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Post-normal science in the multilateral trading system: social science expertise and the *EC–Biotech* Panel

MARY E. FOOTER*
School of Law, University of Nottingham

Abstract: The recent *EC–Biotech* case highlights the emerging regulatory divide between WTO Members and reveals a deepening crisis over issues of science and governance in the world trading system. This article focuses on the potential role that social science expertise might play as an analytical tool in understanding trade disputes involving scientific expertise relating to matters of risk assessment and polycentric decision-making. Particular consideration is given to the paradigm of 'post-normal' science, which pertains in situations where competent national authorities have to frame and implement policies before all the (scientific) facts are known. As the *amicus curiae* brief by a group of five social scientists before the *EC–Biotech* Panel demonstrates, where there is a high degree of scientific uncertainty, as in the case of GM products, post-normal science can offer a valuable means of framing the dispute in a broader societal context than the sound science approach, which is used to assess health, safety, and environmental risks under the SPS Agreement.

1. Introduction

The recent WTO case of *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (*EC–Biotech*)[1] reflects two emergent issues. One is the growing interface between international trade law and agro-biotechnology, which is leading to actual or potential conflicts between them. The other is the regulatory polarization, which has been emerging between some WTO Members and has been evident in a line of cases from *European Communities – Measures Concerning Meat and Meat Products* (*EC–Hormones*)[2] onwards.

* Professor of International Economic Law, University of Nottingham; Member of the International Law Association (ILA) Committee on International Trade and the ILA Committee on Biotechnology and International Law. The author is grateful for comments received from an anonymous reviewer.

1 Report of the WTO Panel, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, 21 November 2006, WT/DS291/R, WT/DS292/R, and WT/DS293/R ('*EC–Biotech*').

2 Report of the Appellate Body, *European Communities – Measures Concerning Meat and Meat Products*, 13 February 1998, WT/DS26/AB/R and WT/DS/48/AB/R ('*EC–Hormones*').

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The *EC–Biotech* Panel decision continues this trend and delivers some fascinating insights into the emerging regulatory divide between individual WTO Members. It also highlights a deepening crisis over science and governance in the world trading system. None of the conditions set out in the SPS Agreement[3] on the adoption or maintenance of SPS measures directly limits a WTO Member government from seeking protection for a risk that threatens the health or safety of its citizens.[4] Even so, the application of the Agreement in practice is causing us to question how far and under what circumstances WTO Members may go in asserting the right to protect their citizens and to reappraise the role of social, economic, and political factors in regulatory decision making.

This article examines the potential role for social science expertise in assessing health, safety, and environmental risks under the SPS Agreement and as a means of framing those risks more broadly 'within patterns of human behaviour and social practice'.[5] My starting point is the *amicus curiae* brief by five social scientists that was submitted to the *EC–Biotech* Panel.[6] It forms the basis for analysis and draws on notions of 'post-normal science' that challenge the foundation of sound science upon which much risk assessment is based.

After a brief summary of the factual and legal issues in this dispute, I consider what role social science expertise might play as an analytical tool in understanding trade disputes involving scientific expertise on matters of risk assessment and polycentric decision making. Social science expertise is understood as embracing the concept of 'post-normal' science, which, according to Silvio Funtowicz and Jerome Ravetz, pertains in situations where competent national authorities have to frame and implement policies before all the (scientific) facts are known. More specifically, authorities find themselves in situations where 'facts are uncertain, values in dispute, stakes high and decisions urgent'.[7] Following a short discussion of the different regulatory approaches towards risk analysis that divide the complainant and respondent parties I focus on the *amicus* brief before the Panel in *EC–Biotech* and conclude with some considerations of the potential for social science expertise in WTO cases involving risk and scientific evidence in SPS cases.

3 Agreement on Sanitary and Phytosanitary Measures ('SPS Agreement' or 'SPS'), reprinted in *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* (Geneva: World Trade Organization, 1999) ('*The Legal Texts*'), 69–84.

4 A. T. Guzman, 'Food Fears: Health and Safety at the WTO', 45 *Virginia J. Int'l L* 1 (2004) at 13.

5 D. Winickoff, S. Jasanoff, L. Busch, R. Grove-White, and B. Wynne, 'Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law', 30 *Yale J. Int'l L* 81 (2005) at 98.

6 *Amicus Curiae* Brief, Submitted to the Dispute Settlement Panel of the World Trade Organization in the case of *EC: Measures Affecting the Approval and Marketing of Biotech Products*, authored by L. Busch (Michigan State University), R. Grove-White (Lancaster University), S. Jasanoff (Harvard University), D. Winickoff (Harvard University), and B. Wynne (Lancaster University), 30 April 2004 ('*amicus* brief'). See also, C. E. Foster, 'Social Science Experts and *Amicus Curiae* Briefs in International Courts and Tribunals: the WTO *Biotech* Case', LII *Netherlands International Law Review*, 433 (2005).

7 S. Funtowicz and J. R. Ravetz, 'Three Types of Risk Assessment and the Emergence of Post-Normal Science', in S. Krimsky and D. Golding (eds.), *Social theories of risk* (Westport, CN: Praeger, 1992), 251–274 and S. Funtowicz and J. R. Ravetz, 'Science for a post-normal age', 25(7) *Futures* 739 (1993).

