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Whither Science in WTO Dispute Settlement?

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Abstract
This article understands risk dialectically as a decision-making resource stressing probability but as also giving rise to further uncertainties. It shows that the panel report in *EC – Biotech* reflects an understanding of risk as decision-making that is deterministic and leaves little room for the application of precautionary approaches and non-scientific factors. It submits that such an approach is unsuitable for novel technologies with limited background knowledge and reduces the accountability of risk regulators. A different approach is put forth, which allows members greater scope for precautionary action while preventing trade protectionism. The article concludes that law can enhance its authority and epistemic validity through scientific evidence but only if it recognizes science's epistemic and its own limitations. Law has to approach science as contested knowledge and risk regulation as political decision-making, leading – inevitably – to more indeterminate solutions to legal conflicts.

Key words
genetically modified organisms; legitimate risk regulation; non-scientific factors; precautionary principle; scientific validity; SPS Agreement; WTO law

1. Risk and the law

1.1. The notion of risk and its functionality for law

An exclusively probabilistic understanding defines risk as the product of the probability of a hazard and the magnitude of that hazard. This article understands risk dialectically as a probabilistic framing of hazard that always coexists with uncertainties. Risk is seen as a decision-making resource that enables decisions in the face of uncertainty.[1] This is achieved through a probabilistic framing of hazards. Risk does not imply that the hazard will actually occur, so uncertainty persists. However, risk assessments provide a structured way of dealing with this uncertainty by giving indications of what outcome to expect. Risk thereby suggests some control of the

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1 J. Steele, *Risks and Legal Theory* (2004), 4, 6–7, 18–21, 29; A. Giddens, 'Risk and Responsibility', (1999) 62 *Modern Law Review* 1, at 3. Other authors employ the term 'risk' differently. Beck's term 'risk society' denotes a society whose dominant feature has become the distribution of pervasive risks that can no longer be completely controlled. U. Beck, *Risk Society – Towards a New Modernity* (1992). Cultural theorists employ the term 'risk' to denote world views of actors concerning the resilience or sensitivity of the environment. M. Douglas and A. Wildavsky, *Risk and Culture* (1982).

future by indicating how to mitigate hazards and by enabling us to reap benefits in spite of some possible negative consequences.[2]

Understanding risk as a probabilistic framing of hazards also implies that it can be distinguished from other framings of uncertainty, and notably from those where the hazard is known but likelihood cannot be determined (lack of probability), the hazard cannot be determined because of high variability in outcomes (ambiguity), neither hazard nor probability can be reliably determined (uncertainty), or there is complete ignorance.[3]

Two further remarks are in order here. First, framing an issue as one of risk does not mean that the other forms of uncertainty cease to exist as facts or frames. They persist where the accuracy of the risk assessment is claimed to be reduced by data gaps, the high variability of observed effects in risk assessment studies due either to intervening factors that were overlooked, to the inadequacy of the method for assessing risk, or to more fundamental flaws in the hypotheses underlying the risk assessment. Framing something as risk implies dealing with these uncertainties by either integrating them into the risk assessment where the sources of uncertainty are in principle known (e.g. through stating the confidence level or error rate of a study) or blending them out of the assessment as too speculative and hypothetical pending the generation of further knowledge about these uncertainties. Second, the notion of risk is here primarily understood as a construction, based on certain social and scientific conventions, and not as a fact. As should be clear from the preceding paragraph, framing an issue as one of risk may sometimes coincide with there actually being a risk in the sense of a calculable probability of hazard. At other times, it may not.

However, for all its emphasis on probability and the possibilities of taking decisions, a contrapuntal undercurrent of uncertainty remains when frames of risk are used. Science and expert knowledge used in the assessment of risks are 'an inherently sceptical endeavour, involving a process of that constant revision of claims to knowledge'.[4] One cannot therefore be sure that today's knowledge is accurate. The aspiration to certain knowledge and control that risk promises remains unfulfilled because it leads to more and more questions being posed to experts who cannot answer them. An example where scientific methods fail to provide clear answers is the question of whether small, cumulative exposure to several substances is harmful. Risk also reveals that complete safety is not possible, because its very notion

2 Giddens stresses this element of enabling risky choices to obtain benefits. See Giddens, *supra* note 1, at 3–4.

3 C. Alexandru Parvu, 'Deliberative Administration and Risk Regulation', available at http://absp.spri.ucl.ac.be/dgt-actionpublique.htm, at 4; similarly, B. Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventative Paradigm', (1992) 2 *Global Environmental Change* 111 (distinguishing between risk, with known probability; uncertainty, due to lack of a probability determination, indeterminacy, when causation mechanisms cannot be predicted; and uncertainty). Two examples may be useful to illustrate the difference between situations with a lack of probability and those with ambiguity. A lack of probability exists where it is known that a substance causes cancer but no dose-response curve can be established. Ambiguity exists where it is known that a substance is harmful but the harmful effects can range from morbidity to mortality at the same exposure level.

4 Giddens, *supra* note 1, at 1.

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implies that the future can turn out differently from what is predicted and because risk highlights that alternative actions are also risky.[5]

Finally, the assessment of modern technologies increasingly requires projections into the future for which past experience is no longer a useful source of knowledge.[6] Technologies and sources of hazards have become so complex that their assessment increasingly exceeds even the grasp of a single expert and requires both a cognitive shift from singular cause-and-effect models to a systemic assessment and the involvement of a multitude of experts. Under such circumstances, the attribution of responsibility for the materialization of hazards – and with it the idea of anyone controlling risks – is increasingly overtaken by the nature of these hazards. In these circumstances, the notion of taking rational decisions on the basis of risk looks doubtful,[7] because there is no outside vantage point from which to assess the correctness of complex, multi-expert risk assessments.[8] This is not to say that we live in a more dangerous world or that complex, systemic risk assessment is necessarily impossible. But it does suggest a schism between risk's promise of taking a decision notwithstanding uncertainties and the increasing complexity of the hazards and assessments required, which themselves constitute a source of uncertainty.

What does legal analysis gain from this dialectical understanding of risk? It allows insights into law's propensity for endorsing risk as a decision-making resource but it also allows one to see how the law's reliance on risk poses a challenge to the law's fundamental aspirations because of the uncertainties that framings of risk entail.

Regarding the functionality of risk as a decision-making resource for law, certain parallels between the notion of risk and the key occupations of law exist. Law is after all concerned with decision-making, whether regarding regulation or the control and review of decisions. When law as regulation is at issue, law is usually the form through which decisions are implemented and social phenomena are steered in the *Rechtsstaat*. When law as the control and review of decisions is at issue, law prospectively or retrospectively applies to decisions and develops standards for decision-making.[9]

In both instances, law has certain affinities with the concept of risk, which may lead it to be more receptive to framings of risk than to other forms of uncertainty out of concern for its own authority. Law as regulation is premised on the idea that phenomena can be effectively controlled. Risk is therefore helpful for the law's task of ordering behaviour because it reduces uncertainty, randomness, and ambiguity, and suggests that they can somehow be held at bay.

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5 N. Luhmann, 'Die Beschreibung der Zukunft', in N. Luhmann, *Beobachtungen der Moderne* (1992), at 129, 140–1, 146; N. Luhmann, 'Risiko und Gefahr', in N. Luhmann, *Soziologische Aufklärung 5 Konstruktivistische Perspektiven* (2005), at 126, 128, 130, 152.

6 Giddens, *supra* note 1, at 4.

7 Luhmann, 'Risiko und Gefahr', *supra* note 5, at 155.

8 There are no clear protocols for how to combine expertise from different scientific specializations within one discipline, let alone across disciplines. Determining an individual's risk of death from cancer from exposure to a substance may hinge on combining standard toxicology testing with molecular and cell biology and oncology.

9 This function encompasses the control and review of decisions through administrative law and judicial review of administrative decisions, but also through tort law.

