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Risk Regulation Under the WTO SPS Agreement: Science as an International Normative Yardstick?

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RISK REGULATION UNDER THE WTO SPS AGREEMENT: SCIENCE AS AN INTERNATIONAL NORMATIVE YARDSTICK?

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ABSTRACT

Processes of scientific risk assessment, carried out by specialized agencies, are a familiar part of health and environmental regulation in countries like the United States, and increasingly, in the trans-national decision-making structures of the European Union. Challenges to risk regulatory measures, mounted through the courts, present judicial decision-makers in both systems with similar problems as they attempt to grapple with issues arising at the interface of law and science. In an era of globalization, tradeoffs reached in domestic risk regulatory processes are also likely to be subject to international scrutiny, in no case more than when governments are asked to defend their risk regulatory measures under the *Sanitary and Phytosanitary Agreement* of the World Trade Organization. This Agreement, with its requirement for regulatory measures to be scientifically justified and based on a risk assessment, echoes the quest for science-based, rational decision-making on questions of health and environmental risk found at the national and trans-national levels. These similarities suggest the potential for comparative borrowing where the models for managing law and science interactions developed in the US or EU would serve as guides for WTO decision-makers reviewing the credibility of scientific theories underlying national SPS measures, and their connection to an adequate risk assessment. This paper examines the 'law and science' models that have emerged from the jurisprudence of the American and European courts which, despite employing a very different rhetoric, take similar, broadly deferential approaches to the review of science-based risk regulatory measures. However, deference to the judgment of regulators balancing social against scientific considerations has not been a feature of the SPS case law to date. This jurisprudence – notwithstanding attempts

by the WTO Appellate Body, in some cases, to permit flexibility in domestic risk assessment processes and preserve Members' rights to establish risk regulatory measures according to their own, societally-accepted levels of SPS risk – continually returns to a position that gives a privileged role to science, and the views of scientists, in determining the proper scope of risk regulation. The paper argues that the different direction taken by WTO decision-makers in the SPS context, when compared with their judicial counterparts in the US and EU, reflects the absence of normative reference points in the international trading system which could guide WTO decision-makers in striking a "balance … between the shared, but sometimes competing, interests of promoting international trade and of protecting … life and health (*Beef Hormones*)." The result, increasingly, in SPS cases is a move away from recognizing the legitimacy of Members' risk management policies motivated by domestic social considerations towards the seemingly more neutral and universal criterion of science. The irony, however, is that the value-laden questions inherent in much health and environmental risk regulation are thereby delegated to a body of knowledge whose claims to authority rest on its very lack of normative content.

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by Jacqueline Peel[*]

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I INTRODUCTION

In the twenty-first century, science and risk assessment are a pervasive feature of health and environmental regulation in many Western nations. The concern of industrialized societies with potential, rather than proven, harm[1] has seen a shift in policy focus from the remediation of damage to the prediction of risk.[2] Techniques of 'risk assessment', pioneered in the United States (US), are designed to provide a rational mechanism for distilling and evaluating scientific knowledge regarding potential hazards to human health or the environment.[3] In a process known as 'risk management', scientific risk assessments then inform policy decisions about measures to reduce identified risks to a level acceptable to broader society.[4] Structures of risk regulation, based on the risk

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[1] This is described as the phenomenon of 'risk society': see Ulrich Beck, *Risk Society: Towards a New Modernity* (SAGE Publications, London, 1992).

[2] Nicholas de Sadeleer, *Environmental Principles: from Political Slogans to Legal Rules* (Oxford University Press, Oxford, 2002), 91.

[3] For a history of the development of risk assessment techniques in the US see Sheila Jasanoff, *The Fifth Branch: Science Advisors as Policymakers* (Harvard University Press, Cambridge MA, 1990), 181-193.

[4] National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (The National Academies Press, Washington DC, 1983), 18-19. Later publications of the NRC, while maintaining the risk assessment, risk management terminology, have recognized the difficulties of maintaining a sharp dividing line between the two processes. See Paul Stern & Harvey Fineberg (eds),

assessment/risk management model, have been widely adopted in other national legal systems and in the trans-national regulatory processes of the European Union (EU).[5] In recent times, scientific risk assessment has also begun to appear in international legal regimes concerned with health and environmental protection.[6] The most prominent example of this trend is in the area of international trade law, where the *Sanitary and Phytosanitary Measures Agreement* (SPS Agreement)[7] of the World Trade Organization (WTO) prescribes scientific risk assessment as a basis for measures dealing with risks to human, animal and plant life or health.

Risk assessment techniques, adopted as a basis for health and environmental decision-making at the national and trans-national level, have not proved uncontroversial. The very nature of health and environmental 'risk' (referring to the possibility, rather than the

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Understanding Risk: Informing Decisions in a Democratic Society (National Academy Press, Washington DC, 1996).

[5] See, for example, Commission of the European Communities, *Communication from the Commission on the Precautionary Principle*, (2000) which prescribes risk assessment as a prerequisite to the adoption of precautionary measures. Similarly, the new European Food Safety Authority will undertake risk assessments as the basis for Community decisions on food safety regulatory measures.

[6] For example, see the Cartagena *Protocol on Biosafety to the Convention on Biological Diversity*, opened for signature 29 January 2000, 39 ILM 1027 (2000) (entered into force 11 September 2003), Articles 15, 16 and Annex III and the *Stockholm Convention on Persistent Organic Pollutants*, opened for signature 22 May 2001, 40 ILM 531 (2001), (entered into force 17 May 2004), Art. 8 and Annex E.

[7] *Agreement on Sanitary and Phytosanitary Measures*, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, General Agreement on Tariffs and Trade, Annex 1A, 15 April 1994 (hereafter 'SPS Agreement').

actuality of harm) means that scientific knowledge used in risk prediction and evaluation is often affected by uncertainty.[8] Moreover, decisions on measures to address health and environmental risk inevitably involve social value judgments as to the significance (or otherwise) of a particular risk.[9] Where the scientific data available to decision-makers is uncertain and there are strong divergences of view within a community regarding whether particular levels of health and environmental risk are acceptable, disputes over risk regulation are often brought before the courts. In resolving such disputes, courts – usually made up of generalist, non-scientifically trained decision-makers – must determine whether risk regulatory measures pursue legitimate health or environmental objectives, in light of scientific risk assessments performed by agencies with superior technical expertise. The approach taken by courts in such cases is generally one which defers to the judgment of regulators about the existence of risk and the appropriate response, particularly in circumstances of scientific uncertainty. In the US, the judicial approach is labeled the 'frontiers of science doctrine'.[10] In the EU context, it is more common to refer to policies of risk management based on the 'precautionary principle'.[11]

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[8] See Brian Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventative Paradigm'. (1992) June *Global Environmental Change* 111.

[9] National Research Council, above n 4, 19.

[10] See Martin Shapiro, 'The Frontiers of Science Doctrine: American Experiences with the Judicial Control of Science-Based Decision-Making' in Joerges, Ladeur and Vos (eds), *Integrating Scientific Expertise into Regulatory Decision-Making* (Nomos Verlagsgesellschaft, Baden-Baden, 1997) 325.

[11] See Commission Communication on the Precautionary Principle, above n 5.

With the international endorsement of science-based risk assessment in decision-making under the SPS Agreement, many of the same questions encountered in the domestic context resurface in international disputes between WTO Members. Generalist panels (the primary fact-finders in the WTO dispute settlement system) and the WTO's Appellate Body are called upon to determine whether WTO Members' measures for managing SPS risks are "maintained without sufficient scientific evidence"[12] and are "based on" a risk assessment.[13] Like reviewing courts in national and trans-national systems, WTO decision-makers encounter questions as to how intensely the scientific justification for a Member's measures must be scrutinized, and the extent of flexibility that should be granted to Members to pursue their own health and environmental objectives where there are claims of scientific uncertainty.

Given the similarity between the issues encountered domestically and those emerging in the international context of decision-making on SPS measures, it is tempting to think that solutions to global problems can be fashioned on the basis of national and trans-national experience. By prescribing deference on the part of generalist decision-makers to the judgments of specialist regulators, or adherence to risk management policies based on the precautionary principle, some commentators believe that will be possible to promote, at the international level, rational processes of decision-making that respect social value judgments about risk.[14] Solutions derived from national and trans-national experience are

[12] SPS Agreement, Article 2.2.

[13] SPS Agreement, Article 5.

[14] See Part V of this article for a discussion of these proposals.

thus thought to offer the basis for ensuring, in the words of the WTO's Appellate Body, an appropriate "balance … between the shared, but sometimes competing, interests of promoting international trade and of protecting … life and health."[15]

This article questions the viability of an approach to the international review of risk regulatory measures adopted for SPS purposes which simply seeks to translate solutions derived from experience with judicial oversight of science-based decision-making in other arenas. It argues that, in both the US and the EU, judicial review of risk regulation takes place in a context where there exist normative reference points or 'yardsticks' (whether implicit or explicit) that can guide decisions in the face of competing views as to the acceptability of risks and different accounts concerning the extent of scientific uncertainty. Comparable normative yardsticks, which could aid decision-makers in striking a 'balance' between the competing interests raised by supranational risk regulation, are not readily apparent in the international context. In the ensuing 'normative vacuum', science supplies a default criterion for decision-making, not only as to what is possible, but also what is desirable.

The article begins in Part II with an overview of the SPS Agreement, outlining its provisions requiring a basis in science and risk assessment that WTO decision-makers must apply in the review of national SPS measures. The article then turns to consider comparative experience with judicial review of risk regulatory measures dealing with

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[15] See *EC - Measures Concerning Meat and Meat Products*, Report of the Appellate Body, WT/DS26/AB/R & WT/DS48/AB/R, 16 January 1998, para. 177 (hereafter '*Beef Hormones*').

health and environmental issues. Part III examines first the experience in the US, which has a long jurisprudential tradition considering such questions, followed by the more recent experience in the trans-national setting of the EU. Despite very different institutional contexts (and even greater differences in rhetoric when it comes to the role of science in decision-making)[16] remarkably similar approaches have been developed in both jurisdictions. Part IV of the paper turns to a survey of the SPS case law, which while full of protestations that national policy choices about acceptable risk are preserved, invariably returns to a position that gives a prominent role to science in determining the outcome of risk-related decision-making. The concluding section, Part V, examines why solutions drawn from comparative experience with the judicial review of science-based risk regulation fail to translate to the international forum of SPS disputes.

II SCIENCE AND RISK ASSESSMENT IN THE SPS AGREEMENT

The WTO SPS Agreement has attracted much international attention (even notoriety) since coming into force in January 1995, as a result of high-profile disputes such as the *Beef Hormones* case between the US and the European Communities (EC).[17] Although

[16] Differences most clearly manifested in bitter trade disputes between the US and the EU over hormone-treated beef and genetically modified organisms, where the US insists on a 'sound science' approach and the EU on the necessity for 'precaution'.

[17] Another high-profile dispute between the US and EU over the latter's restrictions on imports of genetically modified crops and foods also looks set to be brought under the SPS Agreement: see DS291:

their innocuous-sounding title, 'sanitary and phytosanitary' (SPS) measures, might suggest otherwise, SPS measures potentially encompass a broad range of national regulations designed to protect against risks to human, animal or plant life or health. The SPS Agreement covers risk regulatory measures such as quarantine restrictions on imported agricultural products, intended to prevent the introduction of pests or diseases which could harm domestic industries or the natural environment within the territory of a WTO Member,[18] as well as bans on imported food products given concerns that they contain "contaminants" or "additives" which pose a risk to human health.[19]

The goal of those negotiating the SPS Agreement during the Uruguay Trade Round (1986-1994) was to reduce unnecessary trade impacts of national SPS measures by promoting greater convergence of the risk regulatory requirements applied by Members. The primary 'tool' selected to achieve this aim was that of harmonization of WTO Members' SPS measures,[20] based on the international standards, guidelines and

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European Communities: Measures affecting the approval and marketing of biotech products (Brought by the United States), 20 May 2003. For details of the US and EU submissions in the dispute, which is currently before a WTO Panel see http://www.trade-environment.org/page/theme/tewto/biotechcase.htm

[18] SPS Agreement, Annex A, para. 1(a) and (d). A footnote to the Annex explains that the definition of the term "animal" includes wild fauna and fish and that the term "plant" includes wild flora and forests.

[19] SPS Agreement, Annex A, para. 1(b). "Contaminants" are defined to include "pesticide residues, veterinary drug residues and extraneous matter".

[20] See, e.g., GATT Secretariat, Summary of the Main Points Raised at the Eighth Meeting of the Working Group on Sanitary and Phtyosanitary Regulations and Barriers of the Negotiating Group on Agriculture, MTN.GNG/NG5/WGSP/W/24, 2 July 1990, para. 3.

recommendations developed by organizations such as the Codex Alimentarius Commission, the International Office of Epizootics and the International Plant Protection Convention.[21] Although harmonization was to be encouraged, it was recognized that it would not be feasible in all cases.[22] Where Members' SPS measures cannot be harmonized because no international standard exists, or some Members opt for more stringent regulations,[23] the SPS Agreement requires that such national measures have a scientific basis.

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[21] See SPS Agreement, Preamble, para. 6. Article 3.1 of the SPS Agreement requires Members to "base" their SPS measures on the international standards, guidelines and recommendations developed by the Codex Alimentarius Commission (in the area of food safety), the International Office of Epizootics (in the area of animal health) and the International Plant Protection Convention (in the area of plant health). Members' measures that conform to such international standards are, in accordance with Article 3.2 of the SPS Agreement, "deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of [the] Agreement and of GATT 1994."

[22] Harmonization is not feasible, for example, where countries differ significantly as regards their prevailing climatic conditions and disease profiles. Equally, differences between countries as to the acceptability of certain levels of risk may prevent agreement on harmonized standards at the international level.

[23] The SPS Agreement specifically allows for this possibility in Article 3.3, although Members must be able to show a "scientific justification" or that SPS measures are in "consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5" (dealing with risk assessment). This rather confusing provision was interpreted by the WTO Appellate Body in the *Beef Hormones* case (para. 175) as requiring a Member to undertake a risk assessment in accordance with Article 5 of the SPS Agreement in order to demonstrate a scientific justification for its measures.

Two provisions of the Agreement are particularly important in describing the nature of the requirements established for measures to have a basis in science. The first is Article 2.2, one of the 'basic rights and obligations' WTO Members have under the SPS Agreement. This provision requires WTO Members to base any SPS measures they wish to introduce on "scientific principles" and to ensure that their SPS measures are "not maintained without sufficient scientific evidence." Article 2.2 is subject to an 'exception' set out in Article 5.7 of the Agreement, which allows Members to adopt SPS measures "on the basis of available pertinent information" in circumstances where "relevant scientific evidence is insufficient." However, measures may only be adopted pursuant to Article 5.7 "provisionally" as Members are subject to ongoing requirements "to seek to obtain the additional information necessary for a more objective assessment of risk" and to "review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

The second important provision is Article 5, which establishes obligations for Members to ensure that their SPS measures are "based on" a risk assessment.[24] In carrying out an assessment of SPS risks, Members must take into account "available scientific evidence"[25] and risk assessment techniques developed by the international organizations

[24] SPS Agreement, Article 5.1.

[25] SPS Agreement, Article 5.2.

whose standards are referenced in the Agreement.[26] Members are also required to take into account practical constraints affecting risk regulation such as "relevant inspection, sampling and testing methods"[27] and, where quarantine risks are concerned, relevant economic factors, including lost production or sales in the event of introduction of a pest or disease, and costs of control and eradication.[28] Although there is no mention of 'risk management' in the SPS Agreement, pursuant to Article 5.6 a Member selects risk regulatory measures according to what is considered necessary, but not more trade restrictive than required, to achieve its own risk management objectives, referred to as the Member's "appropriate level of SPS protection" or "acceptable level of risk".[29] The SPS Agreement makes it clear that it is up to each Member to determine the level of SPS protection it considers appropriate,[30] subject to some trade-based requirements but not to any (explicitly) science-based criteria. For instance, a Member should consider the objective of minimizing negative trade effects (Article 5.4) and seek to ensure that it

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[26] SPS Agreement, Article 5.1. Relevant risk assessment techniques include those developed by the Codex Alimentarius Commission, the International Office of Epizootics and the Secretariat of the International Plant Protection Convention.

[27] SPS Agreement, Article 5.2. The Appellate Body has indicated that Article 5.2 does not provide a "closed list" of such factors: *Beef Hormones*, para. 187.

[28] SPS Agreement, Article 5.3. See also the definition of a quarantine risk assessment in Annex A, para. 4, sentence 1 which refers to an evaluation of the "associated biological and economic consequences" of a pest or disease introduction.

