

GMO TRADE WARS:

THE SUBMISSIONS IN THE US-EC BIOTECH DISPUTE IN THE WTO

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I INTRODUCTION

Over the short history of dispute settlement in the World Trade Organisation (WTO),¹ few cases have excited as much anxious anticipation as the current dispute between the United States (US) and the European Communities (EC) concerning the latter's "measures affecting the marketing and approval of biotech products".² The dispute, much like its predecessor regarding hormones in beef,³ has been slowly simmering away for many years. It finally came to a head in May 2003 when the US, along with

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¹ When the WTO came into being on 1 January 1995, it introduced a new system of dispute settlement based on the *Dispute Settlement Understanding (DSU): Marrakesh Agreement Establishing the World Trade Organisation*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 2 (Understanding on Rules and Procedures Governing the Settlement of Disputes). The DSU substantially modified the previous system of dispute settlement under the 1947 *General Agreement on Tariffs and Trade*, opened for signature 30 October 1947, 55 UNTS 194 (entered into force 29 July 1948), introducing a new 'Appellate Body' to hear appeals from first-instance panels on questions of law, and making provision for Panel and Appellate Body reports to be adopted automatically unless all WTO Members vote to reject the reports. For an overview of these developments see Michael J. Trebilcock and Robert Howse, *The Regulation of International Trade* (2nd ed, 1999) 51–53.

² This is the way the dispute is described in the US request for consultations with the EC in the WTO. The Americans prefer the neutral terminology of 'biotech products' whereas the Europeans speak of genetically modified organisms (GMOs), genetically modified (GM) crops and GM foods.

³ *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB-2000-11 (2001) [123] (Report of the Appellate Body) ('*Beef Hormones*'). The *Beef Hormones* dispute also concerned a US and Canadian challenge to EC measures, which had been the subject of many years of negotiation and wrangling between the parties before the matter was finally brought before the WTO in 1998. Although the WTO Appellate Body ruled against the EC, nearly ten years on the dispute has still not been resolved: see 'EU Asks WTO To Intervene on US-Canadian Beef Hormone Sanctions', *Deutsche Presse-Agentur*, 8 November 2004.

other large agricultural biotechnology producers, Argentina, and Canada,⁴ requested the initiation of formal dispute settlement proceedings against the EC in the WTO.⁵ At the heart of the dispute, lie fundamentally different regulatory approaches to the assessment and management of possible risks posed by the most controversial products of biotechnology – genetically modified organisms (GMOs).⁶ At stake is not only the multi-billion dollar agricultural gene technology industry,⁷ but also (depending on who you listen to) the viability of organic farming practices, future food security in developing countries, agricultural sustainability, global biodiversity, long-term human health, and national regulatory autonomy regarding health and environmental concerns.⁸

The intense public interest in the dispute has prompted the parties to adopt an unprecedented level of transparency regarding their arguments and submissions to the

⁴ GM agricultural production in 2003 in the US, Canada and Argentina amounted to 107.5 million acres, 10.9 million acres and 34.3 million acres, respectively: International Service for the Acquisition of Agri-biotech Applications, 'Double-Digit Growth Continues for Biotech Crops Worldwide: US Biotech Crop Area Up 10 Percent' (Press Release, 13 January 2004).

⁵ *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WTO Doc WT/DS291/23 (2003) (Request for the Establishment of a Panel by the United States). Egypt was also one of the original complainants but has subsequently withdrawn from the dispute.

⁶ The US regulatory approach sees GMOs as 'substantially equivalent' to conventional organisms and imposes no special requirements for their approval. The EU regime by contrast is based on a policy of 'precaution' and requires stringent safety assessments for each new GMO sought to be commercialised. See David Vogel, 'Ships Passing in the Night: The Changing Politics of Risk Regulation in Europe and the United States' (2001) RSC No. 16/2001 *EUI Working Papers*.

⁷ In the US, the value of GM crops was over \$20 billion in 2002 and the sales of the agricultural divisions of the 6 leading agricultural biotechnology companies totaled \$28 billion: C Ford Runge and Barry Ryan, *The Economic Status and Performance of Plant Biotechnology in 2003: Adoption, Research and Development in the United States* (2003) ii, iii. However, the total economic contribution of the industry is difficult to measure: *ibid* 102.

⁸ Anticipation of, and speculation about, the dispute has produced a substantial literature on the topic which presents a range of views. See, e.g., Brett Grosko, 'Genetic Engineering and International Law: Conflict or Harmony? An Analysis of the *Biosafety Protocol*, *GATT*, and the *WTO Sanitary and Phytosanitary Agreement*' (2001) 20 *Virginia Environmental Law Journal* 295; Grant E Isaac and William A Kerr, 'Genetically Modified Organisms and Trade Rules: Identifying Important Challenges for the WTO' (2003) 26 *World Economy* 29; Gilbert R Winham, 'International Regime Conflict in Trade and Environment: The *Biosafety Protocol* and the WTO' (2003) 2 *World Trade Review* 131; Nicholas Perdakis, William A Kerr Shelburne and Jill E Hobbs, 'Reforming the WTO to Defuse Potential Trade Conflicts in Genetically Modified Foods' (2001) 21 *World Economy* 379; Robert Howse and Petros C. Mavroidis, 'Europe's Evolving Regulatory Strategy for GMOs - the Issue of Consistency with WTO Law: of Kine and Brine' (2000) 24 *Fordham International Law Journal* 317 and Joanne Scott, 'European Regulation of GMOs and the WTO' (2003) 9 *Colum. J. Eur. L.* 213.

WTO Panel that will initially decide the matter. The US, EC and Canada have all released their first detailed written submissions in the case, totalling some 470 pages in length.⁹ On the complainants' side, the submissions are quite carefully framed; they do not purport to attack the EC GMO regulatory regime as such – indeed Canada argues that all would be well if only the EC would follow its legislated assessment and approval processes.¹⁰ Instead the complainants are arguing that excessive delay in the EC approval process and/or bans on genetically modified (GM) crops maintained by individual Member States of the European Union violate the obligations of the EC under several of the WTO Agreements. The EC's arguments suggest that it at least sees much more at stake than any current 'moratorium' on approvals for new GM crops. It argues vigorously in its submission that the dispute raises complex factual, scientific, social and legal issues which extend far beyond the jurisdiction and capacity of the WTO to resolve.¹¹ In this respect, the EC position is supported by three *amicus* submissions which have been filed in the case by interested non-State actors, ranging from academics to environmental and public interest organisations.¹²

⁹ The submissions of the parties, together with other documents and new reports concerning the case, are available from the website: <http://www.trade-environment.org/page/theme/tewto/biotechcase.htm>.

¹⁰ *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WTO Doc WT/DS292 (2004) [48], [139], [184], [189], [264] (First Written Submission of Canada) ('*GMO Case*').

¹¹ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [10] (First Written Submission by the European Communities).

¹² Three groups have made *amicus* submissions in the dispute—a coalition of 15 public interest groups; a group of five expert academics; and a group of five environmental groups: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) (Amicus Curiae Brief: Center for International Environmental Law, Friends of the Earth – United States, Defenders of Wildlife, Institute for Agriculture and Trade Policy, Organic Consumers Association – United States) ('Environment group'); *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) (Amicus Curiae Brief: International Coalition of 15 Public Interest Groups) ('Amicus coalition'); *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) (Amicus Curiae Brief: Lawrence Busch, Robin Grove-White, Sheila Jasanoff, David Winickoff and Brian Wynne) ('Expert group').

Although the EC might ultimately have to concede the pragmatic point that the WTO is the international forum in which the issues surrounding GMO risks will be litigated,¹³ it argues that even under WTO law the complainants have framed the dispute far too narrowly. The arguments put forward by the US focus exclusively on compliance with one of the WTO Agreements, the *Sanitary and Phytosanitary Measures Agreement (SPS Agreement)*,¹⁴ which covers trade-restrictive measures of WTO Members put in place to protect against risks to human, plant or animal life or health. The *SPS Agreement* has only been applied in past cases to deal with domestic food safety laws and quarantine requirements that affect international trade.¹⁵ While there is scope for arguments to be made that the EC's GMO regulatory regime is caught by the *SPS Agreement*, obligations under other WTO Agreements, such as the *General Agreement on Tariffs and Trade (GATT 1994)*¹⁶ and the *Technical Barriers to Trade Agreement (TBT Agreement)*¹⁷ might also be relevant.¹⁸ In fact the EC maintains that its laws are best assessed in light of relevant international treaties outside of the WTO regime, like the *Cartagena Biosafety Protocol to the Convention on Biological Diversity*.¹⁹

¹³ At the international level, few environmental dispute resolution fora enjoy the WTO's advantages of compulsory dispute settlement, binding judgments and reasonably effective remedies to enforce rulings: see Robyn Eckersley, 'The Big Chill: The WTO and Multilateral Environmental Agreements' (2004) 4(2) *Global Environmental Politics* 24.

