the fact that these leaks did occur.'[181] The Panel also found it 'surprising and disturbing' that two non-governmental organizations (the Institute for Agriculture and Trade Policy and Friends of the Earth), whose *amicus curiae* briefs the Panel accepted, disclosed the confidential Report on their websites.[182] In response, the Friends of

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[176] For discussion, see chapter 3, section 5.1.2
[177] For example, see http://www.foeeurope.org/biteback/WTO_report_descriptive.pdf and http://www.tradeobservatory.org/library.cfm?refid=78475 accessed 11July 2008
[178] See Lothar Ehring, 'Public Access to Dispute Settlement Hearings in the World Trade Organisation' (2008) 11(4) Journal of International Economic Law
[179] Panel Reports *Biotech*, Appendix k.
[180] Panel Reports *Biotech*, para. 6.185.
[181] Panel Reports *Biotech*, para. 6.195.
[182] Panel Reports *Biotech*, para. 6.196.

the Earth reportedly stated that it 'acted in the public interest.' [183] The Institute for Agriculture and Trade explained that it tried to prevent a disinformation campaign by US diplomats and industry officials for using purported content of the Interim Report. It has used the result to warn parties to the Biosafety protocol, and threatening possible WTO litigation.[184]

This leak highlighted the lack of transparency in the WTO, which can lead to manipulation of information in matters that are of direct concern to all WTO Members, as well as to the public. This matter is clearly reflected in the rushed responses to the Reports of Panel with the release of the Interim Report. (See section 6 below)

4.1.1 Public participation

Not only had the GMO disputes attracted significant attention and huge media coverage, but they also drew the interest of some interest groups, NGOs, and academics who have discussed the safety of GMOs; these actors submitted their own *amicus curiae* brief to the WTO.[185] They requested the Panel in *Biotech* to accept and consider the *amici* briefs as 'information and technical advice' essential to the Panel's deliberations under Article 13 of the (DSU).[186] In *Biotech*, the Panel noted that the briefs were submitted prior to the first substantive meeting of the Panel with the parties. The parties and third parties were given an opportunity to comment on these briefs.[187]

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[183] 'WTO: Biotech Panel Largely Confirms Interim Findings against EU', 10(32) Bridges Weekly Trade News Digest (Oct. 4, 2006).
[184] A letter from Jim Harkness, Presedent, Institute for Agriculture and trade policy to Pascal Lamy, Director General, World Trade law (5 October 2006), http://www.iatp.org/files/451_2_89189.pdf. Accessed 5 June 2008.
[185] ***Amicus curiae***- (plural ***amici curiae***) is a legal Latin phrase, literally translated as "friend of the court", that refers to someone, not a party to a case, who volunteers to offer information on a point of law or some other aspect of the case to assist the court in deciding a matter before it.
[186] The Panel has authority to accept and consider *amicus* briefs under Article 13(1) of the WTO DSU, which ensures access to information and technical advice relevant to Panel deliberations.
[187] Panel Reports *Biotech*, paras. 7.10-7.11.

The AB in *Shrimp-Turtle* ruled that accepting non-requested information is compatible with the provisions of the DSU, based on Article 13 of the DSU, which gave comprehensive authority to a panel to 'seek' information and technical advice from any relevant source. The AB also added that it is up to the Panel to decide what weight to ascribe to such information or advice.[188] In line with previous disputes, the Panel in *Biotech* restated its discretionary authority to accept and consider, or reject any information submitted to it. Although the Panel accepted *amici curiae* submissions discussed below, the Panel did not find it necessary to take them into account. No further explanation was offered regarding the reasons behind its decision.[189]

Group of Academics[190] of science, technology, and social science from the US and UK presented *amicus curiae,* which focused largely on issues related to science, risk assessment, and precaution.[191] The briefs highlighted the complexities in risk assessment, and the low levels of certainty and consensus over the technical aspects of GM technologies. They called on the Panel to recognise that risk assessment is not a singular concept, but rather varies with context and decision-making cultures. In light of the developing status of risk assessment, they added that the moratorium should be seen as a reasonable time for the EU to collect additional information.[192]

This *amicus curia* demonstrates, where there is high degree of scientific uncertainty, 'post-normal science can offer valuable means of framing the dispute

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[188] Subsequently, the compliance panel in *Australia -Salmon* relied on non-solicited information while the adoption of the additional procedures on *Amicus Curiae* briefs by the *Asbestos* AB generated big controversy. Since then few panels have accepted unsolicited briefs submitted by non-parties to the dispute.
[189] Panel Reports, *Biotech,* para 7.11.
[190] Group of Academics (n 23). Their opinion was also published as David Winickoff and others, 'Adjudicating the GM Food War: Science, Risk, and Democracy in World Trade Law', 30 Yale Journal of International Law, 81.
[191] See Chapter 2, section 2.8.
[192] Group of Academics, (n 23) p. 5-8.

in the broader social context than the sound science approach', which is used to assess health safety, and environmental risks under the SPS agreement.[193]

The **Group of five NGOs,**[194] composed of CIEL, FOE-US, Defenders of Wildlife, ITAP, and OCA-USA, presented a brief in favour of precautionary decision making, basing its arguments on what they saw as prevailing scientific uncertainty surrounding the risks of GMOs. This uncertainty, they argued, 'is, in fact so substantial that it impedes an adequate consideration of those risks', thus allowing for the application of precautionary decision-making pursuant to Article 5.7 of the SPS Agreement, as well as relevant rules and principles of international law.

Finally, the '**Public Interest Coalition**',[195] comprised of 15 public interest groups submitted an *amicus curiae* brief that explained the relevance of critical science to the dispute. It supported the EU's argument that the *de facto* moratorium was not a measure subject to WTO rules, but rather an 'expression of political intent'. The Group continued, arguing that even if the Panel did find the moratoria and national measures to fall within the scope of the WTO agreements, it refuted the Complainants' arguments because the measures were consistent with the precautionary principle, and consequently with international standards, and thus necessary to achieve their objectives, based on non-discriminatory, transparent, and fair risk assessment.

The overwhelming evidence of the amicus briefs supported the EU position; reference to arguments in *amici curiae* will be made where necessary.

This disregard of these submissions was heavily criticized by NGOs. For example, CIEL responded:

> The deficits of democracy in the WTO are augmented by the secrecy of interim rulings and the failure of dispute settlement panels or the Appellate

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[193] Group of Academics (n 23) p. 4-5.
[194] Group of five NGOs. (n 25)
[195] Public Interest Coalition (n 24).

> Body to consider *amicus curiae* briefs. In that regard, accepting *amicus curiae* briefs only to neglect them afterwards further underscores the closed door characteristics of dispute settlement in the trade arena, which ultimately leads to reasoning and decisions of lesser quality. Cases involving public health and the environment cannot afford poorly reasoned decisions.[196]

Providing more openness at the DSU is vital in order to provide easy and full access to information for all those affected, and to ensure public participation in the decision making process. Failure to do so may impair the public's ability to meaningfully contribute to the debate at the international level. The role of public participation and NGOs in the dispute settlement procedure remains unresolved. Disregard of *amicus curiae* can be damaging to the credibility of the WTO as an inter-governmental organisation, therefore weakening the legitimacy of its decisions. This is discussed in more depth in Chapter 4.

4.2 The need for scientific experts

Initially, the appointed Panel recognised that it was qualified to address disputes about science. However, in August 2004, the Panel stated that certain aspects of the dispute raised scientific and/or technical issues, and decided to consult individual experts and seek information from certain international organizations that might help it in its work by providing conceptual clarity.[197] A search began for scientific and technical experts to serve as advisors to the Panel. The experts were appointed in November 2004.[198]

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[196] 'EC-Biotech: Overview and Analysis of the Panel's Interim Report' CIEL (March 2006), p.9, http://www.ciel.org/Publications/EC_Biotech_Mar06.pdf. Accessed November 2006.

[197] Article 13(2) DSU.
Article 13(2) DSU permits the Panel to 'seek information and technical advice from any individual or body which it deems appropriate,' including sources other than the parties to the dispute, at its discretion. It also empowers the Panel to 'seek information from any relevant source and … consult experts to obtain their opinion.'

[198] Panel Reports, *Biotech*, para. 1.17.

During the proceedings, the Panel sought information from individual experts on issues of scientific or technical complexity in accordance with the relevant WTO agreements. Six independent experts were selected who provided evidence on 114 questions from the Panel. Further information was also solicited from international organizations in the field of biotechnology.[199] The Panel invited these organisations to 'identify appropriate standard references (scientific or technical dictionaries, documents adopted or circulated by the relevant international organization, etc.) that would assist the Panel in ascertaining the meaning of certain terms and concepts.' [200] Other than that, the Panel did not seek out the views or specific expertise of any of these organizations. Since the Panel requested expert opinions, it is vital to the credibility of the ruling that the experts' opinions, the documentary basis for the opinion, and questions put to the experts be appended to the ruling.

It was not clear why the Panel chose to do so, the Panel also showed similar attitude with interpreting the applicable law.[201] Suppan commented, '[s]ince the panel has requested expert opinion, it is vital to the credibility of the ruling that the experts' opinions, the documentary basis for the opinion and questions put to the experts be appended to the ruling'.[202] Chapter 4, section 2.3 and 4.3 explains how expert opinion could have had impact on the scope and applicability of the SPS Agreement.

5 Unresolved issues

The Biotech dispute raises a wide range of complex factual, scientific, and legal issues. Apart from the Panel's findings on the applicability of the SPS Agreement, it should be noted that the Report itself is a narrow and specific ruling.

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[199] The Panel sought information from the secretariats of the Convention on Biological Diversity, Codex Alimentarius, Food and Agriculture Organization, International Plant Protection Convention, Office of the Epizotics, United Nations Environment Programme and World Health Organization.
[200] Many examples available, Panel Reports, *Biotech,* paras. 7.212-7.437.
[201] See Chapter 4, sections 2.3, and 3.2
[202] Steve Suppan, 'US Vs EC Biotech Products Case: WTO Dispute Backgrounder', (2005) ITAP http://www.tradeobservatory.org/library.cfm?refid=76644%20 accessed 4 September 2009

Subsequently, the Reports of Panel left many questions about important substantive issues with respect to GMOs without answers. Specifically and admittedly the Panel it did not examine the following points:[203]

1) Whether GMOs/'biotech products in general are safe or not'. Chapter 2 addresses complexity of the science of GMOs, the debate surrounding it, and extent of disagreement over the regulation of GMO in relation to the WTO regime.[204]

2) Whether the 'biotech products at issue in the dispute are "like" their conventional counterparts'. Moreover, the Panel avoided addressing a number of legal issues that many expected would be addressed in this case. For example, it explicitly did not find it necessary to address the challenges under the GATT or TBT Agreements.

3) Whether the EU had the 'right to require the pre-marketing approval of biotech products'. This issue was not raised by the Complainants.

4) Whether the EU's 'approval procedure under its biosafety regulation was consistent with its obligations under the WTO agreements'. This issue was not raised by the Complainants therefore the Panel did not actually consider the merits of the EU regulatory framework.

5) The EU's relevant scientific committees' conclusions regarding the 'safety evaluation of specific biotech product'.

The Panel was keen to stress that the challenge did not address the WTO-consistency of the EU biotech regulations or the safety of GMOs, but rather the failure of the EU to properly apply its own procedures. Thus, the WTO findings

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[203] Panel Reports, *Biotech*, para. 8.3. The Panel stressed that it did not find it necessary to rule on those issues.

[204] Many NGOs do not regard this point as implicit recognition the WTO as the appropriate venue to rule over the safety of GMOs, see for example, FoE International, 'Looking behind the US spin' (n 166); See Chapter 2 on the contested risks and benefits.

were neither a verdict in favour of biotech products, nor a prohibition to regulate the use of biotech products based on precaution. One may argue that this was a procedural decision, and therefore does not impose a substantive requirement in relation to biotech products with pending or future applications. The WTO's ruling does not question the right of its Members to adopt strict biosafety legislation, or even bans, in order to protect the public and the environment from GMOs. All in all, the Panel Report raises many interesting legal questions which were not fully addressed, and thus remain controversial. Chapter 3 explains EU's authorisation framework. It also addresses the question of its compatibility with WTO obligations. The following sections will identify the unresolved substantive issues.

5.1 Implementation of the Reports[205]

The implementation of the adopted Reports proves that this dispute is far from easy to resolve.

At its meeting on 21 November 2006, the DSB adopted the Panel's Reports. None of the parties appealed against the ruling.[206] Despite civil society efforts to appeal the ruling, the European Commission did not appeal the Panel's Ruling against the EU's application of its approval procedures. It considered that much of the Panel Report had become theoretical because its approvals regime had been functioning normally and some 10 GM products had been authorized since the Panel's establishment.[207]

In general, the illegal measure must, in all cases, be removed within 15 months of the decision. If the losing party does not act in compliance with the decision of the dispute resolution process, other countries may withdraw trade concessions and

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[205] Agreement under Article 21.3(b) DSU.
[206] See Arts 16(1), 16(4), and 17(4) DSU. Appeal on the ruling should be filed within 60 days of receiving the final Report of the Panel. The appeal has to be based on points of law only. See also, Understanding the WTO: Settling Disputes, http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm. accessed 4October 2008.
[207] Minutes of the meeting of the WTO dispute Settlement body of 21 November 2006, WT/DSB/M/222 (12 January 2007).

impose retaliatory tariffs under the authorization of a DSB. The possibility of retaliation may also be arbitrated through the DSB. If there is a disagreement on the implementation of the conclusion, the parties may resort to the original DSB Panel, which will examine the consistency of the implementation of the measures. If the Panel finds the losing party has indeed conformed to its decision then the process is completed. If they find that the losing party has not implemented the measure in full, retaliatory tariffs and withdrawal trade concession may take place as described above.[208]

At the DSB meeting on 19 December 2006, the EU announced its intention to implement the recommendations and rulings of the DSB in a manner consistent with its WTO obligations. However, due to the complexity and sensitivity of the issues involved, the EU would need a reasonable period of time for implementation. Pursuant to Article 21.3(b) of the DSU, the EU was ready to discuss an appropriate timeframe with Argentina, Canada and the United States.[209]

On 21 June 2007, the US, the EU, Canada and Argentina respectively notified the DSB that they had agreed that the reasonable period of time for the EU to implement the recommendations and rulings of the DSB shall be twelve months from the date of the adoption of the Panel's Reports. Accordingly, the reasonable period of time should have expired on 21 November 2007. All the parties agreed to modify the reasonable period of time so as to expire on 14 January 2008.

At the same time, the European Commission took action against Member States. For example, it referred France to the Court of Justice of the European Union because of its failure to adopt an EU law governing laboratory and research use

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[208] Implementation Report by loosing party should be submitted within reasonable period of time (Art. 21.3 DSU). In case of non-implementation, parties negotiate compensation pending full implementation (Art. 22.2 DSU). If no agreement on compensation. DSB authorises retaliation pending full implementation (Art 22 DSU). See also, WTO-Understanding the WTO: Settling Disputes. available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm.

[209] *Biotech,* Summary of the dispute to date, http://www.wto.org/english/tratop_e/ds291_e.htm. Accessed November 2010.

of genetically modified microorganisms. The EU is particularly concerned about the country's failure to design emergency plans to deal with an inadvertent release of such organisms, and asked the Court to impose a fine of 168,800 Euros (US $204,200) per day until such legislation is enacted.[210] The referral was the second time the EU had taken action against France for not updating its biotechnology regulations to conform to EU requirements.[211]

This deadline for implementation was never met. The EU, Canada, and Argentina agreed on another extension for a 'reasonable period of time' to implement the recommendations and rulings of the DSB. This date was extended a few more times.

Eventually, the EU and Canada reached a settlement to implement the recommendations and rulings of the DSB in July 2009. The settlement set a framework for annual bilateral dialogue on 'Biotech Market Access Issues of mutual interests'.[212] A similar settlement was reached with Argentina. This settlement established bilateral dialogue on 'issues related to the application of biotechnology to agriculture'. The dialogue has EU authorities meet with their Argentinean counterparts to discuss agricultural biotechnology and trade issues of mutual interest, such as the authorization processes of GM products of mutual interest, measures related to biotechnology which may affect trade, evaluation of the economic and trade outlook of future GM product approvals, and the renewal of GM product authorizations.[213] The EU insists that the dialogue will not influence any decisions made on biotech policy in Brussels. Rather, it says the dialogue is expected to act as an exchange of information on contentious biotech issues in an attempt to avoid any unnecessary trade obstacles.[214]

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[210] 'France chided for Tardiness in GM Legislation', (2006), 25 Biotechnology L. Report, 292.
[211] See chapter 3 for more on the difficulties facing the EU in balancing the complex internal multilevel decision making with their external obligations under WTO.
[212] Notification of a Mutually Agreed Solution, *Biotech* WT/DS292/40 (17 July 2009).
[213] Notification of a Mutually Agreed Solution, *Biotech,* WT/DS293/41 (23 March 2010).
[214] 'EU, Argentina End Seven-Year WTO Biotech Row', 10(5) *Bridges Trade BioRes* 19 March 2010 http://ictsd.org/i/news/biores/72588/. Accessed 12 March 2011.

Canada, Argentina, and the US have been meeting regularly with the European Commission to discuss biotech-related issues since the adoption of the WTO Panel Report in 2006. While discussions with Canada and Argentina have been fruitful, the US remains a hold out.[215] On 14 January 2008, the EU and the US informed the DSB that they had reached an agreement on procedures under Articles 21 and 22 of the DSU with respect to dispute WT/DS291. On 17 January 2008, the United States requested authorization from the DSB to suspend concessions and other obligations with respect to dispute WT/DS291. On 6 February 2008, the EU objected to the United States' request for authorization to suspend concessions and other obligations and referred the matter to arbitration under Article 22.6 of the DSU. At its meeting on 8 February 2008, the DSB agreed that the matter had been referred to arbitration under Article 22.6 of the DSU. On 15 February 2008, the EU and the United States requested the Arbitrator to suspend its work pursuant to their agreed procedures under Articles 21 and 22 of the DSU. In accordance with the parties' joint request, the Arbitrator suspended the arbitration.

To conclude, the EU is still showing resistance to implementing the full recommendations of the Panel. It is very similar to its resistance to implement the recommendations in *EC Hormones*. The ruling of *EC Hormones* did not force the EU to remove its prohibition on meat from Canada and the US containing hormones. Instead it adopted a new directive reaffirming the prohibition and issued a new request at the WTO to end the retaliatory measures by Canada and the US.[216] In spite of this, the EU keeps expressing its will to engage in constructive discussions with the US.[217]

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[215] Document WT/DS293/41; EU; Argentina End Seven-Year WTO Biotech Row, 10(5) Bridges Trade BioRes19 March 2010, available http://ictsd.org/i/news/biores/72588/. Accessed March 2011.
[216] US Continued Suspension of Obligation of Obligations in *Hormones* (n 79). See www.wto.org/english/tratop_e/dispu_e/cases_e/ds320_e.htm. accessed 23 September 2010
[217] Status Reports by the European Communities- Addendum, WT/DS291/37/Add.21, WT/DS293/31/Add.21, 13 October 2009. Status Reports by the European Communities- Addendum, WT/DS291/37/Add.59, 7 December 2012.

5.2 Like product

The Complainants accused the EU of discriminating between 'like products', reflecting their view that genetic modification should not be a reason *per se* to treat products differently. Specifically, they argued that as a result of the specific product bans and the national measures, biotech products were treated less favourably than their imported and domestically grown non-biotech counterparts. They based their argument on four commonly used criteria for establishing likeness, noting that the product did not differ in terms of properties, end use, consumers' tastes and habits, and tariff classification. Argentina, argued that the bans were in violation of Annex c1(a), second sentence, and Article III:4 of GATT. In its response, the EU noted that a product was only like if it was similarly subject to the approval procedure; this was clearly not the case for conventional products. Moreover, the EU stated that the international community, through the Biosafety Protocol, recognised that GM products require their own, distinct authorisation process.[218]

The panel stated that Members are authorised in their approval procedures to treat differently imported products and domestic products. Where that distinction can be justified based on the difference in safety features of the products, unless that differential treatment was based on the origin of the products. The complainants did not provide evidence to show that the differential treatment was based on the origin of products.[219] Therefore, the Panel did not rule on whether or not GMOs are 'like' their counterparts. This was closely related to the complicated issue of 'substantial equivalence', one of the central pillars of the American regulatory approach to GMOs. The Panel, as did previous panels in previous situation such as *Hormones*, found no need to examine the safeguard measures under Article III:4 of the GATT,

[218] See discussion in Chapter 4, section 3.1.2.
[219] Reports of the Panel*, Biotech,* para 7.2415, 7.2514

since they were already in breach with Articles 5.1 and 2.2 of the SPS Agreement.[220] (Chapter 3 section 5.1.2 addresses question of like product)

5.3 Risk assessment and scientific uncertainty

The Complainants argued that EU Member State safeguards 'were not based on risk assessment' in violation of Article 5.1 of the SPS Agreement, and were not otherwise 'consistent with the requirements of Article 5.7'. They argued that both articles need to be reviewed by the Panel because Article 5.7 is an 'exception' to the requirements 'based on risk assessment' under Article 5.1.[221]

The EU argued for the independent application of Article 5.7, which allows WTO Members to establish a provisional SPS measure without a risk assessment precisely because of the insufficiency of scientific evidence and uncertainty about risks that makes it impossible to carry out a full risk assessment.[222] Regulatory review delays resulting from requests by regulators to obtain sufficient relevant scientific evidence to perform a risk assessment and to design risk management measures (e.g. traceability systems) and risk communication measures (e.g. labelling of GMOs) should therefore not be characterized as 'undue delays' in violation of the SPS agreement.[223] The EU noted Canada's three-year delay in approving Monsanto's application to commercialize genetically engineered wheat as an example of the delay required by thorough regulatory review.[224]

The Panel's analysis started with claims under Article 5.1 because the critical issue, in its view, was 'whether the relevant safeguard measures meet the requirements set out in the text of Article 5.1, not whether they are consistent with Article 5.7.' [225] For the definition of 'risk assessment' as set forth in Annex A, the Panel made

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[220] Panel Reports, *Biotech,* paras. 7.3421-7.3423, 8.29 This issue will be discussed further in Chapter 3, section 5.1.2
[221] The EU argued that only article 5.7 applied. See Panel Reports, *Biotech,* paras. 7.3000-7.3004.
[222] Second Written Submission by the European Communities, *Biotech,* paras. 80-103.
[223] Second Written Submission by the European Communities, *Biotech,* paras. 281-282.
[224] First Written Submission by the European Communities, *Biotech,* paras. 486-489.
[225] Panel Reports, *Biotech,* para. 7.3006.

reference to analysis of the Appellate Body in the *Australia- Salmon* case, in which the AB noted that 'risk assessment' must evaluate 'the probability' of entry and establishment or spread of disease or pest. On that basis, the Panel dismissed scientific studies in support of the safeguard measures because they did not address the issue of probability. Therefore, The Panel found that none of the EU Member States' safeguards were based on risk assessment.[226]

The Panel agreed with the Complainants assertion that 'the body of scientific evidence permitted the performance of risk assessment as required under Article 5.1', and that, consequently, Article 5.7 did not apply. The Panel focused on risk assessment, concluding that the EU level was sufficient for a risk assessment in each case. Consequently, the Panel found that each Member State safeguard was inconsistent with the obligations under Article 5.1, and 'by implication,' was also inconsistent with requirements of Article 2.2 that an SPS measure be 'based on scientific principles' and not maintained without sufficient scientific evidence.[227]

In the Panel's view, 'evolving science' and the application of a 'prudent and precautionary approach' could not justify a delay in the operation of procedures because regulators have the option of adopting temporary measures, or placing conditions on final approvals, where scientific evidence is 'insufficient'.[228] The Panel said delays caused by new information coming to light, or caused by extreme events beyond the EU's control, such as natural disasters, civil war or an unexpected administrative overload, might be considered justified. Moreover, delays attributed to the applicant for an approval could not, in the view of the Panel, amount to 'undue' delays by the EU.[229]

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[226] Panel Reports, *Biotech,* para. 7.3040.
[227] Panel Reports, *Biotech,* para. 7.3399.
[228] Panel Reports, *Biotech,* para. 7.1525.
[229] Panel Reports, *Biotech,* paras. 7.1527- 7.1529.

In *Biotech,* the Panel acknowledged that there may be uncertainties in science. It held that the state of scientific information can be taken into account in the risk assessment process, but it cannot be invoked as ground for delay.[230]

5.4 The relationship between the WTO rules and other rules of international law

As part of its defence, the EU argued that the WTO agreements must not be read in clinical isolation; rather they should be interpreted in light of other international rules and principles relevant to the dispute. It alleged that the complaining parties treated the legal issues concerning the authorisation and the international trade of biotech products as though they are regulated exclusively by WTO rules. In particular, the EU suggested that the Panel should take into account the Convention on Biological Diversity, which was ratified by the EU, Argentina, and Canada, and signed by the US, and its supplement, the Cartagena Protocol on Biosafety which was ratified by the EU, and signed by Argentina and Canada. [231]

The EU asserted that the Cartagena Protocol is the most advanced and specific international legal text in the field of trade in GMOs. The EU considered the Protocol was appropriate to assist the WTO in the interpretation of specific issues.[232] The Cartagena protocol is of particular relevance since its objective is to 'contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movements.'[233] The Protocol provides *inter alia* for a

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[230] For full analysis see Chapter 4, section 4.
[231] First Written Submission by the European Communities, paras. 453-459.
[232] First Written Submission by the European Communities, paras. 453-459.
[233] Protocol on Biosafety, Article 1. The Protocol provides *inter alia* for a prior approval procedure for the importation of living modified organisms as well as handling, transport, packaging and identification obligations. It also requires risk assessment to be carried out. Several references to the precautionary approach are found in the preamble and the text of the Protocol. Its preamble also notes that trade and environment agreements should be 'mutually supportive'.

prior approval procedure for the importation of living modified organisms as well as handling, transport, packaging, and identification obligations. It also requires risk assessment to be carried out. Several references to the precautionary approach are found in the preamble and text of the Protocol. In other words, because the Biosafety Protocol is a specific international legal text in the field of trade in GMOs concluded latter than the WTO agreements, it can be used to clarify provisions present in the WTO agreement.

Although the Protocol was binding on more than 110 states at the time of the dispute, the United States rejected any application of non-WTO agreements to this WTO dispute.[234] The US argued that the Protocol was not binding on the US (since it is not a party to the protocol), or on any other complaining parties.[235] In addition, it noted that the EU had not identified how the 'Biosafety Protocol' or the 'precautionary principle' would be of relevance to interpreting any particular provision of the WTO agreements at issue. The complaining parties further argued that even if the Biosafety Protocol was applicable, it did not affect rights arising from other international treaties.

The Panel treated this link as a treaty interpretation issue. The Panel held that Article 31(3)(c) of the Vienna Convention on the Law of Treaties (VCLT) [236], which governs the force to be given to other international agreements, did indicate that any relevant rules of international law should be taken into account in WTO rulings only if these rules are 'applicable in the relations between the parties.'[237] Because the CBD and the Biosafety Protocol did not have the force of law in all Member States to the dispute,[238] the Panel held that it could, but was not 'required'

[234] Panel Reports, *Biotech*, para. 7.56.
[235] Panel Reports, *Biotech*, para. 7.58.
[236] UN Doc. A/Conf.39/27; 1155 UNTS 331; 8 ILM 679 (1969); 63 AJIL 875 (1969).
[237] Panel Reports, *Biotech*, paras. 7.69-7.71.
[238] Panel Reports, *Biotech*, para. 7.75.

to, take those treaties into account. With little explanation, the Panel held it was not necessary or appropriate to rely on these treaties in the present case.[239]

Given that the US was not a party to the CBD, the Panel ruled that it was not required to take the CBD into account in interpreting the WTO agreements at issue in the dispute. Similarly, the Panel considered that it was not required to take the Protocol into account since Argentina, Canada and the US were not parties to it.[240] Moreover, the Panel noted that the Protocol had entered into force after the Panel was established. In the Panel's words, 'we do not consider that in interpreting the relevant WTO agreement we are required to take into account other rules of international law which are not applicable to one of the parties to this dispute.'[241]

Despite this restrictive interpretation of Article 31(3)(c) of VCLT, the Panel noted that, like dictionaries, other rules of international law may be useful in aiding an interpretation of WTO agreements. The Panel requested other international organizations to identify other materials that might aid in identifying the ordinary meaning of the WTO agreements. These instruments would be taken into account where appropriate.[242]

A United Nation Environment Programme recent publication suggests that adequate classification of trade related measures should be developed in a manner that takes into account the context of the Cartagena Protocol, and recommends a framework for considering trade-related measures in reference to the functions they perform.[243]

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[239] Panel Reports, *Biotech*, para. 7.89.
[240] Panel Reports, *Biotech*, para 7.75.
[241] Panel Reports, *Biotech*, see reasoning in paras. 7.92-7.94.
[242] Panel Reports, *Biotech,* paras. 7.95-7.96.
[243] 'Trade-related Measures and Multilateral Environmental Agreements' prepared by CIEL for UNEP (*UNIP* 2007). http://www.unep.ch/etb/areas/pdf/MEA%20Papers/TradeRelated_MeasuresPaper.pdf accessed July 2009.

The Reports of Panel fail to address this matter. This was a crucial issue that needed to be addressed. Therefore, Chapter 4 provides wider analysis of international law applicable to GMOs, the linkage between trade and other concerns, and the role of the Cartagena Protocol's trade related measures in responding to this relationship. To do so, the chapter will provide a review of the overall objectives and main provisions, and also assess the status of the precautionary principle in light of the Protocol.

5.5 The precautionary principle as defence

The EU argued in defence that the precautionary principle should be taken into account because it was a general principle of customary international law. The EU attempted to justify some Members States' national bans on GMOs with reference to the precautionary principle as general principle of customary international law and as provided in the 2000 Cartagena Protocol on Biosafety to the Convention on Biological Diversity.[244]

The Panel construed this to mean that the principle was either a rule of customary international law or a general principle of law recognized by States. Noting that it was unclear whether the Members had widely accepted the precautionary principle, the Panel followed the Appellate Body's lead in the earlier *Hormones* case, and declined to 'take a position on whether or not or not the precautionary principle is recognised principle of general customary international law.' It instead noted that there has 'been no authoritative decision by international court or tribunal' which so recognizes the precautionary principle, and that legal commentators remain divided as to whether the precautionary principle has attained such status. [245] The Panel ruled the precautionary principle to be too 'complex' and 'unsettled' an issue

[244] First Written Submission by the European Communities, *Biotech,* paras. 79- 86 and 105-110; See also, Panel Reports, *Biotech*, paras. 7.73-7.75 (Cartagena Protocol) and 7.76-7.89 (precautionary principle).
[245] Panel Reports, *Biotech*, paras. 7.77-7.87.

in international law to serve as a basis for the Panel's Ruling. In any case, the Panel found it unnecessary to take a position in order to dispose of this specific dispute.[246]

Citing the Appellate Body Report of the *EC-Hormones* ruling as its authority, the Panel stated that 'even if a Member follows a precautionary approach', its SPS measure needs to be 'based on' (i.e. 'sufficiently warranted' or 'reasonably supported') by a 'risk assessment'. Further, the Panel disallowed the risk management option of taking a precautionary approach to regulating GMOs if a risk management decision is not based on a risk assessment as defined by the SPS Agreement.[247]

Indeed, in applying the SPS agreement, the Panel did address the precautionary approach. In the Panel's view, Annex C(1)(a) was not inconsistent with the precautionary approach. It held:

> Annex (c)(1), first clause, allows a Member to take time that is reasonably needed to determine with adequate confidence whether its relevant SPS requirements are fulfilled. Consistent with this, we consider that a Member which finds it appropriate to follow a prudent and precautionary approach in assessing and approving applications concerning GMOs and GMO derived products, might, for instance, be justified in requesting further information or clarification of an applicant in a situation where another Member considers that the information available is sufficient to carry out its assessment and reach a decision on an application.[248]

The role of the precautionary principle in the application of EU legislation is one of the dispute's main issues. The gaps and lack of consensus in scientific knowledge and the application of the precautionary principle are fundamental issues in

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[246] Panel Reports, *Biotech,* paras. 7.78-7.89.
[247] Panel Reports, *Biotech*, paras. 7.3067-7.3069.
[248] Panel Reports, *Biotech*, para. 7.1522.

ensuring biosafety. See Chapter 3, section 4 for critical analysis of the status of the precautionary principle.

The Panel ruling also included several decisions favourable to the complaining parties and future GMO exporters. First, the Panel held that it was not required to (and did not) consider the international environmental norms embodied in the CBD or the Cartagena Biosafety Protocol. Second, the Panel held that a Member could not unduly delay a substantive decision on pre-marketing approval applications of GMOs by means of procedural roadblocks. Third, the Panel somewhat restricted the ability of Members to impose SPS measures based on a perceived inadequacy of the scientific evidence available, thus limiting the precautionary principle to cases where the scientific evidence in a particular risk assessment is internally inconsistent, or where there is insufficient evidence to even conduct a risk assessment as defined in Annex A(4).[249]

5.6 The needs of developing countries

Argentina argued that the moratoria related to Argentine product applications violated Article 10.1of the SPS Agreement on special and deferential treatment, which requires Members to 'take account of the special needs of developing country Members.'[250] The Panel rejected this argument, relying on the Oxford dictionary's definition of the expression 'take account of'. It found that Article 10.1 does not prescribe a specific result to be achieved. More specifically, nothing in Article 10.1 suggests that in weighing and balancing the various interests at stake, the EU had to necessarily give priority to those needs of Argentina (export levels) as a developing country over other domestic concerns, such as protection of its own consumers or the environment. [251] The Panel also added that burden of proof in relation to Article 10.1 of the SPS Agreement was incumbent on Argentina, and as

[249] As explained in sections 3.5, 5.1.3 and 5.14 above.
[250] Article 10.1 of the SPS Agreement 'in the preparation and application of sanitary or pytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the leased developed country Members.'
[251] Panel Reports, *Biotech*, p. 692, para 7.1627.

the complaining party it had to prove that the EU did not take account of developing countries' needs. The fact that the EU did not accord special and differential treatment in comparison with other developed country exporters did not demonstrate, by itself, an inconsistency with Article 10.1.[252] Numerous articles address this matter, and show that, as a consequence, it has become difficult for developing countries to establish their policies on GMOs without interference from the main parties of the *Biotech* dispute.[253]

The significance of Argentina's argument lays in the fact that it draws attention to the questions of the needs of developing countries and how they should approach GMOs. Chapter 2 identifies the main concerns of developing countries as regards GMOs. Chapter 4 demonstrates their strong interest in international regulation of GMOs, and considers the effect the *Biotech* dispute will have on their choices and needs.

6 Response to the 'Reports' of the Panel

With the issuance of the Panel's Interim Reports, the United States and the European Union rushed statements about their views on the implication of the Reports on both parties and the rest of the world. They both gave the impression that the ruling was in their favour. It can be seen as an attempt by both sides of the dispute to influence other countries to favour their policies. At this point one may wonder whether both parties are trying to use the WTO dispute mechanism to promote their domestic policies on GMOs.

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[252] Panel Reports, *Biotech*, paras. 7.1615 and 7.1626.
[253] Nuffield Council on Bioethics, *The Use of Genetically Modified Crops in developing countries: A Follow up Discussion Paper to the 1999 Report "Genetically Modified Crops: the Ethical and Social Issues"* (Nuffield Council on Bioethics, December 2003), p113.

6.1 US's response

US trade officials quickly announced the result as a win for farmers around the globe, pointing to the removal of barriers to the further development and dissemination of a 'safe and beneficial technology that is improving food security and helping reduce poverty worldwide.'[254] The US Trade Representative (USTR) issued a statement, noting that the WTO ruled the EU's moratorium on GMOs illegal. It also added that this ruling 'brings the United States one step closer to clearing barriers...and expanding global use of promising advances in food production.'[255]

Mike Johanns, the US Agriculture Secretary, as quoted by the Office of the USTR said, 'today's decision affirms what the world farmers have known about biotechnology for many years.' He added, 'since the first biotechnology crops were commercialized in 1996, we've seen double digit increase in their adoption every single year. Biotechnology crops not only are helping to meet the world's food needs, they also are having a positive environmental impact on our soil and water resources. Farmers, who grew biotechnology crops in 21 countries around the world, including 5 in the EU, stand to benefit from today's decision.'[256]

The US explained that the WTO ruling would require GMO regulations to be based on scientific evidence. It acknowledged that the EU approved a 'handful' of biotech product applications, but the broad ban remained in effect.[257] Ambassador Schwab, quoted by Office of the United States Trade Representative (USTR), said, 'the

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[254] 'US Trade Representative Rob Portman and US Agricultural Secretary Mike Johanns on Agricultural Biotechnology and the WTO', USDA, Release No. 0040.06, 7 February 2006,.http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=2006/02/0040.xml. Accessed 14 December 2007.

[255] 'World Trade Agency Upholds Challenge of European Biotech Ban', USPOLICY Embassy of the United States, Belgium, 29 September 2006, http://www.uspolicy.be/Article.asp?ID=BFD0D73c-E01B-478C-A16. Accessed 14 December 2007

[256] 'US Trade Representative Susan Schwab and US Agriculture Secretary Mike Johanns Announce Favourable Ruling in WTO case on Agricultural Biotechnology' USTR, 29 September 2006, http://www.ustr.gov. Accessed 14 December 2007

[257] 'World Trade Agency Upholds Challenge of European Biotech Ban' (n 255)

WTO has ruled in favour of science-based policymaking over the unjustified, anti-biotech policies adopted by in the EU.'[258] Schwab urged the EU to 'fully comply with its WTO obligations and consider all outstanding biotech product applications, and evaluate their scientific merits in accordance with EU's own laws, without undue delay.'[259]

Despite these statements declaring victory, the USTR spokeswoman commented at a later time that 'the United States remains very concerned with EU treatment of agricultural biotech products.' At the same time, the 'US's goal is to normalise trade in biotech products, not to impose trade sanctions on EU goods.' She also added that American seed companies, farmers, and exporters continue to experience significant commercial losses as a result of EU's actions. [260]

These statements show that the US government is still trying to dissuade the EU, and other governments around the world, from to restricting the cultivation or the entry of GMOs into their countries.

6.2 EU's response

The EU's initial response to filing the complaint at the WTO was immediate and brief. 'We regret this more to an unnecessary litigation', said Pascal Lamy, EU trade commissioner at the time. He also claimed that the case would confuse already sceptical European consumers.[261]

In a press release issued same day of Interim Report, the EU stressed the need for strong regulatory oversight of GMOs, and noted that the approvals process it has in place had led to the authorisation of more than 30 biotech products. It argued that

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[258] 'US Trade Representative Susan Schwab and US Agriculture Secretary Mike Johanns Announce Favourable Ruling in WTO case on Agricultural Biotechnology' (n 256)
[259] 'World Trade Agency Upholds Challenge of European Biotech Ban', (n 255)
[260] 'US to Evaluate EU Progress on Biotech Approvals, Temporarily suspends WTO sanctions Process, The United States Mission to the European Union (Brussels, 14 January 2008). http://useu.usmission.gov/Dossiers/Biotech/Jan1408_WTO_EU.asp. Accessed 13 September 2009
[261] Andrew Osborn in Brussels, US Escalates GM food row with Europe, The Guardian 19 August 2003 http://www.guardian.co.uk/ Accessed 19 August 2007,

it does not have a ban in place, suggesting that the implications of the biotech case for current EU processes are likely to be minimal because the ruling does not apply to regulatory framework that came into effect in 2004.[262] Therefore, The EU observed that since it resumed the approval of GMOs in 2004, the Panel's recommendations based on the old situation have had no practical impact on the EU.[263]

As regards the national safeguard bans, efforts to remove them by the European Commission have been met with sustained resistance amongst Member States and in the Council of Ministers.[264] EU Member States remained largely hostile to GMOs. In her statement, Austria's Health Minister, Maria Rauch-Kallat, asserted that 'the protection of people and environment have absolute priority…we will exhaust all possibilities to keep Austria's agriculture GM free and ensure consumers safety.'[265] France, Germany, Greece, Hungary, Italy, Luxemburg, Poland, and Romania also imposed different bans on the cultivation of GMOs.[266]

The EU continues to defend its regulatory system. For example, in a speech to the European Biotechnology Open day in Brussels, EU Trade Commissioner, Peter Mandelson strongly defended the EU's approach to biotechnology and GM food, one that prioritises strict science-based health and safety testing, but which also recognises that safe biotechnology has a crucial role to play in agriculture and agricultural trade both in Europe and the developing world.[267]

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[262] 'Europe's rules on GMOs and the WTO EU' European Commission, Press Release, Brussels, 7 February 2006 http://europa.eu/rapid/press-release_MEMO-06-61_en.htm Accessed 17 March 2009

[263] See 'WTO Panel Provisionally Rules against EU Moratorium on Biotech Approvals', 10(4) Bridges Weekly Trade News Digest, 8 February 2006. http://ictsd.org/i/news/biores/9425/ Accessed 18 April 2009

[264] FoE International, 'Looking behind the US spin' (n 166).

[265] FoE International, 'Looking behind the US spin' (n 166).

[266] 'EU Cultivation bans in Europe' http://www.gmo-free-regions.org/gmo-free-regions/list.html. Accessed January 2013. For details about the current bans see Chapter 3, section 2.3.

[267] Speech by EU Trade Commissioner Peter Mandelson: Biotechnology and the EU (SPEECH/07/397, Brussels, 14 June 2007), http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/07/397&format=HTML&aged=0&language=EN&guiLanguage=en. Accessed 21August 2009.

6.3 Identifying Civil Society Concerns

Civil society was also quick to attack the decision, accusing the US of trying to force biotech foods on European consumers. They stressed the right of European governments to protect their farm land, environment and consumers from the risks posed by GMOs.[268] The following extracts demonstrate the anger not only with GMOs, but also with the WTO as a legitimate forum with effect on domestic regulations.[269]

For many civil society groups and NGOs, the WTO is seen as the enforcer of the interests of global corporations at the expense of people and the environment. Eric Gail of Greenpeace said 'all this verdict proves is that the WTO is unqualified to deal with complex scientific and environmental issues, as it puts trade interests above all others.' [270] Their stand is not surprising since most of the anti-GMO pressure came from environmentalists and consumer groups.[271]

Adrian Bebb, GM food campaigner at Friends of Earth Europe said, 'Whatever the World Trade Organisation says, the dispute over genetically modified foods has created no clear winners but many losers. The public faces contaminated foods resulting from weak regulations in the United States and farmers see their livelihoods threatened by contamination. This trade dispute has been pointless exercise that will change absolutely nothing. Europeans will continue to reject genetically modified foods.'[272]

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[268] Some NGO groups have sent their own legal submissions to the WTO. Group of Academics brief explaining the relevance of critical science to the dispute (n 23) See section 4.2.1 above.
[269] 'EU GMO Ban Was Illegal, WTO Rules' EurActive 12 May 2006. http://www.euractiv.com/trade/eu-gmo-ban-illegal-wto-rules-news-216529 accessed 19 June 2008.
[270] 'Right to Remain GMO-free Overrides WTO Ruling' Greenpeace, 10 May 2006, http://www.greenpeace.org/eu-unit/en/News/2009-and-earlier/right-to-remain-gmo-free-overr/. Accessed 9 June 2009.
[271] David Vogel and Olivier Cadot, 'France, the United States, and the Biotechnology Dispute' *Brookings* (4 June 2008). http://www.brookings.edu/research/articles/2001/01/01france-cadot. Accessed 9 January 2009.
[272] FoEE mentions the rice contamination in 2006, See 'Transatlantic biotech trade war', FoEE Press Release, 29 September 2006 http://www.foeeurope.org. accessed 29 March 2008

Sonja Meister, Trade Campaigner at Friends of Earth Europe declared, 'This ruling shows that the WTO is the wrong forum to deal with environmental trade disputes and the international community must find an alternative before another case occurs. The WTO ignored international environmental laws, met in secret behind closed doors and barred any public involvement, even though we have a strong public resistance against GMOs in Europe.'[273]

Director of Friends of Earth, Martin Rocholl asserted that, 'the Bush Administration is using the undemocratic and secretive WTO to force feed GM food on the World. Decisions about the food we eat should be made in Europe, not the White House or the WTO.'[274]

In a very sharp statement Lorry Wallach, director of Public Citizen, added 'The United States may have won this battle, but it is rapidly losing the GMO war'. This WTO ruling will only increase consumer suspicion of GMOs and of a global trading system that subsumes the public interest to the interests Monsanto and other agribusiness giants eager to force feed consumers products about which consumers have deep concerns.[275] Public Citizen added, '[f]orcing unwanted GMOs on unwilling nations is not just stupid politics: It is a violation of international law. The Biosafety Protocol protects the right of nations to regulate these products in the public interest. The best way for nations to greet this news from the WTO is to stand their ground and implement much-needed pre-market approval, safety testing, traceability and labelling programs.'[276]

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[273] 'Transatlantic biotech trade war', FofEE, Press Release, 29 September 2006 http://www.foeeurope.org.
[274] The US Attempts to Force Feed GM to Europe: GMO Trade war escalates, FoEE, Press Release, 5 March 2004. http://www.genet-info.org/ Accessed 4 May 2007
[275] 'Public Citizen Denounces WTO Tribunal Decision on Genetically Modified Foods' Statement of Lori Wallach, Director, Public Citizen's Global Trade Watch 7 Feb 2006 http://www.citizen.org/documents/gmodayof_FINAL.pdf. Accessed 4 May 2007.
[276] 'Public Citizen Denounces WTO Tribunal Decision on Genetically Modified Foods' Statement of Lori Wallach, Director, Public Citizen's Global Trade Watch, 7 February 2006, p. 2. http://www.citizen.org/Page.aspx?pid=2871 accessed 3 May 2008.

Over 740 organisations with combined membership of 60 million people have supported the campaign of '**Bite back: Hands off our food**'. This campaign demands that the WTO does not force GM foods onto people against their wishes, and asserts that the WTO is an illegitimate forum to deal with GMOs.[277] The Panel ruling might have adverse effects, and prompt more and more consumers around the globe, through their representatives, to lobby and enact policies declaring their regional and national governments GMO-free and to campaign against the WTO. [278]

Many NGOs also viewed the ruling as an attack, or an attempt to undermine other international agreements, in particular, the Biosafety Protocol. They believed that this ruling was a warning to members of the Biosafety Protocol to regulate biotech products according to their protocol commitments. A Protocol-based defence of those regulations cannot prevail at the WTO if the plaintiffs are not Protocol members[279]

The Panel's decision was seen by some as an attempt to force 'Frankenfoods' on the rest of the world, regardless of what consumers and their elected representatives say.[280] According to Friend of the Earth Europe, public opinion remains hostile towards GM food, and this WTO ruling did not persuade Europeans them to change. The number of bans from national governments has increased since the beginning of the dispute, and over 170 EU regions have declared themselves GM Free zones.[281]

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[277] For more information on the campaign, see http://www.bite-back.org.
[278] 'World Trade Organisation dispute on genetically engineered organisms', Greenpeace, Briefing, May 2006. http://www.greenpeace.org. accessed 3 May 2008.
[279] 'WTO Biotech Ruling Threatens Precautionary Approach', IATP Press Release, 29 September 2006 http://www.iatp.org ; see Steve Suppan 'US vs EC Biotech Products Case: WTO Dispute Backgrounder' IATP, September 2005.
[280] 'Public Citizen Denounces WTO Tribunal Decision on Genetically Modified Foods' (n 276)
[281] FoEE, 'Trying to Force feed the world: The transatlantic trade dispute over genetically modified foods' FoFF, 14 December 2005 http://www.foe.co.uk/resource/press_releases/wto_gm_trade_war_has_europ_14122005.html

NGOs view the WTO as a trade body incapable of reconciling the growing conflict between 'free' trade and what citizens require of their governments in relation to complex scientific matters (e.g. those surrounding GMOs). They also stressed that *Biotech* did not rule on the safety of GMOs, or on other EU legislation, such as labelling. [282]

6.4 Identifying Industries

A number of industry and farmer groups in the US, which is the world leader in the adoption of GM crops, expressed their support for the preliminary report, and the subsequent Panel ruling. The American Soybean Association welcomed the WTO ruling against the EU, announcing victory against 'Europe's flawed and non-science based approval processes. The American Soybean Association also called on the US government to promptly mount a WTO challenge against Europe's discriminatory traceability and labelling laws that apply to biotech crops.[283] The American National Corn Growers Association made similar threats, noting that 'we do not expect Europe to become big importers of US corn but the moratorium cast a big shadow across other nations. This is a message to the world that we won't put up with the EU violating the rules.'[284] The GM industry in the US continues to back the science-based regulatory system.

The European Association for Bio-industries stated that the biotech dispute was not 'about safety, the crops being grown around the world have passed stringent food, feed and environment safety standards and are as safe as, or safer than, conventional

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[282]For example, FoE & Greenpeace, 'Groups publish conclusions of WTO dispute: IATP, Friends of the Earth and Greenpeace: WTO secrecy an outrage' FoE & Greenpeace, Press Release, 8 Feb 2006, http://www.foeeurope.org/press/2006/joint_8_Feb_WTO_conclusions.htm. Accessed 3 April 2007.

[283] American Soybean Association, 'ASA hails victory against Europe's biotechnology approval system, call for prompt challenge of Europe's discriminatory Biotech labelling rules' ASA News Release, 7 February 2006, Saint Louis, Missouri, http://www.soygrowers.com/newsroom/releases/2006_releases/r020706.htm

[284] 'The WTO condemns EU over GMO Moratorium: Diplomats' Reuters, 7 February 2006. http://www.nwrage.org/content/wto-condemns-eu-over-gmo-moratorium-diplomats

crops.'[285] Industries try to prove their view by highlighting the increasing use and cultivation of biotech crops around the world.

It is interesting to note that corporations, producers, and patent owners of GM seed, such as Monsanto, preferred not to draw attention, and did not make big announcements about the result of the dispute.

7 Conclusion

The *EC-Biotech* dispute highlights the regulatory divide between WTO Members, and reveals a deepening crisis over issues of science and governance. It has proven to be a big challenge for the WTO dispute settlement mechanism. It placed very complex issues in the spotlight, while also bringing into focus the role of the World Trade Organization in protecting values other than trade, such as human health and the environment.

The Panel's Report did *not* rule on the general safety of GMOs, or on the general legality of the EU approval procedure. Yet, the Panel spent three years and produced a 1000-page report, plus yet another 1,000 pages of Annexes. The politically charged nature of the debate was clearly reflected in this dispute. The Panel was very careful and hesitant in its Reports. The B*iotech* dispute brought attention to several procedural issues pertaining to the WTO dispute settlement system, such as the role of advisory experts and of *amicus curiae* briefs, as well as the extended time taken to resolve these special cases marked with a high level of complexity and political sensitivity. Although the Panel report retained a narrow frame of reference, the case also drew attention to significant substantive issues, such as the definition of 'undue delay', the role of science and precaution, and the inter-relationship between trade law and public international law. There remain,

[285] EuropaBio statement on WTO ruling on biotech crops, EuropaBio, Brussels, 8 February 2006. http://www.europabio.org/ accessed 19 February 2006.

however, several questions on which the Panel commented either inconclusively or not at all.

The immediate result of the Panel's Reports has been to further inflame and politicize an already sensitive issue in transatlantic relations. In order to understand the full implications of this dispute and to assess the best solution, we need a better contextual understating of the issues at stake. The next chapter takes the crucial step of unfolding the complexity of this dispute by providing an explanation of the science related to GMOs, and considering the aspects that make GMOs highly contentious.

CHAPTER 2

GNETICALLY MODIFIED ORGANISMS EXPLAINED

'Mixing genetic material from species that cannot breed naturally takes into areas that should be left to God.'
Prince Charles[1]

1 Introduction

Although the transfer of genetic material has long occurred through selective breeding and other techniques, new technologies permit more controlled transfers, and transfers of genes from completely unrelated species. Hence, 'GMOs are created by transferring genetic material from one organism to another. This process is called genetic engineering or biotechnology.'[2] On the one hand, GMOs offer significant potential benefits to society in areas like agriculture, environmental management, and human health protection. On the other hand, much of the concern stems from a lack of scientific certainty associated with GMOs and their impact on human health and surrounding environment.

While GMOs are fast joining agriculture throughout many parts of the world, the world remains split; countries do not agree on the best way to protect against these potential threats, and they have different regulations regarding the testing and approval procedures necessary to place GMOs and their products on the market.[3]

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[1] 'Prince Charles Speaks Out Against GM Food' BBC News, 09 April 1999 http://news.bbc.co.uk/1/hi/special_report/1999/02/99/food_under_the_microscope/285408.stm. Accessed 13 May 2007.
[2] WTO, 'Genetically Modified Organisms (GMOs)' (Current issues in SPS Agreement Training Module) http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s1p1_e.htm. Accessed 3 April 2012.
[3] Also, when they disagree about labelling and identification requirements. See WTO, 'Genetically Modified Organisms (GMOs)' (Current issues in SPS Agreement Training Module)

Some countries like the US, Canada, and Argentina endorse GMOs, allowing cultivation and commercialisation of GMOs. Others, such as the Member States of the European Union, embrace more cautious approach towards GMOs. Still other countries ban imports and sales of GMOs and their products altogether.

These differences create trade problems, such as the *Biotech* dispute. The dispute is the product of great resistance to allowing unrestricted marketing of GMO products in the European Union. It also placed GMOs in the spotlight, bringing wider attention to GMOs. The parties' submissions show conflicting understanding and approaches to GMOs, with their arguments making a case for and against GMOs. The Panel sought expert advice to on issues of 'scientific or technical complexity' in order to help it decide which factual issues were relevant to the allegations of violations charged by the plaintiffs under four WTO agreements.[4] Finally, the *Biotech* ruling has the potential to shape the relationship between the SPS Agreement (WTO law) and the Cartagena Protocol regimes, both domestic and international. Therefore, it will have important implications for both developed and developing countries, as well as the import and export of GMOs. It may also influence developing countries considering what laws to introduce to regulate GM crops and products.

The concept of 'risk' has emerged as a central concern of regulation in the world 'risk society'.[5] This chapter explores how the determination of risks to health and the environment has come to be heavily reliant on scientific evidence and expertise based procedures. Hence, understanding global legislative efforts at regulation requires a basic knowledge of the science behind GMOs. Such knowledge is essential since it is the starting point for conducting risk assessment. This has led to the development of different procedures for conducting risk assessment at national, and international level.

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http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s1p1_e.htm. Accessed 3 April 2012.

[4] Panel Reports, *Biotech,* paras. 4.160-4.359. The complainants challenged the lack of scientific justification for the *de facto* moratorium and national bans. They also added that the EU delays hindered development of GM technology, which is of proven safety and brings great benefits.

[5] Brian Wynne, 'Uncertainty and environmental learning: reconceiving science and policy in the preventive paradigm' (1992) 2(2) Global Environmental Change, 144; For more on risk society see Ulrich Beck, *Risk Society: Towards A New Modernity* (London; SAGE Publication, 1992)

This chapter introduces background information on plant breeding and genetic modification of plants, placing modern biotechnology techniques in their historical and scientific context. It also explains the main uses of genetically modified crops and food. It then presents data about crops that are currently grown commercially around the world and the future varieties that are currently being developed.

While genetically modified crop varieties promise benefits to the corporations, farmers, food producers, consumers, and the environment, they may also pose unknown risks to the human health and many other environmental issues. To contrast the contested benefits with the potential risks resulting from GMOs, this chapter will assess arguments set forth for and against the use of GMOs.
Finally, this chapter draws attention to the argument raised by the United to States in its allegations that GMOs can feed the worlds, the last section examines the impact of the *Biotech's* Ruling on developing country choices with regard to the role that genetically modified organisms might play in their food security.