[29] SPS Agreement, Annex A, para. 5.

[30] SPS Agreement, Preamble, para. 6.

adopts 'consistent' levels of protection for risks which are 'similar' in nature (Article 5.5).[31]

Where a dispute arises over a particular Member's compliance with the SPS Agreement (as, for example, in the *Beef Hormones* case), the matter will be referred initially to a three-member WTO panel which is charged with making "an objective assessment of the facts", including facts of a scientific or technical nature.[32] WTO panellists are usually drawn from national trade ministries and are unlikely to have scientific or technical training relevant to the SPS risks raised in a dispute. Parties present detailed scientific arguments in their submissions and frequently include scientists on their delegations, but WTO panels in SPS disputes are not limited to these sources in determining the scientific 'facts'. Instead, panels may appoint independent experts to advise the panel on relevant scientific and technical matters.[33] Generally a panel in an SPS dispute will appoint three to five experts covering a range of disciplines on the advice of secretariats of

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[31] Article 5.5, in particular, may impose significant constraints on a Member's prerogative to select an appropriate level of SPS protection. A full examination of this provision is beyond the scope of this article but see Jeffrey Atik, 'The Weakest Link: Demonstrating the Inconsistency of "Appropriate Levels of Protection" in Australia-Salmon' (2003) *Risk Analysis: an International Journal* (forthcoming; available from SSRN at http://ssrn.com/abstract_id=379580) and Vern R. Walker, 'Consistent Levels of Protection in International Trade Disputes: Using Risk Perception Research to Justify Different Levels of Acceptable Risk'. (2001) 31 *Environmental Law Reporter* 11317.

[32] *WTO Dispute Settlement Understanding*, Annex 2, (1994) 33 I.L.M. 28, Article 11 (hereafter 'DSU').

[33] See SPS Agreement, Article 11.2 and also DSU, Article 13.2.

international organizations such as the Codex Alimentarius Commission.[34] The panel consults with the experts but is not bound to follow their advice, although in practice panels tend to stick closely to the opinions of advising experts when determining scientific questions in dispute.[35] Panels' findings on 'factual' matters are usually determinative since only matters which can be framed as legal claims may be raised on appeal to the WTO Appellate Body, and even then the Appellate Body will not interfere with a panel's assessment of the facts unless there is "an egregious error that calls into question the good faith of a panel."[36]

In reviewing a Member's risk regulatory measures under the SPS Agreement, a panel is not supposed to undertake a 'de novo' assessment of the matter but nor is it limited to issues of procedure or manifest error as is frequently the case for a court undertaking judicial review.[37] The claims of violation of the SPS Agreement a panel may examine are limited by its terms of reference to those nominated by the complaining party, which also bears the burden of making a *prima facie* case of inconsistency with provisions of

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[34] For criticism of this procedure 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'. (2000) 8 *N.Y.U. Environmental Law Journal* 622, 630-1.

[35] For an excellent discussion of the use of experts in WTO dispute settlement see Joost Pauwelyn, 'The Use of Experts in WTO Dispute Settlement'. (2002) 51 *International and Comparative Law Quarterly* 325.

[36] See *Beef Hormones*, para. 133.

[37] Id. at para. 117.

the SPS Agreement.[38] The panel may choose to commence its analysis with any of the breaches alleged by the complainant,[39] often beginning with those relating to the risk assessment the respondent has put forward as the basis of its SPS measures. If this is the case, the panel will generally examine (with the aid of advice from its expert advisors) whether the studies or reports cited by a Member amount to a 'risk assessment' for the purposes of the SPS Agreement. An important component of this analysis will be whether "available scientific evidence" has been taken into account in the carrying out of the risk assessment, in order to meet the 'basic obligation' in Article 2.2 not to maintain SPS measures without sufficient scientific evidence, as well as the more specific requirements for risk assessment in Article 5.[40] Depending on the type of measure at issue, the panel will also examine whether the risk assessment evaluates either the "likelihood" of introduction of a particular pest or disease "according to the sanitary or phytosanitary measures which might be applied" (for quarantine risk assessment)[41] or the "potential" for adverse effects on health (in the case of food safety measures).[42] Provided

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[38] Id. at para. 103.

[39] Although in the *Beef Hormones* case, the Appellate Body suggested an analysis beginning with Article 2, which naturally precedes Article 5 in the text of the SPS Agreement, is "logically attractive" (para. 250), a sentiment taken to heart by later panels.

[40] The Appellate Body has indicated that Articles 5.1 and 5.2 "may be seen to be marking out and elaborating a particular route leading to the same destination set out in … Article 2.2": see *Australia – Measures Affecting Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R, 20 October 1998, para. 137 (hereafter '*Australia Salmon*').

[41] SPS Agreement, Annex A, para. 4, sentence 1.

[42] SPS Agreement, Annex A, para. 4, sentence 2.

the material put forward by a Member amounts to a 'risk assessment' for SPS purposes, the panel will go on to assess whether the Member's SPS measures are "based on" that risk assessment.[43] The final part of the enquiry will generally turn to the trade impacts of the SPS measures and whether they are "not more trade-restrictive than required to achieve [the Member's] appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."[44]

An alternative starting point for a panel's analysis of a Member's SPS measures is Article 2.2 and its requirement for Members to demonstrate that their measures are supported by "sufficient scientific evidence." This was the approach taken by the reviewing panel in the most recent SPS dispute concerning Japanese phytosanitary measures applied to US apple imports. Where a panel assesses compliance with Article 2.2 directly (rather than indirectly through an examination of a Member's risk assessment) it must address the question of what is meant by "sufficient" scientific evidence. Similar questions arise if the Member argues (often in the alternative) that its SPS measures have been "provisionally" adopted as "relevant scientific evidence is *insufficient*" to allow a full risk assessment.[45] In the *Japan Apples* case,[46] the reviewing panel, relying heavily on its expert advisors, carried out a detailed review of the available scientific evidence

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[43] SPS Agreement, Article 5.1.

[44] SPS Agreement, Article 5.6.

[45] SPS Agreement, Article 5.7 (emphasis added).

[46] See *Japan – Measures Affecting the Importation of Apples*, Report of the Panel, WT/DS245/R, 15 July 2003 (hereafter, '*Japan Apples* Panel Report').

concerning the SPS risk at issue (transmission of the plant disease, fire blight) to determine such questions as whether the material put forward by Japan was 'scientific', its evidentiary value for demonstrating the risks of concern and its 'sufficiency' as a justification for Japan's SPS measures.[47] Although the Panel also went on to consider Japan's risk assessment, this seemed to be done primarily for reasons of completeness[48] as the case could have been disposed of on the basis of the Panel's finding of a breach of Article 2.2.[49]

At first blush, a panel's decision to commence its analysis of a Member's SPS measures by directly examining their basis in science would seem to involve a very different kind of assessment to a review of a Member's science-based risk assessment. Certainly the former approach requires a panel to delve more deeply into the scientific evidence and may magnify the risk of decision-makers 'getting the science wrong' in their attempts to come to terms with complex scientific and technical issues.[50] However, in practice there may be little difference between the tasks involved in reviewing the scientific basis of

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[47] *Japan Apples* Panel Report, para. 8.89.

[48] Panels are permitted to exercise "judicial economy" when making findings on the parties' claims but as the WTO dispute settlement system makes no provision for the remand of cases following appellate review, panels usually undertake a full analysis of the claims of violation, in case any particular finding is overturned on appeal.

[49] In fact complainants often push for panels to make a finding under Article 2.2, rather than simply under Article 5, as the respondent will then need to produce 'sufficient' scientific evidence in order to introduce new measures, rather than simply undertaking a new, 'improved' risk assessment.

[50] Christoforou, above n 34, 636-637.

SPS measures and reviewing their basis in a risk assessment that is required to take appropriate 'scientific evidence' into account. In both cases, where the parties to an SPS dispute disagree over the interpretation of the available science and its relevance in determining the significance of the risks at issue, WTO decision-makers are likely to encounter complex questions which lie at interface between law and science.

III COMPARATIVE EXPERIENCE WITH JUDICIAL REVIEW OF RISK REGULATION

'Law and science', as an academic discipline, was largely developed by scholars in the US and has been enthusiastically taken up by their colleagues across the Atlantic examining the evolving governance structures of the EU.[51] Scholars in the 'law and science' field have tended to focus their study on the area of health and environmental protection, given the extent to which contemporary regulation of this kind draws on scientific inputs.[52] Beginning in the 1960s in the US, the proliferation of health and environmental statutes, together with the creation of new federal agencies engaged in risk regulation, provided those studying law and science interactions with ample raw material,

[51] See, e.g., Christian Joerges, Karl-Heinz Ladeur and Ellen Vos (eds), *Integrating Scientific Expertise into Regulatory Decision-Making* (Nomos Verlagsgesellschaft, Baden-Baden, 1997).

[52] Health and environmental regulation is not unique in this respect although it tends to draw more heavily on science than regulation in other areas, given the extent to which health and environmental issues are framed in terms of, and diagnosed, by science.

much of which has focused on the role of the courts in overseeing agency action.[53] In the EU, regulation by Community institutions in the field of health and environmental protection is a more recent phenomenon and regulatory structures, such as the new European Food Safety Authority,[54] are still in a developmental phase. Nevertheless there is an emerging body of case law in the European Court of First Instance and Court of Justice dealing with measures taken by Community institutions and EU Member States to address risks to health and the environment.

At face value, the challenges now facing WTO decision-makers, as they are asked to review national SPS measures, are very similar to those encountered by their judicial counterparts in the US and the EU. Although the institutional settings differ, the essential task is much the same: examining whether regulations to address risks are based on legitimate health and environmental concerns. In modern society this is a task that cannot be undertaken without scientific assistance, although communities seem loathe to entrust decisions with such significant social and economic consequences entirely to

[53] See, for example, Sheila Jasanoff, *Science at the Bar* (Harvard University Press, Cambridge MA, 1995).

[54] The EFSA was established by the European Parliament and Council regulation (EC) No 178/2002 of 28 January 2002 and formally opened for business in May 2003. It undertakes risk assessments in order to provide risk managers in EU institutions with a 'sound scientific basis' for defining measures required to ensure consumer protection with regards to food safety.

scientists.[55] Where there are disputes this inevitably places generalist legal decision-makers in the position of having to make judgments on risk regulatory measures despite their comparative lack of technical expertise. Given that decision-makers in all three settings – national, trans-national and international – are essentially engaged in the same exercise should the same principles not apply?

This solution is advocated by a number of commentators who offer a range of proposals for SPS decision-making recommending versions of the approaches seen in national and trans-national judicial review of risk regulation. Before assessing these proposals, it is worthwhile examining the differing (although perhaps not so different) approaches to judicial oversight of the adoption of risk regulatory measures in the US and EU, the two jurisdictions most commonly proposed as models that international decision-makers might draw upon when reviewing national SPS measures. The American story of the involvement of courts in risk regulation may already be familiar to many; the EU experience, given the recent origin of much of the case law, is likely to be less so. Both approaches are reviewed below in some detail in order to allow comparisons to be drawn, in Part IV, with the treatment of 'law and science' issues seen so far in the SPS jurisprudence.

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[55] Proposals for 'science courts' floated at one time in the US have not attracted widespread support because it is recognized that 'regulatory science' often involves resort to subjective judgment and policy in the absence of hard data: see Jasanoff, above n 53, 94.

US - Deference at the Frontiers of Science

Accounts of the role of US courts in risk regulation usually begin with the decades of the 1960s and 1970s, which ushered in a period of unprecedented federal regulatory activity in the field of health and environmental protection. During this period, new federal agencies were established, such as the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA), charged with the task of ensuring high levels of health and environmental protection for the American population.[56] Various health and environmental statutes were promulgated by Congress, calling for clean air,[57] clean water[58] and protection from cancer-causing substances.[59] Agencies' mandates under these statutes extended beyond merely addressing technologies and substances known to be harmful; instead they required agencies to predict and prevent risks to health and the environment which were yet to materialize.

As the fledgling agencies struggled to meet the regulatory goals set by Congress and to develop appropriate procedures for risk assessment, they often found themselves under attack from different interest groups. With the expanding reach of risk regulatory

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[56] Ibid, 2-3.

[57] *Clean Air Act 1963*, 42 U.S.C. §7401-7671q.

[58] *Clean Water Act 1972*, 33 U.S.C. § 1251-1387.

[59] See, e.g., *Occupational Health and Safety Act 1970*, 29 U.S.C. § 651-678; *Toxic Substances Control Act 1976*, 15 U.S.C. § 2601-2692 and the strongly 'precautionary' Delaney clause, incorporated into the 1958 amendment to the *Food, Drug, and Cosmetic Act*, 21 U.S.C. §348(c)(3)(A).

measures, industry became concerned over the potential costs and restrictions that might be imposed on its activities. Uncertainties in the scientific data relied upon by the agencies' in promulgating new rules opened them up to industry challenge on the basis that measures were not supported by 'sound science' but simply driven by policy judgments. On the other side, agencies faced action from public interest activists concerned that in carrying out their 'precautionary' legislative mandates, agencies were acting too slowly to relax the traditional dependence on findings of actual harm.[60]

Agencies' initial efforts to develop risk regulatory structures for dealing with health and environmental issues coincided with a period of considerable judicial activism in American administrative law.[61] Led by the federal courts in the District of Columbia (DC) circuit, judges were devising new doctrines of judicial review that called for a 'hard look' at the exercise of agency discretion.[62] The *Administrative Procedure Act* of 1946, together with sweeping provisions for judicial review in the new health and environmental statutes,[63] provided significant scope for those dissatisfied with agencies' rule-making in the risk regulatory area to ask judges to invalidate agency decisions as "unsupported by substantial evidence" or amounting to action that was "arbitrary,

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[60] Jasanoff, above n 53, 72.

[61] Richard B. Stewart, 'The Reformation of American Administrative Law'. (1975) 88 *Harv. L. Rev.* 1669.

[62] See, e.g., *Greater Boston Television Corp. v FCC*, 444 F. 2d 841, 850-1 (1970).

[63] For example, the judicial review provision in OSHA's governing statute requires 'substantial evidence on the record as a whole'.

capricious, an abuse of discretion, or otherwise not in accordance with law."[64] For reviewing judges this raised the question of what was entailed by the doctrine of 'hard look' where agencies' decision-making (at least purportedly) was undertaken on the basis of scientific information, an area in which the agencies had greater technical expertise than the courts.

The federal courts were well-aware of the difficulties presented by the review of technical decision-making and professed a policy of judicial restraint. Moreover, in the case of statutes with a 'precautionary' mandate,[65] courts recognized that scientific evidence might be "difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge" and declared that where "the regulations [are] designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect."[66] However, the practice of courts was much more interventionist, especially in the Court of Appeals for the DC Circuit before which many of cases concerning the regulation of new technologies were brought. An influential approach, championed by Judge Leventhal of the Court of

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[64] Although, as a formal matter, "substantial evidence" is associated with 'formal adjudication' procedures and the "arbitrary, capricious" standard with 'informal rule-making', in practice there is little difference in the stringency of judicial review applicable under each standard and courts reviewing decisions based on scientific evidence commonly apply the standards interchangeably.

[65] Although now more favored by the EC than the US in trade disputes, precaution (in the sense of regulatory action in the absence of scientific proof of harm) was an essential element of many American health and environmental statutes enacted during this era, such as the *Clean Air Act*.

[66] *Ethyl Corporation v EPA*, 541 F. 2d 1, 28 (1976).

Appeals, called for reviewing judges to scrutinize the substantive underpinnings of an agency's decision to determine whether its exercise of discretion was reasonable. Judge Leventhal argued that judges needed to "acquire whatever technical knowledge is necessary as background for decision of the legal questions", acting with restraint but not abdicating decision-making on factual questions to the agencies.[67] By taking a 'hard look' at the agency's record and reasoning supporting a decision, courts often undertook a searching review of the underlying scientific evidence.

In contrast to his judicial colleague, Chief Judge Bazelon of the Court of Appeals believed that reviewing judges should "scrutinize agency proceedings with extreme care" focusing on ensuring that agency procedures were adequate to allow for public participation in rule-making and full disclosure of areas of scientific uncertainty.[68] While stressing that judges "lack the technical competence to resolve scientific controversies",[69] court rulings following Chief Judge Bazelon's lead devised increasingly more stringent procedural requirements to be met by agencies in order to satisfy the demands of the 'hard look' doctrine.[70] However, this did not guarantee judicial restraint since judges often needed to probe the science underlying measures to determine whether additional procedures were necessary, and the lack of a clear dividing line between scientific and

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[67] *Ethyl Corporation v EPA*, 541 F. 2d 1, 68-69 (1976) (per Leventhal J).

