

COMMENTARIES

GMO TRADE WARS: THE SUBMISSIONS IN THE EC — GMO DISPUTE IN THE WTO

JACQUELINE PEEL,* REBECCA NELSON† AND LEE GODDEN‡

[The release of the parties' submissions in the long-awaited EC — GMO dispute provides an opportunity to assess the likely implications of this important dispute for the relationship between international trade law and domestic health and environmental regulatory schemes. The dispute raises a myriad of legal questions, many of which have long been thorny issues in the 'trade and environment' context. However, the greatest significance of this dispute may ultimately lie in what it reveals about the capacity of global markets, through the instruments of the World Trade Organization agreements, to shape the way in which WTO Members regulate their own territories, issues of health and environmental risk associated with internationally traded products. We argue that the EC — GMO dispute can be conceived of as a clash between different approaches to the regulation of uncertain risks surrounding genetically modified organisms. Viewing the dispute in this way raises questions as to whether the WTO agreements, applied by the WTO Dispute Settlement Body, are capable of accommodating legitimate regulatory diversity or whether global markets could become the means for harmonising domestic structures for the regulation of health and environmental risk, particularly in countries lacking the economic power to stand outside the WTO system on any one issue.]

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* BSc, LLB (Hons) (Queensland); LLM (NYU); Senior Lecturer, Faculty of Law, The University of Melbourne.

† BE(Environmental) candidate, LLB candidate (Final Year) (Melbourne); Research Assistant, Faculty of Law, The University of Melbourne.

‡ BA (Hons) (Melbourne), BLegS (Macquarie); MA (Melbourne), PhD (Griffith); Senior Lecturer, Faculty of Law, University of Melbourne. Some of the work on this project was undertaken while Dr Godden was a visiting research fellow at BRASS Cardiff University.

I INTRODUCTION

Over the short history of dispute settlement in the World Trade Organization,¹ few cases have excited as much anxious anticipation as the current dispute between the United States, Canada, Argentina and the European Communities concerning the latter's 'measures affecting the marketing and approval of biotech products'.² The *EC — GMO* 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 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

¹ When the WTO came into being on 1 January 1995, it introduced a new system of dispute settlement: *Marrakesh Agreement Establishing the World Trade Organization*, 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*) 1869 UNTS 401 ('*Dispute Settlement Understanding*'). The *Dispute Settlement Understanding* 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 187 (entered into force 29 July 1948) ('*GATT 1947*'). It introduced a new Appellate Body to hear appeals from first instance panels on questions of law and made 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 Trebilcock and Robert Howse, *The Regulation of International Trade* (2nd ed, 1999) 51–3.

² This is the way the dispute is described in the US request for consultations with the EC in the WTO: *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 US) ('US Request for Panel'). The US prefers the neutral terminology of 'biotech products' whereas the EC speaks of genetically modified organisms ('GMOs'), genetically modified ('GM') crops and GM foods. *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, WTO Doc WT/DS291, WT/DS292, WT/DS293 (2004) [1] (First Written Submission by the EC) available from <<http://www.trade-environment.org/page/theme/tewto/biotechcase.htm>> at 1 May 2005 ('EC Submission'). Throughout this commentary this dispute shall be referred to as the *EC — GMO* dispute.

³ *European Communities — Measures concerning Meat and Meat Products (Hormones)*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB–1997–4 (1998) [123] (Report of the Appellate Body) ('*Beef Hormones Appellate Body Report*'). The *Beef Hormones* dispute also concerned a US and Canadian challenge to EC regulatory measures. It was subject to many years of negotiation and wrangling between the parties before finally being brought before the WTO in 1998. Although the WTO Appellate Body ruled against the EC, nearly ten years later the dispute has still not been resolved: see 'WTO to Rule on EU Complaint against US, Canada Sanctions in Beef Row', *Agence France Presse*, 17 February 2005.

⁴ GM agricultural production in 2003 in the US, Canada and Argentina amounted to 105.7 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 No 30, 13 January 2004) [6] available at <http://www.isaaa.org/kc/CBTNews/press_release/briefs30/b30_english.pdf> at 1 May 2005.

⁵ US Request for Panel, above n 2. Egypt also announced that it would be a complainant but never began formal dispute settlement proceedings in the WTO.

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 *EC — GMO* dispute has prompted the parties to adopt an unprecedented level of transparency regarding their arguments and submissions to the WTO Panel that will initially decide the matter. Canada, the EC and the US have all released their first detailed written submissions, which together total some 470 pages in length.⁹ The complainants' submissions are quite carefully framed; they do not purport to attack the EC's 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 argue that excessive delay in the EC approval process and/or bans on genetically modified ('GM') crops maintained by individual Members of the European Union violate the obligations of the EC under several

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 generally David Vogel, 'Ships Passing in the Night: The Changing Politics of Risk Regulation in Europe and the United States' (Working Paper No 2001/16, Robert Schuman Centre for Advanced Studies, European University Institute, 2001).

⁷ In the US, the value of GM crops was over US\$20 billion in 2002 and the sales of the agricultural divisions of the six leading agricultural biotechnology companies totalled US\$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 <<http://www.apec.umn.edu/faculty/frunge/plantbiotech.pdf>> at 1 May 2005. However, the total economic contribution of the industry is difficult to measure: at 102.

⁸ Anticipation of, and speculation about, the *EC — GMO* dispute has produced substantial literature on the topic presenting a range of views: see generally 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 Isaac and William Kerr, 'Genetically Modified Organisms and Trade Rules: Identifying Important Challenges for the WTO' (2003) 26 *World Economy* 29; Gilbert Winham, 'International Regime Conflict in Trade and Environment: The *Biosafety Protocol* and the WTO' (2003) 2 *World Trade Review* 131; Nicholas Perdakis, William Kerr and Jill Hobbs, 'Reforming the WTO to Defuse Potential Trade Conflicts in Genetically Modified Goods' (2001) 24 *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; Joanne Scott, 'European Regulation of GMOs and the WTO' (2003) 9 *Columbia Journal of European Law* 213.

⁹ The submissions of the parties, together with other documents and new reports concerning the case, are available from International Centre for Trade and Sustainable Development, *EU Biotech Case* (2004) <<http://www.trade-environment.org/page/theme/tewto/biotechcase.htm>> at 1 May 2005.

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) available from <<http://www.trade-environment.org/page/theme/tewto/biotechcase.htm>> at 1 May 2005 ('Canadian Submission').

WTO agreements.¹¹ The respondent's arguments suggest that it sees much more at stake than any current 'moratorium' on approvals for new GM crops. The EC argues vigorously in its submission that the dispute raises complex factual, scientific, social and legal issues, which the WTO has neither the jurisdiction nor the capacity to resolve.¹² In this respect, the EC position is supported by three amicus curiae submissions which have been filed by interested non-state actors — ranging from academics to environmental and public interest organisations.¹³

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,¹⁴ it argues that even under WTO law the complainants have framed the dispute far too narrowly. The US argument focuses exclusively on compliance with one of the WTO agreements, the *Sanitary and Phytosanitary Measures Agreement*.¹⁵ The *SPS Agreement* covers trade-restrictive measures of WTO Members put in place to protect against risks to human, plant or animal life or health. In past cases, the *SPS Agreement* has only been applied to deal with domestic food safety laws and quarantine requirements that affect international trade.¹⁶ While there is scope for arguments to be made that the EC's GMO regulatory regime is caught by the *SPS Agreement*, obligations created by

¹¹ Canadian Submission, above n 10, [320], [321], [327]–[328]; *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, WTO Docs WT/DS291, WT/DS292, WT/DS293 (2004) [4] (First Submission of the US) available from <<http://www.trade-environment.org/page/theme/tewto/biotechcase.htm>> at 1 May 2005 ('US Submission').