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Law as the control and review of decisions in turn hinges on the existence of standards for rational and reasonable decision-making and the attribution of decisions to one or more decision-makers. Here, risk is attractive because it suggests that it is possible to take rational decisions under conditions of uncertainty. It provides a way of distinguishing between irrational anxieties, false information, or incomplete knowledge. Risk also allows for cost–benefit analysis, suggesting rational choices.[10] Finally, risk is a standard for the judicial review of regulatory decisions whose validity is universally intelligible and which provides some uniformity in the assessment of different but comparable cases, thereby removing suspicions of bias or arbitrary unequal treatment of similar situations by judicial review.[11]

Concerning risk's contrapuntal undercurrent of uncertainty, it can be seen that the provisional status of knowledge claims, the limits of expert prediction, and the complexity and exploratory dimension required for the assessment of hazards challenge the law's authority. Decision-making is overburdened where rational decisions on the basis of risk but in the face of complex, novel hazards are required.[12] With it, the law's authority is called into question and the law's search for rational standards of decision-making and the ascription of responsibility increasingly attract the suspicion of being out of touch with reality.[13] The difficult challenge for the law consists in acknowledging that the usefulness of a probabilistic risk frame for the epistemic authority of decisions is limited under conditions of multi-expert assessment of complex, systemic hazards while preserving the idea that rational decisions are still possible.

Against the backdrop of this dialectical understanding of risk, an analysis of the panel report in *EC – Biotech* is revealing, because it shows the panel's propensity for accepting framings of risk over other framings of uncertainty in the face of a technology that is claimed to have the characteristic features of complexity, systemic hazard, and exploratory projection into the future without a stock of past experience. As will be seen below, the panel defined head-on that the existence of a risk assessment precluded recourse to Article 5(7) of the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), which comes into play when scientific evidence is insufficient.[14] Paradoxically, however, the panel shied away from

10 Suffice it to say that there are many difficulties with the accurate valuation of costs and benefits, notably whether to use 'objective' evaluations or evaluations based on stated or revealed citizen preferences and difficulties with how to compare costs and benefits of two different activities. The rationality of decisions based on cost–benefit analysis is thus not clear-cut.

11 If two different hazards can be evaluated against a single benchmark (e.g. health expenditure), it becomes possible to compare their risks.

12 N. Luhmann, 'Risiko und Gefahr', *supra* note 5, at 142, 152.

13 Ibid., at 138–9, 148.

14 The *Japan – Apples* report already contained some suggestions to this effect. See A. Herwig, 'The Precautionary Principle in Support of Practical Reason: An Argument against Formalistic Interpretations of the Precautionary Principle', in C. Joerges and E. U. Petersmann (eds.), *Multilevel Trade Governance, Social Regulation and the Constitutionalization of International Trade Law* (2006), 301, at 314–17. However, the facts of *Japan – Apples* were different, as direct scientific evidence showed that the less corroborated indirect and circumstantial evidence adduced by Japan was baseless. Panel Report, *Japan – Measures Affecting the Importation of Apples*, adopted 10 December 2003, WT/DS245/R, paras. 8.114–19, 8.125–7, 8.132–5, 8.116; Appellate Report, *Japan – Measures Affecting the Importation of Apples*, adopted 10 December 2003, AB-2003–4, WT/DS245/AB/R. For another discussion of the report, see G. Goh, 'Tipping the Apple Cart: The Limits of Science and Law in the SPS Agreement after *Japan–Apples*', (2006) 40 *Journal of World Trade* 655.

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examining whether there were scientific grounds for the moratorium imposed by the European Community (EC) on products of biotechnology, perhaps because it realized that this might have exposed the shaky grounds of its refusal to permit an Article 5(7) defence of the EC member states' safeguards and examine the less corroborated evidence in greater detail.

1.2. Science and the SPS Agreement

The SPS Agreement grapples with the difficult task of balancing the trade liberalization objectives inherent in World Trade Organization (WTO) law with members' autonomy to regulate risks to human, animal, or plant life or health.[15] Discrimination is no longer central to an inconsistency with the SPS Agreement. It suffices that WTO members have enacted unreasonable regulation.[16] The 'invention' of the SPS Agreement is to require some scientific support of human, animal, or plant life or health protection measures. Normally, risk regulation measures should only be maintained with sufficient scientific evidence, which the Appellate Body has likened to their being based on a risk assessment.[17] Where members determine that scientific evidence is insufficient, Article 5(7) allows them to adopt provisional protection measures on the basis of available pertinent information.[18] Members are largely free in their evaluation of risk – that is, in their determination of what protection against a risk is desirable.[19] However, they must avoid arbitrary and unjustifiable distinctions in protection levels adopted in respect of comparable risks if such distinctions result in discrimination or a disguised restriction on international trade,[20] and the measures adopted shall not be more trade-restrictive than required in order to achieve the member's appropriate protection level against risk.[21]

The text of the SPS Agreement is thus premised on the idea that it is possible to distinguish analytically between risk and uncertainty or, in the terminology of the SPS Agreement, between sufficient and insufficient scientific evidence. Article 5(7) provides that '[i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information'. Note that this does not preclude uncertainty from persisting despite a risk assessment because an existing risk assessment could be available pertinent information. It would thus be conceivable for a member to argue that a risk assessment supports parts of a measure while also arguing that scientific evidence

15 Risk regulation can be analytically distinguished as the phases of risk assessment, risk evaluation, and risk mitigation. Risk assessment involves technical or scientific expert knowledge; risk evaluation – judging the acceptability of risk – draws on normative or ethical value considerations; while mitigation concerns the means taken to reduce risk to acceptable levels.

16 A. Arcuri, 'The Post-discriminatory Era of the WTO: Toward World-Wide Harmonization of Risk Law?', working paper, 2005, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=974981.

17 SPS Agreement, Arts. 2(2) and 5(1) Appellate Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, adopted 13 February 1998, AB-1997-4, WT/DS26/AB/R, WT/DS48/AB/R, paras. 129, 250 (hereinafter Appellate Report, *EC – Hormones*); Appellate Report *Australia – Measures Affecting Importation of Salmon*, adopted 6 November 1998, AB-1998-5, WT/DS18/AB/R, para. 138.

18 SPS Agreement, Art. 5(7).

19 Appellate Report, *EC – Hormones*, *supra* note 17, at paras. 104, 172.

20 SPS Agreement, Art. 5(5).

21 SPS Agreement, Art. 5(6).

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is insufficient in respect of other aspects of the hazard and warrants provisional measures in the sense of Article 5(7). In terms of the dialectical conceptualization of risk discussed in section 1.1, the text of the SPS Agreement seems to acknowledge that probabilistic risk assessments can coexist with uncertainty.

Various academic commentators applaud the fact that the SPS Agreement draws on scientific evidence in order to balance the conflicting objectives of trade liberalization and regulatory autonomy. Some authors maintain that requiring members to provide scientific evidence in support of their regulatory measures effectively curbs overt and disguised protectionism and streamlines procedures of risk regulation, while accommodating national diversity regarding the outcomes of risk regulation.[22] Scientific proof of the existence of a risk here plays the role of clearing national risk regulation from the suspicion of disguised protectionism[23] or of fostering reasonable regulation.[24]

Robert Howse submits that the main benefit of requiring members to provide scientific evidence lies in rendering national risk regulation more transparent, accountable, and considered.[25] Scientific evidence can expose prejudices, arbitrariness, and false information. According to Howse, members remain free to disregard science if there are overwhelming demands for stricter regulation or other considered, political reasons for adopting stricter measures.[26] On this view, science informs national decision-making about risk but does not predetermine outcomes and the SPS Agreement positively supports national regulatory autonomy.

For Christian Joerges, scientific evidence in the SPS Agreement is really concerned with co-ordinating conflicts of jurisdiction between importing and exporting countries. The starting point is the democratic deficit of national risk regulation, which produces extraterritorial effects on firms and other WTO members, who will be affected but not represented in the political decision-making processes. Where the importing member puts forward scientific evidence in support of its regulatory measures, it renders its regulatory decision intelligible to exporting members, even if they ultimately disagree over the acceptability of risk.[27] Because the scientific method is universally accessible and because scientific evidence is varied and does

22 D. Victor, 'The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years', (2000) 32 *New York University Journal of International Law and Policy* 865, at 872, 879–80, 913, 926; J. Söderbom, 'Balancing National Sovereignty against Disguised Protectionism', World International Community Experts Report, 2004, available at http://world-ice.com/Articles/SPS.pdf, at 9.

23 L. Gruszczynski, 'The Role of Science in Risk Regulation under the SPS Agreement', EUI Working Paper Law No. 2006/03, 2006, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=891114, at 25–6 (with further references).

24 Ibid.

25 R. Howse, 'Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization', (2000) 98 *Michigan Law Review* 2329, at 2330, 2334–8, 2341–4.