2 Genetically modified organisms

There is no universally accepted definition of genetically modified organisms (GMO), even though many attempts have been made to find an exhaustive definition. The references and definitions vary across countries and regulatory agencies. In the following, the terms, 'Genetic Modification' (GM),'genetically engineered', 'GE organisms', 'genetically engineered organisms', 'genetically modified', 'genetic modified organisms' (GMOs), 'living modified organism' (LMO), 'transgenic crops', and 'transgenic organisms' will be used synonymously.[6]

The World Health Organisation provides that: [7]

[6]Please note that some terms are wider than the others. The *Biotech* Panel adopted a similar approach, using the terms, 'biotech products', 'GMOs', 'GM plants', 'GM crops', or 'GM products' interchangeably, Panel Reports, *Biotech,* paras. 7.1-7.2.
[7] WHO, '20 Questions on Genetically Modified (GM) Foods' http://www.who.int/foodsafety/publications/biotech/en/20questions_en.pdf. Accessed 5 March 2008.

> Genetically Modified Organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The technology is often called "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another, also between non-related species.
>
> Such methods are used to create GM plants- which are then used to grow GM food crops.

Although citizens and governments in different countries all want to ensure that these GMOs do not pose a threat to human health or the environment, they do not agree on the best way to protect against these potential threats.[8] The *Biotech* dispute clearly demonstrates how deeply this division is based on how they define GMOs. The next section illustrates the extent of this division.

2.1 The definitional problem of GMOs

Responses to the challenges raised by agricultural biotechnology seem to have diverged. In the regulatory arena, the differences in approach are significant. At the heart of the divergence is the fact that the definition of genetically modified organisms (GMOs) is far from clear. The differences are clearly reflected in the *Biotech* dispute.

The US and Canada consider 'Genetic modification' a broad term, covering a variety of scientific methods designed to improve the productivity and functionality of plants, animals, and micro-organisms. They provide historical and scientific development of traditional techniques of plant breeding and present 'modern biotechnology' or 'recombinant technology' (rDNA) as simply the latest and most

[8] WTO, 'Genetically Modified Organisms (GMOs)' (n 2).

advanced technique in genetic modification of crop plants. In other words, genetic modification is basically an extension of traditional breeding techniques. [9]

The US denies any potential hazards arising from GMOs.[10] The US chose to use the expression 'biotech products' which refers to 'plant cultivars that have been developed through recombinant deoxyribonucleic acid ("recombinant DNA) technology.'[11] The US government use the term 'genetic modification' to cover both modern (recombinant DNA) techniques and traditional breeding techniques.[12] Argentina uses the phrase 'biotech agriculture products' to describe 'genetically modified organisms (GMOs)' or 'novel foods' as they are designated in EU legislation.[13]

The EU considered that the terms used by the Complainants were misleading since biotechnology covers techniques and practices other than genetic modification, referring to a press release concerning the Food and Agriculture Organization of the United Nations' (FAO) annual report, 'The State of Food and Agriculture 2003-04',[14] which pointed out that '…biotechnology, one of the tools of the gene revolution, is much more than genetically modified organisms (GMOs), [and] sometimes also called transgenic organisms.' These were at issue in the *Biotech* case. Consequently, some of the potential benefits described in paragraphs 17-26 of the first written submission of the USA might not derive from GMOs, but other forms of modern biotechnology.

The EU's legislation relevant to the dispute refers to 'genetically modified organisms' (GMOs) as contained in Article 2(2) of EC Directive 2001/18 'on the

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[9] First Written Submission of Canada, *Biotech,* paras. 3-6. Traditional breeding methods include, selective breeding, crossbreeding (hybridization) and grafting. See also First Submission of the United States, *Biotech,* paras. 7-15.
[10] First Submission of the United States, *Biotech,* para. 27.
[11] First Submission of the United States, *Biotech,* para 10. The US in their submission used the phrase " modern technology" to refer to "recombinant DNA"
[12] 7 Code of Federal Regulation, Section 340.1, see 'Statement on Biotechnology Issues', by James H. Maryanski, FDA Biotechnology Coordinator, before the senate Committee on Agriculture, Nutrition and Forestry, 7 October 1999, available at www.hhs.gov/progorg/asl/testify/t991007a.htm. Accessed 13 April 2010.
[13] Directive 2001/18/EC and its predecessor Directive 90/220/EEC and Regulation (EC) No. 258/97.
[14] 'The Gene Revolution: Great Potential for The Poor, But No Panacea' FAO Press Release 17 May 2004, http://www.fao.org/newsroom/en/news/2004/41714/index.html Accessed 13 April 2010.

deliberate release into the environment of genetically modified organisms'[15] (and Article 2(2) of its predecessor, EC Directive 90/220[16]), and under Articles 1(2)(a) and 1(2)(b) of EC Regulation 258/97, concerning 'novel foods and novel food ingredients'.[17] Naturally, 'genetically modified organisms' (GMOs) is the EUs term of reference in the dispute.[18] The EU defined GMO as '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.'[19] The European Communities argues that none of the current biotech gene transfer methods are able to precisely control where a foreign gene will be inserted into the recipient cell's genome, or whether that insertion will be stable, and further describes the screening for the desired traits.[20] The EU highlights main difference between genetic modification and conventional breeding practices as being that the latter does not allow for the crossing of natural species barriers or for the transfer of a single or few genes instead of whole genomes.[21] Similarly, Norway, a third party to the dispute, defined GMOs as one of the results of modern biotechnology, which are created by a particular set of techniques used to genetically modify (or 'genetically engineer') organisms.[22]

The *amicus curiae* brief submitted by NGOs to the WTO Panel provided that 'Genetic Modification', the process through which an organism is modified by the application of recombinant DNA (rDNA) technology, can involve either the transfer of genes from one (or more) species to another or the manipulation of genetic material within species.[23] The *amicus curiae* brief submitted by a trans-Atlantic group of expert academics defined 'genetic modification' or 'genetic engineering' as involving the manipulation of an organism's genetic endowment by introducing or eliminating specific genes through modern molecular biology

[15] OJ 17.4.2001 L106/1
[16] OJ 8.5.1990 L117/15, preamble as amended by Directive 94/15/EC, OJ 22.4.1994 L 103 and Directive 97/35/EC, OJ 27. 6.1997 L169.
[17] OJ 14.2.1997 L043/1.
[18] See Chapter 3 sections 2.1-3 for discussion of EU legislation.
[19] Article 2(2) of Directive 2001/18/EC See also, First Written Submission by the European Communities, *Biotech*, at para. 17.
[20] First Written Submission by the European Communities, *Biotech*, paras. 26-28.
[21] First Written Submission by the European Communities, *Biotech*, paras. 19-20.
[22] Third Party Submission by Norway, *Biotech*, May 24, 2004.
[23] *Amicus curiae* Brief submitted by CIEL, FOE-US, Defenders of Wildlife, IATP and OCA-USA. European Communities- Measures Affecting the Approval and Marketing of Biotech Products (WT/DS/291, 292 and 293), para. 5.

techniques. The production process of genetically modified crops involves transgenesis, or the transfer of genes from one plant, animal, or virus into another organism.[24]

At the international level, the EU made reference to the Convention on Biological Diversity, which defines the revolutionary technology of 'biotechnology' as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.'[25] The use of biotechnology in agriculture has produced a growing number of 'genetically modified organisms' (GMOs) and products derived from them.[26]

Article 3(g-i) to the Cartagena Protocol to the Convention on biological diversity refers to GMOs as 'living modified organisms'.[27] According to the Protocol, a 'living modified organism' is defined as 'any living organism that processes a novel combination of genetic material obtained through the use of modern biotechnology.'[28] In everyday usage, LMOs are usually considered to be the same as GMOs, but their definition and interpretation vary widely.

Article 3(h) of the Cartagena protocol on Biosafety defines 'living organisms' as 'any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.'

Under Article 3(i), "modern biotechnology" means the application of:

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

b. Fusion of cells beyond the taxonomic family,

[24] *Amicus Curiae* Brief, *Biotech*, WT/DS/291,292, and293 (1 June 2004) authored by CIEL, FOE-US, Defenders of wild life, IATP, and OCA-US [hereinafter Group of five NGOs] p. 9.
[25] The Convention on Biological Diversity, 1760 UNTS 79. 31 ILM (1992) 818; B&B Docs, 390. Adopted on June 1992 at Rio de Janero Earth Summit, entered into force 29 December 1993. [hereinafter 'CBD']
[26] The biotechnology industry provides products for human health care, industrial processing, environmental bioremediation, and food and agriculture. See section 2.6 below
[27] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted 29 January 2000, 1760 UNTS 9 [hereinafter Cartagena Protocol'] Article 3(g).
[28] Cartagena Protocol, Article 3(g).

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.[29]

The *Biotech* panel in its Reports briefly noted these differences, choosing to use interchangeably the terms 'biotech products', 'GMOs', 'GM plants', 'GM crops' or 'GM products', 'without prejudice to the views of the Parties to the dispute'.[30] Of these terms, the Panels' preferred choice throughout the reports is '**Biotech products**', as used by the United States to refer to 'plant cultivars that have been developed through recombinant deoxyribonucleic acid ("recombinant DNA") technology.'[31] It did not use '**GMOs**' as reference, or as used by the EU. This thesis tends to more frequently use the term 'GMOs', which is the term used in EU legislation at heart of this dispute.[32] For the purpose of this thesis, a broad definition is used, in which genetically modified organism is an organism that has been modified through the use of modern biotechnology, such as recombinant DNA techniques.

This wide terminology used to describe GMOs only adds to the confusion. The next three sections take a back step in order to explain biotechnology (the science of GMOs). It begins with background information on plant breeding, clarifying what 'plant biotechnology' is. It then explains techniques used to genetically modify plants. These sections will place modern biotechnology techniques in their historical and scientific context.

2.2 History of plant breeding

All plants, fungi, and bacteria contain DNA, and they pass a copy of their DNA to their offspring. Genetic change is a natural and desirable process. 'It results in variation in shape, form and behaviour of the individuals within a species, allowing for evolution and adaptation. It is crucial for the survival of any new species in response to environmental change.' As a result, the evolution of life on earth was dependent on the extraordinary nature of DNA.[33]

[29] Cartagena Protocol, Article 3(i)
[30] Panel Reports, *Biotech*, paras. 7.1- 7.2.
[31] Panel Reports, *Biotech*, para 2.20.
[32] See Chapter 3, sections 2.1-3 for more details on EU regulations.
[33] Nigel G Halford, *Genetically Modified Crops* (Imperial College Press, London, 2003) pp. 4, 9.

Historically, it is possible that crop improvement has been practiced since humans started to plant and harvest crops, rather than forage for food from wild plants, perhaps as long ago as 10,000 years. At first, improvement may have occurred unconsciously but then became more systematic:[34]

> Types of crop plants with different characteristics would be grown in adjacent plots and some of the seed produced would result from crossing of the two types. Farmers would then select the best seed for the next generation. This relatively primitive but effective form of plant breeding is still used in many parts of the world today and through the ages has changed crop plants greatly from their wild ancestors and relatives.

These ancient techniques were developed further by the Chinese, Greeks, Romans, Babylonians, and Egyptians among many others. Farmers were able to select the best suited crops with the highest yields in order to produce enough food to support a growing population. They used 'selective breeding' to improve production of, not only crops, but also livestock to use them for food. They also developed the process of fermentation, bread making, cheese making, and brewing beer. The latter is still done by the same basic method of using malted grains to convert starch into sugar and then adding specific yeasts. [35]

Agriculture and conventional plant breeding was a necessary drive for development of civilizations. Most plants were domesticated in different regions. For example, wheat was domesticated in the Near East; rice was domesticated in eastern Asia and western Africa; and maize and beans were domesticated in the Americas. These centres of domestication usually showed high levels of crop genetic diversity, which was maintained by farmers who planted and exchanged them on a regular basis. In other words, for centuries, farmers have improved crop plants by selective breeding, mostly at a trial and error level. They selected plants with desired traits

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[34] Ibid, p. 10.

[35] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (2nd edn Pearson: Benjamin Cummings, San Francisco, 2009), p.2-3. They also took advantage of microorganisms and used fermentation to make breads, chesses, yogurts, and alcoholic beverages such as beer and wine.

then, used cross breeding to improve the plants through the millennia, giving us the modern wheat, large corn cobs, and juicy apples. It takes many generations of crop cycles to improve the productivity or resilience of a crop. This method has been described by some scientists as slow and uncertain because isolating desired traits in this fashion can take many years.[36]

The 'Green Revolution' of the 1960s and 1970s aimed to aid 'world food security'. 'Green revolution' crops were traditionally bred to yield larger grains per plant volume high yielding varieties, mostly developed by international public research centres, gave farmers, especially in Asia, new crop varieties with substantially higher yields.[37] However, this growth hit a plateau by mid 1980s. This selective breeding can only duplicate reproductive events that might occur in nature. By managing these productive events towards a particular end, the randomness that ordinarily drives natural selection used to achieve human goals.[38] Unfortunately several major parts of the world, particularly Africa gained little, due to the choice of crops that were developed and the high costs of input, 'leaving many goals of increasing world food security unachieved.[39]

Many scientists and farmers still use traditional breeding techniques to enhance crop yields, increase resistance to various pests or diseases, or increase to the tolerance of a particular crop to heat, drought, or wet conditions, even though the process is long. In addition, the possibility of finding improved traits is limited by the amount of genetic diversity already present in the plant.[40] Yet, a major limitation to plant breeding lies in the extent of variation in the parental lines. Farmers and plant breeders cannot select for variation that is not present in their breeding population.[41]

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[36] Ibid, p.2-3.
[37] Robert L Paarlberg et al, 'Regulation of GM Crops: Shaping an International Regime' in Robert E. Evenson and Vittorio Santaniello (eds), *The Regulation of Agricultural biotechnology* (CABI Publishing, 2004), pp. 2-8.
[38] Rebecca Bratspies, 'The Illusion of Care: Regulation, uncertainty, and Genetically Modified Food Crop' (2002) 10 NYU Environmental Law Journal .p 302.
[39] Robert L Paarlberg et al, 'Regulation of GM Crops (n 37) p. 2.
[40] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (Elsevier 2009) 398.
[41] For information about wide and forced crossing see Nigel G Halford, *Genetically Modified Crops* (n 33), p. 14. Another way of increasing the variation within the breeding population is to introduce mutations artificially, using radiation or chemical mutant. It involves the mixing of tens of thousands

In the late 1970s, a number of scientists and firms also started to investigate the possibilities of 'agricultural biotechnology'. A new technique was developed, allowing the artificial insertion of specific genes into the genome of a plant. The new technique was first called 'genetic engineering', and subsequently 'genetic modification', which is related both to genetically modified foods and food products, and to non-food plants (like tobacco and cotton).[42] This rapid development in new technologies led to 'gene cloning', the ability to identify and reproduce, and to 'genetic engineering', manipulating the DNA of organisms. Through genetic engineering, scientists are able to combine DNA from different sources into a specific plant, resulting in 'transgenic plant'.[43]

Hence, the major difference between 'genetic engineering' and traditional breeding is that genetic engineering allows the transfer of genetic material between organisms that would never be able to breed in any natural or laboratory setting. A plant can be transformed with a gene from any source, including animals, bacteria, or viruses as well as other plants, whereas traditional crossbreeding techniques move genes between members of the same species of plants. Example include plants that produce their own pesticides, plants that are resistant to herbicides, and plant vaccine.[44]

The next section offers a brief explanation of the wide discipline of 'biotechnology', then focuses on 'plant biotechnology', which is the science of genetic engineering.

2.3 Plant biotechnology

Biotechnology is an umbrella term. The United Nation Convention on Biological Diversity defines 'biotechnology' as:

of genes, sometimes with unpredictable results (it can introduce unwanted as well as desirable genetic change).

[42] Ibid, (n 33) 17.

[43] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40) p. 398.

[44] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p.157.

> 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'. [45]

Scientists like to broadly define biotechnology as using living organisms, or the products of living organisms, for human benefit (or benefit for human surroundings) to make a product or solve a problem.[46] They also explain that biotechnology is not a single, narrow discipline of study. Instead, it is an expansive field that absolutely relies on contributions of many areas of biology, chemistry, mathematics, computer science, and engineering in addition to other disciplines such as philosophy and economics.[47] This science affects our everyday lives, and 'will become even more important during this century', which some have called the 'century of biotechnology'.[48]

There are many different applications and types of biotechnology, mainly, microbial biotechnology,[49] animal biotechnology,[50] DNA fingerprinting and forensic analysis,[51] bioremediation,[52] aquatic biotechnology,[53] medical

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[45] CBD, Article 2. A Hungarian scientist, Karl Ereky, coined the term Biotechnology in 1919 to refer to the science and methods that permit products to be produced from new materials with the aid of living organisms, see Brian Sheridan, *EU Biotechnology: law and practice: regulating Genetically Modified &novel Food Products* (Palladian Law Publishing 2001).
[46] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology***,** (n 35) p. 5.
[47] Ibid, p. 5.
[48] Ibid, pp.1-3.
[49] 'Microbial biotechnology' manipulates microorganisms such as bacteria and yeast, microbial biotechnology has created better enzymes and organisms for making many foods such as beer and wine.
[50] 'Animal biotechnology' is where animal can be used as 'bioreactors' to produce valuable products such as 'antibodies', transgenic animal containing genes from another source (for instance, human genes for clotting proteins can be introduced into cows for the production of these proteins in their milk. Because many genes found in animals are also present in humans, animal are also important in basic research to learn about gene function, animal cloning has the potential of producing animals with genetically engineered organs that can be transplanted into humans.
[51] 'Forensic biotechnology' applies DNA fingerprinting is a tool used for law enforcement that can lead to inclusion or exclusion of a person from suspicion, based on DNA evidence DNA fingerprinting can be accomplished using trace amounts of tissue, hair, blood, or body fluids left behind in crime science. DNA fingerprinting can be used in paternity cases.
[52] 'Bioremediation' is used to clean up environmental hazards that have been caused by industrial progress, where the use of biotechnology to process and degrade a variety of natural and manmade substances, particularly those that contribute to environmental pollution,
[53] 'Aquatic biotechnology' one important application is 'aquaculture' raising fish and shellfish in controlled conditions for use as food sources. It has also introduced disease resistant strains of oysters and vaccines against viruses that infect salmon and other fish. Also transgenic salmon have been created that overproduce growth hormone leading to higher growth rates over short growing periods, decreasing time and expense required to grow salmon for market sale,

biotechnology,[54] and plant biotechnology. It is important to notice that the different areas of biotechnology are interrelated.[55] Biotechnology is a multi- disciplinary science with many pros and cons, and controversial issues are associated with almost every application. This paper is limited to the latter kind of genetic modification, known as 'plant biotechnology', which is the focus of the *Biotech* dispute. This technology is used for the production of GM seeds, and used to cultivate the GM crops to be sold as GM food, GM animal feed, and in food products.

'Plant biotechnology', or as others refer to it 'agricultural biotechnology', is an already large business that is rapidly expanding. In 2010, the global market value of biotech crops was estimated at US$11.2 billion, up from US$10.6 billion in 2009. This represented 22% of the US$51.8 billion global crop protection market in 2010, and 33% of the US$34 billion commercial seed market.[56] Agricultural biotechnology is the term generally used to describe the use of biotechnology to alter plants in order to improve their characteristics, such as by giving them resistance to a new, safer, and more effective herbicide, resistance to insects, or to fungal or bacterial diseases. These plants are usually termed transgenic, meaning they contain genes from another organism (which may also be a plant). This new technology allows innovations that are impossible to achieve with conventional hybridization methods.[57] It is important to stress that some scientists view this technology as an extension of traditional breeding, while others emphasis that breaking the species barrier is so novel that the GM crops pose uncertain risks to human health and the environment. [58]

The next section will give a brief explanation of the main techniques used in the modern plant biotechnology.

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[54] 'Medical biotechnology' is involved in the whole spectrum of human medicine. From preventative medicine to diagnosis of health and illness to the treatment of human disease conditions, medical biotechnology has resulted wide array of applications designed to improve the human health.

[55] For further information about biotechnology see William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) pp.8-13.

[56] See Clive James, 'Global Status of Commercialized Biotech/GM Crops (ISAAA Brief No 42, ISAAA, 2010), Executive Summary. http://www.isaaa.org. Accessed June 2012.

[57] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 137.

[58] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40) p. 398. Scientists tend to describe biotechnology to include old and new techniques.

2.4 Genetic engineering of plants

The process of 'genetic engineering' is also referred to as 'genetic modification', 'gene technology' or 'recombinant DNA technology'.[59] It allows selected individual genes to be taken from one organism and inserted into another to enhance desirable characteristics, or to suppress undesirable ones, in order to produce a plant that contains a gene or genes that have been introduced artificially from related or unrelated species.[60] It began when DNA cloning techniques were developed (by cutting and pasting DNA from different sources).[61]

The first step is to identify a gene that will confer a specific desirable trait on the plant. Then, scientists cut DNA molecules at specific points, gluing them back together in different combinations to make new molecules. This process is called 'recombinant DNA technology '.[62] The development of this technology meant that, technically, there was no limit to the source of new genes, and enabled plant breeders to bring specific genes into breeding programme without unwanted genetic baggage.[63]

Through recombinant DNA technology, certain desired traits can be conferred on living organisms. It is used for number of purposes, including the production of proteins of medical importance such as insulin, human growth hormone, and blood clotting factors. Recombinant technology has led to hundreds of applications, including the development of disease resistant crops and plants that produce greater yields of fruit and vegetables, genetically engineered bacteria capable of degrading

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[59] Jules Pretty, 'The rapid emergence of genetic modification in world agriculture: contested risks and benefits' (2002) 28(3) Environmental Conservation 248-262. http://www.journals.cambridge.org/abstract_S0376892901000261. Accessed June 2011. Biotechnology or modern biotechnology is also known as genetic modification or engineering.

[60] This section excludes other modern techniques of 'agricultural technology', such as 'marker aided selection', in which DNA segments are used to mark the presence of useful genes, which can then be transferred to future generations through traditional plant breeding using the markers to follow inheritance.

[61] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology* (n 35) p. 58.

[62] Ibid, pp. 2-4. The first commercial use of recombinant DNA technology in the pharmaceutical industry, recombinant human insulin approved by the FDA of the USA in 1981.

[63] Nigel G Halford, *Genetically Modified Crops* (n 33), p. 18.

environmental pollutants, and staple crop engineered to be more nutritious such as the famous 'golden rice' with pro-vitamin A in the rice grain.[64]

The terms 'gene cloning', 'recombinant DNA technology', and genetic engineering' are used to describe the same process when, in fact, these techniques are slightly different methodologies, albeit interrelated.[65] In addition, there are another layer of different techniques used to insert genetic information into plant cells, such as 'protoplast fusion', 'leaf fragment technique', 'gene guns', 'chloroplast engineering', and 'antisense technology'.[66]

One of the most reliable and widely used techniques is tumour-inducing plasmid or 'Ti Plasmid', where transgenic plants are created by placing the foreign gene into the Ti Plasmid of *Agrobacterium tumefaciens* (a bacterium that infects wounded plant tissue and causes the disease known as crown gall), allowing the bacteria to transfer its T-DNA into plant genome.[67] The *Agrobacterium tumefaciens* is also used in 'transformation of protoplast' (protoplast is plant cell without a cell wall) by infecting protoplast and transforming it to produce GM plants, and in 'protoplast fusion' which creates cells that can grow into a hybrid plant. It has been used to create 'brocoflower', a fusion of broccoli and cauliflower.[68]

Another method for getting a specific gene into plant tissue is to blast DNA through the plant cell wall with a 'particle gun'. Unlike the use of Ti plasmid, this technique works with all types of plants. The desired DNA is carried on microscopic metal particles. These are fired by a gun into plant tissue, and penetrate the plant cell

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[64] See next section. Also See William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35), Chapter 1.

[65] Ibid, p.58; First Written Submission of Canada, *Biotech,* paras. 7-12. Attempts to provide background information on plant breeding and genetic modification, it provides modern biotechnology to include induced mutation ("mutagenesis") and recombinant DNA technology (rDNA).

[66] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35), p. 157.

[67] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40) p. 403; Nigel G Halford, *Genetically Modified Crops* (n 33), p. 18.

[68] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35), p. 157.

walls. It has been very successful in the production of genetically modified cereals, including maize, wheat, barley, rice, and oats.[69]

To check whether the transgene is in the plant, scientists use selectable marker/reporter genes on the same segment of DNA as the transgene. In practice, selectable marker genes make the transformed cells and the GM plant resistant to an antibiotic, or tolerant of a herbicide. However, genetic techniques are available that allow the removal of the reporter or resistance gene, after the integration of the incoming DNA has been checked.[70] Removal is due to the fear that reporter genes could find their way to bacterial population in gut or soil.

The final stage of making a transgenic plant is evaluating and testing the transformed plants for harmful side effects on human health and the ecosystem.[71] If no harmful effects found, and then the transgene must be transferred from the experimental plant is back into the original high yielding parent. The seeds are grown, plants with the transgene are selected, and the whole process is repeated about four or five times. Finally, field tests are performed to determine how the transgene affects the growth, yield, disease resistance, and other traits of the plants. Only plants that consistently have the highest yield with the best disease resistance will be selected to be grown again.[72]

Plant biotechnology or agricultural biotechnology has 'truly opened up a whole range of genetic exchanges that could never be possible without human interference.'[73] Genes can now be transferred across species, class, or order, and introduce entirely new traits into organisms that were never before expressed.[74]

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[69] There are other direct gene transfer methods including the use of electroporation, silicon carbide fibre vortexing. For more information see, Nigel G Halford, *Genetically Modified Crops* (n 33), p. 24.
[70] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40) p. 406; Nigel G Halford, Genetically Modified Crops (n 33), p. 22.
[71] 'Biosafety' is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products.
[72] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40), p. 405.
[73] Sarah Lively, 'The ABCs and NTBs of GMOs: The Great European Union-United States Trade Debate—Do European Restrictions on the Trade of Genetically Modified Organisms Violate International Trade Law?' (2002) 23 NW. J. INT'L L. & BUS. 239, p. 243.
[74] Rebecca Bratspies, 'The Illusion of Care' (n 38), 303.

The first GM plants were planted for commercial purposes in the mid-1990s. Since then, Genetic engineering techniques and their applications have developed very rapidly. International production and trade in GMO products has increased rapidly too. The next section provides the main different traits of GMOs available today.

2.5 The main applications of GMOs

The main traits in GM crops are intended to provide:

1. **Herbicide resistance** Researchers have introduced a gene from bacterium conveying resistance to some herbicides, and created transgenic crops that produce an alternative enzyme that is not affected by chemical herbicides (weed killers).[75] By making the crop plants resistant to the herbicide by genetic engineering, both weeds and crops and weeds may be sprayed together. The weeds are killed but the crop survives. Most soybeans grown today contain herbicide resistant genes. The same is true of cotton, oilseed rape, maze, canola, and more.[76] (Herbicide tolerance was one of the first GM traits to be tested in the field, and subsequently for commercial production)
2. **Insect/Pest resistance** Insects can be very damaging to plants. Farmers spraying crops with insecticides find it a very costly and dangerous procedure. Therefore, plants engineered to contain *Bacillus thuringiensis* (Bt) toxin have a built in defence against certain insects. Then Bt toxin is sprayed on crops to prevent insects such as the cotton bollworm and European corn borer from destroying cotton and maize.[77] In fact, most cotton seeds planted today contain the gene for Bt toxin, which effectively

[75] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 163.
[76] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40), p. 410; Nigel G Halford, *Genetically Modified Crops* (n 33), p. 43.
[77] This enhanced pesticide was introduced into wide range of plants, including tobacco, tomato, corn, and cotton. See also David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40) p. 412; Nigel G Halford, *Genetically Modified Crops* (n 33) p. 47.

kills cotton infesting insects by damaging their digestive system when they eat leaves.[78]

3. **Disease resistance**[79] This is achieved through the introduction of a gene form certain viruses which cause disease in plants.[80] It provides vaccines for plants by having the vaccine encoded in a plant's DNA, which turns on the plant immune system to certain virus. It helped revive the papaya industry in Hawaii.[81] It is also being introduced to coffee, bananas, cassava, papaya, and others.
4. **Improvement of crop yield and quality** The above strategies all contribute to an improvement in crop yield by allowing the plant to better withstand external factors that reduce the amount and quality of harvestable plant material. In addition, GM crops can increase the amount, or improve the quality, of material produced by the crop. For example, FlavrSavr tomatoes delay softening on the vine, and golden rice produces pro-vitamin A in the rice grain, leading to improved nutrition.[82]
5. **Environmental stress tolerance** It increases the ability of the plant to survive adverse growing conditions such as drought, oxidative, soil salinity, cold, and heat stress. These abilities are normally associated with specific groups of genes which can be isolated and introduced into crops.

International production and trade in GMO products has increased rapidly. The next section provides crucial statistical information that demonstrates the scale and size of the commercial cultivation of GM crops.

2.6 Commercialisation of GMOs.

GM crops are fast joining agriculture throughout the world, and will play an increasingly important role in global food production. The introduction of these GM products into the food supply has been one of the most rapid adoptions of

[78] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 162.
[79] It is possible to engineer plants for resistance not only for viral diseases but also roundworms, fungal diseases (moulds, blights, rusts, and rots)
[80] WHO, '20 Questions on Genetically Modified (GM) Foods' (n 7).
[81] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 161.
[82] Acceleration of growth time, reduction in the maturation time of trees.

technology in history.[83] The International Service for the Acquisition of Agri-biotech Applications (ISAAA)[84] confirms this. It notes that the year 2010 was the fifteen anniversary of the commercialisation of biotech crops, first planted in 1996. During the sixteen intervening years, planting Agri-biotech/ GMOs, the accumulated hectarage planted exceeded one million hectares.

After over a decade and a half of commercialisation, the global adoption of biotech crops continues to rise. According to ISAAA Brief No. 43 for 2011, 16.7 million farmers planted 160 million hectares of biotech crops in 29 countries, a sustained increase of 8% or 12 million hectares over 2010,[85] when 15.4 million farmers planted 148 million hectares.[86] The number has increased consistently from only 6 countries in the year 1996, the first year of commercialisation.

This growth from 1.7 million hectares of biotech crops in 1996 to 160 million hectares in 2011 is a record ninety four-fold increase between 1996 and 2011, making biotech crops the fastest adopted crop technology in the history of modern agriculture.[87]

Leading countries planting biotech crops are the US, Argentina, Brazil, India, Canada, China, Paraguay and South Africa. [88] American farmers have embraced the technology, and most American corn and soybeans are genetically altered. The US has by far the largest area of planted genetically altered crops. According to the ISAAA, American farmers planted 69 million hectares with biotech crops in 2011 Brazil with 30.3 million hectares, and Argentina with 23.7 million hectares trailed far behind.[89] USDA's National Agricultural Statistics Service estimates that in 2012, 93 % of soybean acreage, 88 % of corn acreage, and 94 percent of cotton acreage in the United States were planted with biotech varieties. New GM crops

[83] Tim Josling, et al, *Food Regulation and Trade: Toward a Safe and Open Global System* (Institute for International Economics, Washington, DC, March 2004) p. 153.
[84] The ISAAA is not-for-profit organisation with centres based in the Philippines, Kenya and United States. The International Service for the Acquisition of Agri-biotech Applications (ISAAA) report provides detailed biotech crop adoption statistics around the world. ISAAA has been tracking the global biotech crop adoption since the technology's inception in 1996. The report is prepared and presented by Dr. Clive James, Chair of the ISAAA Board of Directors. See Clive James, (n 56)
[85] Clive James, (n 56)
[86] Clive James, (n 56)
[87] Clive James, (n 56)
[88] Clive James, (n 56)
[89] U.S. plantings were up 3 percent from 2010. See Clive James, (n 56)

will continue to be brought to market, leading to more acceptance of biotech crops on the one hand, and potentially more trade challenges on the other. [90]

According to James, the technology is becoming increasingly popular in Brazil and Argentina, China, India and South Africa.[91] 19 of the 29 countries that have adopted biotech crops are developing nations, where usage grew at a rate of 17 percent to 10.2 million hectares in 2009, compared to only 5 percent growth or 3.8 million hectares in industrialized countries. The Brief also adds that more than 90 percent of biotech crop growers are small-scale farmers. Of the 15.4 million farmers using the technology in 2010, 14.4 million were small-scale, resource-poor farmers in developing countries.[92]

The Complainants are in the top five countries cultivating GMOs/agri-biotech products. They are considered mega-countries in terms of cultivation and production. Number one is the USA, which cultivates the largest volume of GM crops, leading the way in 2011 with 69 million hectares. Argentina, with 23.7 million hectares, became the second biggest grower in 2011. Canada grew 10.4 million hectares of biotech crops. This data confirms that the Complainants are the biggest producers of GMOs, together they account for about 65% of the global area of GM crops, and therefore have significant interest in promoting trade in GMOs.

Commercial expansion of this scale cannot be ignored. It signals that 'GMOs are here to stay',[93] making this thesis of crucial importance.

2.6.1 Industry

Research and development of GMOs is lead mainly by large corporations. The big players in seed productions are American corporations Monsanto 23% and Dupont 15%, and Swiss Syngenta 9%.; Together they account for $10,282 million, or 47% of the worldwide proprietary seed market.[94]

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[90] USTR, '2013 Report on Sanitary and Phytosanitary (SPS) Barriers to Trade' USTR (March 2013) p. 21 http://www.ustr.gov/sites/default/files/2013%20SPS.pdf. Accessed 2 April 2013.
[91] Clive James, (n 56).
[92] Clive James, (n 56).
[93] Dianna Boweles and Harry Klee, 'Introduction to the Special Issues on Plant Technology' (2001) GM special issue 27(6) The Plant Journal, pp. 481-2.
[94] The proprietary seed market (that is, brand- name seed that is subject to exclusive monopoly – i.e., intellectual property). See, ETC 'Who owns nature' (Miércoles, 12 November 2008) http://www.etcgroup.org/es/node/706 Accessed 20 September 2009.

This biotech industry appeared in the mid-1970s, mainly in the US, and shortly afterwards in Europe and Asia. The companies or corporations are 'set up specifically to turn the science of biotechnology into a commercial product and sell the result.'[95] The US Supreme Court was the first to allow GMOs to be patented, following the *Diamond v Chakrabaty* case in 1980 (Dutfield, 2003a, 154ff). This fuelled further interest and expansion in the biotech industry. It can be summed as 'opportunity created by intellectual resource and inherent entrepreneurial spirit allied to a powerful capitalist environment.'[96]

GM seeds produced by large corporations are subject to Intellectual property rights law [hereinafter IPRs], and patenting obligations of the WTO's TRIPs agreement.[97] These corporations work on the principle that, first, they are protected by IP law, which enables them to capture the benefits by excluding others from using such organisms.[98] Second, the corporation sell their seeds with a licence agreement, allowing use for one year and forbidding farmers from saving seeds. Charging extra (technology fee) recovers the cost of developing GM seeds. Farmers pay more for the seed because they have to spend less on herbicides,[99] although farmers are locked into buying the herbicides produced by the same company marketing the GM seeds.[100] For example, Bollgard cotton verities are sold under a licence agreement in which the growers pay a fee and agree to abide by the terms, which include a 1 year licence to use the technology and an agreement to participate in an insect resistance management programme.[101] Pretty notes that, the technology fee appears to capture most of the entire margin in certain systems. [102] For example, insect tolerant crops have been developed and commercialized by agrochemical companies. It flowed from the advantage to agrochemical corporations of producing

[95] Jason Rushton & Chris Evans, 'The Business of Biotechnology' in Colin Ratledge and Bjorn Kristiansen, *Basic Biotechnology* (3rd ed, Cambridge University Press 2006), p. 313.
[96] Ibid, 313.
[97] 'Intellectual property' is a generic term used to refer to a group of legal regimes such as patents, trade-marks and copyright. For more on IPRs and GMOs debate see Geoff Tansey & Tasmin Rajotte eds, *The Future Control of Food: A guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security* (Earthscan 2008).
[98] Geoff Tansey & Tasmin Rajotte (eds) *The Future Control of Food* (n 97) p. 21.
[99] Jason Rushton & Chris Evans, 'The business of biotechnology' (n 95) p. 312.
[100] Jules Pretty 'contested risks and benefits' (n 59), p. 250.
[101] Frederick J Perlak et al., 'Development and commercial use of Bollgard cotton in the USA- early promises versus today's reality' GM Special Issue (2001) 27(6) The Plant Journal, *p.* 489.
[102] Jules Pretty 'contested risks and benefits' (n 59) p. 257.

crops tolerant to specific insecticide, particularly when manufactured by the same company.

A few corporations, including Dow, DuPont, Syngenta, Aventis and Monsanto, own 3 out of 4 GM crop patents in the United States. The situation is much worse internationally, where Monsanto, the world's biggest seed company, is by far the GM crop leader, owning 90% of the GM seeds and associated licenses. ETC Group estimates that Monsanto's biotech seeds and traits (including those licensed to other companies) accounted for 87% of the total world area devoted to genetically engineered seeds in 2007.[103]

Monsanto has crafted crops that tolerate dousing in herbicides, and crops that are designed to resist pests, effectively creating their own insecticide.[104] A typical bailment license forbids saving these seeds, and also requires that farmers sign a separate patent license agreement, which typically include language such as:[105]

> The purchase of these seeds/bailment/transfer of these seeds conveys no license under said patents to use these seeds or perform any of the methods covered by these patents. A license must first be obtained before these seeds can be used in any way... Progeny of these seeds cannot be cleaned or used as planting seed or transferred to others for planting. This seed may only be offered for sale and distribution by authorized seed companies or their dealers.

IPRs are outside the scope of this thesis, however they are useful to illustrate the effect on the debate surrounding GMOs, which is limited to international trade implications.[106] There is intense interest in how power relation and IPRs will play out. The critical issue relating to the GM debate is who owns the benefits of the new technology? Add to it that in agriculture there is greater concentration of power

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[103]ETC 'Who owns nature' (Miércoles, 12 November 2008), http://www.etcgroup.org/es/node/706 accessed 11 June 2010.

[104] See Clive James, (n 56).

[105] Eagle seed is company selling Monsanto Roundup ready soybeans, http://www.eagleseed.com/roundup.html accessed 11 June 2010.

[106] For more on the subject see, Geoff Tansey & Tasmin Rajotte eds, *The Future Control of Food* (n 97). At this stage the issue of genetic resource ownership has not been settled. There is a need to find the right balance between the use of genetic resources and at the same time reward the players involved.

at every stage of the food chain, especially the vertical integration of corporations.[107] Therefore, IPR may pose potential problems with regards to monopoly and availability of a diversity of crops.

Many commentators and NGOs worry that GMOs may be another technological fix to patch up the problems of modern agriculture caused by previous agrochemical technologies, such as pesticide resistance and pollution which were promoted by the same companies now leading the biotechnology revolution. Additionally, they consider this as undesirable level of control of seed markets by few chemical companies.[108] For example, ETC Group released a 48-page report (industry statistics), warning of corporate concentration and commoditisation of nature, as well as highlighting global resistance grounded in "Food Sovereignty".[109] The Council for Responsible genetics fears that 'through their monopoly and patents, and technologies that promote increased monoculture, agribusiness is leading us into a perilous future where they will control a basic human resource – food'.[110] An example of this control is that exclusive use of herbicide-tolerant GM crops would make farmers dependent on industry for these chemicals.[111]

Friends of Earth issues a series of heavily footnoted, yearly reports on the impact of Genetically Modified Crops (GM) in agriculture titled 'Who benefits from GM Crops?'. This series of reports is a counterweight to the ISAAA annual reports on genetically modified (GM) crops. FOE claims that the ISAAA is biased to industry, and issues exaggerated and unsubstantiated claims about the successes of GM crops. According to FOE, ISAAA does so because it is partly funded by big corporations and pro-GM US government bodies.[112]

The next section counts the current commercial applications of GMOs. It also sheds light on future promises of the technology.

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[107] Jules Pretty 'contested risks and benefits' (n 59) 256-257.
[108] WHO, '20 Questions on Genetically Modified (GM) Foods' (n 7).
[109]ETC 'Who owns nature' (Miércoles, 12 November 2008) http://www.etcgroup.org/es/node/706.
[110] Such as, Council for Responsible Genetics, '"Coalition of the Willing" Files Complaint Against EU GM Food Restrictions' (Press release, Council for Responsible Genetics 14 May 2003 http://www.gene-watch.org/press/us-eu-wto_051403.html Accessed 11 September 2009
[111] WHO, '20 Questions on Genetically Modified (GM) Foods' (n 7).
[112] See the main statement by Friends of Earth, 'Who benefits from GM Crops?' FoE 2006-2011, http://www.foei.org/en/resources/publications/pdfs/2011/who-benefits-from-gm-crops.

2.6.2 Commercial adoption of the different applications of GMOs

The first food on the market derived from GM plants was the Flavr-savr slow-ripening tomatoes with supposedly improved flavour.[113] Slow ripening fruit can be beneficial for growers and retailers since the fruit will have a longer shelf life. Commercially, Flavr-savr was largely unsuccessful in the market due in part to a decline in quality related to the modification.[114]

Current GM food comes primarily from four crops that dominate GM agriculture: soybeans, maize, cotton and canola. It adds up to almost 99% of global biotech area.[115] Biotech soybean continued to be the principal biotech crop in 2011, occupying 75.4 million hectares, or 47% of global biotech area, followed by biotech maize (51.00 million hectares at 32% of the global biotech crop area), biotech cotton (24.7 million hectares at 15% of the global biotech crop area) and biotech canola (8.2 million hectares at 5% of the global biotech crop area).[116] Other crops also cultivated on smaller scale include squash, papaya, alfalfa, and sugarbeet.[117]

Initially, the biotech industry wanted their products to be accepted by farmers and food produces. Research has focused primarily on developing GM plants to improve crop protection, such as improving resistance to pests, reducing the need for pesticides resulting in agronomic traits. Herbicide tolerance was one of the first GM traits to be tested in the field, and subsequently for commercial production.[118]

Within commercial GM crops, in 2011, the predominant genetic modification was herbicide resistance (deployed in soybean, maize, canola, cotton, sugar beet and alfalfa), which accounting for 59% of global biotech products, and insect resistance which occupying 15%.[119] There is notable increasing growth in stacked double and triple traits (varieties combining two different traits) accounting for 26%. Such varieties have been introduced in cotton and corn. The addition of new traits, such

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[113] Nigel G Halford, *Genetically Modified Crops* (n 33), p. 39.
[114] Laylah Zurek 'The European Communities Biotech Dispute: how the WTO Fails to Consider Cultural Factors in the Genetically Modified Food Debate' (2007) 42 Tex Int'l LJ 345.
[115] Clive James, (n 56) 'Biotech soybean continued to be the principal biotech crop in 2011, occupying 75.4 million hectares or 47% of global biotech area, followed by biotech maize (51.00 million hectares at 32%), biotech cotton (24.7 million hectares at 15%) and biotech canola (8.2 million hectares at 5%) of the global biotech crop area.'
[116] Clive James, (n 56).
[117] Clive James, (n 56).
[118] World Health Organization '20 Questions on Genetically Modified (GM) Foods' (n 7).
[119] Clive James, (n 56).

as resistance to root-worm in maize, and the combinations of traits with similar functions, such as two genes for resistance to lepidopteran pests in maize, is also increasing. [120]

While the improvement of agronomic characteristics in major crops has been highly successful, few products genetically engineered to meet the specific needs of either food processors or consumers have yet been commercialized. Recently, however, a renewed emphasis on developing agricultural biotechnology applications more beneficial to consumers has accompanied continuing efforts to develop crops with improved agronomic traits. Although genetically engineered crops with enhanced health, nutrition, functional, and consumer benefits have lagged behind agronomic applications, research on many such products is in the advanced stages of development. These applications could improve human and livestock nutrition and health, the nutritional quality of food animals for human consumption, and create ingredients with superior properties for food manufacturing and processing.[121]

This expansion beyond food and feed crops can be achieved via increases in molecular farming. Molecular farming describes the application of molecular-biological techniques to the synthesis of commercial products that are already extracted from plants through to the manufacture of compounds that are completely novel to plants such as novel or modified carbohydrates, oils, fats, and proteins. Potential future applications might include an edible source of vaccines and antibodies, plant based petroleum for fuel, alternatives to rubber, nicotine-free tobacco, caffeine-free coffee, biodegradable plastics, stress tolerant plants for agricultural and forest production, and industrial fibres.[122] Some of these GM Plants are expected to reach the market in the next 10 years.[123]

Pretty categorizes the different applications into three main generations depending on their commercial availability.[124] The first GM generation was modified in ways

[120] Tim Josling, et al, *Food Regulation and Trade* (n 83) p. 153.
[121] Jules Pretty 'contested risks and benefits' (n 59) 255.
[122] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 165. See also David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40), p. 413. Nigel G Halford, Genetically Modified Crops (n 33), pp. 50-56.
[123] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 156.
[124] Jules Pretty 'contested risks and benefits' (n 59) p. 249-250.

beneficial to the agri-chemical companies, the seed suppliers, or the farmers, but not for the consumers. The second generation comprises those GMOs already developed and tested, but not commercially released, either because of uncertainties of the technology itself, or over concerns for potential environmental concern. An example is the so called 'Terminator' technology protection system, this involves the insertion of gene switching mechanisms to prevent any seed saved after harvest from being replanted. The second generation is likely to bring more public and consumer benefits. Second generation biotech crops, such as alfalfa, wheat, and potatoes, will come to the market within 10 years, as well as high oleic acid soybean and vitamin A-enriched rice (golden rice).[125] The third generation of GMOs are those that are still far from the market, but generally require the better understanding of whole gene complexes that control such traits as drought, salt, or metal tolerance. They will allow farmers to cultivate on problem soil, and produce faster growth in rice, wheat, and more. The third generation has the potential to bring more public and consumer benefits. Though, these are still under research, they will have their own risks.[126]

Finally, the ISAAA expects the number of biotech farmers globally to reach 20 million or more in 40 countries on 200 million hectares in 2015. ISAAA predicts further adoption increases will also come from:

- significant expansion of biotech soybean, maize, and cotton in Brazil.
- commercialisation of Bt cotton in 2010 by Pakistan, the fourth-largest cotton growing country.
- expansion of Bt cotton in Burkina Faso with potential adoption of biotech cotton and or maize in other African countries including Malawi, Kenya, Uganda, and Mali.
- adoption of golden rice by the Philippines in 2012, and by Bangladesh and India before 2015.[127]

The use of GMOs *per se* does not necessarily raise alarm. But there is considerable concern about the unknown effects of the modified organisms on the environment,

[125] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 156.
[126] Jules Pretty 'contested risks and benefits' (n 59) p. 250.
[127] Ibid.

and on human health when GM plants and their products are consumed as food. Alarm is also being raised by the ethics of industrial involvement in development and sale of GMOs.[128]

It is clear that cultivation, production, and consumption of GMOs are increasing in many parts of the world. Combined with the fact that techniques used in creating GMOs are relatively new and very complex, each application brings different potential benefits and risks for different stakeholders, which triggered wide debate on the matter.[129] Commercialisation of GMOs only intensifies the debate, prompting wide media coverage.[130] The commercialisation of GMOs may now be inevitable, but its benefits, in terms of size, nature and distribution, are not. The next section will highlight the main arguments from both sides, reflecting sharp divisions of opinions on benefits and risks.

2.7 Contested risks and benefits

The creation of GMOs or so called 'Frankenstein' foods has generated much debate and controversy. Current debates reveal substantial differences in perceptions of the associated risks and benefits. Some strongly argue that GMOs are safe and essential for world progress. Others state they are not needed, and involve too many risks.[131] Potential benefits and potential risks of GMOs presented so far raise *highly* interdisciplinary and complex issues. There is no clear division as the environmental and health concerns raise ethical and political questions around the distribution of risks and benefits.[132] However, this chapter focuses on concerns over human health and protection of the environment take centre stage in this debate, and have driven both sides of the argument.

It must be borne in mind that GMOs have been developed and commercialized over short period of time. The technology is very new, and still in its infancy. It is impossible to accurately predict its full effect on human health and the

[128] Dianna Boweles and Harry Klee, 'Introduction to Plant Technology' (n 93) p 481-2.
[129] Jules Pretty 'contested risks and benefits' (n 59) 259.
[130] Antony M Sheton and Mark K Sears, 'The monarch butterfly controversy: scientific interpretations of a phenomenon' GM Special Issue, (2001) 27(6) The Plant Journal, p. 483-488.
[131] For analysis of the controversy surrounding GMOs, see Thomas Bernauer, *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology* (Princeton University Press 2003) 44-65
[132] Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Biotechnology Regulation Series, Edward Elgar Publishing, 2008), p. 22.

environment.[133] There are unknown factors in the new science behind biotechnology, and until it is thoroughly understood the risks cannot be completely characterized.[134]

2.7.1 Potential benefits

Proponents claim that GMOs improve efficiency of agricultural production and overall safety of food, increase the economic vibrancy and vitality of the communities, and foster sustainable development. They also advocate that GM crops can grow faster, produce more, yield better quality, and use fewer chemicals.[135] The ISAAA Brief claims that agri-biotechnology is able to deliver healthier crops that produce more food, often in areas with less than perfect growing conditions. [136] The 2011 ISAAA Brief illustrates that biotechnology is a key component contributing to a sustainable agriculture. It also adds that more and more farmers around the world are turning to biotechnology so they can grow plants that yield more per acre and reduce production costs, while being resistant to disease and insect pests.[137]

2.7.1.1 Agriculture economic (agronomic) benefits

Biotechnology traits developed and commercialized to date have largely focused on herbicide resistance and pest control (primarily Bt crops).[138] GMOs commonly found on the market include Roundup ready soybeans and Bt corn and cotton.[139] Many plant pests have proven either difficult or uneconomical to control with chemical treatment, traditional breeding, or other agricultural technologies, and in these instances, in particular, biotechnology has proven to be an effective agronomic tool. Herbicide resistance allows farmers to control weeds with chemicals that would otherwise damage the crop itself. This can lead to economic

[133] Sarah Lively, 'The ABCs and NTBs of GMOs' (n 73) p 243;
[134] Robert L Paarlberg et al 'Regulation of GM Crops: Shaping an International Regime' (n 37) p.4.
[135] Frederick J Perlak et al, 'Bollgard cotton in the USA' (n 101) p. 489.
[136] Clive James, (n 56)
[137] Clive James, (n 56)
[138] Jules Pretty 'contested risks and benefits' (n 59) p. 249.
[139] Tim Josling, et al, *Food Regulation and Trade* (n 83) p. 153.

advantage from reduction in weed and insect control cost. For example, tomatoes with improved shelf life can result in energy and water savings as consequence of the tomatoes being easier to process. [140] With regard to pesticide reduction, the ISAAA explains that biotech crop varieties require less cultivation and fewer pesticide applications, thereby saving fuel and reducing carbon dioxide emissions into the air. Reduction in input leads to improved agronomic practice.[141]

GM herbicide tolerance will provide not only more efficient, but also more flexible weed control for growers of these crops. Weed control is an important aspect of growing each of these crops, and herbicides will continue to be the major method of control when used with either conventional or GM crops. GM crops are likely to be cheaper for the grower than the current methods, and involve fewer sprays and use relatively benign herbicides.[142] These crops can be expected to sustain less weed and insect damage, and therefore to produce higher yield per acre, leading to another agronomic advantage.[143] Many look hopefully towards this new technology for help in increasing global food security in the future.[144] So far there is no clear evidence to support this claim.[145]

Finally, GM crops have also a wide range of non-food applications that provide agronomic benefits, such as stronger fibres in cotton, where gene insertion technology has increased the strength of one major upland cotton variety by 60% and provided softer, more durable clothes for consumers and greater profits for farmers.[146] Gene insertion has also provided vaccines for plants by encoding the vaccine in a plant's DNA to turn on the plant immune system when certain viruses are present. This technology helped revive the papaya industry in Hawaii.[147] Future application may include improved varieties that allow safer transport storage.

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[140] Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* (Nuffield Council on Bioethics, 1999), p. 29, http://www.nuffieldbioethics.org/sites/default/files/GM%20crops%20-%20full%20report.pdf. Accessed 15September 2012

[141] See Clive James, (n 56).

[142] Hubert P J M Noteborn et al, *GM Crops: Understanding the issues*, produced with support of the UK Agricultural Biotechnology Industry (not dated).

[143] Rebecca Bratspies, 'The Illusion of Care' (n 38) 304.

[144] Robert L Paarlberg and others 'Regulation of GM Crops: Shaping an International Regime' (n 37) p.3.

[145] Jules Pretty 'contested risks and benefits' (n 59) p. 255.

[146] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 164.

[147] Ibid, p. 161.

Studies show, for example, that transgenic corn that expresses 'avidin', which is a protein found in egg whites, is highly resistant to pests during storage.[148]

2.7.1.2 Environmental protection

Proponents also argue that GM plants are environmentally friendly since they reduce the amount of pesticides and herbicides sprayed on the plants, thus conserving the soil health, improving water retention, and increasing energy conservation.[149] Insecticide use appears generally to be down with GMOs (by reduction on the numbers of sprays per hectare per year), particularly in cotton and maize. On the other hand, herbicide use appears to have increased. [150]

ISAAA officials have maintained that there is substantial evidence that crops genetically modified to withstand drought, salt, insects, and diseases are safe for human consumption. According to them, biotechnology delivers food that is as safe as those produced through conventional agriculture.[151]

GM crops such as cotton and maize are modified to express protein known as Bt toxins. Bt crops contain genes introduced from *Bacillus thuringiensis* Bt, a soil bacteria commonly found in the environment that kills certain classes of insects, making the GM plants more insect resistant.[152]

Using fewer insecticides, GM crops can have many advantages for the environment, the farmer, and especially the farm workers who currently deal with constant or repeated exposure to subtoxic levels of chemicals. Bollgard cotton is the trade mark given to a number of verities of cotton with built in Bt protein, providing insect control against mainly budworm, and bollworm.[153] Cultivation of Bollgard cotton should lead to reduced use of chemical insecticides, reduced trips across the field, reduced worker exposure, and reduced chemical load on the environment.[154]

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[148] Ibid, p. 163.
[149] See Clive James, (n 56)
[150] Jules Pretty 'contested risks and benefits' (n 59) p. 256.
[151] Clive James, (n 56).
[152] Rebecca Bratspies, 'The Illusion of Care' (n 38), p. 304.
[153] Frederick J Perlak et al, Frederick J Perlak et al, 'Bollgard cotton in the USA' (n 101) p. 489.
[154] Ibid, p. 494.

2.7.1.3 Consumer benefits

GM crops can produce foods with a variety of advantages to the consumer. This can be done by introducing new plant genes that enhance existing gene action to improve starch or oil yield, modified oils or starches, and enhance fruit flavour, colour or nutrition. For example, genetic modification of potatoes can improve flavour and mash texture through modification of starch and sugar content. It can also produce high starch potatoes by reducing water content in potatoes, and alter cell-wall composition so they absorb less fat when fried.[155] This type of modification may have dietary benefits for consumers.

Moreover, GMOs are hopeful products aimed at ending malnutrition in the developing world. 'Golden rice' is an example of genetically engineered rice that produces large amounts of beta carotene which the body converts into vitamin A. Researchers are developing rice that provides extra iron and protein. However, this rice would not work alone. It will need to be paired with a balanced diet, which includes fat necessary for it to be absorbed.[156] Additionally, new plant products with a range of gene- inactivating techniques can reduce the activity of, or switch off, specific unwanted genes. These genes might affect fruit softening, toxin or allergen genes.[157]

Plants could also be genetically modified to produce vaccines or other medicines. Potatoes have been modified to produce edible vaccines against E. Coli bacteria, which causes diarrhoea. This would allow cheap and easy distribution of the vaccine, but research is still at a very early stage.[158]

Future GM crops should be able to conform more closely to consumer wishes. Theoretically, it is possible that genetic modification could improve the flavour, texture, appearance, price, and nutritional content of plants. However, it is very difficult to predict exactly when these new developments will become

[155] Such as oils which contain lower saturated fat, see, Nuffield Council on Bioethics, *The Ethical and Social Issues* (n 140) p. 29
[156] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 164.
[157] Nuffield Council on Bioethics, *The Ethical and Social Issues* (n 140) p 28.
[158] Ibid, p 28

commercially available.[159] Some believe that when these become available, it will be easier to convince consumers to accept them.[160]

While genetically modified crop varieties promise benefits to the corporations, farmers, food producers, and consumers, and the environment, they may also pose a range of risks. The next section explores these risks and the associated concerns

2.7.2 Potential risks

Opponents might have nothing against genes *per se*, instead they fear the effects of foreign genes not naturally found in the plant.[161] They are not only sceptic about the alleged benefits, but also warn against a number of risks, which in their opinion, are posed by GM crops and food products. Generally opponents have two types of worries. The first relates to food safety and risk to human health; the second concerns risk to the environment. Such fears should not be underestimated; they might have the power to shake up the industry. We will dwell on these two issues in turn.