[68] David L. Bazelon, 'Science and Uncertainty: A Jurist's View'. (1981) 5 *Harv. Envtl. L. Rev.* 209, 212.

[69] Id. at 211.

[70] See, e.g., *Natural Resources Defense Council v Nuclear Regulatory Commission*, 547 F. 2d 633 (1976).

policy judgments in 'regulatory science' made it difficult for judges to determine when they were straying into areas of agency expertise.[71]

Procedural obligations imposed by reviewing courts on agency risk regulation drew criticism for unnecessarily complicating the regulatory process without improving transparency in agencies' use of science,[72] and were eventually overruled by the Supreme Court in its *Vermont Yankee* decision.[73] Although the Supreme Court in this case prevented judges from imposing novel procedural requirements on agencies undertaking risk regulation,[74] it did not overturn the 'hard look' doctrine. Courts thus remained free to scrutinize the scientific underpinnings of agencies' risk regulatory measures, a power which was used increasingly in the more conservative Reagan-Bush era to reign in agency discretion in the implementation of 'precautionary' statutes. One concern was that by giving too much leeway to agencies to interpret scientific data, regulatory measures might be introduced on the basis of mere speculation about uncertain risks.[75]

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[71] Jasanoff, above n 53, 77.

[72] See Wendy E. Wagner, 'The Science Charade in Toxic Risk Regulation'. (1995) 95 *Colum. L. Rev.* 1613.

[73] *Vermont Yankee Nuclear Power Corp. v Natural Resources Defense Council*, 435 U.S. 519 (1978).

[74] 435 U.S. 519, 547-9 (1978).

[75] A phenomenon criticized by Stephen G. Breyer, *Breaking the Vicious Circle: Towards Effective Risk Regulation* (Harvard University Press, Cambridge MA, 1993).

This led courts to clarify, in cases such as *Monsanto Co. v Kennedy*, that precautionary statutes did not require the regulation of *de minimis* risks.[76]

The Supreme Court's decision in the *Benzene* case went even further.[77] The case concerned OSHA's workplace standard for exposure to air-borne benzene, which the agency had reduced from ten parts per million (ppm) to 1 ppm. OSHA's action was based on its policy that, in the case of known carcinogens (such as benzene), it would presume that no safe level of exposure existed in the absence of clear scientific proof establishing such a level. While there was ample scientific evidence demonstrating the adverse health effects of exposure to air-borne benzene at levels above 10 ppm there was inadequate quantitative data at the time on which to assess the cancer risk at low levels of exposure. In accordance with its statutory mandate, OSHA thus set the workplace exposure standard for air-borne benzene "on the basis of the best available evidence" at the lowest level technically and economically feasible to ensure that no employee would suffer material impairment of health.[78]

Reviewing OSHA's measure, the Supreme Court concluded that the agency had neglected a necessary "threshold" step in the promulgation of the measure, by failing to demonstrate that risk levels at the existing standard were "significant" and that a new,

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[76] *Monsanto Co. v Kennedy*, 613 F. 2d 947, 955 (1979). In that case, the *de minimis* risk at issue was the potential for single molecule of a harmful substance to migrate from plastic containers into food.

[77] *Industrial Union Department, AFL-CIO v American Petroleum Institute*, 448 U.S. 607 (1980).

[78] See § 6(b)(5), *Occupational Health and Safety Act 1970*.

more stringent standard was reasonably necessary or appropriate to provide workplace safety.[79] Although it apparently recognized the difficulties of proving significance where scientific knowledge is imperfect and the precise quantification of risks is impossible,[80] the Court criticized the agency for making only a qualitative assessment of the likelihood of harm and for rejecting industry testimony that it was possible to construct a dose-response curve for exposure to low-levels of air-borne benzene on the basis of existing data.[81] With a judicial nod in the direction of the 'frontiers of science' doctrine, the Court acknowledged that the agency was not required to support its finding that a significant risk exists "with anything approaching scientific certainty", and, so long as its findings were "supported by a body of reputable scientific thought", the agency would be permitted to use "conservative assumptions", erring "on the side of overprotection rather than underprotection."[82] However, these considerations did not dilute the Court's expectation that, prior to regulating, the agency would determine the 'significance' of the risk concerned, based on information estimating the likely probability of harm in quantitative terms.[83]

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[79] *Industrial Union Department, AFL-CIO v American Petroleum Institute*, 448 U.S. 607, 614-5, 639-640 (1980).

[80] Id. at 652.

[81] Id. at 653-4.

[82] Id. at 656.

[83] The Court remarked that some risks, such as a one in a billion risk of dying from cancer by taking a drink of chlorinated water, "clearly could not be considered significant." On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors containing 2% benzene will be fatal, "a reasonable person might well consider the risk significant": id. at 655.

The Supreme Court's ruling in the *Benzene* case spurred extensive review and formalization of agency risk assessment procedures used in establishing regulatory measures in the health and environmental field.[84] However, following the *Benzene* decision, judicial intervention in risk regulation carried out by agencies became more infrequent. This trend was consolidated by a later decision of the Supreme Court in *Baltimore Gas and Electric Company v Natural Resources Defense Council*[85] which concerned a rule adopted by the Nuclear Regulatory Commission regarding assumptions to be made about the level of risk posed by permanent storage of nuclear wastes. The Court of Appeals had found that because the scientific evidence underlying the assumptions made was subject to uncertainties, the Commission's decision was arbitrary and capricious. However, the Supreme Court reversed the Court of Appeals, remarking that

> a reviewing court must remember that the Commission is making predictions within its area of special expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.[86]

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[84] See, e.g., NRC, above n 4; EPA, *Guidelines for Carcinogen Risk Assessment* (1986) 51 Fed. Reg. 33992.

[85] 462 U.S. 87 (1983).

[86] Id., at 103.

Indeed, the trend in the more recent case law concerning health and environmental risk regulation has been to extend deference even further. In the *Chevron* decision, for example, the Supreme Court determined that where the legislative mandate established by a statute is silent or ambiguous, courts must defer to a "reasonable interpretation made by the administrator of an agency."[87] In its latest decision in the *American Trucking* dispute, the Supreme Court also demonstrated a reluctance to interfere with agency discretion to set science-based standards for the protection of public health and the environment.[88] At issue in the case were the EPA's new, more stringent air quality standards for ozone, a so-called 'non-threshold' pollutant that is thought to inflict a continuum of adverse health effects at any airborne concentration greater than zero. The DC Circuit of the Court of Appeals had ruled that EPA's new ozone standard lacked determinate criteria for drawing lines, thus failing to state intelligibly how much risk to health is too much.[89] However, the Supreme Court, in marked contrast to its decision in *Benzene*, held that there was no unconstitutional delegation of legislative power in the *Clean Air Act*'s instruction to the EPA Administrator to set ambient air quality standards that in her judgment ("based on" technical data about air quality and allowing "an adequate margin of safety") were "requisite to protect the public health."[90] Justice Scalia, delivering the opinion of the Court, found that the agency was required "to set air quality standards at the level that is "requisite" that is, not lower or higher than is necessary – to

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[87] *Chevron U.S.A. Inc. v Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984).

[88] *Whitman v American Trucking Associations Inc*, 531 U.S. 457 (2001).

[89] *American Trucking Associations, Inc. v EPA*, 175 F.3d 1027, 1034 (C.A. D.C. 1999).

[90] Section 109(a), *Clean Air Act*, 42 U.S.C. § 7409(a).

protect the public health with an adequate margin of safety",[91] taking into account scientific data but not considering the economic costs imposed by the introduction of more stringent standards.[92]

The Supreme Court's finessing of risk assessment requirements in the *Benzene* case notwithstanding, it seems that the 'frontiers of science' doctrine, and the principle of deference more generally, continue to hold considerable sway in the judicial review of risk regulatory measures in the US.[93] Courts will be at their most deferential in cases where an agency is genuinely operating 'at the frontier', in the sense of making a policy choice among a range of options left open by scientific uncertainty.[94] In some cases this will see courts upholding agency decisions which err on the side of caution,[95] but equally courts will not interfere to prevent an agency authorizing a technology in circumstances

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[91] *Whitman v American Trucking Associations Inc*, 531 U.S. 457, 475-6 (2001).

[92] Id. at 465 upholding decisions of the DC Circuit Court of Appeals to the effect that economic considerations may play no part in the promulgation of national ambient air quality which are designed to protect public health.

[93] See Richard A. Merrill, 'Science in the Regulatory Process'. (2003) 66 *Law and Contemporary Problems* 1.

[94] Shapiro, above n 10, 334-339.

[95] See David A. Wirth, 'The Role of Science in the Uruguay Round and NAFTA Trade Disciplines'. (1994) 27 *Cornell Int'l. L.J.* 817, 851 although acknowledging that deference can be a 'two-edged sword' from an environmental perspective.

where scientific uncertainty over the level of risk still remains.[96] The guiding rationale is implicitly one that sees agencies' claims to expertise as superior to those of generalist decision-makers and trusts to the capacity of regulators to make appropriate policy choices in the face of imperfect scientific knowledge. Where the powers granted by health and environmental statutes to establish risk regulatory measures are very broad (as in the case of ambient air quality standards under the *Clean Air Act*), normative choices about acceptable levels of risk may effectively be delegated to specialist agencies, exercising powers on the basis of their interpretation of the available scientific evidence.

EU - A Precautionary Approach to Risk Management

In comparison to the American courts, forays by the EU's judicial bodies into the field of reviewing risk regulatory measures are of relatively recent origin, as is the underlying structure of EU risk regulation itself. Most of the relevant case law has been decided within the past five years and some issues are yet to be explored fully by the European Court of Justice (ECJ). Nevertheless, from a comparative 'law and science' perspective, the trans-national governance structures of the EU provide a closer match to the supranational arrangements of the WTO than the hierarchical organization of government

[96] See, e.g, *Alliance for Bio-Integrity v Shalala*, 116 F.Supp. 2d. 166 (D.D.C. 2000) upholding the Food and Drug Administration's policy as to the safety of genetically modified foods and the lack of necessity for consumer labeling on the basis of deference to the agency's expertise.

characteristic of nation States.[97] Moreover, as the WTO, like the EU, has moved more into the domain of governance, rather than simply coordinating the actions of governments, the impact of its rules on national regulatory autonomy has become more pronounced, carrying with it similar legitimacy concerns to those which have faced EU institutions.[98]

During the 1960s and 1970s when American risk regulation was pushing at the 'frontiers' of scientific knowledge, comparable regulation in the Member States of the then European Economic Community was largely conservative in its goals, consensual in its mode of promulgation and fairly non-contentious.[99] European-level institutions lacked competence in the field of environmental policy until the treaty reforms of the late 1980s, a time (ironically as it now seems) when US agencies were retreating from a highly precautionary stance on issues of risk towards an approach which emphasized quantitative risk assessment. With the signing of the Single European Act in 1986, the environment was constituted as an area of official Community policy.[100] The trend

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[97] Christian Joerges, 'Law, Science and the Management of Risks to Health at the National, European and International Level - Stories on Baby Dummies, Mad Cows and Hormones in Beef'. (2001) 7 *Colum. J. Eur. L.* 1.

[98] Robert Howse, 'Democracy, Science and Free Trade: Risk Regulation on Trial at the World Trade Organisation'. (2000) 98 *Michigan L. Rev.* 2329.

[99] Ragnar E. Löfstedt and David Vogel, 'The Changing Character of Regulation: a Comparison of Europe and the United States'. (2001) 21 *Risk Analysis* 399, 402.

[100] Article 25 of the Single European Act added a new Title VII on 'Environment' to the European Economic Community Treaty, consisting of Articles 130r, 130s and 130t, now Articles 174-175 of the

towards centralization was consolidated by the Maastricht Treaty of 1992, which elaborated the objectives of Community environmental policy (including that it encompassed the protection of human health)[101] and added the 'precautionary principle'[102] to the suite of environmental principles on which that policy was to be based.[103] The amendments required Community environmental policy to "aim at a high level of protection",[104] taking account of available scientific and technical data, as well as the potential benefits and costs of action or lack of action.[105] A high level of protection was also established as a goal that the Community was to contribute to in the new activity areas of public health[106] and consumer protection.[107] Like environmental protection

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Treaty Establishing the European Community, *Official Journal*, C 325, 24 December 2002 (hereafter 'EC Treaty').

[101] Article 130r(1), now Article 174(1) of the EC Treaty.

[102] This principle is not defined in the EC Treaty. The most cited definition of the principle is that found in the *Rio Declaration on Environment and Development*, 14 June 1992, 31 ILM 874 (1992). Principle 15 of the *Rio Declaration* provides: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

[103] Article 130r(2), now Article 174(2) of the EC Treaty. The precautionary principle takes its place alongside the principles of prevention, rectification at source, and polluter pays introduced in the earlier amendments of the Single European Act.

[104] Ibid.

[105] Article 130r(3), now 174(3) of the EC Treaty. Article 100a of the Treaty was also amended to specify that environmental policy aiming at a high level of protection should nevertheless be based "on scientific facts": Article 100a(3), now Article 95(3) of the EC Treaty.

[106] Article 129(1), now Article 152 of the EC Treaty.

requirements, which must be integrated into the definition and implementation of all EC policies and activities,[108] health protection requirements were also to form a constituent part of the Community's other policies.[109]

In the 1990s, however, a series of scandals in the EU, primarily relating to food safety and public health, provided highly visible evidence that regulation at the European level could not always be trusted to ensure protection against EU-wide risks.[110] Public faith in the regulatory institutions of the EU, and the scientific bodies on whose expertise they relied, evaporated with each new incident. The Bovine Spongiform Encephalopathy (BSE or mad cow disease) 'crisis' provided a particularly telling example of the failures of Community regulation to protect against risks to human health In March 1996, an independent scientific advisory body to the United Kingdom (UK) government announced that ten cases of the human variant of BSE, Creutzfeldt-Jakob disease, had been detected, with the most likely explanation being exposure to BSE, despite the fact

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[107] Article 129a(1), now Article 153 of the EC Treaty.

[108] Article 6, EC Treaty.

[109] Article 129(1), now Article 152 of the EC Treaty.

[110] Although the Mad Cow disease (BSE) crisis was the most prominent of such scandals, public confidence in Community and Member State risk regulation was also damaged by incidents such as the discovery of dioxin in Belgian chicken feed and tainted blood found in French blood banks. Commentators trace the current public skepticism in Europe regarding genetically modified organisms to the "crisis in science and government" sparked by these incidents: Löfstedt & Vogel, above n 99, 403.

that both UK and Community risk reduction measures for BSE had been in place for a number of years.[111]

Questions over the legitimacy and credibility of its institutions and regulatory structures for dealing with risk forced the EU to rethink its approach to risk regulation in the health and environmental field. The resulting policy reforms sought to improve the transparency and accessibility of Community-level decision-making, to ensure a clear separation between risk assessment and risk management, and to promote greater reliance on the precautionary principle as a basis for risk management measures.[112] These themes were reflected in the Commission's Communication on the Precautionary Principle, issued in 2000, which sought to clarify both how the Commission interpreted the principle and how it intended to apply it in risk regulation. The Commission advised that it saw the precautionary principle as a risk management tool, used in the process of reaching political decisions on levels of acceptable risk. However, it stressed that precautionary risk regulation needed to be preceded by "a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty."[113] In December 2000 in Nice, the Council of the EU adopted a

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[111] See Case C-180/96 *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities* [1998] ECR I-02265, para. 9 (hereafter '*BSE* case').

[112] In addition to its Communication on the Precautionary Principle, the Commission issued a White Paper on Food Safety (COM/99/0719), as well as a Communication on Consumer Health and Food Safety (COM/97/0183).

[113] See Commission Communication on the Precautionary Principle, above n 5, p. 3.

resolution endorsing the 'broad lines' of the Commission's Communication, although it seemed to envisage the need for a less onerous risk assessment process prior to the principle being invoked. The Council also took the view that the principle should apply to Member State policies as well as those of Community institutions.[114]

The current atmosphere of risk regulation in the EU has been likened by some commentators to that which prevailed in the US in the 1970s, when regulatory agencies also sought to gain public trust through pursuing precautionary health and environmental policies.[115] As in the US, the EU's pursuit of a 'high level' of health and environmental protection and consumer safety has generated conflicts over whether the objectives of regulatory measures reflect real health and environmental risks, which are adequately supported by available scientific data. Disputes may arise when Community institutions take preventative measures in circumstances of scientific uncertainty, which adversely impact the interests of EU Member States or industries, as occurred when the EU adopted 'emergency measures' in response to the risk of BSE transmission.[116] More recently, however, differences have emerged between EU Member States and Community institutions as to what measures are necessary to ensure a high level of protection against risks to human health and the environment. Increasingly, the precautionary principle is

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[114] de Sadeleer, above n 2, 111.