¹⁴ *Marrakesh Agreement Establishing the World Trade Organisation*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 1A (Agreement on the Application of Sanitary and Phytosanitary Measures) ('*SPS Agreement*')

¹⁵ The four 'SPS' disputes determined so far are *Beef Hormones*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, (2001) (Report of the Appellate Body), *Australia – Measures Affecting Importation of Salmon*, WTO Doc WT/DS18/AB/R (1998) (Report of the Appellate Body); *Japan – Measures Affecting Agricultural Products*, WTO Doc WT/DS76/AB/R (1999) (Report of the Appellate Body) and *Japan – Measures Affecting the Importation of Apples*, WTO Doc WT/DS245/AB/R (2003) (Report of the Appellate Body).

¹⁶ *Marrakesh Agreement Establishing the World Trade Organisation*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 1A (General Agreements on Tariffs and Trade) ('*GATT 1994*').

¹⁷ *Marrakesh Agreement Establishing the World Trade Organisation*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 1A (Agreement on Technical Barriers to Trade) ('*TBT Agreement*').

¹⁸ See David Morgan and Gavin Goh, 'Genetically Modified Food Labelling and the WTO Agreements' (2004) 13(3) *Review of European Community and International Environmental Law* 306.

¹⁹ *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, opened for signature 29 January 2000, 39 ILM 1027 (2000) (entered into force 11 September 2003) ('*Biosafety Protocol*')

The parties' submissions are now before a WTO dispute settlement panel which is due to issue a ruling on the matter in June 2005.²⁰ It is probable that the Panel's decision will be appealed by the losing party to the WTO Appellate Body, pushing a final resolution of the dispute out to late 2005.²¹ Nevertheless, the publication by the parties of their submissions, together with those of non-State actors seeking *amicus curiae* status,²² provides a useful insight into the issues that will fall to be determined by decision-makers of the WTO's dispute settlement arm. These issues, and the findings of WTO decision-makers concerning them, are likely to resonate in many areas of international law beyond the field of international trade law or the particular WTO Agreements raised by the dispute. Given the intense international interest in the case, this commentary provides an overview of the arguments raised by State parties to the dispute, as well as those contained in the *amicus* briefs submitted by non-state actors. The commentary is directed less to trade law specialists than to general international lawyers, wishing to obtain an understanding of the main issues being argued in this important case. For this reason, Part II includes a brief overview of the relevant WTO Agreements at issue in the dispute and Part III outlines the EC regulatory system for GMOs which is the subject of challenge. Part IV then goes on to highlight the major arguments being advanced by the parties and other participants in the dispute. Part V concludes with a consideration of the broader potential implications of the case for the

²⁰ *GMO Case*, WTO Doc WT/DS291/27, WT/DS292/21, WT/DS293/21 (2004) (Communication from the Chairman of the Panel, 2 November 2004).

²¹ A panel's decision in a WTO dispute can be appealed on questions of law to the standing Appellate Body. The Appellate Body has 90 days in which to render a decision on the appeal: *Marrakesh Agreement Establishing the World Trade Organisation*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 2 art 17(5) (DSU); *Working Procedures for Appellate Review*, WTO Doc WT/AB/WP/7 (2003) annex 1.

²² Both panels and the Appellate Body have a discretion to receive and consider *amicus curiae* submissions in a dispute, regardless of whether the submissions were solicited: *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (1998) (Report of the Appellate Body) [89].

interaction of international trade law and domestic health and environmental regulatory regimes.

II OVERVIEW OF THE RELEVANT WTO AGREEMENTS

The *GMO* dispute involves a claim by the US, Canada and Argentina that measures taken by the EC in administering its GMO regulatory framework constitute trade barriers which violate obligations found in the WTO multilateral trading regime. These obligations appear in the *GATT 1994* (the institutional basis for the regime, which reiterates the provisions of the pre-WTO *GATT 1947*), and in two new WTO agreements: the *TBT and SPS Agreements*. All three agreements came into force in 1995 following the Uruguay Round of trade negotiations. These negotiations focused upon strategies to reduce both border measures affecting trade (such as tariffs and customs duties), and so-called ‘non-tariff trade barriers’.²³ The latter include aspects of the internal taxation and regulatory regimes of WTO Members that might impact trade by imposing onerous requirements on products sought to be marketed within a country. Requirements under domestic health and environmental laws may potentially amount to non-tariff trade barriers under WTO Agreements since they often require compliance with particular technical standards, or the satisfaction of a risk assessment process, as a condition of product authorisation.

A *GATT 1994*

²³ Jeff Waincymer, Martin Davies and Michael Pryles, *International Trade Law: Commentary and Materials* (2nd ed, 2004) 686.

The *GATT 1994* is a framework of wide-ranging but general obligations that oblige Members to enter into ‘reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international commerce’.²⁴ One of the foundational principles of the *GATT 1994* is the principle of ‘national treatment’: that Members must not discriminate between imported and domestically produced goods where they are ‘like products’.²⁵ This complements another important principle of the *GATT 1994*, the principle of reciprocity, which requires that trade concessions granted by a Member to a product of another Member also be granted to ‘like products’ of all other Members.²⁶ Among its other rules on trade barriers, the *GATT 1994* outlaws the use of quantitative trade restrictions, such as quotas and import bans.²⁷

Some exceptions to the GATT’s rules against trade barriers are allowed under Article XX on specified public policy grounds. One such exception is trade barriers which are ‘necessary to protect human, animal or plant life or health’, as long as they are ‘not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade’.²⁸ Another exception, often invoked to justify trade-restrictive measures adopted for an environmental purpose, permits measures ‘relating to the conservation of exhaustible natural resources’ provided the measures ‘are made effective in conjunction with restrictions on domestic production or consumption’.²⁹

²⁴ *Marrakesh Agreement Establishing the World Trade Organisation*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 1A (General Agreements on Tariffs and Trade) preamble.

²⁵ *Ibid* art III:4.

²⁶ Also referred to as the ‘most-favoured nation’ principle: *ibid* art I.

²⁷ *Ibid* art XI.

²⁸ *Ibid* art XX (b) and art XX *chapeau*. The conditions of the *chapeau* apply to all the exceptions listed in art. XX.

²⁹ *Ibid* art XX (g).

Interpretation of this exception by the WTO Appellate Body suggests that what are ‘exhaustible natural resources’ for this purpose is to be determined in light of contemporary international environmental concerns relating to endangered species and biodiversity conservation.³⁰

The original *GATT 1947* framework was reviewed during the Uruguay Round of trade negotiations in light of concerns that its rules were not adequate to prevent the adoption of non-tariff trade barriers in the form of domestic regulatory requirements for the placing of goods on a country’s market. Of particular concern to negotiators were laws and other measures maintained ostensibly for the purpose of protecting human health and safety, and the environment, but which in practice served to exclude, or significantly disadvantage, competing imported products.³¹ The solution agreed to by participants in the negotiations was that the general GATT provisions should be supplemented by detailed rules on particular kinds of non-tariff trade barriers under the *TBT and SPS Agreements*.

B *TBT Agreement*

The *TBT Agreement* builds upon the provisions of the Code on Technical Barriers to Trade concluded during the Tokyo Round of trade negotiations in the 1970s.³² Unlike its predecessor, the *TBT Agreement* applies to all WTO Members adopting technical

³⁰ *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (1998) (Report of the Appellate Body) [127] – [134]. See also the earlier Salmon/Herring case, herring and salmon were agreed to be exhaustible natural resources: *Canada – Measures Affecting Exports of Unprocessed Herring and Salmon*, adopted 22 March 1988, GATT BISD, 35S/114 [3.29].

³¹ Michael J Trebilcock and Robert Howse, *The Regulation of International Trade* (2nd ed, 1999) 135.