26 Ibid.

27 C. Joerges, 'Juridification Patterns for Social Regulation and the WTO: A Theoretical Framework', Transstate Working Paper 17, 2005, available at http://www.sfb597.uni-bremen.de/homepages/joerges/arbeitspapierBeschreibung.php?ID=18&SPRACHE=de&USER=joerges, 30; C. Joerges and C. Godt, 'Free Trade: The Erosion of National and the Birth of Transnational Governance', in M. Zürn and S. Leibfried (eds.), *Transformation of the State* (2005), 93, at 111. Gruszczynski also notes but does not conclusively assert that the SPS Agreement fosters the external accountability of states for transboundary effects. Gruszczynski, *supra* note 23, at 29.

not determine what level of regulation is justified, it is seen as an acceptable meta-norm for resolving conflicts.[28]

Without fundamentally questioning the role of science in the SPS Agreement, some authors caution that the SPS Agreement may lead to excessive legal and judicial control over regulatory politics[29] or that science is not equally suited to all stages of risk regulation. Cheyne argues for risk evaluation (determining a protection level against risk) to be reviewed with a light touch and risk management being subject to stricter scrutiny.[30] Goh submits that disputes over the appropriateness of risk-management measures are more apposite for review focusing on their scientific basis than are the more politicized disputes over whether a risk exists.[31] In respect of the latter, he recommends political and negotiated solutions. In a similar vein Joerges argues that some disputes are too political in nature to be legitimately resolved through WTO dispute settlement, but nevertheless sees a possibility that the SPS Agreement at least encourages *comitas*, that is, resolution through diplomatic-political means in the shadow of the law.[32]

Jacqueline Peel criticizes the fact that the SPS Agreement uses a criterion without normative content (science) in order to review normative decisions about risk regulation.[33] She sees judicial review of risk regulation in the United States and the European Union (EU), where normative yardsticks guide judges in their review, in a more positive light.[34] She does not think that the US or EU approach can be a model for the SPS Agreement because an internationally agreed basis for a normative yardstick is currently missing.[35]

As will be seen, the present author shares concerns over intrusive judicial review of scientific evidence for risk regulation. However, Peel's contribution does not state whether and when it would be acceptable to decide regulatory issues outright on empirical (scientific) grounds, for instance because the science is really defective or invalid. It also leaves unclear which ideal model about the right balance between science and policy she uses to found her critique of the SPS Agreement. Are the US or EU approaches unsuitable as ideal models because internationally diverse judgements about the acceptability of risk and intensity of judicial review are valid and legitimate? Or is the absence of an international yardstick merely an empirical obstacle to the transplantation of the otherwise desirable US or EU model?

Marsha Echols offers a criticism that the SPS Agreement is anchored in a paradigm of scientific rationality that ignores social, cultural, or religious perceptions of risk.[36]

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28 Joerges, *supra* note 27, at 16, 18–19, 21.

29 T. Makatsch, *Gesundheitsschutz im Recht der Welthandelsorganisation (WTO): Die WTO und das SPS-Übereinkommen im Lichte von Wissenschaftlichkeit, Verrechtlichung und Harmonisierung* (2004), *passim.*

30 See also I. Cheyne, 'Risk and Precaution in World Trade Organization Law', (2006) 40 *Journal of World Trade* 837, at 841.

31 Goh, *supra* note 14, at 675.

32 Joerges, *supra* note 27, at 18–19, 35.

33 J. Peel, 'Risk Regulation under the WTO/SPS Agreement: Science as an International Normative Yardstick', New York University School of Law Jean Monnet Working Paper, New York, 02/04, 2004, available at http://www.jeanmonnetprogram.org/papers/04/040201.pdf, 95–7.

34 Peel, *supra* note 33, at 95–6.

35 Ibid.

36 M. Echols, *Food Safety and the WTO: The Interplay of Culture, Science and Technology* (2001), at 3 ff. and 148 ff.

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According to her, science does not answer the question of which hazards are worthy of regulation.

The criticism by Echols begs the question of why and when social, cultural, or religious perceptions of risk should be taken into account under the SPS Agreement. Should these always determine whether to regulate risks? Are not the trade interest of exporting countries and the development interest of developing countries also legitimate considerations? And are there instances where scientific evidence shows social, cultural, or religious perceptions of risk to be misguided and thus not worthy of our allegiance? Finally, how uniform must these social, cultural, or religious perceptions of risk be in order to influence decisions over risk regulation?

One may also wonder whether the criticism of the SPS Agreement's interference with risk perceptions is appropriate in all instances. For WTO members to be claiming to regulate hazards even if there is no empirical support whatsoever for their existence is inconsistent. In this sense, the SPS Agreement's reliance on science serves to verify the consistency or honesty of members' attempts to justify their risk-regulatory policies. Moreover, the existence of the SPS Agreement does not preclude members from adopting other measures to protect cultural diversity in foods, traditional foods, and production processes or religious concerns – they just have to rely on different legal provisions of the WTO agreements to justify them.

The preceding discussion has shown that a critique of the SPS Agreement requires the elaboration of an ideal normative model for risk regulation in an international context (and by implication for judicial review). As risk regulation is characterized by bringing together empirical knowledge with normative or ethical judgement about the acceptability of a risk or hazard, the issue is how to balance the two in a framework of legitimate risk regulation. Such an attempt is made in section 2.2.2, but some remarks about the role of scientific evidence in risk regulation are in order here.

Science provides a systematic and verifiable way of assessing the existence of hazards. It has not been contradicted by other knowledge claims, such as religion or astrology, and it is different from normative judgements. This is not to say that science is always right or free of policy aspects. Risk assessment is always interwoven with uncertainty because it must rely on inferences and extrapolations whose correctness cannot be proven by scientific methods.[37] This introduces scope for value judgements and calls into question rigid distinctions between risk assessment as factual and risk management as value-based.[38] However, these inferences and extrapolations can still be judged on empirical grounds even if they are also influenced by values.[39] Science thus differs from normative judgements whose validity depends on other factors, such as equal regard for the concerns of others. If one were to

37 For an excellent overview of the various sources of uncertainty in risk assessment, see E. K. Silbergeld, 'Risk Assessment and Risk Management: An Uneasy Divorce', in D. G. Mayo and R. D. Hollander (eds.), *Acceptable Evidence: Science and Values in Risk Management* (1991), 99, at 104–7.

38 Ibid., at 99, 104, 110–11.

39 D. Mayo, 'Sociological versus Metascientific Views of Risk Assessment', in Mayo and Hollander, *supra* note 37, at 252–3, 257, 267–8. For instance, standards of good science can tell us something about whether an extrapolation from animal bioassays to humans is empirically reasonable even if science cannot prove that animal bioassays always correctly predict risk in humans. In that sense, uncertainty remains.

collapse scientific assessment entirely into values, science would lose its potential of sanctioning policy decisions on empirical grounds,[40] and analytical clarity and transparency in risk regulation would be lost.[41]

Scientific evidence actually strengthens rather than undermines normative or ethical decision-making about hazards. It contributes to establishing a sound empirical basis for value-based decisions. Conversely, even the most participatory or just form of governance will be distorted if no or patently wrong facts are considered. It can therefore be concluded that the consideration of scientific evidence in regulatory decision-making about hazards is crucial. It should be pointed out that this does not preclude assigning higher weight to normative or ethical dimensions of risk regulation than to the scientific basis for regulation or criticizing the legal definition of acceptable science. It merely means that *some* scientific evidence is important and that the SPS Agreement's reliance on science is not per se inconsistent with democratic decision-making about hazards.

The SPS Agreement's recognition of the right to regulate may also tempt laggard members to regulate obviously harmful products in order to gain access to export markets. For less clear risks, a pro- or de-regulatory effect of the SPS Agreement hinges on the interpretation of the Agreement and the role accorded to international standards and their pro- or de-regulatory effects.[42] The privileging of scientific research may also lead to the increased discovery of risks and the adoption of more protective regulations.