¹² EC Submission, above n 2, [3]–[10].

¹³ Three groups have made amicus curiae submissions in the *EC — GMO* dispute: a coalition of 15 public interest groups, a group of five expert academics and a group of five environmental groups: *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, WTO Docs 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) available from <<http://www.trade-environment.org/page/theme/tewto/biotechcase.htm>> at 1 May 2005 ('Environment Group Brief'); *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, WTO Docs WT/DS291, WT/DS292, WT/DS293 (2004) (Amicus Curiae Brief: International Coalition of 15 Public Interest Groups) available from <<http://www.trade-environment.org/page/theme/tewto/biotechcase.htm>> at 1 May 2005 ('Amicus Coalition Brief'); *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, WTO Docs WT/DS291, WT/DS292, WT/DS293 (2004) (Amicus Curiae Brief: Lawrence Busch, Robin Grove-White, Sheila Jasanoff, David Winickoff and Brian Wynne) available from <<http://www.trade-environment.org/page/theme/tewto/biotechcase.htm>> at 1 May 2005 ('Expert Group Brief').

¹⁴ 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: Robyn Eckersley, 'The Big Chill: The WTO and Multilateral Environmental Agreements' (2004) 4(2) *Global Environmental Politics* 24, 24.

¹⁵ *Marrakesh Agreement Establishing the World Trade Organization*, 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*) 1867 UNTS 493 ('*SPS Agreement*'); US Submission, above n 11, [4].

¹⁶ The four disputes concerning the *SPS Agreement* determined so far are *Beef Hormones Appellate Body Report*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB-1997-4 (1998); *Australia — Measures Affecting Importation of Salmon*, WTO Doc WT/DS18/AB/R, AB-1998-5 (1998) (Report of the Appellate Body); *Japan — Measures Affecting Agricultural Products*, WTO Doc WT/DS76/AB/R, AB-1998-8 (1999) (Report of the Appellate Body); *Japan — Measures Affecting the Importation of Apples*, WTO Doc WT/DS245/AB/R, AB-2003-4 (2003) (Report of the Appellate Body).

other WTO agreements — the *General Agreement on Tariffs and Trade*¹⁷ and the *Technical Barriers to Trade Agreement*¹⁸ — may also be relevant.¹⁹ Conversely, the EC maintains that its laws are best assessed in light of relevant international treaties outside of the WTO regime, such as the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*.²⁰

The parties' submissions are now before a WTO dispute settlement panel which is due to issue a ruling on the matter in June 2005.²¹ It is probable that the losing party will appeal to the WTO Appellate Body, pushing a final resolution of the dispute out to late 2005.²² Nevertheless, the publication by the parties of their submissions, together with those of non-state actors seeking amicus curiae status,²³ provides a useful insight into the issues to be determined. These issues, and the subsequent findings of WTO decision-makers, are likely to resonate in many areas of international law beyond the field of international trade law or the particular WTO agreements relevant to 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 curiae briefs submitted by non-state actors. This commentary is directed more to general international lawyers wishing to obtain an understanding of the main issues being argued in this important case than to trade law specialists. For this reason, Part II includes a brief overview of the WTO agreements relevant to the *EC — GMO* dispute. Part III outlines the EC regulatory system for GMOs which is the subject of the challenge. Part IV goes on to highlight the major arguments advanced by the parties and other participants in the dispute. Part V concludes with a consideration of the broader implications of the case for the interaction of international trade law and domestic health and environmental regulatory regimes.

II OVERVIEW OF THE RELEVANT WTO AGREEMENTS

The *EC — GMO* dispute involves a claim by the US, Canada and Argentina that measures taken by the EC in administering its GMO regulatory framework

¹⁷ *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*').

¹⁸ *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 1A (*Agreement on Technical Barriers to Trade*) 1868 UNTS 120 ('*TBT Agreement*').

¹⁹ See David Morgan and Gavin Goh, 'Genetically Modified Food Labelling and the WTO Agreements' (2004) 13 *Review of European Community and International Environmental Law* 306, 310–11.

²⁰ Opened for signature 29 January 2000, 39 ILM 1027 (2000) (entered into force 11 September 2003) ('*Biosafety Protocol*').

²¹ *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, WTO Docs WT/DS291/27, WT/DS292/21, WT/DS293/21 (2004) (Communication from the Chairman of the Panel, 2 November 2004).

²² 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: *Dispute Settlement Understanding*, above n 1, art 17(5); *Working Procedures for Appellate Review*, WTO Doc WT/AB/WP/5 (2005) annex 1.

²³ 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: *US — Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R, AB-1998-4 (1998) [89] (Report of the Appellate Body).

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 WTO agreements: the *TBT Agreement* and the *SPS Agreement*. All three agreements came into force in 1995 following the Uruguay Round of trade negotiations. These negotiations focused on strategies to reduce both border measures affecting trade, such as tariffs and customs duties, and so-called ‘non-tariff [trade] barriers’.²⁴ 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 the 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

The *GATT 1994* is a framework of wide-ranging but general obligations that require 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’.²⁵ One of the foundational principles of the *GATT 1994* is the principle of ‘national treatment’: Members must not discriminate between imported and domestically produced goods where they are ‘like products’.²⁶ This complements another important principle of the *GATT 1994*, the principle of ‘most favoured nation’ treatment, 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.²⁷ Among its other rules on trade barriers, the *GATT 1994* outlaws the use of quantitative trade restrictions, such as quotas and import bans.²⁸

Some exceptions to the *GATT 1994*’s rules against trade barriers are allowed under art XX on specified public policy grounds. One exception is trade barriers that are ‘necessary to protect human, animal or plant life or health’,²⁹ 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’.³⁰ 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 that the measures ‘are made effective in conjunction with

²⁴ Jeff Waincymer, Martin Davies and Michael Pryles, *International Trade Law: Commentary and Materials* (2nd ed, 2004) 686.

²⁵ *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) (‘*Marrakesh Agreement*’) preamble.

²⁶ *GATT 1994*, above n 17, art III:4.

²⁷ *Ibid* art I.

²⁸ *Ibid* art XI.

²⁹ *Ibid* art XX(b).

³⁰ *Ibid* art XX. This condition and other conditions in the *chapeau* apply to all the exceptions listed in art XX.

restrictions on domestic production or consumption'.³¹ WTO Appellate Body rulings on this exception suggest that what constitutes 'exhaustible natural resources' for this purpose is to be determined in light of contemporary international environmental concerns relating to endangered species and biodiversity conservation.³²

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.³³ Of particular concern to negotiators were laws and other measures maintained ostensibly for the purpose of protecting human health, safety and the environment, but which in practice served to exclude or significantly disadvantage competing imported products.³⁴ The solution agreed to by participants in the negotiations was that the *GATT 1947* provisions would be supplemented by detailed rules on particular kinds of non-tariff trade barriers under the *TBT Agreement* and the *SPS Agreement*.

B TBT Agreement

The *TBT Agreement* builds upon the provisions of the *Agreement on Technical Barriers to Trade*³⁵ concluded during the Tokyo Round of trade negotiations in the 1970s. Unlike its predecessor, the *TBT Agreement* applies to all WTO Members adopting technical regulations, standards (including packaging, labelling and marking requirements) and conformity assessment procedures with the potential to impact trade.³⁶

Under the *TBT Agreement*, international standards are promoted as a method of harmonising technical regulations,³⁷ 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 favourabl[y]' than domestic 'like products',³⁸ and that they satisfy time and notification requirements directed to facilitating transparency and reducing delays in trade.³⁹

Although the *TBT Agreement* seeks to minimise the extent to which technical regulations create 'unnecessary obstacles'⁴⁰ to international trade — much like

³¹ *Ibid* art XX(g).