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2. Brief summary of the factual and legal issues in dispute

The factual and legal basis for the *EC–Biotech* case is relatively straightforward. The three complainants – the United States,[8] Canada,[9] and Argentina[10] – all concentrated on two distinct matters. One of those was 'the operation and application by the European Communities of its regime for the approval of biotech products', which can be identified as food or food ingredients containing, consisting of, or produced from genetically modified organisms or GMOs.[11] At the time the complaint was brought against the EC its approval regime consisted of Directive 2001/18/EC (replacing Directive 90/220/EEC) governing the 'deliberate release into the environment of genetically modified organisms' or GMOs (the 'Deliberate Release Directive')[12] and Regulation 258/97/EC regulating 'novel foods and novel food ingredients' (the 'Novel Foods Regulation').[13]

Aside from seeking to protect human health and the environment, the EC's regime for approval of biotech products was an elaborate pre-marketing approval system. The legal instruments that underpinned the approval system contained detailed administrative procedures for corporate entities and others seeking to obtain approval to place a biotech product on the European market and for which an application for approval first had to undergo evaluation.[14]

The other matter concerned 'certain measures adopted and maintained by EC Member States prohibiting or restricting the marketing of biotech products'.[15] Under the Deliberate Release Directive and the Novel Foods Regulation certain EC Member States – Austria, France, Germany, Greece, Italy, and Luxembourg – continued to maintain safeguard measures in respect of biotech products or GMOs that had obtained approval for EC-wide marketing under the EC regime because they considered them to be 'too risky'.[16] Under EC legislation individual EC

8 Request for a panel by the United States, WT/DS291/23 (7 August 2003).

9 Request for a panel by Canada, WT/DS292/17 (7 August 2003).

10 Request for a panel by Argentina, WT/DS293/17 (7 August 2003).

11 Foster, 'Social Science Experts and *Amicus Curiae* Briefs', above n. 6, 438.

12 Council Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, OJ 2001 L 106/1 thereby replacing Council Directive 90/220/EEC, OJ 1990 L 117/15, as amended by Council Directive 94/15/EC, OJ 1994 L 103/20 and Directive 97/35/EC, OJ 1997 L169 ('Deliberative Release Directive').

13 Council Regulation (EC) 258/97, OJ 1997 L 43/1 concerning novel foods and novel food ingredients ('Novel Foods Regulation'). Although not relevant to the case of *EC–Biotech*, this Regulation has subsequently been replaced by Regulation 1829/2003/EC of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ 2003, L 268/1; see further E. Brosset, 'The Prior Authorisation Procedure Adopted for the Deliberate Release into the Environment of Genetically Modified Organisms: the Complexities of Balancing Community and National Competences', 10 *European Law Journal* 555 (2004).

14 For further details of the EC's approval scheme, see Brosset, ibid., 556.

15 *EC–Biotech*, above n. 1, para. 2.5 and Foster, 'Social Science Experts and *Amicus Curiae* Briefs', above n. 6, at 437–439.

16 A. Klinke and O. Renn, 'A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based and Discourse-Based Strategies', 22:6 *Risk Analysis* 1071 (2002).

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Member States could provisionally restrict or prohibit the use and/or sale of an approved biotech product in their own territory but they could only do so if they had 'detailed grounds for considering, based on new or additional information or scientific knowledge, that the particular product pose[d] a risk to human health or the environment'.[17] A further requirement was that the relevant EC Member State, which intended to take such a safeguard measure, was under a duty to inform other EC Members and the Commission. This led to a decision being taken at Community level on that Member State's safeguard measure within a prescribed period of time.[18]

The complainants' in *EC–Biotech* argued that the EC regime for approval of biotech products was effectively a moratorium on the review of application for the commercialization and marketing of GMOs. Specifically they alleged that the EC had suspended consideration of applications under relevant EC processes for the approval of products such as canola/grape seed, maize, soybean, cotton, chicory, sugar and fodder beet, potato, tomato, and lettuce. They also claimed that certain EC Member States had introduced and/or were maintaining measures that prohibited the importation, marketing, or sale of biotech products or GMOs.

3. Social science expertise, 'post-normal' science and the risk discourse

When trade negotiators set out to draft the SPS Agreement during the Uruguay Round (1986–1994) the emphasis on risk assessment reflected the prevailing view in the international trade community that a robust and transparent means of evaluating 'food-borne' risks and 'pest' or 'disease-borne' risks was necessary in order to counter forms of neo-protectionism that WTO Members might pursue through stringent regulatory regimes for the importation of agricultural and processed agricultural products into their territories. Hence, SPS measures must not be maintained without sufficient scientific evidence[19] and must be based upon a risk assessment.[20] Where relevant scientific information is deemed insufficient, and on the basis of any pertinent information, a provisional SPS measure may be maintained.[21] WTO Members also have to ensure that their management of SPS risks does not lead to discrimination or a disguised restriction on trade between situations or products, irrespective of their origin, and are required to work together in seeking to achieve consistency in the level of risk that is acceptable in different situations.[22]

17 *EC-Biotech*, above n. 1, para. 2.5.
18 Brosset, above n. 13, at 566–567 and 572–573.
19 Article 2.2 SPS, *The Legal Texts*, above n. 3, 70.
20 Article 5.1 SPS, ibid., 72.
21 Article 5.7 SPS, ibid., 73.
22 Article 5.5 SPS, ibid., 72–73.