2. THE WTO DISPUTE SETTLEMENT DECISION IN *EC – BIOTECH*: PROBABILISTIC RISK WITHOUT UNCERTAINTY?

2.1. Overview of the panel findings

In the light of the endorsement that the approach of the SPS Agreement has won in the literature, it is surprising that the panel in *EC – Biotech* largely declined to examine scientific evidence. In the EC, genetically modified crops have to be authorized before they can be used for planting or consumption as food or feed. The *EC – Biotech* dispute concerned three distinct measures. The EC had (i) put a stop on the approval of all GM crops presented for authorization (the general moratorium), and it had (ii) stopped the approval of specific GM crops (the product-specific moratoria). Several EC member states had also (iii) banned the marketing of GM products that had received prior approval by the EC (the member states' safeguards). The finding has several practical consequences: it affects the speed with which EC authorization procedures for genetically modified organisms (GMOs) have to be completed and

40 Ibid., at 253, 256, 259–61, 265–6. Mayo shows how collapsing science into values reaffirms positivist, neutral science as the unattainable ideal and makes scientific criticisms of scientifically doubtful evaluations of scientific evidence impossible.

41 Arcuri, *supra* note 16, at 22. As is well known, the Appellate Body in *EC – Hormones* rejected the panel's view that risk assessment must be kept free of risk management considerations. Appellate Body Report, *EC – Hormones*, supra note 17, para. 181. It remains unclear whether the Appellate Body thereby included a broad range of policy considerations or only a more restricted, largely technical notion of risk management as the process whereby risks are controlled or minimized.

42 See also Arcuri, *supra* note 16, at 15–16, 26–7.

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the justification of member states' safeguards. The findings also indicate how future cases on SPS matters will be decided: because the existence of a risk assessment makes recourse to Article 5(7) difficult, countries producing GMOs can carry out a risk assessment and seek market access in more risk-averse WTO members on that basis.

2.1.1. The procedural turn taken by the panel

The first threshold issue the panel had to decide was whether the SPS Agreement applied to the three types of measures in the light of their proclaimed objectives and legal form. In an intricate interpretation of its scope, the panel decided that the SPS Agreement applied to the three measures.[43] The panel next had to decide whether the general and specific moratoria constituted SPS measures and whether, consequently, the obligations of the SPS Agreement requiring scientific justification applied to them. The definition of an SPS measure is contained in Annex A(1) of the SPS Agreement, which speaks of laws, decrees, regulations, requirements, and procedures applied to achieve protection against specific risks.[44]

The panel differentiated between requirements and procedures implying a protection level and a procedural decision to delay final approval, which relates to the application or operation of the existing EC approval procedures.[45] It found that the application or operation of procedures was not covered by the definition of an SPS measure.[46] The panel characterized the EC moratorium as a procedural decision to delay approval and on that basis found that the moratorium was not an SPS measure.[47] It also found that the procedural decision to delay approvals did not achieve or imply a particular level of protection and therefore found that the moratorium was not an SPS measure within the meaning of Article 5(1).[48] The panel thus rejected the claimants' arguments that the moratorium was equivalent to a marketing ban on GM products[49] and that the moratorium establishes a procedure or amends an existing procedure.[50] The panel reasoned that the moratorium did not result in the EC applying approval procedures different from those set out in the relevant EC legislation.[51] The panel also stated that it was unclear what new course of action the moratorium established since it did not predetermine a particular mode of action.[52] It essentially applied the same finding to the product-specific moratoria.[53]

43 Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, adopted 21 November 20006, WT/DS291/R, WT/DS292/R, WT/DS293/R, paras. 7.432 (hereinafter Panel Report *EC – Biotech).*
44 SPS Agreement, Annex A(1).
45 Panel Report *EC – Biotech*, *supra* note 43 at paras. 7.1379, 7.1382.
46 Ibid., at para. 7.1335.
47 Ibid., at para. 7.1381.
48 Ibid., at para. 7.1393.
49 Ibid., at para. 7.1359.
50 Ibid., at paras. 7.1371, 7.1378.
51 Ibid., at paras. 7.1373, 7.1375, 7.1377.
52 Ibid., at para. 7.1374.
53 Ibid., at paras. 7.1686, 7.1689.

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The result of the panel finding was that the EC moratorium could not be examined with respect to its scientific justification. The only part of the SPS Agreement considered by the panel to be applicable was the procedural obligations set forth in Annex C of the SPS Agreement, more particularly those calling on members to complete their approval procedures without undue delay.[54] Even in interpreting Annex C the panel did not have recourse to any scientific considerations in deciding whether there was undue delay in the completion of the EC approval procedures. Instead, the panel examined whether the EC had followed the steps set out in its approval procedure for GMOs.[55]

Given the usefulness of risk for legal concerns with rational decision-making, the panel's reluctance to examine the scientific basis for the moratorium and the delay is surprising. A defensible legal interpretation would have offered ample opportunities for considering the moratorium in the light of the SPS Agreement's scientific disciplines. Contrary to what the panel claims, the moratorium implies a protection level of zero risk against GMOs and can therefore be considered as a measure applied to protect against SPS risks. The moratorium also laid down a course of action, namely to prevent the approval of GM products, and modified the existing approval procedure by removing the possibility for positive approval. One may speculate why the panel took this procedural turn. Perhaps it realized that examining the risk of GMOs seriously would have brought to light significant uncertainties and unclear standards of rational decision-making and, with them, would have diminished the law's role in controlling decisions.

2.1.2. The panel's application of the substantive obligations concerning scientific evidence

The only measure in respect of which the panel found the substantive obligations in Articles 2(2), 5(1), and 5(7) to be applicable were the EC member states' safeguards. The panel first examined whether the safeguards were based on a risk assessment in the sense of Article 5(1). As all the parties in the dispute agreed that the EC's original assessments and the reassessments in the light of the EC member states' concerns constituted risk assessments, the panel found that these were risk assessments within the meaning of Annex A(4).[56] In each case the EC committees found no safety concerns with the biotech products and authorized their placing on the market. In respect of the evidence brought forward in support of the EC member states' safeguards the panel found that none of them constituted a risk assessment and made the provisional finding that the safeguards were not based on a risk assessment since they contradicted the conclusions of the original risk assessments.[57]

The panel then examined whether the EC member states' safeguards were justified by Article 5(7). The panel adopted a largely procedural and indirect approach to this question. Since it had found that a risk assessment already existed (the original risk assessment and the reassessment in the light of the member states' concerns), it

54 Ibid., at paras. 7.1466–570.
55 Ibid., at paras. 7.1553–60, 7.1564–5, 7.1567. See also paras. 7.1524–7, 7.1529.
56 Ibid., at paras. 7.3054, 7.3082, 7.3103, 7.3124, 7.3134, 7.3154, 7.3174, 7.3192, 7.3208.
57 Ibid., at paras. 7.3060–7.3062, 7.3067–7.3069, 7.3085–7.3086, 7.3106, 7.3127, 7.3137, 7.3157, 7.3177, 7.3195, 7.3211.

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concluded that scientific evidence was no longer insufficient to perform a risk assessment and that the safeguards were therefore definitely inconsistent with Articles 5(7) and 2(2).[58] In other words, the panel really faulted the EC for its inconsistency in accepting that the original assessment and reassessment were risk assessments and then denying that scientific evidence was sufficient.

On a benign reading of the *EC – Biotech* report, the panel avoided deciding the scientifically and politically controversial issue of whether GMOs are harmful. Since the EC had started to approve GMOs again, the panel essentially made the finding that the EC should continue what it was already doing anyway – that is, approve GMOs. On this reading, all the panel did was to take the EC at its word and hold it to its self-imposed constraints on regulating GMOs. It also completely deferred to scientists the EC trusted.

However, the panel also made four substantive findings concerning the role of science. It is submitted that the panel took a deterministic view of science by considering risk and uncertainty to be mutually exclusive as soon as a risk assessment exists. It thereby neglected the dialectical nature of risk as interwoven with uncertainty and overemphasized the role of science in risk regulation at the expense of normative or ethical elements.

First, to the extent that uncertainty remains intertwined with risk and cannot always be resolved by scientific methods, decisions about appropriate regulation of risk must also involve normative or ethical judgement. The panel neglected this by holding that the protection purposes of the regulator were not relevant for determining the insufficiency of scientific evidence within the meaning of Article 5(7) of the SPS Agreement.[59] According to the panel, the insufficiency of scientific evidence is exclusively a scientific determination and requires that scientific evidence does not allow the performance of a risk assessment.[60]

The EC had argued that the protection purposes of the regulator also needed to be taken into account in determining whether scientific evidence was insufficient. The EC had attached particular importance to the word 'adequate' in the Appellate Body's statement in *Japan – Apples*, according to which scientific evidence had to be insufficient to perform an adequate risk assessment. The EC submitted that the term 'adequate risk assessment' should be interpreted as a risk assessment adequate for the protection purposes of the regulator. As Article 5(1) requires a risk assessment appropriate to the circumstances, the EC also submitted that the regulators' protection purposes could be circumstances that make scientific evidence an inappropriate risk assessment and justify recourse to Article 5(7). The potential problem with the EC's argument is that it would allow members to tailor their SPS obligations to protectionist purposes or irrational public anxieties by claiming to be highly risk-averse, without there currently being another yardstick under the SPS Agreement to avoid just this.

