I. INTRODUCTION

On 29 September 2006, a World Trade Organization (WTO) Dispute Resolution Panel released its decision in the long-standing dispute between the United States and Europe over the regulation of genetically modified (GM or, ‘biotech’) food and seed. The Panel found that, because the European Community (EC) and several EU Member States had acted primarily out of non-scientific concerns to justify their trade-restrictive food safety measures, they clearly violated the tightly drafted provisions of the WTO Sanitary and Phytosanitary (SPS) Agreement. This decision is significant because it clarifies the central role of science in evaluating the presence of health and environmental risks prior to the adoption of national food safety regulations not otherwise based on relevant international standards.

The EU Commission had, from 1998 to 2004, refused to approve outright, and/or unduly delayed approval of, various new biotech crop varieties for cultivation or consumption on health and environmental ‘safety’ grounds. This occurred despite the fact that EU Commission scientists had already cleared 25 of the 28 products applied for as being ‘safe’ enough for approval. Six individual EU countries (Denmark (later replaced by Austria), France, Germany, Greece, Italy, and Luxembourg) had also imposed their own blanket bans on biotech crops and biotech-derived foods, without scientifically demonstrating that they were ‘unsafe’ on health or environmental grounds. After approximately five years, the frustrated governments of Argentina, Canada and the United States finally sought legal recourse at the WTO during May 2003. Their complaints alleged that these bans constituted an unjustified and illegal denial of access to European markets under WTO SPS law, and that such bans had unnecessarily caused their seed producers and users (farmer-exporters) to incur hundreds of millions of dollars of economic losses each year that such bans continued.

Significantly, the complainants did not challenge the EC’s or EU Member States’ right under WTO law to undertake a rigorous regulatory review of such products. In addition, the WTO Panel did not itself attempt to evaluate the safety of the individual biotech products in question. Nor did the Panel review the stringency of the biotech product measures per se. Rather, the Panel focused on the type of evidence that a WTO member government is permitted to rely on as justification for the imposition of national/regional health and environmental regulatory restrictions that have a substantial impact on international trade flows.

II. THE FUNDAMENTAL REQUIREMENT OF AN ‘Adequate’ Science-based Risk Assessment – SPS Article 5.1 and Annex A(4)

In its decision European Communities – Measures Affecting the Approval and Marketing of Biotech Products (hereinafter EC – Biotech Products), the Panel reaffirmed that WTO member countries concerned about the safety of specific biotech food-related imports must follow the specific terms of the WTO SPS Agreement. Pursuant to the SPS Agreement, countries may restrict imports of certain products in...
order to safeguard human or animal health, or to protect the environment, provided the regulations they enact either are in accordance with existing relevant international standards, or are narrowly drafted in order to protect against a genuine ascertainable risk, as determined by the application of best available science.

This most recent WTO Panel decision makes clear that, in the absence of relevant international standards, or where a concerned national government refuses to adopt them, a WTO member bears the burden of conducting an objective empirically based scientific risk assessment of identified or ascertainable potential health or environmental risks posed by specific products. And this must be done before a WTO member promulgates regulations that have the effect of denying or restricting market access to those products. Although there is an additional requirement, that proposed or adopted regulations qualifying as SPS measures may be only as restrictive as necessary to eliminate or mitigate the demonstrated risk, the Panel did not reach this issue. The Panel instead looked to whether the EC and the several EU Member States had fulfilled their threshold task: to undertake an ‘adequate risk assessment’. In this regard, the Panel found that, while the EC and several EU Member States had endeavoured to conduct a risk assessment, that which they did perform failed to qualify as an adequate assessment of the risks within the meaning of SPS Article 5.1 and Annex A(4).

The WTO Panel reasoned that the EC and EU Member States could not rely on either non-expert civil society (non-governmental organization – NGO) reports or general scientific studies appearing in peer-reviewed journals that did not otherwise provide an assessment of specific context-based health or environmental risks pursuant to specifically defined scientific protocols. Indeed, in the Panel’s view, these sources did not constitute ‘adequate’ risk assessment’ because, prima facie, they did not look to or take ‘into account risk assessment techniques [protocols] developed by the relevant international organizations’. These organizations and their protocols include the International Standards for Phytosanitary Measures (ISPMs) prepared by the International Plant Protection Convention (IPPC) Secretariat, which focuses on the prevention and spread of plant and plant product pests; and the animal health standards prepared by the Office International des Epizootics (International Epizootic Office – OIE), which focuses on animal health issues and their relationship to human food safety.