2.7.2.1 Concerns about food safety and risks to human health

The concerns about food safety and risks to human health focus on two main areas: allergenic and immune system reactions to new substances, and antibiotic marker genes.[162] New GM crops may contain new proteins transferred together with the desired trait. A risk to humans arises if these products provoke an additional allergenic reaction. For example, a 1996 report in the New England Journal of Medicine seemed to confirm at least some of those fears. The study found that soybeans containing a gene from Brazil nut could trigger an allergic reaction in people who were sensitive to Brazil nuts.[163] The work on these soybeans was discontinued, and none of the plants were ever released to the public.[164] In spite of

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[159] Ibid, p 88
[160] Patrice Laget and Mark Cantley, 'European Responses to Biotechnology: Research, Regulation, and Dialogue', (2001) Issues in S. and T., available at http://www.issues.org/17.4/laget.htm. Accessed 13 November 2008.
[161] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 168.
[162] Simonetta Zarrilli, *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks*, (Policy Issues in International Trade and Commodities Study Series No.29, UNCTD, UN – New York and Geneva, 2005) p. 1-2.
[163] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 147.
[164] The FDA in the US ordered tests for allergenicity. This transgene was found to cause allergic reactions; see David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40), p. 418.

this risk, scientists believe that the odds of an unknown allergen being found in GM foods sold to consumers are very small.[165] As a matter of principle, the transfer of genes from commonly allergenic foods is discouraged unless it can be demonstrated that the protein product of the transferred gene is not allergenic.[166]

Another example is the StarLink corn, which was found to have a higher concentration of protein than expected after processing and cooking. The protein can cause an allergic reaction if consumed by the public. Companies pushed for approval. The EPA gave split approval for StarLink corn to be grown as long it was only used to feed livestock.[167] The lack of labelling and segregation in the US allowed the StarLink corn to mix with all other corn from the region, which was then shipped together to processing centres.[168] In 2000, an unapproved transgenic corn called StarLink was detected in taco shells found in American grocery stores. This led The EPA to revoke its approval, and withdraw the product from the market. The company offered to buy back all the remaining StarLink corn so that no more food would became contaminated. In addition, all StarLink seed was pulled from the market to prevent its future growth. StarLink is no longer grown anywhere in the world. [169] The lack of segregation can led to worse situations, where GM crops intended for industrial or pharmaceutical processes, becomes commercially widespread, the risks from unwanted material in the human food chain are intensified.[170]

Another concern regards antibiotic resistance marker genes. It is feared that these genes may be transferred to bacteria, which would then acquire the antibiotic resistance themselves, rendering many antibiotics useless. There is worry that overuse of antibiotics may render some human drugs ineffective, and/or make some

[165] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 147.
[166] WHO, '20 Questions on Genetically Modified (GM) Foods' (n 7).
[167] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40), p. 417.
[168] Ibid, p. 417.
[169] Ibid, p. 417.
[170] Maria Lee, *EU Regulation of GMOs* (n 132) p. 28.

strains of bacteria untreatable.[171] Alternatives to antibiotic marker genes now exist, and many believe antibiotics should not be used in commercial GMOs.[172]

Similarly, gene transfer from GM foods to cells of the body, or to bacteria in the gastrointestinal tract, could cause concern if the transferred genetic material adversely affects human health. [173] This would be particularly relevant if antibiotic resistance genes used in creating GMOs were to be transferred. Arpad Pusztai first suggested this following a study on the effects of consumption of genetically modified potatoes on rats, in which subjects fed the altered potatoes suffered stunted internal organ growth and weakened immune systems.[174] The research, however, has been criticized.[175]

2.7.2.2 Concerns about the environment

Environmental concerns mainly relate to the plants themselves, and the effect on the non-target species, such as insects in their environment.[176] Many fear gene flow and cross pollination, where transgenes could transfer from GMO to conventional crop, related species in the wild, and/or to bacteria in soil or human guts. It is difficult to predict the effects on native plant ecology.[177] At first, this concern was raised in relation to open-air crop trials, with possibility of cross pollination, and on-the-ground and in-the-soil contamination of non-GMO crops.[178] It was then a problem for farmers growing conventional crops near GM farms. Cross pollination is a complex risk to assess as it varies from country to country. If a crop has native wild relatives the risk is higher than it would be in another country where there are few or no relative wild relatives.[179] Cross pollination within species can be limited

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[171] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 147. There is no evidence that this kind of transfer has actually taken place, but opponents warn that if it does, it is already too late.
[172] Jules Pretty 'contested risks and benefits' (n 59) p. 248-262.
[173] WHO, '20 Questions on Genetically Modified (GM) Foods' (n 7).
[174] 'Top Scientist Backs Calls for GM Safety Screen' *The Guardian* (London, 9 March 1999), cited in 'The GMO Dispute: Bush Administration Attack on European Food Safety Policy Latest Challenge to WTO's Legitimacy', Public Citizen (June 2003), http://www.citizen.org/trade/wto/agriculture/. Accessed 29 October 2007.
[175] Jules Pretty 'contested risks and benefits' (n 59) p. 248-262.
[176] Nuffield Council on Bioethics, *The Ethical and Social Issues* (n 140) p. 103.
[177] WHO, '20 Questions on Genetically Modified (GM) Foods' (n 7).
[178] 'The GMO Dispute: Bush Administration Attack on European Food Safety Policy Latest Challenge to WTO's Legitimacy', Public Citizen (n 174).
[179] Jules Pretty 'contested risks and benefits' (n 59) p. 248-262.

by management practice, and appropriate further studies are needed to clarify the extent of this threat.[180] Such a gene flow may lead to a chance of recombining viruses and bacteria to produce new pathogens leading to novel and non-desirable traits.[181] The concern is whether different viruses subsequently infecting the plant might incorporate some of the original viral DNA, giving rise to a new hybrid virus.[182]

Herbicide tolerant crops raises concerns regarding new forms of resistance. The main fear is that GM plants may confer their genetically modified traits on weedy relatives that live nearby, leading to resistant weeds, sometimes referred to as 'super weeds'.[183] Just as genes for antibiotic resistance could theoretically spread from plants to bacteria, genes for pest or herbicide resistance could potentially spread to weeds. Many plants including squash, sunflower, and canola are close relatives to weeds. Cross breading occasionally occurs, allowing the genes from the plant to mix with the genes from the other plant. Herbicide tolerant crops themselves may also become problem weeds in the rotation. New secondary pest and weed problems can also arise. [184] Gene Watch cites an example from Canada, where GM oilseed rape pollinated other oilseed rape. The other oilseed rape developed resistance to a few herbicides, and farmers had to use alternative herbicides to control them.[185]

There are concerns on three fronts with regard to the introduction of Bt crops. First, there is the possibility of insects building up resistance against the Bt toxin.[186] The fear is that some insects will survive the toxins, developing resistance and then mating with other resistant insects, likely producing offspring also resistant to the pesticide. The Bt toxin in the plants act as selection pressure on the variations

[180] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, ((n 35) p. 147.
[181] Jules Pretty 'contested risks and benefits' (n 59) p. 252.
[182] Nuffield Council on Bioethics, *The Ethical and Social Issues* (n 140) p 103.
[183] 'The GMO Dispute: The GMO Dispute: Bush Administration Attack on European Food Safety Policy Latest Challenge to WTO's Legitimacy', Public Citizen (n 174).
[184] The EPA and the USDA have set out guidance for integrated resistance management (IRM) for Bt GM crops such as maize, cotton, and potato. See Jules Pretty 'contested risks and benefits' (n 59) p. 252.
[185] Gene Watch UK 'GM Crops: Environmental Saviour or New Form of Pollution' Gene Watch UK, December 2002 www.genewatch.org/uploads/.../Environment.doc accessed 2 February 2010.
[186] The GMO Dispute: Bush Administration Attack on European Food Safety Policy Latest Challenge to WTO's Legitimacy', Public Citizen (n 174).

inherent within a pest population, driving them toward resistance. In a short period of time, much shorter than the evolutionary timeline, the entire population will be resistant, and the pesticide will no longer be effective.[187] These crops would exert strong selection pressure on any resistant insects, potentially making that pest resistant and forcing farmers to go back to spraying.

Second, there is concern as regards the effect of GM plants on 'non-target organisms', that is, any plants or animals inadvertently exposed to it.[188] An article in the journal 'Nature' suggested that Monarch butterflies were killed by eating pollen from corn carrying the Bt gene. This article alarmed the science community as well as environmental advocacy groups, and spurred public debate.[189] Much controversy surrounded this study, and led to further studies examining the effect on butterflies and other non-target organisms. Some showed adverse effects of transgenic corn pollen on the Monarch butterfly. However, the studies were conducted in the laboratory where caterpillars had no choice but to eat milkweed contaminated with pollen, a much different setting from a corn field. Clark argues that more studies in the actual environment are necessary to allow reliable conclusions to be reached.[190] The monarch butterfly became the symbol of the anti-GMO movement in the early 2001.[191]

Third, there is fear of changes to farm practices, which would lead to loss of biodiversity.[192] Bt trait in the crops is very effective, more thoroughly killing pests than spraying, and resulting in less food for birds and other animals further up the food chain. This is also of concern to biodiversity because it reduces the number of different varieties available.[193] Proponents argue that any potential environmental

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[187] Rebecca Bratspies, 'The Illusion of Care' (n 38) p 304. Pesticide pray applications typically coat the plant's leaves for a short time. Bt crops by contrast, constantly produce fairly high doses of Bt toxins in every cell of the plant. It is this property that raises concerns about pest resistance.
[188] Nuffield Council on Bioethics, *The Ethical and Social Issues* (n 140) p 102; Jules Pretty 'contested risks and benefits' (n 59) p. 253. He refers to it as direct and indirect effects on novel toxins.
[189] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 40), p. 418.
[190] Ibid, p. 419.
[191] The migrating monarch butterfly has fascinated generations of both public and scientific communities because of the beauty and complex biology. For more on the controversy see, Antony M. Sheton and Mark K. Sears, 'The monarch butterfly controversy' (n 130) p. 483-488.
[192] WHO, '20 Questions on Genetically Modified (GM) Foods' (n 7).
[193] Jules Pretty 'contested risks and benefits' (n 59) p. 253.

hazard from agricultural biotechnology must be weighed against the clearly established benefits.[194]

2.7.3 Other issues and concerns

A wide range of ethical, legal, political, economic, and social implications of biotechnology are a source of great debate and discussion by scientists, the general public, clergy, politicians, lawyers, and many others around the world.[195] This brief section only draws attention to some of the many issues to highlight the intensity and complexity of the debated.

People's right to eat GM free food: Many NGOs took this argument forwards, particularly with the launch of the *Biotech* dispute. For example, Friends of the Earth strongly demanded that the WTO not deny people the right to know and choose what they eat and farm.[196] It was also argued that it must not undermine the right of the European Union and others to take appropriate steps to protect their citizens and the environment from GMO food and farming.[197] In this respect, labelling requirements for GM foods can be effective tools that allow consumers to make an informed choice about the food they eat. Additionally, GM crops and foods can be treated differently in terms of sales and imports.[198]

Ethical and cultural issues: Potential risks of GMOs raise ethical issues, such as the ethical acceptability of risk to the environment or the health of producers, or responsibilities to future generations. Assessing the ethical implications of GMOs is very difficult. It requires dwelling on the 'natural' and 'unnatural', and is beyond the scope of this thesis.[199] Another specific ethical concern is that GM crops are 'unnatural' food because they are the result of human manipulation of living

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[194] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 35) p. 164.
[195] For more on the wider debate see, Nuffield Council on Bioethics, *The Ethical and Social Issues* (n 140).
[196] Friends of the Earth International, 'Moment Of Truth Over Gm As Us Files WTO Complaint' 13th of May 2003, Press Release, http://www.foei.org/en/media/archive/2003/0513.html. Accessed 21 September 2006; Council for Responsible Genetics, 'Coalition of the Willing' (n 110).
[197] See also, 'WTO attacking people's right to eat GM free', Public Citizen, http://www.citizen.org/trade/wto/agriculture/gmo/articles.cfm?ID=11052. Accessed 18 August 2009.
[198] Maria Lee, *EU Regulation of GMOs* (n 132) Chapter 4. This chapter explores also the limitations of labelling.
[199] Maria Lee, *EU Regulation of GMOs* (n 132) pp. 34-6.

matter.[200] Moreover, '[d]epending on the region of the world, people often have strong and clear attitudes to food. In addition to nutritional value, food often has societal and historic connections, and in some instances may even have religious importance.'[201] In line with this, vegetarians and persons of the Islamic and Jewish faiths may be averse to eating food containing pig genes.[202]

Coexistence between GMOs, and organic and conventional farming: Cross pollination presents risks, such as genetic contamination, which occurs if a GMO cross pollinates with neighbouring non-GM fields, or when they cross pollinate with wild relatives.[203] GM crops make it difficult for organic and conventional farming to distinguish themselves on the market. This also relates to consumer choice, and the visibility of options for consumers wanting to avoid GM food. [204]

GMOs may damage the environment and human health. Farmers whose crops are contaminated by GMOs may experience economic loss. Who should take responsibility for the harm? Should the industry be liable for damage caused to the environment?[205]

Other concerns regard the socio-economic impact of the new technology on the survival of traditional and biological agricultural models, as well as the impact on indigenous and local communities. However, the socio-economic impacts of GMOs are hard to predict.[206]

Issues relating to commercialisation of GMOs and corporate power:[207] Private corporations claim IP rights for most GMOs. This 'private ownership of seed patents raised ethical concerns about future fairness of availability of these crops to the world's farmers.'[208] The GM seed market is big, and expanding steadily. In

[200] Nuffield Council on Bioethics, *The Ethical and Social Issues* (n 140).
[201] WHO, '20 Questions on Genetically Modified (GM) Foods' (n 7).
[202] The GMO Dispute: Bush Administration Attack on European Food Safety Policy Latest Challenge to WTO's Legitimacy', Public Citizen (n 174).
[203] Gene Watch UK 'GM Crops: Environmental Saviour or New Form of Pollution' (n 185).
[204] Maria Lee, *EU Regulation of GMOs* (n 132) p. 34.
[205] Maria Lee, *EU Regulation of GMOs* (n 132) Chapter 4. The author describes the extent to which coexistence of GM and traditional agriculture, liability and labelling are entangled.
[206] Maria Lee, *EU Regulation of GMOs* (n 132) p. 33.
[207] For a discussion of issues relating patents and ownership of GMOs see Maria Lee, *EU Regulation of GMOs* (n 132), Chapter 5, pp. 150-187.
[208] Robert L Paarlberg and others 'Regulation of GM Crops: Shaping an International Regime' (n 37) pp. 150-187.

2009, it was worth US$10.5 billion, and yielded crops that were worth US$130 billion.[209]

There is distrust of the large multinational corporations that control both the GM seed and herbicide markets. This distrust contributes to suspicions of the entire technology. 'Terminator' seeds, for example, transfer power from farmers to companies. It prevents farmers from saving and reusing seeds, which is a widespread practice both in developing and developed countries.[210] This type of application intensifies concerns about the increase of corporate power, the dependency of farmers on corporations for seeds, and the limitations imposed by the licence agreement.

The success of GMOs, arguably, will rely on public acceptance, particularly in Europe where it has proven to be a major stumbling block in the development of GM crops.[211] The challenge for biotechnology industry is to convince the public that GMOs offer real advantages which cannot be achieved realistically any other way, and that the technology is safe. The industry will need to demonstrate that it is not only concerned with shareholders profit, but also willing to engage with farmers and consumer's needs.[212]

People's distrust of large companies stems from the fear of these corporations putting financial gain ahead of public welfare. Many commentators have argued that GM technology represents 'no more than a further technological fix on the intense agriculture mill.'[213] If research is conducted by public interest bodies, such as universities or non-governmental organizations, whose concern is to produce public goods, then biotechnology could result in the spread of technologies that have immense benefits.[214]

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[209] 'Genetically Modified Foods: Attack of the Really Quite Likeable Tomatoes' The Economist, (25 Feb 2010) http://www.economist.com/node/15579956. Accessed 2 August 2011.

[210] Jules Pretty 'contested risks and benefits' (n 59) p. 250. He adds that But in defence of the terminator seed, the argument that it would prevent the spread from GMOs to wild relatives.

[211] See Chapter 3 for public perception in the EU and the US.

[212] Jules Pretty 'contested risks and benefits' (n 59) p. 248-262; Maria Lee, *EU Regulation of GMOs* (n 132) p. 31.

[213] Jules Pretty 'contested risks and benefits' (n 59) p. 256; TNS Opinion & Social, 'Biotechnology' Special Eurobarometer 341 /Wave 73.1, Report for the European Commission (October 2010); see also Chapter 3, section 4.4 on EU public acceptance of GMOs

[214] Jules Pretty 'contested risks and benefits' (n 59) p. 258.

This distrust in corporations led some to believe in conspiracy theory that assumes some people have plans to control world population growth over the coming decades.[215] For example, William Engdahl's critique 'seeds of destruction' goes far beyond the familiar controversies surrounding the practice of genetic modification as a scientific technique. He describes a world driven by profit and government corruption, where GMOs are used to gain worldwide control over food production. [216] He believes that 'genetic manipulation' unleashes great potential, as 'control of food supply of entire nations is too much power to give to any single corporation or government.'[217]

For many people, tabloid newspapers are the only source of information about GMOs. At the same time, there is plenty of conflicting information provided by governments, the big corporations that control agriculture, and interest groups with anti-biotechnology views. Yet, the GMO debate is most intense in Europe, where public concern about GM foods is higher than in other parts of the world such as the United States, where GM crops are more widely grown and the introduction of these products has been less controversial. EU citizens' strong views on the matter have influenced the evolution of the regulatory system. See Chapter 3, sections 2.4 and 4.7 on public distrust of GMOs.

2.8 Risk regulation and assessment of GMOs

The *Biotech* dispute raises concerns regarding the role of science in shaping regulatory choices and measures that address possible risks and related uncertainties posed by GMOs.[218] This section considers the interaction of science and society in risk assessment and its effect on regulatory choices regarding the control of risks arising from GMOs.

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[215] Some NGOs such as Greenpeace accused the US government and the GM industry of imposing GM crops on the South. See Greenpeace, 'The US War on Biosafety: Renewed Aggression by Rouge State' (June 2003), www.greenpeace.org/.../Global/...2/.../the-us-war-on-biosafety-rene.p. accessed 18 May 2010

[216] William Engdall 'Seeds of Destruction: The Geopolitics of GM Food' (2004) 5 Current Concerns, http://www.currentconcerns.ch/archive/2004/05/20040505.php. Accessed June 2008.

[217] Ibid, p.14.

[218] See chapter 1, sections 5.3 and 5.5.

Risk is generally defined as probability of particular event occurring and the consequent severity of the impact of that event.[219] There seems to be a contemporary obsession with anticipating risks, acting to prevent them and having in place plans to manage risk events should they occur. [220] According to Beck we live in the age of 'risk society' where risk has been regarded as one of the key unifying themes that shape the contemporary social sciences. He notes that 'Risks are always events that are threatening' and he makes a distinction between risk as an anticipated event and catastrophe as an actual event.[221]

Regulation can be seen to be centrally concerned with the control of risks, identifying and assessing risk is not a simple matter. A host of different approaches to defining and assessing risks can be taken.[222] Risk analysis for new technologies can take a number of forms, and choices of appropriate methods depend on the scientific and regulatory context.[223] Advocates of GMOs focus on cost benefit approaches to risk, weighing the scale of harm against potential benefits, while opponents of GMOs argue over the applicability of the key concepts of 'risks' and 'uncertainty'.[224] The role of the precautionary principle can be used as a risk assessment tool to be employed in the absence of scientific literature, precautionary principle can also be used as risk management tool.[225]

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[219] For more on the definition of risk and the different types of risks see Robert Baldwin, Martin Cave, and Martin Lodge, *Understanding Regulation: Theory, Strategy, and Practice* (2nd edn, OUP, 2011) 86-87.

[220] For wider discussion see Bridgget M Hutter, ed, *Anticipating Risks and Organising Risk Regulation* (Cambridge University Press, 2010)

[221] Ulrich Beck, 'Living in the world of risk society', (2006) 35(3) Economy and Society, 332

[222] For more on the different perspectives to calculate risk ranging from technical, economic, psychological, to cultural approaches see. Robert Baldwin, Martin Cave, and Martin Lodge, *Understanding Regulation* (n 219) 86-92.

[223] The basis for regulating new technology products is 'Risk Analysis Framework' which has three components: (1) risk assessment, is designed to provide an objective and neutral product risk profile identifying the actual risk; (2) risk management, is designed to make regulatory decision based upon product risk profile established by the risk assessors; and (3) risk communication is designed to ensure transparency; a two way flow of information between both the risk assessors and the risk managers but also between the Risk Analysis Framework and stakeholders. See Grant E Isaac and William A Kerr, 'Genetically Modified Organisms at the World Trade Organisation: A Harvest of Trouble' (2003) 37(6) Journal of World Trade 1083, 1086.

[224] Mark A. Pollack and Gregory C. Shaffer, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*. (Oxford: Oxford University Press, 2009), p. 9.

[225] See Grant E Isaac and William A Kerr, 'A Harvest of Trouble' (n 223) p. 1088.

Managing and regulating risk in an effective manner is a key regulatory challenge: to potentially avoid the under regulation of risk, or potentially be biased to the over regulation of risk.[226] Regulators must chose a method to assess risk that will unleash the benefits of GM crops whilst avoiding its pitfalls. 'Regulators walk fine line, if they are too stringent, billions of dollars of unnecessary costs will be imposed. If standards are too lenient, the scope of health or environmental harm maybe too high.'[227] In making regulatory choices under these circumstances, the root question becomes how to account for scientific uncertainties in the regulatory process, and how to balance risks and benefits in the absence of critical scientific information.

The main focus of theoretical attention has been on the 'new risk environments' created by science and technology and particularly on 'technologies of the future'.[228] Lezaun- believes that there is a volatility attached to risks in modern society, where new scientific developments are highly volatile with new developments being herald as success one day and hazardous shortly afterwards.[229] Thus, in a relatively short period of time many issues traditionally, which national governments enjoyed full regulatory control, have come to be viewed of global importance requiring systems of international regulation.[230]

It is true in the case of GMOs that advances in biotechnology intensified the debate about the proper balance between engagement with the wider public and the precautionary principle and its relationship to risk, scientific evidence and uncertainty.[231] Pretty explains that GMOs are not a single, homogenous technology. Each application and product brings different benefits for different stakeholders, and each poses different environmental and health risks. It is important, therefore, to distinguish between the major types of applications and the different generations

[226] for more on the different challenges that face regulators see Robert Baldwin, Martin Cave, and Martin Lodge, *Understanding Regulation* (n 219) 92-97
[227] Rebecca Bratspies, 'The Illusion of Care'(n 38) p 299
[228] There are many areas of science, particularly in the field of environment, see Bridgget M Hutter, ed, *Anticipating Risks and Organising Risk Regulation* (n 220), p. 5
[229] See Javier Lezaun, 'Bioethics and Risk Regulation of 'Frontier Research': the Case of Gene Therapy' in Bridgget M Hutter, ed, *Anticipating Risks and Organising Risk Regulation* (n 220)
[230] For more see Jacqueline Peel, *Science and Risk regulation in International Law* (e-book, Cambridge University Press, 2010) chapter 2
[231] see Bridgget M Hutter, ed, *Anticipating Risks and Organising Risk Regulation* (n 220) , p.7 The development of biotechnology with global reach focus concerns on permanent widespread changes which may occur to DNA through these interventions

of GM technologies.[232] Different GM organisms include different genes inserted in different ways. This means that individual GMOs and their safety should be assessed on a case by case basis and that it is not possible to make general statements on the safety of all GMOs.[233]

In such area, some would consider that there are significant unknowns, 'we do not know what we don't know'.[234] Like any new technology, biotechnology carries risks, and those risks must be properly assessed and managed. GMOs may pose risks to human health and the environment which are presently beyond the ability of science to predict, and have the potential to trigger social and political tensions.[235] It is hard to do so when 'everything we know about GMOs lies in the shadow of ignorance, the prospect of harm that we have not even thought of.' [236]

Further, the acceptability of risk depends not simply on 'how likely any particular bad outcome is, but also of the type of world in which we want to live', which hugely complicates decision making on the regulation. So cultural and social background to risk affect which risks are selected for concern, and which are dismissed as unimportant.[237]

Particular concerns in the control of risks relate to divergences in lay and expert approaches; to the use of information in regulating uncertainties; and the susceptibility of risk control regimes to democratic and participatory mechanisms.[238] Consequently, regulatory solutions are fundamentally shaped by

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[232] Jules Pretty 'contested risks and benefits' (n 59) p. 248-262. Pretty contends that neither side of the GMO debate is entirely correct.

[233]William Kerr, 'International Trade in Transgenic Food Products: A new Focus for Agricultural Trade Disputes' (1999) 22(2) *World Economy*, p. 245; WHO, '20 Questions on Genetically Modified (GM) Foods'(n 7).

[234] Brian Wynne, 'Uncertainty and environmental learning: reconceiving science and policy in the preventive paradigm' (1992) 2(2) Global Environmental Change, 144

[235] Maria Lee, *EU Regulation of GMOs* (n 132) p. 12.

[236] The science is compounded by banal errors, data gaps, and necessary assumptions. 'The most intractable issue around new technology is the nature of scientific uncertainty. Maria Lee, *EU Regulation of GMOs* (n 132) p. 29-30; see also Alexia Herwig, 'Whither Science in WTO Dispute Settlement?' (2008) 21(8) *LJIL* 824

[237] Maria Lee, *EU Environmental law: Challenges, Change and Decision Making* (Hart Publishing 2005), p. 80; Maria Lee, *EU Regulation of GMOs* (n 132) p. 30, 39-41.

[238] See Keven E Jones and Alan Irwin, 'Creating Space for engagement? Lay Membership in Contemporary Risk Governance' in Bridgget M Hutter, ed, *Anticipating Risks and Organising Risk Regulation* (n 220)

worldviews and 'approaches' towards risk regulation. They emphasize that risk regulation is about choices that reflect fundamental assumptions about the vulnerability of particular social systems.[239] Many actors are involved in influencing and shaping regulatory choices regards GMOs at the national and international levels. It involves biotechnology companies, governmental regulators, non-governmental organizations, scientists, consumers and farmers; their views and interests are shaped by a variety of economic, moral and scientific considerations. Bernauer regards EU and US policies on GMOs as outcome of interaction between the above actors, shaped by differences in public perception of agricultural biotechnology, consumer trust in regulatory authorities, and institutional settings.[240] The EU and the US do not just disagree on the appropriate role of 'agricultural technology', but also disagree on what counts as science for legitimate regulation.[241] Due to lack of public trust in the regulatory agencies and negative public perception of GMOs, the collective action civil society, farmers and consumers groups have reduced the collective action capacity of pro biotech interests in the EU pushing for stricter regulation. In contrast, a well organised biotech producer coalition has prevailed in the US due to lower public outrage and weaker campaigns by civil society. [242] Such events have shaken confidence in experts and governments and led to fundamental questioning of new scientific and technological development.[243]

The debate over the regulation of GMOs has been dominated by two models. The US adopted a 'product approach', and the EU adopted a 'process approach'.[244] Assessment of the risks and benefits related to GMOs varies substantially between countries and regions, as do regulatory approaches. On the one hand, 'substantial

[239] See Robert Baldwin, Martin Cave, and Martin Lodge, *Understanding Regulation* (n 219) 92, 98-102.
[240] Thomas Bernauer, *The Seeds of Conflict* (n 131) pp. 66-101.
[241] Cinnamon Carlarne, 'From the USA with love: Sharing Home Grown Hormones, GMOs, and Clones with reluctant Europe' (30 April 2007) 37(2) Environmental Law, 301; Maria Lee, *EU Regulation of GMOs* (n 132) p. 211. Chapter 3 focus on how and why the EU and the US have taken starkly different approaches to the regulation of GMOs.
[242] For elaboration on this interaction see Chapter 3, section 2.4 and section 4.4.
[243] See also Brian Wynne, 'Creating public alienation: expert cultures of risk and ethics on GMOs', (2001) 10(4) Science as Culture, 445-81; see also chapter 3, section 2.4 & 4.4 on how scares such BSC affected the choices of the public in Europe.
[244] See generally Thomas Bernauer, *The Seeds of Conflict* (n 131) p44-66; Grant E Isaac and William A Kerr, 'A Harvest of Trouble' (n 223) p. 1083.

equivalence' is a starting point for the safety assessment of GM foods. It is used by some national and international agencies, including the Canadian Food Inspection Agency, the U.S. Food and Drug Administration, Japan's Ministry of Health and Welfare, the United Nations Food and Agricultural Organization, the United Nations World Health Organization (WHO), and the Organisation for Economic Co-operation and Development (OECD). For example, the FAO supports a 'science based evaluation system' that would objectively determine the benefits and risks of each individual GMO. This has called for a cautious case by case approach to address legitimate concerns for the biosafety of each product or process prior to its release.[245] On the other hand, the EU, CBD, and Cartagena Protocol endorse precautionary attitude when assessing the benefits and risks of introducing a specific GM crop, which allows the socio-economic and agricultural context of individual countries to be considered.[246]

The above analysis highlights that different governments want to ensure that these GMOs do not pose a threat to human health or the environment, yet they do not agree on the best way to protect against these potential threats.[247] Most developed counties like the US, the EU, Canada, and Japan already have regulatory frameworks to deal with different aspects of GMOs, 'focusing primarily on domestic priorities and strategies.'[248] Many developing countries are increasingly expected to set up their trade national regulatory schemes based on the requests and expectations of their main trade partners. They are caught in the middle of the dispute, and are expected to choose whether to line up behind the United States or the European Union on the question of GMOs.[249]

In the *Biotech* dispute, the parties differ in their interpretation of the commitment to market access for GMOs pertaining to the use of science in the decisions. This

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[245] FAO 'FAO Statement on Biotechnology' Agricultural Biotechnologies (March 2000), http://www.fao.org/biotech/fao-statement-on-biotechnology/en/. Accessed 20 September 2010.
[246] See Chapter 3, section 2 and 3 on regulatory attitudes. The criteria for authorization fall in four broad categories: 'safety', 'freedom of choice', 'labelling', and 'traceability'.
[247] WTO, 'Genetically Modified Organisms (GMOs)' (n 2).
[248] Simonetta Zarrilli, International Trade in GMOS: Legal Frameworks and Developing Country concerns, (UNCTD, 8 November 2004); Jan-Peter Nap et al., 'The Release of Genetically Modified Crops into the Environment, part I. Overview of Current Status and Regulation' (2003) GM Special Issue 33 The Plant Journal 8-13.
[249] Simonetta Zarrilli, 'Legal Frameworks and Developing country concerns' (n 248). See statements of US and EU.

clash is clear in the parties' submissions. The US adopted a 'sound science' approach, and mainly applied a conventional risk assessment approach, and widely authorised most GM products for production and consumption. It stressed the need for 'basis in science' and argued, *inter alia* that the EU's actions were not supported by 'sufficient scientific evidence', and rigorous risk assessment, and therefore the measures violated Articles 2.2 and 5.1 of the SPS Agreement. This was particularly submitted in respect to EU Member State bans on products for which risk assessment found the products in question were adequately safe to be approved in the EU. [250]

In its defence, the EU considered GM crops and products profoundly different from other conventional foods and food products, being particularly concerned with the unknowns associated with GMOs. The EU presented 'prudent and precautionary approach' because the science on GMOs is constantly evolving, and that 'new risk considerations sometimes arise spontaneously and change the scope of the risk assessment.' It relied particularly on the precautionary principle as provided under the Cartagena Protocol.[251]

The Panel in *Biotech* dispute appointed several experts to provide expert opinion and to review the scientific justification for the measures. The Panel in *Biotech* rejected the EUs defence, instead provided a broad interpretation of 'SPS measure' which will continue to place the onus on the EU to demonstrate that its authorisation framework pertaining to GMOs is based on scientific risk assessments and not otherwise disguised restrictions on trade.[252] In turn, this has placed increased importance on scientific knowledge and expertise in national and international legal processes dealing with highly technical and complex matters of health and environmental risk. Acceptance of science as sound foundation for international risk regulation is underpinned by perceptions that scientific knowledge offers an 'objective' and 'universally applicable' basis for rational decision making, as well

[250]First Written Submission of the US, *Biotech,* pp.86, 109–111; see also, First Written Submission of Canada *Biotech* (First Written Submission of Canada), pp. 177-179.
[251] First Submission of the EU, *Biotech*, p12. EU also argued that GMOs cannot be treated as 'like' or 'equivalent to' their non-GMO counterparts because they raise the potential for new types of harm p. 51-63
[252] The Panel also ruled against applying sources external to the WTO covered agreements. see chapter 4 for full discussion on the implications of extending the scope of SPS Agreement.

as the close association between the notions of risk, and the scientific understanding of them, that has developed over time.[253]

Some social scientists question the authority of scientific knowledge and the objectivity of risk assessment by exposing the uncertainties in various areas dealing with health and environment. They argue that emphasis on sound science in international regulation of risks may often downplay the role of non-scientific consideration in producing social and scientific consensus on the importance of risks posed by a given activity, especially in the face of the unknowns.[254]

Winickoff and others (the authors of the Academic brief) provide useful criteria for distinguishing different types of risk based on associated levels of uncertainty and social consensus. 'Using these criteria, the authors argue that risk situations can be conceptualised on a "continuum", running from "low certainty and low consensus" at one end, to high certainty and high consensus" at the other'.[255] They argue that, in cases of low certainty and low consensus situations should invite a 'more differential approach to the science based decision making of members' giving national regulators greater room to take public input into the risk decision-making process.[256] On the other hand, they acknowledge that in cases where consensus and certainty are high, 'the range of rational measures to address the risk situation should be more limited.[257] Accordingly, they contend that in situations of high consensus and high certainty, a heavier burden should be placed on countries to establish that their measures stem from non-protectionist values.[258]

The Panel in the *Biotech* dispute did not comment on the general debate of safety of GMOs despite the fact that the parties provided the Panel with extensive information regarding their views on the matter.[259] The Panel avoided on ruling whether GMOs should be treated with the same or more stringent regulation than

[253] For more see Jacqueline Peel, *Science and Risk regulation in International Law* (n 230) 61-92.
[254] Jacqueline Peel, *Science and Risk regulation in International Law* (n 230), 93-107.
[255] David Winickoff and others, 'Adjudicating the GM Food War: Science, Risk, and Democracy in World Trade Law', 30 Yale Journal of International Law, 104
[256] Ibid, 105-6
[257] Ibid, 118
[258] Ibid, 123
[259] Panel Reports, *Biotech*, paras. 7.3421-7.3423.

that of traditional varieties, leaving the choices as regards the regulation of risk an ongoing contested matter.

3 Trade dispute or trade war?

In the past 16 years, the global production of genetically modified crops has increased dramatically. Yet more than 43 percent of the global area devoted GM crops is located in the US. Another 47 percent of the global area devoted GM crops is located is only in four countries: Argentina, Brazil, Canada, and India.[260] At the same time there are countries, led by the EU and Japan, which have implemented cautious policies regulating import approval of GM crops, and the marketing of GM food.[261] This leaves many developing countries with few alternatives: they may allow the cultivation of GM crops, but risk the loss of potential exports; they may reject the commercialization of any cultivation of GM crops; or they may allow the cultivation of GM and non-GM crops, a costly alternative. In the context of international trade in GM crops, the *Biotech* dispute represents the war over the expansion of GM technology into more countries, the fear of export loss is a major driver for developing countries choice making.

The US justified its complaint by contending that biotech products were necessary to feed developing countries.[262] After the filing the complaint, President Bush brought the dispute to wider public attention by charging that EU's moratorium was impeding efforts to feed the world. He stated that 'European governments should join, not hinder, the great cause of ending hunger in Africa.'[263]

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[260] See section 2.6 above.
[261] Nuffield Council on Bioethics, *The Use of Genetically Modified Crops in Developing Countries- A Follow up Discussion Paper*, (Nuffield Council on Bioethics December 2003).
[262] 'U.S. and Cooperating Countries File WTO Case Against EU Moratorium on Biotech Foods and Crops: EU's Illegal, Non-Science Based Moratorium Harmful to Agriculture and the Developing World,' Office of the U.S. Trade Representative press release, and U.S. letter from Ambassador Linnet Deily to EC Ambassador Carlos Trojan, May 13, 2003 at http://www.ustr.gov. accessed 12 April 2010.
[263] Steve Suppan, 'US Vs EC Biotech Products Case: WTO Dispute Backgrounder', (2005) ITAP p.6, http://www.tradeobservatory.org/library.cfm?refid=76644%20 accessed 23 October 2010; Tom Hayden, 'Globalisation and GMOs', The Nation (23 June 2003) http://www.thenation.com/article/globalization-and-gmos.

Egypt's participation as complainant was crucial to the American claim that the EU's ban was hurting developing countries as well as US biotechnology companies. Some suggest that Egypt pulled out of the case due to domestic backlash, and instead decided to pursue its complaint against the EU separately.[264] Despite Egypt's withdrawal, the US maintained its argument about feeding the world. In its submission to the Panel, the US claimed that the EU's effective ban on GM imports was denying the claimed benefits of GM technology to developing countries fearful of EU bans on their own exports if they were to accept GM imports and grow GM crops.[265] The US did not specify which WTO provisions had been violated by the EU measures in relation to developing countries exports, but it did, however, underline strongly their negative impact. The US submitted that countries whose population is starving denied American aid consisting of GM food, and continues to do so, for fear that their meat exports to the EU would be hindered.[266]

This next section aims to examine the impact of the ruling on developing countries' choices with regard to the role that genetically modified organisms (GMOs) might play in their food security, and in tackling related problems like, hunger and malnutrition, while keeping in mind that, the task of reconciling national trade interests, environmental preservation and food security (starvation and malnutrition) is a very difficult task.

3.1 Can GMOs 'feed the world'?

Developing countries are facing continuously rising food demand due to growth in population. However, many face low crop yields related to several factors, like droughts, extreme humidity, pests, cost of fertilizers, and transport. Add to that political instability, war and HIV/AIDS which have adversely impacted agriculture.[267] Most commentators agree that food production will have to increase, and that the increase will have to come from existing farmland.[268]

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[264] Edward Alan, 'US Retaliation against Egypt hits Trade Plans', Financial Times, 29 June 2003, http://news.ft.com/servlet/ContentServer?pagename=ft.com/StoryFT/FullStory&c=stor
[265] First Written Submission of the United States, para.64.
[266] First Written Submission of the United States, paras. 64-66.
[267] Ernestine Meijer and Richard Stewert, 'The GM Cold War: How Developing Countries Can Go from Being Dominos to Being Players', 13(3) RECIEL 2004, p. 247.
[268] Jules Pretty 'contested risks and benefits' (n 59) p. 257

Advocates of GM crops believe that they can be of particular benefit in improving agricultural production in the developing world. The US, in particular, continues to be vocal proponent, noting that:

> 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.[269]

Claiming that genetically modified crops can feed the whole world is disingenuous because food security is a complex issue.[270] Some recognize that food security is less about food availability, than a lack of access to food.[271] Even if GMOs leads to increased crop yields, the problem is not that there is not enough food on the planet but how wealth is distributed; the argument is that people go hungry because they cannot afford food or the land to grow it.[272] Pretty contends that 'in most cases, people are hungry because they are poor.' They don't have the money to buy the food they need. Poor farmers cannot afford expensive modern technologies that could theoretically increase their yields. 'What they need are readily available and cheap means to improve their farm productivity.'[273]

Another factor contributing to poverty is agricultural subsidies worth about US$300 billion in developed countries to protect their farmers and agribusinesses. These

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[269] 'US Trade Representative Susan Schwab and US Agriculture Secretary Mike Johanns Announce Favourable Ruling in WTO case on Agricultural Biotechnology' USTR, 29 September 2006, http://www.ustr.gov. Accessed 10 October 2006. She also added that agricultural biotechnology is continuation on the long tradition of agricultural innovation that has provided the basis for rising prosperity for the past millennium.

[270] Food security is beyond the scope of this study.

[271] Council for Responsible Genetics, 'Coalition of the Willing' (n 110).

[272] 'African Groups Condemn Bush Administration's WTO Challenge of European GMO Policies; GMOs Not Answer to African Hunger', Public Citizen (18 June 2003), http://www.citizen.org/pressroom/release.cfm?ID=1464. Accessed 18 August 2009. See also 'US Complaint. In Whose Interest?' Public Citizen, http://www.citizen.org/trade/wto/agriculture/gmo/articles.cfm?ID=11052. Accessed 18 August 2009. They do not View GMOs as answer to African hunger but as 'in fact really about trying to overcome the growing public antipathy to GMOs worldwide and the related disappointment for U.S. industries who gambled on this technology.

[273] See Jules Pretty 'contested risks and benefits' (n 59) p. 257. In average, the world produces enough food to feed everyone with nutritious and adequate diet 354kf per person per year) yet there about 790 million people in serious food insecurity.

subsidies, found in the US, the EU, and Japan amongst others, negatively affect developing countries, and contribute to keeping the poor mired in poverty.[274]

GMOs of interest and relevance to the needs of developing countries, such as crops that can survive in dry or could climates, crops with improved nutritional quality, crops that produce higher yields, or crops with increasing salt or acid soil tolerance (environmental stress), are still being refined in laboratories.[275] 'Commercially available GM crops are largely dominated by herbicide or insecticide tolerant crops. These varieties can be useful for big farmer in developing countries, but they are not likely to improve the situation of smaller farmers.'[276]

Many factors affect a country's position on agricultural biotechnology (GMOs), such as policy awareness of the country, the level of risk they are willing to accept, their capacity to carry out risk assessment and implement adequate legislation, their perception of the benefits they could gain, their dependence on agriculture exports, their reliance on food aid, and the investment they have already made in the sector.[277] There is not one solution to fit all; the term developing country, covers many countries in different continents and different climates, with different needs, and a variety of local conditions and problems.

According to figures from ISAAA, of the 29 countries planting biotech crops in 2011, 19 were developing and 10 were industrial. The five lead developing countries in biotech crops are India, China, Brazil, Argentina, and South Africa, which collectively represent 40% of the global population. The major GM crop approved for commercial release in developing countries is Bt cotton, which is grown commercially in China, India, and Indonesia and is the fastest expanding GM crop.[278]

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[274] Council for Responsible Genetics, 'Coalition of the Willing' (n 110).
[275] See Clive James, (n 56).
[276] 'US vs EU: An Examination of the Trade Issues Surrounding Genetically Modified Food' Pew Initiative on Food and Biotechnology (DECEMBER 2005), p.8-9, http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Biotech_USEU1205.pdf. Accessed 3 February 2009.
[277] Simonetta Zarrilli, *National and Multilateral Legal Frameworks*, (n 162) p. 2.
[278] Clive James, (n 56).

Many NGOs, scientists, and academics remain sceptical of the benefits, highlighting a wide range of potential risks. Some maintain that '[m]ost benefits are noble in nature and cause, yet these benefits are only the could bes of the future.' Therefore, since most of these benefits are just, 'sweeping predictions seem quite idealistic considering the relative novelty of agricultural genetic engineering.' Most developing countries lack capacity to assess and manage potential risks of GMOs.[279]

Another fear relates to poor farmers depending on big corporations for seeds rather being self-sufficient. Seed saving is an ongoing practice in developing countries. However, since IPRs of GMOs are held by private corporations, GM farmers are not allowed to save seeds from their harvests for replanting in subsequent years; rather, they must buy new seed annually.[280] This results in adverse consequences, and those poor farmers most susceptible to hunger would unable to afford to use GM seeds, even if they were proved to be safe.[281]

Finally, there are also unknown health effects for the poor who consume GMOs. Corn and other grains comprise 70 percent of the average African's caloric intake as opposed to just 3 to 4 percent of the average American's caloric intake, exposing them to greater risk as regards the potential negative health impacts.[282]

3.2 The challenge facing developing countries

Many developing countries are exporters of conventional agricultural products. They are concerned with export opportunities, especially towards markets like the EU where a GM free label is important. These countries maintain this GM status by refraining from planting any type of GM crop in order to avoid cumbersome documentation and traceability requirements, as well to meet consumers' expectations.

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[279] Sarah Lively, 'The ABCs and NTBs of GMOs' (n 73) p. 243.

[280] Jules Pretty 'contested risks and benefits' (n 59) p. 250; Maria Lee, *EU Regulation of GMOs* (n 132) pp 156–7.

[281] 'WTO and Genetically Modified Organisms (GMOs)', Public Citizen, http://www.citizen.org/trade/wto/agriculture/gmo/. Accessed 18 August 2009.

[282] 'African Groups Condemn Bush Administration's WTO Challenge of European GMO Policies; GMOs Not Answer to African Hunger' Public Citizen (18 June 2003), http://www.citizen.org/pressroom/release.cfm?ID=1464. Accessed 18 August 2009.

The EU's strict import measures have implications for developing countries. Developing countries relying on exports of conventional agricultural products to the EU find it difficult to adopt GMOs for domestic consumption in fear of losing their export opportunities. Maintaining 'GM-free' status allows them to avoid cumbersome documentation and traceability requirements, as well to meet consumers' expectations.[283]

This perception has contributed to some African countries refusing food aid that includes GMOs. In 2002, Zambia declined an American food aid offer of GM maize. In particular, the '[m]ain Zambian concerns relate to uncertainty and regarding the safety of GM maize for human consumption, as well as the possible contamination of local varieties which could allegedly imply rejection by EU Countries of Zambian food exports.'[284]

In May 2004, the South African Development Community (SADAC) approved guidelines on handling GM food aid. These guidelines fully endorsed the recommendation of the SADAC Advisory Committee on Biotechnology and Biosafety which reflected the concerns of African countries relating both to possible adverse effect on human health and the environment, and to the fact that GM imports may jeopardise exports of conventional agricultural products.[285]

The US wanted the *Biotech* dispute's outcome to 'serve as a warning to other WTO Members, particularly developing countries, not to restrict access to their markets banning or restricting GMOs.'[286] In a similar case over beef hormones, once the US started a WTO trade complaint, no countries took steps to ban them.[287]

US officials also believed that a challenge was necessary to discourage other countries, especially those in the developing world, from using the EU regulatory approach as the basis for their own regulations on agricultural biotechnology

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[283] Simonetta Zarrilli, *National and Multilateral Legal Frameworks*, (n 162) p.7.
[284] Ibid, p.7.In July 2002, Zambia allowed the food aid into the country provided that it was milled immediately upon arrival to avoid any possible contamination of local varieties
[285] Ibid, p. 8-9.
[286] 'USTR Seeks Industry Input on Possible Challenge in Biotech Dispute', Trade Observatory, 19 February 2002, http://www.tradeobservatory.org/headlines.cfm?refID=17257 access 12 May 2010.
[287] Neither the U.S. nor Canada has changed its domestic standards for the use of growth hormones in meat production, also, the international standards on growth hormones in beef have not been strengthened in response to the European ban, see Sebastian Princen, *EU Regulation and Transatlantic Trade* (Kluwer Law International, 2002) p.183-4.

products, which could result in even wider-scale disruptions to US trade. President Bush was concerned that stringent EU restrictions led to the refusal of several southern African nations to accept American food aid that included GM corn, further exacerbating famine. EU officials vehemently rejected that charge.[288]

Palmer argues that 'GM exporters could use the Panel's interpretation of the SPS Agreement, and its reasoning on the relevance of international law, to undermine efforts by WTO Members to:

• regulate GM imports;

• implement and negotiate new commitments under the Biosafety Protocol; or

• regulate other products that might cause harm to human health and the environment.'[289]

'Because plaintiffs almost always win WTO challenges, mere threats of challenges often result in the challenged country changing its policy. In this GMO case, the United States figured that if the claim is to succeed, mere threats against other countries might suffice to quash other similar rules.'[290] The US already threatened to use the WTO dispute procedure against a number of small countries considering GMO legislation or bans, such as Bolivia, Croatia and Sri Lanka. [291]

Reports of WTO disputes guide Panels of future WTO disputes, which will in turn influence the future regulatory behaviour of WTO Members.[292] In other words, the findings of the Reports are of importance to other WTO Members wanting to regulate GM imports. The lack of international consensus on how to regulate

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[288] US. vs EU: the Pew Initiative on Food and Biotechnology (n 276) p. 12; Council for Responsible Genetics, 'Coalition of the Willing' (n 110).
[289] Alice Palmer, 'The WTO GMO Dispute: Implications for Developing countries and the need for an appeal', *GeneWatch UK*, (November 2006), p.5-6, available at http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/WTO_Biotech_case_dcsummaryfinal_1.pdf . accessed 21 June 2010.
[290] The GMO Dispute: Bush Administration Attack on European Food Safety Policy Latest Challenge to WTO's Legitimacy', Public Citizen (n 174).
[291] Ibid.
[292] Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, adopted Panels Reports 'create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute.'

GMOs, made it hard to conclude the Panel Reports. However, when it was finally published, the Report had no clear answers; instead it increased tension at the international level, which most probably led to fragmentation of international law.[293] Greenpeace explained that developing countries fear WTO enforcement mechanisms, and losing a case could cost millions of dollars.[294]

3.3 The way forward for developing countries

Biotechnology alone will not be able to address all of the underlying causes of food insecurity. Low income, poor infrastructure, and lack of access to credit are all factors at the root of the food crisis, and can only be addressed by long term sustainable development.[295] GMOs can help to feed the world if 'attention is paid to the processes of technology development, benefit sharing, and more especially to alternative or low cost methods of production.' Where there are no alternatives, GM technologies are likely to represent novel and effective options. [296]

Pretty indicates that sustainable agriculture is an increasingly viable option for developing countries' farmers. It makes better use of knowledge and skills of farmers, improving their self-reliance and capacities. GMOs need to contribute to sustainable agriculture through increased eco-efficiency in order to benefit developing countries. The main aspects to determine whether it is achievable are: increase in yield; reduction in insecticide; reduction in herbicide; and the extent of secondary problems arising from monocultures of GMOs.[297]

If research is produced by public interest bodies, such as universities or NGOs whose concern is to produce public goods, then biotechnology could result in the spread of technologies that have immense benefits.[298] Increasingly, countries like China, India, and Brazil are intensifying agricultural research, including research on GM crops. In 2009, a GM version of an Indian cotton variety, developed by the

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[293] See Chapter 4, Section 3.
[294] 'World Trade Organisation dispute on genetically engineered organisms', Greenpeace, Briefing, May 2006 http://www.greenpeace.org accessed 9 May 2010
[295] 'WTO case on GMOs' Times Higher Education, (Brussels 18 June 2003), http://www.timeshighereducation.co.uk/story.asp?storyCode=177451&sectioncode=26. Accessed 6 February 2008.
[296] Jules Pretty 'contested risks and benefits' (n 59) p.257-8.
[297] Jules Pretty 'contested risks and benefits' (n 59) p. 255.
[298] Ibid, p. 258.

public sector, came to market, and a variety engineered by private Indian firm was approved for commercialisation.[299]

The divergent policies toward GMOs in rich countries have now created a complicated problem of policy choice in the developing world. Developing countries need to find ways to increase regulatory and scientific capacity in order to assess the effects of modern agricultural technology on their environments. This may be costly and lengthy process.[300]

Many developing countries still lack, or are in the process of developing, comprehensive regulatory systems to deal with GMOs.[301] We see most developing countries doing so even under harder circumstances. Many developing countries are not able to deal with the scientific aspects of GMOs, or 'the main concern seems to be finding the appropriate balance between pursuing their development objectives and at the same time complying with their mutually agreed obligations.'[302]

As larger sets of developing countries make regulatory choices, some similar to the US, such as in Argentina and Brazil, others similar to EU's such as the African Model Law on Safety in Biotechnology,[303] it imposes further burdens and complications for international trade, which are already reflected in the current *Biotech* dispute.

Some commentators see this dispute as a signal from the US to warn other countries not restrict or ban the GMOs.[304] Therefore, it may be wise for developing countries to avoid copying the GMO policies of developed countries, whether its intensive cultivation of GM crops as in the US, or full rejection as encouraged by some EU countries and NGOs.[305] Indeed, '[i]t might be wiser to take a 'wait and see'

[299] 'Genetically Modified Foods: Attack of the Really Quite Likeable Tomatoes' (25 Feb 2010) The Economist http://www.economist.com/node/15579956. Accessed 2 August 2011.
[300] Jules Pretty 'contested risks and benefits' (n 59) p. 259.
[301] Simonetta Zarrilli, *National and Multilateral Legal Frameworks*, (n 162) p. 6.
[302] Ibid, p.6-7.
[303] Available at http://www.nepadst.org. Accessed 3 July 2009.
[304] Grant E Isaac and William A Kerr, 'A Harvest of Trouble' (n 223) p 1083-4.
[305] Ernestine Meijer and Richard Stewert, 'The GM Cold War '(n 267) p 247.

approach, and to resist the temptation to join forces with GMO exporting countries.'[306]

4 Conclusion

The expansion in the development and commercial cultivation of many GM crops has been extraordinary rapid. This chapter demonstrated the increasingly important role of GMOs in global food production. They have the potential to influence and change agriculture as we know it. The science behind GMOs is new and very complex, and despite the promise, there are many concerns (scientific, social, ethical, and political), relating mainly to human health and the environment.

The entire debate regarding GMOs, and GM technology, is a minefield, with polarized opinions, considerable frustration, and a growing sense of concern globally. The outcome of the dispute did not ease any of these aspects; it only added more challenges to regulation. Arguably, the debate over potential benefits versus potential adverse effects of GMOs over the long term is due to insufficiencies in available scientific evidence. However, subsequent development in the science could reduce the potential risks of GMOs, or highlight their more positive aspects,

The gaps and lack of consensus scientific knowledge allowed both the US and the EU to rely on scientific statements and studies to support their approaches towards GMOs. The US emphasises the promises of biotechnology and the potential benefits that may be achieved, while the EU highlights the possible risks and dangers of GMOs.[307]

In recent years, 'sound science' and 'precautionary principle' have emerged as competing paradigms for assessment and management of environmental health and environmental risk; whereas proponents of 'sound science' emphasise the importance of empirical studies as prerequisite for risk regulation, 'precautionary

[306] Mathew Stilwell, 'Implications for Developing Countries of Proposals to Consider Trade in Genetically Modified Organisms (GMOs) at the WTO'. (CIEL Discussion Paper, undated), available at http://www.twnside.org.sg/title/ciel-cn.htm. Accessed 08 January 2008. The Author believes that the Biosafety Protocol provides the appropriate forum for dealing with GMO.
[307] See Chapter 1, sections 6.1 and 6.2.

approach' advocate for action to address where potential risks are not well established in scientific evidence.

Science clearly cannot provide all of the information and judgements needed to make decisions on agricultural technology.[308] The difficulty remains in determining how to assess the potential benefits and risks, and whether regulation can adequately manage the risks in the face of rapidly developing technical application.[309] One should also question the commercial direction of the biotechnology industry, address who carries the risk and gets the benefits, and consider the possible longer-term effects and implications. In the absence of scientific certainty, it is not surprising that GMOs have spawned controversy.

With a large number of GM crops available, and a large number under development, developing countries are caught in the middle of the dispute. They are expected to choose between supporting the United States or the European Union on the question of GMOs. They are also faced with two main approaches to the regulation of GMOs. The first, assumes that GMOs are safe after limited testing. The second assumes that more extensive testing on a broader scale is required to prove its safety. The next chapter elaborates on these competing approaches to regulation, which underline the different positions in *Biotech* dispute.