³² *Agreement on Technical Barriers to Trade* opened for signature 12 April 1979, 18 ILM 1079 (1979) (entered into force 1 January 1980) (*TBT Agreement*).

regulations, standards (including packaging, labelling and marking requirements) and conformity assessment procedures with the potential to impact trade.³³

Under the *TBT Agreement*, international standards are promoted as a method of harmonising technical regulations,³⁴ although Members ultimately retain the ability to choose the form and level of their standards. Where Members decide to adopt their own technical regulations they must ensure that such standards treat imported products ‘no less favourably’ than domestic ‘like products,’³⁵ and that they satisfy time and notification requirements directed to facilitating transparency and reducing delays in trade.³⁶

Although the *TBT Agreement* seeks to minimise the extent to which technical regulations create ‘unnecessary obstacles’ to international trade, much like the *GATT 1994* it recognises scope for national regulatory autonomy to ensure the achievement of legitimate public policy objectives. Members are thus permitted to adopt trade-restrictive technical regulations provided this is necessary³⁷ to fulfil a ‘legitimate objective’, such as the protection of human health or safety, animal or plant life or health, or protection of the environment.³⁸ The *TBT Agreement* states that available scientific and technical information is a ‘relevant element of consideration’ in assessing risks to health or the environment, but does not require a formal process of risk assessment prior to putting in place protective standards. The lack of an overt

³³ *TBT Agreement*, art 1.5.

³⁴ *Ibid*, arts 2.4, 2.5. Under art 2.5, Members whose technical regulations accord with international standards are presumed not to create an unnecessary obstacle to international trade.

³⁵ *Ibid*, art 2.1.

³⁶ *Ibid*, arts 2.9, 5.2.1.

³⁷ In trade agreements, the term ‘necessary’ is usually interpreted as meaning that the regulation at issue is the least trade-restrictive measure available that can achieve the chosen objective.

³⁸ *TBT Agreement*, art 2.2.

requirement for regulations to have a scientific basis is the key difference between the *TBT Agreement* and its counterpart dealing with sanitary and phytosanitary measures: the *SPS Agreement*.³⁹

C *SPS Agreement*

Whereas the *TBT Agreement* applies generally to technical regulations, the *SPS Agreement* focuses upon a specific class of potential non-tariff barriers to trade known as ‘SPS measures’.⁴⁰ SPS measures are defined as laws, decrees, regulations, requirements and procedures that affect international trade in seeking to protect human, animal and plant life and health.⁴¹ Measures of this kind often vary from country to country given differing sensitivities to food safety and quarantine concerns, different levels of environmental non-governmental activism, and differing domestic regulatory structures for health and environmental protection.⁴² In acknowledgement of this diversity, the Agreement seeks to regulate the ways SPS measures are set, rather than imposing uniform levels of protection or specifying the type of measures chosen to implement SPS goals.⁴³ Although conceding to Members the ‘right’ to determine their ‘appropriate level’ of SPS protection,⁴⁴ the *SPS Agreement*, like the *TBT Agreement*, promotes harmonisation of divergent national SPS measures by reference to

³⁹ Gabrielle Marceau and Joel P Trachtman, 'The *Technical Barriers to Trade Agreement*, the *Sanitary and Phytosanitary Measures Agreement*, and the *General Agreement on Tariffs and Trade: A Map of the World Trade Organization Law of Domestic Regulation of Goods*' (2002) 36(5) *Journal of World Trade* 811, 849.

⁴⁰ *SPS Agreement*, art 1.1.

⁴¹ Specific categories of SPS measures are set out in Annex A of the *SPS Agreement*.

⁴² For a discussion on differences between EC and US sensitivities in these areas, see David Vogel, 'Trade and the Environment in the Global Economy: Contrasting European and American Perspectives' in Norman J Vig and Michael G Faure (eds), *Green Giants? Environmental Policies of the United States and the European Union* (2004) 231.

⁴³ David G Victor, 'The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years' (1999-2000) 32 *New York University Journal of International Law and Politics* 865, 883, 913–914 .

⁴⁴ *SPS Agreement*, art 5.6.

international standards. Where Members' measures adopt appropriate international standards, they are presumed to be consistent with the Agreement and the *GATT 1994*.⁴⁵

Measures not based on international standards must comply with scientific, trade-related and procedural requirements to be legitimate. Measures must be scientifically justifiable in the sense that they must be 'based on scientific principles and ... not maintained without sufficient scientific evidence'.⁴⁶ Specifically, they must be 'based on' a scientific risk assessment,⁴⁷ unless 'relevant scientific evidence' is insufficient. In this case provisional SPS measures may be based on 'available pertinent information' while the Member seeks more information to allow a full risk assessment and reviews the measure 'within a reasonable period of time'.⁴⁸

In addition to being scientifically justified, SPS measures must comply with specific trade-related obligations. Measures must not arbitrarily or unjustifiably discriminate against imported products where similar conditions prevail or by requiring different levels of protection in situations of comparable risk.⁴⁹ Further, SPS measures may not be more trade restrictive than necessary to achieve the appropriate level of SPS protection chosen by the Member.⁵⁰ Like TBT regulations, SPS measures must also

⁴⁵ Ibid, art 3.2. The international standards referenced by the *SPS Agreement* are those adopted by the Codex Alimentarius Commission, the International Office of Epizootics and the International Plant Protection Convention.

⁴⁶ Ibid, art 2.2.

⁴⁷ Ibid, art 5.1.

⁴⁸ Ibid, art 5.7. In the *Beef Hormones* dispute, the Appellate Body found that the precautionary principle 'finds reflection' in this article, as well as the provision allowing for measures more stringent than international standards (art 3.3): *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R (2001) [29] (Report of the Appellate Body).

⁴⁹ *SPS Agreement*, art 2.3, 5.5.

⁵⁰ Ibid, art 5.6.

satisfy publication and notification requirements to ensure transparency.⁵¹ In addition, related approval procedures must comply with timeline requirements.⁵²

Although the *SPS* and *TBT Agreements* initially received relatively little attention, commentators increasingly view their requirements as a significant constraint on domestic regulatory autonomy. The *SPS Agreement* has come in for the greatest share of censure given the role it grants science and scientific risk assessments in justifying trade-restrictive health and environmental laws⁵³ (a role that *amicus* submissions in the *GMO* dispute suggest is fraught with ‘interpretive hazards.’)⁵⁴ Commentators also predict that the emphasis placed by the *SPS Agreement* (and to a lesser extent the *TBT Agreement*) on the legitimising effect of scientific procedure for national regulatory approaches will considerably change how countries manage health and environmental risk in the post-Uruguay Round era.⁵⁵

III EC REGULATORY SYSTEM FOR APPROVING GMOS

The Members of the European Union (EU), like many other countries around the world, have adopted a special regulatory regime to deal with the potential health and

⁵¹ Ibid, art 7 and annex B.

⁵² Ibid, art 8 and annex C.

⁵³ See, e.g., Joanne Scott, 'On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO' in J.H.H. Weiler (ed), *The EU, the WTO, and the NAFTA: Towards a Common Law of International Trade?* (2000) 125; Anne Orford, 'Globalisation and the Right to Development' in Philip Alston (ed), *Peoples' Rights* (2001) 127; Vern R. Walker, 'Keeping the WTO from Becoming the "World Trans-science Organisation": Scientific Uncertainty, Science Policy and Fact-Finding in the Growth Hormones Dispute' (1998) 31 *Cornell Int'l. L.J.* 251 and Christian Joerges and Jürgen Neyer Neyer, 'Politics, Risk Management, World Trade Organisation Governance and the Limits of Legalisation' (2003) 30(3) *Science and Public Policy* 219.

⁵⁴ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) (Amicus Curiae Brief: Expert group) 15–19.

⁵⁵ David G Victor, 'The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years' (1999-2000) 32 *New York University Journal of International Law and Politics* 865, 923.

environmental risks posed by products of biotechnology.⁵⁶ These requirements are often described as ‘precautionary’ as they cite scientific uncertainty surrounding GMO risks as a reason for a cautious regulatory approach.⁵⁷ The EU’s GMO laws apply equally to entities within the EU seeking the approval of particular GMOs, and to foreign entities wishing to market overseas-produced GMOs in EU countries. The present dispute with the US, Canada and Argentina focuses on a series of measures allegedly taken under the EU’s GMO regulatory framework, and their effects on foreign applications for market authorisation of various GMOs. This section briefly describes the approval procedures that operate under this framework and its evolution – a key aspect of the dispute.