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While the conditions for the use of science in establishing and applying health and food safety regulations remain unchanged, the first decade of the SPS Agreement has been marked by a period of considerable uncertainty in the world of science and technology. In particular during the late 1990s there was a growing recognition of a need for a new 'Social Contract for Science' in order to deal with some of the pressing scientific and social issues raised by new technologies such as biotechnology or nanotechnology.[23] The international community faced the challenge of how to focus on linkages between social, political, and economic systems on the one hand and biological, physical, and chemical systems on the other.[24]

Traditionally, applied scientific research took place under conditions that have more or less been described by Thomas Kuhn[25] as the conduct of 'puzzle-solving normal science within a paradigm that ensures the steady accumulation of relatively stable and certain facts, employing recognized methods'.[26] An alternative paradigm of post-normal science, offered by Funtowicz and Ravetz, is science for policy, which embraces a situation where scientific uncertainty and value issues are commonplace, where objectivity is not possible, where prediction and control are limited, and where society and politics have a key role to play.[27]

As a rule, post-normal science can be located in relation to other traditional strategies that can best be described by placing the criterion of 'systems uncertainty' along a horizontal axis, while 'decision stakes' is placed along a vertical axis. When both systems uncertainty and decision stakes are low, a situation of applied science pertains and results in a situation that is usually referred to as normal or 'safe' or 'sound' science. When either systems uncertainty or decision stakes are medium, the routine application of scientific knowledge is judged to be inadequate and there is a need to resort to the specific skills and judgements of professionals in the sense of professional consultancy. When both systems uncertainty and decision stakes are high, a situation of post-normal science prevails.[28]

A situation of post-normal science may pertain irrespective of the nature of the subject matter, the degree of scientific uncertainty or the level of ignorance and

23 'Declaration on Science and Use of Scientific Knowledge' and the 'Science Agenda – Framework for Action', adopted by the International Council of Scientific Unions (ICSU) at the World Conference on Science, 'Science for the 21st Century', Budapest 1999, to be found in the *Special Issue of Science International* (Paris: ICSU, September, 1999).

24 See for example G. C. Gallopín, S. Funtowicz, M. O'Connor, and J. Ravetz, 'Science of the 21st Century; from Social Contract to the Scientific Core', 53 (Issue 168) *International Journal of Social Science*, 219 (2001).

25 T. S. Kuhn, *The Structure of Scientific Revolutions*, 3rd edn (Chicago, IL: University of Chicago Press, 1996), 36.

26 R. Strand, 'What is Post-Normal Science?', adapted from a lecture given at the University of South Carolina (Columbia) and Virginia Tech (Blacksburg), November 2002.

27 Funtowicz and Ravetz, 'Science for a Post-Normal Age', above n. 7, 739.

28 Ibid., at 749–754.

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without all the factors of the problem having been observed. It applies as much to the depletion and/or replenishment of fish stocks or global warming brought about by climate change as it does to developments in the field of gene technology. Post-normal science usually presents itself in situations where the sheer complexity of the object of scientific research is coupled with issues of uncertainty or ignorance but governments and society need to deal with a situation immediately rather than waiting for a future event. It is in this context that post-normal science has been called upon as a problem-solving strategy.[29]

Risk has come to play an increasingly important role in decision-making in the field of environmental law and public health but it is something of a newcomer with respect to food safety. Not surprisingly, the main emphasis has been on the development of (quantitative) risk assessment techniques, while the role of risk assessment in standard setting, previously discernible in evidence before domestic and regional courts, has moved centre stage in international adjudicative fora.[30] Even so, scientific risk assessment often cannot deal adequately with issues of uncertainty and variability, both of which may prevail with respect to certain categories of risks and certain types of products or processes. Put simply: '[T]here is no scientific definition of terms such as "acceptable", "reasonable", and "sufficient"'[31] and attempts to deal with these terms in legal practice may get lost in translation.

If one takes the post-normal science approach to the issues of assessing and managing risk, then 'inevitably various sorts of uncertainty and value-commitments enter into any decision on risks, and because of that the scientific side of the work must be complemented by other considerations, deriving from its policy aspects.'[32] Not only must society cope with changes that often occur with increasing intensity, rapidity, and complexity[33] but there is also a need to deal with the failure of public trust in scientific information.[34]

Lack of public trust in scientific information can result from the (in)ability of governments to manage risk, especially where there are difficulties in assessment of that risk, as occurred in the case of some high-profile environmental disasters such as Chernobyl and Seveso.[35] It may also arise where there is an unresolved debate about instances of hazard involving a new disease with a real but unquantifiable

29 Ibid.

30 E. Fisher, 'Risk and Environmental Law: A Beginner's Guide', in Benjamin J Richardson and Stephan Wood (eds), *Environmental Law for Sustainability* (Oxford and Portland, Oregon: Hart Publishing, 2006), 97, at 104–107.

31 D. Crawford-Brown, J. Pauwelyn, and K. Smith, 'Environmental Risk, Precaution and Scientific Rationality in the Context of WTO/NAFTA Trade Rules', 24(2) *Risk Analysis* 461 (2004) at 467.

32 B. De Marchi and J. R. Ravetz, 'Risk Management and Governance: A Post-Normal Science Approach', 31 *Futures* 743 (1999).

33 Ibid.

34 P. Jensen, 'Public Trust in Scientific Information', Special Issue of the Institute for Prospective Technological Studies (ITPS), 14/09/2000, available at http://governance.jrc.it/publicperception/ipts.pdf.

35 Ibid.

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incidence rate that creates a high level of uncertainty, such as occurred in the Bovine Spongiform Encephalopathy or BSE crisis in Europe,[36] or threatens to occur if there is a significant increase in the incidences of Avian or bird flu in humans. Significantly, the sheer novelty of the technology coupled with high uncertainty and high decision stakes may lead to a complete erosion of public trust in the relevant scientific information, as is the case with respect to GM foods and food crops.