[308] Maria Lee, *EU Regulation of GMOs* (n 132) p. 41.
[309] Nuffield Council on Bioethics, *The Ethical and Social Issues* (n 140).

CHAPTER 3

THE US v. THE EU: CLASHING ATTITUDES TOWARDS GENETICALLY MODIFIED FOODS

> …Europe's consumers want food that it is safe and wholesome. The concern of European Union is to make sure that the food we eat is of the same high standard for all its citizens, whether the food is home-grown or comes from another country, inside or outside the EU.[1]

1 Introduction

In the *Biotech* dispute, the complaining countries challenged the 'suspension' and 'failure' by the EU to consider applications for approval of GM products. It also challenged national bans in six EU Member States on some GM products, which had been approved in European Union before October 1998, arguing that they adversely affected imports of agricultural and food products from the US, Argentina, and Canada.[2]

The Complainants specifically maintained that they were arguing against the application of the old legislation, and did not want the Panel to take into account recent developments in EU law and its application.[3] Yet, the fact that two GMOs had been authorised under the new legislation and placed on the market in the EU during the months preceding the formal initiation of the complaint at the WTO did not change the Complainants' position; they maintained their challenge against the

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[1] *From the Farm to the Fork: Safe Food for Europe's Consumers*, (Europe on the move, European Commission, 2004), p.1, http://ec.europa.eu/publications/booklets/move/46/index_en.htm. Accessed 15 August 2009.

[2] Panel Reports, *European Communities- Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, AND WT/DS293/R (29 September 2006) [hereinafter *EC- Biotech* or *Biotech*] paras. 4.160-4.359 claims mainly under GATT, TBT, and SPS agreement.

[3] For example, Executive Summary of the First Written Submission of the United States, *Biotech*, para.16

EU's measures despite resumption of authorising of new GMOs.[4] Indeed, many US government representatives confirmed that the main issue at stake was the way the EU applied its GMO authorisation regulation rather than the scheme itself.[5]

Substantial variation in the regulation of GMOs in the US and EU produced different conditions of access to international markets, and ultimately led to the dispute. On the one hand is the 'permissive' approach favoured by the Complainants, the US in particular. This approach allows restrictions on the production, sale, and use of foodstuffs (including GMOs), but only where justified by scientifically proven risks for human health, the environment, or other important goods. On the other hand is the 'precautionary' approach, largely favoured by the EU. This approach allows policy makers to make discretionary decisions in situations where there is evidence of potential harm in the absence of complete scientific proof.[6]

This chapter shows that while both the United States and the European Union share a common desire to provide a safe food supply complimented by credible regulatory systems, they have adopted two very different regulatory approaches to deal with the increasing numbers of GM food and feed products coming to market.[7] Consequently, the transatlantic relationship has become fraught with conflict over the issue of GM foods. The main points of difference between the EU and the US relates to uncertainties over the nature and extent of risks associated with GMOs, and the potential socio-economic implications of GMOs.

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[4] The EU Approved Bt-11 sweet maize and, NK603 maize, see Panel Reports, *Biotech*, para. 7.1669.
[5] USTR, '2013 Report on Sanitary and Phytosanitary (SPS) Barriers to Trade' (March 2013) USTR 3-4 http://www.ustr.gov/sites/default/files/2013%20SPS.pdf. Accessed 2 April 13; Thomas Bernauer, *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology* (Princeton University Press 2003).
[6] European Commission, 'Communication on the Precautionary Principle' (COM (2000)1 final, Brussels, 02 February, 2000); see Speech by EU Trade Commissioner Peter Mandelson 'Biotechnology and the EU' (SPEECH/07/397, Brussels, 14 June 2007), http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/07/397&format=HTML&aged=0&language=EN&guiLanguage=en. Accessed 21August 2009. On the precautionary principle in the EU, see section 4; and Panel Reports, *Biotech*, paras. 7.53-7.55.
[7] Patterson, Lee Ann and Josling, Tim (2002) 'Regulating biotechnology: comparing EU and US approaches'. Issue 8 European Policy Papers, European Union Centre. http://aei.pitt.edu/28/1/TransatlanticBiotech.pdf accessed 3 January 2011.

This chapter explores the nature of the two regulatory systems and the underlying social, political, and institutional factors that contributed to the development of these systems. It focuses on how and why the EU and the US have taken starkly different approaches to the regulation of GMOs. It outlines European and American regulation of GMOs, highlighting the attitudes underlining the differences in regulation. However, it is not theintention to provide a full analysis of EU or US law concerning GMOs, which extends over variety of topics such as labelling, traceability and co-existence. Rather, this chapter will focus on the authorisation framework and of national attitudes towards GMO's risks and benefits

This chapter analyses the conceptual framework with respect to national regulation, as well as its justification. This is a crucial step in assessing whether the ruling in *Biotech* weakens the EU's ability to maintain its existing authorisation framework, which employs a precautionary approach in regulating GMOs, to meet public health and protect the environment.

It begins with an examination of the EU's regulation of GMOs, and underscores recent legislative changes that led to the dispute. It is not the intention of this section to thoroughly discuss and analyse all relevant regulatory frameworks covering GMOs. Instead, it will provide a sketch of the EU regulatory framework, based on its chronological development in parallel to the *Biotech* dispute.

The focal points of this chapter are the challenged measures, the authorisation of GMOs, and their placement on the market. The chapter also examines aspects of specific provisions on the labelling of GMOs in food and feed products. It does not cover the full range of issues in EU law relating to GMOs. For instance consideration of intellectual property rights and tort liability, the coexistence of GMOs with conventional and organic crops, and liability for environmental damage from GMOs are omitted.[8]

Furthermore, this chapter will delineate the divergent attitude of the United States towards GMOs. This contrast allows for drawing distinctions between and

[8] For more on these issues see Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Biotechnology Regulation Series, Edward Elgar, 2008), Chapters 4 and 5; Maria Lee, 'The Governance of Coexistence' between GMOs and Other Forms of Agriculture: A Purely Economic Issue? (2008) 20(2) Journal of Environmental Law 193.

investigating the motives behind European and American approaches towards GMOs. It will also examine how and why consumer preferences in the EU and US differ, explaining how these differences impact policy formulation.

The chapter then examines the main legal differences arising from the dispute, specifically as regards the role of the precautionary principle in EU regulation of GMOs. The impact of biotechnology on international trade relations between the US and the EU will also be examined, as will public trust and acceptance of GMOs, and their ability to affect the ongoing GMO debate. Whether the GMO debate will shift will be accorded consideration as well. Finally, this chapter will appraise the EU's ongoing implementation of the Panel's Ruling.

2 The EU regulatory framework[9]

At the time the complaint was brought against the EU, its approval regime consisted of Directive 2001/18/EC, replacing Directive 90/220/EEC governing the deliberate release into the environment of GMOs (the 'Deliberate Release Directive')[10] and Regulation 285/97/EC regulating novel foods and novel food ingredients (the 'Novel Foods Regulation').[11] These three pieces of legislation were the provisions that dealt with before the Panel.

The EU's regime for approval of biotech products was an elaborate premarket approval system, in which GMOs could only be placed on the market after having undergone a stringent science-based risk assessment on a case-by-case basis. The

[9] For detailed and comprehensive description and analysis see Theofanis Christoforou, 'The Regulation of Genetically Modified Organisms in the European Union: The interplay of science, law and politics', (2004) 41 CMLR, pp.637-709; Maria Lee, *EU Regulation of GMOs* (n 8); and legislation summary http://europa.eu.int accessed 12 May 2012.

[10] Council Directive 2001/18/EC of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms, OJ 2001 L 106/1 thereby replacing Council Directive 90/220/EEC, OJ 1990 L 117/15, as amended by Council directive 94/15/EC, OJ 1994 L 103/20 and Directive 97/35/EC, OJ 1997 L169 [hereinafter 'Deliberate Release Directive' or 'Directive 2002/18/EC'].

[11] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients [1997] OJ L 043/1 [hereinafter: 'Novel foods Regulation' or 'Regulation (EC) No 258/97'] Regulation 258/97/EC has been substantially modified and reduced in scope by Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 of September 2003 on genetically modified food and feed, OJ 2003, L268/1.

process also had to observe the precautionary principle when assessing the products.[12]

The general objective of the legislation is to avoid adverse effects on human health and the environment arising from the deliberate release into the environment, or the placing on the market of GMOs.[13] The Complainants specifically maintained that they were arguing against the application of the old legislation, and did not want the Panel to take into account subsequent legislative developments in the EU and their application.[14] Despite the fact that more GMOs have been placed on the EU's market since 2003, the Complainants' position did not change. Therefore, the EU regulatory framework continued to be a problem for the Complainants.

This section starts by describing the EU's GMO approval legislation prior to and during the *Biotech* dispute. It then explores the factors leading to the halt of authorisation of GMOs, known as a *de facto* moratorium, which was the process in which the EU revised its regulatory framework as it related to releasing GMOs into the environment and in food and food products. This backdrop is essential to understanding the challenged measures, and why they were opposed by the US.

2.1 Authorisation of GMOs challenged in '*Biotech*'

Council Directive 90/220/EEC on the 'Deliberate Release into the Environment of Genetically Modified Organisms' is the first binding piece of legislation regarding GMOs. It was approved in 1990.[15] After substantial revisions, Directive 90/220/EEC was replaced in 2001 by Directive 2001/18/EC. The aim of the new Directive was to ensure a high and uniform level of protection of human health and the environment from the deliberate release of GMOs into the environment, or their

[12] See section 4 below for more on the precautionary principle.
[13] Novel Food Regulation, Article 3.1.
[14] Executive Summary of the First Submission of the United States, *Biotech*, 30 April 2004, http://www.ustr.gov/assets/Trade_Agreements/Monitoring_Enforcement/Dispute_Settlement/WTO/Dispute_Settlement_Listings/asset_upload_file737_5542.pdf, para. 16.
[15] Council Directive 90/220/EEC

placement on the market throughout the EU while maintaining the efficient functioning of the internal market.[16]

Directive 90/220/EEC established a process for assessing and approving all GMOs (including GM crops and seeds) before they were deliberately released into the environment, including through field trials or commercial cultivation which extended to the marketing of GMOs.[17]

Directive 2002/18/EC added a procedural stage for placing GMOs on the market, which was 'tightly controlled, with precautionary measures…and highest degree of public participation' in order to accommodate public concerns.[18] Directive 2001/18/EC set up complex approval procedures and criteria requiring case-by-case evaluation involving both competent national authorities and EU bodies. It sought to balance the need for individual EU Member States to retain some decision-making control over matters of domestic concern, with the principle of harmonizing regulations throughout the EU to ensure the free movement of goods.[19]

Under the Deliberate Release Directive, a company wishing to market a GMO must first submit a notification to the competent authority of the EU Member State where the GM product to be marketed was first placed on the market.[20] This application must contain a full environmental risk assessment.[21] The competent authority then prepares an initial assessment of the product on the basis of a scientific risk

[16] Deliberate Release Directive 2001/18/EC.
[17] This not to be confused with Council Directive 90/219/EEC of the 23 April 1990 on the contained use of genetically modified micro-organisms [1990] OJ L 117/1, which was replaced with Directive 2009/41 of the European Parliament and the Council on contained use of genetically modified micro-organisms [2009] OJ L117/15. After the contained use and before placing on the market, the Deliberate Release Directive applies. It has given rise to far more political controversies. This is linked to the scope of the latter Directive that relates to teaching, research, development, and the contained non-commercial uses of GMOs.
[18] Marine Friant-Perrot, 'The European Union Regulatory Regime for Genetically Modified Organisms and its Integration intro Community Food Law and Policy' in Luc Bodiguel and Michael Cardwell, *the Regulation of Genetically Modified Organisms: Comparative approaches* (OUP, 2010), p. 84.
[19] For analysis of the complexity of EU's multi level governance see Maria Lee, 'Multi-Level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy' in Luc Bodiguel and Michael Cardwell, *the Regulation of Genetically Modified Organisms: Comparative approaches* (OUP, 2010) 101
[20] Article 9 of Directive 2001/18/EC: Member State authorities must make their decision-making processes more transparent, holding consultations and making information on all releases and reports publicly available.
[21] Directive 2001/18/EC, Article 13. Also, it is for the applicant to submit technical information indicated in Annex II.

assessment by a national food assessment body, which will take into account direct and indirect effects on human health and the environment which may arise from deliberate release or marketing of GMOs. The assessment must also consider whether these effects might be manifested immediately, cumulatively, or on a long-term basis.[22] The risk assessments and information to be considered therein were substantially changed from its predecessor, Directive 90/220/EC, as is demonstrated by the inclusion of indirect, long term effects, and even potential threats. For instance, the environmental risk assessments were to take into account scientific uncertainty, in light of the precautionary principle.[23] Within 90 days of notification, the competent authority had to prepare an assessment report in conformity with the precautionary principle as set out in article 4.[24] If the national authority was satisfied with the application, the authority informed the other EU Member States through the European Commission.[25] If within a specified time limit no objection from other Member States was received, approval was granted and the national authority had to give its written consent to the applicant for placement on the market for a maximum duration of 10 years.[26]

Any other Member State or the Commission could then present reasoned objections to the initial assessment. If the Member State and the Commission failed to settle their differences, a procedure was initiated. The Commission prepared a draft decision recommending approval or non-approval of the GM-product on the basis of an additional assessment by an EU scientific committee composed of Member States' representatives.[27] If the committee failed to reach a qualified majority, the Commission submitted the decision to the Council which then had three months to decide on the draft decision.[28] After that period the Commission could approve the decision if the Council failed to reach an agreement. [29]

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[22] Directive 2001/18/EC, Article 1.
[23] Commission Decision 2002/623/EC Establishing Guidance Notes Supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, 2002 OJ (L 200) 22.
[24] Directive 2001/18/EC, Article 14(2).
[25] Directive 2001/18/EC, Articles 14(2) and 15(2).
[26] Directive 2001/18/EC, Art 15(3). The AB which was originally notified consents in writing to placing the product on the market and may apply conditions.
[27] Directive 2001/18/EC, Articles 18(1) and 30(2).
[28] Directive 2001/18/EC, Article 30(2).
[29] Directive 2001/18/EC, Article 30(2).

The Deliberate Release Directive laid down rules for monitoring and handling new information on risks. If new information emerged, the applicant had to immediately take the necessary protective measures to inform the competent authority, possibly leading to amendment of the conditions of the consent. [30] Furthermore, the Deliberate Release Directive required that GMOs placed on the market be labelled, but subject to the *de minimise* threshold.[31]

Even if a product was approved by the Commission, Members could still institute 'safeguard measures' to prohibit marketing of the GMO in their territories. This power could only be exercised by Member States on the basis of new scientific information suggesting the GMO posed a risk to human health or the environment, and was subject to review by the Commission. On the adoption of safeguard measures, a Member State had to inform the Commission and other Member States that the advice of European Food Safety Authority (EFSA) may be sought to evaluate the information supporting the measure. It was then for the Council to decide by qualified majority.[32] There is no maximum duration for the entire procedure.

It was the applicant who had to demonstrate the safety or lack of harm for each individual product. The product was deemed to be dangerous until the interested manufacturer carried out the necessary scientific work and demonstrated its safety.[33] This authorisation procedure was in accordance with the precautionary principle,[34] as '[t]he level of appropriate health and environmental protection chosen in the directive is a level of "no risk".' This procedure conferred considerable powers on EU Member States.[35]

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[30] Directive 2001/18/EC, Article 20.
[31] Directive 2001/18/EC, Article 21. The threshold was subsequently fixed at 0.9 per cent under Regulation 1830/2003. See section 2.3 below.
[32] Directive 2001/18/EC, Article 23.
[33] Simonetta Zarrilli , *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks*, (Policy Issues in International Trade and Commodities Study Series No.29, UNCTD, UN – New York and Geneva, 2005) p. 10.
[34] The precautionary principle is noted in Articles 1 and 4, and paragraph 8 of the preamble of Directive 2001/18/EC. EU treaties recognise that environmental policy is to be based on the precautionary principle. See section 4 below on the precautionary principle.
[35] Marine Friant-Perrot, 'The European Union Regulatory Regime for Genetically Modified Organisms and its Integration intro Community Food Law and Policy' (n 18). p.86

Deliberate Release Directive does not cover products derived from GMOs. Instead, Regulation 258/97/EC on **'Novel Foods and Novel Food Ingredients'**[36] covered products derived from GMOs but no longer containing any genetic material, like tomato paste or ketchup derived from GM tomatoes, oil from GM corn, and sugar from sugar beet. The Regulation became the specific measure governing GMOs destined for food use.[37]

The novel foods Regulation also addressed GM food safety issues, establishing an approval process based on risk assessment for novel foods, including those containing GMOs before they are placed on the market. While this process replicated the Deliberate Release Directive, a key difference was that a second more streamlined and 'simplified procedure' applied to GM foods and food ingredients that were 'substantially equivalent' to existing foods. The second procedure consisted of a notification requirement.[38]

In order to receive market approval, GMOs must not 'present a danger for the consumer', must not 'mislead the consumer', and must 'differ from the foods that they are intended to replace to such an extent' for them to be 'nutritionally disadvantageous for the consumer.'[39] This was determined by an initial assessment made by a Member State Food Assessment Body,[40] which followed a formal request from an applicant to place a GM product on the market. This request had to provide information demonstrating the product met the three criteria above mentioned. The applicant was also obliged to carry out a full health and environmental risk assessment.[41]

The Novel Foods Regulation required labelling of novel food products containing or consisting of GM ingredients, or had been produced from GMOs. It also created

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[36] The Novel Food Regulation remains in effect for the placing in the market of 'novel food' other than those produced from GMOs.

[37] It also covers enzymes produced from bacteria and yeasts used as processing aids. See Marine Friant-Perrot, 'The European Union Regulatory Regime for Genetically Modified Organisms and its Integration intro Community Food Law and Policy' (n 18) p. 88.

[38] Novel Food Regulation, Articles 3(4) and 5. See also, Simonetta Zarrilli, *National and Multilateral Legal Frameworks*, (n 33) p. 9-10.

[39] Regulation (EC) No. 258/97, Article 3(1).

[40] Regulation (EC) No. 258/97, Article 6(2).

[41] Brian Sheridan, *EU Biotechnology Law & Practice: Regulating Genetically Modified & Novel Food Products* (Palladian Law Publishing 2001), pp. 132-141.

a more simplified approval procedure for food products that were 'derived from GMOs' but did not contain GMOs, such as highly refined soy oil or corn syrup. A food 'derived from GMOs' could be brought to the market as long as the developer had a scientific basis for determining that the product was 'substantially equivalent' to existing foods, notified the Commission, and delivered an opinion to the same effect from competent authorities of a Member State.[42] A number of food products 'derived from' GM crops, such as cooking oils, were introduced into the EU market as 'substantially equivalent' to conventionally-produced products under the Novel Food Regulation 258/97/EC.[43]

Before 1998, fourteen GM plants, including eleven crops, had been approved for release or marketing under previous Directive 90/220/EEC. They included a number of crops, mainly a few varieties of maize, oilseed rape, carnation, one variety of chicory, one variety of soybean, and one variety of tobacco.[44] These GM crops were approved for different uses: cultivation, import and processing, and food and feed.[45] An additional thirteen applications for approval received favourable opinions from the Scientific Committee on Plants, and were pending authorization at the time that the new Directive 2001/18/EC took effect. These applications included five varieties of maize/sweet maize, three varieties of oilseed rape, two varieties of cotton, one variety of chicory, and one variety of potato.[46]

However, shortly after implementation of the Deliberate Release Directive, EU Member States decided that it should be amended in light of the considerable advances in genetic modification in the 1990's. This point was clearly raised in the EU's first submission during the *Biotech* dispute. The change in the legislation was

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[42] Brian Sheridan, *EU Biotechnology Law* (n 41) pp. 143-6.
[43] European Commission, 'summary of Applications under Regulation (EC) N° 258/97 of the European Parliament and of the Council' (18 April 2004). http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf accessed 30 March 2010.
[44] As of March 2001 the total number of GMOs approved under this Directive is eighteen. 'GMOs approved under Directive 90/220/EEC As of March 2001', http://ec.europa.eu/environment/archives/biotechnology/authorised_prod_1.htm. Accessed Nov 2012.
[45] 'US vs EU: An Examination of the Trade Issues Surrounding Genetically Modified Food' Pew Initiative on Food and Biotechnology (December 2005), pp. 40-45, http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Biotech_USEU1205.pdf. Accessed 3 February 2009.
[46] Ibid pp. 40-45. Some of these applications were resubmitted for consideration under Directive 2001/18/EC.

due to increased scientific knowledge regarding the risks of GMOs, and international regulatory developments, including the entry into force of the Cartagena Protocol.[47]

The EU Regulation covering GMOs reflects debates over risk regulation.[48] The next section provides details of the EU's measures challenged in the *Biotech* dispute, and explains the reasons behind the challenges.

2.2 The '*de facto*' moratorium; 'product specific delays' and national bans

There were two serious public health scares in the mid 1990s: the contaminated blood affair in France; and bovine spongiform encephalopathy, known as 'BSE', in England and latter in the rest of the EU.[49] The EU experienced popular and high profile campaigns. In the UK and France protestors destroyed GM crops, triggering wide media coverage of scientific uncertainty about the effects of GMOs. A number of EU Member States stressed that the EU regulatory framework was inadequate, particularly with regard to risk assessment, labelling, post market traceability, and monitoring.[50] Member States also claimed that the regulatory framework was lacking with respect to the coexistence of GM crops with conventional and organic farming.[51]

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[47] First Written Submission o the European Communities, pp 7-20.
[48] It also experienced similar debates over nuclear energy, salmonella in egg, and mad cow disease see Maria Lee, *EU Environmental Law: Challenges, Change and Decision – Making* (Hart Publishing, Oxford and Portland, Oregon, 2005), p. 79.
[49] See section 2.4 below.
[50] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed. [2003] Official Journal L 268/1; Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and amending Directive 2001/18/EC. [2003] Official Journal L 268/24. [hereinafter 'Traceability and Labelling Regultion']; *Farm to Fork: Safe Food for Europe's Consumers* (n 1).
[51] Coexistence refers to the choice of consumers and farmers between conventional, organic and GM crop production, in compliance with the legal obligations for labelling defined in Community legislation. The possibility of adventitious presence of GM crops in non-GM crops cannot be excluded. Therefore, suitable measures are needed during cultivation, harvest, transport, storage, and processing to ensure coexistence. See European Commission 'Coexistence of genetically modified crops with conventional and organic agriculture', http://ec.europa.eu/agriculture/coexistence/index_en.htm accessed 25 July 2011.

This contributed to make EU politicians and regulators extremely cautious with regard to GMOs.[52] The European Commission published 'White Paper on Food Safety', which called for the adoption of legislation to cover assessment, authorisation, and labelling in the case of novel food for animals. It also proposed improvements to the authorisation procedure under the Novel Food Regulation, suggesting adoption of a single assessment for all ingredients in food stuff and harmonisation of measures governing the labelling of food, additives, and flavourings containing GMOs or derived from GMOs.[53]

As a result of those concerns, as well as in reaction to rapid developments in the scientific and regulatory fronts, and to the negotiations on the Cartagena Protocol on Biosafety between October 1998 and 19 July 2004, no new GMOs were authorised for planting or use in the EU.[54] This situation has been referred to as a '*de facto'* moratorium. It was made 'official' at an EU Environment Ministers Council meeting in June 1999 when five Member States - Denmark, France, Greece, Italy, and Luxembourg - declared that they were opposed to further authorisations, and invoked the 'safeguard clause' of Directive 90/220/EEC in 1998.[55] The clause allowed Member States to rely on the precautionary principle to provisionally restrict or prohibit the use of a GM-product on its territory if, 'as a result of new information', or a 'reassessment of existing information on the basis of new or additional scientific knowledge', it had grounds to believe that the GM-product endangered human health or the environment.[56] This stalled evaluations of further applications.

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[52] David Vogel and Olivier Cadot, 'France, the United States, and the Biotechnology Dispute' *Brookings* (4 June 2008), http://www.brookings.edu/research/articles/2001/01/01france-cadot. Accessed 9 June 2009.
[53] European Commission, White Paper on Food Safety, COM (1999) 719.
[54] First Written Submission of the European Communities, pp 24 -51.
[55] 2194th Council Meeting 24/25 June 1999: *Declaration by the Danish, Greek French, Italian, and Luxemburg Delegations concerning the suspension of New GMO Authorisation*. This declaration was followed by another similar declaration with a similar emphasis. 2194th Council Meeting 24/25 June 1999: *Declaration by Austrian, Belgian, finish, German, Netherlands, Spanish and Swedish Delegations.* This secured a majority in the council.
[56] Article 16 states 'where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the European Commission and the other Member States of such action and give reasons for its decision'.

Following the revision of the Deliberate Release Directive regulating the release of GMOs into the environment (Directive 2001/18/EC), these five countries, subsequently joined by Austria, again declared that they would not lift the moratorium until issues like 'traceability' and 'labelling', and rules on coexistence to protect conventional and organic farming from GM contamination were resolved.[57] Again, they maintained that Article 12 of Regulation 258/97 and Article 23 of Directive 2001/18 allowed Member States to invoke 'safeguard' measures to justify national bans on some GM crops that have received European-level approval.[58]

Additionally, supermarket chains responded to low consumer acceptance of GMOs by announcing their own policies for labelling their own products to avoid the sale of meat from animals fed GM cereals or oilseed products. This was an attempt to maintain consumer trust, even if it compromised their access to low cost supply sources.[59]

The *de facto* moratorium on GM approvals was not lifted until the conclusion of the political process that produced the new Directive 2001/18/EC which took effect in 2001, and with the later entry into force in April 2004 of Regulation 1829/2003/EC on Genetically Modified Food and Feed,[60] and by Regulation 1830/2003/EC on labelling and traceability of genetically modified organisms.[61] The Complainants in the *Biotech* dispute maintained that the *de facto* moratorium led to delays in the final approval of specific notifications. They also argued that this 'product specific moratorium' existed with regard to 27 GM products notified

[57] Article 12 of Regulation (EC) 258/97 and Article 23 of Directive 2001/18/EC authorize a Member State, See 'Protecting People's Health and the Environment: Is the EU Guilty?', http://www.citizen.org/trade/wto/agriculture/gmo/articles.cfm?ID=11052; and 'US vs EU: An Examination of the Trade Issues' Pew Initiative on Food and Biotechnology (n 45) p.10.

[58] Under Article 23 of Directive 2001/18/EC. There is a distinction between the types of safeguard measures used. Austria, Germany, Italy and Luxembourg use safeguard measures to prohibit the marketing of particular GM corn products, while the French and Greek measures prohibit the marketing and import of canola. See generally EU First Submission, pp. 339–361.

[59] Supermarkets' anti GMOs marketing increased calls for labelling. See Tim Josling et al., *Food Regulation and Trade: Towards a Safe and pen Global System* (Institute for International Economics Washington DC, 2004), p. 163; and Maria Lee, *EU Regulation of GMOs* (n 8) p. 8.

[60] Food and Feed Regulation

[61] Traceability and Labelling Regulation; Also see section 2.4 below for discussion regards the moratorium.

for approval.[62] In this period, the Commission stopped pushing GMOs through the authorisation process.

The EU never denied these delays in approvals, although it asserted that they were all due to legitimate reasons. According to the EU, requests for additional information from the applicants, or the drafting of new legislation constituted legitimate reasons for WTO Members to prolong approval procedures.[63] The Commission worked with the Member States and others to renegotiate the regulatory framework that applied to GMOs, completely replacing and strengthening the EU's legislative framework.[64]

In *Biotech*, the Panel found that EU 'product specific moratorium' violated Article 8 and Annex C (a) of the SPS Agreement by allowing unnecessary delays in the approval of **two** of the **twenty seven** products specified by the complaining parties.[65] The *Biotech* Panel's recommendations requested that the EU bring the relevant 'product specific measures' into conformity with its obligations under the SPS Agreement, and that it bring the safeguard measures into conformity with its SPS obligations under the SPS Agreement. In other words, the Panel wanted the EU to complete the approval process for the outstanding applications, and to either revoke the safeguard measures or justify them on scientific grounds under the SPS treaty.

Following the implementation of the new Regulations the moratorium on authorisation of GMOs and GM food was lifted. A year after the initiation of the WTO *Biotech* dispute, on 28 of January 2004, the European Commission approved a proposal to authorise import of Syngenta's GM canned sweet corn (Bt-11) for use in food under the newly adopted legislation.[66] A number of additional GMOs have

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[62] The US alleges that 18 notifications for placing GM products on the market have been delayed under Directive 90/220/EEC (and then resubmitted under Directive 2001/18/EC), and that nine applications under Regulation 258/97 have been delayed: First Written Submission of the US, pp. 48–55. Canada alleges four such delays: First Written Submission of the Canadian, pp. 68–94.
[63] First Written Submission of the European Communities, pp. 147-150.
[64] Maria Lee, *EU Regulation of GMOs* (n 8) p. 3.
[65] Panel Reportss, *Biotech*, p. 845. The Panel recommended the EU bring it into conformity with its obligations under the SPS Agreement.pp.1072-1078.
[66] First Written Submission of the European Communities, p. 100; See 'Europe Takes First Step Towards Removing De Facto Ban' 8(3) Bridges Weekly Trade News Digest, 28 January 2004, http://ictsd.org/i/news/bridgesweekly/6975/. Accessed 3 June 2006.

been authorised by the Commission since the lifting of the moratorium. A few months later, in July 2004, the Commission also approved a Monsanto GM Roundup Ready maize variety (NK 603) for human and animal consumption, but not for planting. In August 2005, the Commission approved the import of Monsanto GM maize (MON 863) for animal feed, but not for cultivation or food use in accordance with Directive 2001/18//EC.[67] The EU therefore argued in *Biotech* that the *de facto* moratorium ceased to exist, citing theses authorisations as evidence.

The European Commission has been a strong supporter of GM crops despite a lack of popular support from EU citizens. It has also pushed for the approval of several GM crops despite disagreement between the between EU Member States. In each of these cases, the Commission acted to approve the applications after the Council failed to approve or reject the Commission's proposed action by a qualified majority vote.[68]

The *Biotech* Panel condemned not only the *de facto* moratorium, extensive delays, but also **national bans**, rejecting the EU's defence of the precautionary principle, as it found a satisfactory risk assessment could be carried out and deemed the measures were not justified, even under Article 5.7 of the SPS Agreement.[69]

The Commission and the EFSA reviewed the information provided by Member States to justify their bans. In April, 2005, it informed France, Austria, Luxembourg, Germany, and Greece that they lacked scientific justification for those bans, and would therefore face legal action by the Commission. In June 2005, however, the Commission recommendation to force the lifting of the national bans was rejected by a qualified majority of the Environment Ministers Council, leaving the national bans in place.[70]

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[67] To date, nine GMOs have been placed on the market in accordance with the Deliberate Release Directive see 'Deliberate Release of Genetically Modified Organisms', Summaries of EU legislation http://europa.eu/legislation_summaries/agriculture/food/l28130_en.htm.

[68] Knowing that if the Member States cannot reach agreement on Authorisation in 90 days, the European Commission allowed granting the authorisation on its own initiative.

[69] The EU's obligations under the WTO not to negatively discriminate or impose trade restrictions on imports, except under certain circumstances.

[70] FoE International, 'Looking behind the US spin: WTO ruling does not prevent countries from restricting or banning GMOs' FoE International, Briefing Paper, February 2006 www.foeeurope.org/publications/2005/alternatives-wto.pdf accessed November 2006 accessed 12 June 2010.

The European Commission then sent ten Member States a letter of formal notice '*mise en demeure'* because it was believed they had not implemented Directive 2001/18/EC in time. Pursuant to Article 260 of the Treaty on the Functioning of the European Union (TFEU), it brought enforcement proceedings against some Member States in the Court of Justice of European Union (CJEU) for breaching of treaty obligations.[71] On 9 December 2008, the EUCJ in *Commission v France*, ordered France to pay a lump sum as a penalty for the delay in complying with a previous judgment, which established France's failure to fulfil obligations relating to the transposition of the Directive on genetically modified organisms.[72] Another case was in 2009 which was brought by the Commission against Poland for imposing a general ban on placing GMOs on the market based on ethical and religious reasons.[73] Another case which is worth mentioning was the case concerning unsuccessful challenge by Austria of the Commission's decision to disallow the Austrian province's ban on GMOs in order to protect nature as well as organic farming interests.[74]

Despite the new EU legislation, GMOs remain unpopular in many parts of Europe, and national politicians have acted to assert independence and autonomy over GM crops and foods. Six countries (Austria, France, Germany, Hungry, Greece, and Luxembourg) are currently blocking or temporarily restricting the use and/or sale of five GMO varieties (three modified maize varieties and two types of oilseed rape) that were previously approved by the Commission by invoking the 'safeguard clause' on their territory.[75]

2.3 The single authorisation procedure

During the moratorium, EU GMO regulation was complemented by two more instruments: Regulation 1829/2003/EC of the European Parliament and of the

[71] (ex Article 228 EC)

[72] In Case C-121/07, *Commission of the European Communities v. France* 2008 E.C.R. I - 9159, the Court imposed a fine upon France for failure to implement Directive 2001/18/EC

[73] Case C-165/08 *Commission of the European Communities v Republic of Poland* OJ C 183, 19 July 2008.

[74] Joined cases C-439/05P and C-454/05P, Land Oberösterreich and Republic of Austria v. Commission of the European Communities [2007] ECR I-7441, 64

[75] Under Art. 23 Dir. 2001/18/EC. See a list of Safeguards, http://ec.europa.eu/food/plant/gmo/safeguards/index_en.htm accessed 15 June 2010.

Council on Genetically Modified Food and Feed (hereinafter 'Food and Feed Regulation'),[76] and by Regulation 1830/2003/EC European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms (hereinafter 'Traceability and Labelling Regulation').[77] The European Commission explained that the aim of the new regulations was to 'develop proactive policies to exploit them in a responsible manner, consistent with European values and standards',[78] to protect human and animal health through stringent safety assessment of GM food and feed before it can be sold, to ensure common procedures for risk assessment and authorisation are efficient, transparent and do not take too long, and to ensure clear labelling that responds to the concerns of consumers (including farmers buying feed) and enables them to make informed choices.[79]

The Food and Feed Regulation replaced the authorisation for GM foods and food ingredients previously covered by the Novel Food Regulation (Reg. 258/97/EC). Its objective is to provide a high level of protection to human life and health, the environment, and the interests of consumer in relation to GM food and feed, whilst ensuring the effective working of the internal market.[80]

The new Regulation introduced a single centralised authorisation procedure for placing GMOs used as food or animal feed, or products containing or consisting of GMOs on the market.[81] The applicant may file single notification for the GMO food and feed consisting of, containing, or produced from GMOs. All intended uses (cultivation, importation, and processing) are covered under the Regulation, in

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[76] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. [2003] OJ L268/1. It came into force on 18 April 2004.
[77] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms [2003] OJ L268/24.
[78] European Commission, 'Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions: Life Science and Biotechnology- a Strategy for Europe' COM (2002)27 [2002] OJ C55/3, para. 1.
[79] European Commission, 'Existing rules on GM food and animal feed', http://ec.europa.eu/food/plant/gmo/legislation/gm_food_animal_feed_en.htm. Accessed 7 November 2012.
[80] Article 1. Another two objectives are listed: to establish Community procedures for assessment, authorisation, and supervision of GM food and feed; and to establish provisions for the labelling of GM food and feed.
[81] See European Commission 'Questions and Answers on the regulation of GMOs in the EU', (MEMO/06/58, 22 June 2006) http://europa.eu.int/ accessed 1 October 2009.

accordance with the 'one door, one key' principle.[82] This means that those wishing to market GM crops in the EU need not request separate authorisations for the use of the crop as food or feed; in the EU a crop is either authorised for both uses, or for neither.[83] This single authorisation also applies to GMOs that fall under the scope of the deliberate Release Directive and the Food and Feed Regulation.[84]

An application first goes to the Member State where the marketing of the product is sought. A scientific risk assessment is then carried out by a single agency, the European Food Safety Authority.[85] Its opinion will be made available to the public, and the public will have the opportunity to make comments.[86] On the basis of risk assessment by EFSA and other legitimate factors relevant to the matter under consideration,[87] the Commission drafts a proposal for granting or denying the authorization.[88] If it disagrees with the EFSA opinion, it must justify its position.

The Commission's draft proposal is submitted for approval by a qualified majority of the 27 representatives of Member States within the Committee on the Food Chain and Animal Health. If the Committee approves it, the Commission then adopts the decision. If not, the draft decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council fails to act, or fails to muster a qualified majority to accept or reject the proposal, the Commission then adopts the decision. The authorisation should be granted for a period of 10 years, subject, where appropriate, to a post-market monitoring plan.[89]

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[82]European Commission 'European legislative framework for GMOs is now in place' (Press Release, IP/03/1056, 22 July 2003) http://europa.eu.int/ accessed 1 October 2009

[83] Article 5. One of the reasons for this approach is to prevent controversies such as those caused by the Bt maize variety StarLinkTM. StarLinkTM, produced by the company Aventis, received regulatory approval from the US Environmental Protection Agency (EPA) to be used as animal feed only. However, in 2000, traces of StarLinkTM were found in taco shells which were sold in American supermarkets.

[84] Subject to environmental risk assessment under the Deliberate Release Directive. Or, alternatively, two separate applications filed under the two regulations. Maria Lee, *EU Regulation of GMOs* (n 8) p. 65.

[85] Food and Feed Regulation Articles 5(3) and 17(3). The Food and Feed Regulation centralized authorization of GMOs in the Food Safety Authority (EFSA), which is responsible for the scientific assessment of genetically modified food and feed.

[86] Food and Feed Regulation, Articles 5(2) and 17(2) (b).

[87] Articles 7(1) and 19(1).

[88] Article 6. As well as a single management process.

[89] Food and Feed Regulation Articles 7(5) and 19(5). Authorisations are renewable for 10-year periods. See 'European legislative framework for GMOs is now in place' IP/03/1056 (n 82).

The Regulation expanded the scope of product coverage. First, in addition to food for human consumption, the Regulation's authorization and labelling requirements extended to GM animal feed for the first time. Second, the regulation covered food and feed that do not contain or consist of GMOs, but nonetheless are derived, in whole or in part, from GMOs' or contain ingredients that are 'derived, in whole or in part, from GMOs.' [90] The process or production method of GM food or feed became a relevant factor that justifies labelling. The Regulation abandoned the notification procedure for novel foods considered 'substantially equivalent' to existing foods[91] on the basis that 'whilst substantial equivalence is a key step in the procedure for assessment for the procedure for assessment of the safety of genetically modified foods, it is not safety assessment itself'.[92]

The Food and Feed Regulation includes specific provisions for their labelling.[93] Labelling is required for foods that are delivered as such to the final consumer or mass caterers in the Community, and which contain or consist of GMOs, or are produced from or contain ingredients produced from GMOs. The labelling requirements are applied irrespective of the deducibility of DNA or protein resulting from the genetic modification in the final product. In effect, the Food and Feed Regulation allows consumers to exercise their freedom of choice. The label must include language such as 'This product contains genetically modified organisms' or '... produced from genetically modified (name of organism)'.[94] However, no labelling is required for foods or feed with ingredients containing less than 0.9% GM material, provided the presence of GM material is adventitious or technically unavoidable.[95] The Regulation does not cover all food or food ingredients. Excluded products include highly refined soya or maize oil, milk and meat obtained from animals fed with GM crops, and food and animal feed made

[90] See Articles 2.10 and 3.1 (defining the scope of coverage). See also Marine Friant-Perrot, 'The European Union Regulatory Regime for Genetically Modified Organisms and its Integration intro Community Food Law and Policy' (n 18), p. 89.
[91] Ibid, p. 89.
[92] Food and Feed Regulation, Recital 6
[93] Food and Feed Regulation, Articles 12 and 24.
[94] Food and Feed Regulation, Article 13; and also required under the Traceability and Labelling Regulation, Article 4(6).
[95] Food and Feed Regulation, Articles 12(2) and 24(2); Traceability and Labelling Regulation, Article 4(7). See also Simonetta Zarrilli , *National and Multilateral Legal Frameworks*, (n 33) p. 12.

'with' a GMO, for example GM enzymes used in cheese production. [96] The regulations also required animal feed to be labelled along the same principles as for GM food.[97] The use of GMOs in animal feed did not previously require a specific authorisation procedure. The Regulation will thus impact imported GM crops, which are predominantly used as feed for animals.

Under Regulation 1830/2003/EC, the Traceability and Labelling Regulation, which entered into force on 18 April 2004, products containing GMOs could be traced and recalled if necessary. Labelling required by the Regulation ensured consumers would know when they were buying a GM product. [98] The Traceability and Labelling Regulation applied to products placed on the market under EU legislation that consisted of or contained GMOs, or food or feed produced from GMOs.[99] The Regulation's key objective was to guarantee reliable information to consumers.[100] Traceability is defined as 'the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market.'[101] Producers, processors and distributors using or handling GM products were required to transmit and retain, for five years, information at each stage of placing products on the market. GMOs were assigned a code, which was to be passed in writing to operators involved.[102] Similarly, farmers who buy GM seed were required to transmit relevant information to those who buy their harvest, and to keep a register of recipients. In the case of food and feed produced from GM crops, the process was repeated throughout the production and distribution chain in accordance with the precautionary principle.[103] Traceability is regarded as a safety net in case of unforeseen effects on human health, animal health or the environment. Traceability ensures all foodstuff, feed and feed ingredients can be traced through the food chain from the 'farm to the fork' in order

[96] Article 3(1)(c); Lissa Carson & Robert Lee 'Consumer Sovereignty and the regulatory History of the European market for Genetically Modified Foods' (2005) Enviro LR 7(3), p. 181-82.
[97] In accordance with Articles 24 and 25 of the Food and Feed Regulation.
[98] *Farm to Fork: Safe Food for Europe's Consumers* (n 1).p 5
[99] Which have been authorized under the Deliberate Release Directive (section C) or under the Food and Feed Regulation. See Traceability and Labelling Regulation, Article 2.
[100] Traceability and Labelling Regulation, Preambular paragraph 11.
[101] Traceability and Labelling Regulation, Article 3.
[102] Traceability and Labelling Regulation, Articles 4 and 5.
[103] Traceability and Labelling Regulation, Preambular paragraph 3.

to facilitate a withdrawal of food and feed from the market if any unexpected adverse effects were to arise.[104]

Linking access to information with the precautionary approach to the enactment of legislation, demonstrates the importance of ensuring freedom of choice for consumers where science is uncertain.[105] For this reason, some NGOs are still critical of the Regulation as it does not require labelling of products, such as medical products for human or veterinary use, animal products such as meat, milk and eggs that come from animals fed GMOs, non-food derivatives like cotton and tobacco, and food produced with the help of a GM enzyme, such as bakery products involving use of amylase.[106]

The Regulation expanded labelling requirements significantly while also mandating traceability, or the ability to track a GM product from the farm through all phases of distribution in accordance with Regulation 178/2002/EC of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety [2002] OJ L31/1 (Hereinafter **'Food Law Regulation'**). This Regulation provides for an integrated approach towards food policy in the EU, and clearly applies to GM food production.[107]

According to the European Commission, the central goal of food safety policy is 'to ensure a high level of protection of human health and consumers' interests in relation to food, taking into account diversity, including traditional products, whilst ensuring the effective functioning of the internal market.'[108] The Commission's guiding principle, primarily set out in its White Paper on food safety, is the application of an integrated approach from farm to table, covering all sectors of the

[104] Articles 3(3)-3(5). *Farm to Fork: Safe Food for Europe's Consumers* (n 1) pp. 5, and 11.
[105] Marine Friant-Perrot, 'The European Union Regulatory Regime for Genetically Modified Organisms and its Integration intro Community Food Law and Policy'(n 18) pp. 97 and 99.
[106] See GMO Compass 'GMO labelling guidelines: these products do not require labelling' http://www.gmo-compass.org/eng/regulation/labelling/88.gmo_labelling_these_products_require.html accessed 4 September 2010.
[107] For more on the subject see Maria Lee, *EU Regulation of GMOs* (n 8) Chapter 4.
[108] DG Health Commission 'Genetically Modified Food and Feed' http://ec.europa.eu/food/food/biotechnology/index_en.htm. Accessed 15 November 2012.

food chain, including feed production, primary production, food processing, storage, transport, and retail sale.[109]

The European Commission used the controversy surrounding the science of GMOs to justify their regulations. They acknowledge both the benefits and risks of biotechnology. However, it emphasised that risks must be properly assessed and managed: 'EU legislation on the approval of biotech products requires all new products to be thoroughly tested to. So we have developed the precautionary principle which is now incorporated in most EU policy on environmental and health protection (is not about purely hypothetical hazards).'[110]

Article 7 of the Food Safety Regulation expressly refers to the precautionary principle. Additionally, the Commission may adopt emergency measures under Article 34 of the Food and Feed Regulation where it is evident that products which have been authorised are likely to constitute a serious risk to human health, animal health, or the environment. A Member State may adopt an interim protective measure, if it has informed the Commission subsequent to its failure to act.[111]

In sum, the current EU rules stem from the Deliberate Release Directive, the GM Food and Feed Regulation, and the Labelling and Traceability Regulation.[112] They aim to protect not only the environment, but also public health and consumer considerations.[113] The rules are grounded in the precautionary principle and centralised authorisation procedure, which is based on the protection of the environment and public health. They allow evaluation, tracing, and monitoring of GM production from 'farm to fork'. Once a GM food is placed on the market, it must be labelled and traceable at all times in order to keep consumers informed about their choices.[114]

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[109] Commission of the European Communities, White Paper on Food Safety, COM (1999) 719 final (12 Jan 2000). [hereinafter White Paper].
[110] Speech by EU Trade Commissioner Peter Mandelson: 'Biotechnology and the EU' (n 6).
[111] Food Law Regulation, Articles 53 and 54.
[112] See European Commission, 'Existing rules on GM food and animal feed' (n 79).
[113] Marine Friant-Perrot, 'The European Union Regulatory Regime for Genetically Modified Organisms and its Integration intro Community Food Law and Policy' (n 18) p. 100.
[114] *Farm to Fork: Safe Food for Europe's Consumers* (n 1).

The European Commission stressed that 'because new foods and new production methods are emerging all the time, the EU constantly evaluates and re-evaluates the risks posed by new food-stuff.'[115] The creation of the EFSA as an independent agency in 2002 sought to provide EU decision-makers with scientific advice in a more efficient and transparent way than previous efforts.[116] The EFSA's constitution emphasises scientific excellence and the independence of science from political and industry influence. It also aims to increase consumers' confidence in GMOs.[117] Meeting public concerns in such a manner can also contribute to the political legitimacy and popular relevance of the EU.[118]

The single authorisation procedure subjects EFSA to multiple obligations of consultation, networking, and dialogue with national authorities. This is due to the inherent complexity of decision making and hierarchy within the EU, and complex interaction between central and national experts, where the EU remains far from speaking with one voice on agricultural technology. The authorisation of GMOs thus attempts 'to tread a delicate path between National and central authorisation and between reaping the benefits and protecting public interests, as well as between scientific and political understanding.' [119]

Since the US did not challenge all of the EU's legal framework in the *Biotech* dispute, the EU remains confident that its current regulatory regime over GMOs and GM food and feed is fully compatible with its international commitments including those under the WTO.[120]

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[115] *Farm to Fork: Safe Food for Europe's Consumers* (n 1).
[116] EFSA is responsible for all scientific aspects of food and feed production, processing and marketing its work not only covers GMOs but also a wide field including nutrition, animal health, animal welfare and plant health. see *Farm to Fork: Safe Food for Europe's Consumers* (n 1).
[117] Alessandro Nucara, Precautionary Principle and GMOs: Protection or Protechtionism, 9(2) Int. T. L.R. 2003, 48.
[118] Maria Lee, *EU Regulation of GMOs* (n 8) p. 62.
[119] Ibid, pp. 68 and 102. See also Maria Lee, 'Multi-level Governance of Genetically Modified Organisms in the European Union: ambiguity and hierarchy' (n 19) p. 101.
[120] See European Commission 'Europe's rules on GMOs and the WTO' Press Release, MEMO/06/61 (Brussels 07 Feb 2006), http://europa.eu/rapid/press-release_MEMO-06-61_en.htm. Accessed 12 September 2008. Speech by EU Trade Commissioner Peter Mandelson: 'Biotechnology and the EU' (n 6).

2.4 Behind the scene: motives of EU - US clash

The EU legislation on GMOs has been in place since the early 1990s. At the time, it had two main objectives: to protect human health and the environment, and to ensure the free movement of safe genetically modified products in the EU.[121] When EU standards for the commercial authorization and approval of agricultural biotechnology were first issued in 1990, they did not differ substantially from those of the United States.[122]

Several regulatory failures and food crises led to increased public and political support for more stringent protective regulation of GM crops. Food has also been strongly influenced as these failures and crises increased 'the political salience of regulatory issues and undermined public confidence in the ability of national or EU regulatory official to adequately protect their health, safety and environment.'[123] As '[w]idespread media coverage of anti-GM activists helped move the issue of GM foods quickly to the forefront of political debate in Europe,' many consumers in the EU lost trust in science, and demanded higher levels of protection in the form of product bans or labelling.[124] Almost overnight political opposition to GM seeds and products began to surface, and in 1996 European regulatory policy transformed.[125]

The most important EU failure involved Bovine Spongiform Encephalopathy (BSE), a disease spread among cattle through their consumption of contaminated feed. Also known as 'mad cow disease', BSE is a lethal disease, which if transmitted through meat consumption may cause a related disease in humans. When the first BSE cases were discovered, the British government denied the

[121] See European Commission 'Questions and Answers on the regulation of GMOs in the EU' MEMO/06/58 (n 81).
[122] David Vogel, 'The New Politics of Risk Regulation in Europe' (2001) CARR Discussion paper no 3, LSE London, pp. 3-4, http://eprints.lse.ac.uk/35984/1/Disspaper3.pdf . Accessed June 2008; and David Vogel, 'The Politics of Risk Regulation in Europe and the United States', manuscript for publication in (2003) 3 Yearbook of European Environmental Law. pp.15-23
[123] David Vogel, 'The Politics of Risk Regulation in Europe and the United States' (n 122) pp.24-34
[124] Cinnamon Carlarne, 'From the USA with Love: Sharing Home-Grown Hormones, GMOs, and Clones with reluctant Europe' (30 April 2007) 37(2) Environmental Law 305.
[125] Increased representation of the Green Party in Member State parliaments and cabinets, as well as in the European Parliament, ensured that these concerns would be reflected in national and European politics, 'US vs EU: An Examination of the Trade Issues' Pew Initiative on Food and Biotechnology (n 45) p. 10.

connection between the disease and risks to human health.[126] The initial risk assessments of BSE were based on scientific information incorrectly thought to be sufficient at the time. This failure to recognise the health hazards of eating meat from BSE diagnosed cattle had a severe negative impact on the public.[127] The failure undermined public trust in EU food safety regulation, as well as the scientific expertise on which it was based. It has also significantly affected the attitude of the European public towards the potential threat caused by artificial hormones in American beef, and latter in GM food.[128]

A second major food scandal occurred when the public discovered that Belgian farm animals had been fed dioxin-contaminated feed. This resulted in the removal of Belgian chicken, eggs, pork, and beef from the EU market, and led to the fall of the Christian Democratic government of Jean-Luc Dehaene.[129] Other food safety scares arose, including the possible contamination of Coca-Cola products in northern Europe, and a French admission that sewage sludge containing human and animal wastes was found in feed destined for pigs and chickens.[130]

According to Vogel, BSE failure had two important political consequences. First, it increased sensitivity to new technologies in the food supply industry and shifted attention from the safety of end product to a focus on the entire process of food production. Second, it highlighted the inability of EU institutions to assure the safety of food and products produced and sold anywhere within the single market.[131] This increased pressure on the EU to adopt stricter and more extensive rules and regulation since a regulatory failure in any Member State endangers the single market as a whole.

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[126] Laylah Zurek, 'The European Communities Biotech Dispute: How the WTO Fails to Consider Cultural Factors in the Genetically Modified Food Debate' 42 Tex Int'l L J, p. 358.
[127] Ibid, p. 358.
[128] Gregory C. Shaffer and Mark A. Pollack, 'Regulating Between National Fears and Global Disciplines: Agricultural Biotechnology in the EU', Jean Monnet Working Paper 10/04, NYU School of Law, New York, NY 10012, USA, 2004. A shorter, edited version of this paper appears in Helen Wallace, William Wallace, and Mark A. Pollack, eds., *Policy-Making in the European Union* (New York: Oxford University Press, 2005), p. 11.
[129] Maria Lee, *EU Regulation of GMOs* (n 8) p. 5.
[130] Gregory C. Shaffer & Mark A. Pollack, (2004) 'Regulating Between National Fears and Global Disciplines: Agricultural Biotechnology in the EU' (n 128) pp.16-20.
[131] David Vogel, 'The Politics of Risk Regulation in Europe and the United States' (n 122) pp.26-27; Nigel Williams, 'Plant Genetics: Agricultural Biotech Faces Backlash in Europe' *Science*, 7 August. 1998, 768-71.

EU legislation, therefore, established a distinctive and complex set of new regulatory requirements that apply only to this new agricultural technology, while the US has chosen to regulate both GM foods and seeds under existing laws.[132] EU policy in this area is predominantly regulatory in character, creating an increasingly detailed regulatory framework within which genetically modified foods and crops may be developed, introduced into the environment, and work their way into the food supply.[133]

On the other side of the Atlantic, the absence of major regulatory failures explains the degree of public acceptance of GMO's. Americans are more trusting of their government to adequately protect public health and the environment. In addition, businesses became more politically effective, which played a role in shaping American opposition to some multilateral environmental agreements such the Biosafety Protocol. Since 1994, American NGO's have fought to prevent rolling back existing statues and to maintain the regulatory *status quo*, rather than to expand the scope of consumer or environmental protection.[134]

In reality, few farmers in the EU grow approved GM crop varieties. Within the EU, Spain is effectively the only Member State that is growing significant amounts of GM crops. Spain accounts for 85% of all GM crops grown in the EU.[135] In 2011, Spanish farmers planted 0.1 million hectares of Bt maize. Other EU countries Portugal, Czech Republic, Poland, Slovakia and Romania planted 114,490 hectares of biotech Bt maize. In 2011, EU Member States combined together cultivate less than 0.2 million hectares of GM crops, compared to 69 million hectares in the US.[136]

European attitudes towards GM crops and food have been shaped by a variety of factors, including the experience of major food safety crises, lack of confidence in food regulators, different cultural attitudes toward food, and involvement of

[132] Now it is the EU in the leadership in addressing global environmental problems. See David Vogel, 'The Politics of Risk Regulation in Europe and the United States'(n 122) pp.19-22

[133] For more on the EU' regulation of GMOs See Maria Lee, *EU Regulation of GMOs* (n 8).

[134] Similarly, the US is not signatory to the Kyoto Protocol dealing with climate change, see David Vogel, The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe, 33 B.J.Pol.S. p. 578.

[135] Clive James, 'Global Status of Commercialized Biotech/GM Crops' (ISAAA Brief 43, ISAAA 2011) http://www.isaaa.org. Accessed June 2012.

[136] An additional two countries (Sweden and Germany) planted 17 hectares of the new biotech quality starch potato named 'Amflora' for seed production for a total of 114,507 hectares of biotech crops planted in the EU. See Clive James, (n 135).