58 Ibid., at paras. 7.3262, 7.3275, 7.3288, 7.3302, 7.3316, 7.3329, 7.3343, 7.3358, 7.3371.
59 Ibid., at paras. 7.3234–7.3246.
60 Ibid., at paras. 7.3234, 7.3237.

The panel rejected the EC's argument, reasoning that 'adequate' referred to nothing more than a risk assessment as defined in Annex A(4) of the SPS Agreement or to 'a more objective assessment of risk' called for in Article 5(7).[61] It also found that the SPS Agreement does not allow a member to reject a risk assessment meeting the criteria of Annex A(4) as inappropriate on the ground that the risk assessment does not give the member enough subjective confidence that its level of protection will be achieved.[62]

The panel's rejection of the EC's argument seems to be based on a selective reception of prior SPS dispute settlement reports. In the light of these earlier reports, the protection purposes of regulators might matter more for the determination of the (in)sufficiency of scientific evidence than the panel thought. In *EC – Hormones*, the Appellate Body stated that panels reviewing the scientific basis of a member's SPS measure should bear in mind that governments commonly act on the basis of prudence and caution when irreversible risks are concerned.[63] This suggests that the evidentiary requirements for SPS measures can be adjusted because of qualitative differences in risk – which are ultimately normative or ethical judgements about the acceptability of certain risks and the associated duty of protection incumbent on governments. It could therefore be imagined that the SPS Agreement allows members to adopt provisional measures against irreversible and perhaps other classes of risk even if evidence of safety is of relatively high quality, while they might not be able to do so in case of innocuous risks.

Second, the panel found that because the original risk assessment and the reassessment by the EC were risk assessments, scientific evidence was no longer insufficient and recourse to Article 5(7) was precluded in respect of the safeguard measures.[64] In the panel's mind, situations where science is sufficient and where it is insufficient are mutually exclusive. The distinction between the two hinges primarily on whether data allows for applying risk assessment methods to determine the risk and not on whether there are scientific doubts regarding the validity of the risk assessment method or its underlying theories or on whether preliminary scientific evidence suggest a potential hazard. Once a framing of risk is used, in other words, the rationality of decisions about hazards is determined by that frame and no longer by any persisting uncertainties. This deterministic understanding of the panel is also reflected in the panel's statement that

> where a risk assessment has been performed, and that risk assessment meets the standard and definition of Annex A4(d), it does not cease to be a risk assessment within the meaning of Annex A4 merely because a particular Member judges that the risks have not been assessed with a 'sufficient' degree of precision, that the assessment has not 'withstood' the passage of time, and that it is 'likely' that the assessment may need to be revised at some point in the future. If there are factors which affect scientists' level of confidence in a risk assessment they have carried out, this may be taken into account

61 Ibid., at paras. 7.3235–7.3237.
62 Ibid., at para. 7.3244.
63 Appellate Report *EC – Hormones*, *supra* note 17, at para. 124.
64 Panel Report *EC – Biotech*, *supra* note 43, at paras. 7.3260, 7.3273, 7.3286, 7.3300, 7.3314, 7.3327, 7.3341, 7.3356, 7.3369.

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by a Member in determining the measure to be applied for achieving its appropriate level of protection.[65]

What is the implication of what the panel says? Once scientists consider evidence before them to be a risk assessment, they may absorb uncertainty into risk through levels of confidence. But would they also accept that there can be uncertainty which cannot be absorbed into a framing of risk? Hardly, because this would call into question their conclusion that the evidence before them is a risk assessment – that is, an assessment that really does tell us something about the probability of a hazard. After its report the panel elaborated on the concept of insufficiency in a letter to the parties, which is of no legal value. This letter reconfirms the bright line between risk and uncertainty. In it, the panel explains that scientific evidence which is at one point sufficient for a risk assessment can later become insufficient if new scientific evidence becomes available that negates the validity of the existing risk assessment but is itself insufficient to perform a risk assessment.[66] The bottom line of the panel's finding is that an existing risk assessment can only be trumped by definite, falsifying evidence and not by preliminary evidence of lesser corroboration. The result of this boundary-drawing for the EC in this dispute was that the evidence put forth in support of the EC member states' safeguards could no longer be examined on its merits as a possible ground for recourse to Article 5(7).

At least one study on Bt (Bacillus thuringiensis) maize and lacewings adduced by the EC in support of a safeguard measure comes quite close to a direct risk assessment. As discussed below, the panel did not consider this study to be a risk assessment. If this type of evidence is not even enough to constitute a risk assessment within the meaning of Article 5(1), *where another risk assessment already exists*, it will equally not be enough to convince the panel that scientific evidence is thereby rendered insufficient within the meaning of Article 5(7). But if risk assessment and more fundamental uncertainty can coexist despite framings of risk, it is suggested that it would not be unreasonable to consider that such a study renders a prior risk assessment insufficient.

Third, the panel established high thresholds for when evidence could be considered a risk assessment in the sense of Annex A(4) of the SPS Agreement. As has been argued in section 1.1, the temptation of using frames of risk is to ask ever more accurate and detailed answers of scientists that the scientific method will soon be unable to supply. The panel seems to have fallen into this trap, because it rejected several studies on lacewings which confirmed the harmfulness of Bt toxin residues for lacewings under laboratory conditions. The panel found fault with one study in which lacewing larvae were fed a liquid diet containing Bt toxins on the basis that the study did not feed the MON810 maize plant[67] and was not conducted under field conditions.[68] Subsequent studies by the same scientists using Bt-corn-fed prey

65 Panel Report *EC – Biotech, supra* note 43, at para. 7.3240.
66 The panel's letter to the parties is discussed in D. Prévost, 'Opening Pandora's Box: The Panel's Findings in the *EC – Biotech* Dispute', (2007) 34 *Legal Issues of Economic Integration* 67, at 85 ff.
67 Panel Report *EC – Biotech, supra* note 43, at para. 7.3098. Lacewings are predatory insects that do not feed on maize.
68 Ibid., at para. 7.3098.

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as feed for the lacewings were rejected because they were not conducted under the field conditions,[69] where the larvae would have a choice between Bt-corn-fed prey and prey not raised on genetically modified corn. The panel's examination of the lacewing study also indicates what, counterfactually, might be accepted as a risk assessment: a direct, dose-dependent risk assessment for the specific risk likely to be encountered under realistic circumstances.

The primacy of the role given to science rather than value-based judgement about risk regulation is, fourth, reflected in the panel's approach to the interpretation of the SPS Agreement in the light of other international law. According to Article 31(3)(c) of the Vienna Convention on the Law of Treaties, international treaties are to be interpreted in the light of relevant rules of international law applicable in the relation between the parties.[70] The issue that arose in *EC – Biotech* was whether the reference to 'the parties' in the Vienna Convention applied only to the disputing parties or to the whole membership of a multilateral treaty. If 'the parties' referred only to the disputing WTO members, a second treaty concluded only between the disputing WTO members but not the whole WTO membership could be considered in the interpretation of the SPS Agreement. If 'the parties' referred to all the members of the WTO, only treaties with an identity of membership to that of the WTO agreements could be referred to as an outside interpretative source in the sense of Article 31(3)(c).

The panel found that only treaties concluded between all WTO members were an outside interpretative source and therefore declined to consider the Convention on Biological Diversity and its Biosafety Protocol.[71] It held that treaties whose membership is not identical to the WTO agreements could only be used by an interpreter to confirm the ordinary meaning of terms of a treaty.[72]

The panel's finding can be criticized on textual grounds.[73] Article 2(1)(g) of the Vienna Convention states that 'party' means a state which has consented to be bound by the treaty and for which the treaty is in force. This definition says nothing about disputing parties, some of or the whole membership of a multilateral treaty. Article 31(3)(c) read in conjunction with this definition merely tells us that the treaty interpreter must look to rules of international law that apply in the relations between WTO members, and not rules of international law that apply between non-WTO members. Article 31(3)(c) would then merely reflect the principle that treaties cannot affect the rights and obligations of non-parties. For interpreters to have recourse to other international treaties binding even only the disputing parties but not the whole WTO membership does not violate this principle because the

69 Ibid., at paras. 7.3099, 7.3147–7.3148. For one study a further reason was that it did not use the maize variety at issue in the safeguard to feed the prey.