Aside from this, the objective scientific or 'sound science' approach, which underpins the form of risk assessment, prescribed by the SPS Agreement in Article 5.1[37] and Annex A.4[38] raises some serious questions, which are of relevance in this case and potentially others like it in future. Who are the scientific experts? What is the quality of the information available to such experts? What are the uncertainties and sources of ignorance that we know of with respect to GM products? How precautionary can one be with respect to certain products and should the element of precaution be included in the methodological choices of scientific investigation?

Perhaps the most important question is who should judge such matters? To which social science in general, and post-normal science in particular, would answer: those most affected by the design of policies, the quality of information, and the quality of the methodology used; in every instance it is the ordinary citizen or the consumer who should have a right to participate in these processes. Thus, post-normal science is identified with three methodological elements: the analysis of uncertainty and its management, the integration of different sources of knowledge across the lay-expert divide, and the participation of non-scientific experts in forms of extended peer review.

4. Differing approaches towards risk analysis: the regulatory divide

There are different regulatory approaches to risk in WTO Member states, largely based upon the public's perception of risk and differing social and cultural preferences. The regulatory divide is most apparent in the process of risk analysis that exists in the United States as opposed to that of the European Communities.

From the 1970s, onwards US government agencies like the Food and Drug Administration (FDA), the Environment Protection Agency (EPA), and the US Department of Agriculture (USDA) moved away from the precautionary approach in risk regulation towards adoption of a sound science approach. For the United States, as one of the complainants in *EC–Biotech*, a risk assessment is a factually

36 Ibid., 748–750.
37 Article 5.1 SPS, *The Legal Texts*, above n. 3, 72.
38 Annex A.4 SPS, ibid., 79.

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grounded, objective, and value-free analytic exercise that precisely identifies possible harms to human health and the environment. The means for achieving this is a formal, expert-based assessment of the potential harm that GMOs may cause, i.e. a straightforward hazard identification process. A further feature of the US system is that decisions of governmental agencies are subject to judicial review[39] and this leads to an 'adversarial' system, which stands for openness and transparency in the public scrutiny of governmental activity.

The regulatory approach towards risk regulation in the EC – at least in the field of food safety – is in the first instance not so different to that of the United States. This is clear from the establishment of the European Food Safety Authority (EFSA), the legislative basis of which anticipates three distinct processes of scientific risk assessment, political risk management, and risk communication.[40] The EC's view of risk assessment is that the process is not the subject of a single methodology nor is it a purely scientific exercise. Indeed, where it has not been possible to make a quantitative assessment of the risk with reasonable scientific confidence the precautionary approach may be adopted,[41] which is an approach that is informed by the most appropriate science.[42] In strict procedural terms, risk assessment consists of 'hazard identification, hazard characterization, appraisal of exposure and risk characterization'.[43]

39 Fisher, 'Risk and Environmental Law', above n. 30, at 104. Challenges to governmental decisions in US courts are easier. Regulatory agencies can be more readily sued for setting standards that producers consider too stringent or public interest groups (civil society) consider not stringent enough; see Funtowicz, Miege and Shepherd, Summary of a Workshop, on Science and Governance, Brussels, 29–30 March 2000 and S. Jasanoff, *Science at the Bar: Law Science and Technology in America* (Cambridge, MA/London, England: Harvard University Press, 1995), at 37–39.

40 See Fisher, 'Risk and Environmental Law', above n. 30, at 112. Due to the earlier accountability crises in EC public administration a division between science and politics was seen as a necessary way of ensuring that EC decision makers did not usurp their powers; see further E. Fisher and R. Harding, 'The Precautionary Principle and Administrative Constitutionalism: The Development of Frameworks for Applying The Precautionary Principle', in E. Fisher, J. Jones, and R. von Schomberg, *Implementing the Precautionary Principle: Perspectives and Principles* (Cheltenham, UK/Northampton, MA: Edward Elgar, 2006), 113 at 125 and footnote 10 at 133.

41 I. Holland and A. Kellow, 'Trade and Risk Management: Exploring the Issues', in D. Robertson and A. Kellow, *Globalization and the Environment: Risk Assessment and the WTO* (Cheltenham, UK/Northampton, MA: Edward Elgar, 2001), 229, at 232.

42 D. Kriebel, J. Tickner, and C. Crumbley, 'Appropriate Science: Evaluating Environmental Risks for a Sustainable World', paper presented at a conference on Education for Sustainable Development, Committee on Industrial Theory and Assessment, University of Massachusetts, Lowell, MA, 23–24 October 2003, available at: http://www.uml.edu/com/cita/Kriebel.pdf.

43 Fisher, 'Risk and Environmental Law', above n. 30, at 112 and Fisher and Harding, 'The Precautionary Principle and Administrative Constitutionalism', above n. 40, at 125 together with footnote 11 at 133, noting that the EC's approach is based on the distinction between risk assessment and risk management, pursued by the US government in the National Research Council (NRC) Report of 1983, otherwise known as the 'Red Book'; see also Commission of the European Communities (European Commission), *Communication from the Commission on the Precautionary Principle*, Brussels, 2 February 2000 COM(2000) 1, Final, which maintains this distinction and includes risk communication as a third element of any risk analysis.