[115] Löfstedt & Vogel, above n 99, 403-404.

[116] See the series of cases commencing with the ECJ's *BSE* decision in 1998: Case C-365/99 *Portuguese Republic v Commission of the European Communities* Reports [2001] ECR I-05645 and Case C-241/01 *National Farmers' Union v Secretariat general du gouvernement* [2002] ECR I-09079.

being raised by Member States as a 'defense' to justify action which would otherwise constitute a barrier to intra-Community trade.[117] The cases raise questions over how the precautionary principle is to be interpreted in EU law and the nature of the relationship between science, risk assessment and precautionary measures in circumstances where there are serious concerns over potential health and environmental risks but no conclusive scientific evidence of harm.

In assessing the development of the EU approach to judicial review of risk regulation it is of significance that the ECJ's first major case in the area was one involving the Community measures taken to address BSE. The ECJ's decision in the *BSE* case did not mention the precautionary principle expressly and was taken in an atmosphere where the seriousness of the potential consequences of the Community failing to act were not in question, notwithstanding considerable scientific uncertainty as to the modes by which BSE could be transmitted to humans and give rise to disease. The Court readily came to the conclusion that uncertainties as to the adequacy and effectiveness of the previous national and Community measures dealing with BSE, in light of risks regarded as serious to public health, meant that the Commission "did not clearly" exceed the bounds of its regulatory discretion in seeking to contain the disease and ban exports of beef from the affected areas.[118] The ECJ declared that:

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[117] Pursuant to Article 30 of the EC Treaty, Member States are permitted to introduce quantitative restrictions on trade in goods which would otherwise infringe Articles 28 and 29 provided such measures can be justified on various public policy grounds, including the protection of human life and health.

[118] *BSE* case, para. 62.

> Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.[119]

This approach, in the Court's opinion, was borne out by the provisions of the EC Treaty requiring Community environmental policy to pursue the objective of safeguarding human health and to aim at a high level of protection in that regard.[120] Moreover, in view of the urgency of the situation and the seriousness of the risks involved, the Court found that the Commission had not acted in an inappropriate or disproportionate manner in imposing what was in any case a temporary ban, pending the production of more detailed scientific information.[121]

The *BSE* decision was interpreted by the regulatory institutions of the EU as a judicial endorsement of the precautionary approach to risk regulation, in the name of promoting the Community's policy objectives in the field of health and environmental protection.[122] Certainly the decision seemed to signal the Court's preparedness to take precautionary considerations into account when reviewing risk regulatory measures adopted by Community institutions, as well as the importance of giving effect to the Treaty's policy

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[119] Id. at para. 99.

[120] Id. at para. 100.

[121] Id. at paras 101-111.

[122] See, for instance, the Commission's Communication on the Precautionary Principle, above n 5, 23.

aims concerning the need for high levels of health and environmental protection in the EU. However, the *BSE* decision left unresolved questions concerning the extent to which EU measures must be supported by scientific evidence, even in circumstances of scientific uncertainty, and especially in situations where the 'seriousness' of the risks at issue is not as manifest as in the case of BSE.[123]

Two recent decisions of the European Court of First Instance (CFI) illustrate the lengths to which Community judicial organs may be prepared to go to support precautionary EU risk regulation in conditions of scientific uncertainty. The cases of *Pfizer* and *Alpharma* both involved challenges to an EU Council Regulation revoking the authorization for certain antibiotics to be used as growth promoters in animal feed.[124] Although antibiotics have been used as animal growth promoters for a number of years, in recent times concern has grown, both in the EU and internationally, that this practice could lead to the development of resistant bacterial strains, eventually posing a problem for the treatment of infections in human medicine. Neither of the antibiotics at issue in the cases was widely used in human medicine but there was some potential that each might become

[123] In the most recent of the BSE decisions, Case C-393/01 *French Republic v Commission of the European Communities* [2003] ECR I-05405, the ECJ noted that, in several cases, it had "drawn attention to the reality and the seriousness of the risks associated with BSE and the appropriateness of interim protective measures justified on the ground of protection of human health in the light of that disease": para. 42.

[124] Case T-13/99 *Pfizer Animal Health SA v Council of the European Union* [2002] ECR II-03305 (hereafter '*Pfizer*') and Case T- 70/99 *Alpharma Inc. v Council of the European Union* [2002] ECR II-03495 (hereafter '*Alpharma*').

important in the future treatment of infections caused by multiply-resistant bacterial strains.[125]

In taking action to ban the use of antibiotics as growth promoters, the Community institutions relied on the precautionary principle, citing uncertainties in the currently available scientific data. A full risk assessment had not been taken prior to the adoption of the Regulation in either case and, in respect of one of the antibiotics, the Commission also had not obtained an opinion from its scientific advisory committee.[126] The manufacturers of the antibiotics challenged the Council's regulation, arguing that it was not based on a proper risk assessment and that the Community institutions had

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[125] Virginiamycin (at issue in the *Pfizer* case) is an antibiotic exclusively used as a growth promoter in animal feed, although antibiotics belonging to the same class are used in human medicine. Bacitracin zinc (at issue in the *Alpharma* case) is used mainly for topical treatment of infections of the skin and mucosal surfaces, although there is some possibility that it could be used in the future to treat infections caused by resistant strains of bacteria.

[126] In the *Alpharma* case, the contested Regulation had been issued without the Commission first seeking an opinion from the Scientific Committee for Animal Nutrition, an expert committee specifically established to provide scientific advice to Community institutions on issues relating to animal feedstuffs. The CFI ruled that such consultation was not mandatory although it was "only in exceptional circumstances and where there are adequate guarantees of scientific objectivity that the Community institutions may, when … they are required to assess complex facts of a technical or scientific nature, adopt a preventive measure withdrawing authorisation from an additive without obtaining an opinion from those scientific committees" (para. 213). Nevertheless the CFI was satisfied that 'exceptional' circumstances had been established and accepted that the Community institutions were able to reach conclusions about the risk at issue on the basis of other scientific information available to them, albeit general in nature.

misapplied the precautionary principle. However, the Court found that the Community institutions were entitled to rely on the precautionary principle to adopt preventative measures in circumstances where, owing to existing levels of scientific uncertainty, the reality and seriousness of risks to human health are not yet fully apparent.[127] It added the rider that while the reality and extent of the risk did not need to be demonstrated by conclusive scientific evidence, this did not mean the institutions could act on the basis of a mere hypothesis that had not been scientifically verified.[128]

Despite the limited nature of the scientific evidence available to the Community institutions and the lack of anything indicating an immediate health threat, the CFI found that the Commission and Council had not committed any manifest errors in their review of scientific studies and assessment of the risks to health prior to adopting the measure.[129] Although the Court stressed that regulatory authorities must have at their disposal scientific information which is sufficiently reliable and cogent to allow them to understand the ramifications of the scientific questions raised and to make a decision on policy measures in full knowledge of the facts,[130] the CFI displayed a strongly deferential attitude when reviewing the institutions' interpretation of the scientific material and their judgments as to the existence of genuine scientific uncertainty.

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[127] *Pfizer*, para. 140; *Alpharma*, para. 153.

[128] *Pfizer*, para. 143; *Alpharma*, para. 156.

[129] *Pfizer*, paras. 325, 341 and 387; *Alpharma*, paras. 267-269, 294 and 312.

[130] *Pfizer*, para. 162; *Alpharma*, para. 175.

The latest decision of the ECJ in the case of *Bellio F.lli Srl v Prefettura di Treviso* also displays a deferential attitude towards the view of scientific evidence taken by Community institutions, and is sympathetic to the institutions' stated aim to achieve risk management objectives based on a high level of protection, especially in the context of the serious risks posed by BSE.[131] In the *Bellio* case, the ECJ upheld the right of the Community to pursue a policy of 'zero tolerance' in regard to the contamination of animal feed with material possibly containing the agent that causes BSE, even in circumstances where contamination was most likely accidental, levels of contaminants were very low and there was scientific uncertainty as to the minimum amount of infected material required to lead to disease in humans.[132] In approving the Community regulation as a precautionary human health measure,[133] the Court commented that the measure had been adopted on the recommendation of experts who had the relevant scientific data at their disposal and formed part of a coherent body of Community legislation designed to combat transmissible spongiform encephalopathies.[134]

While the EU judiciary has generally been supportive of Community efforts to undertake precautionary risk regulation,[135] and deferential when it comes to the institutions'

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[131] Case C-286/02 *Bellio F.lli Srl v Prefettura di Treviso*, ECJ, 1 April 2004 (not yet reported).

[132] Id. at paras. 48-52.

[133] Id. at paras. 57-58.

[134] Id. at para. 61.

[135] See also Case T-199/96 *Bergaderm and Goupil v Commission* [1998] ECR II-2805 and Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211.

interpretation and use of science in pursuing risk management goals, a markedly different approach is taken in respect of the invocation of precaution by Member States to justify regulatory measures on health or environmental grounds. In the absence of harmonized Community measures in a regulatory field, and to the extent that uncertainties continue to exist in the current state of scientific research, Member States have discretion to decide on their intended level of protection against risks to human health, safety or the environment.[136] However, since such national measures generally impact intra-Community trade, Member States must be able to justify their stricter standards on public policy grounds in accordance with the discipline of Article 30 of the EC Treaty. Like the Community institutions, Member States are entitled to invoke the precautionary principle in arguing that their regulatory measures address a particular health or environmental risk of concern.[137] Nevertheless, the courts seem to scrutinize Member States' claims of scientific uncertainty with much greater stringency and will not permit Member States to diverge from harmonized action taken at the Community level on precautionary grounds alone.[138]

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[136] See Case C-174/82 *Sandoz* [1983] ECR 2445, para. 16.

[137] See Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, para. 63.

[138] See, e.g., Case C1/100 *Commission v France* [2001] ECR I-9989 where France refused to lift its restrictions on British beef in defiance of a Community decision requiring Member States to do so. France argued that the Commission had infringed the precautionary principle by failing to take account of minority opinions about pathways of BSE transmission expressed by Members of one of the Commission's scientific advisory bodies and by failing to revise its decision on lifting the ban in light of scientific arguments contained in an opinion of the French food safety authority. The ECJ dismissed France's claims that it was entitled to rely on Article 30 to justify precautionary measures subsequent to harmonizing action being

The Court's approach to reviewing national risk regulatory measures, taken on the basis of the precautionary principle, is illustrated by the case of *Commission v Denmark*.[139] The Commission had brought proceedings against Denmark under Article 28 of the EC Treaty (which prohibits all measures taken by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade)[140] in respect of a Danish regulatory practice under which 'enriched' foodstuffs lawfully produced or marketed in other Member States could not be marketed in Denmark unless shown to meet a nutritional need in the Danish population.[141] The Danish authorities relied on the precautionary principle to argue that, as the toxicity of vitamins and minerals added to foods making up a consumer's diet could not be determined with

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taken by the Community. One commentator interprets this finding of the Court as demonstrating that "Member State governments mat not invoke precaution to regulate risks that the Commission has deemed insignificant": Wiener, above n 115, 216. Cf. *France v Commission* [2003] ECR I-5405 where the French challenge to the Commission's decision to lift the ban on Portugese beef was successful, the Court finding that the Commission had not properly carried out the necessary verifications and compliance checks to ensure that trade in Portugese beef would not pose a risk of BSE transmission.

[139] See also the decision of the EFTA Court in Case E-3/00 *EFTA Surveillance Authority v Norway* [2001] 2 C.M.L.R. 47.

[140] See the ECJ's decision in Case C-8/74 *Dassonville* [1974] ECR 837.

[141] Case C-192/01 *Re the Prohibition of Marketing of Enriched Foods: Commission of the European Communities v. Denmark* [2003] 3 C.M.L.R. 29 (hereafter '*Commission v Denmark*').

sufficient scientific certainty, it only had to establish that enriched foodstuffs did not meet a real need in order to invoke Article 30.[142]

Although the Court recognized that Member States had a discretion to choose their own level of protection and risk regulatory measures in default of harmonization, it found that any claim that a risk to health existed had to be sufficiently established on the basis of the most reliable scientific data available and the most recent results of international research.[143] If having undertaken a comprehensive risk assessment, "it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures" by a Member State.[144] In the foodstuffs area, what the Court means by scientific uncertainty is that, according to the current state of Community and international research, it has not been possible to calculate acceptable daily intake allowances for particular food additives.[145] Even in circumstances where such uncertainties exist, Member State's precautionary measures must also be proportionate, a condition which the Court found was not met by

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[142] Id. at paras. 28-35.

[143] Id. at para. 51.

[144] Id. at para. 52.

[145] Sabine Schlacke, 'Foodstuffs Law and the Precautionary Principle: Normative Bases, Secondary Law and Institutional Tendencies' in Joerges, Ladeur and Vos (eds), *Integrating Scientific Expertise into Regulatory Decision-Making* (Nomos Verlagsgesellschaft, Baden Baden, 1997) 169, 176.

the Danish practice because "it systematically prohibit[ed] the marketing of all foodstuffs to which vitamins and minerals ha[d] been added, without distinguishing according to the different vitamins and minerals added or according to the level of risk which their addition may possibly pose to public health."[146]

The case law of the EU judicial bodies on risk regulation, while it pursues a consistent goal of furthering high levels of health and environmental protection, thus appears to be more deferential to the Community institutions' vision of the risk regulatory measures that goal requires, rather than that of Member States', particularly where unilateral precautionary action, unchecked, could seriously disrupt the functioning of the internal market. In both cases, scientific uncertainty can justify precautionary measures, provided some attempt is made to evaluate the scientific evidence, and the risks at issue are not merely 'hypothetical'. But these preconditions are reviewed more lightly in the case of Community measures, where the countervailing considerations of internal market regulation are less salient. Formally this compromise is achieved through the adoption of different standards of judicial review when it comes to Community, as opposed to Member State, precautionary action. Where the Community measure at issue is taken in the field covered by the common agricultural policy (which enjoys a privileged status in EU law) or based on complex scientific and technical assessments, courts will limit their review to examining whether Community institutions have made a manifest error of

[146] *Commission v Denmark*, para. 55. Compare the much more lenient assessment of the 'proportionality' of risk regulatory measures taken by Community institutions in the *Pfizer* and *Alpharma* cases.

assessment, misused powers or manifestly exceeded the limits of discretion.[147] However, in cases where Member States invoke the precautionary principle to justify measures that would otherwise amount to trade barriers, the 'exceptional' nature of that action dictates a more exacting standard of judicial review. Essentially the burden of proof rests on Member States in such cases, to demonstrate that their concerns of risk are justified, based on an assessment of the best available scientific evidence and the latest international research on the question.[148]

As the EU judicial approach to reviewing science-based risk regulation is deferential to the definition of risk management goals by Community institutions, it relies on those regulatory institutions having a coherent view of what health and environmental policies are necessary to pursue a high level of protection in any case, notwithstanding scientific uncertainty. The case of risk regulation in the field of genetically modified organisms (GMOs) and GM foods puts this assumption under severe strain, given inconsistencies in the approach of the Commission, and differences between the Commission and the other governing institutions of the EU as to the seriousness of the risks at issue.[149] The dilemmas this situation presents for the courts are illustrated by the ECJ's recent judgment in the *Monsanto GM Food* case.[150] In advising on the question of whether the

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[147] See *Pfizer*, paras. 166-168, *Alpharma*, paras. 177-179 and the cases cited therein.

[148] *Commission v Denmark*, para. 46.

[149] Joanne Scott, 'European Regulation of GMOs and the WTO'. (2003) 9 *Colum. J. Eur. L.* 213.

[150] Case C-236/01 *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others*, ECJ, 9 September 2003 (not yet reported).

Italian government is justified in prohibiting the marketing of certain GM-derived foods, the Court vacillates between requiring a thorough assessment of health risks as a basis for any regulatory measures, and allowing Member States precautionary opt-outs where they can point to specific evidence which, without precluding scientific uncertainty, indicates potential risks to human health.[151]

Different Rhetoric, Similar Approaches

Although the rhetoric used by the US and EU (particularly in SPS disputes) is very different when it comes to the role of science in risk regulation, there are still striking similarities between the judicial approaches in each jurisdiction to the review of risk regulatory measures, taken to address risks considered serious in circumstances of scientific uncertainty.[152] While the approaches to risk regulation in the two jurisdictions cannot be described as 'convergent', they seem to be following parallel trajectories, albeit temporally asynchronous. Deference to the judgment of regulators to select the most appropriate risk management policies on the basis of complex scientific evidence is a feature of both bodies of jurisprudence. In the US, deference may be moderated by a concern to ensure that agencies are addressing 'significant' risks rather than pursuing a

[151] Id. at 112-3.