The Panel then proceeded to explain in more detail how the EC and EU Member States had failed to undertake an ‘adequate risk assessment’ of their own. While doing so, it also clearly distinguished between the environmental and health concerns of scientists, which are typically substantiated through application of scientific method, and those of legislators, which are often based on unverifiable facts, public fears and a need to politically address them. In the Panel’s view, legislators’ concerns are relevant primarily for managing potential product risks whose degree of ‘safety’ scientists have already assessed in gauging how to arrive at the ‘appropriate level of regulatory protection’ (i.e., fulfilling the legislators’ protection goals). Legislators’ concerns may even ‘have a bearing on the question of which risks a Member decides to assess with a view to taking regulatory action, if necessary’ on safety grounds. Scientists’ concerns, on the other hand, are relevant for identifying and evaluating (i.e., assessing), in the first instance, the existence and magnitude (severity) of potential health and/or environmental safety risks posed by a specific product. In effect, the Panel rejected the EC’s and EU Member States’ argument, and focused on how neither the language of the SPS Agreement, nor relevant WTO jurisprudence ‘suggest[s] that a risk assessment had to be adequate for the purposes of a Member’s legislator’ (emphasis added).

According to the Panel, there is ‘only one relevant relationship: that between the scientific evidence and the obligation to perform a risk assessment under Article 5.1’: [T]he definition of the term “risk assessment” in Annex A(4) does not indicate that a Member’s appropriate level of protection is pertinent to an assessment of the existence and magnitude of risks . . . Also, Annex A(5) to the SPS Agreement states that the concept of the appropriate level of protection is referred to by some Members as the concept of the ‘acceptable level of risk’. We do not think that scientists need to know a Member’s

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4 Ibid., para. 7.3238, p. 1013.
6 Ibid., para. 7.3234, p. 1012.
‘acceptable level of risk’ in order to assess objectively the existence and magnitude of a risk.7,8 (emphasis added)

Consequently, the WTO Panel, by raising this issue, once again reaffirmed that a science-based risk assessment and a politics-based risk management decision are indeed two distinct but related disciplines involving different experts and considerations.9 It also clarified that only science-based risk assessments are relevant for purposes of determining whether a WTO member has satisfied SPS Article 5.1 and Annex (A)(4).

### III. THE UNAVAILABILITY OF SPS ARTICLE 5.7 SAFEGUARD (PRECAUTIONARY) MEASURES

The EC – Biotech Products decision is significant for a variety of reasons, but perhaps none more than its discussion of the Precautionary Principle’s legal status within the confines of WTO law. The broad Precautionary Principle (as opposed to a more limited, provisional and facts-oriented Precautionary Approach) is a general European ‘better-safe-than-sorry’ philosophy of regulation that has assumed the status of regional law within the EC. Although the EC and EU Member States argued in this case that it has also become a general principle of international environmental law, the Panel refused to adjudicate its legal status beyond the WTO regime.

The EC has effectively-based regulations on the Precautionary Principle to ban or severely restrict the market access of substances, products and activities if they are merely believed to pose uncertain future hypothetical health and environmental hazards, as opposed to specific risks. The EC has repeatedly argued that a lack of scientific uncertainty as to cause and effect, magnitude or severity is not an excuse to avoid employing precautionary measures, and that the conventional science-based risk assessments required by SPS Article 5.1 are not enough, and must be bypassed, to prevent such hazards from materializing in the first place. The Appellate Body previously acknowledged that SPS Article 5.7 reflects a Precautionary Approach as opposed to the Precautionary Principle.10

The WTO Panel, in EC – Biotech Products, found that the EU and the several EU Member States were ineligible to invoke the limited and provisional safeguard measures (a Precautionary Approach) afforded by SPS Article 5.7. Apparently, these parties had claimed that SPS Article 5.7 entitled them to employ the broader Precautionary Principle because of the ‘scientific uncertainty’ surrounding the health and environmental risks about which their legislators were concerned. In effect, the EC and the several EU Member States had argued that, the SPS Article 5.1 requirement that an adequate science-based risk assessment be performed was not a prerequisite to employing a Precautionary Approach under Article 5.7. In addition, they argued that, ‘scientific uncertainty’ had rendered them unable to conduct an adequate science-based risk assessment, as required by SPS Article 5.1. They also argued that, in any event, the concepts of ‘scientific uncertainty’ (relating to the Precautionary Principle) and ‘insufficient scientific evidence’ (relating to a Precautionary Approach) as defined by SPS Article 5.7 were interchangeable as a matter of WTO law, thereby rendering the requirement of a science-based risk assessment inapposite.