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Again for a long time in the US it was accepted that risk management was 'purely a problem of the application of the conclusions of the relevant quantitative sciences', although there was a growing appreciation that risk management involved governance issues as well.[44] However, changes came about from the late 1970s, as a result of judicial review in US courts of agency action pertaining to risk assessment which was followed by legislative action. The latter led to a 'clear conceptual distinction' being made in the United States between 'a "scientific process" of risk assessment, in which the scientific information about risk was collected and evaluated, and a "political" process of risk management, in which a policy decision was made about what regulatory action should be taken in relation to that risk'.[45] Overall, the US pursues an approach to risk management that involves a balancing of environmental/quarantine risks against the costs and benefits of the policy pursued.[46]

In the case of the EC, when it comes to risk management, matters are less clear. The EC approach reduces risk management to balancing a policy of precaution against the costs and benefits of the policy pursued. It is also seen as assigning 'subjective valuations of risk as an implicit rather than [an] explicit part of risk management'.[47] Additionally, the whole process of scientific advice in policy making in the EC is essentially a political one. From one point of view it is considered to offer few guidelines for the process of evaluation and its consensual character has been described as 'one in which members of the "club" meet to negotiate behind close doors'.[48] From another view, however, the Court of First Instance of the European Communities in *Pfizer* has upheld the role of the EC's scientific committees in assisting political bodies in the process of scientific policy making. In the Court's view, such scientific advice is based on the principles of excellence, transparency, and independence and serves as 'an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures'.[49]

44 De Marchi and Ravetz, 'Risk Management and Governance', above n. 32, 743.

45 Fisher, 'Risk and Environmental Law', above n. 30, 105. The Appellate Body in *EC–Hormones*, above n. 2, paras. 181 and 187, has subsequently stated that there is no authority for making such a clear distinction between risk assessment and risk management and that to do so could exclude from the scope of the analysis 'all matters not susceptible of quantitative analysis', thereby broadening the scope of a risk assessment to include qualitative factors.

46 Holland and Kellow, 'Trade and Risk Management', above n. 41, at 232.

47 Ibid.

48 G. J. Lake, Directorate-General for Research, '2(b) or not 2(b): that *was* the question: committology, scientific advice and uncertainty, and open decision-making in the EU – an up-date', paper presented at the seminar Handling Scientific Uncertainty in EU Decision-Making organized by the Green Alliance (*et al.*), London, 17–18 April 2000, who also describes the arcane 'com(m)itology' process in EC scientific decision-making.

49 Case T-13/99 *Pfizer Animal Health SA* v. *Council of the European Union* [2002] ECR II-03305, para. 172.

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5. The five person *amicus curiae* brief before the *EC–Biotech* Panel

The *amicus* brief was submitted by five social scientists to the Panel[50] in *EC–Biotech*.[51] Ultimately, it was not considered by the Panel,[52] nor taken up in the record. Nevertheless, it offers some important lessons for the future. It is distinguishable from other *amicus* briefs brought in the case in that it specifically seeks to provide expertise from a social science perspective. In so doing, it raises a number of key issues concerning the way in which the SPS Agreement is drafted and how it should be interpreted.

Of particular note is the way in which the *amicus* brief tries to convey the authors' views on how the concept of risk and risk assessment should be applied in the field of biotechnology. For example, it recommends full consideration of the range of relevant scholarship, including the social sciences, in interpreting terms such as 'risk', 'risk assessment', 'rational', 'objective', and the contestable issue of 'sufficient scientific evidence'.[53]

It also recognizes that risk assessments of GMOs, which are conducted in specific national or institutional settings, may be limited, partial, and constrained by the decision-making cultures within which those assessments are produced.[54] The *amicus* brief therefore advocates using extensive forms of public deliberation in order to fill some of the gaps in knowledge and values in the field. Absent widespread public inputs, there is an insufficient basis for conducting a risk analysis and for resolving such threshold questions as the proper difference between GM and non-GM products.[55]

The *amicus* brief recognizes that risk assessment is not a singular concept but varies with the context in which it is found. Thus, where there is a situation of low certainty about facts and low consensus about methods, as in the case of GMOs, the scientific basis for the regulation of the risk and the very notion of risk analysis remains a fluid one. However, the situation changes dependent upon the national decision-making context, which the authors illustrate by reference to US regulatory practice, and is not helped by the fact that international guidelines for analysing the risk of GM foods are still emerging and not yet universally accepted.[56]

50 *Amicus* brief, above n. 6.

51 The panel in *EC–Biotech* (para. 7.11) stated in a very manner-of-fact way that it 'accepted the information submitted by the *amici curiae* into the record' but in rendering its decision the panel 'did not find it necessary to take the *amicus curiae* briefs into account'.

52 One of those was prepared on behalf of the so-called *Amicus* coalition – a transnational coalition of 15 NGOs, submitted by the Foundation for International Environmental Law and Development (FIELD), London. Another was from a group of five NGOs – Center for International Environmental Law (CIEL), Friends of the Earth – United States (FOE–US), Defenders of Wildlife, the Institute for Agriculture and Trade Policy (IATP) and the Organic Consumers Association – United States (OCA–USA).

53 *Amicus* brief, above n. 6, p. 6 under point 1, supported by arguments at §IV. A, pp. 20–21.

54 Ibid., p. 6, under point 2.

55 Ibid., p. 22 and conclusion 1B under §VI, at p. 44.

56 Ibid., p. 6, under point 3, supported by arguments at §IV. A.1–3, at pp. 22–23 and conclusions 1A, 1C, and 1D at §VI, at p. 44.