³² *United States — Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R, AB-1998-4 (1998) [127]–[134] (Report of the Appellate Body). See also *Canada — Measures Affecting Exports of Unprocessed Herring and Salmon*, GATT BISD, 35th Supp, 98, GATT Doc BISD/35S/98 (1989) [3.29] (Report of the Panel, adopted on 22 March 1988), in which herring and salmon were agreed to be exhaustible natural resources.

³³ Trebilcock and Howse, above n 1, 138–42.

³⁴ *Ibid* 135.

³⁵ GATT BISD, 26th Supp, 8, GATT Doc LT/TR/A/5 (1980).

³⁶ *TBT Agreement*, above n 18, arts 2–8.

³⁷ *Ibid* arts 2.4–2.5. Under art 2.5, Members' technical regulations that accord with international standards are presumed not to create unnecessary obstacles to international trade.

³⁸ *Ibid* art 2.1.

³⁹ *Ibid* arts 2.9, 5.2.1.

⁴⁰ *Ibid* art 2.2.

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 that this is ‘necessary’⁴¹ 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.⁴² 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 instituting protective standards.⁴³ The lack of an overt requirement that regulations have a scientific basis⁴⁴ is the key difference between the *TBT Agreement* and its counterpart dealing with sanitary and phytosanitary measures — the *SPS Agreement*.

C SPS Agreement

Whereas the *TBT Agreement* applies generally to technical regulations, the *SPS Agreement* focuses on a specific class of potential non-tariff barriers to trade known as ‘SPS measures’.⁴⁵ 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.⁴⁶ 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.⁴⁷ In acknowledgement of this diversity, the *SPS Agreement* seeks to regulate the way that SPS measures are set, rather than imposing uniform levels of protection or specifying the type of measures chosen to implement SPS goals.⁴⁸ Although recognising that Members have the ‘right’ to determine their ‘appropriate level’ of SPS protection,⁴⁹ the *SPS Agreement*, like the *TBT Agreement*, promotes harmonisation of divergent national SPS measures by reference to international standards. Where Members’ measures

⁴¹ 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: Gabrielle Marceau and Joel 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 *Journal of World Trade* 811, 825–6.

⁴² *TBT Agreement*, above n 18, art 2.2.

⁴³ *Ibid.*

⁴⁴ Marceau and Trachtman, above n 41, 834–7.

⁴⁵ *SPS Agreement*, above n 15, art 1.1.

⁴⁶ Specific categories of SPS measures are set out in annex A of the *SPS Agreement*: *ibid.*

⁴⁷ 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 Vig and Michael Faure (eds), *Green Giants? Environmental Policies of the United States and the European Union* (2004) 231, 239–48.

⁴⁸ David Victor, ‘The *Sanitary and Phytosanitary Agreement* of the World Trade Organization: An Assessment after Five Years’ (2000) 32 *New York University Journal of International Law and Politics* 865, 882–3, 913–14.

⁴⁹ *SPS Agreement*, above n 15, art 3.3.

adopt appropriate international standards, they are presumed to be consistent with the *SPS Agreement* and the *GATT 1994*.⁵⁰

Measures not based on international standards must comply with scientific, trade-related and procedural requirements in order 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’.⁵¹ Specifically, they must be ‘based on’ a scientific risk assessment.⁵² 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 risk assessment and reviews the measure ‘within a reasonable period of time’.⁵³

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,⁵⁴ or require different levels of protection in situations of comparable risk.⁵⁵ Furthermore, SPS measures may not be more trade-restrictive than necessary to achieve the appropriate level of SPS protection chosen by the Member.⁵⁶ Like TBT regulations, SPS measures must also satisfy publication and notification requirements to ensure transparency.⁵⁷ In addition, related approval procedures must comply with timeline requirements.⁵⁸

Although the *SPS Agreement* and the *TBT Agreement* initially received relatively little attention, commentators increasingly view their requirements as a significant constraint on domestic regulatory autonomy. The *SPS Agreement* has been subject to the greatest share of censure, due to the role it grants science and scientific risk assessments in justifying trade-restrictive health and environmental laws.⁵⁹ (Amicus curiae submissions in the *EC — GMO* dispute also suggest that

⁵⁰ 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*, opened for signature 6 December 1951, 150 UNTS 67 (entered into force 3 April 1952): at annex A [3].

⁵¹ *SPS Agreement*, above n 15, art 2.2.

⁵² Ibid art 5.1.

⁵³ Ibid art 5.7. In the *Beef Hormones Appellate Body Report*, 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 (*SPS Agreement* art 3.3): *Beef Hormones Appellate Body Report*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB-1997-4 (1998) [29].

⁵⁴ *SPS Agreement*, above n 15, art 2.3.

⁵⁵ Ibid art 5.5.

⁵⁶ Ibid art 5.6.

⁵⁷ Ibid art 7, annex B.

⁵⁸ Ibid art 8, annex C.

⁵⁹ See, eg, 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, 126; Anne Orford, ‘Globalization and the Right to Development’ in Philip Alston (ed), *Peoples’ Rights* (2001) 127, 161–2; Christian Joerges and Jürgen Neyer, ‘Politics, Risk Management, World Trade Organisation Governance and the Limits of Legalisation’ (2003) 30 *Science and Public Policy* 219; Vern Walker, ‘Keeping the WTO from Becoming the “World Trans-Science Organization”’: Scientific Uncertainty, Science Policy and Fact-Finding in the Growth Hormones Dispute’ (1998) 31 *Cornell International Law Journal* 251.

this practice is fraught with ‘interpretive hazards’.⁶⁰ Commentators 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.⁶¹

III EU REGULATORY SYSTEM FOR APPROVING GMOs

The Members of the EU, like many other countries around the world, have adopted a special regulatory regime to deal with the potential health and environmental risks posed by products of biotechnology.⁶² These requirements are often described as ‘precautionary’ because they cite scientific uncertainty surrounding GMO risks as a reason for a cautious regulatory approach.⁶³ The EU’s GMO regulations apply equally to entities within the EU seeking the approval of particular GMOs and 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 Part briefly describes the evolution of approval procedures operating under this framework — a key aspect of the dispute.

A Evolution of GMO Regulation in the EU

The first generation of EU regulation for GMOs, 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’.⁶⁴ The latter goal is consistent with the requirements of the treaties establishing the EC, which require EU environmental policy to be based on the

⁶⁰ Expert Group Brief, above n 13, 15–19.

⁶¹ Victor, above n 48, 923.

⁶² Heike Baumüller, ‘Domestic Import Regulations for Genetically Modified Organisms and their Compatibility with WTO Rules’ (2004) 6(3) *Asian Biotechnology and Development Review* 33, 34.

⁶³ 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: UN Environment Program, *Rio Declaration on Environment and Development*, annex, UN Doc A/CONF.151/26REV.1 (3–14 June 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: see, eg, James Cameron and Juli 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) 29, 36–50; Nicolas de Sadeleer, *Environmental Principles: From Political Slogans to Legal Rules* (2002) 97, 318–19. Others disagree: see, eg, Sonia Boutillon, ‘Precautionary Principle: Development of an International Standard’ (2002) 23 *Michigan Journal of International Law* 429, 447, 469.