70 Vienna Convention on the Law of Treaties, Art. 31(3)(c), available at http://untreaty.un.org/ilc/ texts/ instruments/english/conventions/1_1_1969.pdf.

71 Panel Report *EC – Biotech*, *supra* note 43, at para. 7.68.

72 Ibid., at para. 7.92.

73 A. Herwig and T. Hüller, 'Zur normativen Legitimität der Welthandelsordnung', in M. Hilf and T. Niebsch (eds.), *Perspektiven des internationalen Wirtschaftsrechts* (2008), 117, at 154 (lack of clear textual support in Vienna Convention for panel's interpretation).

rulings and recommendations of panels or the Appellate Body are only addressed to the disputing parties and WTO law knows of no *stare decisis*.

What is more, had the parties to the Vienna Convention on the Law of Treaties wished to require an identity of membership between multilateral treaties, they could have stated so explicitly. It is even arguable that a contextual and teleological interpretation of the term 'applicable in the relations between the parties' of Article 31(3)(c) should lead to the conclusion that treaties binding only disputing parties to a multilateral treaty are a permissible outside interpretative source. The preamble of the Vienna Convention on the Law of Treaties recognizes the importance of international treaties as a means of peaceful co-operation between states and notes the universal recognition of the *pacta sunt servanda* rule.[74]

As a result of requiring an identity of membership between multilateral treaties as the panel has done, states will find themselves subject to conflicting obligations without the interpretative means of attenuating them. This increase in conflicts of obligations makes it more difficult for states to observe all their international obligations and diminishes the role of international treaties in fostering peaceful co-operation, since abiding by one treaty will often mean violating the other. Taking into account the preamble of the Vienna Convention should therefore lead to an interpretation of Article 31(3)(c) that reconciles international obligations to the greatest extent possible by allowing treaty interpreters also to consider treaties that do not bind all the parties to a multilateral agreement.

The panel's finding can be criticized because it increases the fragmentation of international law, ignores the regulatory character of other international treaties, and turns WTO law into a largely self-contained regime.[75] The panel seems to misconstrue WTO obligations as being *erga omnes* rather than *inter partes*. Pauwelyn has convincingly argued that WTO obligations are best seen as *inter partes* obligations because they can only be violated in case of nullification and impairment vis-à-vis complainants.[76]

If one takes the view that risk regulation and the decision of whether and when scientific evidence is (in)sufficient should also be a political one, the panel's dismissal of most international treaties as an interpretative source is unfortunate. Non-WTO treaties may represent plurilateral or bilateral consensus on the appropriate regulation of specific risks and do not raise concerns over discriminatory trade barriers as between the parties since they have agreed to the same risk regulation. Diversity between WTO members can also lead to different political evaluations of risk and

74 Vienna Convention on the Law of Treaties, Preamble.

75 G. Marceau, 'A Call for Coherence in International Law – Praises for the Prohibition against "Clinical Isolation" in WTO Dispute Settlement', (1999) 33 *Journal of World Trade* 87, at 110 (against interpreting WTO law without consideration of international law).

76 J. Pauwelyn, 'A Typology of Multilateral Treaty Obligations: Are WTO Obligations Bilateral or Collective in Nature?', (2003) 14 EJIL 907, at 925–41. If WTO obligations are *inter partes* and can be modified through a simple bilateral treaty between two parties, it only seems necessary to ascertain how the WTO members parties to another treaty understood terms in the WTO agreements. Pauwelyn himself would not go as far in J. Pauwelyn, 'The Role of Public International Law in the WTO: How Far Can We Go?', (2001) 95 AJIL 535, at 573–6 (only non-WTO treaties establishing the common intention of all WTO members could be drawn upon, including those accepted by acquiescence rather than express consent).

provide good reasons for adopting regionally divergent responses in the form of treaties.[77]

Finally, to change WTO law requires the consent of all members and is very difficult.[78] The panel's finding leads to a catch-22: as membership of the WTO increases, so should the membership of other international treaties if they are to remain relevant. However, because diversity of preferences amongst WTO members increases, it becomes less likely that they will all agree on non-WTO treaties. In terms of readjusting the balance between WTO law and the development of international regulatory capacity, nothing is therefore gained by the possibility of interpreting WTO law in the light of other international law since the consensus requirements for changing WTO law or concluding another treaty with identical membership are the same. Lamentably, the panel's finding might have a chilling effect on the further development of international treaties on SPS matters since they are often likely to be irrelevant to the interpretation of the SPS Agreement. The use of international treaties to confirm the ordinary meaning of treaty terms, *nota bene*, does not offer this same possibility of adjusting the SPS obligations to multilateral political preferences about risk.

2.2. Evaluation of the panel's conceptualization of risk regulation in *EC – Biotech*

The following subsection evaluates whether the scientific assessment of GMOs is infused with uncertainty and whether the dialectical conceptualization of risk in section 1.2 is pertinent to a critique of the panel findings on empirical grounds. Subsection 2.2.2 puts forth a critique of the panel finding in the light of what an ideal normative model for risk regulation would require.

2.2.1. Evaluation on empirical grounds

Some commentators have maintained that the regulation of novel technologies should not be reviewed with the same level of scrutiny as the regulation of more established risks.[79] They argue that panels should adjust their level of scrutiny in accordance with the background knowledge available about a technology and potential hazard.[80] In other words, the application to biotech risks of overly strict levels of scrutiny might produce wrong results and lead to the importation of hazardous products.

The crux in relation to biotech products is that scientific knowledge still emerges. Some scientists have raised the criticism that the customary methods for the safety

77 For instance, in fragile ecosystems such as the rainforest, the introduction of alien species can have more severe consequences than in more robust ecosystems. Because the threshold for harm (invasiveness) differs, it would be rational to accept evidence of lesser scientific corroboration as a sufficient ground for regulation in a regional treaty.

78 C.-D. Ehlermann and L. Ehring, 'Decision Making in the World Trade Organization: Is the Consensus Practice of the World Trade Organization Adequate for Making, Revising and Implementing Rules on International Trade?' (2005) 8 *Journal of International Economic Law* 51.

79 L. Busch et al., '*Amicus Curiae* Brief Submitted to the Dispute Settlement Panel in the Case of EC: Measures Affecting the Approval and Marketing of Biotech Products', available at http://www.lancs.ac.uk/fss/iepp/wtoamicus/amicus.brief.wto.pdf, at 5.

80 Ibid., at 5.

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assessment of GMOs are inadequate, others see the relevance of alternative potential methods without being able to characterize exactly what hazard GMOs might pose, let alone assess risk with these methods.[81] Under the panel's approach in *EC – Biotech*, these general concerns are no longer relevant once a majority of scientists accepts the customary methods of GMO safety assessment as risk assessments. It privileges the customary methods of GMO safety assessment and treats GMO risks in much the same way as, say, toxicological risk, in spite of the fact that the customary methods of GMO assessment have not yet withstood the passage of time and that general scientific knowledge about genetics, gene expression, and the effects of transgenic proteins on the metabolism of the host organism remains incomplete.[82]

Furthermore, the standards for a valid risk assessment imposed by the panel on the lacewing studies are too high and contradictory. The requirements that the evidence for Article 5(1) purposes has to identify the agent with precision, assess exposure using realistic exposure scenarios, and offer conclusive proof can be difficult to meet for certain risks. For instance, it can be difficult to model realistic exposure scenarios or devise a useful test for chronic, low-dose exposure or multiple, interacting hazardous agents.[83] Note that there is a conflict between requiring conclusiveness and realistic exposure scenarios, for the more closely scientists have to model the real world, the more difficult it becomes for them to make useful, conclusive observations.