NGOs.[137] This pressure led to the moratorium (as discusses above in section 2.2) on new authorisations made under Directive 90/220, its successor Directive 2001/18, and Regulation 258/97. In response, the EU modified its regulatory procedures to meet public pressure as described in section 2.2 above.[138]

The EU's regulation of genetically modified foods and crops can impact the flow of genetically modified foods and crops from third countries, such as the United States, and hence falls under the jurisdiction of the WTO. The EU claims that its regulatory framework for GMOs takes account of the EUs international trade commitments and the requirements of the Cartagena Protocol on Biosafety, specifically as regards the obligations of EU importers, and exporters of products to third countries. Regulation of the European parliament and of the Council on the Transboundary Movement of Genetically modified organisms[139] implemented the provisions of the Protocol into Community law.[140] The EU maintains that its regulatory system is in line with WTO rules: it is clear, transparent and non-discriminatory.[141]

The US, which is the world largest producer and exporter of GM crops and GM products, [142] has long expressed its dissatisfaction with the *de facto* moratorium in the EU and the Member States' safeguard measures.[143] This dissatisfaction is easy to understand as the EU is the fourth largest market for US agricultural exports (nearly 12% of all agricultural exports from the US are destined the EU).[144] In 2002, the US State Department of Agriculture (USDA) claimed at least $300 million in

[137] On food attitudes see section 4.4 below.
[138] See *Farm to Fork: Safe Food for Europe's Consumers* (n 1).
[139] Regulation (EC) No 1946/2003, OJ L287 of 05/11/2003. The Protocol was incorporated into EU legislation through a wide range of legislative measures governing the use of GMOs within the EU.
[140] For example, Article 32 of The Deliberate Release Directive (Directive 2001/18/EC) clarified that the EU GMO legislation had to be modified in order to be compatible with new international community consensus on trade in GMOs framed in the Cartagena Protocol.
[141] Speech by EU Trade Commissioner Peter Mandelson 'Biotechnology and the EU' (n 6); 'Questions and Answers on the Regulation of GMOs in the European Union', MEMO/06/58 (n 81).
[142] Clive James, (n 135). See also Chapter 2, section 2.6. The US is the world's largest commercial grower of GM crops.
[143] According to the US, the EU measures lack a scientific basis. USTR, 'Statement on the EC Biotech Dispute' USTR (11 Jan 2008), http://www.ustr.gov/about-us/press-office/press-releases/archives/2008/january/statement-ec-biotech-dispute accessed 3 Febreaury 2010.
[144] 'US vs EU: An Examination of the Trade Issues' Pew Initiative on Food and Biotechnology (n 45) p 11

lost sales of genetically modified corn and soy products as a result of EU policies.[145] Isaac and others contend that at the heart of the dispute is market access barriers that arise 'not because of border measures but because of differences in domestic regulatory approaches.'[146] US biotech corporations have invested heavily in GM applications in agriculture. These corporations have seen their access to the EU market severely restricted by the EU regulatory regime. Although at the time of filing the complaint, regulation had a limited impact on soybean and corn exports to the EU, American corporations worried about future growth opportunities.[147]

Shortly after taking office in 2009, President Obama reaffirmed America's commitment to ensuring the effective implementation and enforcement of the WTO system of multilateral trading rules, and confirmed that US exports of biotech corn and soybeans, as well as other agricultural products that contain, or may contain biotech-derived ingredients, continue to face a multitude of trade barriers.[148] The President's 2009 Trade Policy Agenda outlined an 'aggressive and transparent program recognized that 'behind the border' measures and other non-tariff barriers have grown in significance for US exporters seeking access to foreign markets.'[149]

NGOs were quick to point the finger at intense lobbying by US agribusiness and biotech corporations.[150] American farmers and industry trade bodies have pushed the US government to take further steps against the moratorium, resulting in the initiation of the WTO *Biotech* dispute. Furthermore, many agriculture and agri-business groups in the US are calling for a second case at the WTO, challenging new European legislation on GMO traceability and labelling in an effort to prevent

[145] 'European Commission Opts Not To Push for End of GMO Moratorium', INSIDE U.S. TRADE, 25 January 2002.
[146] Grant E. Isaac and William A. Kerr, 'Genetically Modified Organisms at the World Trade Organisation: A Harvest of Trouble' (2003) 37(6) Journal of World Trade, p. 1085; David Vogel and Olivier Cadot, 'France, the United States, and the Biotechnology Dispute' (n 52).
[147] David Vogel and Olivier Cadot, 'France, the United States, and the Biotechnology Dispute' (n 52).
[148] USTR, '2013 Report on Sanitary and Phytosanitary (SPS) Barriers to Trade' (n 5) p. 21
[149] One type of non-tariff measure poses increasing challenges to U.S. producers and businesses seeking to export products abroad are SPS measures. See USTR, '2013 Report on Sanitary and Phytosanitary (SPS) Barriers to Trade' (n 5) p 3-4.
[150] FoE International, 'Looking behind the US spin' (n 70).

further disruption of transatlantic trade, and to ensure that other countries do not adopt similar legislation.[151]

Developing countries are caught in the middle of this dispute between the US and EU. For example, an unresolved problem for a developing country is whether it can import corn or soybean from the US for human consumption, or approve GMOs for domestic production, yet still seek to export crops to the EU. Solving this problem alone would have an important beneficial impact on the operation of addressing world food insecurity.[152] This issue arose when three African countries declined shipment of US corn as food aid.[153] The underlying problem was that these countries were mainly agricultural producers exporting to the EU. They did not want to compromise their trade with the EU in case farmers were going to save and plant the GM corn. The solution was to require that the corn be ground before distribution in the recipient country.[154]

A similar dilemma can occur if a country imports soybeans or oil from the US and exports processed foods, as happened in the Thailand-Egypt dispute. Thailand formally challenged Egypt's decision to restrict food imports containing GMOs. Moreover, Thailand claimed it was not possible to identify the origin of soybean oil because the final stages of processing destroyed genetic material. Thailand therefore found restrictions on its canned tuna discriminatory, and asked the Egyptian government to lift them.[155]

The EU denies that the challenged measures in *Biotech* and latter legislation are protectionist. Instead, it maintains that it made a political choice not to compromise

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[151] In November 2003, the 22 members of the Agriculture Biotech Planning Committee wrote to the US Trade Representative and Secretary for Agriculture arguing the EU regulation to be WTO-inconsistent and urging the Administration to prevent further disruption to US exports. The letter is reproduced in 'Agriculture Groups Seek New WTO Action Against EU on GMO Rules', Inside US Trade (28 November 2003), pp. 6-8.
[152] Tim Josling, et al, *Food Regulation and Trade* (n 59) p. 165.
[153] Zambia would not accept GM food aid at all. See Maria Lee, *EU Regulation of GMOs* (n 8) p. 21.
[154] Tim Josling, et al, *Food Regulation and Trade* (n 59), p. 165.
[155] Request for consultation, *Egypt — Import Prohibition on Canned Tuna with Soybean Oil* WT/DS205/1(2000).

over food safety rules because they apply as much to its own Member States as it does to other countries wanting to export to the EU.[156]

The next section describes, in general, US federal policy and the regulatory framework applying to GMOs. This provides necessary background for assessing how they differ on assessing the risks.

3 The 'permissive' approach of the USA

The US has chosen to regulate both GM foods and seeds under current statutes and existing agencies responsible for the safety of food, drugs and other products.[157] American regulatory policy is governed by the 'Coordinated Framework for Regulation of Biotechnology'.[158] The Coordinated Framework concluded that biotechnology products are not fundamentally different from conventional products. It also decided that the products, rather than the process, should be regulated based on their use, which suggests that GMOs would not pose regulatory and scientific issues substantially different from those posed by traditional products.[159] Therefore, biotechnology products would be regulated much like traditional products. The Coordinated Framework described the federal system for evaluating products developed using modern biotechnology as ensuring 'new biotechnology products are safe for the environment and human and animal health.'[160] This regulation was drafted, in conjunction with the Office of Science and Technology Policy (OSTP),

[156] *Farm to Fork: Safe Food for Europe's Consumers* (n 1).
[157] William J. Thieman & Michael A. Palladino , *Introduction to Biotechnology* (2nd edn Pearson: Benjamin Cummings, San Francisco, 2009), pp. 306-311.
[158] OSTP, 'Coordinated Framework for the Regulation of Biotechnology', 51 Fed Reg 23,302 (26 June, 1986). This section does not cover crops that produce pharmaceutical or industrial compounds, which are subject to stricter regulation.
[159] See also Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' in Luc Bodiguel and Michael Cardwell (eds), *the Regulation of Genetically Modified Organisms: Comparative approaches* (OUP, 2010), p. 300.
[160] United States Regulatory Agencies Unified Biotechnology Website, 'Welcome' http://usbiotechreg.epa.gov/usbiotechreg/. Accessed July 2007. See also William J. Thieman & Michael A. Palladino , *Introduction to Biotechnology* (n 157) p. 307.

with the identified goals of enabling industry to proceed safely and efficiently, and reducing barriers to trade in biotechnology.[161]

Three federal agencies are responsible for regulating most production and marketing of genetically modified foods: the Department of Agriculture (USDA) oversees growing practices (e.g. whether something is safe to grow); the Environmental Protection Agency (EPA) ensures safety of the environment; and the Food and Drug Administration (FDA) regulates food products on the market as opposed to plants (e.g. whether something is safe to consume, for example, it controls the use of Bt proteins and other pesticides).[162] For example, before a Bt crop is approved for commercial use, its developer must demonstrate that it conforms with the standards set by federal law in order to demonstrate to the USDA that the crop will not threaten agriculture, to satisfy the EPA that it is safe for the environment, and to establish to the FDA that the resulting product will be as safe as other foods.

Oversight by these agencies is based on a mixture of pre-existing statutes. The 'Coordinated Framework for Regulation of Biotechnology' relies on several federal health and safety laws developed to address specific product classes. These laws are statutes the agencies review when determining the safety of a particular GM food.[163]

3.1 US Department of Agriculture

[161] Rebecca Bratspies, 'The Illusion of Care: Regulation, Uncertainty, And Genetically Modified Crops' (2002) vol10/3 NYU Environmental Law Journal.

[162] See Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) pp. 300-301; and Philip Katz et al, 'The evolving GMO Food and Trade Policy Debate: Towards a Global Regulatory Regime?' in Robert E. Evenson and Vittorio Santaniello (eds) *The Regulation of Agricultural Biotechnology* (CABI Publishing 2004), p. 26.

[163] Pew Initiative on Food & Biotechnology, 'Issues in the Regulation of Genetically Engineered Plants and Animals', (Pew Initiative on Food & Biotechnology, 2004) available at http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/food_biotech_regulation_0404.pdf. Accessed September 2007. These laws include: The Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA) (EPA); The Toxic Substances Control Act (TSCA) (EPA); The Federal Food, Drug, and Cosmetic Act (FFDCA) (FDA and EPA); The Plant Protection Act (PPA) (USDA); The Virus-Serum-Toxin Act (VSTA) (USDA); The Public Health Service Act (PHSA)(FDA); The Dietary Supplement Health and Education Act (DSHEA) (FDA) The Meat Inspection Act (MIA)(USDA); The Poultry Products Inspection Act (PPIA) (USDA); The Egg Products Inspection Act (EPIA) (USDA); and The National Environmental Protection Act (NEPA).

The USDA was created in 1862. The Department has many functions related to the advancement and regulation of agriculture, including regulating plant pests, plants, and veterinary biologics in agriculture under the Federal Plant Protection Act.[164]

Because most GM plants are potentially invasive, they are treated as plant pests or 'regulated articles', and regulated by the by the 'Animal and Plant Health Inspection Service' (APHIS) under the requirements of the Federal Plant Protection Act. The USDA also regulates interstate movement, import, field testing, and eventual release GM plants. GM plants that are 'regulated articles' must be evaluated and determined to be 'unregulated' before they can be sold.[165] The APHIS is the branch of the USDA which provides permits for developing and field testing genetically engineered plants. If an experimental organism poses a potential threat to pre-existing agriculture, the Service makes certain that safeguards are in place.[166]

The APHIS governs field trials of GMOs, which take place while new crop is still a 'regulated article' under the Plant Protection Act, through either a notification or permit process. Under the notification process, the APHIS Investigative process is initiated by a petition to the APHIS for deregulated status (GM plants are monitored in the same way as traditional plants). The APHIS reviews field test reports, scientific literature, and any other pertinent records before it determines whether the GM plant is as safe to grow as traditional varieties. The APHIS uses a 'scientific – based regulatory framework that allows for the safe development and use of GM plants.'[167]

The APHIS considers three broad areas while evaluating the petition for deregulation, Specifically, the biology of the plant is scrutinized to evaluate the possible threat to other plants, the risks to other wildlife and other organisms, and the possibility of the plant will be unwelcome and invasive (weed consequences).[168]

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[164] A biologic is broadly defined as any medical preparation made from living organisms or their products. See T William J. Thieman & Michael A. Palladino , *Introduction to Biotechnology* (n 157) p. 308.
[165] Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) pp. 301-2.
[166] T William J. Thieman & Michael A. Palladino , *Introduction to Biotechnology* (n 157) p. 308.
[167] Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) p. 301.
[168] T William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology* (n 157) pp. 308-9.

During field testing, a GM plant is still a 'regulated article'. After the safety of the new plant is determined, the grower can petition for its classification under non-regulated status. The application includes information and data necessary to satisfy that the GM plant is unlikely to pose greater plant pest risk than the unmodified organism from which it was derived. If the petition is granted, the grower can cultivate, test, or use the plant for crossbreeding purposes without monitoring or approval by the APHIS.[169] Because non-regulated status means the GM plant poses no environmental or agricultural risks, the APHIS lacks authority to impose conditions on the use of biotech crops, or to require biotech developers to monitor the impact of the crop on the environment.[170]

The permit procedure applies to experimental release of GM plants that may carry higher risks, such as plants with industrial compounds, or plants with human or animal genetic material. The applicant includes detailed technical information about experiment design, location, plans to prevent escape, and final disposal. The APHIS prepares an environmental assessment, and after review of the application, it either denies or grants the permit. The permit includes conditions for the introduction of the GM plants. The permit holder must notify the APHIS of the result of the field tests, accidental or unauthorised releases, and any other unusual occurrence.[171]

3.2 The Environmental Protection Agency

The EPA was established in 1970. Its responsibilities range from protecting endangered species to establishing emission standards for cars. A major duty is setting standards to manage the environmental impact of pesticides and

[169] As of February 2009, APHIS had granted 75 petitions. See Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) pp. 303-5.
[170] Should it latter become a plant pest, however, it will again be subject to regulation, see Donald L. Uchtmann, 'Agricultural Biotechnology Regulation: the Pew Initiative and its Stakeholder Forum', (2004) *9* Drake J Agric L*,* 63.
[171] As of February 2009, APHIS had granted 75 petitions. See, Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' n 159) p. 303.

herbicides.[172] In 1992, it agreed that GM plants expressing pesticide substances are pesticides, new uses of existing pesticides, and novel microorganisms. This understanding includes any plant that is genetically engineered to express proteins that provide pest control, such as Bt crops. A permit is generally required for testing any unregistered pesticides in accordance with the Federal Insecticides, Fungicide, and Rodenticide Act. An applicant must provide data on safety and efficiency, which the EPA evaluates for potential effects on the environment and on animals or insects that also inhibit the farmers' fields.[173] The EPA has also determined that, when used in accordance with normal practice, such plants must not 'cause unreasonable adverse effects on the environment.' Tests in laboratories and greenhouses are exempt. A small scale field test does not require a permit. The EPA encourages those conducting field trials to consult with it.[174]

The EPA issues Experimental Use Permits to plant developers to conduct field experiments involving 10 acres or more of land. The EPA reviews data collected during the experiments. This review concentrates on four areas of concern: the source of the gene, how it is expressed, and the nature of the pesticide- protein produced; the health effects of the plants; the 'environmental fate' of the effect at large; and the effect on non-target species. The EPA review balances risks and benefits. [175] Like the USDA, the EPA can grant deregulated status to any plant that meets the requirements of all these tests, which then allows the plant to be sold or distributed like any other plant. The EPA has the power to amend or revoke existing regulation whenever required.[176]

In 2001, the EPA adopted a regulatory framework for 'plant-incorporated protectant' to regulate food safety issues associated with pesticides. The FDA is responsible other food safety issues.[177] The EPA also sets pesticides tolerances for foods. On a

[172] Donald L Uchtmann, 'Agricultural Biotechnology Regulation: the Pew Initiative and its Stakeholder Forum' (n 170) p. 63.
[173] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (Elsevier 2009), p. 409.
[174] Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n n 159) p. 308.
[175] T William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology*, (n 157) p. 308-9.
[176] Ibid, p. 310.
[177] Some instances require expertise of both EPA and FDA; Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) p. 307.

case-by-case basis, it grants temporary or permanent exemptions for tolerance requirements if there is a 'reasonable certainty that no harm will result'.[178]

3.3 The Food and Drug Administration

The FDA is charged with ensuring food, feed, food additives, veterinary drugs, human drugs, and medical devices are safe. [179] The FDA regulates GMOs under the same act that regulates other food products. Under the Federal Food, Drug, and Cosmetic Act, premarket approval is required only for unsafe food additives. Premarket approval of a transgenic crop is only required if the novel protein, or other new substance expressed in the crop by the inserted gene, is considered an unsafe 'food additive'. The potential toxicity of the transgenic crop, and nutritional quality of the product are also tested.[180]

In 1992, the FDA issued a policy statement indicating that it would focus on the food product, rather than the process by which the food was produced. It stated that GM foods were not 'materially' different from conventional food, limiting regulation to changes that could be tasted, smelled, detected, through the other human senses.[181] Because GM foods cannot be 'sensed' in this way, the FDA declared them 'substantially equivalent' to conventionally produced foods, GM varieties and their food products 'are as safe as safe and as nutritious as their traditional counterparts, and would be regulated by the same through standards that applied to regular food, nothing more, nothing less.' [182]

There is no mandatory risk assessment requirement in the USA. 'Substantial equivalence' is not part of a safety assessment, but is rather a starting point for the

[178] Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) p. 310.
[179] This done mainly under Federal Food, Drug, and Cosmetic Act, 21 USC S 348 (2000). See T William J. Thieman & Michael A. Palladino , *Introduction to Biotechnology*, (n 157) p. 311; and Cinnamon Carlarne, 'From the USA With Love'(n 124) 317.
[180] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 173) p. 409.
[181] Statement of Policy: Foods Derived from new plant Varieties, 57 Fed, Reg 22,984,22,985 (29 May 1992) as quoted in Donald L Uchtmann, 'Agricultural Biotechnology Regulation: the Pew Initiative and its Stakeholder Forum', (n 170) p. 60.
[182] See 21 USC S 348 (2000); Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) p. 310.

safety assessment for GM foods by the US Food and Drug Administration.[183] 'Substantial equivalence' measures whether a biotech food or crop shares similar health and nutritional characteristics with its conventional counterpart. Biotech foods that are 'substantially equivalent' have been determined to be as safe as their conventional counterparts. Products that are not substantially equivalent may still be safe, but must undergo a broader range of tests before they can be marketed. [184]

'Substantial equivalence' evaluations are conducted to assess whether the key nutrients or anti-nutrients in the plant components used for feed or food have been changed. If a biotechnology product is found not to have any differences in the composition of nutritional or anti-nutritional components from its conventional counterpart, it is considered substantially equivalent. However, a product that is determined to not be substantially equivalent would be subject to a broader analysis on a case-by-case basis, with the safety assessment focusing on established differences between the product and its conventional counterpart. [185]

Only foods with characteristics that carry higher risks, and therefore lack 'substantial equivalence', are subjected to FDA premarket review.[186] Substances that are 'generally- recognised- as - safe' (GRAS) by scientists are excluded from this requirement.[187] The FDA can grant (GRAS) status to food products or additives that pose no foreseeable threat, like food additives used prior to 1958 which can be included under the GRAS exception because of their common use in food. If the food product or additive proves to be unsafe, the FDA has the responsibility and the power to remove it from the market. In 1992, the FDA indicated that most GM foods will be considered GRAS because most new plant foods had been accepted widely as safe. [188]

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[183] Council for Biotechnology Information, 'Substantial Equivalence in Food Safety Assessment' (2001), http://foodsafety.ksu.edu/articles/497/Substantial_Equivalence.pdf. Accessed April 2006.
[184] Ibid.
[185] Ibid.
[186] Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) p. 312.
[187] Donald L Uchtmann, 'Agricultural Biotechnology Regulation: the Pew Initiative and its Stakeholder Forum', (n 170) p. 60, explaining the definition of food additive under S 321(s) of Federal Food, Drug, and Cosmetic Act 21 USC S 348 (2000).
[188] Donald L Uchtmann, 'Agricultural Biotechnology Regulation: the Pew Initiative and its Stakeholder Forum', (n 170) p. 60-62; and T William J. Thieman & Michael A. Palladino , *Introduction to Biotechnology* (n 157) p. 311.

The FDA serves as a consultant to biotechnology developers and advises them on testing practices. The 1992 Policy statement urged industry to consult with the FDA before commercial distribution of food and feed from new plant varieties using new technologies. Even though they were not bound by law, food companies voluntarily consulted with the FDA before marketing any product. The FDA now uses the notification procedure outlined in its 1997 regulatory proposal, which has not yet been promulgated.[189]

1992 policy statement does not require labels for most GM foods. The US does not have a traceability or labelling requirement. Instead, GM products are treated in the same manner as unmodified foods on the basis that they are 'substantially equivalent' to conventional products. The United States only requires labelling if the composition of a food developed through genetic engineering, or any other method, differs significantly from its conventional counterpart. [190]

The FDA requires special labelling of foods and food products that present known safety or usage issues. If a biotechnology food product includes a protein that is not usually found in the food and is a known allergen, mandatory GMO labelling is required only where there have been significant nutritional changes, the product is considered to be a different product, or to alert consumers of possible safety concerns, such as the presence of food allergens. This standard is also applied to traditional food products. [191]

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[189] Consultations include information on nutritional and safety assessment. Margaret Rosso Grossman 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) pp. 312, 315.

[190] FDA does not require disclosure in labelling of information solely of informing the consumers. See William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology* (n 157) p. 316. However, the EU regulations require labelling of GMOs if the product to be sold in the EU, see section 2.1-3 above.

[191] Statement of Policy: Foods Derived from new plant Varieties, 57 Fed, Reg 22,984,22,985 (29 May 1992), Shirley A. Coffield, 'Biotechnology,Food, And Agriculture Disputes Or Food Safety and International Trade', 2000, 26 Can.-U.S. L.J. , p. 238; and Philip Katz et al., 'The evolving GMO Food and Trade Policy Debate: Towards a Global Regulatory Regime?' (n 162) p. 26.

Post-market oversight of GMOs has limited resources and is given relatively low priority in the US.[192] The FDA takes regulatory action when it determines that a food already on the market is 'misbranded' or 'adulterated'.[193] Over half a dozen unauthorised releases of GM crops have occurred in the US.[194] In October 2000, GM corn 'StarLink', which is not approved for human consumption, was found to have entered large amounts the US food supply chain.

'StarLink' corn was developed and introduced commercially by Aventis CropScience to contain insecticidal protein derived from Bt, and herbicide tolerant trait. It was approved by the EPA for commercial use as animal feed only. After processing and cooking, 'StarLink' corn had a higher concentration of protein than expected, which can cause allergic reaction if consumed by the public.[195] It was also found to have infiltrated the seed supply for other corn varieties. The lack of labelling and segregation in the US allowed the 'StarLink' corn to mix with all other corn in that region and be shipped together to processing centres.[196] More than 300 product brands had to be recalled from supermarkets by US authorities. The incident prompted a review of the potential effects on health of the gene inserted in the corn, resulting in a finding that the gene was likely to be a potential allergen. At the strong urging of American authorities, 'StarLink' corn was also withdrawn from non-food agricultural uses.[197] The EPA revoked its approval of 'StarLink' corn, and to withdraw the product from the market. The company offered to buy back all the remaining 'Starlink' corn so that no more food would be contaminated. In addition, all 'Starlink' corn seed was pulled from the market to prevent its future use. 'Starlink' corn is no longer grown anywhere in the world.[198]

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[192] Donald L Uchtmann, 'Agricultural Biotechnology Regulation: the Pew Initiative and its Stakeholder Forum', (n 170) p. 63.
[193] 'Food is considered misbranded if, among other things, it is not labelled in accordance with FDA regulations, or if its labelling is false or misleading. Labelling can be misleading not only by virtue of statement made, but also by way material omissions. Adulterated food includes food with unsafe food additive and food containing a deleterious substance that may be injurious to health.' See Philip Katz et al., 'The evolving GMO Food and Trade Policy Debate: Towards a Global Regulatory Regime?' (n 162). p. 64
[194] 'Prodigene' maize in 2002, 'Bt 10' in 2004, 'Event 32' maize in 2006, 'Liberty Link' rice in 2006, and more.
[195] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 173), p. 417.
[196] Ibid, p. 417.
[197] 'WTO case on GMOs' Times Higher Education, (Brussels 18 June 2003), http://www.timeshighereducation.co.uk/story.asp?storyCode=177451&sectioncode=26. Accessed 6 February 2007.
[198] David P. Clark & Nanette J. Pazdernik, *Applying the Genetic Revolution* (n 173) p. 417.

In response to this episode in 2001, the Agency suggested a stricter, more formal approach to deal with premarket notification and labelling issues. Under the proposed rules, companies must notify the FDA at least 120 days before genetically altered food reaches the market. The manufacturer must also provide evidence that the new product is no more dangerous than food it replaces.[199] The FDA also published draft guidance for industry for voluntary labelling.[200]

3.4 Regulatory reform

In 2002, the Office of Science and Technology Policy proposed federal measures to update field testing requirements for plants derived from biotechnology as a means of establishing early food safety assessments for food and feed proteins from these new plants. The aim of these measures was to reduce the risk of cross pollination and commingling until safety standards had been met, and thus protect public health and the environment, and increase public confidence in the regulatory oversight of GM food.[201]

This policy outlined the lead agencies' plans for enhanced regulatory measures. The USDA intended to amend its GM regulations by considering new criteria for defining the acceptable low level of regulated materials in seeds and grain.[202] The EPA planned to publish guidelines on safety review of low level residues and containment in field testing on plant incorporated pesticides, and to review its requirements for experimental use permits to minimise gene flow from field trials.[203] The FDA planned to publish guidelines encouraging early evaluations of crops so that new crops would not raise food safety issues.[204]

In 2007, the USDA issued a list of nine lessons learned from its experience in regulating biotechnology. It highlighted issues such as 'quality and completeness

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[199] William J. Thieman & Michael A. Palladino, *Introduction to Biotechnology* (n 157) p. 311.
[200] Current status of proposal remains not adopted, only in a draft form. See Margaret Rosso Grossman, 'Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort' (n 159) p. 312.
[201] Ibid, p. 301.
[202] Ibid, p. 301, The USDA It had already made field testing requirements for permits more stringent for GMOs intended for pharmaceutical or industrial products, not commodity products.
[203] Ibid, p. 301.
[204] Ibid, p. 301.

of records', the 'availability of samples', and maintaining identity and control of regulated materials'.[205] In 2008, the APHIS published its proposed regulations, which suggested expanding regulatory oversight beyond 'plant pests' to include 'noxious weed and biological control organisms'. It proposed to revise its permit system, establishing four permit categories for environmental release of GM plants, as well as outlining permit conditions and obligations. This proposal would eliminate the notification procedure. The APHIS also proposed procedure to revoke approval of non-regulated status and new measures to strengthen compliance and enforcement.[206]

In 2007, the EPA proposed a new guidance document focused on small scale field studies and low level presence of 'plant- incorporated protectant' in food. It also elaborated on the policies described in the OSTP's 2002 policy. The EPA's aim was to meet 'current scientific advances and improve the agency's ability to make regulatory decisions' about human health and environmental effects of 'plant-incorporated protectant' pesticides to better protect wildlife, the environment, and people.[207]

In June 2006, the FDA issued new guidance for industry in its '*Recommendation for the Early Food Safety Evaluation of New Non- Pesticidal Proteins Produced By New Plant Varieties Intended For Food Use*'. It encourages developers to submit information about new proteins, as it relates to food safety, early in the development process, in order to address the possibility of the inadvertent, intermittent, low level presence in the food supply of proteins that have not been evaluated through FDA's voluntary consultation process. Developers can use the data from the food safety evaluation in later consultations. [208]

Overall, regulation of GMOs by the FDA and the USDA primarily relies on notification and informal consultation. The United States has widely authorised most GM products for cultivation, production and consumption.

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[205] USDA, Lessons Learned and Revision under Consideration for APHIS' Biotechnology Framework (October 2007) as cited in Ibid, pp. 305-7.
[206] Ibid, p. 306.
[207] EPA, Plant-Incorporated protectants: Potential Revision to Current Production Regulation, 72 Fed Reg 16,312 (4 April 2007) as cited Ibid, p. 309.
[208] CFSAN, FDA, (June 2006) as cited Ibid, p. 313.

4 Precaution or protectionism?

Biotech dispute between the EU and the US over GMOs is putting the precautionary principle onto the political agenda of both parties. While the EU has a GMO regulatory framework based on the precautionary principle, the US places little restriction on the approval and sale of GMOs. This divergence was clearly reflected in *Biotech*. The American submissions alleged that the EU *de facto* moratorium and 'product specific Moratoria' were 'arbitrary' or unjustified distinctions on the level of protection against risk that have resulted in discrimination or disguised restriction on the international trade. It also asserted that all three challenged measures were not based on 'scientific principles', and were maintained without 'sufficient scientific evidence', in violation of several provisions under the SPS Agreement.[209] The EU, in defence, stressed that states have the right to adopt a precautionary approach when dealing with GMOs. The EU invoked the Biosafety Protocol as evidence of a strong international consensus on this point.[210] The EU latter added that the US was not seeking settlement in *Biotech;* rather one of the United States' main objectives was to get a dispute panel ruling confirming that there is no basis under WTO law to support the EU's regulations based on the precautionary principle.[211]

In order to assess the EU's ability to maintain and develop a regulatory system for GMOs that allows for the use of precautionary measures to protect in the face of 'insufficient scientific evidence', we have understand how it is applied in the EU,

[209] First Written Submission of the United States, *Biotech,* paras. 109-113, 147-152, and 167-173. See also Chapter 1, section 2.2.1.
[210] First Written Submission of the European Communities, *Biotech*, para. 12. The EU was unable to cite any such international consensus in its defence in *Hormone* case. See David Vogel, 'The WTO, International Trade, and Environmental Protection: European and American Perspectives', in Norman Vig and Michael Faure, (eds), G*reen Giants? Environmental Policy of the United States and the European Union* (MIT Press, 2004), p 14. The EU has the right to establish the level of protection that it deems appropriate as it clarified in European Commission, 'Communication on the Precautionary Principle' (n 6).
[211] Oral Statement by the European Communities at the First Meeting of the Panel, *Biotech* (2 June 2004), para. 28. Particular emphasis was placed on Article 5.7(f) the SPS Agreement to defend domestic SPS measures. See also, Grant E. Isaac and William A. Kerr, 'A Harvest of Trouble' (n 146) p.1084.

as well as the extent of its application the US. The next section reflects on the origin of the precautionary principle, and delineates its meaning.

4.1 The origins of the precautionary principle

The EU's attitude towards food safety is characteristic of Europe's broader concern with risk and safety issues as expressed in the precautionary principle. This section provides closer examination and understanding of what the principle stands for.

Historically, the precautionary principle has its roots in what is described in German environmental law as the *'Vorsorgeprinzip',* which was first enunciated and described by the German Federal Government in 1976 as follows: 'Environmental policy is not fully accomplished by warding off imminent hazards and elimination of damage which has occurred. Precautionary environmental policy requires furthermore that natural resources are protected and demands of on them made with care.'[212]

The German notion of *vorsorge* was initially perceived to connote more than the English translation of 'foresight planning'. The principle encompassed the notions of risk preservation, cost effectiveness, ethical responsibilities towards maintaining the integrity of natural systems, and the fallibility of human understanding. This notion is 'an interventionist measure, a justification for state involvement in the day to day lives of the citizen in the name of good government.' [213]

Thus, social planning in the design and take up of technology, in the management of the economy, especially through the introduction of environmental lives, and in social initiatives in the practice of democracy were all introduced and justified in the name of precaution.[214] This means that if there is a strong suspicion that a certain

[212] David Freestone and Ellen Hey, 'Origins and Development of the Precautionary Principle' in David Freestone and Ellen Hey (eds) *The Precautionary Principle and International Law* (Kluwer Law International 1996) p. 30; and Robert V Percival, 'The North American Symposium On The Judiciary And Environmental Law: Who's Afraid Of The Precautionary Principle?'(2005) 23 Pace Envtl L Rev 23.
[213] David Freestone and Ellen Hey, 'Origins and Development of the Precautionary Principle' (n 212) p. 30.
[214] Tim O'Riordan, et al, 'The Evolution of The Precautionary Principle' in Tim O'Riordan & Andrew Jordan (eds) *Reinterpreting the Precautionary Principle* (Cameron May, London, Reprint 2002), pp. 11-12.

activity may have environmentally harmful consequences, it is better to act before it is too late rather than wait until scientific evidence is available. At the same time, Germany wanted to promote preventative environmental technologies, for example efficient waste reduction strategies and devices for removing CO2 emissions.[215]

At the core of the precautionary principle is the notion that 'once a risk has been identified the lack of scientific proof of cause and effect shall not be used as a reason for not taking action to protect the environment' or human health. It embodies the sayings of 'better safe than sorry' and 'stitch in time saves nine'.[216] Accordingly, policy makers and governments use it to impose restrictions on otherwise legitimate commercial activities for the purpose of protecting the environment. The distinctive feature of the precautionary concept is, therefore, not that it dictates specific regulatory measures, but rather allows many different types of measures to be used to implement it. As the scale of possible damage increases, so does the need to act with precaution. Where the potential damage is less obvious (i.e. GMOs), it is common to expect controversy over precautionary action, as affected stakeholders seek to protect their interests.

During the 1980's, the precautionary principle was employed in an international context in response to trans-border environmental concerns, notably acid rain, global warming, pollution of the North Sea, and biological diversity.[217] The precautionary principle first appeared in international law in the 1980s, with the Ministerial Declarations of International Conference on the Protection of the North Sea 1984, and was later affirmed by European countries in the 1990 Bergen Ministerial Declaration on Sustainable Development.[218]

It found further expression internationally in Principle 15 of the Rio Declaration on Environment and Development (1992):

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[215] Robert V Percival, 'Who's Afraid Of the Precautionary Principle?'(n 212) 24.
[216] David Freestone and Ellen Hey, 'Origins and Development of the Precautionary Principle' (n 212) pp.12-13.
[217] David M. Ong, 'International environmental law governing threats to biological diversity' in Malgosia Fitzmaurice, David M Ong and Panos Merkourris, *Research Handbook on International Environmental Law* (Research handbooks in international Law, Edward Elgar, Cheltenham, UK, 2010), pp. 519-521.
[218] Patricia Birneie et al, *International Law and the Environment* (3rd ed OUP. Oxford, 2009), p. 154.

> 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 reason for postponing cost-effective measures to prevent environmental degradation.[219]

As articulated in the Rio Declaration, the precautionary approach provides that while science is the starting point, the lack of conclusive scientific evidence or uncertainty does not justify inaction, particularly when the consequences of inaction may be devastating or when the costs of action are negligible.[220]

The principle is now embodied in many multilateral environmental agreements, and provides the basis for a number domestic measures in both developed and developing countries, representing the major legal systems and regions of the world.[221] The widespread adoption of the precautionary principle in international law reflects the appeal of caution as a prudent regulatory response to scientific uncertainty, and possibilities of serious health or environmental damage.

While recognising that the complexity of many environmental and health threats may preclude clear science from emerging in time to take policy action, the precautionary principle advocates against deferring action in the face of potential consequences. However, the interpretation and application of the precautionary principle is disputed.[222]

4.2 Precautionary principle in EU Law

Within the EU legal order, the Single European Act implied the precautionary principle by requiring that harmonised standards take, as a matter of principle, a

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[219] (1992) *The United Nations Conference on Environment and Development*, Rio de Janeiro, 3-14 June 1992, available: http://habitat.igc.org/agenda21/rio-dec.htm. Accessed on 10 January 2007. The non-binding declaration was agreed by 178 governments. See also, Patricia Birneie et al, *International Law and the Environment* (n 218) pp. 154-166.

[220] '*Environment and Trade: A Hand Book*' (second edition, IISD, UNEP, 2005) p.59.

[221] For further reading see Arie Trouwborst, *Evolution and Statues of the Precautionary Principle in International Law* (The Hague: Kluwer Law International, 2002).

[222] Nuffield Council on Bioethics, *The Use of Genetically Modified Crops in Developing Countries-A Follow up Discussion Paper*, (Nuffield Council on Bioethics December 2003), p.113; and Alessandro Nucara, 'Precautionary Principle and GMOs: Protection or Protectionism', 9 (2) Int. T. L.R. 2003, p. 47.

'high level of protection'.[223] Article 130 of the Maastricht Treaty (1993)[224] made precaution an official guiding principle of EU environmental policy. This was subsequently reiterated in the Amsterdam Treaty (1997),[225] and subsequently in Article 191(2) of the Treaty on the Functioning of the European Union:

> Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken…and that the polluter should pay.[226]

Article 191(3) states further that 'In preparing its policy on the environment, the Union shall take account of available scientific and technical data, environmental conditions in the various regions of the Union'. Despite this reference to the precautionary principle neither the Treaty nor early case law contained a definition of the precautionary principle.[227]

In 2000, the European Commission issued a 'Communication on the Precautionary Principle'. [228] Central to the Commission's Communication is the proposition that the precautionary principle is a risk management tool applied as part of a risk analysis framework. The Communication broadened the scope of the precautionary principle to encompass human, animal, and plant health as well as environmental protection. It provided that the precautionary principle would be applied whenever decision makers identify 'potentially negative effects resulting from a phenomenon, product or process', and when 'a scientific evaluation of the risk which because of insufficiency of the data, their inconclusive imprecise nature makes it impossible to determine with sufficient certainty the risk in question of the insufficiency of the data, their inconclusiveness or imprecise nature.'[229] The Commission set out a

[223] (1987) OJ L 169.
[224] Treaty on European Union [1992] OJ c191/1.
[225] Article 174(2) of Treaty of Amsterdam Amending the Treaty on European Union, The Treaties Establishing the European Communities [1997] OJ c340/1.
[226] Consolidated Version of the Treaty on the Functioning of the European Union, OJ C 115/133.
[227] Andreas F. Lowenfeld, *International Economic Law* (International Economic Law Series, OUP, Oxford 2008), p. 410.
[228] European Commission, 'Communication on the Precautionary Principle' (n 6)
[229] European Commission, 'Communication on the Precautionary Principle' (n 6) p. 15.

structured approach to risk analysis that comprises three different stages of 'risk assessment', 'risk management', and 'risk communication'.[230]

However, the Commission acknowledged the danger that the precautionary principle could potentially be used to justify unwarranted restrictions on trade that could in certain 'cases serve as a justification for disguised protectionism.' Consequently, where action is deemed necessary, measures based on the precautionary principle should be proportional to the chosen level of protection, non-discriminatory in their application, and consistent with similar measures already taken based on an examination of the potential benefits and costs of action or inaction, and subject to review in the light of new scientific data.'[231]

Latter in December 2000 the Nice Summit issued a Resolution on the precautionary principle which reaffirmed the 'insufficiency' of data while conducting risk assessment and the need for functional separation between risk assessors and risk management decision making. However it provided that risk assessment should be undertaken in 'multi-disciplinary, independent and transparent manner that all views are heard'.[232] Vogel observed that the precautionary principle explicitly acknowledges the inherently political nature of regulatory decision making by 'enabling policy makers to take into account a wide variety of non-scientific factors, including public opinion and social values.' In effect, it reduces the scientific threshold for regulatory policy making.[233]

Under the Treaty on the Functioning of the European Union, the precautionary principle is recognised as an important basis for the adoption of a wide range of risk-adverse policies applicable in the EU, including the regulation of environmental protection, human health and safety, consumer protection, and

[230] 'Risk assessment' is a technical process, and 'risk management' is a political decision. See European Commission, 'Communication on the Precautionary Principle' (n 6) p. 17.
[231] European Commission, 'Communication on the Precautionary Principle' (n 6), p10
[232] Council Resolution on the Precautionary Principle, Nice summit, 7-10 December 2000, p 9-10, 11.
[233] David Vogel, 'The Hare and the Tortoise Revisited' (n 134) 556-7. See section 4.3 and 4.4 below for more on how public opinion helped shape EU law.

promotion of measures at the international level to deal with regional or worldwide environmental problems, such as restrictions on GM foods and seeds.[234]

In relation to GMOs, the precautionary principle is incorporated into the Deliberate Release Directive. The preamble refers to the need for the precautionary principle to be taken into account in implementing the Directive. Moreover, the objective of the Directive is to protect human health and the environment when GMOs are deliberately released to the environment in accordance with the precautionary principle (Article1). Additionally, there is a 'general obligation', requiring all appropriate measures be taken to avoid adverse effects on human health and the environment which might arise when GMOs are released (Article 4). [235] Furthermore, Article 23 which allowed the EU national bans, can be understood as a precautionary feature of the Directive.

In a speech on biotechnology and the EU, EU Trade Commissioner Peter Mandelson defended the EU's regulatory framework on the approval of GMOs as a regime that is open to new technologies, but one that requires all new products be thoroughly tested to the most rigorous scientific standards, with protection of public safety and health being paramount. Mandelson noted 'so long as we apply the same rules and standards across the board the protectionist label doesn't stick.'[236]

For some, in light of GMOs 'profound technological changes that contribute to the appearance of new risks that may appear unmanageable', the precautionary principle in EU law offers reassurance for civil society that policy makers act responsibly (the precautionary principle may be applied to justify measures to prevent damage in some cases even though the casual link cannot be clearly

[234] Consolidated Version of the Treaty on the Functioning of the European Union, OJ C 115/133, Articles 191(1) and 169. TFEU explicitly defined consumer policy and health protection as 'rights', and extended the precautionary principle to consumer protection.
[235] Deliberate Release Directive , Preamble: 'in accordance with the precautionary principle', Member States 'ensure that all appropriate measures are taken to avoid adverse effect on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs.'; see section 2 above.
[236] He justified it because '[L]ike any new science, biotechnology carries risks and those risks must be properly assessed and managed'. Speech by EU Trade Commissioner Peter Mandelson: 'Biotechnology and the EU' (n 6).

established on the basis of available scientific evidence).[237] This creates an interesting problem of what is the threshold of scientific evidence to be considered safe by the EU.

Both the Court of Justice of the European Union (CJEU) and the EU General Court have delivered rulings relevant to the application of the precautionary principle. It is not possible to provide a comprehensive analysis and judicial interpretation of the precautionary principle under EU law. However, some tenets will now be briefly reviewed.

As a general definition the Court held that:[238]

> Where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent.

The General Court in *Pfizer* reaffirmed to a large extent the principles stated by the Commission in its 2000's Communication on the precautionary principle. *Pfizer* concerned a challenge related to the risk of transferring the resistance of antibiotics from animals to humans. The General Court rejected 'hypothetical' risk as a basis for regulation, and stated that the degree of risk cannot be set at 'zero risk'.[239] Acceptance of the precautionary principle further acknowledged the fragility of scientific information as the sole provider of legitimacy for a decision.[240]
The precautionary principle was also brought up in enforcement actions by the Commission against Member States. In the case of *Commission v France*, the Court of Justice of the European Union held that a correct application of the precautionary

[237] Helen Trudeau and Celine Negre, 'Precaution in the Multilateral Environmental Agreements and its Impact on the World Trading System' in Marcus W. Gehring and Marie Clair Cordonier Segger (eds), *Sustainable Development in World Trade Law* (Kluwer Law International, the Hague 2005), p. 628.
[238] Case C-236/01 *Monsanto Agricoltura Italia* [2003] ECR I-8105, 111
[239] Case T-13/99 *Pfizer Animal Health SA v Council* [2002] ECR II-3305, para.139. The court considered proportionality as ground for judicial review, as well as risk assessment and risk management. The court concluded that the principle of proportionality required the measures adopted by institutions not to exceed the limits of what necessary to obtain the legitimate objectives of the legislation in question. Where there is a choice between several appropriate measures, recourse must head to the least onerous, in addition, the disadvantages caused must not be disproportionate to the aims perused.
[240] European courts placed strong emphasis on scientific evidence, see Maria Lee, *EU Regulation of GMOs* (n 8) p. 243.

principle presupposes identification of the potentially negative consequences for health of the proposed use of the substance at issue, and a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research.[241] Furthermore, where the likelihood of real harm to public health persists should the risk materialise, but it proves to be impossible to unequivocally determine the existence or extent of the alleged risk because of the insufficiency, inconclusiveness, or imprecision of the results in scientific studies, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective.[242]

In the recent case of *Gowan*, the Court of Justice of the European Union confirmed the decision in *Commission v France.* The Court ruled on the scope of the precautionary principle, the conditions triggering its invocation, and when it applies. The Court concluded that 'some scientific uncertainty regarding the assessment' allows application of the precautionary principle.[243]

In the case of *Austria v Commission* the Court's interpretation seems more restrictive. This case concerned an Austrian province's ban on GMOs aimed atprotectecting the environment as well as organic farming interests under the Deliberate Release Directive (discussed above). The Commission disallowed the Austrian's ban based on EFSA's report which was dismissive of Austria's scientific report. The General Court upheld the commission's decision. On appeal the CJEU ruled that the General Court did not seem to have 'erred in law by stating that EFSA's findings concerning the absence of scientific evidence demonstrating the existence of a specific problem had been taken into consideration by the Commission'.[244]

Biotech generated disagreements between the Commission and individual Member States over the application and scope of the precautionary principle, fuelling further

[241] Case C-333/08 *Commission* v *France* [2010] ECR I-0000, para. 92.
[242] Ibid, para. 93.
[243] C-77/09 *Gowan Comércio Internacional e Serviços Lda Ministero della Salute* ECR 2010 I 13533, paras. 75-78.
[244] Joint Cases C-349/05P and C-454/05/P *Land Oberosterreich and Republic of Austria v Commission of the European Communities* [2007] ECR I-7441, 64.

the inconsistency of its application. This has created an interesting problem in identifying what counts as a sufficient proof of safety, and under what circumstances.

4.3 Precaution in the EU and the US

Risk regulation frequently requires regulators to act in the face of uncertainty regarding the nature and extent of the risks posed by new products and processes, raising the fundamental political question of how governments should regulate risk. Frequently, regulators take *precautionary* measures, regulating or even banning certain products or activities, including in the absence of complete information about the potential risks. For example, from the 1960s until the 1980s, the US developed an elaborate environmental regime with major statutes and regulations covering air and water pollution, chemical exposures, solid and hazardous waste management, the clean-up of abandoned toxic waste sites, and a number of other issues.[245]

Vogel argued that the EU's approach to risk regulation evolved quite differently than in the US. Whereas the US began with highly precautionary legislation in areas like the environment, consumer protection, and worker health and safety, only to adopt scientific risk assessment and cost-benefit analysis more recently, regulators in the EU arguably became more precautionary and more 'risk-averse' over time.[246] In effect, Vogel writes, US and EU risk regulation resemble 'ships passing in the night,' with the EU becoming more precautionary, and the US less precautionary

[245] David Vogel, 'Ships Passing in the Night: GMOs and the Politics of Risk Regulation in Europe and the United States' (European University Institute Working Paper, No 2001/16).

[246] Between the 1960s and the 1990s, Vogel writes, 'a number of US regulations were more stringent, innovating and comprehensive than those adopted by European countries and the EU. However, since the mid 1980s, this pattern has changed. Now in a number of significant areas of regulatory policy, EU regulations are more stringent, innovative, and comprehensive than those adopted by the US. Prior to the mid 1980s, US policy-makers identified more products and processes as posing unacceptable risks to public health or the environment than did regulatory authorities in Europe. Now the latter regard a number of products and processes as posing unacceptable risks to consumers and the environment that US policy-makers do not. Since the mid 1980s, the political influence of constituencies favouring more risk averse regulatory policies have strengthened in Europe while since the early 1990s it has declined in the US. Likewise, since the mid 1980s regulatory politics and issues have become more politically salient in Europe, while since the early 1990s, they have declined in the US.' See David Vogel, 'The Politics of Risk Regulation in Europe and the United States' (n 122) pp. 7-16

over time. A central cause of this increasingly precautionary approach has been the long series of European regulatory failures and crises over the past several decades, including most notably the BSE or "mad cow" crisis discussed above in section 2.4. As we shall see, these crises have weakened public trust in EU regulators and scientific risk assessments, while increasing support for highly precautionary regulations. Responding to this crisis, EU institutions adopted strict new regulations for GM foods and crops, elevating the 'precautionary principle' to the status of doctrine in EU regulation.[247]

Other authors dispute Vogel's 'ships passing in the night' description of American and European risk regulation, noting that the purported 'flip-flop' in US and EU approaches to risk regulation draws disproportionately from a few controversial issue areas, such as the use of growth hormones in beef cattle and the regulation of GMOs. In a wide-ranging survey of US and European risk regulation, Wiener and Rogers[248] find a more complex set of outcomes in which the US is more precautionary in some areas (e.g. nuclear energy, particulate air pollution) while the EU demonstrates greater precaution in others (GMOs, hormone-treated beef). They note that '[t]his broader analysis indicates that neither the US nor the EU is a more precautionary actor across the board, today or in the past. Relative precaution appears to depend more on the particular risk than on the country or the era.'[249]

Europeans have been willing to accept the safety of traditional foods, such as raw milk, cheeses and cured meats, while challenging the adoption of new technologies for food production and preservation such as irradiation and genetic modification.

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[247] The literature on the precautionary principle in risk regulation has mushroomed in recent years. For a range of supportive and critical views, see e.g. Bodansky, Daniel (1991). 'Scientific Uncertainty and the Precautionary Principle,' (1991) 33 Environment, pp. 4-5, 43-44.; Cameron, and Abouchar; 'The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment' (1991) 14 Boston College International & Comparative Law Review pp. 1-27; European Commission (2000), Commission Communication on the Precautionary Principle, (n 6) 1; Majone Giandomenico, 'Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform' in Giandomenico Majone, (ed), *Risk Regulation in the European Union: Between Enlargement and Internationalization* (Florence: European University Institute, 2003); and Jonathan B. Wiener, and Michael D. Rogers 'Comparing Precaution in the United States and Europe' (2002) 5(4) Journal of Risk Research, pp. 317-349.

[248] Jonathan B. Wiener, and Michael D. Rogers 'Comparing Precaution in the United States and Europe' 5(4) *Journal of Risk Research*, 317 pp. 317-349

[249] Ibid, pp. 317-349.

Americans, in contrast, have generally been sceptical of traditional European methods, while remaining more open to the use of new technologies in food production and preservation.[250] On the international level, in some cases the US has explicitly endorsed the precautionary principle. It signed the 1985 Vienna Convention on Ozone Depleting Substances, which recognized the importance of taking precautionary measures to address the gangers of ozone depletion. The US also signed the 1992 Rio Declaration, which emerged from the UN Conference on Environment and Development. The Declaration is regarded as the most influential international statement of the precautionary principle. In addition, the US signed the CTIES, which endorses precautionary principle as regards ocean dumping of radio active waste.[251]

As the widely divergent attitudes toward GMO food demonstrate, the American public generally sees promise in technological change while Europeans tend to be more sceptical. This translates into a tendency in Europe to favour a strong version of the 'precautionary principle'.[252] Accordingly, the US utilizes the precautionary principle as a 'risk assessment' tool. The precautionary principle can be invoked in the absence of scientific literature, or when sufficient scientific literature exists to establish a causal link of risk likelihood.[253] The EU, however, utilizes the precautionary principle as 'risk assessment' and 'risk management tool. Therefore, the principle can be used to ensure precaution in light of non-scientific perceptions and concerns.[254] In both the US and EU the use of precautionary principle revolves around scientific risk assessment, but in the EU the principle also mediates between scientific and lay perspectives on risk.[255]

In sum, the precautionary principle has emerged as a critical component of the new European approach to risk regulation, as well as an important focus of disagreement

[250] Gregory C. Shaffer & Mark A. Pollack, 'Regulating Between National Fears and Global Disciplines: Agricultural Biotechnology in the EU' (n 128) p. 13.
[251] Robert V. Percival, 'The North American Symposium On The Judiciary And Environmental Law: Who's Afraid Of The Precautionary Principle?'(2005) 23 Pace Envtl L Rev, p 21.
[252] Daniel C. Esty, Strengthening the International Environmental Regime: A Transatlantic Perspective, in Ernst-Ulrich Petersmann & Mark A. Pollack, (eds) *Transatlantic Economic Disputes: The EU, the US, and the WTO* (International Economic Law, OUP, 2003), p. 373.
[253] Grant E. Isaac and William A. Kerr, 'A Harvest of Trouble' (n 146) p. 1088.
[254] Grant E Isaac and William A Kerr, 'A Harvest of Trouble' (n 146) p. 1083.
[255] See Maria Lee, *EU Environmental Law* (n 48), p. 105.

between the US and Europe regards GMOs. Based on this comparison we can conclude that the EU seeks to widen the grounds upon which a country may exclude products that pose either unknown or unacceptable risks. Conversely, the US seeks to strengthen the role of risk assessment in order to limit the ability of its trading partners to seek regulations, and invokes international law as evidence of and support for its position.[256] The next section analyses various factors explaining the extent of opposition to GMOs in the EU.

4.4 Public acceptance of GMO: EU v US

Concerns about food safety are not the only factors influencing European public opinion about GM crops and foods. Europeans also seem to have a deeper cultural connection to their food. Supermarkets have not entirely replaced the local, food producers such as local markets, bakers, and butchers. In contrast, most urban American consumers have little connection with the food production process, and most products are marketed and shipped nationwide, often with an emphasis on novelty, consistency and convenience.[257]

'Europeans and biotechnology' is a series of Eurobarometer surveys, [258] which demonstrate that for the EU's general public, GM foods are perceived above all as hardly useful, non-natural, and risky, accompanied with limited trust in the institutions and corporations concerned, from the fear of putting financial gain ahead of public welfare. A Eurobarometer survey conducted in 2002 indicated that 54% of European consumers think GM foods are dangerous.[259] The Eurobarometer 2005 survey showed general opposition to agricultural biotechnologies, despite widespread support for medical and industrial biotechnologies. The majority of Europeans saw GM foods as not useful, as morally unacceptable, and as a risk for

[256] This point will be explored further in Chapter 4.
[257] 'US vs EU: An Examination of the Trade Issues' Pew Initiative on Food and Biotechnology (n 45) p.7.
[258] The 'Europeans and biotechnology' is a series of Eurobarometer surveys measuring the attitudes and perceptions of a representative sample of the adult population of each Member State. Previous surveys are not considered. They are: 1991 (Eurobarometer 35.1); 1993 (Eurobarometer 39.1); 1996 (Eurobarometer 46.1); 1999 (Eurobarometer 52.1).
[259] Europeans and Biotechnology in 2002, Eurobarometer 58.0, http://ec.europa.eu/public_opinion/archives/ebs/ebs_177_en.pdf accessed 13 march 2012.

society. A majority (58%) also believed that the development of GM foods should not be encouraged.[260]

The latest Eurobarometer survey, conducted in 2010, maintained that Europeans generally do not see benefits of genetically modified food, regard it as probably being unsafe or even harmful, and are not in favour of developing genetically modified food. [261] When asked about attitudes towards genetically modified foods, a high proportion, 70%, agreed that GM food is fundamentally unnatural. Sixty one percent of Europeans agreed that GM food makes them feel uneasy. In addition, 61% of Europeans disagreed that the development of GM food should be encouraged, 59% regarded GM food as unsafe for their health and that of their family, and 58% viewed GM food as unsafe for future generations.[262] As regards attitudes towards those responsible for biotechnology, Europeans trusted and were most positive about medical professionals (81%). Views of university scientists (77%), consumer organisations (73%), and environmental groups who campaign about biotechnology products (66%) were also broadly positive.[263]

The survey also showed that Europeans are divided in their optimism about biotechnology and genetic engineering as a science. A slim majority of 53% saw it as being a positive influence on their way of life over the next 20 years. The country results, however, highlight wide differences in opinion or knowledge about the subject between the Member States. The survey showed that Iceland has the highest proportion of respondents who see biotechnology and genetic engineering as positive (79%). At the other end of the scale, only 38% of respondents in Bulgaria see biotechnology and genetic engineering as positive, whereas 22% see the science as negative.[264]

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[260] However, it's not top of most people's environmental worries. Eurobarometer poll published in 2005 indicated that 'GMOs in farming' came 11th on a list of 15 environmental concerns. Europeans and Biotechnology in 2005: Patterns and Trends, Eurobarometer 64.3, http://ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf.