[152] See Jonathan B. Wiener, 'Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems'. (2003) 13 *Duke Journal of Comparative and International Law* 207. See also David Vogel, 'Ships Passing in the Night: The Changing Politics of Risk Regulation in Europe and the United States'. (2001) RSC No. 16/2001 *EUI Working Papers*.

precautionary legislative mandate to the limit for its own sake.[153] This had led to institutional changes which are reflected in a more quantitative, and 'sound science' based approach to risk assessment on the part of federal health and environmental agencies. In the EU, the judicial organs have, so far, been prepared to give Community regulatory institutions substantial leeway in their use of science and risk assessment citing the precautionary principle, but cautions against acting on the basis of 'hypothetical' risk indicate it may not be long before the courts impose more stringent requirements on institutions' risk assessment processes. Certainly the ECJ has been prepared to take a stricter approach in reviewing the risk regulatory measures taken by EU Member States on precautionary grounds, with national governments generally required to make showings of genuine scientific uncertainty and attempts to undertake as comprehensive a risk assessment as possible before measures may be adopted.

The most important difference between the approach of US and EU courts overseeing risk regulation seems to lie less in the rhetoric used and more in the normative reference point that orients the 'compass' of judicial review when each assesses the health and environmental justifications for risk management measures. Science can only go so far in informing risk management, particularly where cautious policies are seen as necessary;

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[153] Some analyses of the Supreme Court's decision in the *Benzene* case suggest that it is best interpreted as the correction of a 'political failure' to specify limits in setting the risk regulatory mandates of agencies: see Jasanoff, above n 53, 83. However, the *American Trucking* decision demonstrates the opposite tendency, with the Court shying away from placing any limitations on the EPA's discretion to set air quality standards for the protection of public health.

eventually there comes a point where social value judgments are required as to whether risks, even if not conclusively demonstrated by scientific evidence, are considered unacceptable by society. In the US, normative judgments on such questions are, by and large, left by the judicial 'frontiers of science' and deference doctrines to the regulatory agencies. Initially this approach seemed to rest on US courts' belief in the technocratic legitimacy of federal agencies, specifically entrusted by Congress with the task of regulating health and environmental risks posed by complex technologies.[154] During the 1970s and 1980s the legitimacy claims of the agencies sustained a serious challenge both on technocratic and democratic grounds, but there is now some evidence to suggest that levels of public trust in agencies are improving.[155] US agencies are increasingly moving towards a negotiated rule-making model with greater public input and a more integrated approach to risk assessment and risk management.[156]

In the wake of the legitimacy crisis provoked by regulatory failures in the case of BSE, a judicial approach to EU risk regulation that left value judgments about appropriate levels of risk solely to the discretion of Community institutions and Member State governments would have done little to restore public faith in European regulators. The reliance of the EU judiciary upon the EC Treaty's call for Community policy to aim at high levels of health and environmental protection provides an alternative, far less contentious

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[154] Shapiro, above n 10, 326; Jasanoff, above n 53, 87.

[155] Löfstedt & Vogel, above n 99, 402-403.

[156] Ortwin Renn, 'Commentary on the Article by Löfstedt and Vogel'. (2001) 21 *Risk Analysis* 406, 406.

normative justification for the tradeoff of interests inherent in decisions to address health and environmental risks where no there is currently no scientific proof of harm.[157] This approach still leaves open the question of what 'a high level of protection' entails in circumstances of scientific uncertainty over the nature and extent of health or environmental risk. Lack of public confidence in EU regulatory institutions demands a strong separation between scientific risk assessment and risk management policy. But by relying on the precautionary principle, coupled with a deferential attitude on the part of the EU judiciary when it comes to reviewing the scientific basis for Community risk regulatory measures, the courts are able to provide Community institutions with flexibility to regulate risks generally considered to be serious despite a lack of conclusive scientific evidence of harm.

IV SCIENCE AND RISK ASSESSMENT IN THE SPS CASE LAW

The involvement of WTO 'judicial' decision-makers in health and environmental risk regulation is of even more recent origin than in the EU and is subject to much greater institutional constraints than apply at the national, or even trans-national, level. The

[157] In an interesting aside, the CFI in the *Pfizer* case commented that the 'scientific legitimacy' of EU expert committees "is not a sufficient basis for the exercise of public authority" (para. 201) seeing the Commission's claims to 'democratic legitimacy' as superior in that regard.

WTO has no general authority to set health and environmental policy for its Members[158] and the dispute settlement arm of the organization has a fairly narrowly focused mandate, addressed to ascertaining compliance with the WTO Agreements.[159] Perhaps it is not surprising in this setting that science, a body of knowledge which is often represented as being a-political and value-neutral,[160] plays an important role in judging the validity of national SPS regulations where they impact international trade. But exactly how is scientific knowledge and science-based risk assessment used by WTO decision-makers in maintaining "the delicate and carefully negotiated balance in the SPS Agreement between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health",[161] and are there any lessons that comparable US and EU experience with the judicial review of risk regulation can offer in this regard?

The four SPS disputes decided to date – *Beef Hormones*, *Australia Salmon*, *Japan Varietals*[162] and *Japan Apples*[163] – have involved quite different SPS measures and

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[158] The Appellate Body has continually stressed that the determination of goals of health and environmental protection in the SPS field "is a prerogative of the Member concerned and not of a panel or of the Appellate Body": *Australia Salmon*, para. 199.

[159] See Articles 7 and 13 of the DSU.

[160] Although these claims have been seriously challenged in post-modern and deconstructionist literature concerning scientific knowledge, science continues to enjoy broad international acceptance as a universally applicable, largely impartial body of knowledge about the natural and physical world.

[161] *Beef Hormones*, para. 177.

[162] *Japan – Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R, 22 February 1999 (hereafter '*Japan Varietals*').

scenarios of risk regulation. As in the EU, where the *BSE* decision played an important part in defining the role that the ECJ would play in reviewing risk regulation, the fact that the first SPS case of *Beef Hormones* concerned a highly visible dispute over food safety measures taken to protect against uncertain risks, has also had a significant impact on the shape of the SPS jurisprudence that followed. The three later disputes have concerned challenges to quarantine regulations imposed by particular WTO Members, although in both *Australia Salmon* and *Japan Apples*, the measures at issue were argued to have a larger environmental goal.[164] In all four cases, scientific evidence played a prominent role as the parties advanced differing views regarding the appropriate interpretation of scientific data and its relevance in defining the significance of risks at issue for risk management purposes. It is not proposed in the sections that follow to examine the rulings in the SPS disputes in extensive detail.[165] Rather the focus is on what the jurisprudence reveals about the role that science plays in SPS regulation at the

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[163] *Japan – Measures Affecting the Importation of Apples*, Report of the Appellate Body, WT/DS245/AB/R, 26 November 2003 (hereafter '*Japan Apples*').

[164] In the *Australia Salmon* case, Australia argued that its measures were designed to prevent the introduction of diseases which could harm native fish species as well as farmed salmon. In the *Japan Apples* case, the Japanese measures were taken to protect against the risk of introduction of fire blight, a plant disease that affects wild and ornamental plants in the *Cotoneaster*, hawthorn, firethorn and mountain ash genera, as well as commercial plants such as apples and pears.

[165] The facts and findings of the disputes have been reviewed extensively elsewhere. For an overview of the decisions in the SPS disputes prior to *Japan Apples* see David G. Victor, 'The Sanitary and Phytosanitary Agreement of the World Trade Organisation: An Assessment After Five Years'. (2000) 32 *N.Y.U. J. Int'l L. & Pol.* 865.

international level, and the standards of risk assessment that are required of Members for the adoption of national SPS measures.

'Based on' risk assessment – a procedural or substantive requirement?

One of the most important questions raised by international judicial review of national regulations taken to address SPS risks concerns what is meant by the obligation in Article 5.1 of the SPS Agreement for WTO Members' measures to be "based on" a risk assessment. As has been observed in the US context, judicial review of risk regulation according to standards such as whether measures are "unsupported by substantial evidence" may equally be interpreted in a substantive or procedural sense. In the EU, the case law indicates that a requirement for a prior scientific evaluation of risk can be assessed with more or less stringency, depending upon the level of deference applied by the reviewing court.

In the SPS context, the importance of the meaning of "based on" in Article 5.1 lies in defining the standard of rationality expected of WTO Members in regulating SPS risks. If, analogously to the approach of Judge Bazelon in the US context, the standard of rationality selected is a procedural one, WTO Members could comply with the standard by showing that an assessment of risks, taking into account available scientific evidence, was actually referred to by decision-makers in the process of deciding on measures to address risks. Where a procedural approach to the requirement for risk assessment is coupled with a deferential standard of judicial review (as has often been the case in the

EU) it would be enough for Members to show that a risk assessment was taken into account in the process of establishing risk management measures, although those measures might not reflect the same view of risk as that found in the risk assessment. This approach would not necessarily guarantee a harmonized content for national SPS measures dealing with like risks, but the very fact of having to take a risk assessment into account and respond to its findings could have the salutary effect of forcing national regulators "to articulate objectives, to assess means, and to rationalize results",[166] a substantial improvement for the regulatory processes of many nations.

A substantive approach to risk assessment, on the other hand, seeks a different standard of rationality that lies not in the procedures used in deciding upon measures but in whether risk regulatory measures are justifiable by reference to objective findings about risk. This approach has the potential to promote greater convergence of Members' risk regulatory measures by requiring them to be rationally linked to the results of a risk assessment. Interpreting "based on" as imposing a substantive requirement also addresses the concern that a procedural test alone might allow regulators to disregard the scientific findings of a risk assessment entirely and instead establish measures in response to political and social pressures.[167] Concerns of this nature underlie both the substantive version of the 'hard look' doctrine of judicial review in the US, and the more stringent

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[166] See Henrik Horn and J.H.H. Weiler, *European Communities – Trade Description of Sardines: Textualism and its Discontent*, Discussion Paper prepared for the American Law Institute project 'The Principles of World Trade Law: The World Trade Organization', November 25, 2003.

[167] A concern voiced by the Appellate Body in the *Beef Hormones* case: see para. 189.

approach of the EU judiciary to risk regulatory measures adopted by Member States. In both cases, courts are looking for a demonstration that there exists a reasonable link between an assessment of the scientific evidence concerning a potential risk, and the measures adopted to address that risk.

The meaning of "based on" in Article 5.1 was raised in the first SPS dispute of *Beef Hormones* as it was argued that the EC's measures banning beef containing hormone residues could not be 'based on' scientific reports concluding that there was no evidence of a risk to human health where hormones were administered in accordance with "good veterinary practice." The Panel in the *Beef Hormones* dispute interpreted "based on" in Article 5.1 as imposing both a substantive and procedural requirement for Members' risk assessments. According to the Panel, a Member imposing SPS measures would need to show "that at least it actually took into account a risk assessment when it enacted or maintained its [SPS] measure."[168] However, it found that the "based on" criterion was also substantive in nature necessitating, in the Panel's view, a comparison between the scientific conclusions reached by studies relied upon by a Member in carrying out a risk assessment and the scientific conclusions reflected in the Member's measures, to ascertain whether they were "in conformity".[169] Applied strictly by the Panel, these

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[168] *EC - Measures Concerning Meat and Meat Products*, Report of the Panel, WT/DS26/R & WT/DS48/ R, 12 July 1999, para. 8.112 (hereafter '*Beef Hormones*, Panel Report').

[169] The Panel's finding was influenced by its interpretation of the term "based on" in Article 3.1, which it had held was equivalent in meaning to "conforms to" in Article 3.2. The Appellate Body, however,

findings effectively required the EC to demonstrate that it had considered scientific assessments of the risk in enacting its regulatory measures and that there was a high level of correlation between the scientific conclusions reached in those assessments and the approach taken by the EC in risk management.

In contrast to the Panel, the Appellate Body in the *Beef Hormones* case saw no merit in using "based on" to impose a procedural obligation on Members to take a risk assessment into account before adopting SPS measures. It rejected the Panel's "procedural requirement" as lacking a basis in the text of the SPS Agreement,[170] although it hinted that the real reason lay in its recognition that a requirement of prior risk assessment for every national SPS measure would be a significant procedural burden for many Members,[171] particularly developing countries. WTO Members adopting SPS measures are thus not required to have carried out their *own* risk assessment, but may rely on a risk assessment carried out by another (more technically and economically advanced) Member or by an international organization.[172] Nevertheless, even if Members do not engage in a process of risk assessment before adopting SPS measures the Appellate Body found they must still be able to demonstrate an objective or rational relationship between

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found that "based on" has a different meaning from "conforms to" i.e. measures based on international standards do not have to be identical in content to those standards: see *Beef Hormones*, para. 163.

[170] *Beef Hormones*, para. 189.

[171] Id. at para. 129.

[172] Id. at para. 190.

those measures and a risk assessment.[173] It is doubtful whether this requirement imposes any less significant burden on countries wishing to adopt SPS measures than a procedural standard. The latter might at least be satisfied by some kind of deliberative process initiated by the national government which took account of international scientific findings on the risk at issue. With a substantive standard, unless a Member simply adopts the same risk regulatory measures as are recommended by international bodies or taken by other Member States, it will need to have sufficient technical capacity to be able to verify that there is an objective link between the scientific findings of a risk assessment and the measures it wishes to adopt.[174]

As to how a substantive relationship between Members' SPS measures and a risk assessment is to be evaluated, the Appellate Body considered that "in principle" the Panel's approach of comparing the scientific findings of a risk assessment and the scientific conclusions implicit in a Member's SPS measures was a "useful" one.[175] The Panel's approach to this task differed markedly from similar exercises undertaken by courts in the EU, reviewing the scientific material taken into account by Community

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[173] Id. at paras. 189 and 193.

[174] During negotiations for the SPS Agreement, the Food and Agriculture Organization voiced concerns that the application of strict rules on sound scientific evidence for regulations, restrictions and prohibitions would require very substantial technical assistance to developing countries and that many countries would not be in a position to do the risk assessment required under the SPS Agreement: see FAO, 'Technical Assistance in the Field of Plant Protection', Paper submitted by FAO to the Working Group on Sanitary and Phytosanitary Regulations and Barriers, MTN.GNG/NG5/WGSP/W/16, 20 April 1990.

[175] *Beef Hormones*, para. 193.

institutions in risk assessment. Rather than giving deference to regulatory authorities' interpretation of the scientific evidence, the Panel looked at the conclusions of certain scientific studies cited by the EC, indicating no evidence of a risk, and compared those with the scientific conclusion implicit in the EC measures that there was in fact a significant risk to health. This approach left the EC regulatory institutions little leeway to argue that their assessment of risk was based on particular elements of the scientific reports (an approach, for example, that was allowed by the CFI in the *Pfizer* and *Alpharma* cases)[176] or that it took into account risks that could not be assessed in a scientific manner, such as risks arising from non-compliance with regulatory measures. The Appellate Body was evidently more sensitive to these concerns than the Panel, criticizing the latter for the narrow view it had taken of the notion of 'risk' and the process of 'risk assessment'.[177] In the Appellate Body's view, the relationship between the scientific conclusions of a risk assessment and those underlying regulatory SPS measures was a relevant consideration in assessing whether the measures were "based

[176] In the *Pfizer* case, the CFI found that the Community institutions were able to rely on parts of the scientific opinion offered by the relevant scientific advisory committee, although the ultimate conclusion reached by in the opinion was not followed: paras. 199-200. In the *Alpharma* case, where a scientific opinion had not been sought from the relevant Community advisory committee, the Court found that the Community institutions were entitled to rely on more general scientific information available from other committee reports (dealing with different antibiotics) as well as reports on antimicrobial resistance produced by various national and international bodies: see para. 314.

[177] *Beef Hormones*, paras. 186-187.

on" the risk assessment, but it cautioned that they could not be assigned relevance "to the exclusion of everything else."[178]

A Role for Risk Management Considerations?

What "else" is permitted to enter into a Member's decision-making process when it determines the SPS measures it will adopt in response to a risk assessment is critical to the scope of risk regulation the Member is authorized to carry out. In both the US and EU, the courts have clearly appreciated that considerations other than scientific views on the risks involved go into the process of establishing risk regulatory measures. By giving flexibility to regulatory agencies to act even where there is scientific uncertainty, courts in both jurisdictions allow scope for policy considerations and social value judgments about the significance of risks to enter into policy level or political decisions about risk regulatory measures. In the US, this result is promoted by a judicial policy of deference that leaves policy choices made 'at the frontiers' of scientific knowledge to federal agencies. In the case of the EU, the precautionary principle is used as a way of justifying regulatory institutions' decisions to pursue high levels of health and environmental protection, even where the existence and extent of risk is not yet fully apparent. In the scheme of the SPS Agreement, the ability of Members to establish risk regulatory measures according to their own 'appropriate level of SPS protection', suggests that non-

[178] Id. at para. 193.

scientific factors may also play some role in determining how national governments address SPS risks.