⁶⁴ EC Submission, above n 2, [133]. The EC’s GMO legislation takes the form of Directives, which Member States must implement through domestic legislation, and Regulations, which are directly applicable throughout the EU: at [132]–[139].

precautionary principle.⁶⁵ The original *Council Directive 90/220/EEC* provided the key procedure for authorising the deliberate release of GMOs into the environment, which extended to the marketing of GMOs.⁶⁶ A second legislative act, *Council Regulation 258/97*, established an approval process for novel foods, including those containing GMOs.⁶⁷ While this process largely replicated *Council Directive 90/220/EEC*, a key difference was that a more streamlined procedure applied to GM foods and food ingredients that were ‘substantially equivalent’ to existing foods.⁶⁸

According to the submissions of the EC in the *EC — GMO* dispute, increased scientific knowledge regarding the risks of GMOs and international regulatory developments, including the conclusion of the *Biosafety Protocol*,⁶⁹ led to legislative reform in 2001.⁷⁰ *Council Directive 2001/18/EC* repealed *Council Directive 90/220/EEC* but kept its authorisation procedure and overall aim of protecting human health and the environment.⁷¹ Key changes implemented in the new directive included:⁷²

- elaboration of a detailed set of principles required to be considered in environmental risk assessments;
- 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;⁷³ and
- a requirement that the aspiring marketer of the GMO performs its own risk assessment prior to submitting an application for approval.

The *EC — GMO* dispute straddles the first and second regulatory eras, involving applications for authorisation made under *Council Directive 90/220/EEC*, *Council Directive 2001/18/EC* and *Council Regulation 258/97*.⁷⁴

⁶⁵ The EU first explicitly recognised the precautionary principle in the *Maastricht Treaty: Treaty on European Union*, opened for signature 7 February 1992, [1992] OJ C 224, 1 (entered into force 1 November 1993) art 174(2). For an overview of the history and current status of the precautionary principle in Europe, see, generally, José Luís da Cruz Vilaça, ‘The Precautionary Principle in EC Law’ (2004) 10 *European Public Law* 369.

⁶⁶ [1990] OJ L 117/15. *Council Directive 90/220/EEC* dealt with both placing GMOs on the market and their deliberate release into the environment.

⁶⁷ [1997] OJ L 43/1.

⁶⁸ *Council Regulation 258/97* [1997] OJ L 43/1 preamble [2]. 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 95/93* [1993] OJ L 14/1.

⁶⁹ Above n 20.

⁷⁰ EC Submission, above n 2, [94]–[112], [155].

⁷¹ [2001] OJ L 106/1; EC Submission, above n 2, [136].

⁷² 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 *Review of European Community and International Environmental Law* 309.

⁷³ *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, for example, in the development of multiple herbicide resistance.

B *Approval Process for GMOs*

Without being approved, GMOs and products containing GMOs may not be marketed or otherwise released into the EU environment. Once given, however, an approval is valid throughout the EU.⁷⁵ The GMO regulatory framework thus seeks to balance the need for individual EU Members to retain some decision-making control over matters of domestic concern, with the principle of harmonising regulations throughout the EU to ensure the free movement of goods. The resulting regulatory requirements applied to GMO approvals are complex enough to have earned the label of a ‘Gordian knot’.⁷⁶

The main elements of the GMO approval procedure established under *Council Directive 90/220/EEC* and *Council Directive 2001/18/EC* are summarised in Figure 1 below. The first stage of the process involves the applicant submitting a dossier on the new GMO to the relevant assessment body of a Member, which evaluates the potential for the release to give rise to adverse effects on human health or the environment.⁷⁷ Where this assessment is favourable, the assessment body concerned distributes its assessment report to the European Commission — effectively the executive branch of the EU regulatory structure — and to other national assessment bodies to allow for comments and requests for further information.⁷⁸ This can lengthen the procedure considerably. If, following this process, no Member objects to the application, the matter is returned to the initiating national assessment body for approval and a decision on any applicable conditions relating to the release.⁷⁹

Where objections that cannot be resolved are raised by one or more Members, the application is referred to the Scientific and Regulatory Committees for their opinion on the matter.⁸⁰ The Scientific Committee draws on the expertise of independent scientists but serves an advisory role only.⁸¹ On the other hand, the Regulatory Committee is made up of representatives of Members and has a more substantial role to play in the process. A favourable opinion from this committee results in the authorisation of the release of the GMO.⁸² However, where the

⁷⁴ 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 and 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 *European Law Journal* 555.

⁷⁵ EC Submission, above n 2, [141].

⁷⁶ Joel Andriantsimbazoniva, ‘Le CE et le principe de précaution, l’affaire du maïs transgénique’ [1999] *Droit administratif* 4, as cited in Brosset, above n 74, 559.

⁷⁷ *Council Directive 2001/18/EC* [2001] OJ L 106/1, annex VI.

⁷⁸ *Council Directive 2001/18/EC* [2001] OJ L 106/1, art 14.

⁷⁹ *Council Directive 2001/18/EC* [2001] OJ L 106/1, art 15(3).

⁸⁰ *Council Directive 2001/18/EC* [2001] OJ L 106/1, art 18.

⁸¹ *Council Directive 2001/18/EC* [2001] OJ L 106/1, art 28.

⁸² EC Submission, above n 2, [153].