A *Evolution of GMO Regulation in the EU*

The first generation of EU regulation for GMOs,⁵⁸ established and modified between 1988 and 1990, was based upon principles of case-by-case assessment and achieving a ‘high level’ of protection of human health and the environment. The latter goal is consistent with the requirements of the foundational treaties establishing the European Communities, which also require EU environmental policy to be based on the

⁵⁶ See Heike Baumüller, *Domestic Import Regulations for Genetically Modified Organisms and their Compatibility with WTO Rules* (2003).

⁵⁷ The ‘precautionary principle’ is found in a large number of international environmental agreements and has been adopted in the environmental laws of many countries. It requires that where there are threats of serious or irreversible damage, measures to protect the environment should not be postponed because of scientific uncertainty: *Rio Declaration on Environment and Development*, A/CONF.151/26 (vol 1) (12 August 1992), 31 ILM 874 (1992) principle 15. Much debate has surrounded the status and scope of the precautionary principle in international law. Some commentators argue that it has achieved the status of a binding principle of customary international law: James Cameron and July Abouchar, ‘The Status of the Precautionary Principle in International Law’ in David Freestone and Ellen Hey (eds), *The Precautionary Principle and International Law: The Challenge of Implementation* (1996) 36–50; Nicolas de Sadeleer, *Environmental Principles: from Political Slogans to Legal Rules* (Oxford University Press, Oxford, 2002), 94 and 319. Others disagree: see eg Sonia Boutillon, ‘The Precautionary Principle: Development of an International Standard’ (2002) 23 *Michigan Journal of International Law* 429, 447, 469.

⁵⁸ EC GMO legislation takes the form of Directives, which Member States must implement through domestic legislation, and Regulations, which are directly applicable throughout the EU.

precautionary principle.⁵⁹ The original Directive 90/220/EC⁶⁰ provided the key procedure for authorising the ‘deliberate release into the environment’ of a GMO, which extended to its marketing. A second legislative act, Council Regulation 258/97,⁶¹ established an approval process for novel foods, including those containing GMOs. While this process largely replicated that in Directive 90/220, a key difference was that a faster, simpler procedure applied to GM foods and food ingredients that were ‘substantially equivalent’ to existing foods.⁶²

According to the submissions of the EC in the present dispute, increased scientific knowledge regarding the risks of GMOs and international regulatory developments, including the conclusion of the *Biosafety Protocol*,⁶³ led to legislative reform in 2001. Council Directive 2001/18/EC (‘Directive 2001/18’) repealed Directive 90/220⁶⁴ but kept its authorisation procedure and overall aim of protecting human health and the environment.⁶⁵ Key changes implemented in the new directive included:⁶⁶

- elaboration of a detailed set of principles required to be considered in environmental risk assessments;

⁵⁹ The precautionary principle was explicitly recognised in the EU first in the Maastricht Treaty: *Treaty Establishing the European Community*, *Official Journal*, [2002] OJ C 325 art 174(2) (art 130r(2) under the original numbering scheme). For an overview of the history and current status of the precautionary principle in Europe, see José Luís da Cruz Vilaça, ‘The Precautionary Principle in EC Law’ (2004) 10 *European Public Law* 369.

⁶⁰ Council Directive, 90/220/EEC [1990] OJ L 117/15. The directive dealt with both the placing on the market of GMOs and their deliberate release into the environment.

⁶¹ Council Regulation, 258/97 [1997] OJ L 43/1 (‘Regulation 258/97’).

⁶² In addition to this general regulatory framework for GMOs, some GM products are covered by ‘sectoral’ legislation, such as medicinal products, which are governed by Council Regulation, 2309/93 [1993] OJ L 14/1.

⁶³ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [94]-[112], [155] (First Written Submission by the European Communities).

⁶⁴ Council Directive, 2001/18/EC [2001] OJ L 106/1; *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [136] (First Written Submission by the European Communities)

⁶⁵ Council Directive, 2001/18/EC [2001] OJ L 106/1, art 1.

⁶⁶ See generally Silvia Francescon, ‘The New Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment: Changes and Perspectives’ (2001) 10(3) *Review of European Community and International Environmental Law* 309.

- post-market surveillance requirements;
- provision for public consultation regarding applications;
- broadening of the relevant matters to be considered in assessing applications to include ethical concerns and the cumulative, long-term effects of GMOs on human health and the environment;⁶⁷ and
- a requirement for the aspiring marketer of the GMO to perform its own risk assessment prior to submitting an application for approval.

The present dispute straddles these first and second regulatory eras, involving applications for authorisation made under Directives 90/220 and 2001/18, and Regulation 258/97.⁶⁸

B *Approval Process for GMOs*

Without being approved, GMOs and products containing GMOs may not be marketed or otherwise released into the environment in the EU. Once given, however, an approval is valid throughout the EU.⁶⁹ The GMO regulatory framework thus seeks to balance the need for individual EU Member States to retain some decision-making control over matters of domestic concern, with the principle of harmonising regulations throughout the EU so as to ensure the free movement of goods. The resulting regulatory

⁶⁷ Council Directive, 2001/18/EC [2001] OJ L 106/1, preamble [19], annex II. Cumulative effects to be considered include interactions with other GMOs which might result, e.g., in the development of multiple herbicide resistance.

⁶⁸ Further changes were later made to remove the substantial equivalence procedure and add traceability and labelling requirements. The result is a complex system with multiple, separate, but in some cases simultaneously applicable components. For a comprehensive discussion of these procedures and their evolution, see Estelle Brosset, 'The Prior Authorisation Procedure Adopted for the Deliberate Release into the Environment of Genetically Modified Organisms: The Complexities of Balancing Community and National Competencies' (2004) 10(5) *European Law Journal* 555.

⁶⁹ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [141] (First Written Submission by the European Communities).

requirements applied to GMO approvals are complex enough to have earned the label of a ‘Gordian knot.’⁷⁰

The main elements of the GMO approval procedure established under Directives 90/220 and 2001/18 are summarised in Figure 1. The first stage of the process involves the applicant submitting a dossier on the new GMO to the relevant assessment body (‘AB’) of a Member State, which undertakes an evaluation of the potential for the release to give rise to adverse effects on human health or the environment. Where this assessment is favourable, the AB concerned distributes its assessment report to the European Commission (effectively the executive branch of the EU regulatory structure) and to other national ABs to allow for comments and requests for further information (something which can lengthen the procedure considerably). If, following this process, no Member State objects to the application, the matter is returned to the initiating national AB for approval and a decision on any applicable conditions relating to the release.

Where objections are raised by one or more Member States and these objections cannot be resolved, the application is referred to two ‘committees’ for their opinion on the application – the Scientific and Regulatory Committees. The Scientific Committee draws on the expertise of independent scientists but serves an advisory role only. On the other hand, the Regulatory Committee, made up of representatives of Member States has a more substantial role to play in the process. A favourable opinion from this committee results in the GMO release receiving authorisation. However, where the Regulatory Committee delivers an unfavourable opinion, or fails to deliver any opinion,

⁷⁰ Brosset, above n 68, 559.

the matter goes to the highest political level for a decision by the Council of the European Union. If the Council does not make a decision on the application within a three month timeframe, the matter returns to the Commission for decision. Even if a product is finally approved by the Commission, Member States may still institute ‘safeguard measures’ to prohibit marketing of the GMO in their territories. This power can only be exercised by Member States on the basis of new scientific information suggesting the GMO poses a risk to human health or the environment, and is subject to review by the Commission.

From October 1998, up to the time the *GMO* dispute was initiated, the approval process under the EU GMO regulatory framework effectively ground to a halt. No new approvals have been issued (until very recently)⁷¹ and applications already within the regulatory system have experienced significant delays.⁷² In addition, six EU Member States – France, Germany, Austria, Greece, Italy and Luxembourg – have instituted ‘safeguard measures’ to prohibit the marketing or import of GM products already approved under EC legislation.⁷³

The complainants in the *GMO* dispute argue that these actions amount to ‘measures’ which breach the obligations of the EC under the WTO Agreements. Specifically they contend that the EC maintains a ‘moratorium’ on the consideration or approval of

⁷¹ Since May 2004, the European Commission has approved seventeen varieties of GM maize to be used as animal feed. At the time of writing, another variety of maize (MON863) and a GM canola variety (GT73) are progressing through the decision-making procedure: ‘Genetic Engineering: EU States Fail To Agree on GM Maize Imports Once Again’, *European Report*, 1 December 2004.

⁷² The US alleges that 18 notifications for placing GM products on the market have been delayed under Directive 90/220 (and then resubmitted under Directive 2001/18) and that 9 applications under Regulation 258/97 have been delayed: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [48]-[55] (First Submission of the United States). Canada alleges 4 such delays: *GMO Case*, WTO Doc WT/DS292 (2004) [68]-[94] (First Written Submission of Canada).