How far Members should be allowed to deviate from scientific risk assessments in the name of risk management policies is not an easy matter to determine in the SPS context. Unlike science, which can make credible claims of universal applicability,[179] the social and economic considerations underlying national risk management policies may not be shared by all WTO Members. Differences between Members in the value placed on avoiding certain types of risks often lie at the heart of disputes between Members over SPS risk regulation. If risk management concerns are allowed to play a significant role in Members' selection of risk regulatory measures, this may lessen the extent to which the SPS Agreement can be used to promote harmonization (and reduce the trade impacts) of national SPS requirements.

By ruling in the *Beef Hormones* case that a rational relationship between a risk assessment and a Member's SPS measures is required, without saying (as the *Beef Hormones* Panel effectively did) that science would be determinative of the existence of that relationship, the Appellate Body raised directly questions as to the role of, and possible scope for, risk management considerations under the SPS Agreement. This issue

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[179] Cf. Jeffery Atik, 'Science and International Regulatory Convergence'. (1996-1997) 17 *Northwestern Journal of International Law and Business* 736, 738 suggesting that culture is a sufficiently powerful determinant to generate multiple scientific consensuses which are varied across nations, contrary to science's claim to universality.

had also been tackled by the *Beef Hormones* Panel, which adopted the conventional approach of separating scientific risk assessment from political risk management, a model characteristic of early risk analysis procedures in the US and now strongly supported by the EU. Following this model, the Panel held that Members would be obliged, in accordance with Articles 2.2 and 5.1 of the SPS Agreement, to carry out "a scientific examination of data and factual studies" relating to the risk at issue. A Member wishing to impose SPS measures would then be required to decide the extent to which it could accept the potential adverse effects related to a specific substance identified in the risk assessment, a process of risk management to which the requirements of Articles 5.4, 5.5 and 5.6 were particularly pertinent.[180] However, the difficulty with this model, as national experience and later SPS disputes have demonstrated, is that the presence of scientific uncertainty (almost impossible to rule out in most cases) makes it difficult to maintain a clear boundary between scientific and political aspects of decision-making. Where there are data gaps, policy judgments will inevitably fill them, which in turn are often informed by a Member's overall risk orientation.

The problem is well-illustrated by the *Australia Salmon* case, where the challenged risk assessments reflected policy judgments taken against a background of Australia's highly conservative quarantine policy.[181] The question that arose was whether, given credible

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[180] *Beef Hormones*, Panel Report, para. 8.94.

[181] As an island country free from many of the plant and animal diseases that affect other parts of the world, Australia has historically maintained a strict quarantine policy which it describes as "a conservative but not zero-risk approach to the management of biosecurity risks." See BA, IRA Handbook, [2.11].

claims of uncertainty in an underdeveloped area of scientific research,[182] policy considerations entering into the process of risk assessment were a valid response to scientific uncertainty or an unacceptable intrusion of political risk management considerations into the scientific evaluation of risk.[183] The Panel and Appellate Body in the case sought to resolve the issue by placing more exacting demands on the nature of the scientific risk assessment to be undertaken, although at the same time they seemed to appreciate the problems posed by deficiencies in the available scientific data. Unlike the US Supreme Court in the *Benzene* case, WTO decision-makers in *Australia Salmon* were

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[182] Before the *Australia Salmon* Panel, Australia highlighted various gaps in available scientific knowledge about diseases affecting salmon and salmonids, deficiencies acknowledged by the experts advising the Panel: see *Australia – Measures Affecting Importation of Salmon*, Report of the Panel, WT/DS18/ R, 12 June 1998, paras. 6.88, 6.89, 6.91 and 6.96 (hereafter '*Australia Salmon*, Panel Report').

[183] One of the experts advising the Panel in the *Australia Salmon* case, Dr Marion Wooldridge, commented that where qualitative risk assessment is used this "often leads very directly into a risk management recommendation, making separation more difficult": *Australia Salmon*, Panel Report, para. 6.11. Dr Wooldridge reiterated her views on qualitative risk assessment before a second WTO panel considering the measures Australia had taken to bring its quarantine requirements for salmon into compliance with the SPS Agreement. On the other hand, another expert advising this Panel, Dr McVicar, took the view that "In both qualitative and quantitative risk assessment, there were inevitable difficulties and differences of opinion in deciding exactly what constituted an acceptable level of risk [and] [s]cience could not provide definitive answers to this essentially social or political problem": see *Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 by Canada*, Report of the Panel, WT/DS18/ RW, 18 February 2000, para. 6.28.

reluctant to go so far as to demand quantitative risk assessment,[184] however, the Appellate Body ruled that a quarantine risk assessment must evaluate the "probability" and not merely the "possibility" of disease introduction[185] and is required to do so comprehensively, rather than simply offering "some evaluation" of the risk.[186] Although, these findings have the effect of requiring SPS risk assessments to be more detailed and more overtly scientific in nature, by permitting Members to make qualitative assessments of SPS risks there is still significant scope for policy considerations to influence risk evaluations.

An alternative way of dealing with the overlap between risk assessment and risk management is to promote a more integrated approach to risk analysis that recognises the influence of policy choices on scientific considerations and of scientific risk evaluations on policy options. The risk regulatory system in the US has moved in this direction with efforts to 'democratize' the process of risk evaluation to take account of the non-scientific considerations that influence public risk perception.[187] In *Beef Hormones*, the Appellate Body also seemed to favor an integrated approach to risk assessment and risk management as a way of allowing scope for public concerns in Europe over the risks

[184] Id. at para. 124. Instead the Appellate Body ruled that a risk assessment for SPS purposes may be either a quantitative or qualitative assessment of risk.

[185] *Australia Salmon*, para. 123.

[186] Id. at paras. 124 and 128.

[187] Joel A. Tickner and Sara Wright, 'The Precautionary Principle and Democratising Expertise: a US Perspective'. (2003) 30 *Science and Public Policy* 213, 217 although the authors express greater confidence in grassroots momentum rather than government initiatives for achieving these changes.

posed by hormone residues in beef to play some role in decisions on risk regulatory measures. However, the absence of a reference in the text of the SPS Agreement to 'risk management' posed an obstacle in the eyes of the Appellate Body to recognising any formal role for risk management; instead it tried to build in some capacity for risk management considerations into the process of risk assessment under the SPS Agreement. For example, it declared that the risk that could be assessed in risk assessment was not limited to that which is identified by scientific methods, or as the Appellate Body put it:

> not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.[188]

Members are also entitled to rely on minority scientific opinion in assessing risks, "especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety",[189] a ruling reminiscent of the ECJ's decision in the *BSE* case. Further, the Appellate Body indicated that, in the case of food safety risks, Members need only evaluate the possibly (as opposed to the

[188] *Beef Hormones*, para. 187.

[189] Id. at para. 194.

probability) of harm,[190] which might suggest that scientific evidence which is only suggestive of risk but does not establish a likelihood of adverse effects could be taken into account. The Appellate Body drew the line, however, at the EC's argument that risk assessment under the SPS Agreement should also allow the application of the precautionary principle. While it was prepared to go so far as to say that the precautionary principle "finds reflection" in provisions of the Agreement such as Article 5.7, it did not follow the lead of the ECJ and find that the principle provided a ground for justifying SPS measures otherwise inconsistent with the obligations of Members set out in particular provisions of the SPS Agreement.[191] Nevertheless, it cautioned reviewing panels to "bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life- terminating, damage to human health are concerned", a statement which again seemed to suggest a more flexible view of risk assessment might be taken in the face of uncertainties over risks considered to be (very) serious.[192]

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[190] Id. at para. 184. This interpretation would seem to produce the result that a more stringent standard (probability of harm) is required for some SPS risks (i.e. quarantine risks) than others (i.e. food safety risks) such that more compelling scientific evidence will be required to support SPS measures in the former case.

[191] Id. at para. 124. According to the Appellate Body, the precautionary principle is also reflected in the sixth paragraph of the preamble and in Article 3.3 of the SPS Agreement.

[192] Ibid.

Role of Science in Risk Assessment

The Appellate Body's approach to the nature of SPS risk assessment in the *Beef Hormones* case would appear to lend considerable support to arguments that the SPS Agreement provides scope for Members' risk management considerations of a non-scientific flavour to enter into the process of deciding on SPS measures. Differences in scientific opinion over the nature of risks, claims of scientific uncertainty and the presence of risks not susceptible to scientific measurement would all seem to give Members flexibility in SPS risk regulation, equivalent to that which their regulatory authorities currently enjoy in national and trans-national settings. However, closer examination of the Appellate Body's treatment of the role of science in the process of risk assessment suggests that, in practice, Members have little discretion to stray too far from a scientific assessment of risk when determining their risk management measures for SPS risks.

Two particular themes in the judgments of the Appellate Body in SPS disputes lead to this result. The first is the finding in *Beef Hormones*, reiterated in later cases, that risks assessed in risk assessment must be "ascertainable" risks and not the "uncertainty that theoretically always remains since science can never provide absolute certainty that a given substance will not ever have adverse health effects."[193] This ruling reflects the concern that Members might maintain SPS measures in respect of *de minimis* risks – risks not supported by available scientific evidence but which, given the limitations of the

[193] Id. at para. 186. See also *Australia Salmon*, para. 125.

scientific method, cannot be ruled out by science. Similar concerns are echoed in the US and EU case law in findings that regulated risks must be more than simply hypotheses unverified by science or should reach some threshold of 'significance'. However, as is well-illustrated by the EU *Pfizer* and *Alpharma* cases, drawing a bright line distinction between risks considered to be 'merely hypothetical' and evidence suggestive of 'a real threat' to health or the environment is not an easy task and depends heavily on the time-point that is determined to be relevant in assessing the current state of scientific knowledge (must risks be imminent or are credible long-term risks sufficient?). This decision in turn will be influenced by how regulators weigh the relevant costs and benefits of responding to uncertain risks and the broader community's sensitivity to particular kinds of risk (in the wake of the BSE scare, for instance, European consumers have become very sensitized to human disease risks). Therefore, in practice, whether a risk is determined to be purely a matter of 'theoretical uncertainty' or a serious cause for concern will depend upon how demanding reviewing courts are in asking for risk regulatory measures to have scientific support.

Despite the Appellate Body's ruling in *Beef Hormones* that Members' risk assessments may rely on minority scientific opinion, WTO decision-makers have tended to take a rigorous approach to the scientific material that may be taken in account in assessing risks, insisting that it must be "sufficiently specific" to the risk at issue. In the *Beef Hormones* case, for example, the Appellate Body found fault with the scientific studies relied on by the EC because they dealt only with the general association between exposure to increased hormone levels and the development of cancer, rather than the

specific situation of cancer risk posed by consuming hormone residues in beef.[194] In *Japan Apples* this question was raised in a slightly different guise before the reviewing Panel when Japan argued that it should be able to rely upon "indirect" evidence of a risk of disease transmission through US apple imports. "Indirect" evidence might include scientific studies or experience which suggested a link between trade in a product and the occurrence of disease, without establishing causality.[195] The Panel found that both "indirect" and "direct" scientific evidence could be taken into account in assessing the sufficiency of scientific evidence supporting a Member's measures but clearly considered that the latter was of greater probative value, not only in scientific terms but also for legal purposes.[196]

Requiring Members to point to "specific" (or "direct") scientific evidence that links a substance or disease agent of concern with a particular health or environmental risk places important practical constraints on the feasibility of Members relying on minority scientific opinion in risk assessment. Oftentimes, a "divergent" scientific viewpoint is held only by a minority of scientists because it is based on the kind of suggestive but not definitive scientific evidence that qualifies as "general" (or "indirect") scientific evidence

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[194] *Beef Hormones*, para. 200.

[195] For example, Japan cited anecdotal evidence that past introductions of fire blight into other countries occurred via fruit boxes contaminated with fire blight bacteria, a hypothesis which it is impossible to test scientifically: see.*Japan Apples*, Panel Report, para. 4.56.

[196] *Japan Apples*, Panel Report, para. 8.98.

in the scheme of WTO decision-makers.[197] The high standard of proof required under the scientific method,[198] as well as the operation of peer review processes in science,[199] may place significant limitations on the ability of a minority viewpoint to attract greater support within the scientific community. Decision-makers, however, do not have the luxury to await the outcome of further scientific research. They must decide whether possible threats to health or the environment are sufficiently 'serious' to warrant action despite uncertainties that exist in the current body of scientific knowledge. Whether regulators decide to 'wait and see' or to act on the basis of the inconclusive scientific information available involves a balancing exercise in which the result will often depend on the level of risk which the authority deems unacceptable for society. EC authorities, sensitized to food safety concerns following the BSE 'crisis' are likely to weigh up the evidence differently to US agencies when it comes to some potential health risks;

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[197] In a well-known monograph Thomas Kuhn describes the history of science as one of long periods of 'normal science', where scientists work within accepted theories and paradigms, punctuated by periods of revolution where new paradigms gain acceptance within the scientific community. During periods of 'normal science' it may be difficult for divergent theories to gain acceptance within the scientific community. See Thomas Kuhn, *The Structure of Scientific Revolutions* (3rd ed., University of Chicago Press, Chicago, 1996).

[198] For a description of standards of proof in science and the difficulties standard methodologies present for precautionary regulation see Lene Buhl-Mortensen, 'Type-II Statistical Errors in Environmental Science and the Precautionary Principle'. (1996) 32 *Marine Pollution Bulletin* 528.

[199] Peer review processes may introduce biases into the body of publicly-available scientific knowledge: see David Fisk, 'Environmental Science and Environmental Law'. (1998) 10 *Journal of Environmental Law* 3.

although it is not beyond the realms of possibility that in the case of say, risks posed by minute amounts of pesticide residues on foods, the responsible US agencies might reach a different result to their EU counterparts.

In and of themselves, requirements for scientific studies used in risk assessment to be specific to the risk at issue and to provide plausible evidence of a real threat might not impose significant limits on the scope of risk assessment undertaken by a Member, if these requirements were reviewed in a deferential light by WTO decision-makers. Unlike courts in the US and EU, however, WTO decision-makers in SPS cases do not adopt a deferential stance in reviewing the scientific basis of national SPS measures. To begin with, panels rely on the advice of independent scientific experts in assessing factual matters of a scientific or technical nature, rather than deferring to the Members' interpretation of the scientific evidence.[200] Claims that panels did not give sufficient regard to a Member's appreciation of available scientific data are usually met with a withering reply from the Appellate Body that such an approach would be hardly adequate to ensure "an objective assessment of the facts" in an SPS case.[201] Scope for deference to operate through a strategic allocation of the burden of proof is also very limited. Although the burden of proof in an SPS dispute initially falls on the Member alleging inconsistency with a particular provision of the SPS Agreement to make out a *prima facie*

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[200] Pauwelyn, above n 35, 361-362.

[201] See, e.g., *Japan Apples*, para. 165, dismissing Japan's argument that the Panel was insufficiently deferential to Japan's approach to risk assessment and interpretation of the available scientific evidence in comparison with its treatment of opinions obtained from its advising experts.

case, it appears that this does not entail a very onerous standard of proof, and the evidentiary ball, so to speak, generally returns speedily to the defending Member's 'court'.[202] In fact, in some cases the defending Member will effectively bear the burden from the outset if it is making a factual assertion in support of its measures (for example, that SPS risks arise because of errors in inspection processes or non-compliance problems).[203] Equally, attempts to shift the burden of proving the absence of an SPS risk on to the complaining Member have not met with success.[204] The result is that a Member adopting risk regulatory measures generally needs to be able to demonstrate scientific

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[202] Horn and Weiler, above n 166, liken the Appellate Body's view of the argumentation by parties in a dispute to a tennis game where the burden of proof moves sequentially back and forth between the parties.

[203] See *Japan Apples*, para. 157. The Appellate Body stresses that this should be seen in terms of "the principle that the party that asserts a fact is responsible for providing proof thereof" rather than any shifting of the burden of proof. However, where facts are asserted as a defence to an alleged SPS violation the effect in practical terms is to transfer the burden of producing substantiating evidence on to the defending party.