[261] TNS Opinion & Social, 'Biotechnology' Special Eurobarometer 341 /Wave 73.1, Report for the European Commission (October 2010), p.7. This Eurobarometer survey measures the overall attitudes and awareness of Europeans in the 27 EU Member States, the two candidate countries, and the EFTA countries towards biotechnology, including genetic engineering.

[262] Ibid, p.18-31.

[263] Ibid, p.153.

[264] Ibidp.1-7. In addition, for some countries, there are many respondents who do not know. In Malta, 46% of respondents are positive, but 43% do not know. Similarly, in Bulgaria, 38% of respondents are positive, and 36% do not know.

Looking at the overall control and influence of biotechnology, Europeans firmly believe that governments should take responsibility to ensure benefits for all, but they are not convinced that governments will act accordingly. The survey showed that three quarters of respondents (76%) are of the view that government should take responsibility to ensure that new technologies benefit everyone. Only 16% felt that it is up to people to seek out the benefits from new technologies themselves.[265] The European Commission found itself in a difficult position. On the one hand, it defended its regulation as prioritising strict science-based health and safety testing.[266] On the other, it was responsible for fulfilling its WTO obligations, including compliance with the ruling in order to avoid trade sanctions.[267] The Commission was accused by some NGOs for taking a proactive position on GMOs, using its legal powers to end the six year long moratorium, and promoting GM foods despite massive objections from its citizens and a lack of sufficient support from EU Member States.[268]

Vogel and others warned that a WTO ruling against the EU could increase this popular opposition, which was already strong.[269] It is not surprising that over 740 organizations with a combined membership of 60 million people have supported a campaign called Bite Back – Hands off our food! The campaign demands that the WTO does not force GM foods onto people against their wishes. It also asserts that the WTO is an illegitimate forum in which to deal with GMOs.[270]

Moreover, the 'GM-free' regions movement is growing in the EU. More than 4,700 elected local governments and 169 regions have declared themselves 'GM free'.[271]

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[265] Ibid, p.182.
[266] Speech by EU Trade Commissioner Peter Mandelson, 'Biotechnology and the EU' (n 6), noting that the Commission also recognises that safe biotechnology has a crucial role to play in agriculture and agricultural trade both in Europe and the developing world.
[267] See the next section compliance with the Panel ruling.
[268] FoEE, 'Trying to Force Feed the World: The Transatlantic Trade Dispute Over Genetically Modified Foods.' (Briefing, FoEE, Brussels, Belgium), www.foeeurope.org. Accessed 7 July 2008.
[269] David Vogel and Olivier Cadot, 'France, the United States, and the Biotechnology Dispute' (n 52); 'US vs EU: An Examination of the Trade Issues' Pew Initiative on Food and Biotechnology (n 45) p.11; Robert L Paarlberg et al., 'Regulation of GM Crops: Shaping an International Regime' in Robert E. Evenson and Vittorio Santaniello (eds) *The Regulation of Agricultural Biotechnology* (CABI Publishing 2004), p.7.
[270] FoEE, 'Trying to Force Feed the World' www.bite-back.org (n 268).
[271] 'List of GMO- Free Regions', (September 2010) http://www.gmo-free-regions.org/gmo-free-regions/list.html. Accessed January 2013.

An increasing number of EU Member States have made statements committing themselves to remaining 'GM free'.[272]

Most European supermarkets choose not to stock products containing GM products on the grounds that many clients would decide to shop elsewhere.[273] Food companies are also unlikely to start using GM ingredients in the face of consumer rejection of GM food. Even if such companies did use GM ingredients, EU labelling laws allow people to choose the non-GM option.[274]

The desire of the Europeans to know what they are eating and their willingness to appropriately exercise their right to choose has also led, not only to the changes in the authorisation procedures relating GMOs based on the precautionary principle, but to the adoption of regulations imposing a mandatory system for the traceability and labelling of GMOs and GM products.[275] The EU's policy and legislative provisions formally create spaces in which citizens can engage in and influence decision processes and outcomes. Public opinion is necessary, but should not be followed in all cases.[276] The Commission acknowledged that public fears may be misplaced, but they cannot and should not be dismissed: '[w]e and by that I mean you the industry and we, public authorities and governments need to do a better job of setting out the issues.'[277]

Opposition of the public supported the EUs authorization system, and in some EU Member States maintained the bans despite the recommendations of the Panel in

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[272] For example, Hungary, Luxemburg, Poland, and Romania impose either general bans or specific bans on the cultivation of the cultivation of 'potato Amflora' or Monsanto's maize MON 810. 'EU Cultivation bans in Europe', http://www.gmo-free-regions.org/gmo-free-regions/list.html. Accessed January 2013.

[273] Tim Josling et al., *Food Regulation and Trade* (n 59) p. 163; and Maria Lee, *EU Regulation of GMOs:* (n 8) p. 8.

[274] The GMO dispute at the WTO: claims of a US victory are misplaced! See Genewatch, ,'Questions and Answers', January 2006, http://www.genewatch.org/WTO/WTO_Q&A_Jan06.htm. Accessed 2 February 2006.

[275] See sections 2.1-2.3 above. Also see Helen Trudeau and Celine Negre, 'Precaution in the Multilateral Environmental Agreements and its Impact on the World Trading System' (n 237) p. 623.

[276] Lee contends that it still to promote truly open and inclusive dialogue with EU citizens. She uses 'The UK's *GM Nation?'* as an example which enjoyed some success as exercise in public deliberation, demonstrating 'what can be done in terms of public involvement in complex policy areas.' Maria Lee, *EU Regulation of GMOs* (n 8) p. 53.

[277] Speech by EU Trade Commissioner Peter Mandelson: 'Biotechnology and the EU' (n 6).

Biotech, some argue that the Panel failed to account for the cultural significance of food, and therefore, the dispute did not end with the panels' ruling.[278]

In contrast to the EU, GMOs have entered the food and feed system in the US without widespread public concern or even noticeable public awareness.[279] In the US, GMOs are largely treated in the same fashion as traditional food items. That is, food products produced with or containing GMOs are not required to carry any special labeling, making it impossible for consumers to express their preferences for or against GMOs through their purchasing power.[280]

However, an increasing number of Americans are concerned with protecting the consumer's right to information in order to facilitate making informed choices about what they eat. They have joined together in support of the FDA petition demanding the mandatory labelling of genetically engineered foods.[281] The 'Just label it' campaign claims that 90% of Americans are in favour of and support mandatory labelling of GM food, citing political and independent surveys.[282]
The recent judicial development in the US has demonstrated that the legal framework relating to the cultivation of GMOs has started to be influenced by concerns that are similar to those in the EU. Most notably by private persons' challenge of APHIS decisions to grant non-regulated status to round up ready alfalfa crops.[283]

In November 2011, the Center for Food Safety filed a ground breaking 'legal petition' with the US Food and Drug Administration demanding the agency require labelling for GMOs. The 'legal petition' was prepared on behalf of the 'Just label it' campaign and a number of organizations representing the healthcare community,

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[278] Laylah Zurek, 'How the WTO Fails to Consider Cultural Factors in the Genetically Modified Food Debate' (n 126).
[279] Cinnamon Carlarne, 'From the USA With Love' (n 124) p. 316.
[280] Ibid, p. 318.
[281] For more details about the campaign visit http://justlabelit.org/.
[282] Frequently Asked Questions, Just label it, available at http://justlabelit.org/faqs/ . Accessed January 2012. Currently, over 1 million people have joined the petition. See also Colin O'neil 'Consumers Call on FDA to Label Foods' Genewatch, http://www.councilforresponsiblegenetics.org/genewatch/GeneWatchPage.aspx?pageId=393. Accessed 24 October 2012.
[283] See a comment Alberto Alemanno, 'The First GMO Case in Front of the US Supreme court: To Lift or Not to Lift the Alfalfa Planting Ban' (2010) 2(1) EJRR 152-153.

consumer advocates, farmers, concerned parents, environmentalists, food and farming organizations, businesses, the faith-based community, and more.[284] The Center for Food Safety, maintains that twenty states have considered bills requiring labelling for or prohibiting GM foods over the past three years. In November 2012, California's legislature turned down legislation on labelling.

The Center for Food Safety issued an updated report on Monsanto's unprecedented use of patents and restrictive licensing agreements to investigate and sue farmers for suspected seed saving. Monsanto and its hired investigators continue to harass, intimidate and prosecute American farmers, primarily in cases involving alleged saving and replanting of the company's Roundup Ready soybeans.[285] As of 13 January 2010, Monsanto had filed 136 lawsuits against farmers for alleged violations of its Technology Agreement and/or its patents on genetically engineered seeds. Monsanto has sued farmers and small farm businesses in at least 27 different states. These cases have involved 400 farmers and 53 small farm businesses. Sums awarded to Monsanto in 70 recorded judgments against farmers total $23,345,820.99.[286]

The Center for Food Safety seeks to 'halt the approval, commercialization or release of any new genetically engineered crops until they have been thoroughly tested and found safe for human health and the environment. CFS maintains that any foods that already contain genetically engineered ingredients must be clearly labelled. Additionally, Center for Food Safety advocates the containment and reduction of existing genetically engineered crops.'[287] This effort does not go as far to demand full revision for authorisation. Rather it is mainly driven by consumers demanding labelling (right to know what they are eating), although it does not reflect the same

[284] Center for Food Safety, 'Groups File Legal Petition with FDA Demanding Labelling of Genetically Modified Foods', Press Release, Washington DC (4 November 2011), http://www.centerforfoodsafety.org/2011/10/04/groups-file-legal-petition-with-fda-demanding-labeling-of-genetically-engineered-foods/. Accessed 30 September 2012

[285] Center for Food Safety, 'Monsanto v US Farmers: 2010 Update', http://www.centerforfoodsafety.org/wp-content/uploads/2012/03/Monsanto-v-US-Farmer-2010-Update-v.-2.pdf. Accessed 30 September 2012

[286] Ibid.

[287] See Center for Food safety on 'Genetically Engineered Crops', http://www.centerforfoodsafety.org/campaign/genetically-engineered-food/crops/. Accessed 30 September 2012.

hostile attitude of EU citizens. This trend may be linked to the few cases of food supply contamination with GM products or seeds.[288]

Theoretically, according to Vogel, if in the near future there is an increase in public hostility in the US, combined with 'internationalisation' where industry and farmers adjusting to meet EU market demands, it may result in the 'California effect', a strengthening standards in the US.[289] The phrase 'California effect' refers to the American state that has often been a frontrunner in raising regulatory standards in the United States. California, for instance, has had America's strictest automotive pollution-control standards for more than three decades, making American mobile emissions standards steadily stronger. Car producers had strong incentive to produce vehicles that comply with California's stricter standards so they could continue to market their cars in its large market.[290]

A 'California effect' takes place when a country (or coalition of countries) exports it own more stringent standards to, or imposes them upon, one or more of its trading partners through the use of market access. For example, a country may ban or threaten to ban imports of products that do not conform to certain standards. If, in reaction, that country's trading partners raise their regulatory standards in order to export their products a 'California effect' will have taken place.[291] The 'California effect' holds not only for product standards, but also for production standards. It takes place when a country uses restrictions, or the threat of restrictions, on access to its markets to force trading partners to change their production standards despite the fact that such practices violates WTO rules.[292]

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[288] US authorities have few initiatives and proposals to reduce such future incidents. See section 3 above.

[289] Vogel provides two mechanisms by which the standards of 'greener' countries can be 'exported' to other, less green ones: one has to do with the term market access, the other with international agreements. See David Vogel, 'Trading Up and Governing Across: Transnational Governance and Environmental Protection', (1997) 4(4) Journal of European Public Policy, p. 561.

[290] Ibid, p. 561. The term 'California effect' is used as a synonym to 'trading up'. See Thomas Bernauer, 'Causes and Consequences of International Trade Conflict over Agricultural Biotechnology' (2005) 7(1/2/3) Int J Biotechnology p.15.

[291] Sebastian Princen, *EU Regulation and Transatlantic Trade* (Kluwer Law International, 2002) pp.5-7.

[292] David Vogel, 'Trading Up and Governing Across' (n 289) p. 563.

Vogel admits that the 'California effect' has a limited impact. Its use has been limited to a small number of highly visible and largely symbolic products usually associated with natural resources.[293] Factor in the wide ranging debate on the safety of GMOs as discussed in chapter 2 and the lack of international consensus on safety and trade in GMOs (as will be covered in Chapter 4), and we can rule out its influence for the time being. Arguably, the European measures led to a limited degree of strengthening in American and Canadian standards, although only in an indirect sense, and more so in the US than in Canada. Only US exporters have made efforts to accommodate changes in the EU' regulations and consumer preferences. For example, soybean producers have restricted cultivation of GM soybean varieties not approved by the EU, and corn processors set up systems that keeps GM corn not approved in the EU out of the export production chain.[294]

Without the consent of society at large, GM crops will fail in the market place. The actual future of GM crops is therefore likely to depend primarily on social, political, and legislative developments.[295]

5 Post Panel's Ruling

The EU informed the DSB that it intended to comply with the recommendations of the rulings of the Panel, but needed a reasonable period of time to do so.[296] Canada, Argentina, and the US have been meeting regularly with the EU to discuss biotech-related issues since the adoption of the WTO panel report in 2006. This resulted in a partial settlement to the long-running dispute. Discussions with Canada and Argentina have been fruitful, resulting in settlement and providing annual bilateral dialogue aimed at exchange of information that contributes to avoiding unnecessary obstacles to trade. [297]

[293] Also, the WTO rules have played a role in discouraging rich countries from using production standards to restrict imports from less developed ones on environmental grounds. See David Vogel 'Trading Up and Governing Across' (n 289) p. 564-5.
[294] Other voluntary action relate to halting commercialisation of GM wheat for fears of losing export markets. See Thomas Bernauer, 'Conflict Over Agricultural Biotechnology' (n 290).
[295] Jan-Peter Nap et al., 'The Release of Genetically Modified Crops into the Environment, part I. Overview of Current Status and Regulation' (2003) GM Special Issue 33 The plant Journal, p. 2, 8.
[296] Agreement under Article 21.3(b) of the DSU, *Biotech,* WT/DS291/35 (26 June 2007).
[297] Dispute Summary, *Biotech*, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm. Accessed August 2012.

Canada and the EU established a bilateral dialogue on agricultural biotech market access issues of mutual interest.[298] Meetings will be held bi-annually, generally in person, alternating between Brussels and Ottawa. Both sides will ensure the participation in the meetings of the competent services of their respective administrations depending on the specific subject matter discussed. The dialogue covers issues such as 'GM product approvals' in the territory of Canada and the EU, 'any biotech-related measures' that may affect trade between Canada and the EU, including measures of EU Member States, and 'any new legislation in the field of agriculture biotechnology'.[299]

Argentina reached a similar settlement with the EU. This settlement also established annual bilateral dialogue on 'issues related to the application of biotechnology to agriculture'. EU authorities meet with their Argentinean counterparts to discuss agricultural biotechnology and trade issues of mutual interest, such as the 'authorization processes of GM products' of mutual interest, 'measures related to biotechnology' which may affect trade, 'evaluating the economic and trade outlook of future GM product approvals', and the 'renewal of GM product authorizations.[300]

The EU maintained that it was not expected to modify its current regulatory regime on biotech products, which was not subject to the *Biotech* dispute.[301] The *de facto* moratorium, arguably, ceased to exist after the approval of several applications as described in section 2.3 above. Similarly, the matter of product specific measures was resolved either by undertaking and completing the approval procedure, or withdrawal by applicant. By the end of 2012, the EU had approved only six GM products for the year, with an average processing time of 40 months. In addition, the EU has not approved for cultivation a single GM product of commercial significance to the United States in over 12 years.[302] The US continues to stress its concerns regarding the EU's regulatory framework. European delays in GM

[298] Notification of a Mutually Agreed Solution, WT/DS292/40 (17 July 2009).
[299] Ibid.
[300] Notification of a Mutually Agreed Solution, WT/DS293/41 (23 March 2010).
[301] 'EU and Canada settle WTO case on Genetically Modified Organisms', press release IP/09/1142 (Brussels, 15 Jul 2009), http://europa.eu/rapid/press-release_IP-09-1142_en.htm. Accessed 2 March 2010.
[302] 72 GM product applications (for import, renewal, and cultivation) were pending approval in the EU system. See USTR, '2013 Report on Sanitary and Phytosanitary (SPS) Barriers to Trade' (n 5) p42-43.

product approvals can block trade not only for the products subject to the delays, but also for approved varieties. Traceability and labelling pose another threat. Under the EU's implementation of its biotechnology legislation, 'the presence in US grain or oilseed shipments of trace amounts of GM crops that are legally grown in the United States, but not yet approved in the EU, can make US crops unmarketable in the EU'.[303] In 2008, the US requested authorisation from the DSB to suspend concessions and other obligations with the EU.[304] In July 2011, the EU implemented a 'technical solution' to address the presence of trace amounts of unapproved GM products in imported animal feed, but this did not satisfy the US as it excluded food for human consumption.[305] The United States has maintained its suspended concessions.

The *Biotech* dispute shares many similarities with the *Hormones* dispute because the latter not only focused on scientific and technical aspects of the hormone ban and its validity under terms of the SPS, but also because the disagreement on implementation was a long battle. The *Hormones* dispute was a prolonged battle between the EU and the US over the safety of the use of synthetic and natural growth promoting hormones in cattle. The EU banned the use of hormones, and banned the importation of all beef and beef products containing any of six banned hormones.[306]

In *Hormones,* the Panels ruled against the EU, and the AB confirmed the ruling.[307] The European Commission, failed to supply the requisite scientific evidence to

[303]Since 2006, European rice importers and retailers have largely refused to purchase U.S. rice out of fear of the legal and commercial consequences should a detection of Liberty Link 601 (LL601) trait, which had to be withdrawn from the US market. This is an example of the effect of traceability and labelling. See USTR, '2013 Report on Sanitary and Phytosanitary (SPS) Barriers to Trade' (n 5) p.44-45.

[304] At the time of writing this chapter, the suspension of concessions was still an open question. See Recourse to Article 22.2 of DSU by the United States, *Biotech,* WT/DS291/39 (21 March 2008).

[305] USTR, '2013 Report on Sanitary and Phytosanitary (SPS) Barriers to Trade' (March 2013) (n 5) p 44; and 'EU, Argentina End Seven-Year WTO Biotech Row', 10(5) Bridges Trade BioRes (19th March 2010) http://ictsd.org/i/news/biores/72588/, Accessed March 2011.

[306] Cinnamon Carlarne, 'From the USA with Love' (n 124) p. 305.

[307] The Appellate Body decision and the consequent countermeasures did not bring an end to the United States-Canada-EU hormone dispute. Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States*, WT/DS26/R/USA, adopted 13 February 1998, modified by Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:III, 699; and Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998.

establish danger within the set period of time. The EU also refused to bring its measure into compliance with the WTO ruling. As a consequence, the United States and Canada suspended concessions on EU items, including Roquefort cheese, foie gras, and Perrier water. In total, the compensation amounted to approximately US $117 million in concessions for the United States, and approximately US $8 million for Canada. [308]

On November 2004, the EU requested consultations with respect to the United States' continued suspension of concessions and other obligations under the covered agreements in the *Hormones* dispute. The Appellate Body issued its Reports in October 2008.[309] The AB was unable to complete the analysis as to whether Directive 2003/74/EC brought the EU into substantive compliance within the meaning of Article 22.8 of the DSU. Therefore, the AB found that the recommendations and rulings adopted by the DSB in *Hormones* remain operative.

Finally, on December 2008, the EU requested consultations with the US pursuant to Articles 4 and 21.5 of the DSU, regarding the EU's implementation of the DSB's recommendations and rulings in the *Hormones* dispute. Discussions between the EU and US resulted in the Conclusion of the Memorandum of Understanding regarding the importation of beef from animals not treated with certain growth-promoting hormones. It also resulted in increased duties applied by the United States to certain products of the European Communities as agreed by the United States and the European Communities on 13 May 2009.[310]

With regard to the *Biotech* dispute, the United States and European Commission renewed a consultative Task Force on Biotechnology Research. The Task Force on Biotechnology Research aims 'to promote information exchange and coordination between biotechnology research programs funded by the European Commission and the United States government.' The Task Force opens dialog between

[308] Cinnamon Carlarne, 'From the USA with Love (n 124) p. 307.
[309] AB Report *United States- Continued Suspension of Obligations in the EC – Hormones Dispute* WT/DS320/AB/R 16 October 2008.
[310] *European Communities- Measures Concerning Meat and Meet Products (Hormones)* – Joint Communication from European Communities and the United States, WT/DS/26/28, (30 September 2009).

American and European agencies that conduct biotechnology research. Its stated mission is 'to anticipate the needs of tomorrow's science, today'.[311] However, it is unlikely that the dialog will lead to a settlement on the *Biotech* dispute because the Task Force does not include the agricultural applications of biotechnology/GMOs. Instead, it covers other applications of biotechnology and promotes research in the field of 'neuroinformatics, nanobiotechnology, environmental biotechnology, application of biotechnology to fuels and other products and synthetic genomics'.[312]

The Commission has indirectly favoured the cultivation of GM crops by fulfilling its task of enforcing EU legislation, it also bought successful enforcement actions before the CJEU against some EU Member States. Despite the Commission's commitment, compliance has proved to be complicated, and not fully resolved with all parties, in particular with regard to the recommendations on national safeguards measures.[313] *Biotech* demonstrates that EU GMO policies are so important that the EU is willing to remain in contravention of full implementation of the ruling. The next section tackles recent revision of the EU regulatory framework and the improvement in its implementation, which may potentially widen the gap between the US and the EU.

5.1 Beyond authorisation

GMO regulatory framework reflects the complexity of decision making and the value basis of decision making in the EU.[314] It is not only a 'process of authorisation new technology'. It is also about what happens afterward as 'rules on labelling, coexistence, liability and intellectual property rights are a crucial part of regulatory settlement of GMOs, influencing the relationship between the biotechnology industry and those it affects.'[315]

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[311] Agreement signed 8 June 2006 by John Marburger, Director of the White House Office of Science and Technology Policy, and Janez Potocnik, Commissioner for Science and Research for the European Commission. For more information about the Task Force, see http://ec.europa.eu/research/biotechnology/ec-us/index_en.html; 'United States, European Commission Renew Biotech Task Force', USINFO, 12 June 2006 http://usinfo.state.gov/xarchives/display.html?p=washfile-english. See also http://usmission.gov.

[312] 'United States, European Commission Renew Biotech Task Force' USPOLICY, Embassy of the United States, Belgium 12 June 2006.

[313] See Sara Poli, 'The EC's Implementation of the WTO Ruling in the Biotech Dispute' 32 *E L Rev,* p. 719.

[314] Maria Lee, *EU Regulation of GMOs* (n 8) p. 243.

[315] For discussion regards labelling, coexistence, liability and intellectual property rights see Maria Lee, *EU Regulation of GMOs* (n 8) Chapters 4 and 5.

In *Biotech*, violations found in connection with the approval process related to the procedural requirement not to cause 'undue delay'. The Panel did not find other violations of the SPS Agreement in this context. In fact, the Panel specifically stated that it did not address the question of whether the EU product-by product 'approval procedures' were consistent with EU obligations under the WTO agreements.[316] If the 'approval procedure' as such was to be challenged, it should be done by filing a new complaint.

The EU and the US also disagree on how to regulate 'around and after authorisation' of GMOs.[317] This section focuses on two urgent points that may lead to the next significant trans-Atlantic trade tension: the EU's recent regulatory proposal, giving more flexibility for EU Member States to restrict the cultivation of GMOs; and traceability and labelling requirements, which is attracting increasing attention as possible restriction on international trade.

5.1.1 **Traceability and labelling**

Under the EU's GM labelling regime, any GM product must, under defined conditions, carry a label. By contrast, the US finds no basis to treat GM food and feed any differently from food or feed produced through conventional breeding. It regards such labelling and segregation requirements as based on politics, not science. In the US, labels that identify foods as derived from biotechnology are likely to be seen by consumers as 'warning labels', which would be misleading and decrease the demand for these products. The US has only issued guidelines for the private sector on the use of voluntary claims for GM-free products.[318]

While labelling requirements apply to food and feed that are intended to be marketed as non-GM in the EU, products derived from animals fed with GM feed, such as meat, milk and eggs, are not required to be labelled. As a result, some US exports, such as soy and corn gluten intended for feed uses, do not need to be

[316] Panel Reports, *Biotech*, para. 8.3.
[317] Maria Lee, *EU Regulation of GMOs* (n 8) pp. 243-5.
[318] 'US vs EU: An Examination of the Trade Issues' Pew Initiative on Food and Biotechnology (n 45) p.17.

segregated since there continues to be an active EU market for GM-labelled feed.[319] Broadly speaking, '[l]abelling GM food is both popular with consumers in both countries and an apparently reasonable way of allowing the market to decide on the premiums for desired attributes.' However, labels are by no means a simple solution, and merely move the debate to discussing how to label and how to enforce labelling requirements.[320]

The US commodity grain system routinely mixes GM varieties with conventional varieties of corn and soybeans. To avoid the EU threshold for labelling, US farmers, food manufacturers, and food and grain exporters must segregate GM crops and foods derived from such crops at every step of the production process, 'a costly requirement'. Additionally, '[m]eeting the EU threshold of no more than 0.9 percent GM content is also difficult to achieve and equally difficult to test with consistency, creating uncertainty about liability despite efforts to comply.'[321] The US may argue that it is unnecessary and very costly to keep GMOs separate. It also considers labelling requirements or import bans unnecessary trade barriers.
In line with this position, many agriculture and agri-business groups in the US have called their government to initiate another challenge of EU GMO legislation on traceability and labelling before the WTO. This additional threat of dispute resolution is aimed at preventing further disruption of transatlantic trade, and at ensuring other countries do not adopt similar legislation.[322]

The EU regulatory system on authorisation, labelling and traceability are likely to raise further questions about compliance with WTO law. It is not clear which part of which WTO agreement is likely to apply to the EU legislation. Discussion of the

[319] 'US vs EU: An Examination of the Trade Issues' Pew Initiative on Food and Biotechnology (n 45) p.16
[320] Tim Josling, et al, *Food Regulation and Trade* (n 59) p. 164. Labelling implies some form of legal liability, and food sellers cannot ignore this liability. For more, see Philip Katz et al., 'The Evolving GMO Food and Trade Policy Debate: Towards a Global Regulatory Regime?' (n 162) p. 25.
[321] Although total costs of compliance are not available. See 'US vs EU: An Examination of the Trade Issues' Pew Initiative on Food and Biotechnology (n 45) p.16.
[322] Simonetta Zarrilli, *National and Multilateral Legal Frameworks*, (n 33) p.13.

compliance of these legislation with the covered agreements goes beyond the scope of this thesis. There is, however, extensive academic literature on the topic.[323]

5.1.2 **Compliance with WTO law**

If the US or other WTO Member chooses to challenge current EU's authorisation framework, *Biotech* ruling will be of key importance. In particular, it is worth recalling the Panel's reasoning regards the applicable law which gave a broad reading to the definition of an SPS measure, it adopted an expansive understanding of the concept of an SPS measure, seeming to bring an unexpectedly wide range of EU's legislation concerning authorisation procedure. (For full analysis see chapter 1, section 3.2) Following the detailed analysis of Annex A of the SPS Agreement, the Panel held that many of the potential effects at which the EU measures were aimed fell within the scope of the SPS Agreement. The Panel held that Directives 90/220 and 2001/18 as well as Regulation 258/97 were, for the most part, SPS measures which may, directly or indirectly, affect international trade within the meaning of the SPS Agreement.[324] Overall, the Panel's interpretations of key terms of EU's authorisation framework, and of the national bans, qualified as purposes covered by the SPS Agreement.

The Panel somewhat restricted the ability of Members to impose SPS measures based on a perceived inadequacy of the scientific evidence available, thus limiting the precautionary principle to cases where the scientific evidence in a particular risk assessment is internally inconsistent, or where there is insufficient evidence to even conduct a risk assessment as defined in Annex A(4) (see chapter 1, sections 5.3-5). Panel's reasoning implies a broad applicability to the scientific justification requirements of the SPS agreement.[325] (Chapter 4 covers the implications of expansion of the scope of the SPS Agreement) which is used to cover environmentally related measures rather than the TBT and/or the GATT agreements,

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[323] Mark Mansour and Sarah Key, 'From Farm to Fork: The impact on Global Commerce of New European Union Biotechnology Regulatory Scheme' (2004) 38 Int'l Law 55; and Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (OUP, Oxford, 2007), pp. 230-241.

[324] Panel Reports, *Biotech,* paras. 7.432-7.437. The panel noted that Regulation (No) 258/97 was not an SPS measure to the extent it applied to ensure either that novel foods do not mislead the consumer or that they are not nutritionally disadvantageous.

[325] Christiane R Conrad, 'PPMs, the *EC Biotech* dispute and the Applicability of SPS Agreement' (2007) 6(2) World Trade Review. 243.

unless the Panel or Appellate Body choose to overturn these holdings in the future.[326]

another fundamental and contested question in relation to EU's authorisation framework is whether GMOs are substantially different from non-GMOs and pose greater risks to human health and the environment. A future dispute may also raise the issue of 'like product' by arguing that various features of EU regulations and policies violate the national-treatment obligation in the GATT (Article III:4) because they provide 'less favourable treatment' to imported GMO products than to domestic non- GMO products.[327] For guidance on the issue we can turn to older disputes, such as *EC-Asbestos*[328]in which the AB provided guidance on assessing whether one product is 'like' another. The AB stressed, the determination of whether a measure violates Article III:4 entails a two-step test. The first step is to ascertain whether the imported products are 'like' the domestic products in relation to which the complainant is claiming that the imports are being treated less favourably. The second step, in turn, is to ascertain whether the measure in fact causes less favourable treatment of the 'group' of like imported products versus the group of domestic products.[329] Four general criteria apply in analysing 'likeness': (i) the properties, nature and quality of the products; (ii) the end uses of the products; (iii) consumers' tastes and habits in respect of the product; and (iv) the tariff classification of the products.[330]

EC-Asbestos involved a challenge under the TBT Agreement and the GATT to a French ban on imports of asbestos fibres, and products containing them. The AB acknowledged the value of the traditional test, but noted that its general criteria are neither treaty mandated, nor composed of a closed list. Use of the criteria 'does not

[326] This also means that very few measures will fall under the TBT Agreement. See discussion in section 3.2 below.
[327] *Biotech* Panel's ruling did not consider a breach under Article III:4 because it established a breach under the SPS Agreement, following the reasoning in *Hormones.* See chapter 1, section 5.2
[328] Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, adopted 5 April 2001 [hereinafter '*EC-Asbestos*'], In overturning the Panel's decision that the TBT Agreement did not apply, the Appellate Body determined that it did not have an 'adequate basis' to complete an analysis of the measure under TBT Agreement.
[329] *EC- Asbestos*, para. 100
[330] *EC-Asbestos*, para. 10, 85. For discussion on 'like products' see Maria Lee, *EU Regulation of GMOs* (n 8) pp. 238-240.

dissolve the duty or the need to examine, in each case, all, of the pertinent evidence.' The AB stated:

> …the kind of evidence to be examined in assessing the "likeness" of products will, necessarily, depend upon particular products and the legal provision at issue. When all the relevant evidence has been examined, panels must determine whether that evidence, as a whole, indicates that the products in question are "like" in terms of the legal provision at issue.[331]

The AB adopted the view that different production methods cannot render two otherwise identical products. Consequently, differential treatment of such like products based on their production methods was found to violate the GATT non-discrimination obligation (Article III's national treatment obligation). The French measure was found to be justified as a necessary measure for the protection of human life or health (Article XX(b)).

In *Biotech*, the Panel did not follow this order, it started with assessing the 'no less favourable treatment' obligation contained in Article III:4, rather than on the 'like product' element. The Panel held that Argentina is not alleging that the treatment of products has differed depending on their origin. It held that in these circumstances: [332]

> 'it is not self-evident that the alleged less favourable treatment of imported biotech is explained by the foreign origin of these products rather than, for instance, a perceived difference between biotech products and non-biotech products in terms of their safety, etc…'

The panel explained is that Argentina has not provided specific factual information about the treatment accorded by the EU to the non-GMOs which Argentina considers to be like the GMOs at issue.[333] Therefore the Panel managed to avoid tackling the issue.

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[331] *EC- Asbestos*, paras. 101-103.
[332] Panel Reports, *Biotech*, para. 7.2514.
[333] Panel Report, *Biotech,* para. 7.214

Similarly, in *United States — Poultry (China)*, [334] the Panel supported a 'hypothetical' 'like product' analysis where a difference in treatment between domestic and imported products is based exclusively on the products' origin it also reaffirmed that 'like product' analysis must always be done on a case-by-case basis in determining 'likeness' of products:[335]

> A different approach used by panels and the Appellate Body to determine the likeness of the products has been to assume — hypothetically — that two like products exist in the market place when one of two situations arises: first cases concerning origin-based discrimination, and second, cases where it was not possible to make the like product comparison because of — for example — a ban on imports.

The Panel in In *United States — Poultry (China)* noted that the United States has argued that the differing safety levels of poultry from China *vis-à-vis* other WTO Members may have an impact on the like products analysis. However, the United States did not provide specific evidence relating to different safety levels between poultry products From China and other WTO Members. Therefore, it did not see no reason not to proceed with the 'hypothetical' like products analysis and base our determination on whether the products alleged to be 'like' are distinguished solely because of their origin.[336] Noting that the funding restriction in question was 'origin-based in respect of the products it affects', that Panel followed a hypothetical like products analysis.[337]

In the recent dispute *United States- Cigarettes,*[338] the Appellate Body disagreed with the Panel that 'like products' in Article 2.1 of the TBT Agreement should be interpreted based on the regulatory purpose of the technical regulation at issue. The Appellate Body considered that the determination of whether products are 'like' within the meaning of Article 2.1 of the TBT Agreement is a determination about the competitive relationship between the products, based on an analysis of the

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[334] Panel Report, *United States –Certain Measures Affecting Imports of Poultry from China* WT/DS392/R adopted 25 October 2010 [hereinafter *United States-Poultry (China)*]
[335] *United States-Poultry (China),* para. 7.424
[336] Panel Report, *US Poultry (china)* paras. 7.424–7.427, 7.429
[337] Panel Report, *US Poultry (china)* paras. 7.430–7.432
[338] Appellate Body Report, *United States- Measures Affecting the Production and Sale of clove Cigarettes*, WT/DS406/AB/R adopted 13 August 2013 [hereinafter *United States- Cigarettes*]

traditional 'likeness' criteria, namely, physical characteristics, end-uses, consumer tastes and habits, and tariff classification. The Appellate Body considered that the regulatory concerns underlying a measure, such as the health risks associated with a product, may be relevant to the determination of 'likeness' to the extent they have an impact on the competitive relationship between the products. Based on this interpretation of the concept of 'like products', the Appellate Body agreed with the Panel that clove cigarettes and menthol cigarettes are 'like products' within the meaning of Article 2.1 of the TBT Agreement. [339]

Yet, a full analysis of 'likeness' under Article III:4 based on the approach used in *EC-Asbestos*, would seek to determine what a hypothetical 'reasonable' consumer would infer about the risks of the two types of products. It remains unclear whether the consumers make a sharp distinction between GMO products and non GMO products. (see section 4.4 above). Moreover, given the significance of physical characteristics in *EC-Asbestos,* including any differential health risks that might follow from different physical characteristics, the Panel would have had to consider the implications of the physical differences between GMO and non-GMO products: conceptually, differences that flow from genetic dissimilarity are 'physical'. This also a contested mater (see chapter 2).

If in a future dispute involving EU authorisation framework to be in violation of WTO, the EU can try to justify such breaches under Article XX similar to the earlier decisions of *Shrimp/Turtle* [340] and *US-Shrimp* [341] suggest that process-based measures may, under certain circumstances, be permissible under Article XX. In those cases, the United States' measures effectively required exporting countries to use a production method involving 'turtle excluder devices' as a precondition to market entry for their shrimp products. The outcome of the Appellate Body decision in *US-Shrimp* was to permit the US to retain its process-based measure as long as it continued to satisfy the requirements set out by the Appellate Body, including the requirement to seek a negotiated solution. Reference to these cases does not provide

[339] Appellate Body Report, *United States- Measures Affecting the Production and Sale of clove Cigarettes*, WT/DS406/AB/R adopted 13 August 2013 [hereinafter *United States- Cigarettes*]
[340] Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998. [hereinafter '*US-Shrimp*']
[341] *US-Shrimp.*

a precise meaning of the notion 'like products' or the conditions of justification.[342] The ruling in *Shrimp* dispute can be applied to justify violations under GATT, but it does not apply to violations under the SPS agreement. In future disputes, the EU is likely to argue again that the existing evidence is not sufficient, inconclusive or uncertain when conducting risk assessment.[343]

Following the Biotech dispute the Commission launched re-evaluation of its newly adopted authorisation framework which also took into consideration its compliance with WTO commitments.

5.1.3 **Re-evaluation of EU's authorisation framework for GMOs**

In mid 2010, as part of continuous process of reviewing the existing legislation on GMOs and the improvement of its implementation between 2009 and early 2011, the European Commission proposed conferring on Member States the freedom to allow, restrict, or ban the cultivation of GMOs on part or all of their territory, while keeping the EU's science-based GM authorisation system unchanged.[344] The adopted 'package on GMO cultivation' consists of a Communication, a new Recommendation on co-existence of GM crops with conventional and/or organic crops,[345] and a draft Regulation proposing a change to the GMO legislation.[346] The new Recommendation on co-existence allows more flexibility to Member States, taking into account their local, regional, and national conditions when adopting co-existence measures. The proposed Regulation amends Directive 2001/18/EC, allowing Member States to restrict or prohibit the cultivation of GMOs in their territory. The Recommendation on co-existence took immediate effect.[347]

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[342] Christiane R Conrad, 'PPMs, the *EC Biotech* dispute and the Applicability of SPS Agreement' (2007) 6(2) World Trade Review, p. 243.
[343] See chapter 4, section 3.1.3 and 4.3 covers application of Article 5.7 to justify a contested measure.
[344] European Commission 'GMOs: Member States to be Given Full Responsibility on Cultivation in Their Territories', (Press Release, IP/10/921, Brussels, 13 Jul 2010).
[345] Commission Recommendation on Guidelines for the Development of National Co-existence Measures to Avoid the Unintended Presence of GMOs in Conventional and Organic Crops, 2010 OJ (C 200) 1.
[346] Proposal for a Regulation amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory, COM (2010) 375 final (July 13, 2010).
[347] European Commission 'GMOs: Member States to be Given Full Responsibility on Cultivation in Their Territories', (n 344).

In addition, the Commission proposes to include Article 26b, which would be applicable to all GMOs authorized for cultivation in the EU, under either Directive 2001/18/EC or under Regulation (EC) N°1829/2003. Member States will be able to exclude or prohibit GMO cultivation in part or all of their territory without recourse to the safeguard clause. Their decisions will not need to be authorized by the Commission, although Member States will have to inform other Member States and the Commission one month before the adoption of their measures. Member States will also have to respect the general principles of the Treaties and the Single Market, and their measures must be consistent with the international obligations of the EU.[348]

EU countries will be able to restrict or ban GMO cultivation on their territory without making a judgment on the safety of authorised GMOs but on the basis of their local, regional and national conditions when preparing their relevant legislation. The EU risk assessment procedure remains unchanged. However, two limitations apply: the measures may not be based on human health or environmental reasons due to the presumption that the authorisation procedure and safeguard clause suffice. The measures must also comply with the EU Treaties. This new approach can be considered an attempt to overcome some of the implementation problems arising from the Panel's recommendation because it can be considered a risk management measure. This proposal presents other problems and inconsistencies with respect to application of several principles of EU law, but such discussion is beyond the scope of this study.[349]

The Commission is aware of legal consequences and implications of proposed Article 26b of Directive 2001/18/EC. Reviewing the WTO compliance of trade restrictive measures under GATT agreement in cases such *Shrimp/Turtle* and *Asbestos* allow countries more autonomy in reaching decisions about acceptable types and levels of risk. The Commission considers that national measures

[348] European Commission 'GMOs: Member States to be given full responsibility on cultivation in their territories', (n 344). Proposal for a Regulation amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory (n 346).

[349] In particular, this may be inconsistent with free movement in the single market, such as Article 34 and 36TFEU, and non-discrimination principle.

(restrictions) adopted by a Member State based on this provision as defensible within the WTO system by utilising Article III:4 and Article XX of the GATT. the rational is that Article 26b allows EU Member States to restrict or prohibit the cultivation of GMOs in all or parts of their territory on grounds other than health and environment considerations, which does not trigger the application of SPS Agreement [350] However, considering the impact of the *Biotech* dispute, the Commission's approach to national measures may well alter depending on whether Article 26b and national measures are found to be in compliance with, or breach of, the WTO legal instruments.

the Commission' services provided, inter alia, general considerations concerning the compatibility with WTO of possible national measures adopted by Member States on the basis of Article 26b of Directive 2001/18/EC

In effect, the European Commission has made the post authorisation regime more flexible.[351] This has been confirmed by two independent evaluation reports carried out by independent consultants on the European Commissions' behalf. The first focused on the legislative framework in the area of GMO cultivation.[352] The second evaluated the EU's legislative framework in the field of GM food and feed.[353] The evaluations assessed the effectiveness and efficiency of legislative process, and formulated options for the system's improvement and adjustment. They were carried out as part of the continuing process of reviewing the existing legislation and improving its implementation.[354] In the field of GMO cultivation, the report concluded that under the Deliberate Release Directive and the Novel Food

[350] For an analysis of how the reform of the CMOs cultivation could be defended under the WTO provisions, see Commission Staff Working Paper n.9648/11, 5 May 2011. http://register.consilium.europa.eu/doc/srv?l=EN&t=PDF&gc=true&sc=false&f=ST%209648%202011%20INIT accessed 12 April 2014. It also added that that the SPS Agreement is unlikely to be an issue.
[351] Commission Communication on the Freedom for Member States to Decide on the Cultivation of Genetically Modified Crops, COM (2010) 380 final (Jul. 13, 2010); and Recital 7 of the Commission Recommendation on Guidelines for the Development of National Co-existence Measures (n 345).
[352] Evaluation Of The EU Legislative Framework In The Field Of Cultivation Of GMOs Under Directive 2001/18/EC And Regulation (EC) NO 1829/2003, And The Placing On The Market Of GMOs As Or In Products Under Directive 2001/18/EC, Final Report, March 2011 *EPEC.*
[353] Evaluation of the EU legislative framework in the field of GM food and feed, Final Report, *FCEC* 12 July 2010.
[354] Questions and answers on the evaluation of the European Union's GMO legislation MEMO/11/742 Brussels, 28 October 2011, http://europa.eu/rapid/press-release_MEMO-11-742_en.htm. Accessed 14 Oct 2012.

Regulation 'the system is not working as envisaged and is not, in aggregate meeting its objective.'[355]

The European Parliament supported the Commission's initiative but introduced a number of changes to the proposal designed to detail grounds that could justify restrictions on the cultivation of GMOs and to better reflect the Member States' concerns; for example emphasis was placed on the need to evaluate the long term environmental effects of GMOs, the precautionary principle, and the liability requirements in case unintended effects or damage that might occur due to the deliberate release or the placing on the market of GMOs.[356]

The Council of the European Union held a public exchange of views on the draft Regulation amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation, in all or part of their territory, of GMOs that have been authorised at EU level. The exchange of views confirmed the Member States' willingness to re-open discussions on this legislative proposal on the basis of the presidency compromise text. The Hellenic presidency aims to reach a political agreement and prepare the adoption of this important legislation by the end of 2014. [357]

EU Member States welcomed the proposal because it gives greater choice to farmers and consumers, including the presumably the choice to reject GMOs. The proposal also found approval from some commentators who criticised the Commission's previous narrow approach to coexistence as treating GMOs as a mainly economic issue since it underestimated the importance of public goods, such as sustainable development of rural areas and the environment.[358] This goes along with the view that regulation of risks must reflect what is socially acceptable in term of risk and benefit trade-offs. These trade-offs must be effectively communicated

[355] Ibid.

[356] See, European Parliament Legislative Resolution of 5 July 2011 on the Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory COM(2010)03 7 5 - C7-0178/2010 - 2010/0208(COD), 5 July 2011.

[357] Council of the European Union, 3297th Council meeting on Environment, Press Release 7094/24, 3 March 2014, p.8 A first working party meet to examine the proposal on 13 March 2014

[358] Lee considered rules on coexistence as defined by the Commission as very burdensome for those who grow non-GM crops. Maria Lee, 'The Governance of Coexistence' (n 8) p 199-205. See also Maria Lee, *EU Regulation of GMOs* (n 8) pp. 118-126.

to the public since avoiding the risk altogether may increase exposure to other risks.[359]

Critics of the EU argue against this proposal, accusing the EU regulatory process of being highly politicized and contentious, with both the public and non-governmental organizations enjoying considerable access and influence.[360]

American biotech corporations, GM farmers, and food industry, all of which make extensive use of GMOs, will find this proposal adds obstacles. It is an additional burden that may impact on trade in GMOs, and may lead food manufacturers to avoid the use of some plants despite any scientific evidence that they are harmful.

6 Conclusion

With regard to the regulation of GMOs, the US led the way with a permissive approach, assessing GM seeds and GM food products for release using essentially the same methods employed for conventional crops and foods. It also allows private markets for GM crops to operate without any new labelling or segregation restrictions. The EU initially took the same approach, but then quickly became more cautious as opposition grew among domestic consumers and environmental organizations in response to events such as the 1996 'mad cow disease' crisis. Once the European media became sensitized to food safety issues, the GM crop revolution encountered strong social resistance.[361] The regulatory systems in place in the EU and US are still responding to this new form of technology. This chapter reviewed the regulatory changes, and considered the relationship between these changes.

The EU maintains that its current system for authorising GM products on a case-by-case basis is designed to ensure they are safe for the environment, as well as human and animal health. The EU's GMO regulation is based on the precautionary

[359] Sweta Chakraborty, 'The Role of Communication in Promoting a European Wide Approach to risk based Regulation (2012) 3(1) EJRR, 112

[360] David Vogel, 'The New Politics of Risk Regulation in Europe' (n 122)

[361] Robert L. Paarlberg, *The Politics of Precaution: Genetically Modified Crops in Developing Countries* (International Food Policy Research Institute, Washington D.C., U.S.A, 2006), pp. 3-8.

principle and on authorisation procedure, which follows an environmental and health risk assessment. Once a GM product is placed on the market, it must be labelled and traceable at all times. Under various authorities, a number of GM crops and foods derived from GM crops have been approved for food use and marketing in the EU.

This chapter demonstrates that at the heart of the dispute lie fundamentally different regulatory approaches to the assessment and management of possible risks posed by the most controversial GMOs. The United States has chosen to bring the issue before the WTO, addressing it only in terms of trade agreements based on scientific risk analysis. The European Union, however, sees the issue as one encompassing social and environmental concerns in addition to trade concerns.[362]

The Ruling did not reverse European consumer distaste for GMOs, or its growing preference for organic products. Kerr explains that 'food policy may not be established on purely rational basis' he based his opinion on Adam Smith's theory that laws concerning food may be compared to the laws concerning religion. [363] In line with public support, under the revised EU legislation, the authorisation process remains complicated, long, and slow, in particular those authorisations made under the Deliberate Release Directive and the Food and Feed Regulation. Therefore, the *Biotech* ruling did not weaken the EU's ability to use a precautionary approach in regulating to meet public health, safety and environmental objectives. However, it may influence some developing countries, in particular those that have not established regulatory regimes for GMO crops. *Biotech* will very likely be used as a guide by future WTO panels on food safety, public health and environmental health measures applied to international traded goods and services.

The US and EU have not only adopted different approaches towards GM crops, but also have to sought to see their approaches reflected on the international level, which in turn seek to provide legitimacy for the increasing transfer of decisions on risk issues from national to international level. Since EU regulations continue to have an impact on the flow of genetically modified foods and crops from other

[362] See Chapter1, sections 2.2.1 and 2.2.2.
[363] William Kerr, 'International Trade in Transgenic Food Products: A new Focus for Agricultural Trade Disputes' (1999) 22(2) *World Economy*, 254.

countries, mainly the United States, they fall under the jurisdiction of the WTO. The next chapter will examine the main international instruments applying to the dispute, and highlight the interface and involvement of the EU and US at the international level, with a specific focus on the WTO Agreements and the Cartagena Protocol on Biosafety.

CHAPTER 4

GMOs, THE WTO, AND NON-SCIENTIFIC FACTORS:

MOVING TOWARDS COHERENCE

If the WTO is to become a vehicle for global governance one thing has to be clear: this vehicle ought not to travel without a road map, and should be mindful of other traffic.[1]

1 Introduction

Biotech raises questions about the degree of risk judged to be acceptable to society, as well as about how to regulate specific products or processes in the face of continuing uncertainty about the risks they may pose to human health and the environment. The US argument focused on 'risk assessment' based on sound science in compliance with the WTO's SPS agreements. On the other hand, the EU argued that it should be able to establish its own level of protection from the risks of GMOs. It maintained that its regulatory regime needed to be assessed in light of the precautionary principle, which has arguably gained the status of customary international law, as incorporated in WTO treaties, with additional reference to Cartagena Protocol commitments, which take a precautionary approach to regulating GMOs.[2] The Panel in *Biotech* rejected the EUs defence, and applied the far reaching discipline of the SPS Agreement by providing very a broad

[1] Footnote omitted, Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, Cambridge 2003).
[2] The EU obligation under the Cartagena Protocol were incorporated into their regulatory framework by Council Regulation (EC) 1946/2003 of the European Parliament and of the Council on Transboundary Movements of Genetically Modified Organisms [2003] OJ L287/1.

interpretation of 'SPS measure'.[3] It also ruled against applying sources external to the WTO covered agreements.[4]

This chapter argues that extending the scope of the SPS Agreement is problematic and will continue to place the onus on the EU to demonstrate that its regulatory framework pertaining to GM products is based on scientific risk assessments and not otherwise disguised restrictions on trade. In Scott's words, the SPS Agreement 'is said to look to science based truth where there is only disagreement, uncertainty, and ignorance about potentially catastrophic risks.' It does so because it operates in 'institutional framework which lacks epitomic and moral authority.' In doing so it has been charged with ignoring the cultural dimension of risk and the democratic underpinning of regulation.[5]

In addition, the chapter emphasizes the multi-level nature of the process, which involves overlapping and sometimes conflicting regulations promulgated at the EU and international levels. It argues that some of the Panel's findings were unduly dismissive of relevant sources of international law outside the WTO framework by declining to consider their relevance in interpreting substantive provisions of the SPS Agreement, and failing to show an appropriate degree of deference towards EU's regulatory autonomy.

Many scholars fear that situations like this likely to lead to fragmentation in international law.[6] They find it impossible to ascertain that one rule is more special than another. Consequently, potential conflicts between WTO law and national,

[3] It found that having disposed the claims under SPS Agreement, it was not required to assess the complaints under the TBT Agreement or the GATT.
[4] Panel Reports, *Biotech,* paras. 7.3407-7.3430; for analysis of the panels application Article 31(1)(c) see Margaret A Young, 'The WTO's Use of Relevant Rules of International Law: An Analysis of the Biotech Case' (2007) 56(4) ICLQ 909.
[5] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (OUP, Oxford, 2007) p. 3; *Amicus* brief Group of Academics, *Biotech*, WT/DS/291,292, and 293 (30 April 2004)also submitted that risk assessment of GMOs is characterised by low certainty and low consensus, pp. 5-6, 8; see section 4 below.
[6] Philip Katz and others, 'The evolving GMO Food and Trade Policy Debate: Towards a Global Regulatory Regime?' in Robert E. Evenson and Vittorio Santaniello (eds) *The Regulation of Agricultural Biotechnology* (CABI Publishing 2004) p. 33; Study Group of the International Law Commission, 'Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law', ILC, UN Doc. A/CN.4/L.682 (13 April 2006).

regional, and other international treaties persist. In line with this, the European Commission acknowledges that 'trade disruptions could become more frequent and severe and affect more products and as more GMOs are more approved outside Europe.'[7]

Therefore, this chapter focuses on important issues regarding the interpretation and application of the SPS Agreement in relation to regulatory measures aimed at GMOs, in particular the concept of measure and how to base risk assessment. It also raises questions over the relationship between WTO agreements and other rules and principles of international law related to human and environment protection. It aims to find interpretative approaches that can work not just for the US or EU, but rather ones that make GMOs beneficial on a global scale, in particular for developing countries.

This chapter starts with assessment of the choice of applicable law by the Panel in *Biotech*. It then provides an understanding of how the dispute should be viewed as part of a broader debate. Finally, this chapter addresses the ability of the WTO's Dispute Settlement Body and applicable agreements to accommodate this broader debate. It concludes that future panels and appellate bodies will have judicial residual discretion in this area to clarify contested interpretations. Increased sensitivity of WTO law to environmental and non-scientific factors will allow it to show an appropriate degree of deference towards EU's regulatory autonomy, to coexist with other international treaties.

2 WTO jurisprudence

The WTO is based on voluntary submission of a dispute by Members to the dispute settlement body. The submission initiates court-like proceedings, incorporating short timetables, a right of appeal, and strict implementation and enforcement procedures.[8] If a WTO Member finds that another WTO Member's trade measure

[7] Questions and answers on the evaluation of the European Union's GMO legislation MEMO/11/742 Brussels, 28 October 2011. http://europa.eu/rapid/press-release_MEMO-11-742_en.htm accessed 14 Oct 2012.

[8] The WTO, by default became the frequent forum of choice for trade disputes with key health and environmental component. See, Frieder Roessler, 'The Institutional Balance Between the Judicial and Political Organs of the WTO' in Marco Bronckers & Rienhard Quick eds., *New Direction in International Economic Law, Essays in Honour of John H. Jackson* 324-45 (Kluwer International ,

is inconsistent with the substantive obligations under a WTO agreement, it can submit it for review under the Dispute Settlement Mechanism (DSM), in accordance with the rules laid down in Dispute Settlement Understanding (DSU).[9]

WTO dispute settlement is intended to preserve the rights and obligations of Members under the covered agreements. This means that if a dispute is brought to the WTO, the Panel can only judge compliance with WTO Agreements.[10] The DSM of the WTO does not have the authority to change the legislation of any Member, but the Member may be subject to trade sanctions if it does not bring its measures into conformity with its WTO obligations.[11] The issue of applicable law is controversial. Scholars hold opposing views. Some affirm that rules of customary international law and international agreements which bind the disputing parties could be invoked in defence against WTO claims, and would be part of the applicable law before the WTO Panel.[12] Others hold the views that WTO covered agreements are the only law applicable in WTO dispute resolution. Any other solution would go against the fact that the Panels are prohibited from reaching any conclusion that would constitute an amendment to the WTO, or would add to or diminish rights and obligations under the WTO Agreements.[13]

Trade barriers arising out of environmental, human health, or public morals can be analysed under three different WTO Agreements: The General Agreement on Tariffs and Trade (GATT),[14] the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement),[15] and the Agreement on technical

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2000).

[9] See Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, WTO Agreement Annex 2, Legal Instruments - Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter DSU]. Article 23 of DSU states that 'any WTO Member can initiate a case in the WTO if it considers that its market access rights have been violated'.

[10] Article 3(2) and 19(2) of the DSU; WTO, 'Genetically Modified Organisms (GMOs)' (Current issues in SPS Agreement Training Module) http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s1p1_e.htm accessed 3 April 2012.

[11] See DSU Article 22.