⁷³ There is a distinction between the types of safeguard measures used: Austria, Luxembourg, Italy and Germany used safeguard measures to prohibit the marketing of particular GM corn products, France and Greece to prohibit the marketing *and* import, respectively, of canola.

GMOs.⁷⁴ In the alternative, the complainants claim that the EC has instituted ‘product-specific moratoria’ preventing the marketing of particular products through excessive delays in processing applications, and has failed to take action to overturn the ‘safeguard measures’ put in place by Member States.⁷⁵ In reply, the EC denies the existence of a general moratorium and the stalling of individual applications.⁷⁶ It claims that legislative changes to embrace a more ‘precautionary approach’ have necessarily slowed the process but are justifiable in light of evolving science and the inadequacies of original applications.⁷⁷ It explains the national safeguard measures as the result of national disagreement with Community-level risk assessments, reflecting different levels of risk considered ‘acceptable’ within individual Member States.⁷⁸

IV THE SUBMISSIONS BEFORE THE PANEL

An underlying theme of the submissions before the WTO Panel in the *GMO* dispute concerns the role that science should play in shaping regulatory decisions about measures to address risk. GMOs, like many novel technologies, may pose risks to

⁷⁴ This argument is based on various official statements and documents including the announcement by Environment Ministers of five Member States, statements in Commission working documents and press releases and statement by EC officials: see *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [34]-[45] (First Submission of the United States); *GMO Case*, WTO Doc WT/DS292 (2004) [45]-[67] (First Written Submission of Canada).

⁷⁵ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [57]-[63] (First Submission of the United States); Canada seeks to challenge only those measures of France, Greece, Austria and Italy: *GMO Case*, WTO Doc WT/DS292 (2004) [95]-[137] (First Written Submission of Canada).

⁷⁶ The EC argues that statements used as evidence of a general moratorium instead refer to a transition approach which applied during legislative changes or a ‘precautionary approach to individual applications’: see *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [197], [198] (First Written Submission by the European Communities).

⁷⁷ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [197], [198] (First Written Submission by the European Communities). In its submissions, the EC provides product chronologies which it claims show that each application is assessed individually, that legislated deadlines are still running in some cases and that GM products were in fact approved (under substantial equivalence procedures): *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [562], [564], [547]-[549] (First Written Submission by the European Communities).

⁷⁸ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [339] (First Written Submission by the European Communities).

human health and the environment which are presently beyond the realm of science to predict and characterise. In its submissions, the EC highlights potential problems with, and the current limitations of, scientific knowledge surrounding questions of toxicity, allergenicity and gene transfer from GM products to those who ingest them.⁷⁹ The EC also raises the potential for environmentally adverse effects if insecticidal GM plants harm ‘non-target’ organisms (like butterflies), become invasive weeds or give rise to altered farm management practices with cumulative impacts on biodiversity.⁸⁰ Likewise, the *amicus* briefs submitted to the Panel stress the issue of scientific uncertainty associated with gene technology and the potential for adverse effects to humans, animals, plants and the environment.⁸¹

For the complainants, the uncertainties cited do not justify the ‘measures’ taken by the EC under its GMO regulatory framework. They insist that the EC’s actions are scientifically baseless as they are not supported by ‘sufficient scientific evidence’ and a rigorous risk assessment. The EC, on the other hand, emphasises the issue of regulatory autonomy in the face of uncertain risks and differences in levels of ‘acceptable risk’ between countries.⁸² It argues that its regulatory approach is not unique and finds support in international instruments like the *Biosafety Protocol*,⁸³ which the EC considers should influence the interpretation of WTO agreements.⁸⁴

⁷⁹ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [39]-[50] (First Written Submission by the European Communities).

⁸⁰ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [51]-[63] (First Written Submission by the European Communities).

⁸¹ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [8]-[39] (Amicus Curiae Brief: Amicus coalition); *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [18]-[33] (Amicus Curiae Brief: Environment group).

⁸² *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [71]-[75] (First Written Submission by the European Communities).

⁸³ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [90], [98], [107], [111] (First Written Submission by the European Communities).

⁸⁴ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [112] (First Written Submission by the European Communities).

These arguments reveal very different understandings of the appropriate approach to questions of health and environmental risk regulation undertaken against a backdrop of incomplete or inadequate scientific information. The fundamental cleavage can be described in terms of a division between two different models of risk regulation - 'science-based' and 'precaution-based' - which respond differently to the problem of limited scientific knowledge of the health and environmental risks of many human activities and new technologies.⁸⁵ Whereas the 'science-based' model embodies the idea that risk regulation – including the way in which it deals with scientific uncertainty – should be founded in scientific methods and risk assessment techniques, under a 'precaution-based' approach, risks that are subject to uncertainty are treated as complex problems best resolved by way of an inclusive and deliberative decision-making process.⁸⁶ In the *GMO dispute*, the clash of these two approaches to risk regulation is evident principally in the parties' arguments over the extent to which GMO laws construed as 'SPS measures' must be based on scientific evidence and 'expert' risk assessment. Divergent regulatory 'worldviews' also feed into other aspects of the legal differences between the parties, many of which concern issues that have independently been the subject of intense debate in a 'trade and environment' sense. These include:

- the nature of health and environmental laws caught by the SPS Agreement;
- the scope for GMO regulatory measures to distinguish between GM and non-GM products on the basis of the 'process' by which GM products are produced, or to distinguish between different types of GM product;

⁸⁵ Andreas Klink and Ortwin Renn, 'A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies' (2002) 22(6) *Risk Analysis* 1071.

⁸⁶ Sheila Jasanoff, 'Between Risk and Precaution - Reassessing the Future of GM Crops' (2000) 3(3) *Journal of Risk Research* 277.

- the relevance of the precautionary principle (or approach) as a justification for a regulatory system that leads to substantial delays in approval processes; and
- the relevance of international treaties outside the WTO multilateral trading regime to understanding the nature of obligations of Members under the WTO Agreements.

The following sections summarise the main arguments of the parties concerning these questions and their links to the central issue of contention between the parties – the role that science should play in international regulation of the possible risks, and attendant uncertainties, posed by GMOs.

A *GMO regulations as SPS measures*

Although the style and content of the complainants' submissions differ,⁸⁷ they coincide in their primary challenge to the EC's measures as breaching obligations under the *SPS Agreement*. Each of these measures, they argue, affects international trade by effectively blocking the importation of GM products.⁸⁸ In seeking to rely on the *SPS Agreement*, the main legal hurdle the complainants face is establishing that the actions of the EC under its GMO regulatory framework are properly construed as 'measures' taken for 'sanitary or phytosanitary' purposes. The complainants' approach is to argue that the EC's GMO regulatory framework as a whole is a SPS measure and that the various acts in question are components of this structure, which by extension makes

⁸⁷ Canada also makes subsidiary arguments under the *GATT 1994* and the *TBT Agreement*, the content of which is similar to its SPS contentions: *GMO Case*, WTO Doc WT/DS292 (2004) [320], [321], [327]-[328] (First Written Submission of Canada).

⁸⁸ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [85], [165] (First Submission of the United States); *GMO Case*, WTO Doc WT/DS292 (2004) [388] (First Written Submission of Canada).

each of them SPS measures.⁸⁹ They claim that the GMO regulatory framework aims to address SPS objectives of protecting animal or plant life or health or the environment from risks arising from disease-causing organisms,⁹⁰ contaminants, toxins⁹¹ or the spread of pests.⁹²

The EC's submissions regarding the applicability of the *SPS Agreement* reflect a very different conception both of the purposes of its GMO regulatory framework and the nature of the possible risks involved. It argues on technical grounds that its regulatory framework addresses risks not covered by the *SPS Agreement* and that therefore these non-SPS 'measures' cannot be inconsistent with the *SPS Agreement*.⁹³ To the extent that it concedes that its GMO regulations should be considered under any of the WTO Agreements, the EC's submissions suggest that the most relevant obligations for this purpose are those arising under the *GATT 1994*⁹⁴ and the *TBT Agreement*.⁹⁵ But the EC

⁸⁹ The complainants have also made extensive arguments as to whether a 'moratorium' can be considered a 'measure' for these purposes. Essentially they contend that that measures need not be embodied in a single written document, but rather, can be an unwritten procedure setting out general rules or 'an act or omission of a non-binding or non-mandatory administrative nature': *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [82]-[83] (First Submission of the United States) and *GMO Case*, WTO Doc WT/DS292 (2004) [155] (First Written Submission of Canada).