2.2.2. Evaluation against an ideal normative model of risk regulation

From the perspective of legitimate risk regulation, assigning science the pivotal role in risk regulation is unconvincing. Commentators have made the criticism that the SPS Agreement relies on the criteria of science that are bereft of any normative content in order to police what ultimately are normative decisions about risk-taking and avoidance.[84] As others have argued, what constitutes sufficient scientific evidence, how to weigh conflicting evidence or interpret data gaps, is not only a matter of scientific validation but also one of value judgement because they contribute to and are influenced by the framing of risk.[85]

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81 Ibid., at 5; E. Millstone, E. Brunner, and S. Mayer, 'Beyond "Substantial Equivalence"', (1999) 401 *Nature* 525; Kuiper, 'Profiling Techniques to Identify Differences between Foods Derived from Biotechnology and their Counterparts', Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, 29 May–2 June 2000, 6.

82 Busch et al., *supra* note 79, at 5; National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* (2000), 56; GM Science Review Panel, 'GM Science Review First Report', available at www.gmsciencedebate.org.uk, at 80, 87.

83 A. O. Sykes, 'Domestic Regulation, Sovereignty, and Scientific Evidence Requirements: A Pessimistic View', repr. in P. C. Mavroidis and A. O. Sykes (eds.), *The WTO and International Trade Law/Dispute Settlement* (2005), 178, at 189.

84 Peel, *supra* note 33, at 95–7, 99.

85 D. Winickoff et al., 'Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law', (2005) 30 *Yale Journal of International Law* 81, at 85, 93 ff. and especially 113; Cheyne, *supra* note 30, at 840, 842. That laypersons not only judge risks by reference to the potential of a hazard but use certain heuristics has been demonstrated in literature on risk perception. To them, mortality has to be evaluated differently depending on the dread factor of a risk or the familiarity with the underlying technology. For an overview of recent studies in risk perception see P. Slovic, *The Perception of Risk* (2000), and for an early study see P. Slovic, 'Perception of Risk', (1987) 236 *Science* 280. Although these heuristics may sometimes lead laypersons to underestimate certain risks and it is not claimed that they must be accepted at face value in decisions

Underlying any answer concerning the right mix between science and policy is ultimately a view on the kinds of result that risk regulation should obtain.[86] An answer will differ depending on whether risk regulation should primarily attain a correct result, a just result, an ethical result, or a mixture of all or some of these.[87] It is submitted that the key difficulty in deciding on standards for rational risk regulation stems from the fact that risk regulation combines two goals that cannot be perfectly reconciled; it is obvious that one would prefer risk regulation to be based on correct information and would want to avoid normatively unacceptable hazards as much as possible. If there were a form of scientific evidence that always yielded correct outcomes compared with any other form of evidence, it would be rational generally to accept the former type of evidence as decisive for the question of whether regulation is justified. The problem stems from the fact that criteria for validation of scientific evidence do not necessarily guarantee correct results across all types of risk or hazard, or that unacceptable hazards can always be avoided.

The argument that direct, conclusive scientific evidence in the form of a risk assessment is always to be preferred over other, less confirmed forms of evidence also creates an accountability gap from the perspective of citizens.[88] On the one hand, policymakers will base their decision not to take measures against less corroborated hazards on their lack of a mandate to do so in the absence of a direct risk assessment. On the other, scientists will not accept responsibility for the occurrence of hazards that they have not had an opportunity to verify experimentally. Even then they do not accept responsibility for their findings as being 'the true result', but only as having applied methods correctly and made consistent deductions from a general hypothesis. From the perspective of citizens, any decision not to regulate suspected but little-confirmed hazards appears to emerge out of no-man's-land with neither science nor policymakers having any responsibility if the hazards do materialize.

The further reason why it is implausible always to prefer direct, corroborated evidence over less corroborated evidence is that citizens simply might not care about correct results as much as they care about avoiding normatively unacceptable or catastrophic hazard.[89] In other words, those concerned by risk regulation might reasonably accept the potential for error as long as they can be sure to have avoided normatively unacceptable hazards. Notably, where there are no perceived benefits to an activity but poorly corroborated evidence giving rise to normative concerns there seem to be no good normative reasons why the activity should be authorized.

To reject some forms of scientific evidence on the grounds that they do not reach the same level of confirmation as would be required in research science uses the non-normative evidentiary standards of science to justify what in the final analysis

about how to regulate hazards, it cannot be said that laypersons' qualitative and contextual understanding of hazards is necessarily less rational than the abstract understanding of scientists focusing only on the hazard itself.

86 Alexandru Parvu, *supra* note 3, at 2.

87 Ibid.

88 The following paragraph is based on Herwig, *supra* note 14, at 306.

89 Similarly, O. Perez, 'Anomalies at the Precautionary Kingdom: Reflections on the GMO Panel's Decision', (2007) 6 *World Trade Review* 265, at 279 ff.

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are normative questions.[90] The evidentiary standards of science are appropriate for knowledge generation, but this process, others have also submitted, should not be confused with practical decision-making geared towards (non-)action.[91] If decisions to tolerate tenuous and ill-confirmed potential hazards require normative justification, a decision-making procedure that always bases itself on scientific standards of proof required for research science is not legitimate because it may lead to the imposition of hazards without justification. Scientific evidence is therefore an essential input, but the evidentiary standards for research science should not in all cases be the threshold-determining factor for setting protection levels.

That said, it has been argued in section 1.2 that legitimate risk regulation cannot do away with some empirical standard against which to check the proclaimed factual basis of risk regulation. Sometimes factual allegations underlying regulation may simply be wrong, and related normative or ethical arguments cannot be appraised independently of their wrong factual basis. As I argued in that section, democratic, normative decision-making about hazards becomes distorted if wrong factual bases of normative or ethical arguments cannot be filtered out. Moreover, the trade liberalization objective of the SPS Agreement would be completely undermined if members were allowed to succumb completely to political preferences or consumer anxieties regardless of any facts. Sound empirical evidence is therefore helpful in practical decision-making, and some standards of empirical validity are consequently still needed under the SPS Agreement, but they should be sufficiently broad to encapsulate different forms of scientific evidence – from direct, experimental risk assessment to epidemiological data and indirect evidence.

3. A BETTER APPROACH TO THE TRADE GOVERNANCE OF GMOS

From the above analysis it can be concluded that a different way of striking a balance between normative goals of risk protection, empirical standards of validity, and the trade liberalization objectives is needed under the SPS Agreement. It is suggested that checking scientific evidence against an unreasonableness standard can reconcile the three different objectives of the Agreement.[92] An unreasonableness criterion would examine whether scientific knowledge claims fail to cohere with larger belief systems. Instead of asking whether the regulating member has used the epistemologically best form of scientific evidence (direct, specific, reliable, and conclusive risk assessment), the WTO dispute settlement bodies should only ask the experts to evaluate whether the evidence relied on is not *directly* contradicted by

90 Peel, *supra* note 33, at 95–7, 99.

91 S. Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (1990), 42, 77–9 (arguing that filling gaps in the knowledge base, knowledge synthesis, and prediction of uncertain events are key features of regulatory science distinguishing it from laboratory science and that the same evidentiary standards should not apply to both).

92 Reasonableness tests are advocated by Cheyne, *supra* note 30, at 842; O. Perez, *Ecological Sensitivity and Global Legal Pluralism: Rethinking the Trade and Environment Conflict* (2004), 145 f., 156; Sykes, *supra* note 83, at 190; and V. R. Walker, 'Keeping the WTO from Becoming the "World Trans-science Organization": Scientific Uncertainty, Science Policy and Fact-Finding in the Growth Hormones Dispute', (1998) 31 *Cornell International Law Journal* 251, 280 ff.

other knowledge claims taking into account experience with potential hazards and methods of assessment and general background knowledge about the specific and closely related substances.

An unreasonableness standard is similar to a minimal standard for measuring knowledge developed by epistemic theories. According to these theories, what determines the validity of knowledge claims is their explanatory consistency with our larger system of beliefs.[93] In order to be accepted as valid, a statement must fit with the remainder of our belief systems, and we accept a statement because it provides a higher degree of consistency than any other statement that contradicts it.[94]

It is suggested that an unreasonableness standard constitutes a legal evidentiary standard that bridges differences between direct risk assessments and other forms of evidence, such as epidemiological data or scientific theories, and allow, for comparing their corroboration and reliability. It also constitutes a flexible evidentiary standard that operates more strictly for established risks than for new, potential hazards. This should be particularly so in case of assessments of genetically modified organisms if the background knowledge about genetics does not unequivocally support any particular method of safety assessment. Importing members would therefore enjoy greater leeway to select amongst different types of evidence than under the approach of the panel in *EC – Biotech* and could respond to the normative dimension of decisions on whether regulation is needed. The implications of a deferential reasonableness standard can perhaps best be illustrated through a hypothetical example drawn from WTO dispute settlement decisions.