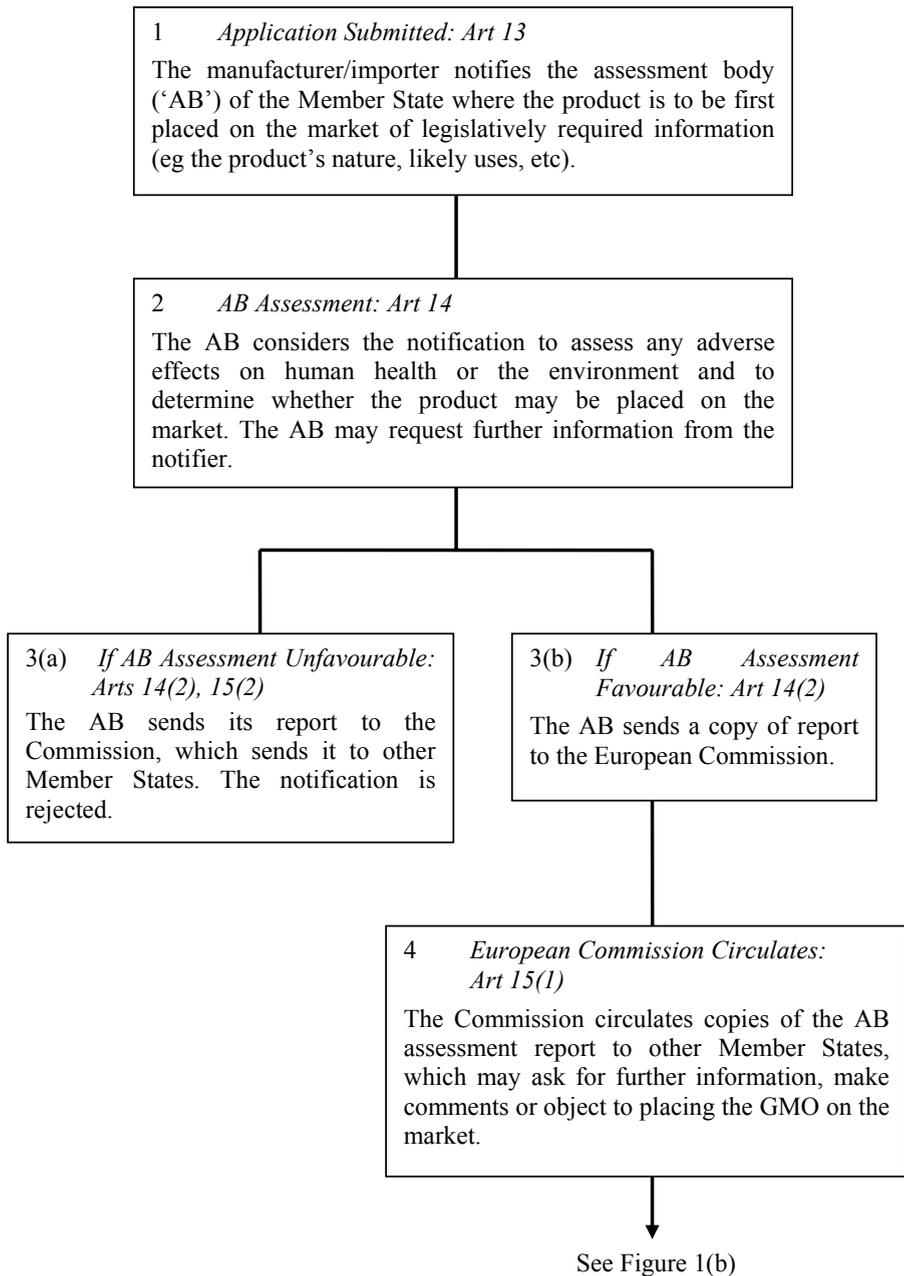


FIGURE 1(a): *Summary of the regulatory approval process for GMOs under Directive 2001/18/EC*

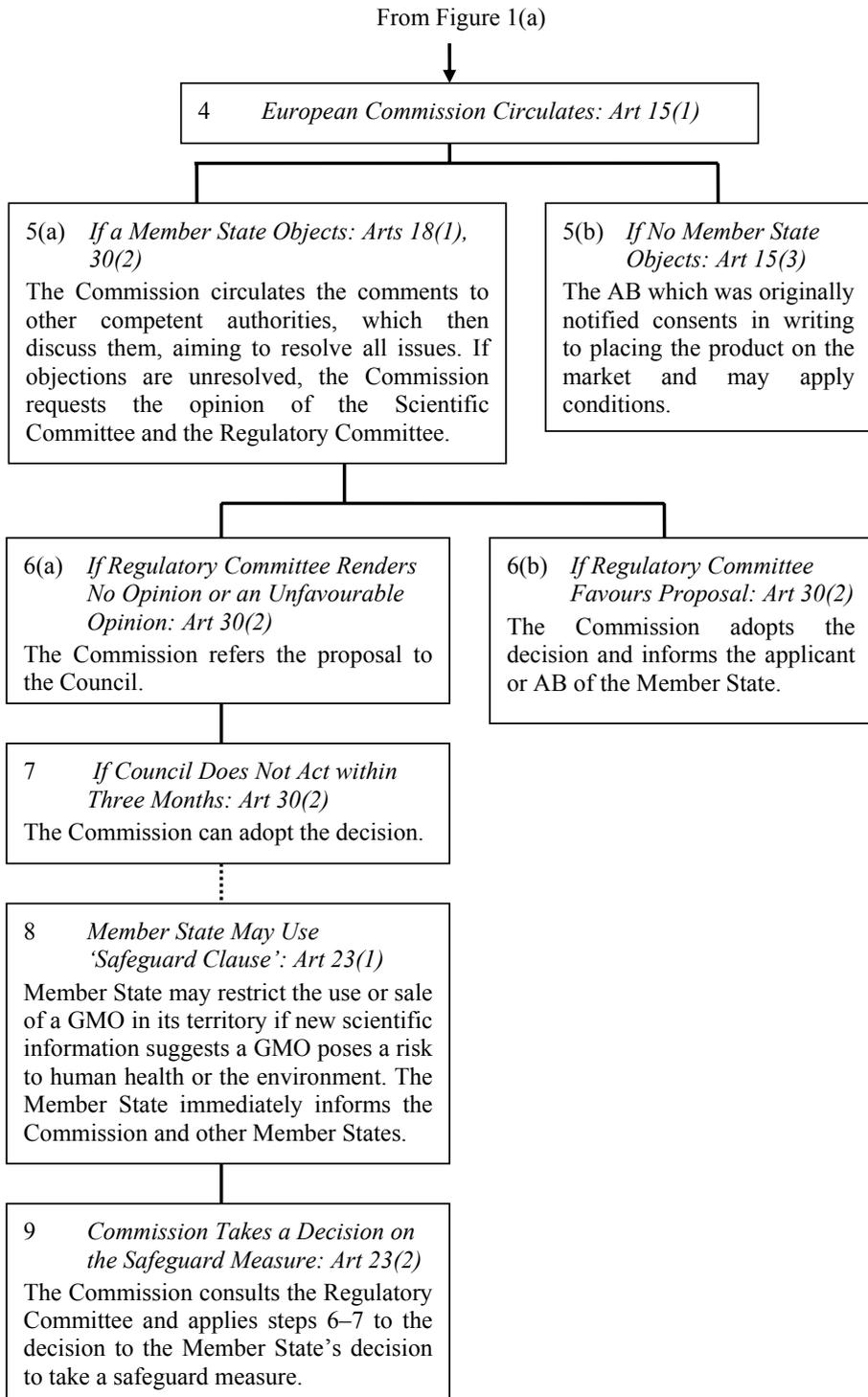


FIGURE 1(b): Summary of the regulatory approval process for GMOs under Directive 2001/18/EC

Regulatory Committee delivers an unfavourable opinion or fails to deliver any opinion, the matter goes to the highest political level for a decision by the Council of the EU. If the Council does not make a decision on the application within a three month timeframe, the matter returns to the Commission for decision.⁸³ Even if a product is finally approved by the Commission, Members may still institute ‘safeguard measures’ to prohibit marketing of the GMO in their territories.⁸⁴ This power can only be exercised by Members 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.⁸⁵

From October 1998 until the time the *EC — GMO* dispute was initiated, the approval process under the EU’s GMO regulatory framework had effectively ground to a halt. No new approvals were issued until very recently⁸⁶ and applications already within the regulatory system have experienced significant delays.⁸⁷ In addition, six EU Member States — Austria, France, Germany, Greece, Italy and Luxembourg — have instituted ‘safeguard measures’ to prohibit the marketing or import of GM products already approved under EC legislation.⁸⁸

The complainants in the *EC — 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 GMOs.⁸⁹ 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 Members.⁹⁰ In reply, the EC denies the existence of a general moratorium and the stalling of individual applications.⁹¹ The EC claims that although legislative changes embracing a more ‘precautionary approach’ have

⁸³ Ibid.

⁸⁴ Ibid [154].

⁸⁵ Ibid [179].

⁸⁶ Since May 2004, the European Commission has approved 17 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* (Brussels, Belgium), 1 December 2004, 407.

⁸⁷ The US alleges that 18 notifications for placing GM products on the market have been delayed under *Council Directive 90/220/EEC* (and then resubmitted under *Council Directive 2001/18/EC*) and that nine applications under *Regulation 258/97* have been delayed: US Submission, above n 11, [48]–[55]. Canada alleges four such delays: Canadian Submission, above n 10, [68]–[94].

⁸⁸ 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 EC Submission, above n 2, [339]–[361].

⁸⁹ 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, press releases and statements by EC officials: see Canadian Submission, above n 10, [45]–[67]; US Submission, above n 11, [34]–[45].