⁹⁰ *SPS Agreement*, Annex A (1)(a) They argue this on the basis of possible allergic/toxic reactions of non-target animals: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [78] (First Submission of the United States).

⁹¹ *SPS Agreement*, annex A para 1(b). This is argued on the basis of the potential development of antibiotic-resistant bacteria and human allergic/toxic reactions: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [78]-[79] (First Submission of the United States).

⁹² *SPS Agreement*: annex A para 1(d) Measures). This is argued on the basis of the development of herbicide-resistant weeds: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [419] (First Written Submission by the European Communities).

⁹³ The EC lists nine such non-SPS measures: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [419]-[432] (First Written Submission by the European Communities). An example of a non-SPS risk to which the EC GMO regulatory framework is directed is the risk of modified genes producing allergens (because allergies are not 'diseases', under annex A para 1(b)): *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [427] (First Written Submission by the European Communities).

⁹⁴ The EC argues that as mere delays, the alleged 'product specific bans' are not covered by the GATT and/or do not violate art. III:4. It reaches the latter conclusion by reasoning that the applications were submitted by companies incorporated in the EC and that they covered cultivation in the EC as well as import: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [525], [529]-[532], [628]-[637] (First Written Submission by the European Communities).

⁹⁵ The EC also denies the applicability of the *TBT Agreement*, arguing that the national safeguard measures do not meet the definition of 'technical regulations' because they are specific

also mounts a broader challenge to the argument that its GMO laws should be subject to international scrutiny in a trade-oriented forum. It suggests that its GMO regulatory framework is more appropriately evaluated in the context of the *Biosafety Protocol*, an international environmental treaty which has objectives relating to the protection of biodiversity and human health from risks posed by transboundary movements of ‘living modified organisms’.⁹⁶

B ‘Product/process’ distinctions and differences in ‘levels of protection’

An important aspect of the Canadian submissions in the dispute is the claim that the gene technology processes used in producing GMOs do not render them a substantially different product from their conventionally produced counterparts, and so do not justify a different regulatory approach to that used for non-GM products. Along these lines, Canada argues that the EC’s product-specific marketing bans and national safeguards⁹⁷ violate the *GATT 1994* and the *TBT Agreement* because they treat imported GM corn and canola less favourably than the domestically grown non-GM equivalents by only prohibiting the sale of the former.⁹⁸

The process/product debate is a well-worn path in the ‘trade and environment’ literature, which turns upon the meaning of the concept of ‘like products’ in WTO

administrative acts rather than abstract, normative rules that set product characteristics. It also briefly argues that any violation of a TBT provision is justified as an exception under art XX GATT 1994, and does not constitute ‘arbitrary or unjustifiable discrimination between countries where the same conditions prevail or disguised restrictions on international trade’: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [644]-[651], [674] (First Written Submission by the European Communities).

⁹⁶ *Biosafety Protocol*, art 1.

⁹⁷ Canada makes a separate argument in relation to the Greek national safeguard under art XI:1 GATT 1994: *GMO Case*, WTO Doc WT/DS292 (2004) [471]-[472] (First Written Submission of Canada).

⁹⁸ *GMO Case*, WTO Doc WT/DS292 (2004) [320], [321] (First Written Submission of Canada).

Agreements such as the *GATT 1994* and the *TBT Agreement*.⁹⁹ The Canadian arguments suggest that GM and non-GM products are ‘like’ in product terms and so can not be treated differently under regulatory schemes. For its part, the EC strenuously denies the argument that non-GM and GM products are ‘like’,¹⁰⁰ pointing to international recognition of the different nature of products produced using processes of gene technology.¹⁰¹ It contends that special procedures applied by its regulatory framework to GMOs are justified because GM and non-GM products are ‘objectively different’.¹⁰² This reflects the view that the *process* by which a product is produced (including its health and environmental consequences) is a relevant consideration in determining ‘likeness’.¹⁰³

Not only distinctions in the EC regulatory scheme between GM and non-GM, but also distinctions between different types of GM products are questioned in the complainants’ submissions. This latter line of argument relies on the controversial provision in the *SPS Agreement* indicating that ‘comparable’ risks should be regulated in a ‘similar’

⁹⁹ See, e.g., discussions in Won-Mog Choi, ‘*Like Products*’ in *International Trade Law: Towards a Consistent GATT/WTO Jurisprudence* (2003); and Daniel C Esty, *Greening the GATT: Trade, Environment and the Future* (1994).

¹⁰⁰ Canada argues GMOs and their non-GM counterparts are ‘like products’ since they are intended to be used interchangeably, are physically virtually identical, share the same tariff classification, and consumer preferences do not conclusively show a difference between them: *GMO Case*, WTO Doc WT/DS292 (2004) [320] (First Written Submission of Canada).

¹⁰¹ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [535], [655] (First Written Submission by the European Communities).

¹⁰² *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [535], [621], [655] (First Written Submission by the European Communities). The EC argues that the *Biosafety Protocol* supports its regulatory view of GMOs in distinguishing GM from non-GM products (that is, not treating them as ‘like’ products), particularly in providing for special risk assessment procedures and the application of the precautionary principle: *ibid*, [90]. In the alternative, the EC briefly argues that any violation obligations with respect to ‘like products’ is justified as an exception under art XX GATT 1994: *ibid*, [674].

¹⁰³ Such distinctions between ‘product’ and ‘process’ are complicated in the GMO context by the fact that the genetic modification process of inserting foreign genes, is also apparent in the product, at least at the level of its genetic material.

fashion in order to avoid discriminatory treatment of products.¹⁰⁴ For the complainants, the EC's GMO regulatory framework applies unjustifiably different SPS protection levels for GM products and foods compared with products produced with GM processing aids. The latter, they argue are 'similar' to other GM products since they may contain the same substances,¹⁰⁵ but are not regulated by the EC.¹⁰⁶ The complainants claim that this 'different treatment' is discriminatory and hint that the reasons for it lie in protectionist, rather than health or environmental, goals.¹⁰⁷

The EC's response to these arguments reflects a more complex conception of GM products, which purports to take account of a range of concerns extending beyond the findings of scientific risk assessments. It argues that different responses to the same GM product could be warranted due to different proposals for its use, different risk management arrangements, monitoring or labelling, or different situations in Member States.¹⁰⁸ The EC's contentions thus raise questions about the extent to which the WTO Agreements regulate the bases upon which Members can distinguish between types of health or environmental risk. Underlying the different arguments of the parties are

¹⁰⁴ *SPS Agreement*, above n 14, art. 5.5. For a critique of this provision see Jeffrey Atik, 'The Weakest Link: Demonstrating the Inconsistency of "Appropriate Levels of Protection" in Australia-Salmon' (2004) 24(2) *Risk Analysis* 483.

¹⁰⁵ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [121] (First Submission of the United States).

¹⁰⁶ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [118] (First Submission of the United States).

¹⁰⁷ For example, the complainants point to the disproportionate effect of the regulations on non-EC producers as compared with those in the EC: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [125]-[126] (First Submission of the United States). Arguments dealing with product specific moratoria are found at *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [152] (First Submission of the United States); *GMO Case*, WTO Doc WT/DS292 (2004) [271]-[287] (First Written Submission of Canada). Canada claims that arbitrary distinctions in SPS protection levels also apply between products approved prior to the moratorium and after the moratorium was introduced; and between GM products under the moratorium and novel non-GM products: *GMO Case*, WTO Doc WT/DS292 (2004) [206]-[211] (First Written Submission of Canada). Canada alone poses these arguments in relation to the national safeguard measures: *GMO Case*, WTO Doc WT/DS292 (2004) [417] (First Written Submission of Canada).

¹⁰⁸ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [620] (First Written Submission by the European Communities). These arguments are raised as an alternative to the EC's primary defence that its safeguard measures are 'provisional measures' under art. 5.7 and so not subject to obligations under art. 5.5: *ibid.*, [618].

opposing views as to the role played by non-scientific factors in influencing decisions about the ‘acceptability’ of risk.

C Precautionary delays or protectionism?

It is possible that in the end result, the resolution of the *GMO* dispute in the WTO may turn upon the parties’ ‘procedural’ arguments rather than those concerning the role of science or the appropriateness of different risk regulatory approaches. One of the complainants’ primary claims relates to ‘undue delays’ in the EC approval processes for GMOs¹⁰⁹ and a lack of ‘transparency’ in respect of its regulatory requirements.¹¹⁰ Underlying these claims is a concern that the EC’s regulatory processes are being used, not as a legitimate means for assessing the risks associated with particular GM products, but rather as an indirect means of banning GMOs by tying authorisations up in bureaucratic red tape.