[12] Joost Pauwelyn, *Conflict of Norms in Public International Law* (n 1) Chapter 8.

[13] Gabrielli Marceau' 'Conflict of Norms and Conflicts of Jurisdiction: the relationship between the WTO Agreement and MEAs and other Treaties' (2001) 35(6) Journal of World Trade 1081.

[14] General Agreement on Tariffs and Trade, (15 Apr 1994) 33 I.L.M 1125 [hereinafter GATT]. GATT 1994 incorporates GATT 1947, and GATT 1994 did not alter the articles in issue; when GATT is mentioned, it is thus done without specifying that it is GATT 1947 as incorporated into GATT 1994.

[15] Agreement on the Application of Sanitary and Phytosanity Measures, (15 April1994), 33 I.L.M. 1125 [hereafter the 'SPS Agreement'].

Barriers to Trade (the TBT Agreement).[16] It is important to stress that GATT applies to all measures affecting any product in international trade, including GMOs.[17]

In *Biotech*, the US and the other Complainants argued that all of the challenged measures taken by the EU in administering its regulatory framework constituted non-tariff trade barriers, violating its obligations under the above WTO Agreements.[18]

2.1 Choice of law

In order to determine which of the WTO Agreements apply to particular trade-related measures involving GMOs taken under national law, the analysis should start with the understanding of the policy objective behind the measure (i.e. what is the risk the measure is designed to protect against). Without knowing the nature of the risk in advance, or the kind of trade-related measure that chosen to regulate that risk, it is not possible to determine in advance which WTO Agreement will apply to trade-related measures taken under the Protocol.[19]

On the question of what constitutes an SPS measure, the SPS Agreement's relationship with the GATT and with the TBT Agreement, and the central importance in the SPS Agreement of WTO Members' autonomy are key in setting their own levels of protection against risks as they consider appropriate. Had the Panel rejected the applicability of the SPS agreement, it would have resorted to the claims under GATT and TBT Agreement, which are less intrusive from the EU perspective because they are broadly focused, and permit the adoption of non-discriminatory, trade restrictive measures necessary to protect public moral, human animal, plant health, or relating to the conservation of natural resources. Some

[16] See Agreement on Technical Barrier to Trade, (15 April 1994), 33 I.L.M. 1125 [hereafter the 'TBT Agreement'].
[17] See also Matthew Stilwell and Jan Bohanes 'Trade and environment' in Patrick F. J. Macrory, and others, eds *The World Trade Organization: Legal, Economic and Political Analysis* (Springer 2005) 551.
[18] In addition to these agreements, WTO's Agreement on Agriculture (15 April 1994) LT/UR/A-1A/2 art 2 may also be relevant to trade in agricultural products, including GMOs. Also, WTO Agreement on Trade-Related Aspects of Intellectual Property Rights may also have a bearing on international trade in GMOs. The challenged measures in biotech do not raise issues under these agreements, will not be considered.
[19] Appendix. 'The Cartagena Protocol and the World Trade Organization in Ruth Mackenzie, et. al. 'An Explanatory Guide to the Cartagena Protocol on Biosafety', IUCN Environmental Policy and Law Paper no. 46 (2003) can be found at http://www.iucn.org last visited 11/07/07, p.231.

commentators have also highlighted that the SPS Agreement may become a significant constraint on a wide range of domestic environmental regulatory activity.[20] Scott raised concerns over SPS 'imperialism' in which the SPS Agreement trumps otherwise applicable WTO law.[21] She added that 'the WTO opened itself to charges of epistemological imperialism, and positivistic simple mindedness', and in doing so it has been charged with ignoring the cultural dimension of risk and the democratic underpinning of regulation.[22] Therefore, claims under GATT and TBT would be less intrusive for the EU.

There is some awareness within the WTO as to complexity and importance of GMOs. In preparations for the Ministerial Conference in Seattle in 1999, several Members proposed the establishment of a WTO working group to examine GMOs and their relationship with the different WTO Agreements, and evaluate the need for further action. However, since then, the issue has not been discussed, and no such working group has been established.[23]

In terms of what is relevant to the present thesis, the WTO has interfered with the ability of Members to enact trade measures affecting trade in GMOs, which are designed to protect human health and the environment, because these measures are most likely to be inconsistent with the substantive obligation under SPS, TBT and GATT Agreements. Trade measures may, however, be justified under the exceptions as will be discussed in the next section.[24]

The following section does not provide a full detailed analysis of the application of the above agreements, rather it analyses the application of the different provisions relating the contested measures of *Biotech* dispute.

[20] Jacqueline Peel, 'A GMO by any Other Name' …Might be an SPS Risk! : Implications of Expanding the Scope of the WTO Sanitary and Phytosanitary Measures Agreement' (2007) 17 EJIL 1009; Christiane R Conrad, 'PPMs, the *EC Biotech* Dispute' and the Applicability of SPS Agreement' (2007) 6(2) World Trade Review.
[21] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) pp. 4-6.
[22] Ibid, p. 3.
[23] WTO, 'Genetically Modified Organisms (GMOs)' (n 10).
[24] Article XX, GATT.

2.2 Relationship between the SPS and GATT/TBT

GATT's aimed to establish a free multilateral trading system and liberalise international trade through the removal of discrimination in international trade and a reduction in trade barriers.[25] GATT adopted principles forbidding unfair trade practices, and set a code of conduct for the Members of particular relevance is the principle of 'national treatment', which stipulates Members must not discriminate between imported and domestically produced goods where they are 'like products'.[26] In principle, GATT applies to trade in goods, including GMOs and GM products, to the extent that it does not conflict with other WTO covered agreements, except where a more specialized WTO agreement applies.

Biotech raised the issue of national treatment, which was an issue in connection with approval procedures of products. This issue was raised not only under article III:4 of the GATT Agreement but also under Annex C1(a) of the SPS Agreement, which prohibits Members from discriminating against imported products compared with like domestic products, by unduly delaying the procedures of testing, and the approval of GMOs..

Once a violation of one of the substantive obligations is found, a defending party may invoke one of the General Exceptions in Article XX to justify trade/import restrictions. Article XX can be invoked to protect public morals, human, animal, or plant life or health, and to conserve exhaustible natural resources (environment) listed in Article XX(b), (d), or (g), providing that they do not constitute arbitrary or unjustifiable discrimination resulting in a disguised restriction on international trade. [27] This Article can be invoked broadly to protect health or the environment, and applies to ordinary products and services. A country would have to show that it is necessary to violate the GATT to achieve the desired health or environmental

[25] First concluded in 1948, forming an integral part of the Uruguay Round results as GATT 1994 It is composed of 37 articles and a number of explanatory understandings and agenda, Marrakesh Agreement Establishing the World Trade Organization, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), Annex 1A: General Agreements on Tariffs and Trade' 1867 UNTS 190 ('GATT 1994' or 'GATT'); draws freely from WTO Legal Texts. http://www.wto.org/english/docs_e/legal_e/legal_e.htm.

[26] GATT, Art II and Art III.4.

[27] Patricia Birneie and others, *International law and the environment* (3rd ed OUP. Oxford, 2009), p. 779.

protection.[28] In *US-Shrimp 21.5,* American measures were found to be justified under Article XX(g), subject to certain requirements, including that the US continue to seek a negotiated solution to protect sea turtles.[29] Accordingly, if the Panel in *Biotech* had applied Article III.4 of GATT, the EU would have had recourse to defence under Article XX to justify its measure.

Following the Uruguay Round of trade negotiations, GATT provisions were supplemented by detailed rules on particular kinds of non-tariff trade barriers under the TBT Agreement and the SPS Agreement[30] to 'further the objectives' and to elaborate rules for the application of the GATT exceptions provided in Article XX.[31] According to the general Interpretative Note to Annex 1A of the Marrakesh Agreement Establishing the WTO, in the event of a conflict between the SPS or TBT Agreements and the GATT, the specific agreement prevails over GATT.[32]

The TBT Agreement[33] applies to all WTO Members adopting technical regulations, standards, 'including packaging, labeling and marketing requirements, and conformity assessment procedures' with the potential to impact trade.[34] The TBT Agreement applies to both industrial and agricultural goods, except for those falling within the scope of the SPS Agreement.[35]

Under the TBT Agreement, Members pledge that technical regulation will not be allowed to create an 'unnecessary obstacle to international trade'.[36] The level of

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[28] WTO, 'Genetically Modified Organisms (GMOs)' (n 10).

[29] This dispute involved unsuccessful challenge to US measures to implement the decision in *US-Shrimp*. The US measures were found to be justified under Article XX, subject to certain requirements, including that the US continue to seek negotiated solution to protect sea turtles. See Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998, DSR 1998. [hereinafter '*US-Shrimp*'].

[30] The Marrakech Agreement Establishing the WTO brought together a number of agreements negotiated in the Uruguay Round, as well as GATT, to form a body of WTO law covering many aspects of trade in goods and services. in light of concerns that its rules were not adequate to prevent the adoption of non-tariff trade barriers for the purpose of protecting human health, safety and the environment, but which in practice served to exclude or significantly disadvantage competing imported products.

[31] TBT Agreement, preamble, 2nd recital; SPS Agreement, preamble, 8th recital.

[32] On this topic see also Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) pp. 27-30.

[33] Agreement on Technical Barriers to Trade, 1868 UNTS 120 ([hereinafter '*TBT Agreement*']. Draws freely from WTO Legal Texts, see http://www.wto.org/english/docs_e/legal_e/legal_e.htm. See also Patricia Birneie et al, *International law and the environment* (n 27), pp. 756-763.

[34] *TBT Agreement*, Preamble and arts 2–8. See also, Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, adopted 5 April 2001, para. 66.

[35] See TBT Agreement, Article 1.3, 1.5.

[36] See TBT Agreement, Annex 1.2, including voluntary standards.

protection is up to the Member. A high level of protection can be chosen. Furthermore, the Member is free to accept or reject international standards, provided that this is 'necessary' to fulfil a 'legitimate objective'.[37] Therefore, if a Member chooses a strict level of environmental protection, it can employ stricter standards than international technical requirements.[38] TBT provides grounds for state regulatory intervention. Where Members decide to adopt their own technical regulations, they must ensure that such standards treat imported products 'no less favourable' than domestic 'like products',[39] and that they satisfy time and notification requirements directed to facilitating transparency and reducing delays in trade.[40]

The GATT and TBT Agreement impose obligations that can apply to the same measure; complying with one does not preclude the application of the other. The SPS Agreement applies independently of any breach of GATT, although conformity with SPS Agreement implies conformity with GATT.[41] For example, in *Hormones*, the Panels turned first to this agreement, making it clear that its application is not dependent upon there being any prior breach of GATT.[42]
In the event that the SPS Agreement does not apply to GMO regulations, the TBT Agreement may still apply. The TBT Agreement allows governments to take measures if they have a legitimate objective, such as protecting health or the environment. Such measures should not be trade-restrictive more than what is deemed to be necessary,[43] but where the SPS Agreement is deemed to be more specific in relation to the contested measure, it will apply to the exclusion of the TBT.[44] This also means that even if no violation of the SPS Agreement is found, a measure cannot alternatively be considered under the TBT Agreement if it had been decided that it falls within the scope of the SPS Agreement.[45]

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[37] TBT Agreement, Article 2.2.
[38] TBT Agreement, Article 2.2.
[39] TBT Agreement Articles 2.4–2.5. Whether products are alike has not yet been considered under the TBT Agreement, but is much debated under the GATT.
[40] TBT Agreement art 2.1.
[41] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) p. 27-30.
[42] Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones) – Complaint by the United States*, WT/DS26/R/USA, adopted 13 February 1998, as modified by the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998, para. 8.41-8.42.
[43] WTO, 'Genetically Modified Organisms (GMOs)' (n 10).
[44] See SPS Agreement, Article 1.4; similarly, see TBT Agreement, Article 1.5
[45] See Panel Reports *Biotech*, para. 7.2527, Patricia Birneie et al, *International law and the*

The SPS Agreement is part of 'an innovative system for managing trade'. It is an 'evolving and novel regulatory mechanism that is dealing with contemporary trade issues of great complexity and political salience.'[46] According to the Panel in *Hormones,* the SPS Agreement imposes specific obligations, different in nature to those under the GATT and its exceptions, to be met in order for a Member to enact or maintain specific types of measures, namely sanitary and phytosanitary measures.[47]

The SPS Agreement is science-based and more restrictive of the two agreements. Therefore, the application of the SPS Agreement is often disputed.[48] It covers 'necessary' measures applied to protect against specific risks to humans, animals, and plants from certain hazards associated with the movement of plants, animals and food-stuffs, beverages, and feed-stuffs in international trade.[49] According to the Preamble, it is conceived as an elaboration of GATT's exception under Article XX(b).[50]

The SPS Agreement is science-based, and applies to 'all sanitary and phytosanitary measures taken by Members which may, directly or indirectly, affect international trade.'[51] The measures must be no more trade restrictive than required to achieve an appropriate level of protection. They are to be applied only to the extent 'necessary for the protection of human and animal health', and must be scientifically justifiable in the sense that they must be 'based on scientific principles and … not maintained without sufficient scientific evidence.'[52] In particular, they must be 'based on' a scientific risk assessment.[53] However, if 'relevant scientific evidence' is insufficient, then provisional SPS measures may be based on 'available pertinent information' while the Member seeks more information to allow a full

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environment (n 27) pp. 778-783.

[46] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5).

[47] Panel Reports, *Hormones*, (n 41) para. 839.

[48] Jacqueline Peel, 'A GMO by Any Other Name' (n 20) p. 1009; and Patricia Birneie et al, *International law and the environment* (n 27), p. 779.

[49] The SPS Agreement. Draws freely from WTO Legal Texts, see www.wto.org/english/docs_e/legal_e/legale.htm.

[50] SPS Agreement, Recital 8; Andreas F. Lowenfeld, *International Economic Law* (International Economic Law Series, OUP, Oxford 2008), p. 399.

[51] SPS Agreement, Article 1.1.

[52] SPS Agreement Article 2.2. The SPS Agreement is an expansion of subsection (b) of GATT Article XX. Article 2 repeats the language in GATT Article XX(b)

[53] SPS Agreement Article 5.1.

risk assessment and reviews the measure 'within a reasonable period of time'. [54] In addition to being scientifically justified, that the measure must not be 'arbitrary or unjustifiably discriminate between [m]embers' and must not be a 'disguised restriction on international trade'.[55]

Furthermore, SPS measures must not require different levels of protection in situations of comparable risk,[56] and must not 'be more trade restrictive than required to achieve the appropriate level of SPS protection' chosen by the Member.[57] SPS measures must also satisfy publication and notification requirements to ensure transparency. [58] In addition, related approval procedures must comply with timeline requirements. [59]

The following section examines the *Biotech* finding on the applicable law. It does not dispute the applicability of SPS Agreement; rather it criticises the interpretations of key terms by the Panel, and assesses the consequences of broadening the scope of the SPS Agreement.

2.3 The concept of an SPS measure

Article 1.1 of SPS Agreement applies to all SPS measures that may, directly or indirectly, affect international trade. Defining SPS measures is the starting point. In *Biotech*, the Panel adopted an expansive understanding of the concept of 'SPS measure' available under Annex A(1).[60] The Panel considered that Article 31(1) allowed for the use of rules of international law that were not binding on the parties, regarding them as informative where those rules provided evidence of the 'ordinary meaning' of the treaty terms.[61] The Panel considered this would not 'mandate' a consideration of relevant rules of international law, but only 'shed light on the meaning and scope of treaty term to be interpreted.' The Panel did not require the consent of the WTO membership or non-WTO Members for use of non-WTO

[54] SPS Agreement Article 5.7.
[55] SPS Agreement Article 2.3. Article 2.3 of the SPS Agreement repeats the requirements of the exceptions under Article XX.
[56] SPS Agreement, Article 5.5.
[57] SPS Agreement, Article 5.6.
[58] SPS Agreement, Article 7 and Annex B.
[59] SPS Agreement, Article 8 and Annex C.
[60] SPS Agreement, Annex A(1) defines the harm to which an SPS measure is to be addressed. See also Chapter 1, Section 3.2.
[61] Panel Reports, *Biotech*, para. 7.92.

sources in interpreting the terms of SPS Agreement.[62] The Panel left itself free to consider international rules 'if it deems such rules to be informative'.[63] The Panel did not find it 'necessary or appropriate' to rely on CBD or the Cartagena Protocol in interpreting the SPS agreement.[64] The Panel referred to *US-Shrimp*, in which the AB's use of relevant rules of international law were not binding on all parties.[65] Similarly, the Panel in *Biotech* looked both to dictionary definitions and the other textual sources in clarifying the scope of the concepts deployed.[66] For example, the Panel's analysis of the phrase 'animal or plant life or health' in the SPS Agreement was meant to be comprehensive in coverage. Therefore it found that risks to animal and plant life or health encompassed concerns relating to the effects of GMO crops on micro-flora and micro fauna, such as soil organisms, as well as non-target organisms such as insects affected by the cultivation of an insecticide producing GMO crops. Similarly, it held that the phrase 'risks arising from' was 'broad and unqualified', allowing its application to both actual and potential risks, as well as those risks 'that arise indirectly or in the longer term from pests, diseases, disease-carrying organisms or disease-causing organisms'. [67]

Such reference allowed the Panel to 'stretch the terms', and repeated recourse to the concept of 'rational relationship' enabled it to justify inclusion of effects which are only indirectly attributable to the GM product subject to the restriction.[68] In *Biotech*, the Panel did not reflect the considerable differences between EU regulations and SPS measures in previous cases, in particular with respect to the nature of the risks addressed with the challenged measures. These findings suggested that the SPS Agreement is not confined simply to risk situations for which there are 'direct and immediate' links between a product and potential harms to human, animal or plant life or health associated with pests and diseases. In, comparison, Conrad makes reference to previous cases like *Australia- Salmon,*

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[62] Margaret A Young, 'The WTO's Use of Relevant Rules of International Law' (n 4) pp. 918-925.
[63] Panel Reports, *Biotech,* para. 7.93.
[64] Panel Reports, *Biotech*, para. 7.94. Materials that did assist the Panel in interpreting certain terms of Annex A of the SPS Agreement were Codex, FAO, IPPC Secretariat, WHO, OIE, the CBD Secretariat and UNEP.
[65] Panel Reports, *Biotech*, para. 7.95.
[66] Panel Reports, *Biotech*, for example paras. 7.222, 7.241. 7.253, 7.269, 7.272, 7.279, and 7.300; See also Chapter 1 section 3.2.

[67] Panel Reports, *Biotech,* para 7.219.
[68] Christiane R Conrad, 'PPMs, the *EC Biotech* Dispute' (n 20) p. 237.

Japan Apples, and *Japan-Agricultural Products* in which the SPS Agreement applicability was not questioned because of the direct link between well-known risks and the well-defined values or objects.[69]

The Panel's assessment of objectives pursued by EU legislation, especially on the protection of the 'environment' and 'diversity', was also based on limited textual approach, ignoring international agreements and documents which the EU has ratified, such as CBD and Cartagena Protocol.[70] Conrad notes that such use would have been important as a tool to interpret WTO Members' national law in light of its international commitments. This would have allowed for more comprehensive interpretation and better understanding of the EU Measures, which is crucial to determining whether measures fall under the SPS Agreement. [71] Next, the *Biotech* Panel examined the types of risks covered by EU legislation. According to the Panel, they pursued a wide range of environmental and health objectives falling within the scope of SPS Agreement. The Panel found that EU approval procedures, relating to environmental release of GMOs, under Directive 90/200 and the Deliberate Release Directive fell within the scope of SPS Agreement.[72] It found that substantial parts of the Novel Food Regulation fell within the definition of SPS measure. Only the labelling requirement was deemed to fall outside the scope of the SPS Agreement because it prevents consumers being misled, or protects them from nutritional disadvantage.[73] Although the Panel did not rule on the safety of GMOs, or their likeness to non-GMOs,[74] its interpretation of SPS Agreement will be of primary relevance.

Scott notes that the Panel's expansive interpretation of the concept of an SPS measure is likely to be 'of the utmost significance' in the future, involving 'SPS 'imperialism' of a kind which is by no means neutral from the point of view of

[69] Ibid, p 245.
[70] Panel Reports, *Biotech*, paras. 7.247, and 7.372; Christiane R Conrad, 'PPMs, the *EC Biotech* Dispute' (n 20) p. 243.
[71] Christiane R Conrad, 'PPMs, the *EC Biotech* Dispute' (n 20) p. 243.
[72] Panel Reports, *Biotech*, paras. 7.212-395.
[73] The only risk was found to be potentially outside the SPS Agreement was one referenced by the Novel Food Regulation directing the labelling to prevent consumers being misled. See, Panel Reports, *Biotech*, paras. 7.415-6, and 8.3.
[74] Panel Reports, *Biotech*, para 8.3

regulating Member States.[75] It would bring a wider range of measures within the scope of SPS Agreement beyond food safety and quarantine risks to wide range of environmental and biodiversity related risks.[76] Further, based on the relevant negotiating history of the SPS Agreement, Peel explains that the SPS Agreement is fairly narrow in scope for it does not specifically address GMOs; hence the inclusion of stringent science-based requirement for SPS measures. She expressed concerns that 'its requirement could be brought to bear on broadly framed environmental regulations with adverse trade impacts might seem far-fetched, even a little surreal.'[77]

The Panel's reasoning in *Biotech* will have implications for other areas of domestic environmental regulation.[78] This could expose a broader array of national 'environmental measures' and 'consumer protection' to the science-based discipline of the SPS Agreement.[79] This wide reach has the potential to cover not only adoption of precautionary and harm prevention approaches in regulations targeting GMOs, but also a wide array of environmental regulations in many countries, as well as biodiversity or chemical pollution risks that could affect international trade, directly or indirectly.[80]

The Panel's determination that the SPS Agreement applies to measures regulating GMOs remains questionable as it allows for the possibility of situation in which a measure pursuing a different objective is in breach of the SPS Agreement, yet consistent with TBT or GATT. Such measures are of great interest to third parties to the *Biotech* dispute and will require attention and clarification by future panels.[81]

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[75] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) p. 17.
[76] See Christiane R Conrad, 'PPMs, the *EC Biotech* Dispute' (n 20) p. 239.
[77] SPS Agreement traditional subject matter, arguably, are concerns that are more applicable to quarantine and food safety measures, which generally used to impose restrictions or other requirements on imported agricultural products, rather than environmental regulation. See Jacqueline Peel, 'A GMO by any Other Name' (n 20) pp.1016-1018.
[78] Expansive interpretation of the concept of an SPS measure will also have implications on international environmental agreements that overlap with trade regimes. See section 3 below.
[79] Jacqueline Peel, 'A GMO by any Other Name' (n 20) p. 1025.
[80] This also will affect environmental regulatory choices of the US, such as those covered in chapter 3 section 4.3; see Jacqueline Peel, 'A GMO by any Other Name'(n 20) p. 1027.
[81] Christiane R Conrad, 'PPMs, the *EC Biotech* Dispute' (n 20) p. 246-7; Joseph McMahon, 'The *EC Biotech* Decision: Another Missed Opportunity' in Luc Bodiguel and Michael Cardwell, *the Regulation of Genetically Modified Organisms: Comparative approaches* (OUP, 2010), p. 341; and Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) p. 19.

Overall, the Panel relied heavily on a range of international sources and dictionary definitions in its interpretation of the terms and definitions in the SPS Agreement, disregarding both extensive scientific evidence assembled in the case. Its unconstraint selection of sources can easily lead to 'decontextualised and arbitrary reasoning'.[82] Conrad argued that in order to promote respect for and confidence in the WTO, 'the adjudicatory bodies need to make sure that their decisions are based on solid legal grounds…future panels should consider supplementing a thorough interpretation of crucial terms with more comprehensive legal analysis without refraining from normative and foresighted consideration.'[83]

3 SPS and other international law

Issues of protection of human health, the environment, and trade in GMOs cut across a number of WTO agreements, as well as those between the WTO and other international agreements and processes administered by other institutions.[84] In *Biotech*, the parties utilized the available international law in ways which supported their causes and opinions. The US focused on the SPS Agreement, while the EU argued that the precautionary principle, the Convention on Biological Diversity and, the Cartagena Protocol should be used by the Panel as interpretive tools according to customary norms of treaty interpretation.[85]

Some scholars view this as an attack on environmental regulation. Issac and Kerr write[86] 'while the EU is the explicit target, an implicit target is the Cartagena Protocol on Biosafety'. Steve Suppan, senior policy analyst at IATP, said: '…the

[82] Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Biotechnology Regulation Series, Edward Elgar Publishing, 2008), p. 23.
[83] Christiane R Conrad, 'PPMs, the *EC Biotech* Dispute' (n 20) pp. 246-7.
[84] 'Agreement on Trade-Related Aspects of Intellectual Property Rights' (TRIPS Agreement) would normally not be invoked in a conflict regarding market access for GMOs, but it might be invoked in a dispute on intellectual property protection related to GMOs. 'The Agreement on Agriculture' applies to trade in agricultural products (non-discrimination and non-trade concerns), including genetically modified ones, Uruguay Round Agreement, Agreement on Agriculture.
[85] The EU also included reference to treaties and soft law instruments that formed the legal framework of international health and safety protection, such as Codex Alimentarius Commission, OECD, and FAO. The relevant provisions of the Cartagena Protocol will be considered in detail in the next sections. See sections 3.1.1, and 3.1.2.
[86] Isaac E Grant and William A Kerr, 'Genetically Modified Organisms at the World Trade Organisation: A Harvest of Trouble' (2003) 37(6) Journal of World Trade 1083.

panel legal reasoning really undercuts the Biosafety Protocol', adding that 'many countries who are signatories to the Protocol, particularly poor countries, have not set up their regulatory framework for genetically engineered crops. This ruling is a warning to Protocol Members that if they regulate biotech products according to their Protocol commitments, a Protocol based defence of those regulations cannot prevail at the WTO if the plaintiffs are not Protocol Members.'[87] Therefore, the *Biotech* ruling might be used by the US in negotiating a trade agreement to deter developing countries from 'emulating' EU's regulations.[88]

Both parties seek to reflect their regulatory views in active in international treaty negotiation. The Cartagena Protocol is clear example, the US had indeed argued that there was no need for a protocol, further asserting that an international one size fits all regime could not be crafted to effectively address environment-specific issues without unduly restricting trade.[89] The EU negotiators felt deep satisfaction, considering that they had contributed substantially to the result and that the EU's negotiation strategy had been successful.[90]

Some commentators argue that the expansion in the scope of the SPS Agreement encourages international disagreements, and facilitates fragmentation of trade and environmental regimes.[91] This section examines the impact extending the scope of the SPS Agreement will have on the broader international relationships between trade and other areas of international law, with a focus on the SPS Agreement and Cartagena Protocol. First, it provides detailed account of the treaty interpretation tools. International instruments regulating different aspects of GMOs are then considered and employed to inform key the complex regulatory problems arising from interdependence created through international trade, 'risk assessment', 'scientific uncertainty', and 'precaution'.

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[87] 'WTO Biotech Ruling Threatens Precautionary Approach', IATP, September 29, 2006, http://www.iatp.org/documents/wto-biotech-ruling-threatens-precautionary-approach

[88] Thomas Bernauer, 'Causes and Consequences of International Trade Conflict Over Agricultural Biotechnology' (2005) 7(1/2/3) Int J Biotechnology 24.

[89] Cathleen A. Enright, 'United States' in Christoph Bail, et al, (eds) *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment & Development?* (Earthscan Publications 2002), p. 98.

[90] Christoph Bail et al., 'European Union' in Christoph Bail, et al (eds), *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment & Development?* (Earthscan Publications 2002), p. 185.

[91] Jacqueline Peel, 'A GMO by any Other Name' (n 20) p. 1028.

3.1 Relationship between WTO and other international law

The relationship between trade and other areas of international law is highly contested.[92] Some advocate that treaty interpretation plays a 'strong role in providing a "bridge" between potentially competing norms.'[93] Article 3(2) of the WTO Dispute Settlement Understanding expressly provides that the existing provisions of the 'covered agreements' are to be clarified 'in accordance with customary rules of interpretation of public international law.'

The Panel in *Biotech* considered Articles 31 and 32 of the Vienna Convention on the Law of Treaties (VCLT),[94] particularly Article 31(3)(c) under which interpretation should take into account 'any relevant rules of international law applicable in the relations between the parties.'[95] It also noted that the reference to rules of international law should be understood expansively not only to include treaty and rules of customary international law, but also general principles of law as included Article 38(1) of the Statute of International Court of Justice (ICJ).[96] Article 38(1) of the ICJ Statute is generally accepted statement of the sources of international law. It enumerates the sources of international law, providing that international law has its basis in international custom, international conventions or treaties, and general principles of law. A rule must derive from one of these three sources in order to be considered international law.[97]

Article 38(1)(a) refers to 'international conventions', which includes conventions, treaties, pacts, protocols or covenants, and international agreements that establish

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[92] Joost Pauwelyn, *Conflict of Norms in Public International Law* (n 1); Margaret A Young, 'The WTO use of relevant rules of international law' (n 4) p 907; Study Group of the International Law Commission, 'Fragmentation of International Law' (n 6).

[93] Duncan French, 'The Regulation of Genetically Modified Organisms and International Law' in Luc Bodiguel and Michael Cardwell, *the Regulation of Genetically Modified Organisms: Comparative approaches* (OUP, 2010), p. 361. Pauwelyn also examined treaty interpretation as a conflict-avoidance tool, among others. It is not always the most effective one. See Joost Pauwelyn, *Conflict of Norms in Public International Law* (n 1) p. 250.

[94] Vienna Convention on the Law of Treaties (23 May 1969) 1155 UNTS 331. [hereinafter 'VCLT']

[95] Study Group of the International Law Commission, 'Fragmentation of International Law' (n 6) p. 88.

[96] Panel Reports, *Biotech*, para. 7.67.

[97] Statute of International Court of Justice, Article 38(1). See also Patricia Birneie et al, *International law and the environment* (n 27), p. 15.

rules expressly recognized by consenting states.[98] Only states that are parties to a treaty are bound by it. However, a very large number of states voluntarily adhere to treaties and accept their provisions as law without becoming parties to them.[99] The 1969 Vienna Convention on the Law of Treaties is important as it codifies rules applicable to written treaties concluded after its entry to force in 1980.[100]

Customary international law is defined as a general 'practice of law' under Article 38(1)(b) of the ICJ. States follow a practice out of a sense of legal obligation. Rules or principles must be accepted by the states as legally binding in order to be considered a rule of customary international law. Thus, the mere fact that a custom is widely followed does not make it a rule of international law. States also must view the practice as obligatory, and they must not believe that they are free to depart from it whenever they choose, or to observe it only as a matter of courtesy or moral responsibility. This latter requirement is referred to as *opinio juris*.[101]

General principles of law refer to 'elements of the domestic legal order of "civilized" states'. General principles include the principle of *estoppel*, neutrality of decision-makers, methodologies of legal interpretation, and equity. Sustainable development and precaution have attracted discussion as to whether they constitute general principles of law.[102]

Treaties, custom, and general principles of law as identified in Article 38(1) of the ICJ Statute are made with the consent of states, and become binding upon them.[103] Therefore, WTO law and international environmental law are both sub-systems of public international law. It is important to note that both are part of international law as whole, not separate, self-contained disciplines.[104] Consequently, the legal

[98] Article 38(a)(1) of the Statute of the International Court of Justice. See, Mark A Drumbl, 'Actors and law making in international environmental law', in Malgosia Fitzmaurice, David M. Ong, Panos Merkouris (eds) *Research Handbook on International Environmental Law* (Research Handbooks in International Law, Edward Elgar, Cheltenham, UK, 2010), p. 14.
[99] Patricia Birneie et al, *International law and the environment* (n 27).
[100] Ibid, p. 16.
[101] Ibid, pp. 22-25.
[102] Mark A Drumbl, 'Actors and law making in international environmental law' (n 98).
[103] Ibid p. 14.
[104] Birnie makes clear that 'the resolution of international environmental problems, however categorized, entails the application of international law as a whole, in an integrated manner.' See Patricia Birneie et al, *International law and the environment* (n 27) pp. 3-4.

analyses of both sub-systems are not detached from the system it belongs to.[105] A study by the International Law Commission argued that treaty interpretation rules provide a 'professional toolbox' for managing global legal fragmentation by requiring decision-makers considering claims under one treaty regime to situate those claims in the wider 'normative environment' of international law.[106] Since WTO law cannot claim primacy over other international or national law, we should regard them as complementary, and recognize that they stand in a non-hierarchical relationship.[107] In *Reformulated Gasoline*, the Appellate Body recognised that GATT is not to be read in clinical isolation from public international law. The famous AB report in *Shrimp/Turtle* applied the same reasoning.

*US-Shrimp/Turtle (*1998) involved a successful GATT challenge to American measures banning the import of shrimp caught with fishing methods that threatened endangered species of sea turtles. Latter in 2001, the AB revoked it and found the US measures to be justified under Article XX(g), subject to certain requirements, including that the US continue to seek a negotiated solution to protect sea turtles.[108] In this case, the AB applied international treaties such as the Convention on Biodiversity, which brought external environmental values into trading system. The AB commented: [109]

> The preamble of the WTO Agreement – which informs not only the GATT 1994, but also the other covered agreements – explicitly acknowledges 'the objective of sustainable development' … From the perspective embodied in the preamble of the WTO Agreement, we note that the generic term 'natural resources' in Article XX(g) is not 'static' in its content or reference but is rather 'by definition, evolutionary'

The next section provides an explanation of instruments referred to by the EU, namely CBD, the Cartagena Protocol, and the precautionary principle. It also considers in detail the relationship between international agreements, specifically

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[105] Joost Pauwelyn, *Conflict of Norms in Public International Law* (n 1) pp. 38-45.
[106] Study Group of the International Law Commission, 'Fragmentation of International Law' (n 6) p. 47.
[107] Ibid, p. 116.
[108] *US- Shrimp* (n 29).
[109]. *US- Shrimp* (n 29), 129-130.

between the SPS Agreement and the Cartagena Protocol.

3.1.1 The Convention on Biological Diversity

The UN Convention on Biological Diversity[110] is one of the most widely ratified environmental conventions.[111] The Convention's objective is to conserve biological diversity, while ensuring the sustainable use of its components, the fair and equitable sharing of the benefits arising from the use of genetic resources, and access to technology, including biotechnology.[112] The CBD recognises that biological diversity is more than plants, animals, microorganisms, and their ecosystems. It broadens the term to include issues such as the need for food security, medicines, fresh air and water, and healthy environment.[113]

Article 8(g) of the CBD requires parties to establish and maintain means to regulate risks arising from biotechnology associated with use and release of living modified organisms (LMOs) which are likely to have adverse environmental impacts that could affect conservation and sustainable use of biotechnology, taking into account also the risks to human health.[114] Article 19(3) requires parties to consider the need for a protocol setting out procedures on safe transfer, handling, and use of LMOs that may have adverse effect on conservation and sustainable use of biodiversity, including, in particular, provision for advanced informed agreement.[115]

The convention seeks to extend a greater and more equitable share of the fruit of commercial genetic research and development to the developing countries from which the original genetic resources so often originate.[116] The Convention has resulted in national biodiversity strategies and action plans in over 100 countries,

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[110] The text of the United Nations Convention on Biodiversity may be found at http://www.biodiv.org.
[111] The Convention on Biological Diversity, 1760 UNTS 79. 31 ILM (1992) 818; B&B Docs, 390. Adopted on June 1992 at Rio de Janero Earth Summit, entered into force 29 December 1993. [hereinafter 'CBD']
[112] CBD, Article 1; See also UNEP, 'About the CBD', UNEP at http://biodiv.org/convention/default.shtml (accessed 23 June 2007) ; Patricia Birneie et al, *International law and the environment* (n 27), pp. 612-639.
[113] UNEP, 'About the CBD' (n 112).
[114] Patricia Birneie et al, *International law and the environment* (n 27) p. 628.
[115] Ibid, p. 629.
[116] Biodiversity Convention, Article 15(7).

and has produced the Cartagena Protocol on Biosafety, which is discussed below. It also plays a major role in highlighting the importance of biodiversity issues globally through research and public education.[117]

In interpreting the WTO agreements the AB, in previous disputes, followed the general rule codified in Article 31(3) of the VCLT. Accordingly, account may be taken of 'any relevant rules of international law applicable in the relations between the parties.'[118] In the *Shrimp-Turtle*, the AB referred, *inter alia*, to the 1992 Rio Declaration on Environment and Development and the 1992 Convention on Biological Diversity. Instead of interpreting the GATT exceptions under Article XX(g) in accordance with whatever might have been the intention of the drafters in 1947, the AB took account of these much latter and directly relevant agreements.

3.1.2 Cartagena protocol

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000) is an international agreement which aims to ensure the safe handling, transport, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.[119] The Protocol can be seen primarily as an 'environmental instrument' concerned with the conservation and sustainable use of 'biological diversity'.[120]

The SPS Agreement and the Cartagena Protocol clearly overlap. Both contain rules that govern the international trade in LMOs, but the relationship between them

[117] UNEP, 'About the CBD' (n 112). The success of the CBD and the Cartagena Protocol relies on individual countries, peer pressure from other countries, and public opinion. To facilitate communication and implementation of the CBD, governments, non-governmental organisations, academics, members of the private sector, and other interested groups or individuals congregate in meetings fashioned as global forum to share ideas and strategies for applying the CBD.
[118] Patricia Birneie et al, *International law and the environment* (n 27) p. 764.
[119] The Cartagena Protocol entered into force on 11 September 2003. The Protocol was signed by 103 countries and as of 4 January 2012, 166 countries including the EU have ratified the protocol; Cartagena Protocol Available: http://www.biodiv.org/biosafety/default.aspx. Accessed 04 Jan 2007.
[120] Patricia Birneie et al, *International law and the environment* (n 27) pp. 612-620, 640-648. See also UNEP, 'Trade-related Measures and Multilateral Environmental Agreements' UNEP 2007 http://www.unep.ch/etb/areas/pdf/MEA%20Papers/TradeRelated_MeasuresPaper.pdf accessed 11 March 2013

remains murky.[121] The WTO's essential purpose is to liberalize markets by removing unnecessary, discriminatory, and protectionist barriers to trade, while the Cartagena Protocol contains trade related provisions which affect international trade in LMOs. It is important to note that during the negotiations of the Cartagena Protocol, developing countries pushed for trade related measures to be included, viewing them as the 'teeth' that would guarantee a strong instrument to meet their needs and concerns.[122] During the negotiation, the EU and many third world countries also insisted on positions that have constantly been rejected within the WTO context, such as those based on the 'precautionary principle'.[123]

The flexibility of the rules under the Protocol has led to suggestions that it 'represents a form of "treaty-based environmental unilateralism" and that it is a "prototype of minimal harmonisation legislation". It establishes principles and procedures to guide national decision-making based on risk assessment and risk management without mandating particular outcome.'[124] Yet, the Cartagena Protocol goes well beyond the minimalist position that the US, Canada, and Argentina, as GM exporting countries, would have preferred. [125]

The Protocol promotes biosafety by establishing rules and procedures for the safe transfer, handling, and use of GMOs, with a specific focus on regulating movements of these organisms across borders. [126] Parties may restrict the import of some LMOs as part of a carefully specified risk management procedure. Therefore, procedures are designed to ensure that recipient counties are provided with the information they need to make informed decisions about whether to accept LMO imports.[127] The Protocol applies to the transboundary movement, transit, handling, and use of all living modified organisms. The protocol provides two main sets of procedures covering LMOs intended for release into the environment (e.g. seeds for cultivation), and those intended for use in food or feed, or for processing (e.g. soy,

[121] For analysis see section 3.2 below.
[122] UNEP, 'Trade-Related Measures and Multilateral Environmental Agreements (n 120).
[123] Cartagena Protocol, Article 1; see Cathleen A. Enright 'United States' (n 89) pp. 96-98; and Simonetta Zarrilli , *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks*, (Policy Issues in International Trade and Commodities Study Series No.29, UNCTD, UN – New York and Geneva, 2005) pp. 24-25.
[124]Patricia Birneie et al, *International law and the environment* (n 27) p. 641, footnotes omitted.
[125] Simonetta Zarrilli, *International Trade in GMOs and GM Products* (n 123) p. 30.
[126] See Cartagena Protocol, Articles 1 and 4.
[127] Articles 8, 9, and 10 of the Cartagena Protocol

corn, and cotton).

An Advanced Informed Agreement procedure (AIA)[128] applies to GMOs that are to be intentionally released to the environment (e.g. seeds for cultivation) from the importing country before the first shipment takes place. These include seeds for planting and other organisms that are destined to grow, and that have the potential to pass their modified genes on to succeeding generations. The AIA procedure not only reconfirms the rights of signatory countries to set their own domestic regulation, but also ensures that recipient countries have the opportunity to assess any risks that may be associated with a GMO before agreeing to its import. Therefore, the recipient country must be notified. The notification must include a detailed description of the LMO, including reference to existing risk assessment reports. Only upon consent of the recipient country may the export take place.[129] The AIA procedure applies only to the first international transboundary movement of any particular GMO intended for introduction to the environment. It does not apply to pharmaceuticals,[130] GMOs in transit through a country,[131] GMOs destined for contained use,[132] or GMOs to be directly used as food or animal feed or for processing.[133]

Second, a simplified procedure exists for GMOs that are to be used directly as food or feed, or for processing, such as GM maize and soybean. Parties to the Protocol who approve these commodities for domestic use have to communicate this decision to the world community via the Biosafety Clearing House (BCH).[134] In addition, parties may decide on whether to import these commodities on the basis

[128] The AIA procedure set forth in Article 7 of the Cartagena Protocol
[129] Cartagena Protocol Articles 7-10.
[130] The Protocol does not cover products derived from GMOs, such as cooking oils from GM corn or pharmaceuticals for humans addressed by other international agreements. (Articles 4-5 of the Cartagena Protocol); *Biosafety and the environment, an introduction to the Cartagena Protocol on Biosafety*, (CBD, UNEP, June 2003) p.6 http://www.biodiv.org/doc/press/presskits/bs/cpbs-unep-cbd-en.pdf accessed 11 March 2013
[131] Cartagena Protocol, Article 6.
[132] Cartagena Protocol, Article 3(b).
[133] Cartagena Protocol, Article 7(1)- 7(2).
[134] Cartagena Protocol, Article 20. Parties to the Protocol exchange information through a 'Biosafety Clearing-House' which contains information on national laws, regulations, and guidelines for implementing the Protocol.

of their domestic law, and must then declare these decisions through the BCH.[135] The protocol **does not cover** consumer products derived from GMOs, such as cornflakes, tomato paste, and cooking oils from GM corn.[136] Thus it is narrower in scope than the SPS Agreement, which applies to all GM products.

The protocol provides for decisions to be based on risk assessment. Parties to the protocol decide whether or not to accept LMOs primarily on the basis of **scientific risk assessment** procedures.[137] However, lack of scientific certainty due to insufficient scientific evidence can be resolved in banning importation following the precautionary principle provisions introduced in the Protocol.[138] In addition, import decisions can be revisited should new scientific information on adverse effects come to light.[139] Under certain circumstances, importers can ask the exporter to carry out the risk assessment.

Parties may also take into account socio-economic implications likely to result from the import of LMOs, especially in relation to the 'value of biological diversity to indigenous and local communities'.[140] A party must adopt measures for managing any risks identified by risk assessment. It can also require the exporter to carry out a risk assessment, and charge the exporting country the full cost of regulatory approval.[141]

Governments must adopt measures for **managing** any risk identified by **risk assessment**. Additionally, they must continue to monitor and control any future risks that may emerge affecting conservation and sustainable use of biodiversity in the receiving environment. This applies to traded as well as domestically produced GMOs. Based on Article 27, Members concluded the Protocol on Liability and Redress to the Cartagena Protocol on Biosafety[142] which aims to contribute to the

[135] Cartagena Protocol, Article 11.
[136] Cartagena Protocol, Article 4.
[137] Cartagena Protocol, Article 15.
[138] Cartagena Protocol, Article 10.6.
[139] Cartagena Protocol, Article 12.
[140] Cartagena Protocol, Article 26.
[141] Cartagena Protocol, Article 15. *Biosafety and the environment, an introduction to the Cartagena Protocol on Biosafety*, (n 130) p. 8.
[142] The new treaty opened for signature at the United Nations Headquarters in New York from 7 March 2011 to 6 March 2012 and will enter into force 90 days after being ratified by at least 40 Parties to the Cartagena Protocol on Biosafety. See Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (The Nagoya – Kuala Lumpur Supplementary Protocol) Nagoya, 16.10.2010. http://bch.cbd.int/protocol/supplementary/ accessed 10 Nov 2012

conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to living modified organisms.[143] In light of the arguments made in this thesis , managing risks of GMOs will benefit from recognition that it is intimately linked to some of the key principle of 'polluter pays' since the new Protocol provides international rules and procedure on liability and redress for damage to biodiversity resulting from living modified organisms (LMO).[144]

Furthermore, the Protocol contains provisions related to identification of LMOs in international trade.[145] When a party decides to allow the import of a GMO, the exporter must ensure that all shipments are accompanied by **appropriate documentation**. The Protocol requires that GMOs intended for international introduction into the environment, or for contained use, must be clearly identified as 'living modified organisms', but modified organisms intended for direct use as food or feed, or for further processing, just require a label stating that product 'may contain' such organisms. No labelling requirements for processed foods, such as cooking oil, were established.[146]

To ensure its own long term effectiveness, the Protocol contains a number of 'enabling' provisions relating to capacity-building, public awareness and participation, and financial mechanism.[147]

3.1.3 The precautionary Principle

While the precautionary principle appears to be a well-accepted tool in the field of environmental law,[148] its application to issues relating to food safety has proven

[143] Article 27 of the Cartagena Protocol provides elaboration of rules and procedures on liability and redress; Article 34 the conclusion of a compliance mechanism.
[144] Press release, 'The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety' (Nagoya, 16 October 2010). http://bch.cbd.int/protocol/NKL_pressrelease.shtml accessed 10 Nov 2012
[145] WTO, 'Genetically Modified Organisms (GMOs)' (n 10).
[146] Cartagena Protocol, Article 18.
[147] Cartagena Protocol, Articles 22-23.
[148] See discussion in chapter 3, section 4; see also David Freestone and Ellen Hey, 'Origins and Development of the Precautionary Principle' in David Freestone and Ellen Hey, eds, *'The Precautionary Principle and International Law* (Kluwer Law International 1996).

more controversial due, generally, to its potential implications for trade in GMOs.[149]

Previously, in *Hormones* the EU argued that the precautionary principle has fully crystallised as a principle of customary international law, and therefore constitutes a relevant 'rule of international law applicable in the relations between the parties' that must be used to interpret WTO agreements.[150] The US and Canada rejected this argument, contending that precautionary approach could be characterized, at most, as an emerging principle that may in the future crystallise into one of the 'general principles of law recognized by civilized nations'. The AB ruled:

> The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as having crystallised into general principle of customary international *environmental* law. Whether it has been widely accepted by Members as principle of *general* or *customary international law* appears less than clear. We consider...that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important but abstract question. We note that the panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation.[151]

In other words, the AB declined to take a position on the EU's claim for customary status for the precautionary principle. The Appellate Body noted in *EC-Hormones* that 'the precautionary principle has been incorporated in, *inter alia*, Article 5.7 of the SPS Agreement', which addresses the right to take a provisional measure where relevant scientific information is insufficient, and 'in the sixth paragraph of the preamble and in Article 3.3'. At the same time the Appellate Body noted that the

[149] See also Matthew Stilwell and Jan Bohanes 'Trade and environment' (n 17) p. 544.
[150] See Chapter 3 section 4.
[151] Footnotes omitted, emphasis in original, see Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998, para. 123, and, Panel Reports, *Biotech*, para. 7.87.

principle 'does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation' in reading the provisions of the SPS Agreement.[152] The AB held that the precautionary principle, as reflected in Article 5.7, could not override the explicit requirements of Articles 5.1 and 5.2, which require measures under the SPS Agreement be based on evidence from a risk assessment.[153] The EU ban on beef hormones was successfully challenged by the United Stated and Canada under the terms of Sanitary and PhytoSanitary Agreement.

In *Biotech*, the precautionary principle was raised again by the EU, which maintained that it had become a 'fully fledged and general principle of international law'. The EU argued that references to precaution in the Protocol should contribute consolidation of the status and relevance of the precautionary principle in both international and national law.[154] Others also argue that the fact that the Protocol reflects the need for precautionary measures provides an additional support for precaution as a principle of international law. It is also clear that the insertion of precaution contributes to the reinforcement of the principle's status, and helps to clarify its meaning and the way it should come into operation.[155]

The Cartagena Protocol gives importers unchallengeable rights to ban imports of living products which are genetically modified, for example grains, seeds, fruit, and vegetables. Importers are entitled to justify such bans by invoking the version of the Precautionary Principle laid down in the Cartagena Protocol.[156] The Protocol contains four references to precaution, ranging from two references to Principle 15 of the Rio Convention in the preamble and in Article 1, which develop its own interpretation of the precautionary approach,[157] to more precise and operational

[152] *Hormones,* para. 124.
[153] *Hormones,* paras. 124-5.
[154] Panel Reports, *Biotech*, para 7.77-7.78 See Chapter 1, section 5.1.5.
[155] Laurence Graffe, 'The Precautionary Princeple' in, Christoph Bail, Robert Falkner & Helen Margot, eds, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment & Development?* (Earthscan Publications, 2002), p. 419.
[156] Annex III states: 'Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk'.
[157] Article 1 of the Cartagena Protocol states that the objective of the Protocol 'is to contribute to

provisions in the decision-making provisions under Articles 10.6 and 11.8 when facing scientific uncertainty.[158] A technical Annex relating to risk assessment also contains a contrary interpretation of lack of scientific knowledge or scientific consensus, which has implications for the precautionary principle and the ways it might be applied.[159] In other words, importing countries can ban imports because of 'lack of scientific certainty'. A trade restrictive measure may be in force without time limits since the importing country is not obliged to seek information necessary to reach scientific certainty.[160]

The *Biotech* Panel rejected this view, relying on the reasoning of *EC- Hormones.* The Panel stated that the precise definition and content of the precautionary principle is not clear, and the 'legal debate of whether the precautionary principle constitutes a recognized principle of general or customary international law is still ongoing', and therefore it 'need not take a position on whether or not the precautionary principle is recognized principle of general or customary international law.'[161]

Biotech's ruling stated four aspects of the relationship between the SPS Agreement and the precautionary principle. First, the precautionary principle does not justify measures otherwise inconsistent with the SPS. Secondly, while the precautionary principle is reflected in Article 5.7, it does not mean that Article 5.7 exhausts the application of the precautionary principle to the SPS. This must be the case since Article 3.3 allows Members to establish their own level of sanitary protection. Thirdly, a panel that has been asked to consider whether or not there was 'sufficient scientific evidence' for a measure should 'bear in mind that responsible, representative governments commonly act from perspectives of prudence and

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ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboudary movement.'

[158] Articles 10.6 and 11.8 of the Cartagena Protocol- 'lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the party of import, taking also into account risks to human health, shall not prevent the party from taking a decision, as appropriate, with regard to the import of the living modified organism…, in order to avoid and minimize such potential adverse effects.'

[159] Annex III states: 'Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.'

[160] Simonetta Zarrilli, *International Trade in GMOs and GM Products* (n 123) p. 27.

[161] Panel Reports, *Biotech*, paras.7.88- 7.89.

precaution where risks of irreversible damage to human health are concerned.' Lastly, the precautionary principle does not replace ordinary principles of treaty interpretation.[162]

3.2 Overlap and linkage (The EU, the US, and international law)

Both the Convention on Biological Diversity and the Biosafety Protocol are signed and ratified by the EU. Argentina and Canada have signed, but not ratified, the Biosafety Protocol.[163] The US is not party to the CBD, and therefore has not signed the Biosafety protocol. However, the US did attend the Convention with a delegation, and worked with-like minded countries (making up the Miami Group, which included Canada, Chile, Argentina, Australia, and Uruguay).[164] The Panel noted that the Protocol became legally effective two weeks after the establishment of the Panel. The Panel added that the fact that the US participates in the Protocol's Clearing House Mechanism does not mean the rules of the Biosafety Protocol can be deemed to apply to the US. Consequently, the Panel is not obliged to take into account an obligation created under the Protocol, or a defence argued by reference to the Protocol.[165] The Protocol is legally binding only on countries that have ratified it.

The *Biotech* Panel confirmed, in line with previous jurisprudence, that it had to interpret WTO agreements in accordance with customary rules of interpretation of public international law as reflected in Article 31(1)(c) of the VCLT. The Panel's analysis of Article 31(1)(c) of the Vienna convention rejected the EU's defence. Having first determined that the two instruments indeed establish 'rules of international law', the Panel then considered whether they were also 'applicable in the relations between the parties'. The Panel focused on the notion of 'parties' in this context, the panel took the view that 'the rules of international law to be taken into account in interpreting the WTO agreements at issue in this dispute are those which are applicable in relations between WTO [M]embers.' It added that Article 31(3)(c) should be interpreted 'as requiring considerations of those rules of

[162] Panel Reports, *Biotech*, para 7.87; Repeated the AB in *Hormones* para. 124.
[163] Last checked on 11 July 2007.
[164] Cathleen A. Enright 'United States' (n 89) pp. 95-100.
[165] Panel Reports, *Biotech*, para. 7.75, p 302,

international law which are applicable in the relations between all parties to the treaty which is being interpreted', because this 'ensures or enhances the consistency of the rules of international law applicable to these states and thus contributes to avoiding conflicts between the relevant rules.'[166]

In *Biotech*, the Panel determined that 'the parties' meant all the parties to the WTO, rather than the 'disputing parties' or 'one or more parties'. Therefore, it could not take account of 'relevant of rules of law applicable in the relations between the parties' in its interpretation of the relevant WTO agreements unless they had identical membership to the WTO. [167] Then, the Panel pointed out that the CBD and Cartagena Protocol did not have the same coverage of Members as the WTO covered agreements, noting, in particular, that the US had not ratified either instrument.[168] Furthermore, the Panel decided not to rule on whether the precautionary principle could constitute a relevant rule of international law according to Article 31(3)(c). The Panel based its decision on a review of recent commentaries and cases regarding the precautionary principle. The Panel also stressed that a treaty interpreter could rely on any relevant international law only if it found such recourse useful, but was under no obligation to do so. Therefore, it simply stated 'We do not consider that in interpreting the relevant WTO agreements, we are required to take into account other rules of international law.'[169]

If all parties to the disputes were parties to the Cartagena Protocol, the EU could have invoked two principles of international law, *lex posterrior derogat legi priori* and *lex specialis derogate legi generali,* which may apply when two conflicting treaties relate to the same subject matter and involve the same parties. The Cartagena Protocol could be said to reflect a more recent and more specific expression of state consent than WTO Agreements.[170]

The Panel's finding leaves the relationship of the Protocol with the SPS Agreement and other international agreements in a grey area.[171] As a result, the EU will be left

[166] Panel Reports, *Biotech*, paras. 7.68-70.
[167] Panel Reports, *Biotech*, para. 7.68.
[168] Panel Reports, *Biotech*, paras.7.47-7.75.
[169] Panel Reports, *Biotech*, para. 7.95.
[170] Simonetta Zarrilli, *International Trade in GMOs and GM Products* (n 123) 16.
[171] WTO, 'Genetically Modified Organisms (GMOs)' (n 10); Alexia Herwig, 'Whither Science in WTO Dispute Settlement?' (2008) 21(8) LJIL 838.

with conflicting obligations without interpretive means, complicating its observance of international obligations. Ultimately, the Panel's ruling contributes to increase the fragmentation of international law.[172] The Panel noted:[173]

Other relevant rules of international law may in some cases aid treaty interpreter in establishing, or conforming, the ordinary meaning of treaty terms…Such rules would not be considered because they are legal rules, but rather they may provide evidence of the ordinary meaning …they would be considered for their informative character.