⁹⁰ US Submission, above n 11, [57]–[63]. Canada only seeks to challenge the measures of Austria, France, Greece, and Italy: Canadian Submission, above n 10, [95]–[137].

⁹¹ The EC argues that statements used as evidence of a general moratorium refer instead to a transition approach which applied during legislative changes or a ‘precautionary approach to individual applications’: EC Submission, above n 2, [197]–[198].

necessarily slowed the process, they are justifiable in light of evolving science and the inadequacies of the original applications.⁹² It explains the national safeguard measures as the result of national disagreement with Community-level risk assessments, reflecting different levels of risk considered ‘acceptable’ by individual Members.⁹³

IV SUBMISSIONS BEFORE THE PANEL

An underlying theme of the submissions before the WTO Panel in the *EC — 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 human health and the environment which are presently beyond the ability 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.⁹⁴ The EC also raises the potential for adverse effects on the environment if insecticidal GM plants harm ‘non-target’ organisms such as butterflies, become invasive weeds or give rise to altered farm management practices, with cumulative impacts on biodiversity.⁹⁵ Likewise, the amicus curiae briefs submitted to the Panel stress the issue of scientific uncertainty associated with gene technology and the potential for adverse effects on humans, animals, plants and the environment.⁹⁶

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 not supported by ‘sufficient scientific evidence’ and a rigorous risk assessment.⁹⁷ 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.⁹⁸ It argues that its regulatory approach is not unique and is supported by international instruments including the *Biosafety Protocol*,⁹⁹ which the EC believes should influence the interpretation of WTO agreements.¹⁰⁰

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 different models of risk regulation — ‘science-based’ and ‘precaution-based’ — which respond differently to the problem of limited scientific knowledge about the health and

⁹² Ibid. 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): at [547]–[549], [562], [564].

⁹³ Ibid [339].

⁹⁴ Ibid [39]–[50].

⁹⁵ Ibid [51]–[63].

⁹⁶ Amicus Coalition Brief, above n 13, [8]–[39]; Environment Group Brief, above n 13, [18]–[33].

⁹⁷ Canadian Submission, above n 10, [177]–[179]; US Submission, above n 11, [109]–[111].

⁹⁸ EC Submission, above n 2, [71]–[75].

⁹⁹ Ibid [90], [98], [107], [111].

¹⁰⁰ Ibid [112].

environmental risks of many human activities and new technologies.¹⁰¹ The science-based model embodies the idea that risk regulation, including the way in which it deals with scientific uncertainty, should be founded on 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 an inclusive and deliberative decision-making process.¹⁰² In the *EC — GMO* dispute, the clash of these approaches is evident in the parties' arguments over the extent to which GMO regulations are construed as SPS measures and must therefore 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 been the subject of intense debate in a 'trade and environment' sense. These include:

- the appropriate characterisation of GMO laws and whether they are 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;
- 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 complainants' submissions differ in style and content,¹⁰³ they coincide in their primary challenge to the EC's measures as a breach of its obligations under the *SPS Agreement*. They argue that each of these measures affects international trade by effectively blocking the importation of GM products.¹⁰⁴ 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 should properly be construed as 'measures' taken for

¹⁰¹ Andreas Klinke and Ortwin Renn, 'A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies' (2002) 22 *Risk Analysis* 1071, 1074.

¹⁰² Sheila Jasanoff, 'Between Risk and Precaution — Reassessing the Future of GM Crops' (2000) 3 *Journal of Risk Research* 277, 281.

¹⁰³ Canada makes subsidiary arguments under the *GATT 1994* and the *TBT Agreement*, the content of which is similar to its SPS contentions: Canadian Submission, above n 10, [320], [321], [327]–[328]. The US arguments instead focus primarily on alleged breaches of the *SPS Agreement*: US Submission, above n 11, [4].

¹⁰⁴ Canadian Submission, above n 10, [388]; US Submission, above n 11, [85], [165].

‘sanitary or phytosanitary’ purposes.¹⁰⁵ The complainants’ approach is to argue that the EC’s GMO regulatory framework is a SPS measure and that the acts in question, as components of this structure, are by extension SPS measures.¹⁰⁶ The US submission, in particular, claims that the EC’s GMO regulatory framework is a SPS measure because it aims to address the SPS objectives of protecting animal or plant life or health, or the environment, from risks arising from disease-causing organisms,¹⁰⁷ contaminants, toxins,¹⁰⁸ or the spread of pests.¹⁰⁹

The EC’s submissions regarding the applicability of the *SPS Agreement* reflect a very different conception 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*. Therefore, these non-SPS ‘measures’ cannot be inconsistent with the *SPS Agreement*.¹¹⁰ The EC’s submissions — to the extent that they concede that their GMO regulations should be assessed by any of the WTO agreements — suggest that the most relevant obligations for this purpose are those arising under the *GATT 1994*¹¹¹ and the *TBT Agreement*.¹¹² The EC 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’.¹¹³

¹⁰⁵ See *SPS Agreement*, above n 15, art 1.1.

¹⁰⁶ The complainants have also made extensive arguments that a ‘moratorium’ can be considered a ‘measure’ for these purposes. Essentially they contend that measures need not be embodied in a single written document but can be an unwritten procedure setting out general rules or ‘an act or omission of a non-binding or non-mandatory administrative nature’: Canadian Submission, above n 10, [155]; see also US Submission, above n 11, [82]–[83].

¹⁰⁷ *SPS Agreement*, above n 15, annex A [1(a)]. The US argues this on the basis of possible allergic or toxic reactions in non-target animals: US Submission, above n 11, [78].

¹⁰⁸ *SPS Agreement*, above n 15, annex A [1(b)]. This is argued on the basis of the potential development of antibiotic-resistant bacteria and human allergic or toxic reactions: US Submission, above n 11, [78]–[79].

¹⁰⁹ *SPS Agreement*, above n 15, annex A [1(d)]. This is argued on the basis of the development of herbicide-resistant weeds: US Submission, above n 11, [79].

¹¹⁰ The EC lists nine such non-SPS measures: EC Submission, above n 2, [419]–[432]. An example of a non-SPS risk to which the EC’s GMO regulatory framework is directed is the risk of modified genes producing allergens, as allergies are not ‘diseases’ under annex A [1(b)] of the *SPS Agreement*: EC Submission, above n 2, [427].

¹¹¹ The EC argues that as mere delays, the alleged product-specific bans are not covered by the *GATT 1994*. Moreover, they do not violate art III:4 as the applications were submitted by companies incorporated in the EC and they covered cultivation in the EC as well as import: EC Submission, above n 2, [525], [529]–[532], [628]–[637].

¹¹² 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 administrative acts rather than abstract, normative rules setting product characteristics. It also briefly argues that any violation of a *TBT Agreement* provision is justified as an exception under *GATT 1994* art XX, and does not constitute ‘arbitrary or unjustifiable discrimination between countries where the same conditions prevail or disguised restrictions on international trade’: EC Submission, above n 2, [644]–[651], [674].

¹¹³ *Biosafety Protocol*, above n 20, art 1.