[204] For example, before the Panel in *Japan Apples*, Japan sought to argue that in order for the complaining party to establish a *prima facie* case under Article 2.2 the US had to prove positively the 'insufficiency' of Japan's scientific evidence in the sense of conclusively refuting it or showing its irrelevancy to the introduction or maintenance of risk management measures. Japan contended that this was consistent with the notion of judicial equity which emphasised the need for a higher burden of proof on the US as the party 'naturally' possessing a large amount of evidence on the risk given that Japan was fire blight-free. The Panel rejected this argument noting that although scientific evidence may be more readily available in some countries than others, this was not a reason for an automatic alteration to the burden of proof: *Japan Apples*, Panel Report, para. 8.45.

evidence supporting the alleged SPS risk which is sufficiently well-developed to amount to more than an "interesting hypothesis" and is specific to the risk at issue.

WTO decision-makers counter claims that this approach restricts Members to dealing only with known, well-established risks by pointing to Article 5.7,[205] which permits Members to take 'precautionary' measures on the basis of available pertinent information where "relevant scientific evidence is insufficient", albeit on a provisional basis. This provision would seem to cover the BSE-type scenario where risks are considered to be sufficiently serious to justify preventative 'emergency' measures despite a lack of scientific evidence as to how the risk arises. Nevertheless, absent consensus that the risks involved are indeed 'serious',[206] national regulators are unlikely to be given as much leeway to act in the face of scientific uncertainty by WTO decision-makers as they might be by their own courts. According to the Panel in *Japan Apples*, Article 5.7 is primarily intended to deal with situations of new risks "where little, or no, reliable evidence [is] available on the subject matter at issue."[207] The Appellate Body in the same case said that the provision must be interpreted in the context of Article 5 as a whole, thus:

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[205] See, e.g., *Japan Apples* Panel Report, para. 8.96-8.98.

[206] Broad consensus on the 'seriousness' of the risk posed by BSE has been achieved in the EU and also internationally, with several countries (including the US) taking measures to ban European beef following the discovery of mad cow disease in a number of EU countries. A similar level of consensus would appear to have been reached on the seriousness of risks posed by asbestos fibers although there is still ongoing scientific dispute about the relative risk posed by asbestos and non-asbestos containing building materials.

[207] *Japan Apples*, Panel Report, para. 8.219.

> "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*.[208]

When coupled with the Appellate Body's rulings on the need for scientific evidence used in risk assessment to be "sufficiently specific to the case at hand", this analysis suggests that provisional measures will be an option available to Members mainly in circumstances where there is inadequate scientific research about a particular risk, but not in a situation where there is a large body of existing scientific research that could be used in risk assessment, although the Member concerned places greater emphasis (in light of its risk management priorities) on divergent scientific viewpoints or uncertainties left unresolved by current scientific knowledge. In *Japan Apples* the Appellate Body was discouraging on the question of whether Members may take uncertainties into account in adopting precautionary risk regulatory measures, stating that:

> The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to "cases where relevant scientific evidence is insufficient", not to "scientific uncertainty." The two concepts are not interchangeable.[209]

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[208] *Japan Apples*, para. 179.

[209] Id. at para. 184.

Assessing the Sufficiency of Scientific Evidence

The difference between the approach of national and trans-national courts when it comes to assessing the scientific basis of risk regulatory measures and that of WTO decision-makers emerges most clearly in SPS disputes where panels have chosen to examine the 'sufficiency' of scientific evidence supporting a Member's SPS measures. The last two SPS cases to come before WTO decision-makers, both involving challenges to Japanese phytosanitary requirements, have seen reviewing panels adopting an analytical approach that requires the relationship between scientific findings and a Members' SPS measures to be assessed more directly that has been the case when examining scientific studies underlying risk assessment. The approach taken by panels in assessing the 'sufficiency' of scientific evidence supporting a Member's SPS measures is analogous to the substantive version of the 'hard look' doctrine espoused by Judge Leventhal of the US Court of Appeals of the DC Circuit. Using the 'basic obligation' of Article 2.2 as a starting point, panels in cases such as *Japan Apples*, take a 'hard look' at the scientific underpinnings of Members' measures and whether the scientific evidence Members' have relied upon in establishing risk regulatory requirements substantiates those requirements. Panels, relying on advice from independent experts, effectively determine whether the scientific theory put forward by a defending Member is backed up by the available scientific evidence.[210]

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[210] Cf. Christoforou, above n 34, 636 who argues that reviewing panels should be "limited to an examination of whether the scientific basis of a contested measure is a scientifically plausible alternative to

As closer attention has been paid to the scientific evidence underlying SPS risk regulatory measures, rather than to its role as part of a process of risk assessment, WTO decision-makers have begun to encounter some of the most difficult issues that lie at the interface between law and science. In the *Japan Apples* case, the panel heard arguments from the parties as to the interpretation of the term "scientific" evidence in Article 2.2 of the SPS Agreement. Questions over what is 'science' for legal purposes have long been an issue of debate amongst 'law and science' scholars. One school of thought holds that judges need to become educated about the nature of 'real' science and exercise controls to ensure that 'junk science', which is not based on accepted scientific methodologies and has not been subjected to rigorous peer view, is screened out of the legal process.[211] Others emphasize that scientific progress occurs as much as a result of major 'revolutions' in research paradigms as through the gradual accumulation of knowledge. Consequently,

> Automatically rejecting dissenting views that challenge the conventional wisdom is a dangerous fallacy, for almost every generally accepted view was once deemed eccentric or heretical. Perpetuating the reign of a supposed scientific orthodoxy in this way,

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the scientific theory advocated by the complaining party, and whether the measure has a rational relationship to the performed risk assessment."

[211] See Kenneth R. Foster, David E. Bernstein and Peter W. Huber (eds), *Phantom Risk: Scientific Inference and the Law* (MIT Press, Cambridge, MA, 1999), 433-437.

whether in a research laboratory or in a courtroom, is profoundly inimical to the search for truth.[212]

In addressing what might count as "scientific" evidence for the purposes of risk regulation, the jurisprudence of the SPS has moved even further on this issue that in the US, the nation with perhaps the longest tradition of 'law and science' thinking.[213] It is telling that in *Japan Apples*, the Panel (following the textualist lead of the Appellate Body) resolves this important question by reference to the dictionary, concluding that "scientific" evidence is "evidence gathered through scientific methods, excluding by the same token information not acquired through a scientific method."[214]

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[212] See *Daubert v Merrell Dow Pharmaceuticals, Inc.*, Brief Amici Curiae of Physicians, Scientists, and Historians of Science in Support of Petitioners, 1992 WL 12006437 (U.S., Dec. 02, 1992), 2.

[213] Whether US federal health and environmental agencies should be subject to greater limitations in terms of the 'science' they take into account in regulation (e.g. through applying the Supreme Court's *Daubert* criteria for expert evidence to material considered by agencies in risk regulation) is a question still being debated in current US law and science scholarship: see, e.g., Thomas O. McGarity, 'On the Prospect of "Daubertizing "Judicial Review of Risk Assessment'. (2003) 66 *Law and Contemporary Problems* 155.

[214] *Japan Apples*, Panel Report, para. 8.92. The Panel's finding on this issue was not appealed by Japan. However, it is possible to interpret some findings of the Appellate Body in the *Beef Hormones* case as similarly establishing "minimum methodological requirements" for evidence to be "scientific" (see 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 The Appellate Body in that case refused to accept an opinion by one of the experts (Dr Lucier) advising the Panel, estimating the additional cancer risk as a result of consuming hormones in beef. The Appellate Body opined that "this opinion by Dr. Lucier does not purport to be the result of scientific studies carried

The directions given by the Appellate Body to panels assessing questions of the 'sufficiency' of the scientific evidence cited by a Member, have also paid more attention to the text of particular provisions than the broader policy questions raised by the use of science in risk regulation. As Article 2.2 is to be "contextually read … in conjunction with" Article 5.1,[215] the Appellate Body in *Japan Varietals* considered that the understanding of "based on" in Article 5.1 would also be relevant in the interpretation of the criterion of "sufficient" scientific evidence in Article 2.2. Panels assessing the 'sufficiency' of scientific evidence underlying a SPS measure must therefore examine whether there is "a rational relationship" between the SPS measure and the scientific evidence. This relationship is to be assessed on a case-by-case basis and "will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence."[216]

It seems that this standard gives panels considerable flexibility to adopt the 'methodology' they see as being most appropriate for evaluating the relationship between the scientific evidence and the requirements of a Member's SPS measure in any case. In *Japan Apples*, for example, the Panel examined the scientific evidence relating to each step of a putative pathway of disease introduction, making findings at each stage as to

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out by him or under his supervision focusing specifically on residues of hormones in meat from cattle fattened with such hormones": para. 198. Certainly, Dr Lucier's estimate was at best a rough guess in light of the limited scientific evidence available about the genotoxicity of hormones at low levels.

[215] *Beef Hormones*, para. 193.

[216] *Japan Varietals*, para. 84.

whether the evidence was "sufficient" to support the conclusion drawn by the Member concerned. Following that analysis, and based on the advice of its experts, the Panel concluded that the overall risk was "negligible." It then contrasted that finding with the nature of the elements composing the Japanese measure, concluding that the measure was "clearly disproportionate to the risk identified on the basis of the scientific evidence available."[217] On appeal, the Appellate Body ruled that the Panel's methodology was but one of many possible approaches to assessing sufficiency that might be appropriate in any given factual situation and upheld the methodology adopted by the Panel as "appropriate to the particular circumstances of the case before it".[218]

Members' 'Right' to Determine Acceptable Levels of Risk

The substantive standard required for risk assessment, the need for scientific evidence relied upon by Members to be 'specific' in nature and for assessed risks to be more than theoretical, together with the trend for panels to examine the scientific basis of Members' SPS measures with increasing stringency, all raise questions about the real scope of a Member's ability to determine autonomously the level of SPS protection it pursues in SPS risk regulation. The Appellate Body has characterized the determination of an 'appropriate level of SPS protection' as a "right" of WTO Members and stridently argues that WTO decision-makers cannot and do not place any restrictions on Member's choices

[217] *Japan Apples*, Panel Report, para. 8.198.

[218] *Japan Apples*, para. 164.

in this regard, other than those established by the trade-related provisions of Articles 5.4, 5.5 and 5.6.[219]

Findings regarding the nature of a Member's 'appropriate level of SPS protection' in the early cases of *Beef Hormones* and *Australia Salmon* seem to support the view that a Member has a great deal of freedom to establish levels of risk it considers acceptable, much as it does in a domestic context. In *Australia Salmon,* the Appellate Body indicated that a Member's chosen level of protection embodies its risk management objectives which do not need to express a quantifiable level of risk the Member considers acceptable[220] and moreover can include a risk management goal of "zero risk".[221] A Member must express its appropriate level of protection with "sufficient precision" to allow an assessment by WTO decision-makers of whether the SPS measures chosen by a Member, or other alternatives, are adequate to achieve its desired level of protection. However, in *Australia Salmon* Australia's quarantine policy goal of "a high or very conservative level of protection aimed at reducing risk to very low levels, but not a zero risk level" was considered 'sufficiently precise' to pass this test.[222] Taken together with the Appellate Body's statement in *Beef Hormones* that a risk assessment is not required to establish a minimum magnitude of risk,[223] this might suggest that any level of risk

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[219] *Beef Hormones*, para. 124.

[220] *Australia Salmon*, para. 206.

[221] Id. at para. 125.

[222] *Australia Salmon*, paras. 206-7.

[223] *Beef Hormones*, para. 186.

established by a risk assessment, even if very low, could found SPS measures, especially where a Member's risk management goal is one of 'zero tolerance'.

In practice, the flexibility engendered by the Appellate Body's broad interpretation of a Member's right to establish autonomously its appropriate level of protection is offset by an approach which draws heavily on scientific advice when determining the relationship between a Member's measures and the risk management goals it has set.[224] Given the technical nature of many of the issues raised by SPS regulation the involvement of scientists in informing risk management decisions is not surprising – an assessment of the effectiveness of a buffer around fruit orchards in reducing the risk of transmission of plant diseases can be usefully informed by scientific studies testing whether buffers reduce the incidence of disease inside buffered orchards.[225] However, courts in the US and EU examining risk management measures have tended to give greater play to policy considerations (and increasingly cost-benefit analyses), exercising deference in favour of regulatory authorities' choices in this regard. Deference to the risk management policies of Members is more difficult for WTO decision-makers to countenance in SPS disputes as there is no guarantee that the social and policy concerns influencing a particular Member's risk management decisions will be recognized as valid by the Membership as a

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[224] The 'consistency' requirement in Article 5.5 also places significant constraints on Members' ability to adopt stringent levels of protection for some risks where more lenient levels have been set for 'similar' risks. See above n 31, and accompanying text.

[225] This was an issue considered by the *Japan Apples* Panel in examining Japan's phytosanitary measures for protection from fire blight.

whole. As a consequence, WTO decision-makers in SPS disputes have generally given a more influential role to science, than would be the case in a domestic context, to determine what measures are available which achieve the level of risk sought by the Member while minimizing impacts on trade. This tendency seems to be most pronounced in those cases where panels have assessed the sufficiency of the scientific underpinnings of a Member's risk regulatory measures directly, rather than coming at this question principally through an analysis of the Member's risk assessment.

Relying upon science to guide decisions as to whether risk management measures are justified may avoid the problem of giving recognition to policy concerns that are not shared by all WTO Members but has not always proved to be a useful way of diagnosing cases of protectionism. In the *Japan Varietals* dispute, for example, the Panel's assessment of whether Japan's measure was the least trade-restrictive available that achieved the country's chosen level of SPS protection, focused on the implications of uncertainties in the scientific evidence although procedural deficiencies in the Japanese risk assessment and lack of transparency in the application of is SPS requirements were suggestive of protectionist motives. Based on the scientific evidence, the Panel reached the conclusion that variability in the results obtained in scientific experiments, testing the efficacy of fumigation procedures on different varieties of fruits, could justify some form of SPS measure, although the practice and experience of regulators suggested that the

variability observed in the scientific data was of little biological or practical significance.[226]

In contrast, legitimate policy or social concerns relevant to decisions about the feasibility of particular risk management strategies and their capacity to meet a Member's risk management objectives will tend to be screened out by an approach that examines the justification for SPS measures in light of the relationship they bear to the scientific evidence about risk. Where, for instance, the risk identified on the basis of scientific evidence suggests the risk is negligible or very low, stringent risk management measures will appear 'disproportionate', although a comparison between the measures and a more broadly oriented risk assessment could produce a different assessment. This can led to a strange paradox, as in *Japan Apples*, where independent experts with their 'scientific hats' on maintain that there is no available scientific evidence which could justify SPS

[226] The Panel came to the conclusion that although varietal testing could not be supported on the basis of the available scientific evidence, scientific uncertainties meant that it was "not possible to state with an appropriate degree of certainty that one and the same treatment would be effective for all varieties of a product": *Japan – Measures Affecting Agricultural Products*, Report of the Panel, WT/DS76/R, 27 October 1998, para. 8.83. Consequently the Panel ruled in favour of SPS measures requiring the measurement of 'sorption levels' for each variety of a fruit (i.e. how much of the fumigant was absorbed by different varieties which would in turn influence the efficacy of fumigation) as the least trade restrictive measure available to achieve Japan's risk management goals.

measures, but wearing a different 'policy advisor' hat recommend prudence in removing SPS controls.[227]

V SCIENCE AS AN INTERNATIONAL YARDSTICK

The SPS jurisprudence to date tells a different story about the role of science in the international review of risk regulatory measures than is found at either the national or trans-national level. Despite apparent attempts by the Appellate Body to create room for non-scientific considerations in risk assessment and to preserve the right of WTO Members to establish SPS measures according to their autonomously defined 'appropriate level of protection', the practice of WTO decision-makers examining the compliance of Members' measures with the SPS Agreement is one that places science in a privileged position when it comes to determining which risks are addressed and what risk management measures may be adopted. Not only does science play an important part in establishing the boundaries of permissible SPS risk regulation, it seems also that the view of 'scientific' evidence which will be accepted as a basis for SPS measures is narrowing. The trend of the existing jurisprudence would predict that in future SPS disputes, the ability of a Member introducing SPS measures to bring forward scientific

[227] See, e.g., the statement of Dr Smith, an expert consulted by the *Japan Apples* Panel, Annex 3, para. 419.

evidence which supports the existence of a threat, and is specific to the risk of concern, will be determinative of the question of SPS-compliance.[228]

In the literature concerning the SPS Agreement, scholars are divided on the question of whether the prominent role played by science in the SPS Agreement and jurisprudence is a positive or negative development. Some see the emphasis on scientific criteria in assessing national SPS measures as a means of bringing "rigor and discipline to a potentially wide-open GATT/WTO loophole" and believe that the science-based provisions of the Agreement offer a "promising model" for the WTO as a whole.[229] Others view the case law's "tendency to privilege scientific rationality" in a distinctly more negative light[230] and worry that it poses a "serious obstacle" to a Member's exercise of its right to establish an appropriate level of SPS protection,[231] as well as the ability of

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[228] It seems likely that the current EC-US dispute over the EC's measures for GMOs and GM foods will be decided (at least partially) under the SPS Agreement: see Howse and Mavroidis, above n 214, 321 (although the authors note that where regulations are based on ethical rationales or rationales connected to the social economy required to preserve indigenous agriculture and traditional ways of life, the application of SPS exclusively may need to be reconsidered).