Criticism of the Panel's ruling on this point is based on the fact that the Panel went too far in interpreting Article 31(3)(c) of the Vienna Convention to apply only if all WTO Members are parties to a treaty. 'Given the number and diversity of WTO Members, this would be requirement impossible to fulfil. It is also unfortunate that the panel seems to have rejected any interpretive value of non-WTO treaties, an approach in stark contrast to that adopted by the Appellate Body in *US-Shrimp.*'[174] The implications of this position are important for future WTO disputes involving conflicting norms.[175] Margaret Young argued further that these non-WTO sources were crucial also to the Panel's analysis of the applicability of the relevant covered agreements.[176]

The next section considers the relationship and the overlap between the Cartagena Protocol and the SPS Agreements in light of EU and US involvement in negotiation of international law.

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[172] Study Group of the International Law Commission, 'Fragmentation of International Law' (n 6) pp. 12-14.
[173] Panel Reports, *Biotech*, para. 7.92
[174] Joanna Gomula, 'Environmental disputes in the WTO', in Malgosia Fitzmaurice (eds) and David M. Ong, and Panos Merkouris (eds) *Research Handbook on International Environmental Law* (Research Handbooks in International Law, Edward Elgar, Cheltenham, UK, 2010).
[175] Margaret A. Young, 'The WTO's Use of Relevant Rules of International Law: An Analysis of the Biotech Case' (2007) 56(4) ICLQ 913. Young also calls into question the Panel's approach of merging the complaints into one proceeding. As each of the parties had different obligations, it would have been better to separate their legal claims and defences.
[176] CBD and Cartagena Protocol should have been used to clarify the concept 'SPS Measure' in section 2.3 above. See Margaret A Young, 'The WTO use of relevant rules of international law' (n 4) p. 908.

3.2.1 SPS v Cartagena Protocol

The drafters of the Protocol, most of which were also WTO Members, were aware of the overlap between the Protocol and the WTO Agreements. They made every effort to ensure that its provisions and other trade agreements would be mutually supportive and complementary.[177] The Preamble of the Protocol emphasizes that the 'Protocol shall not be interpreted as implying a change in the rights and obligations of a party under any existing international agreement', whilst claiming that this statement is 'not intended to subordinate the Protocol to other international agreements'. [178] Therefore, the Protocol's preamble contains a saving clause, which attempts to regulate the relationship between the Protocol and other international agreements.[179]

The second additional phrase captures the political sentiment expressed during the Cartagena Protocol negotiations that environmental agreements are not of a lower status, class, significance, or importance than trade agreements, and that inclusion of a saving clause in the Protocol should not be understood to lower or lessen it.[180] The EU favoured a 'Cartagena Protocol that would support and be supported by other international agreements and apply simultaneously with them.'[181] The EU's view on inclusion of the 'no subordination' preambular language in the Protocol text reaffirms the application of the rule of Article 30(3)(c) of the Vienna Convention. [182]

In spite of this attempt, the relationship of WTO agreements and the Cartagena Protocol is unclear and open to various interpretations. The reason is that WTO agreements do not include a conflict clause, nor do they clarify their relationship

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[177] Appendix. 'The Cartagena Protocol and the World Trade Organization, in, Ruth Mackenzie, et. al. , 'An Explanatory Guide to the Cartagena Protocol on Biosafety', IUCN Environmental Policy and Law Paper no. 46 (2003) can be found http://www.iucn.org last visited11/07/07, p. 226.
[178] *Biosafety and the environment, an introduction to the Cartagena Protocol on Biosafety*, (n 130) p.12.
[179] Sabrina Safrin, 'The relationship with other agreements' in Christoph Bail, Robert Falkner & Helen Margot, eds, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment & Development?* (Earthscan Publications 2002) pp. 445-446.
[180] Ibid p. 446.
[181] Margarida Afonso, 'The relationship with other international agreements: an EU perspective' in Christoph Bail, Robert Falkner & Helen Margot, eds, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment & Development?* (Earthscan Publications 2002), p. 424.
[182] Ibid, p. 434.

with pre-existing or future treaties.[183] The Preamble to the Agreement establishing the WTO recognises that 'trade should protect and preserve the environment' in a manner consistent with Members different levels of economic development.[184]

The EU and US regulatory rivalry played a role in shaping international law since both of them attempted to influence the international legal framework within which WTO rules operate. Both are active within the SPS Committee[185] and other standards setting institutions, such as Codex Alimentarius, with rivalling focuses on definition of science and the use of precaution in trade.[186] Negotiations of the Cartagena Protocol witnessed this rivalry. The EU advocated the incorporation of the precautionary principle into the Cartagena Protocol,[187] while the US actively led the Miami Group in expressly opposing its inclusion.[188] Some commentators, and many NGOs, argued that the US timed its complaint with the entry into force of the Protocol. In *Biotech,* the US wanted to maintain the legal supremacy of the SPS Agreement, whose more demanding scientific standards for trade-restrictive regulatory policies enabled the US to prevail in its dispute over the EU's precautionary measures on GMOs.[189]

Overlap and interaction of the Protocol and the SPS Agreement adds challenges to an already complex scenario, and will continue to give rise to further conflicts

[183] It should also be noted that the Protocol governs some transboundary movements of LMOs that are unrelated to international trade, and would thus fall outside the scope of the WTO. The unintentional transboundary movements of LMOs through, for example, the spread of pollen, is covered by the Protocol, but would not be covered by the WTO.
[184] Marrakesh Agreement establishing the World Trading Organisation, 15 April 1994.
[185] The committee, among other things, is seen to operate as contextualizing regime, whereby Members arrive at settled understanding of the standards laid down in the agreement, and of their implications for the boundaries of legitimate regulation by the Members States. See Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) pp. 41-75.
[186] The EU sought actively to export its precautionary approach to the international trade, environmental, and food safety regimes, and thus help shield the EU from a WTO legal challenge., see Gregory C Shaffer & Mark A Pollack, *Regulating Between National Fears and Global Disciplines: Agricultural Biotechnology in the EU*, (Jean Monnet Working Paper 10/04, NYU School of Law, New York, 2004) 43; Scott, Joanne, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) p. .274.
[187] Christoph Bail et al., 'European Union' (n 90) p. 185; David Vogel, 'The Politics of Risk Regulation in Europe and the United States', manuscript for publication in (2003) 3 Yearbook of European Environmental Law. pp. 61-62
[188] Cathleen A. Enright 'United States' (n 89) pp. 95-98.
[189] Steve Suppan, 'US Vs EC Biotech Products Case: WTO Dispute Backgrounder', (2005) ITAP p. 15, available at http://www.tradeobservatory.org/library.cfm?refid=76644%20.

between GMO exporting countries and potential importers.[190] Potential tension arises from the following of issues.

Risk assessment

The SPS Agreement and the Protocol have different understandings of risk assessment. Under the SPS Agreement, measures must be based upon a risk assessment process 'taking into account available scientific evidence and economic factors, including the objective of minimizing negative trade effects.'[191] The Protocol, on the other hand, endorses a more open-ended approach, drawing on the precautionary approach. Article 15 of the Protocol states that 'risk assessment should be carried out in a scientifically sound manner in order to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking into account risks to human health.'[192] The import of LMOs may be approved by the designated national authority with or without conditions. It may also be prohibited, or subject to requests for additional information. Silence from the party of import in response to an initial notification does not imply consent to transboundary movement.[193] There are also provisions for review of decisions in light of new scientific information regarding the potential adverse effect of the LMO.[194] States are permitted to take action more protective of biodiversity than provided for in the Protocol, such actions must be consistent with both the Protocol and with that state's other obligation under international law, e.g. WTO trade related obligations.[195]

The requirement that risk assessment 'shall be carried out in a scientifically sound manner' entails taking account not only the provisions of the Protocol but also of 'recognised risk assessment techniques'. The Biosafety Protocol also permits importing countries to take into account socio-economic concerns. Article 26 enables the parties to take into account, when deciding whether and under which

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[190] Helen Trudeau and Celine Negre, 'Precaution in the Multilateral Environmental Agreements and its Impact on the World Trading System' in Marcus W Gehring and Marie Clair Cordonier Segger (eds), *Sustainable Development in World Trade Law* (Kluwer Law International, The Hague 2005), p. 595.
[191] Article 5.
[192] See also, Nuffield Council on bioethics, The Use of Genetically Modified Crops in Developing Countries-a Follow up Discussion Paper (Nuffield Council on Bioethics, December 2003), p. 69.
[193] Cartagena Protocol, Article 9(4).
[194] Cartagena Protocol, Article 12.
[195] Patricia Birneie et al, *International law and the environment* (n 27) p. 643.

conditions to allow the import of LMOs, 'socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.' It allows trade restrictive measures justified by the fact that imports will lead to loss of cultural tradition, knowledge, and practices, stressing the special value that biological diversity has to indigenous communities, and its effect on their socio-economic environment.[196] It is clear that decision making regarding LMOs must be grounded in 'sound science' and those non-scientific factors will not provide unchallengeable grounds for refusal to import LMOs under the Protocol. For example, a general consumer concern regarding genetically modified foodstuffs will not provide unchallengeable grounds for refusal to import LMOs under the Protocol.[197]

Neither Article 5(2), nor 5(3) of the SPS Agreement retains socio-economic considerations in its risk assessment. Nevertheless, the list of factors that a party may take into account in its decision making is not exhaustive. Consequently, socio-economic considerations may play a role in a government's decision to be more or less risk averse. However, no trade restrictive measures will be allowed based solely on socio-economic considerations.[198]

Precaution

The Protocol and the WTO SPS Agreement include differing language on how governments should make decisions under conditions of scientific uncertainty. The Protocol explicitly embodies a precautionary approach (preamble, and Articles 10.6 and 11.8), and explicitly permits countries to prohibit the import of certain LMOs (Article 10.3) to protect from risks to biodiversity and human health.[199] The SPS Agreement, by contrast, merely 'reflects' the precautionary principle in Article 5.7, which allows Members to adopt sanitary or phytosanitary measures on a temporary or provisional basis to be reviewed 'within reasonable period of time'.

Even without sufficient scientific evidence, the SPS Agreement includes 'precautionary language' that permits standards to be adopted provisionally.[200]

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[196] Simonetta Zarrilli, *International Trade in GMOs and GM Products* (n 123) p. 29.
[197] Patricia Birneie et al, *International law and the environment* (n 27) p. 645.
[198] See *Hormones,* para195.
[199] The Cartagena Protocol, Article 10.3.
[200] Patricia Birneie et al, *International law and the environment* (n 27) p. 780.

Article 5.7 of the SPS allows for situations in which there is insufficient information available to the import country to make a scientific determination, in particular to take into account available scientific evidence in risk assessment in order to justify trade barriers, which can only be made on a temporary or provisional basis. This does not permit a measure to be justified on the basis of the precautionary principle if it is contrary to the explicit requirements of the SPS Agreement.[201] The Protocol on the other hand, endorses a more open-ended approach, drawing on the precautionary approach.[202] It explicitly adopts the precautionary principle for the regulation of food, feed, and processed LMOs, allowing import regulation even in the face of 'lack of scientific certainty due to insufficient scientific information'.[203]

This major overlap between the Protocol and The WTO raises many questions, for example, regarding the relation between the terms 'insufficient scientific evidence' and 'scientific uncertainties'. The influence of uncertainty in determining whether scientific evidence is insufficient in a given situation. It also raises questions about the status of the principle in international environmental law, and whether it has any contribution towards sustainable development. The Panel in the *EC-Biotech* case did not rule on this conflict as it did not apply the Cartagena Protocol to its analysis of precaution under the SPS agreement, thus raising high the hurdle for the interpretation of WTO agreements in the light of other instruments.

The next section questions whether the science-based obligations of the SPS Agreement are capable of accommodating legitimate regulatory diversity. It focuses on how science, risk assessment, and precaution, as defined and interpreted by the Panels, can be read in light of the wider understanding of science and risk as explained in Chapter 2, section 2.7. It is important because the definition of these concepts determines what is considered a legitimate barrier to trade, a legitimate risk, and essentially, how states set the level of protection.

[201] *Beef Hormones* (AB) paras 124-5; See also Patricia Birneie et al, *International law and the environment* (n 27) p. 780,
[202] Nuffield Council on Bioethics, *The Use of Genetically Modified Crops in Developing Countries- A Follow up Discussion Paper*, (Nuffield Council on Bioethics December 2003) p.69.
[203] Cartagena Protocol, Article 11(8).

4 Science and SPS Agreement

The question of how the WTO Panel can strike an appropriate balance between maintaining domestic regulatory space to respond to scientific uncertainty, on the one hand, and the need for predictable trading relations, on the other, will thus depend on the interpretation of particular WTO obligations and their application on a case by case basis to particular domestic measures.[204] All SPS measures require a scientific basis. The SPS reliance on science serves to verify WTO Members' 'risk regulatory policies' to curb disguised protectionism.[205] Therefore, science and risk assessment lies at the heart of the SPS Agreement's strategy of reviewing and exercising oversight of national regulations.[206]

While science is the primary mechanism underpinning risk assessment, in recent years the 'strength of hold science on society has waned considerably' in some countries. This is due to two main reasons. The first is the low level of public faith in the ability of science to deliver solutions to manifest risks by 'experience'.[207] Chapter 3 explained how public opposition in Europe is notable and shaped the regulatory choices.[208] The second reason is the increasing and complex problems of uncertainty within science itself, making the reliance on science difficult to frame risk. Risk assessment is always interwoven with uncertainty because it must 'rely on the interfaces and extrapolations whose correctness cannot be proven by scientific method'.[209] Chapter 2 demonstrated that the high level of uncertainty surrounding GMOs/biotechnology poses a challenge to the law.

The *Amicus Curie* Brief by the 'Group of Academics' recognised that risk assessment is neither a single methodology, nor a 'science':

> Rather, 'risk' situations lie within a matrix defined by two

[204] Alexia Herwig, 'Whither Science in WTO Dispute Settlement?' (n 171). 826
[205] Ibid, 827
[206] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) Chapter 3.
[207] Karen Morrow 'Genetically Modified Organisms and Risks' in Luc Bodiguel and Michael Cardwell, *the Regulation of Genetically Modified Organisms: Comparative approaches* (OUP, 2010) 57.
[208] Science and technology are blamed for harm, looked for solutions to harm, and then blamed again for not finding them. For more on risk and the EU see, Maria Lee, *EU Environmental Law: Challenges, Change and Decision-Making* (Hart Publishing 2005), pp.80-96.
[209] Alexia Herwig, 'Whither Science in WTO Dispute Settlement?' (n 171) 830; Karen Morrow 'Genetically Modified Organisms and Risks' (n 207) p. 57.

> variables: *certainty* and *consensus*. At one extreme are cases characterized by *high certainty* with respect to the knowledge base to be relied upon, and *high consensus* with respect to the parameters of the scientific issues to be addressed, the analytic methods to be applied, and the values to be protected. At the other extreme are *low certainty* and *low consensus* on such matters. The nature and adequacy of any risk assessment will depend on the position of an issue within this matrix - and GMO technologies fall squarely in the low certainty, low consensus range.[210]

The Group of Academics compared *Biotech* to previous WTO dispute cases, such as *Importation of Salmon* (1998) and *Prohibition of Asbestos and Asbestos Products* (2001), which were characterized by high certainty and high consensus with respect to the basic parameters, scientific knowledge, analytic methods, and values relied upon in risk assessment. [211]

The Group of Academics and others suggest that the SPS Agreement represents a suitable response to attempts by WTO Members to restrict imports for traditional products. It is arguable that for innovative products, such as the GMOs, where challenges are more complex, the SPS may be inadequate.[212] As a result, 'the status of science as a co-traveller with law has become ever more strained and new paradigm for interdisciplinary interaction is urgently required.'[213]

The next two sections analyse the SPS Agreement's science based obligations allowing WTO Members to adopt measures, as laid out in its substantive provisions in Articles 2.2, 3.3, 5.1, and 5.7. These contrast with *Biotech's* perspective, and consider the extent to which the EU can define its own 'appropriate level of protection'. This is done by questioning the interpretation of elements of protective measures, which must be based on a 'risk assessment' and not maintained without 'sufficient scientific evidence' because there is space for judicial discretion to be exercised by future panels and appellate bodies.

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[210] Emphasis in original, Amicus Curiae Brief by Group of Academics (n 5), p 5.
[211] Emphasis in original, Amicus Curiae Brief by Group of Academics (n 5) pp. 5-6 and 8.
[212] Joseph McMahon, 'The *EC Biotech* Decision: Another Missed Opportunity' (n 81) p. 354.
[213] While science may still be viewed as of foundational importance, it cannot be considered adequate in and of itself as the basis for decision making in risk context. See Karen Morrow 'Genetically Modified Organisms and Risks' (n 207) p. 57.

4.1 SPS and International Standards

The SPS Agreements stipulate the need to take into account other existing international agreements and other relevant State practice.[214] Article 3.1 of the SPS Agreement provides that SPS measures to be based 'on as wide basis as possible' on international standards, guidelines or recommendations where they exist. An SPS measure that conforms to international standards is presumed to be necessary to protect health or life.[215] Article 3.3 allows Members to apply higher standards 'if there is scientific justification, or as consequence of the level of sanitary or phytosanitary protection a member determines to be appropriate'.[216]

The SPS Agreement explicitly recognises 'three sister organisations' for setting standards, guidelines, and recommendations relating to food safety issues,[217] and for the harmonization of food safety measures affecting trade.[218] The standard setting organisations are the Codex Alimentarius for food safety, the International Office of Epizootics for animal health, and the Plant Protection Convention for plant health. Neither the CBD, nor the Protocol, is currently recognized as a standard setting body under the SPS Agreement. The SPS Committee also monitors the use of these international standards.[219] WTO Members are required to base their food safety measures on their standards, otherwise they must be based on risk assessment.

The **Office International des Epizooties** (OIE) is the world organisation for animal health. The OIE develops standards and guidelines designed to prevent the introduction of infectious agents and diseases into the importing country during international trade of animals, animal genetic material, and animal products. Some

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[214] SPS Agreement, Article 3.1, Annex A, Article 3. International standards, guidelines and recommendations are defined as:... The TBT Agreement also encourages Member States to base their measures on international standards
(d) For matters not covered by the above organization, appropriate standards, guidelines and recommendations promulgated by other relevant international organization open for membership to all Members, as identified by the SPS Committee.

[215] Article 3.2 of the SPS Agreement.

[216] Articles 2.4-2.5 of the TBT agreement have a similar language.

[217] Annex 3 of the SPS Agreement.

[218] Annex A of the SPS Agreement include appropriate standards from other international organisation open to membership by all WTO Members as identified by the SPS Committee.

[219] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) pp. 65-69.

of the standards developed by the OIE deal with diseases that have human health and biosafety significance. The OIE has had a working group on biotechnology since 1996.[220]

The **International Plant Protection Convention** (IPPC) is a multilateral treaty for international cooperation in plant protection. The IPPC protects plant health by assessing and managing the risks of plant pests and invasive species. It is in the process of setting standards to address the plant pest risk associated with GMOs and 'invasive species'. Any GMO that could be considered a plant pest falls within the scope of this treaty. The IPPC allows governments to take action to prevent the introduction and spread of such pests.[221]

The **Codex Alimentarius Commission** is responsible for compiling global standards, codes of practice, guidelines and recommendations that address food safety and consumer health.[222] The Codex has established an 'ad hoc task force on foods derived from biotechnology' to develop standards guidelines or recommendations, as appropriate, for genetically modified organisms.[223]

In 2003, the Codex Alimentarius Commission adopted a set of 'Principles and Guidelines on foods derived from biotechnology' to help countries coordinate and standardise regulation of GM food to help ensure public safety and facilitate international trade.[224] The guidelines call for safety assessment of all GM foods prior to their approval for commercial use. The Commission sets standards regarding risk analysis, and international guidelines for assessing and managing any health risk for foods derived from biotechnology. Both traceability and food labelling were named as risk management tools. The SPS Agreement grants the Codex Alimentarius Commission a prominent role, with its standards enjoying a considerable weight in determining whether national measures are in conformity with the Agreement. States can establish more exacting conditions than those contained in the Codex standards, but only if justified based upon a scientific risk

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[220] WTO 'Genetically Modified Organisms (GMOs)' (n 10).
[221] Ibid.
[222] The Codex Alimentarius Commission was founded in the early 1960s by Food and Agriculture Organization (FAO) and World Health Organization (WHO); Codex Alimentarius, 'Food Derived from Biotechnology' (WHO, FAO, 2nd ed, Rome, 2009).
[223] FAO/WHO expert consultation on the 'Safety Assessment of Foods Derived from Genetically Animals including Fish, Rome November, 2003.
[224] Codex Alimentarius Commission updated its guidelines for import and export of food in 2008. Full text available on http://www.fao.org/docrep/011/a1554e/a1554e00.htm.

assessment of the products in question.[225]

Member may only depart from international standards when the scientific evidence provides due reason. In *Hormones* the Panel found that the EU violated Article 3.1, determining the import ban was not based on international standards and was imposed without scientific justification. In the *Biotech* dispute over GMOs, the Panel referred to the Codex.[226] The incorporation of the international standards provide a degree of deference to non-WTO rules through the presumption of consistency with certain WTO rules in case international standards are complied with.[227] Scott notes that while 'international standards in particular were regarded as aids to interpretation; they were not treated as dispositive with the panel exhibiting a willingness to depart from them in favour of a more expansive understanding'.[228] Lee also finds '[g]ranting special status to standards is especially strange when considered alongside the irrelevance of Cartagena Protocol.'[229]

4.2 Risk assessment to be based on scientific evidence

Member have an 'autonomous right' to establish their own level of sanitary protection,[230] but it must be based on proper risk assessment and subject to the various requirements of Article 5. In *Biotech*, the Panel suggested that adequate risk assessment had to be based on evidence 'gathered through scientific method' with 'a complete, self-contained, scientific evaluation', result only admissible[231]

In spite of this, the definition in Annex A(4) of the SPS Agreement specifies that risk assessment must first 'Identify', then 'Evaluate the likelihood' of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences, 'according to the SPS measures that might

[225] See Joanna Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5), Chapter 7.
[226] See discussion in the next chapter.
[227] Joost Pauwelyn, *Conflict of Norms in Public International Law* (n 1) pp. 349-350.
[228] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measure* (n 5) p. 14.
[229] Despite the remark, Lee considers the wording of the Cartagena Protocol very ambiguous, and it is not clear whether it would have been helpful for the EU's defense. See Maria Lee, *EU Regulation of GMOs* (n 82) p. 232.
[230] *Hormones* 1998, 172.
[231] Panel Reports, *Biotech*, para 7.3188

be applied'.[232] Risk assessment must be 'specific' to the case at hand, and must take into account 'risk assessment techniques developed by the relevant international organisations'.[233] 'Risk is a complex concept, however, entailing judgments not only about the probability and scale of harm, but about causes of harm, the effects of the activities, substances or processes in question, and their interaction over time.'[234]

According to Article 5.2, risk assessment will take into account available scientific evidence. The importance of such evidence is reinforced by Article 2.2, which requires SPS measures to be 'based on scientific principles', and not 'maintained without sufficient scientific evidence'. In *Japan-Apples*, the Panel indicated that any evidence presented should be gathered through scientific methods.[235] Non-demonstrable hypotheses and purely circumstantial evidence are considered non-scientific.[236] In the *EC-Hormones* case, the Appellate Body determined that sufficient evidence cannot be based on theoretical science, whilst in the same paragraph indicating that science is never absolute and embodies a degree of theoretical uncertainty.[237] This is a narrow risk assessment procedure, in which hypothetical and long term risks are difficult to incorporate, leaving aside the application of the precautionary principle. Furthermore, the tight connection between the SPS measures and the scientific evidence does not allow room for consideration of other legitimate unscientific factors.

In *Hormones*, the EU was found to have violated Article 5.1 of the SPS Agreement because its ban was not based on risk assessment (i.e. an evaluation of potential for adverse effects on human health arising from the presence of certain hormones in meat). The Appellate Body clarified that risk is not exclusively scientific, providing:

> It is essential to bear in mind that the risk that is to be evaluated in a risk

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[232] Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998, DSR 1998, para. 121. [hereinafter '*Australia- Salmon'*]
[233] SPS Agreement, Article 5.1.
[234] Patricia Birneie et al, *International law and the environment* (n 27) p. 153.
[235] Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003. paras. 8.92-8.93 [hereinafter '*Japan- Apples*'].
[236] *Japan- Apples* paras. 8.92-8.94.
[237] Theoretical science predicts future outcomes based on evidence derived from models or hypotheses. *EC-Hormones,* para. 186.

> assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effect on human health in the real world where people live and work and die. [238]

The approach in *Hormones* shows some acknowledgment of the limitation of science as arbiter of SPS risk. It suggests a broader understanding of risk assessment by accommodating the divergent opinions and real world risks. The result is a less intrusive standard of review applicable in the scrutiny of Members' risk assessments. This echoes Appellate Body's reasoning under GATT violations, which allows countries more autonomy in reaching decisions about acceptable types and levels of risk. The Appellate Body in *Shrimp/Turtle* did not rely exclusively on examining the sufficiency of the scientific basis of the measures, and turned to various process based alternatives to evaluate whether risk claims were genuine and legitimate. Similarly in *Asbestos* the Appellate Body undertook an explicit weighing of value concerns in determining the necessity for trade restrictive measures to implement.[239]

Yet, in the *Biotech* dispute, the Panel ruled that all nine national safeguard measures, which were imposed by EU Member States against GMOs and had been approved at the EU level, were not based on risk assessment consistent with Article 5.1. The Panel therefore concluded that the safeguard measures violated WTO rules. Simply by enacting measures that trumped EU risk assessment protocols. It did not need any further investigation.[240] The Panel made no mention of the extensive expert advice it received at any stage in its analysis of the scientific basis of the safeguard measures.

Herwig, criticized the Panel in *Biotech* for not engaging in scientific evidence to determine the sufficiency or otherwise relevant scientific evidence as a basis for provisional restrictions on the marketing of some GMOs. She added that 'had it done so it might have discovered that scientific assessment and regulation of GMOs has to cope with uncertainties and incomplete background knowledge

[238] *EC-Hormones,* paras 179-85
[239] See chapter 3 section 5.1.2
[240] Panel Reports, *Biotech*, p. 1073, p. 1078, and p.1084.

notwithstanding the fact that some scientists consider risk assessment of GMOs to be possible.[241]

Again, the criticism of the Panel's finding has revolved around the role of science in the SPS Agreement. The Panel attributed a broad scope to risk assessment under Article 5.1 of the SPS Agreement. The Panel also read the Article 5.1 exception as placing the burden of proof on the EU to prove GMOs are unsafe.

Herwig noted that the concept of risk assessment as defined in Annex A(4) is sufficiently open to include forms of scientific evidence with different degrees corroboration 'since nothing is said about specificity, conclusiveness, or real world circumstances'. [242] Even though it is clear that the competence of WTO bodies is limited to consideration of claims under covered agreements, when elucidating the content of the relevant rights and obligations WTO bodies must situate those rights and obligations within the overall context of general international law.[243]

Drawing on social scientific findings regarding the limitations of science-based risk assessment in diverse risk settings, Peel contends that a more coherent and principled approach to application of the process based standard of review would allow for its adjustment according to the nature of the risk situation under consideration, WTO should undertake a review of the processes by which a decision on such measure are reached, rather than their technical accuracy.[244]

4.3 'Uncertainty' and precautionary measures

WTO Members could argue that relevant scientific evidence is insufficient, and adopt a provisional measure according to Article 5.7 of the SPS based on the available pertinent information. A number of WTO panels have recognized the right of a Member State to take a precautionary measure under the SPS. In *EC Asbestos,*

[241] Alexia Herwig, 'Whither Science in WTO Dispute Settlement?' (n 171) p 845.
[242] Ibid, p 844.
[243] Article 23 DSU; see more on the subject Study Group of the International Law Commission, 'Fragmentation of International Law' (n 6) p. 90-1.

[244] Jacqueline Peel, *Science and Risk regulation in International Law* (e-book, Cambridge University Press, 2010) 255

the AB held that 'it is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation.'[245]

Nevertheless, they listed strict conditions that must be met for these measures to be compatible with WTO rules.[246] The *Biotech* Panel, following the AB's findings in *Japan- Agricultural products II,*[247] determined that Article 5.7 sets out four cumulative requirements that must be met for adopting and maintaining provisional SPS measures:

1. An Article 5.7 SPS measure may be imposed only in a situation where relevant scientific information is insufficient;
2. The provisional measure must be adopted on the basis of available pertinent information;
3. The Member adopting the measure must seek to obtain the additional information necessary for a more objective assessment of risk; and
4. The Member must review the SPS measure within a reasonable period of time.[248]

Members are obliged to actively seek the needed additional information, which must be 'germane' for conducting a more objective risk assessment, and must do so within a 'reasonable period of time' to be determined on a case-by-case basis.[249]

In the *Japan-Apples* case, the AB confirmed the need for the cumulative requirements to be met in order for WTO Members to adopt and maintain provisional SPS measures. The AB clarified that 'the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the

[245] *Asbestos,* para,168.
[246] See Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999, DSR 1999 [hereinafter '*Japan – Agricultural Products II*'*]; Japan-Apples*
[247] The case was about a complaint by the US relating to requirement imposed by Japan (invoking Article 5.7) for testing and confirming the efficacy of the quarantine treatment for each variety of each certain agricultural product. *Japan-Agricultural products II*
[248] Panel Reports, *Biotech*, para. 7.2973; and *Japan-Agricultural products II*, para. 89.
[249] Based on *Japan-Agricultural products II,* paras. 92-93.

'insufficiency' of 'relevant scientific evidence'. It stated that 'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessments of risks as required under Article 5.1, and as defined in Annex A to the SPS Agreement. The text of Article 5.7 is clear: it refers to "cases where relevant scientific evidence is insufficient", not to "scientific uncertainty". The two concepts are not interchangeable.'[250]

Having rejected the EU's argument that Article 5.7 contains specific rules for the assessment of provisional measures, the *Biotech* Panel also recalled that Article 5.7 could be characterised as a 'qualified right' rather than an 'exception' from the general obligation under Article 2.2. This means that if a challenged SPS measure was adopted, and is maintained consistently with the requirements of Article 5.7, the obligations in Article 2.2 would not be applicable. [251]

Broude criticized the Panel's finding on the relationship between Articles 2.2, 5.1, and 5.7. He found it an obscure textual interpretation that distorts the way they interact. He regarded the Panel's discussion of a 'qualified right' under Article 5.7 unnecessarily confusing. He advocated for a 'substantive, contextual interpretation' in which Articles 5.1 and 5.7 are applications of the general SPS Agreement obligations under Article 2.2 to 'two distinct situations- one, where there exists scientific evidence sufficient to establish an SPS measure on risk assessment; the second where scientific evidence insufficient for such a purpose.'[252]

The Panel went on to interpret Article 5.7 with reference to Article 5.1. The Panel concluded that 'if an SPS measure challenged under Article 5.1 was adopted and is maintained consistently with the cumulative requirements of Article 5.7, the obligations in Article 5.1 to base SPS measures on risk assessment is not applicable to the challenged measure.'[253] The Panel applied this understanding to assess the

[250] *Japan- Apples* para. 184.
[251] Panel Reports, *Biotech*, paras. 7.2969 and 7.2972-6; and *Japan- Agricultural products II,* para. 80.
[252] Tomer, Broude, 'Genetically Modified Rules: the Awkward Rule Exception- Right Distinction in EC Biotech (2007)' 6 World Trade Review, 215, 223.
[253] Panel Reports, *Biotech*, para. 7.2004.

consistency of the different safeguard measures taken by some EU Member States. First, it examined whether risk assessment within the meaning of Annex A(4) and Article 5.1 had been conducted. The Panel seemed to be searching for 'a complete, self-contained, scientific evaluation' of particular GMO risks.[254] To the extent that risk assessment was found to exist, the Panel then considered whether each measure was 'based on' the relevant risk assessment. [255]

Various studies and reports used by EU Member States to support their safeguard measures were framed by the Panel as incomplete risk evaluation. It assumed that the suggestions of uncertainties, the lack of field data and the inability to reach definitive conclusions about risk were failing of the studies as risk assessments and not indications of the unsettled state of the underlying science. Peel noted that the Panel in *Biotech* did not question current state of the underlying science on GMOs to provide the basis for more comprehensive, case by case assessments of the likely health and environmental effects of different GM crops. This failing of the studies could have been 'a reflection of the insufficiency of this body of evidence as a basis for an adequate risk assessment of risks satisfying the requirements of Article 5.1'. [256]

In *Biotech,* the Panel also stated that 'if there are factors which affect scientists' level of confidence in a risk assessment they have carried out, a WTO Member may in principle take this into account.'[257] The Panel added that 'there may conceivably be cases where Member which follows a precautionary approach, and which confronts a risk assessment that identifies uncertainties or constraints, would be justified' in adopting a stricter SPS measure than another Member responding to the same risk assessment.[258] Yet, the Panel took the view that the conclusion of a favourable risk assessment by EFSA indicated the sufficiency of the underlying scientific evidence. It did not question why and how EU Member States assessed risk differently, particularly in cases where alternative assessments turned on

[254] Panel Reports, *Biotech*, para. 7.3148
[255] Panel Reports, *Biotech*, para. 7.3044.
[256] Jacqueline Peel, *Science and Risk regulation in International Law* (e-book, Cambridge University Press, 2010) p 252 ;see chapter 2, sections 2.7-8 for more on debate over potential benefits versus potential adverse effects of GMOs over the long term is due to insufficiencies in available scientific evidence.
[257] Panel Reports, *Biotech*, para. 7.3065.
[258] Panel Reports, *Biotech*, para. 7.3065.

'possible uncertainties or constraints in the risk assessments in question'.[259] The Panel later wrote a letter to the parties, annexed to the decision, seeking to reinforce the capacity of Members to adopt protective measures on the basis of new additional information:

> The panel's findings relating to Article 5.1 of the SPS Agreement preserve the freedom of Members to take prompt protective action in the event that new or additional scientific evidence becomes available which affects their risk assessments. Particularly if the new or additional scientific evidence provides grounds for considering that the use or consumption of a product might constitute a risk to human health and/or the environment, a Member might need expeditiously to re-assess the risks of human health and/or the environment. [260]

This letter can be understood as seeking to reinforce the capacity of Members to adopt protective measures on the basis of new additional information, or reverse of its position in the ruling.

Reading the *Biotech's* Panel's finding together, we find that the broad scope attributed to 'risk assessment' under Article 5.1 combined with the high threshold for precautionary measures adopted on the basis of Article 5.7 of the SPS, made recourse to Article 5.7 difficult on account of its narrow interpretation. The Panel's ruling is restrictive despite its commitment to the 'domestic autonomy' of Member States to choose the appropriate level of protection.[261] In relation to EU Member States' bans, the Panel held that because the studies conducted at the EU level constituted risk assessment, the measures fell outside the scope of Article 5.7, which only applies where there is insufficient evidence to conduct such risk assessment.

An *amicus curia* by the Group of Academics concluded that '[a]n overly rigid conception of risk assessment and regulation in this area…could undermine the legitimacy of the SPS Agreement and the WTO more generally.' The brief

[259] Panel Reports, *Biotech*, para. 7.3085
[260] See *Biotech,* Annex K, Letter of the Panel to the Parties of 8 May 2006, WT/DS291-3/R/Add9 (29 September 2006).
[261] Oren Perez, 'Anomalies at the Precautionary Kingdom: Reflections on the GMO Panel's Decision' (2007) 6(2) World Trade Review 273. See also Maria Lee, *EU Regulation of GMOs* (n 82) pp. 211-220.

recognised the appropriate role of the WTO Dispute Resolution Panel as that of an administrative tribunal reviewing the adequacy of executive decision-making processes not that of an adjudicatory body reviewing the substantive merits of the parties' risk assessments.[262] Therefore, judicial review of decisions about hazards need to take into account the non-scientific qualities of hazards that can be anticipated on the basis of reasonable scientific evidence when determining whether there is sufficient scientific basis for regulatory purposes.[263]

A legal understanding of GMOs concentrating solely on the regulatory details and ignoring the broader context provides less than the whole story. It also has the potential to both mislead and misrepresent the true nature of how GMOs are governed at the international level.[264] On the one hand, there is an interest in deference towards the approach a given Member takes to the management of risks such as, health safety, or the environment. On the other hand, there is also an interest in preventing new protectionist barriers arising under the guise of precaution.

The EU maintained its extensive regulatory framework, covering a number of issues ranging from release into the environment, to food and feed, to allowing Member States to have more options and choices in deciding whether to cultivate GMOs. The EU exercised regulatory autonomy with higher standard as a matter of preference, a long there is no consensus as to the scientific uncertainty it has not been possible to establish a clear and consistent line whether it is legitimate or in breach of Articles 2.2, and 5.5 of SPS Agreement. The inconsistency between trade on the one side, and human and environmental protection on the other will continue to give rise to conflicts between GMO exporting countries and potential importers.

However, further escalation of trade disputes is counterproductive because 'potential plaintiffs may conclude that winning a domestic political support from crucial constituencies by escalating a trade dispute is more important than actually

[262] *Amicus* brief by Group of Academics, (n 5) p. 6.
[263] Alexia Herwig, 'Whither Science in WTO Dispute Settlement?' (n 171) 846.
[264] Duncan French, 'The Regulation of Genetically Modified Organisms and International Law' (n 93) p. 356 and 374.

winning the case.'[265] The EU and US are 'repeat players' at the WTO DSU system, and 'are able to pursue strategic litigation', looking not only for success in a specific case but also for a trade framework interpreted in a way that best reflects their interests.[266]

Political constraints and consumer attitudes may limit the utility of WTO dispute settlement rulings; therefore the outcome of a dispute may be considered a 'negative conflict' whose political costs may be higher than the gains from the legal victories.[267] The *Biotech* dispute has occasionally been criticized for endangering the WTO dispute settlement system as it entailed questions of democracy and the role of government in the WTO system in addition to conflicting and sometimes hidden views on technological development and corporate power.[268]

The key for achieving a balance lies in the preamble to the 1994 Marrakesh Agreement Establishing the World Trade Organization. It provides that the expansion of production and trade must allow 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.' [269]

The preamble has influenced the interpretation of the WTO covered agreements, including the GATT in the *Shrimp-Turtle* and *Asbestos* cases.[270] The Appellate Body's use of internationally principled interpretation have helped it move away from the free trade focus of earlier GATT panel awards, such as in the *Tuna Dolphin* case. This has allowed the AB to 'begin the task of developing a new and more environmentally nuanced jurisprudence, in a manner which appears to justify the

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[265] Thomas Bernauer, *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology* (Princeton University Press 2003), p. 17.
[266] Maria Lee, *EU Regulation of GMOs (*n 82) p. 206.
[267] Ernest-Ulrich Petersmann, 'Prevention and Settlement of Transatlantic Economic Disputes: Legal Strategies for EU/US Leadership' in Ernst-Ulrich Petersmann & Mark A Pollack, (eds) *Transatlantic Economic Disputes: The EU, the US, and the WTO* (International Economic Law, OUP, 2003), pp. 6-3.
[268] Maria Lee, *EU Regulation of GMO* (n 82) p. 255 and 240.
[269] (15 April1994) 1867 U.N.T.S. 154 (entered into force 1 January 1995); reprinted in 33 I.L.M. 1144 (1994).
[270] Patricia Birneie et al, *International law and the environment* (n 27) pp. 763-765.

decision taken at Marrakesh in 1994 to create a more formally judicial dispute-Settlement machinery.'[271]

French points to the following extract from *US-Shrimp* to point that legally there is no distinction between GATT and the SPS Agreement as annexed agreement to the WTO Agreement to justify the diverse approaches:[272]

> The preamble of the WTO Agreement- which informs not only GATT 1994, but also other covered agreements –explicitly acknowledges 'the objective of sustainable development'.
>
> This concept has been generally accepted as integrating economic and social development and environmental protection.
>
> We note once more that this language demonstrates recognition by WTO negotiators that optimal use of the world's resources should be made in accordance with the objective of sustainable development'.

The increase of mutual trust and cooperation between the EU and US is also required to prevent future disputes. Both must be willing to change their own policies, and provide less affluent countries with sufficient incentives to modify their policies as well.[273] It also necessitates efficient systems of identity preservation and labelling.[274]

Furthermore, it is better for the EU and the US to negotiate the differences over risks within the SPS Committee or within the Codex Alimentarius Commission which can be accommodating of risk judgements at the domestic level. Scott describes the SPS Committee as sitting amongst the non-judicial accountability mechanisms of the WTO, as part of its 'largely invisible infrastructure'.[275] The SPS Committee provides Members a participatory and cooperative framework outside of dispute settlement in which proposed regulatory measures can be discussed with reference to the Agreement's provisions, and adjusted to reflect others' trade

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[271] Ibid, p. 765.
[272] Duncan French, 'The Regulation of Genetically Modified Organisms and International Law' (n 93) p.371, *US-Shrimp*, para. 129.
[273] David Vogel and Olivier Cadot, 'France, the United States, and the Biotechnology Dispute' *Brookings* (4 June 2008). http://www.brookings.edu/research/articles/2001/01/01france-cadot accessed 9 June 2009.
[274] Also, similar liability rules that could then be implemented also in other countries. See Thomas Bernauer, *Genes, Trade, and Regulation* (n 265) p. 20.
[275] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures* (n 5) p. 45.

concerns.[276] The SPS Committee can hypothetically adopt 'precautionary principle' similar to that provided in the Cartagena Protocol. This can be used in future disputes as a change to the interpretation of Article 5.7 of SPS Agreement, which would consequently change the rights and obligations of WTO Members in respect to the SPS Agreement.

5 Conclusion

The Panel expanded the scope of the SPS Agreement beyond the traditional sanitary and phytosanitary realm to include a wider range of health and environmental protection measures. At the same time, it disposed of complaining parties' claims on technical grounds to avoid a decision on the validly of the measures under WTO jurisprudence. This has been seen by some as means of sidestepping divisive issues over GMO safety.[277]

The *Biotech* case is a good example of a dispute arising from the intersection of the need for establishing international harmonisation and the need for Members to maintain their sovereign right to acknowledge public policy goals within their health and environment protection measures. It is important for WTO Member States to diminish arbitrary and unjustified trade barriers. However, the WTO must not do so at the expense of a Member's right to consider more than just hard scientific evidence when developing health and safety measures to protect their citizens.

The last section of this chapter offered means for responding to many of the limitations posed by an over-reliance on science and science based risk assessment in complex and uncertain risk situations. In order to avoid conflicts, a country's obligations should be read together and considered cumulatively. The Panel in the *Biotech* dispute limited its analysis to a primarily jurisdictional framework, giving wide scope to the SPS Agreement. It also failed to rule on the nature of GMOs or the relationship between WTO law and the Cartagena Protocol. In doing so, the Panel reinforced the schism between the WTO and Cartagena Protocol.[278]

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[276] Ibid, p. 46.
[277] See chapter 2, section 2.7-8; Jacqueline Peel, *Science and Risk regulation in International Law* (e-book, Cambridge University Press, 2010) 260-3
[278] Steve Suppan 'The WTO's "EC-Biotech Products" Ruling and thee Cartagena Protocol', IATP, March 2006 http://www.saveourseeds.org/downloads/wto_ruling_cartagena.pdf.

We should aim for a system that is able to accommodate and minimise these concerns. The gaps and lack of consensus scientific knowledge, as well as the application of the precautionary principal are fundamental issues. They can be better understood by using international agreements to interpret WTO Agreements and to clarify the meaning of national measures or laws adopted by a WTO Member unilaterally.

Biotech was not appealed, therefore it remains unclear to what extent the Appellate Body might follow the same reasoning on the interpretation of the scope of SPS measure, and insufficiency of scientific evidence for the purpose of Article 5.7.

CONCLUSIONS

GMOs have become one of the most relevant topics today, and it will continue for years to come. GMOs promise significant potential to improve efficiency of agricultural production, environmental management, and ultimately to help feed the world's growing population. The previous chapters demonstrate that GM crops are fast joining agriculture throughout many parts of the world, and are playing an increasingly important role in global food production. More and more of the foods we eat are being produced by genetically altered organisms.

However, GMOs raise concerns over uncertain benefits and risks that are hard to assess due to lack of full scientific knowledge; much concern stems from unknown risks associated with GMOs and their impact on human health and surrounding environment. Moreover, GMOs know no geographical barriers, once they are released to the environment; there are no borders for cross pollination.[1]

We have also seen that the scope of the debate over GMOs is far reaching. There are concerns that have implications in economics, law, science, human rights, technology, international relations and ethics, to name but a few fields of knowledge.

European Communities - Measures affecting the Approval and Marketing of Biotech Products Biotech highlights the divide in regulatory and cultural attitudes between the European Union and the United States over authorisation and access of GMOs.[2] The competing views of the US and the EU offer very different

[1] See Chapter 2, Section 2; Clive James, 'Global Status of Commercialized Biotech/GM Crops' (ISAAA Brief 43, ISAAA 2011) http://www.isaaa.org Accessed June 2012.
[2] *EC- Measures Affecting the approval and marketing of Biotech Products,* WT/(DS291, 292,293), (29 September 2006)

assessments of risk, and advance conflicting visions of the proper role for government regulation of this technology.

On the one hand, the right of the EU to set its own standards and regulatory framework to protect human health and the environment according to the specific alleged preferences of European consumers, and on the other, the market access right of the US products in the EU market. *Biotech* highlights that the conflict about GMO is not limited to the WTO; it also extends to other international agreements, in particular to the Cartagena Protocol which raises a range of overlaps over how to conduct risk assessment and precautionary measures.

This thesis highlights the significant implications of the Panel's Ruling in *Biotech.* In particular, it affects the EU or other WTO Member ability to develop and maintain a regulatory system for GMOs that allows for the use of precautionary measures to protect human and/or environment when there is insufficient scientific evidence to assess the risks of a biotech product presented to governments for commercialization approval?

The Panel in the *Biotech* dispute based its ruling on the narrowest finding against the EU. The Panel found the EU guilty of 'undue delay' in its regulatory approvals or commercial use. It also found the EU at fault for national 'safeguard bans' on EU-approved GMOs, ruling that these national bans were not based, as required, on scientific assessment of the risks.[3] The failure to reach full settlement and the retaliation measures by the US have confirmed that the US-EU dispute over GMOs is far from being over. At first glance, in *Biotech* dispute, the EU again faces a long, drawn out trade dispute with the United States - ie, the United States won victory in the first stage but the battle between 'sound science' and 'precaution' rages on.

[3] The requirement for a scientifically based risk assessment on which to base a trade-related SPS 'measure' under Article 5.1 of the SPS Agreement. Also, the application of provisional SPS measures when there is inadequate scientific information about a specific product on which to base a risk assessment Article 5.7 of the SPS Agreement. See Chapter 1, section 3.5

A number of broad conclusions that are thematic to the biotech dispute emerge out of this research:

First, there is a division among scientists over the safety of GMOs; clearly, the scientific community is not unanimous in its opinion on GMOs. While some praise the potential, others caution against their use. Since science cannot provide all answers or certainties, it raises concerns among the general public about the effects, and whether or not GMOs are safe. The long term consequences of GMO technology is still unknown, it will be matter of time to judge which way is better. It is worthwhile noting that GMOs produced to date may be valuable to US farmers and multinational seed companies, but has no direct consumer benefit, such as added nutritional value or improved taste.[4]

Second, *Biotech* ruling did not reverse European consumers distaste for GMOs. In line with public support, under the revised EU legislation, the authorisation process remains complicated, long, and slow, in particular those authorisations made under the Deliberate Release Directive and the Food and Feed Regulation. Therefore, the ruling did not weaken the EU's ability to use a precautionary approach in order to meet public health, safety and environmental objectives.

Evidently, the EU's regulations imposing restrictions on genetically modified foods and seeds remain an ongoing source of trade tension with the US.

Third, this thesis highlights that decisions regarding the development, planting and regulation of different aspects of GMOs takes place at many levels and are influenced by international regimes and national policies. Currently, there are multi-sources of international instruments that address various aspects of biosafety in general and, GMOs in particular. This reality came to be as a result of having several international organisations that are involved in developing rules applying to GMOs.

[4] 'US vs EU: An Examination of the Trade Issues Surrounding Genetically Modified Food' Pew Initiative on Food and Biotechnology (DECEMBER 2005) p.8-9 http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Biotech_USEU1205.pdf accessed 03 Feb 2009

Fourth, the rules which are included in various legal instruments may not be fully consistent with each other and probably continue to give rise to future conflicts between GMO exporting countries and potential importers. Therefore, until these conflicts between precautionary and more permissive approaches are reconciled, the international regime surrounding GMOs could not be an effective instrument for its members. Clearly, there is a tension between the trade regime, which seeks to limit discretion that might be unfairly used for protectionism, and a principle that grants great deal of discretion to national level regulator. International legal developments illuminate the question of whether it is appropriate for science to play such central role in international legal systems dealing with regulation of health and environmental risk. The challenge is to find a way to limit a potential for protectionism without being so heavy handed as to impede legitimate rule making that accommodate other concerns.

Fifth, some of the Panel's findings were unduly dismissive of relevant sources of international law outside the WTO framework, by declining to consider their relevance in interpreting substantive provisions of the SPS Agreement and failing to show an appropriate degree of deference towards EU's regulatory autonomy.

Finally, The EU did not change its authorisation regulatory framework, the *Biotech* Ruling did not weaken the EU's ability to employ precautionary approach in its regulation to protect public health, safety, and the environment. However, extending the scope of the SPS Agreement is problematic and will continue to place the onus on the EU to demonstrate that its regulatory framework pertaining to GM products is based on scientific risk assessments and not otherwise disguised restrictions on trade. *Biotech* ruling may influence other WTO members, in particular developing countries that have not established regulatory regimes for GMO crops.

The world could use all the benefits GMOs have to offer, but the contested question is how much risk is too much risk? Arguably the EU's regulatory framework takes

into account, while designing their domestic regulatory framework, its obligations under WTO and other international law.[5]

Disappointment from the outcome of the *biotech* was widely expressed by the EU, many of EU Member States, and numerous civil society groups. The EU believes that 'the legal ambiguity surrounding the possibilities of such a challenge causes uncertainty and doubt over the effectiveness and legal status of such measures and thus weakens the Cartagena Protocol'.[6] Moreover, the EU wanted legal recognition to the precautionary principle by the WTO, and further clarification of the relationship in order to harmonise the EU and the WTO approaches to regulatory policy formation in the face of scientific uncertainty.

Central to this research is the Panel's application and interpretation of SPS Agreement to determine its applicability to the EU measures which brought about the dispute. The Panel found that relevant legal instruments constituting EU regulatory framework at the time of the establishment of the Panel constituted SPS measures within the meaning of Annex A of the SPS Agreement.[7] In addition, the Panel found that EU Member State' bans on GMOS fell within the definition of SPS measure in Annex A of the SPS Agreement; the Panel reasoned that the EU failed to conduct appropriate risk assessment before the imposition of the contested measures and thus violating the SPS Agreement.[8] This expansive application of the SPS Agreement makes current EU regulatory framework vulnerable to future challenge through WTO dispute resolution.

Therefore, despite having the right to determine the level of protection of health that they consider appropriate in a given situation, the regulatory freedom of a Member establishing SPS measure is limited to an 'objective and rational relationship' between the scientific evidence and the SPS measure, taking into account that those measures should be the least trade restrictive ones (it does not

[5] EU regulatory framework pursues different objective ranging from protection of 'human life and health', animal health and welfare', 'environment', 'facilitate accurate labelling', monitoring effects on the environment' and more.
[6] Oral Statement by the European Communities at the First Meeting of the Panel, *Biotech* (2 June 2004), para. 28.
[7] Biotech , para 7.438-7.1627
[8] Biotech , para 7.3008- 7.3399

allow any room for the consideration of other legitimate factors that can be far from science).

The problem with SPS Agreement is that it presumes that science can give determinate answer to whether the regulatory mechanism is justified in view its stated objective and whether a less restrictive measure can be found. Notions of risk assessment and scientific justification play a central role in this normative framework. Science holds a key role in turning the distinction between protectionist and legitimate regulations. Therefore, GMOs continue to pose a challenge to the WTO in terms of its capacity to resolve the problem of uncertainty underlying dispute about risks of GMOs.

Proposed solution

The reasoning in Biotech will very likely be used as a guide by future WTO panels, convened to resolve disputes relating to food safety, public health and environmental health measures. However, *Biotech* was not appealed and therefore the impact of its legal conclusions is arguably limited.[9] Therefore, future panels entrusted with disputes raising similar issues still have the opportunity to situate its decision within the broader realm of public international law, and to demonstrate an awareness of the interconnectedness of international instruments.

In the Short term, future panels should utilise the preamble to the WTO Agreement to ensure that appropriate interpretation sensitive to socio economic considerations will be followed when interpreting the SPS Agreement. Increased sensitivity of WTO law to environmental and non scientific factors will allow the WTO to coexist with other international treaties. This change requires an open minded approach to different types of knowledge claims, willingness the risk assessment process to a single discursive universe.

In the long term, most important changes will come from increased dialogue across the Atlantic that builds on agreement among scientists and includes a broader mix

[9] Joanna Gomula, 'Environmental disputes in the WTO' in Malgosia Fitzmaurice, David M Ong, Panos Merkourris, *Research Hand book on International Environmental Law* (Research handbooks in international Law, Edward Elgar, Cheltenham, UK, 2010)

of representatives from both sides within the WTO and other international *fora*.[10] A special emphasis should be placed on the needs of developing countries Therefore, we need '– above all - political will: a desire to make our rules and regulations compatible…'[11] Furthermore, A positive outcome requires appropriate supporting economic and environmental policies at national and international levels.[12]

Addressing GMOs responsibly may help us learn how to address the broad array of risks to human and environmental health and safety on our fast changing planet. It is important to do so because trade liberalization can have a positive impact on the environment by improving the efficient allocation of resources, promoting economic growth, and generating revenues that can be utilized for environmental improvement. However, in the absence of effective environmental policies and regulations, or when distortive domestic policies exist, increased economic activity generated by trade liberalization can contribute to environmental problems.

[10] Patrice Laget and Mark Cantley, 'European Responses to Biotechnology: Research, Regulation, and Dialogue', Issues in S. and T. Summer 2001 http://bob.nap.edu/issues/17.4/p_laget.htm
[11] Statement by President Barroso on the Transatlantic Trade and Investment Partnership, Press Release, (13 Feb2013) SPEECH/13/121
[12] 'Environment and Trade' A Hand Book(second edition)2005 IISD,UNEP, p.117

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- Joined cases C-439/05P and C-454/05P, *Land Oberösterreich and Republic of Austria v. Commission of the European Communities* [2007] ECR I-7441

WTO jurisprudence

- Agreement on Technical Barriers to Trade
- Agreement on the application of Sanitary and Phytosanitary Measures.
- General Agreement on Tariffs and Trade 1947
- General Agreement on Tariffs and Trade 1994.
- Marrakesh Agreement Establishing the World Trade Organization.
- Understanding on Rules and procedures Governing the Settlement of Disputes

Treaties Other international law

- Cartagena Protocol on Biosafety to the Convention on Biological Diversity
- Convention on Biological Diversity
- Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (The Nagoya – Kuala Lumpur Supplementary Protocol)
- Statute of International Court of Justice

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- Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, (2001).
- Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, (1998).
- Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones) – Complaint by the United States*, WT/DS26/R/USA, adopted 13 February 1998, as modified by the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R (1998).
- Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, (1999).
- Panel Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/R, adopted 19 March 1999, as modified by the Appellate Body Report, WT/DS76/AB/R, DSR 1999.
- Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, (2003)
- Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, (1996).
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- Appellate Body Report, *United States- Measures Affecting the Production and Sale of Clove Cigarettes* WT/DS406/AB/R (2013)
- Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, (1998)
- Request for consultation, *Egypt — Import Prohibition on Canned Tuna with Soybean Oil* WT/DS205/1(2000)

Key websites

- WTO http://www.wto.org
- Biodiversity Convention http://www.biodiv.org

- Cartagena Protocol http://www.biodiv.org
- The European Union http://ec.europa.eu/
- USTR http://www.ustr.gov