B 'Product/Process' Distinctions and Differences in 'Levels of Protection'

An important aspect of the Canadian submissions in the *EC — GMO* 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.¹¹⁴ Along these lines, Canada argues that the EC's product-specific marketing bans and national safeguards¹¹⁵ 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.¹¹⁶

The process/product debate is a well-worn path in the 'trade and environment' literature that turns upon the meaning of the concept of 'like products' in WTO agreements such as the *GATT 1994* and the *TBT Agreement*.¹¹⁷ The Canadian arguments suggest that GM and non-GM products are 'like' in product terms and so cannot be treated differently under regulatory schemes.¹¹⁸ For its part, the EC strenuously denies the argument that non-GM and GM products are 'like', pointing to international recognition of the different nature of products produced using processes of gene technology.¹¹⁹ It contends that special procedures applied by its regulatory framework to GMOs are justified because GM and non-GM products are 'objectively different'.¹²⁰ 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'.¹²¹

The complainants' submissions not only question distinctions in the EC regulatory scheme between GM and non-GM but also distinctions between different types of GM products. The latter line of argument relies on the controversial provision in the *SPS Agreement* indicating that 'comparable' risks should be regulated in a 'similar' fashion — differential treatment of products posing 'comparable' risks being classified as discrimination.¹²² In the view of the US, the EC's GMO regulatory framework applies unjustifiably different SPS

¹¹⁴ Canadian Submission, above n 10, [320].

¹¹⁵ Canada makes a separate argument in relation to the Greek national safeguard under *GATT 1994* art XI:1: *ibid* [471]–[472].

¹¹⁶ *Ibid* [320]–[321].

¹¹⁷ See, eg, discussions in Won-Mog Choi, 'Like Products' in *International Trade Law: Towards a Consistent GATT/WTO Jurisprudence* (2003) 14–21; Daniel Esty, *Greening the GATT: Trade, Environment and the Future* (1994) 36, 101.

¹¹⁸ Canada argues that GMOs and their non-GM counterparts are 'like products' since they are intended to be used interchangeably, are virtually physically identical and share the same tariff classification, and because consumer preferences do not conclusively show a difference between them: Canadian Submission, above n 10, [320].

¹¹⁹ EC Submission, above n 2, [535], [655].

¹²⁰ *Ibid* [535], [621], [655]. 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: at [90]. In the alternative, the EC briefly argues that any violation of obligations with respect to 'like products' is justified as an exception under *GATT 1994* art XX: at [674].

¹²¹ 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.

¹²² *SPS Agreement*, above n 15, 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 *Risk Analysis* 483, 484.

protection levels for GM products and foods compared with products produced with GM processing aids. They argue that the latter are ‘similar’ to other GM products since they may contain the same substances but are not regulated by the EC.¹²³ 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.¹²⁴

The EC’s response to these arguments reflects a more complex conception of GM products, which purports to take into account 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 Members.¹²⁵ 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 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 the resolution of the *EC — 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’¹²⁶ in the EC approval processes for GMOs¹²⁷ and a lack of ‘transparency’¹²⁸ in respect of its regulatory requirements.¹²⁹ Underlying these claims is a concern that the EC’s regulatory processes are not being used 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 focus on EC procedure, the reasons put forward by the EC and the amicus curiae submissions justifying the delay and lengthy processing times raise larger issues, such as the relevance of the precautionary principle in the WTO context. In the *Beef*

¹²³ US Submission, above n 11, [118], [121].

¹²⁴ For example, the complainants point to the disproportionate effect of the regulations on non-EC producers as compared to those in the EC: *ibid* [125]–[126]. Arguments in the US submission dealing with product-specific moratoria are found at [152]. The Canadian submissions also present arguments on this issue: Canadian Submission, above n 10, [271]–[287]. 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: at [206]–[211]. Canada alone poses these arguments in relation to the national safeguard measures: at [417].

¹²⁵ EC Submission, above n 2, [620]. These arguments are raised as an alternative to the EC’s primary defence that its safeguard measures are ‘provisional measures’ under art 5.7 of the *SPS Agreement* and so are not subject to obligations under art 5.5 of that *Agreement*: at [618].

¹²⁶ *SPS Agreement*, above n 15, annex C [1(a)].

¹²⁷ Canadian Submission, above n 10, [238]–[239]; US Submission, above n 11, [89]–[90], [138].

¹²⁸ *SPS Agreement*, above n 15, annex B.

¹²⁹ Canadian Submission, above n 10, [246]; US Submission, above n 11, [96]–[97], [141].

Hormones case, the WTO Appellate Body ruled that the precautionary principle cannot be relied upon by Members to excuse non-compliance with their 'black letter obligations' under WTO agreements such as the *SPS Agreement*.¹³⁰ However, the scope for a 'precautionary approach' to apply to the implementation of a Member's WTO obligations where there are 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.¹³¹ 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.¹³² 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'.¹³³

The precautionary principle also comes to the fore in the *amicus curiae* submissions, which support the EC's claim that lengthy delays in its approval process are justified in the circumstances. The Environment Group Brief argues that the uncertainty involved in evaluating the risks posed by GMOs is currently 'so substantial that it impedes any adequate consideration of those risks'.¹³⁴ The Environment Group contends that delays were necessary during a period of national and international regulatory change¹³⁵ and allowed the EC to seek further information about GMO risks, including consideration of the United Kingdom Farm-Scale Evaluations and public opinion.¹³⁶ 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 of the WTO agreements but the *Biosafety Protocol*.¹³⁷ Under the *Biosafety Protocol*, parties are required to apply special risk assessment, notification and consent procedures for

¹³⁰ *Beef Hormones Appellate Body Report*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB-1997-4 (1998) [29]-[30].

¹³¹ EC Submission, above n 2, [604]-[605]. An adequate risk assessment in the EC's view 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': at [604].

¹³² *Ibid* [606]-[608].

¹³³ *Ibid* [615].

¹³⁴ Environment Group Brief, above n 13, [45]; Expert Group Brief, above n 13, 29-30.

¹³⁵ Amicus Coalition Brief, above n 13, [107]-[112].

¹³⁶ Expert Group Brief, above n 13, 31.

¹³⁷ EC Submission, above n 2, [454]-[455].

'transboundary movements' of GMOs,¹³⁸ which are similar to those in international environmental treaties dealing with hazardous wastes.¹³⁹ The *Biosafety Protocol* also makes provision for the consideration of socioeconomic 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.¹⁴⁰ The EC draws parallels between the approaches of the *Biosafety 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.

The Panel may give these arguments short shrift on the basis that its competence is limited to determining compliance with the WTO agreements. In any event, not all of the WTO Members concerned in the dispute are parties to the *Biosafety Protocol*.¹⁴¹ However, a question remains about the extent to which international treaties outside the WTO regime can or should influence the decisions of the panels and the Appellate Body. In the post-Uruguay Round era, the Appellate Body acknowledges that international trade law cannot be considered 'in clinical isolation' from the rest of public international law, including the law dealing with health and environmental concerns.¹⁴² However, the more difficult issue is whether the dispute settlement bodies should undertake the task of deciding the appropriate relationship between the trade and environmental obligations of Members in circumstances where they come into conflict, especially where not all parties to the 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.¹⁴³ 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

¹³⁸ Above n 20, arts 8, 10, 15.

¹³⁹ See, eg, *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal*, opened for signature 22 March 1989, 1673 UNTS 57 (entered into force 5 May 1992); *Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*, opened for signature 10 September 1998, (1999) 38 ILM 1 (entered into force 24 February 2004).

¹⁴⁰ Above n 20, arts 10(6), 11(8).

¹⁴¹ None of the complainants are parties to the *Biosafety Protocol*, raising an issue about the relationship that may exist between the provisions of this multilateral environmental agreement and the WTO Agreements. This general issue has been extensively discussed in the literature: see, eg, Eckersley, above n 14, 41–2; Peter Phillips and William Kerr, 'Alternative Paradigms: The WTO versus the *Biosafety Protocol* for Trade in Genetically Modified Organisms' (2000) 34 *Journal of World Trade* 63, 65–6; Winham, above n 8, 132.