In the *EC – Hormones* dispute, the Appellate Body rejected general studies about the carcinogenity of growth hormones as not sufficient to warrant the ban on their use in beef husbandry, and instead required a specific risk assessment of residue levels of these hormones found in beef. This specificity requirement can be criticized on the grounds that it makes it difficult to demonstrate low-dose risk or combined exposure effects because assessment methods can be too insensitive.[95]

WTO dispute settlement bodies applying the unreasonableness standard would inquire whether general background knowledge and experience lead to the conclusion that a direct, specific risk assessment contradicts other forms of scientific evidence or not. For instance, if the defending member provided circumstantial epidemiological data suggesting that the combined exposure to chemically similar substances is linked to a higher cancer rate, a panel or the Appellate Body should find that an existing direct, specific risk assessment of growth hormone residues in beef does not contradict epidemiological data, since the direct, specific assessment fails to address the same premises as the epidemiological study. Both types of evidence could then be used as bases for SPS measures. If neither background knowledge, experience with direct, specific assessment of hormone residues, nor circumstantial or indirect evidence suggested any problems with the specific risk assessment, the specificity

93 K. Lehrer, *A Theory of Knowledge* (2000), at 97–121.
94 Ibid., at 101, 105.
95 Sykes, *supra* note 83, at 189. Gruszczynski, *supra* note 23, at 17.

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requirement still constitutes a valid epistemological criterion for distinguishing this form of evidence from general studies of a particular substance.

It might be objected that such an approach cannot sufficiently guard against advertent or inadvertent protectionism since WTO members will enjoy greater choice between forms of scientific evidence. This will not be the case if members' greater leeway is counterbalanced by some control of the policy-based reasons for why members prefer to rely on less corroborated evidence. The SPS Agreement already has some legal mechanisms at its disposal whereby the non-scientific policy bases of risk regulations can be assessed in order to ensure that these political claims are genuine and not protectionist. Admittedly, these suggestions depart from interpretations given to them in dispute settlement, but, it is maintained, they can be reconciled with the text of the SPS Agreement.

One of these mechanisms includes the concept of 'based on' in Article 5(1), which, according to the Appellate Body in *EC – Hormones*, requires that an SPS measure be 'sufficiently warranted or reasonably supported' by a risk assessment. The concept of 'based on' could be developed into a test whereby the members' policy reasons for preferring one of several reasonable pieces of scientific evidence are assessed. It should be noted that the concept of risk assessment as defined in Annex A(4) is sufficiently open to include forms of scientific evidence with different degrees of corroboration, since nothing is said about specificity, conclusiveness, or real-world circumstances.[96] In addition to giving scientific justification for an SPS measure a member would therefore also be expected to give normative or ethical justifications for its decision to prefer evidence other than a direct, specific, and conclusive risk assessment.

The concepts of 'sufficiency' or 'insufficiency' of scientific evidence similarly do not preclude interpreting them to include policy-based criteria. The Appellate Body has stated that the existence of a rational and objective relationship between evidence and the SPS measure was required for there to be sufficient scientific evidence for a measure.[97] It also stated that 'sufficient' meant that evidence had to be of adequate quantity, scope, or extent for the SPS measure.[98] If it is true that the evidentiary standards for an optimal assessment of risk used in research science can sometimes fail to yield correct results and use inferences that are also based on value, 'adequacy', 'rationality', and 'objectivity' of the evidence, then they have to be judged by criteria going beyond research science, including policy-based ones. Article 2(1) and the Preamble of the SPS Agreement affirm the right of members to take SPS measures necessary for the protection of life or health.[99] It follows from the above that what is necessary for health protection also has to be judged in the light of policy considerations and evidentiary standards suitable for scientific evidence with different inferences and degrees of corroboration. A WTO adjudicatory body could thus draw on Article 2(1) and the Preamble as context for arriving at an

96 SPS Agreement, Annex A(4).
97 Appellate Report *Japan – Measures Affecting Agricultural Products*, adopted 19 March 1999, WT/DS76/AB/R, para. 84.
98 Ibid., at paras. 73–74.
99 SPS Agreement, Art. 2(1) and Preamble.

interpretation of 'sufficiency' and 'insufficiency' that goes beyond the narrow criteria of good research science.

It might further be objected that WTO dispute settlement panels and the Appellate Body are not sufficiently legitimized to assess the merits of policy-based justifications for regulations and that the approach advocated here is still too vague to really prevent regulatory protectionism. There is no need, however, for panels or the Appellate Body to 'invent' a catalogue of universal normative or ethical standards with which members' risk regulation must comply. The approach under Article 5(5) of the SPS Agreement already constitutes an indirect way that allows panels and the Appellate Body to review some of the normative or ethical dimensions of risk regulation to ensure that they are based on honest concerns. Article 5(5) applies to the stage of risk evaluation – that is, to the stage where members decide on the basis of a risk assessment – what level of risk is acceptable. It requires members to 'avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade'.[100]

Although the contours of the legal obligation in Article 5(5) remain unclear in dispute settlement, I have elsewhere submitted that a legitimate interpretation of Article 5(5) should focus on whether a member employs justifications consistently in different situations of risk.[101] In applying the concept of 'based on' or of '(in)sufficiency', a panel or the Appellate Body might therefore examine whether the member concerned relies on the same normative justification for taking measures on the basis of less confirmed evidence in similar situations. If this were not the case, panels or the Appellate Body could conclude that an SPS measure is inconsistent with the SPS Agreement without having to examine normative or ethical justifications for risk regulation on the merits.

4. Conclusion

Although this article has warned of a scientific 'straitjacket' for regulatory politics, the results of the report in *EC – Biotech* might have been less troublesome had the panel engaged with the scientific evidence more profoundly. On this occasion the panel might have discovered that the scientific assessment and regulation of GMOs has to cope with uncertainties and incomplete background knowledge notwithstanding the fact that some scientists consider risk assessment of GMOs to be possible. The panel is not the only one to blame, since the EC could have made a better case. Admitting that the original and the reassessment were risk assessments was probably not wise and at any rate unnecessary in the dispute.

Recourse to science undoubtedly strengthens the epistemic validity of law and its potential for ordering social phenomena. However, it can do so only to the extent that the law's approach to scientific evidence is capable of filtering out scientific knowledge *accepted as true* in the light of other knowledge about the world *and*

100 SPS Agreement, Art. 5(5).
101 Herwig, *supra* note 14, at 320–1.

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produces normatively acceptable results in the light of the uncertainty that remains when frames of risk are used. It has been submitted that specific and conclusive risk assessment constitutes no bright line at which scientific knowledge becomes consolidated until definitely disproved.

With a dialectical understanding of risk, the legal review of risk regulation becomes messier, since there is no longer a single standard applicable to all types of hazard with which to judge whether regulatory intervention is justified or not. Instead, the judicial review of decisions about hazards needs to take into account the non-scientific qualities of hazards that can be anticipated on the basis of reasonable scientific evidence when determining whether there is a sufficient scientific basis *for regulatory purposes*.

It might be asked whether this reduction in legal certainty in an already fairly indeterminate body of law like WTO law will not then lead to a loss of the law's authority. To be sure, WTO law will become more difficult to use for members seeking market access for their products, as they will also be required to engage with the importing countries' normative and ethical reasons for regulating products.

The reverse might also be true, however. The legitimacy and epistemic appropriateness of judicial review of national risk regulations under the SPS Agreement is not merely an academic issue of little importance to the real world. There is evidence that private firms already cater to market demands for GM-free products and require crop segregation throughout the production chain or impose private food safety standards.[102] If WTO law is perceived as controlling risk regulation and consumer perceptions in an illegitimate manner, there is an even greater danger of the proliferation of private barriers, which would escape scrutiny under WTO law entirely.

102 Discussed in M. Pollack and G. Shaffer, 'The Challenge of Reconciling Regulatory Differences: Food Safety and GMOs in the Transatlantic Relationship', in M. Pollack and G. Shaffer (eds.), *Transatlantic Governance in the Global Economy* (2001), 153, at 168.

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