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As a result of the current status of risk assessment techniques with respect to GMOs and the role of public confidence in regulating new food technologies the European moratorium is not one of 'undue delay' under Article 8[57] and Annex C.1(a)[58] nor is the amount of time, which the European Commission considers necessary in order to collect additional information about GMOs, so as to conduct a better risk assessment, 'unreasonable'.[59] Tellingly also for our consideration of the potential competition between WTO Members' regulatory regimes is the fact that the social science experts' *amicus* considers that the panel's role in reviewing the parties' arguments should be largely a procedural and not a substantive one. In fact, this addresses the applicable standard of review in SPS cases especially since the Panel in *EC–Biotech* appears to have acted more as an adjudicatory body reviewing the substantive merits of each party's risk assessment than an (administrative) tribunal reviewing the adequacy of an executive decision-making process.[60]

A considerable portion of the *amicus* brief is devoted to considering the conceptual foundations of risk-based decision making. In support of the Appellate Body's view in *EC–Hormones*[61] the authors attack such issues as the fallacy of creating a strict separation between risk assessment (based on quantitative analysis of risks) and risk management (incorporating judgements of value), where the former is a technical phase and the latter a political one.[62] Instead, the authors of the *amicus* brief call for a risk analysis to be conducted within a political and cultural context that 'influence both the initial identification of hazard … and subsequent attempts to assess the magnitude, seriousness and distribution of harms'.[63] When assessing the risk of GMOs in the context of the SPS Agreement the *amicus* brief regards risk as embedded in the social system, i.e. within '*human societies as they actually exist*'. [64] Whereas, the Appellate Body in the earlier case of *EC–Hormones* anticipated the resulting difficulties and the political resistance towards a process of risk assessment and risk management based strictly on scientific evidence, and in complete isolation from other deep-rooted societal considerations, the Panel in *EC–Biotech* is clearly of a different persuasion.

The arguments for a broader-based risk assessment are complemented in the *amicus* brief by a call for greater public deliberation in the process of risk assessment, as part of a wider notion of public deliberation in scientific policy making, which is one of the characteristics of post-normal science. In the view of the *amicus* brief, this includes '[D]efining what exactly is "at risk" … [as] properly a matter

57 Article 8 SPS, above n. 3, 74.
58 Annex C.1(a), ibid., 82.
59 *Amicus* brief, above n. 6, §IV.D.4 at p. 32.
60 Ibid., at §V.B at pp. 39–40.
61 *EC–Hormones*, above n. 2, para. 181.
62 *Amicus* brief, above n. 6, §III.A.1 at pp. 12–13.
63 Ibid., §III.B.1 at p. 15.
64 Ibid., §IV.B.3 at p. 24, citing *EC–Hormones*, above n. 2, para. 187.

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of democratic value-commitment and of whatever process is appropriate to meet these needs.'[65] Moreover, there is recognition that 'public attitudes and perceptions … [are] heightened in the GMO case where scientific knowledge is neither uniform nor complete, and because food has a special cultural status in human society'.[66]

Public participation and stakeholder deliberation (in short public deliberation) are central to successful risk-based decision making and the SPS case law should be read in support of this approach – particularly where there is a situation of low certainty and low consensus as exists in the case of GMOs. The *amicus* brief even claims that public consultations on GMOs – such as the farm-scale evaluations of GM crops in the UK[67] – have been essential in dealing with the uncertainties that surround GM crop developments and any attempt to remove planned public consultations as a component of risk assessment 'would be to undermine important democratic elements in the regulatory processes of Member States'.[68]

Given that, democracies can, and do, differ in their assessment and management of risk and the fact that the WTO is a supranational institution, which is trying to resolve a regulatory conflict, it is important to define the role of the judge/arbiter or decision maker in scrutinizing the scientific bases of food regulations. Once again, the *amicus* brief argues that any assessment of facts and law under the SPS Agreement by panelists or the Appellate Body should at best be procedural and not substantive. On a chastening note, they state: 'science-based disciplines should not function as draconian enforcement of substantive standards that have been considered and rejected by the citizens of WTO Members. Rather, the standard of review in science-related rules at the WTO should facilitate an international discourse of rational decision making in the regulatory sphere.'[69]

The *amicus* brief, applying a post-normal science analysis of the situation, considers GM engineering and the products thereof to constitute low systems certainty with respect to the scientific knowledge and to entail low consensus among the public, in which case the requirement of a rational relationship between the risk and measure should be interpreted more broadly.[70] Additionally, risk assessment in the case of GMOs should be seen as an evolving technical practice and should be locally based since it is 'unrealistic to envisage a global risk assessment that could assess the environmental risks posed by particular GM varieties in all, or even many, environments'.[71]

65 Ibid., §III.C.3 at p. 18 and §IV.B.4 at pp. 24–25.
66 Ibid., §III.C.3 at p. 18.
67 Ibid., §IV.D.3 at p. 31.
68 Ibid., §IV.B.5 at p. 26.
69 Ibid., §V.A at p. 39.
70 Ibid., at §IV.A.1 on p. 22.
71 Ibid., at §IV.A.3 on p. 23; see Fisher, 'Risk and Environmental Law', above n. 30, at 124–125 who argues broadly along the same lines.