Although the arguments advanced by the complainants are ‘procedural’ in nature, the reasons put forward by the EC (and the *amicus* submissions) to justify delay and lengthy processing times raise more weighty issues, such as the relevance of the precautionary principle in the WTO context. In a previous case, the WTO Appellate Body ruled that the precautionary principle cannot be relied upon by Members as a reason for excusing non-compliance with their ‘black letter obligations’ under WTO

¹⁰⁹ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [89]-[90], [138] (First Submission of the United States); *GMO Case*, WTO Doc WT/DS292 (2004) [238]-[239] (First Written Submission of Canada).

¹¹⁰ *SPS Agreement*, annex C para 1(b); *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [96]-[97], [141] (First Submission of the United States).

Agreements like the *SPS Agreement*.¹¹¹ However, the scope for a ‘precautionary approach’ to the implementation of a Member’s WTO obligations, to take account of areas of uncertainty surrounding particular risks, remains unclear.

The EC claims that lengthy delays in the assessment and approval process for GMOs are necessary under a ‘precautionary approach’, especially in light of the low level of risk deemed ‘acceptable’ in the EU.¹¹² The EC cites the permanent and uncertain effects of introducing a GMO, the ‘exponential’ rate of change in the biotechnology area and the need to amend legislative rules as reasons for a cautious approach which has generated inevitable delays.¹¹³ In addition, it suggests that precaution is not inconsistent with a science-based approach to determining risks since provisional safeguard measures are ‘based on the need to allow sufficient time for sufficient scientific evidence to be collected’.¹¹⁴

The precautionary principle also comes to the fore in the *amicus* submissions in support of the EC’s claims that lengthy delays in its approval process are justified in the circumstances. The brief put forward by a group of environmental organisations argues that the uncertainty involved in evaluating the risks posed by GMOs is currently ‘so

¹¹¹ *Beef Hormones*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, (2001) [29]-[30] (Report of the Appellate Body).

¹¹² *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [604]-[605] (First Written Submission by the European Communities). An adequate risk assessment in the EC’s submission is one ‘delivered by a reputable source, that unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and that has withstood the passage of time and is unlikely to be revised’: *ibid.*

¹¹³ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [606]-[608] (First Written Submission by the European Communities).

¹¹⁴ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [615] (First Written Submission by the European Communities).

substantial that it impedes any adequate consideration of those risks'.¹¹⁵ The group contends that delays were necessary during a period of national and international regulatory change,¹¹⁶ and allowed the EC to seek further information about GMO risks, including through UK Farm-Scale Evaluations and consideration of public opinion.¹¹⁷ The clear implication from these arguments is not only that the 'precautionary approach' is considered a legitimate mode of risk regulation, but also that this approach may justify a departure from an exclusive focus on scientific considerations in assessing and managing the risks posed by GMOs.

D *Relevance of international agreements to the WTO regime*

Whereas the complainants' arguments are firmly grounded in the WTO sphere, the EC raises questions over the appropriateness of international scrutiny of its GMO regulatory framework exclusively under the laws of international trade. Throughout its submissions, the EC argues that the most relevant international treaty from its perspective is not one the WTO Agreements, but the *Biosafety Protocol*.¹¹⁸ Under the Protocol, parties are required to apply special risk assessment, notification and consent procedures for 'transboundary movements' of GMOs¹¹⁹ that are similar to those in international environmental treaties dealing with hazardous wastes.¹²⁰ The Protocol

¹¹⁵ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [45] (Amicus Curiae Brief: Environment group). See also *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) 29-30 (Amicus Curiae Brief: Academic amicus).

¹¹⁶ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [107]-[112] (Amicus Curiae Brief: Amicus coalition).

¹¹⁷ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) 31 (Amicus Curiae Brief: Academic amicus).

¹¹⁸ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [454]-[455] (First Written Submission by the European Communities).

¹¹⁹ *Biosafety Protocol*, arts 8, 10, 15.

¹²⁰ For example: *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal*, opened for signature 22 March 1989, 1673 UNTS 57, 28 ILM 649 (1989) (entered into force 5 May 1992); *Convention on the Prior Informed Consent Procedure for Certain*

also makes provision for the consideration of socio-economic matters, and permits parties to take into account ‘lack of scientific certainty due to insufficient relevant scientific information and knowledge’ regarding the extent of risks to biodiversity in national decisions on the import of GMOs. The EC draws parallels between the approaches of the Protocol and its regulatory framework for GMOs, focusing particularly on approval procedures and the relevance of a precautionary approach where there are threats to biodiversity and human health.

While the Panel may give these arguments short shrift on the basis that its competence is limited to determining compliance with the WTO Agreements and, in any event, not all of the WTO Members concerned in the dispute are parties to the *Biosafety Protocol*,¹²¹ a question remains as to the extent to which international treaties outside the WTO regime can or should influence the decisions of its dispute settlement bodies. In the post-Uruguay Round era, the Appellate Body in particular, acknowledges that international trade law cannot be considered ‘in clinical isolation’ from the rest of public international law, including that dealing with health and environmental concerns.¹²² However, the more difficult issue is whether the WTO dispute settlement bodies (as opposed to the Members themselves) should take on the task of deciding the appropriate relationship between the trade and environmental obligations of States in circumstances where they come into conflict, especially where not all parties to the

Hazardous Chemicals and Pesticides in International Trade, opened for signature 10 September 1998, 38 ILM 1 (1999) (entered into force 24 February 2004).

¹²¹ None of the complainants are parties to the Protocol raising an issue about the relationship that may exist between the provisions of the multilateral environmental agreement and the WTO agreements. This general issue has been much discussed in the literature. See, e.g., Robyn Eckersley, ‘The Big Chill: The WTO and Multilateral Environmental Agreements’ (2004) 4 *Global Environmental Politics* 24, 39–43; Peter W B Phillips and William A Kerr, ‘Alternative Paradigms: The WTO Versus the Biosafety Protocol for Trade in Genetically Modified Organisms’ (2000) 34 *Journal of World Trade* 63; Gilbert R Winham, ‘International Regime Conflict in Trade and Environment: The Biosafety Protocol and the WTO’ (2003) 2 *Trade Review* 131;

¹²² *United States – Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS2/AB/R (1996) 17 (Report of the Appellate Body).

dispute are subject to the requirements under environmental treaties such as the *Biosafety Protocol*.

E ‘Sound science’ and risk assessment

Perhaps the most controversial aspect of a case which raises many contentious ‘trade and environment’ issues concerns the place of science in regulating GMO risks. In the complainants’ view, GMO risks should be scientifically determined and assessed, such that an absence of ‘sound science’ supporting regulation is fatal to its legitimacy. Under the *SPS Agreement*, the complainants’ principal line of attack is that the EC has not met the requirements that its measures be ‘based on scientific principles and ... not maintained without sufficient scientific evidence’, and ‘based on’ an acceptable form of risk assessment.¹²³ In previous SPS case law, it has been held that measures are only ‘based on’ scientific evidence and a risk assessment where there is a ‘rational relationship’ between the measure and the underlying scientific material or assessment of risk.¹²⁴ The complainants argue that there is no evidence of any risk assessment justifying the general moratorium or the national safeguards.¹²⁵ Moreover, they point to ‘positive’ scientific risk assessments for many of the disputed GM products as

¹²³ The nature of an SPS risk assessment was discussed by the Appellate Body in *Australia – Measures Affecting Importation of Salmon*, WTO Doc WT/DS18/AB/R (1998) [121] (Report of the Appellate Body) and *Beef Hormones*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB-2000-11 (2001) [183]-[184] (Report of the Appellate Body).

¹²⁴ *Beef Hormones*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB-2000-11 (2001) [193] (Report of the Appellate Body); *Japan – Measures Affecting Agricultural Products*, WTO Doc WT/DS76/AB/R (1999) [84] (Report of the Appellate Body).