[229] Warren H. Maruyama, 'A New Pillar of the WTO: Sound Science'. (1998) 32 *International Lawyer* 651, 676.

[230] Joanne Scott, 'On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO' in Weiler (ed.) *The EU, the WTO, and the NAFTA: Towards a Common Law of International Trade?* (Oxford University Press, Oxford, 2000) 125, 157-9.

[231] J. Martin Wagner, 'The WTO's Interpretation of the SPS Agreement has Undermined the Right of Governments to Establish Appropriate Levels of Protection Against Risk'. (2000) 31 *Law and Policy in International Business* 855, 857.

citizens to participate in decisions about the regulation of risk.[232] These critiques raise important issues as to whether the science-based model adopted by the SPS Agreement and consolidated by the SPS case law is an appropriate one to guide decisions on risk regulation taken at the international level. However, criticism of the tendency of the SPS jurisprudence to privilege scientific views of risk, also invites the question of whether there are any viable alternatives to the current approach.

Reference to experience with the judicial review of risk regulation in the US or EU might suggest that there are indeed such alternatives. Some authors, for example, take the US doctrine of deference to the judgments of regulatory authorities in circumstances of scientific uncertainty as a principle which should also guide WTO decision-makers reviewing national SPS regulations. In an early article considering the potential role of science in the SPS Agreement, Professor David Wirth noted various ambiguities in the text which might lead to "the potential for dispute panels to second-guess the relationship between the scientific support and the regulatory [SPS] measure chosen by national governmental authorities by demanding an excessively high correlation between the two."[233] He argued that "experience strongly suggests that the adjudication by a third party of scientific matters that arise in a regulatory setting, in which presumably expert technical authorities have already made scientific determinations, should be limited within clearly defined parameters that control and circumscribe the scope of that

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[232] Anne Orford, 'Globalisation and the Right to Development' in Alston (ed.) *Peoples' Rights* (Oxford University Press, Oxford, 2001) 127, 162.

[233] Wirth, above n 95, 857.

review."[234] Professor Wirth concludes that "a structure in which the members of reviewing panels are generalists may well suggest, or even require, an implicit principle of deference to governmental decision-making processes."[235]

This theme has been developed by other commentators, such as Professor Vern Walker, who argues that, to the extent that scientific uncertainties exist over SPS risks and "science policies" are in play, the same deference that is due to a WTO Member's selection of a level of protection under the SPS Agreement should be given to the Member's selection of science policies guiding risk assessment.[236] "Science policies", in this sense, are "decision rules about the way in which risk assessment scientists should proceed when they encounter specified types of uncertainties", which are set at the political level.[237] Such policies are commonly used by US regulatory agencies in risk assessment as a way of improving the consistency and transparency of risk assessment undertaken against a background of imperfect scientific knowledge. Walker acknowledges that WTO panels in SPS disputes, in carrying out their fact-finding task, cannot simply defer "to any Member that cries 'science'."[238] However, he considers that

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[234] Id. at 841.

[235] Id. at 843.

[236] Vern R. Walker, 'Keeping the WTO from Becoming the "World Trans-science Organisation": Scientific Uncertainty, Science Policy and Fact-Finding in the Growth Hormones Dispute'. (1998) 31 *Cornell Int'l. L.J.* 251, 271. Professor Walker was an advisor to the EC in the *Beef Hormones* case.

[237] Vern R. Walker, 'The Myth of Science as a "Neutral Arbiter" for Triggering Precautions'. (2003) 26 *Boston College International and Comparative Law Review* 197, 214.

[238] Walker, above n 236, 280.

in circumstances of scientific uncertainty (evidenced by a good-faith difference of opinion among scientists) a WTO panel reviewing a Member's risk assessment determinations "should leave undisturbed the science-policy choices of a member, so long as that Member's inferences from the available data are scientifically plausible."[239]

Professor Robert Howse reaches a similar result but by a different route. Contrary to critiques of the SPS Agreement which see it as a constraint on democratic processes concerned with risk regulation, he argues that one way in which the science-based provisions in the Agreement can be understood as a 'win-win' for both democracy and free trade is if the manner in which trade-offs between scientific risk assessments and citizens' intuitive judgments about which risks are acceptable and which are not are respected where they are made within the democratic process of each Member and "provided these trade-offs are themselves made explicitly, transparently, and in a manner consistent with the conception of democratic rationality."[240] This approach would seem to require some level of deference to Members' conclusions about the significance of particular SPS risks, although on the ground of respect for democratic deliberative processes rather than deference to technical expertise or Member's science policies in circumstances of scientific uncertainty.

A growing number of commentators also seek to draw guidance for the use of science in SPS decision-making from the trans-national risk regulatory experience of the EU. In a

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[239] Id. at 280-1.

[240] Howse above n 98, 2337

recent article, Professors Christian Joerges and Jürgen Neyer argue that WTO governance structures, unlike those of the EU, are not able to respond comprehensively to the complexities of risk regulation and should not be expected to provide a solution to international controversies over the adequacy of risk assessment. In view of the WTO's deficiencies as a 'trans-national deliberative forum', they suggest that its decision-makers should refrain from claiming to second-guess risk policies comprehensively, instead searching for a middle ground between politics and law.[241] Other commentators are more sanguine about the capacity of the WTO dispute settlement system to incorporate social perceptions of risk into the assessment of national SPS measures. One proposal is that national legislators and regulators should be granted greater discretion in determining the substance of regulations, including through application of the precautionary principle, in exchange for more stringent procedural constraints imposed on internal risk management processes in order to guarantee transparent, informed and comprehensive deliberation.[242]

Prescriptions for deference on the part of WTO decision-makers in SPS disputes, whether to the substantive judgments of Members about the underlying science or to appropriately transparent and inclusive procedures used in internal processes of risk management, assume a context for judicial review of risk regulation that is much the same at the international level as in other jurisdictions. However, while many similarities exist

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[241] Christian Joerges and Jürgen Neyer Neyer, 'Politics, Risk Management, World Trade Organisation Governance and the Limits of Legalisation'. (2003) 30 *Science and Public Policy* 219.

[242] See Jan Bohanes, 'Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle'. (2002) 40 *Colum. J. Transnat'l L.* 323.

between structures and problems of risk regulation at the national, trans-national and supranational levels (and so there is much to be gained through a comparative analysis of the role science in each) it does not necessarily follow that solutions from national and trans-national fora can be readily translated to the international realm, in the name of promoting greater attentiveness of WTO SPS decision-making to the social concerns that inform risk regulation in many countries. Lying behind the approach to judicial oversight of risk regulation in both the US and EU is a normative backdrop that can orient regulators in their choice of risk regulatory measures and courts in determining the stringency with which they exercise powers to review the scientific underpinnings of those measures. In the US, deference to the judgment of expert agencies in the case of scientific uncertainty is effectively deference to the capacity (and legitimacy) of agencies to make policy and value choices in such situations that will reflect a normative perspective on the risks involved which is acceptable to American society as a whole. In the EU, the relevant normative reference points are formally set by the EC Treaty – institutions must aim for a high level of health and environmental protection – and by the selection of an instrument for achieving that goal – the precautionary principle – which reflects a value choice in favor of erring on the side of health and environmental protection in circumstances of scientific uncertainty.

Comparable normative yardsticks to those which can be identified in the US and EU, as guides for risk regulation, are more difficult to locate in the SPS context. If, taking the US approach, WTO decision-makers in SPS disputes were to defer to the scientific theories advanced by Members, or even the science policies particular Members adopt in

risk assessment to overcome problems of scientific uncertainty, what broader normative justification would lie behind this choice? Deference in such circumstances would certainly allow scope for the internal trade-offs made between science and social risk perception in democratic polities to be respected but would also have the effect of externalizing the value judgments which underlie them to other Members and their societies who might not reach the same trade-off. Taking the EU approach, there do not seem to be similar overriding normative standards in the WTO context which could justify resolving the 'balance' between trade and health or environmental interests in any case in favor of a particular standard of health and environmental protection. Although the Appellate Body in *Beef Hormones* found that the precautionary principle "finds reflection" in Article 5.7 and other provisions of the SPS Agreement such as Article 3.3, scientific risk assessment (or the inability to carry one out due to insufficient "relevant scientific evidence") is a precondition for the invocation of both provisions. It might be possible to see the reference in the preamble to the WTO Agreement in respect of "allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so" as some sort of normative pointer in the direction of measures that enhance protection against environmental risk. But even if it were possible to agree on the normative content of broad concepts like sustainable development,[243]

[243] International agreement on what 'sustainable development' entails has proved elusive, as illustrated by the recent World Summit on Sustainable Development held in Johannesburg in September 2002. While the concept clearly requires "integrating economic and social development and environmental protection"

there would still be a need to take account of other WTO objectives such as "raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand."[244]

Of course it is possible that the international standards referenced by the SPS Agreement, promulgated by organizations such as the Codex Alimentarius Commission, could supply the missing element of normativity, at least in those cases where they already exist or agreement upon new standards is possible.[245] One way of viewing the endorsement of international standards in the SPS Agreement is to infer Members acceptance of the (implicit) value choices such standards make about the significance of certain health and environmental risks. However, over and above any objections that there is little evidence

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(*Shrimp/Turtle* case, Report of the Appellate Body, WT/DS58/AB/R, 12 October 1998, para. 129) it does not necessarily elevate one goal over another in the event of conflict.

[244] Preamble, *Agreement Establishing the World Trade Organization*, Marrakesh, 15 April 1994, 33 ILM 1125 (1994).

[245] Agreement upon new international standards is likely to become increasingly difficult in an environment where countries are aware that whatever is agreed may set the parameters of permissible SPS regulation in a WTO context. The Appellate Body's recent ruling in *EC – Trade Description of Sardines*, WT/DS231/AB/R, 26 September 2002, may add to national wariness when it comes to international standard-setting. In that case, the Appellate Body ruled that, for the purposes of the Agreement on Technical Barriers to Trade (TBT) which, like the SPS Agreement, encourages WTO Members to harmonize their TBT regulations using international standards as a basis, relevant international standards included those *not* adopted by consensus (para. 222). This ruling opens up the possibility, in the SPS as well as the TBT context, of international standards agreed by a majority of countries being imposed on a minority of countries who must then justify divergent measures on the basis of scientific evidence.

that this is what Members actually intended when negotiating the SPS Agreement, such an interpretation would place great strain upon supranational risk SPS standards and the international organizations that develop them. Prior to the SPS Agreement, these organizations did not see their role as drivers of international risk regulatory policy but rather as providers of a source of international technical expertise on sanitary and phytosanitary issues that could inform the risk-related decision-making of national governments.[246] With the global prominence gained as result of the SPS Agreement, organizations like the Codex Alimentarius Commission are working to address concerns that their procedures for standard-setting suffer from a 'democratic deficit',[247] but it is yet to be seen whether these reforms will have a real impact in terms of opening up decisions about levels of acceptable risks to a broader range of inputs than simply that of the organizations' scientific advisory bodies.

In most cases then, WTO decision-makers reviewing national SPS measures will be operating in a 'normative vacuum' where the only criterion available to guide the 'balance' struck between competing risk regulatory policies of Members is that of science. Without the option of being able to defer to a regulatory authority whose policy

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[246] See Terence P. Stewart and David S. Johanson, 'The SPS Agreement of the World Trade Organisation and International Organisations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics'. (1998) 26 *Syracuse J. Int'l L. & Commerce* 27.

[247] For example, there have been initiatives to promote greater transparency and to involve non-governmental organizations in the standard-setting process.

judgments and value choices have global legitimacy, or to adjust the stringency of judicial review of risk regulatory measures according to an agreed normative goal, decision-makers will fall back on the advice of scientists and the opinions they offer about the available evidence of risk. In the absence of a true normative yardstick for evaluating national decisions to address risks in circumstances where no conclusive evidence of harm exists, science becomes a default criterion for determining whether measures pursuing the level of risk chosen by Members receive international endorsement or not.

The irony of constituting science as a default normative yardstick, is that choices about competing risk regulatory policies are thereby yielded to a body of knowledge which has (or is not purported to have) any normative content. Science's only adherence is to the notion of progress, narrowly defined in terms of the improvement of existing levels of scientific understanding about the natural and physical world.[248] Post-modern critiques of science notwithstanding, science's vision is not one which offers value judgments about whether certain forms of progress are right or wrong, a task which it leaves to the community and politicians. In a global 'risk society', where questions concerning the normativity of international health and environmental policy are often viewed in scientific terms,[249] notions of what is possible and what is desirable may sometimes be

[248] Steven Goldberg, *Culture Clash: Law and Science in America* (New York University, New York, 1994), 82.

[249] Beck, above n 1.

aligned. But the history of nuclear power for one,[250] and more recent international debates over agricultural uses of biotechnology,[251] are evidence that this is not always the case.

VI CONCLUSION

International review of national measures taken to address SPS risks shares many similarities with judicial oversight of risk regulation undertaken in many countries and in trans-national settings, such as EU. In all cases, generalist decision-makers are faced with the task of assessing the legitimacy of health and environmental regulatory objectives on the basis of scientific evidence which they are not technically competent to examine in depth. Where measures are taken to address health and environmental risks, this task is complicated by the prevalence of scientific uncertainty and divergences of view that can arise within and between communities over acceptable levels of risk.

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[250] The consequences of development of the atomic bomb used against Japan in World War II dramatically highlighted the difference between scientific notions of progress and moral considerations governing uses to which technology put. See Goldberg, above n 248, 12-13.

[251] Differences in regulatory approaches to biotechnology are often justified on the basis of ethical standards or socio-economic concerns relating to the need to preserve organic or traditional modes of agricultural production. Divergences in policy with respect to GMOs are most marked between the US and EU, but are increasingly being observed in other parts of the world. See, e.g., Biotechnology: Africa GMO Update – Nigeria, GM Food Aid, Botswana, *BRIDGES* Trade BioRes, Vol. 4, No. 9, 14 May 2004.

The solution to this dilemma developed in national contexts, such as that of US, is essentially one that gives deference to the judgment of specialist regulators to make policy choices on the margins of scientific knowledge about risk. In the trans-national setting of the EU, the judicial approach in this field is evolving along similar lines, although the controversial history of Community risk regulation sees the judiciary looking to the policy goals and principles of the EC Treaty, including the precautionary principle, as a guide for their decisions on risk regulatory measures. In both cases, the courts exercise review powers in way that allows regulatory bodies significant scope to incorporate non-scientific considerations when establishing risk management measures. Many commentators see the experience in these jurisdictions as a useful model which could be drawn on in decision-making about SPS risks at the international level.

The SPS jurisprudence to date, decided by panels and the Appellate Body of WTO, has not adopted a deferential approach similar to that of US and EU courts in reviewing the scientific basis of national risk regulatory measures. Although rulings in the early case law suggested that the Appellate Body, in particular, was concerned to project a broader view of SPS risk assessment than merely one of evaluation of risk based on 'sound science', WTO decision-makers' treatment of scientific evidence – its role in risk assessment and its relationship to Members' SPS measures – has worked to place science in privileged a position when comes to determining how SPS risks are managed at the supranational level.

The divergence of international decision-making on SPS risks from models of judicial oversight of risk regulatory measures seen in the US and EU reflects differences in the context of health and environmental risk regulation in each jurisdiction. Critically, comparable normative reference points to those that orient judicial review of risk regulation in national and transnational settings are not readily apparent in the SPS context. Without a strong rationale for deference or international normative standards that could resolve an appropriate balance between different risk regulatory policies where nations disagree on acceptable levels of risk and the underlying scientific evidence, current scientific knowledge concerning whether a product is safe or risky becomes the default basis for determining whether its international dissemination is desirable. But by placing science in the role of arbiter in the SPS context, it is constituted as a normative yardstick against which the validity of national risk regulatory choices is judged, notwithstanding is own lack of normative content. Providing decision-makers in the SPS context, and potentially in other fora of international health and environmental regulation, with an alternative will depend on the willingness of the global community to engage in debate and deliberation over questions concerning the acceptability, or otherwise, of particular health and environmental risks.