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To what extent is this view sustainable given the situation in *EC–Biotech* where the Panel failed to acknowledge the arguments put forward by the EC, in support of Austria's invocation of a safeguard measure for Bt maize varieties, as a precautionary measure on the basis of Article 5.7 SPS? The situation is as follows. As is well established, Article 5.1 SPS when read in conjunction with Article 2.2 SPS requires that there must be a rational relationship between a risk assessment and the measure or in the words of Appellate Body in *EC–Hormones* the results of the risk assessment must 'sufficiently warrant' or 'reasonably support' the SPS measure at issue [72]

However, the Panel in *EC–Biotech* considered that in light of Article 5.1 SPS it was specifically called upon to determine whether each individual safeguard measure was based on a risk assessment which was appropriate to the circumstances existing at the time the Panel was established, i.e. as of 29 August 2003. Whereas in *EC–Hormones* the Appellate Body went to some lengths to stress that a risk assessment could encompass both mainstream scientific opinion as well as divergent views without detracting from the rational relationship test, 'especially where the risk involved [was] life-threatening in character and [was] perceived to constitute a clear and imminent threat to public health and safety',[73] the Panel in *EC–Biotech* dismissed the Appellate Body's pronouncement in *EC–Hormones* as only relating to a hypothetical situation.

It went on to distinguish the situation of GMOs with that of beef hormones on two separate grounds. First, the Panel claimed that it was unaware of any divergent scientific evidence relating to Austria's risk assessment in support of its safeguard measure. Second, based on the evidence provided to it by the Panel's scientific experts, it had formed the view that potential risks arising from the deliberate release of various Bt maize varieties and other biotech products in dispute could not be considered as risks that were 'life-threatening in character' or that 'constitute[d] a clear and imminent threat to public health and safety'.[74]

While it was made clear to the Panel that the Austrian safeguard measure in respect of Bt maize varieties was based on the availability of 'new scientific information', which justified Austria's differing risk assessment, the Panel remained intransient. It was adamant that where there is disagreement 'with some or all of the conclusions' contained in the main EC risk assessment then it would be up to individual Member States, like Austria, to explain 'how and why they assess the risks differently, and to provide *their revised or supplemental assessment* of the risks', i.e. to muster evidence that could pass a new risk assessment.

However, when it came to individual EC Member States' invocation of safeguard measures with respect to GM crops, the Panel disagreed with the EC that the

72 *EC–Hormones*, above n. 2, Appellate Body Report, paras. 193 and 194, taken up in *EC–Biotech*, above n. 1, para. 7.3028.

73 *EC–Hormones*, ibid.

74 *EC–Biotech*, above n. 1, para. 7.3059.

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insufficiency of scientific evidence under Article 5.7 SPS must be assessed in relation to the appropriate level of protection of the importing Member. Instead, sufficiency of scientific evidence to support a risk assessment must be consistent with the requirements of Article 5.1'[75] and as defined in Annex A.4.[76] The Panel then goes further in finding that the individual safeguard measures, such as the Austrian one, could not be justified as precautionary under Article 5.7 SPS because the risk assessment conducted by the EC's Scientific Committee on Plants had concluded that the information provided by Austria 'did not constitute new scientific information which would change the original risk assessment' that had been carried out in the context of the original EC regime for approval of biotech products.[77]

In other words, since the EC was able to maintain its original risk assessment in the light of the 'new scientific information' provided by Austria this confirmed its original risk assessment and meant that individual EC Member States were no longer in a position to claim that there was insufficient scientific evidence.[78] The Panel's reasoning is irrational and stems from its suggestion, implicit in its reasoning, that once one WTO Member (the EC) has been able to make a risk assessment based upon scientific evidence, another Member (Austria) can no longer claim that there is insufficient scientific evidence and is thereby precluded from relying upon Article 5.7 SPS. This does little to facilitate an international discourse of rational decision making in the SPS regulatory sphere as the social science experts propose in their *amicus*. Even the Panel appears to have been sensitive about its findings on this point (leaked at the interim report stage) when it issued an addendum to its Report (Annex K), no doubt in order correct any misunderstandings that a broader public, anxious about a novel technology and the state of the relevant science, might have.[79]

A final note of caution in the social science experts' *amicus* relates to the appropriate selection and use of (scientific) experts. Essentially, what is proposed is 'that appointed experts not be afforded *greater* authority in matters of science policy than national authorities'.[80] The concern here addresses the Panel's discretion, as the 'trier of the facts', which should extend only to taking the views of experts into account and not to allowing scientific truth to privilege the proper application of WTO measures. In *EC–Biotech*, the Panel sought expert advice and

75 Ibid., para. 7.3066.

76 Ibid., para. 7.3239.

77 Ibid., para. 7.3258–7.3259.

78 Ibid., para. 7.3260.

79 Annex K, being addendum 9 to the Panel Reports in *EC–Biotech*, above n. 1, pp. K-1 to K-2. It records the Panel's view that insufficiency of scientific evidence can be assessed both quantitatively and qualitatively, risk can be assessed as risk in the real world rather than simply under laboratory conditions, WTO Members retain their freedom of action with respect to new scientific evidence and the possibility remains that where scientific evidence is sufficient for a risk assessment at a particular time, it may prove insufficient at a later time.

80 *Amicus* brief, above n. 6, §V.D. at p. 41.

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invited suggestions for experts from the parties before making its final selection on scientific expertise.[81] While the choice of experts, the conduct of the proceedings involving the hearing of scientific evidence, and records of those proceedings in no way suggest that these experts acted in excess of their expertise or authority in the relevant scientific field, in future WTO panels might do well to heed the caution in the *amicus* brief and seek to broaden the basis upon which they call upon expertise.