¹²⁵ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [105], [170] (First Submission of the United States).

demonstrating an ‘irrational relationship’ between these assessments and the product-specific moratoria.¹²⁶

The EC, on the other hand, views the roles of science and scientific risk assessment in regulation as much more fluid. It considers that the need to carry out a risk assessment, and the nature of that assessment, vary with the level of scientific uncertainty and that the same assessment can rationally give rise to different, legitimate, regulatory decisions. The EC’s first line of defence is that the extent of scientific uncertainty surrounding GMOs triggers the SPS provision allowing precautionary ‘provisional measures’,¹²⁷ thus rendering a risk assessment unnecessary as a basis for national safeguard provisions.¹²⁸ Alternatively, the EC contends that safeguard measures are ‘based on’ other risk assessments albeit not the Member States’ own, as the latter did not find unacceptable risks associated with specific products. As a further alternative argument, the EC claims that the safeguard measures are based on its own scientific risk assessments, which although producing no finding of risk, could warrant ‘more than one plausible SPS measure’.¹²⁹

The EC’s view of the role of risk assessment in health and environmental regulation is supported by the *amicus* submission of a group of well-known and respected professors of social science. The group urges a broader understanding of risk assessment that

¹²⁶ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [147] (First Submission of the United States); *GMO Case*, WTO Doc WT/DS292 (2004) [261], [269] (First Written Submission of Canada).

¹²⁷ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [574], [590], [591] (First Written Submission by the European Communities).

¹²⁸ The EC did not consider it necessary at this stage to demonstrate in detail that the conditions for a ‘provisional measure’ under art 5.7 were met, given that no complainant argued a violation of this provision: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [594] (First Written Submission by the European Communities).

¹²⁹ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [610] (First Written Submission by the European Communities).

accepts normative elements as both a desirable and unavoidable component of evaluating health and environmental risk.¹³⁰ They argue that value judgments influence the data and methods used in risk assessment, leading to different estimates of risk.¹³¹ Further, cultural and political context influence whether a hazard is identified and how the corresponding possible harm is estimated. This can produce different approaches to similar hazards (or in an international context) divergent developments in national GMO laws.¹³² Differences in national regulatory approaches to GMOs are also explicable, according to the professors, by factors such as the evolving nature of risk assessments of GMOs; the need to assess GMO risks locally due to ecosystem differences;¹³³ and the inclusion of non-quantitative factors and public deliberation in risk assessments.¹³⁴

While the differences between the parties are framed in terms of the provisions of the *SPS Agreement* requiring ‘sufficient scientific evidence’ and the basis of regulation in a risk assessment, the *amicus* submission of the social science professors reveals the dispute’s connection to broader divisions within the international community regarding the utility of ‘science-based’ and ‘precaution-based’ models for risk regulation in conditions of uncertainty. These divisions in turn motivate the other aspects of the legal dispute between the parties discussed above. For example, the EC’s contention that a

¹³⁰ The experts group highlights that public participation is both scientifically and politically important to risk assessment and to defining what is ‘at risk’ in any case: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) 17-19 (Amicus Curiae Brief: Academic amicus).

¹³¹ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) 14 (Amicus Curiae Brief: Academic amicus). This view is supported by another amicus submission from a coalition of public interest groups who cite the precautionary principle as legitimating a broad range of appropriate levels of food protection, given the lack of scientific certainty about facts and methods surrounding gene technology: *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [99]-[106] (Amicus Curiae Brief: Amicus coalition).

¹³² *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) 15-17, 20 (Amicus Curiae Brief: Academic amicus).

¹³³ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) 22-23 (Amicus Curiae Brief: Academic amicus).

¹³⁴ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) 24-26 (Amicus Curiae Brief: Academic amicus).

'precautionary approach' justifies regulatory delays can be explained on the basis of a more general view that risk regulation in uncertainty should build in measures to provide for the occurrence of 'unexpected' adverse outcomes, rather than relying upon scientific tools to contain and manage, as far as possible, uncertainties within risk assessment processes.¹³⁵ Likewise, its attempt to incorporate reference to the *Biosafety Protocol* in the Panel's interpretation of relevant WTO Agreements seems designed to call the attention of WTO decision-makers to the fact that there may be alternative ways of approaching risk regulation than the science-focused approach reflected in the *SPS Agreement*. For their part, the complainants' arguments highlight the potential inconsistencies between a broader-based model of risk regulation and the elements of the institutional context in which it must be implemented.¹³⁶ These include the focus of the existing trade regime on consistent and transparent approaches to regulating trade in products, which can be ascertained by reference to 'objective' standards, such as product characteristics and available scientific data.

V LOOKING TO THE FUTURE

The complexity of the issues raised in the *GMO* dispute promises not only a lengthy dispute settlement process in the WTO, but also far-reaching implications of the case for international trade law and its relationship with domestic health and environmental risk regulatory regimes. Some of the issues raised by the parties' submissions concerning the relationship between trade and environmental laws are among those that have

¹³⁵ See Andreas Klinke and Ortwin Renn, 'A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies' (2002) 22(6) *Risk Analysis* 1071, 1074-1075.

¹³⁶ See Elizabeth Fisher, 'Precaution, Uncertainty and Principles of Good Administration', paper presented at *Uncertainty and Precaution in Environmental Management*, Copenhagen, 7-9 June 2004 (forthcoming in *Water, Science and Technology*).

proved to be the most intractable in inter-governmental negotiations.¹³⁷ These include the validity of creating product distinctions based upon processes of production, the relevance of the precautionary principle in the WTO context, and the question of how potential conflicts between international trade obligations and multilateral environmental agreements should be resolved.

However, as has been emphasised in this commentary, it is the broader issues the dispute raises regarding the role of science and risk assessment in regulating health and environmental threats that are likely to have the most far-reaching future consequences. The dispute brings to the surface, in a very public fashion, simmering disagreements between lawyers, social scientists, politicians and members of the broader international community as to the most appropriate approach to health and environmental regulation in global society increasingly focused on issues of 'risk' and the limitations of scientific knowledge to characterise and predict such risks with accuracy.¹³⁸ On either side of the fault lines of this disagreement are competing approaches to risk regulation which reflect fundamentally different understandings of the importance of 'science-based' and 'broader' approaches to dealing with uncertain risks so as to ensure health and environmental protection over the long-term. In the *GMO* dispute, WTO dispute settlement bodies are placed in the unique (albeit unenviable) position of determining which of these risk regulatory approaches is consistent with international trade law. The institutional strength of the WTO and its associated dispute settlement system has the potential to make any such determination conclusive when it comes to the design of national health and environmental regulatory regimes that will govern products traded in both domestic and international markets.

¹³⁷ These are matters currently under negotiation by WTO Members in the Doha trade round: *Ministerial Declaration*, WTO Doc WT/MIN(01)/DEC/1 (14 November 2001).

¹³⁸ See Ulrich Beck, *Risk Society: Towards a New Modernity* (1992).

No doubt this is a result that WTO dispute settlement bodies are most anxious to avoid. The WTO Appellate Body has stressed the need for WTO decision-makers to respect national regulatory diversity¹³⁹ and clearly sees its role as limited to assessing the compliance of government's measures with the specific obligations established under WTO law. However, the framework that these obligations establish – particularly those under the *SPS Agreement* – offers the WTO dispute settlement bodies little flexibility to accommodate models of health and environmental risk regulation that are not based around assessments of the available scientific evidence and scientific perspectives on risk. The *amicus* submission of the social science professors suggests a possible compromise, arguing that WTO decision-makers should assess compliance with risk assessment obligations on a procedural rather than a substantive basis, which would enable WTO Members to take account of a broader range of information in decision-making than purely the advice of scientific experts.¹⁴⁰ The feasibility and fairness of an approach that would open up supranational risk regulatory review processes to a range of values and policy judgments is less apparent in the international context where normative goals of health and environmental policy are frequently not shared by all countries.¹⁴¹ Moreover there is still a thorny question to be dealt with in considering which international bodies would have the necessary 'legitimacy' to make decisions about the values the international community promotes in any particular context, especially where uncertainties make it more difficult to determine the health and environmental consequences of different courses of action. The submissions of the EC

¹³⁹ *Beef Hormones*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, (2001) [124] (Report of the Appellate Body).

¹⁴⁰ *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) 40 (Amicus Curiae Brief: Academic amicus).

¹⁴¹ Jacqueline Peel, 'Risk Regulation under the WTO *SPS Agreement*: Science as an International Normative Yardstick?' (Working Paper No 02/04, Jean Monnet Program, NYU School of Law, 2004) 63.

and the *amicus* briefs in the *GMO* dispute suggest that in controversial areas like biotechnology regulation not all in the international community currently view the WTO as “the appropriate international forum for resolving all the GMO issues that the Complainants have raised.”¹⁴²

¹⁴² *GMO Case*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [10] (First Written Submission by the European Communities).