¹⁴² *United States — Standards for Reformulated and Conventional Gasoline*, WTO Doc WT/DS2/AB/R, AB–1996–1 (1996) 17 (Report of the Appellate Body).

¹⁴³ Canadian Submission, above n 10, [192]–[194]; US Submission, above n 11, [109]–[111].

evidence' and 'based on' an acceptable form of risk assessment.¹⁴⁴ In previous SPS case law, it has been held that measures are only 'based on' scientific evidence when there is a 'rational relationship' between the measure and the underlying scientific material or assessment of risk.¹⁴⁵ The complainants argue that there is no evidence of any risk assessment justifying the general moratorium or the national safeguards.¹⁴⁶ Moreover, they claim 'positive' scientific risk assessments for many of the disputed GM products demonstrate an 'irrational relationship' between these assessments and the product-specific moratoria.¹⁴⁷

The EC, on the other hand, views the roles of science and scientific risk assessment in regulation as being much more fluid. It considers that the need to carry out a risk assessment, and the nature of that assessment, varies according to the level of scientific uncertainty. Therefore, 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',¹⁴⁸ rendering a risk assessment unnecessary as a basis for national safeguard provisions.¹⁴⁹ Alternatively, the EC contends that safeguard measures are 'based on' other risk assessments, albeit not the Members' own, as the latter did not find unacceptable risks associated with specific products.¹⁵⁰ 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'.¹⁵¹

The EC's view of the role of risk assessment in health and environmental regulation is supported by the amicus curiae submission of a group of well-known and respected professors of social science.¹⁵² The group urges a broader understanding of risk assessment that accepts normative elements as both a desirable and unavoidable component of evaluating health and environmental risk.¹⁵³ They argue that value judgements influence the data and methods used in

¹⁴⁴ *SPS Agreement*, above n 15, art 2.2. The complainants argue that 'based on' is an acceptable form of risk assessment: Canadian Submission, above n 10, [178]–[179] [192]–[194]; US Submission, above n 11, [98]–[111]. 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, AB–1998–5 (1998) [121] (Report of the Appellate Body) and *Beef Hormones Appellate Body Report*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB–1997–4 (1998) [183]–[184].

¹⁴⁵ *Beef Hormones Appellate Body Report*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB–1997–4 (1998) [193]; *Japan — Measures Affecting Agricultural Products*, WTO Doc WT/DS76/AB/R, AB–1998–8 (1999) [84] (Report of the Appellate Body).

¹⁴⁶ Canadian Submission, above n 10, [260]; US Submission, above n 11, [105], [170].

¹⁴⁷ Canadian Submission, above n 10, [261], [269]; US Submission, above n 11, [147].

¹⁴⁸ EC Submission, above n 2, [574], [590], [591].

¹⁴⁹ 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 that there was a violation of this provision: *ibid* [594].

¹⁵⁰ *Ibid* [610].

¹⁵¹ *Ibid*.

¹⁵² Expert Group Brief, above n 13.

¹⁵³ The Expert Group highlights that public participation is both scientifically and politically important to risk assessment and to defining what is 'at risk' in any case: *ibid* 17–19.

risk assessment, leading to different estimates of risk.¹⁵⁴ Furthermore, the cultural and political context influences 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.¹⁵⁵ Differences in national regulatory approaches to GMOs are also explained by factors such as the evolving nature of GMO risk assessments, the need to assess GMO risks locally due to ecological differences¹⁵⁶ and the inclusion of non-quantitative factors and public deliberation in risk assessments.¹⁵⁷

While the differences between the parties are framed in terms of the provisions of the *SPS Agreement* requiring ‘sufficient scientific evidence’ as the basis of regulation when assessing risk, the Expert Group Brief 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, which were discussed above. For example, the EC’s contention that a precautionary approach justifies regulatory delays is premised on a more general view that risk regulation should contain measures to provide for the occurrence of ‘unexpected’ adverse outcomes, rather than relying on scientific tools to contain and manage uncertainties within risk assessment processes.¹⁵⁸ Likewise, the EC’s 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 to the science-focused approach reflected by the *SPS Agreement*. For their part, the complainants’ arguments highlight the potential inconsistencies between a broad concept of risk regulation and the structures of the institutional context in which it must be implemented.¹⁵⁹ This includes 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 *EC — GMO* dispute not only promises a lengthy dispute settlement process in the WTO but also far-reaching implications for international trade law and its relationship with domestic health and environmental risk regulatory regimes. The parties’ submissions have raised issues concerning the relationship between trade and environmental laws that

¹⁵⁴ Ibid 14. This view is supported by another amicus curiae 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: Amicus Coalition Brief, above n 13, [99]–[106].

¹⁵⁵ Expert Group Brief, above n 13, 15–17, 20.

¹⁵⁶ Ibid 22–3.

¹⁵⁷ Ibid 24–6.

¹⁵⁸ Klinke and Renn, above n 101, 1074.

¹⁵⁹ See Elizabeth Fisher, ‘Precaution, Uncertainty and Principles of Good Administration’ (Paper presented at the International Symposium on Uncertainty and Precaution in Environmental Management, Copenhagen, Denmark, 7–9 June 2004) 2–3.

have proved to be among the most intractable in intergovernmental negotiations.¹⁶⁰ 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 raised by the *EC — GMO* dispute regarding the role of science and risk assessment in regulating health and environmental threats that are likely to have the most far-reaching 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 about the most appropriate approach to health and environmental regulation in a global society increasingly focused on issues of ‘risk’ and the limitations of scientific knowledge to characterise and predict such risks with accuracy.¹⁶¹ 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 in dealing with uncertain risks in order to ensure health and environmental protection over the long-term. In the *EC — GMO* dispute, the 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.

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 diversity¹⁶² and clearly sees its role as limited to assessing the compliance of government measures with the specific obligations established under WTO law. However, the framework that these obligations establish — particularly that of the *SPS Agreement* — offers the WTO dispute settlement bodies little flexibility to accommodate models of health and environmental risk regulation that are not based on scientific assessment. The amicus curiae 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.¹⁶³ This would enable WTO Members to take into account a broader range of information in decision-making than purely the advice of scientific experts.¹⁶⁴ The feasibility and fairness of an approach that would open up supranational risk regulatory review processes to a range of value and policy judgments is less apparent in the international context, where normative goals of

¹⁶⁰ These are matters currently under negotiation by WTO Members in the Doha Round: *Ministerial Declaration*, WTO Doc WT/MIN(01)/DEC/1 (14 November 2001).

¹⁶¹ Ulrich Beck, *Risk Society: Towards a New Modernity* (Mark Ritter trans, first published 1986, 1992 ed) 30 [trans of: *Risikogesellschaft: Auf den Weg in eine andere Moderne*].

¹⁶² *Beef Hormones Appellate Body Report*, WTO Doc WT/DS26/AB/R, WT/DS48/AB/R, AB-1997-4 (1998) [124].

¹⁶³ Expert Group Brief, above n 13, 39–40.

¹⁶⁴ *Ibid* 40.

health and environmental policy are frequently not shared by all countries.¹⁶⁵ Moreover, a thorny question remains to be dealt with in considering which international bodies would have the necessary ‘legitimacy’ to make decisions about the values promoted by the international community 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 and the amicus curiae briefs in the *EC — 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’.¹⁶⁶

¹⁶⁵ Jacqueline Peel, ‘Risk Regulation under the WTO *SPS Agreement*: Science as an International Normative Yardstick?’ (Working Paper No 02/04, Jean Monnet Program, New York University School of Law, 2004) 63.

¹⁶⁶ EC Submission, above n 2, [10].