6. Some conclusions concerning the potential use of social science expertise

The *EC–Biotech* dispute highlights the evolving relationship between science and governance in the field of agrobiotechnology and multilateral trade. It is clear that there is a growing tension between WTO Members as to the proper role of risk assessment and risk management in SPS matters. However, it would appear from the findings of the Panel in the GMO dispute that thus far social science expertise in general and post-normal science in particular has made little or no impression at all upon the ongoing debate.

Even so, WTO Members continue to have legitimate concerns over key provisions in the SPS Agreement concerning the 'scientific justification' for any measure they may adopt and they have latent anxieties concerning the provision of an adequate 'risk assessment'. The sound science approach, which underpins the SPS Agreement, places a high burden of justification on Members wishing to regulate health and safety measures. The burden is even greater where there is low certainty as to the science as in the case of GM products and there is low consensus among a Member's citizens as to the viability of such products. Meanwhile the SPS Agreement permits complainants to challenge those measures on the basis of sufficient scientific evidence and reasoning, whereas it would seem that the possibility of maintaining a measure of a provisional nature under Article 5.7 SPS might have its limitations.

One of the key points about the *amicus* brief is the authors' claim that social science research offers different sources of knowledge, which can compare risk-based decision making across different national political systems and can demonstrate how variations in the framing of issues and the conduct of science policy 'can lead to systematic transnational variations in the assessment of health, safety and environmental risks'.[82] Arguably, the SPS Agreement, given its open-ended understanding of science and notion of risk assessment is open to a diversity of regulatory approaches, including the precautionary approach, and multiple science-based arguments.[83]

81 *EC–Biotech*, above n. 2, paras. 7.20–7.30 and Annex J, being a 'Transcript of the Panel's Joint Meeting with Scientific Experts of 17 and 18 February 2005'.

82 Winickoff *et al.*, 'Adjudicating the GM Food Wars', above n. 5 at 97–98.

83 Crawford-Brown *et al.*, 'Environmental Risk, Precaution and Scientific Rationality', above n. 31, 462.

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However, WTO decision makers, as in the case of the Panel in *EC–Biotech*, are minded to apply an objective assessment of the facts in SPS cases. While there is nothing inherently wrong in this approach, Panels have tended to favour particular notions of science and risk assessment over others – the main one being the sound science approach. If nothing else, the *amicus* merits consideration for its rigorous exposure of the notion of risk assessment, in particular its critique of the sound science approach to risk assessment, which is conducted as 'an objective, science-based, value-free analytic exercise requiring precise identification of possible harms to human health, agricultural production, and the environment'[84] rather than a broader approach (possibly a post-normal one), which considers scientific evidence alongside other relevant social, cultural, political and regulatory aspects relating to risk.

While in theory such an approach could be achieved by means of a process of public deliberation, which draws upon a broader range of individuals or groups in WTO risk decision-making processes, the reality is that even in domestic systems like the US, and to some extent the EC, there is frequent lack of understanding as to what constitutes an effective public participation mechanism, in which constituencies should participate, and of how the process of public deliberation should function in the policy-making process. Transposed to the supranational level this suggestion presupposes that participatory reforms exist at the WTO to facilitate public deliberation but this is far from reality.

Even if social science expertise is not acceptable to a WTO panel, elsewhere it has been proposed that when seeking scientific advice, WTO panels 'should step away from their preference of appointing *individual scientists*, to whom they then submit a number of questions, in favour of appointing an advisory *experts group or community*'.[85] What is sought is a broadening of the scope of the scientific expertise upon which a panel may draw by allowing the expert scientific advisory group to establish its own mandate and to discuss and evaluate scientific matters, including social science arguments, before submitting its conclusions to the panel. The benefits that can be derived from this approach are two-fold. First, instead of WTO decisionmakers seeking to establish common ground between divergent scientific opinions, the scientific experts themselves would be in a position to do this. Second, an expert scientific advisory group would be better placed to deal with the formal requirements for assessing and depicting issues such as uncertainty and variability in different risk assessments and in demonstrating how risk varies between citizens in different societies.

Were evidence to be elicited from social scientists by panel-appointed experts, the panel hearing a particular complaint would at all times maintain control over

84 *Amicus* brief above n. 6, §III.A at p. 12.

85 Crawford-Brown *et al.*, 'Environmental Risk, Precaution and Scientific Rationality', above n. 31, 468; for a view on the use of expert scientific review (or advisory) groups, see Theofanis Christoforou, 'Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case-Law in the Face of Scientific Uncertainty', 8 *NYU Env L J* 622 (2000).

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the selection and appointment of persons most qualified to advise it. Again, from a procedural point of view it would be up to the panel in question to determine the weight to be attributed to any relevant evidence drawn from social science expertise that might assist it in reaching its findings with respect to a risk assessment or indeed any other scientific matter. From an evidential point of view, such experts, once appointed, could be subject to examination and cross-examination by parties in the dispute in much the same way as currently occurs with scientific experts but in a manner which would be more transparent than the medium of an *amicus* brief, however well-informed its authors might be.[86]

What is becoming apparent in the use of scientific expertise in WTO decision – and this was already recognized by the Appellate Body in *EC–Hormones* – is that notions of 'risk', sufficiency of 'scientific evidence', and situations of 'scientific uncertainty' are increasingly untenable in isolation and can no longer be separated from their social dimension. The social science experts' amicus may have made no impact on the course, or the outcome, of the *EC–Biotech* dispute but it does contribute significantly to making the trade and scientific communities more aware of the need to engage in a holistic approach towards the introduction of novel technologies like GMOs and their application in our global society.

86 Foster, 'Social Science Experts and *Amicus Curiae* Briefs', above n. 6, 452.

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