The Panel rejected each of these claims, relying on the clear language of Article 5.7. According to the Panel, a WTO member must satisfy all four of Article 5.7’s cumulative requirements in order to invoke its provisions. ‘Whenever one of these four requirements is not met, the measure at issue is inconsistent with SPS Article 5.7.’11

Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure if this measure is: (1) imposed in respect of a situation where ‘relevant scientific information is insufficient’; and (2) adopted ‘on the basis of available pertinent information’. Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure: (1) ‘seek[s] to obtain the additional information necessary for a more objective assessment of risk’; and (2) ‘review[s] the . . . measure accordingly within a reasonable period of time’.12 (emphasis added)

### Notes

7 Ibid., para. 7.3243, p. 1015, and fn. 2067.
8 Ibid., para. 7.3242, p. 1015; para. 7.3238, as note 4 above.
10 EC – Biotech Products decision, para. 7.87, pp. 338–339.
11 Ibid., para. 7.3218, p. 1018.
12 Ibid., citing the Appellate Body in Japan – Agricultural Products II.
The Panel’s decision then proceeded to set forth the following factual and legal bases explaining why Article 5.7 was unavailable to the EC and the several EU Member States.

IV. INSUFFICIENT SCIENTIFIC EVIDENCE DOES NOT EXCUSE THE REQUIREMENT TO CONDUCT A RISK ASSESSMENT

First, the Panel determined, as a matter of law, that the ‘insufficient scientific evidence’ language of Article 5.7 does not permit WTO Member States to bypass the SPS Article 5.1 requirement to conduct an adequate science-based risk assessment. It based its determination on the previous Appellate Body ruling in the Japan – Varietals case.

‘[R]elevant 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.13 (emphasis in original)

In effect, the Panel embraced the proposition that, ‘if a measure is not based on a “risk assessment”, it can be presumed not to be based either on “scientific principles”, within the meaning of SPS Article 2.2,14 or to be maintained without “sufficient scientific evidence”’, as required by SPS Article 5.1.15

A. The EC and EU Member States Actually Possessed Sufficient Scientific Evidence to Conduct a Risk Assessment

Second, the Panel found, as a matter of fact, that the EC and EU Member States had failed to show that there was ‘insufficient scientific evidence’ to conduct a science-based risk assessment on each product, with respect to each risk in question. Indeed, much to the contrary, the WTO Panel determined that the EC’s relevant scientific committees had reviewed and evaluated the human health and environmental risk information provided by both the Community and the various EU Member States. In fact, the relevant EC scientific committees had not even considered whether any EU Member State information called into question their previous conclusions. Consequently, the Panel ruled, as a matter of law, that there existed ‘sufficient scientific evidence’ from which the EU could have conducted a risk assessment.16,17

B. ‘Scientific Uncertainty’ and ‘Insufficient Scientific Evidence’ Are Not the Same

Third, the WTO Panel specifically rejected, as a matter of law, the EC’s and EU Member States’ argument that the extra-WTO Precautionary Principle permitted them to ignore their own scientific risk assessments because of the existence of ‘scientific uncertainty’. Apparently, politicians within the EU Council of Ministers were dissatisfied with the outcomes of those assessments, and had tried to justify their biotech product approval delays by claiming that the scientific committee’s risk assessments left too much ambiguity and too many unanswered questions. The WTO Panel did not ‘buy into’ such post hoc rationalizations. It ruled that a risk assessment otherwise satisfying the conditions imposed by SPS Article 5.1 and Annex A4 would not cease being a credible risk assessment, merely because WTO member legislators lacked absolute confidence in it, due to the absence of an unequivocal and/or comprehensive body of relevant scientific evidence.18 Furthermore, it stated that, to the extent that a WTO member harbours any scientific uncertainties or political discomfort with its risk assessment findings, that member should consider those factors when determining how to manage the health and environmental risk(s) about which it is concerned.19

Implicit within this decision, is the Panel’s pragmatic acknowledgement that some measure of scientific uncertainty is an ever-present phenomenon, as no amount of evidence can ever prove the absence of risk – one cannot prove a negative. The WTO Panel

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14 See SPS Article 2.2.
19 Ibid.
thus left open the possibility that what is considered ‘sufficient scientific evidence’ today may be considered ‘insufficient scientific evidence’ tomorrow, and thereby ‘preserve[d] the freedom of [WTO] Members to take prompt protective action in the event that new or additional scientific evidence becomes available which affects their risk assessments’.20

However, the kind of broad scientific uncertainty relied upon by the EC and EU Member States is not the same thing as having too little (‘insufficient’) scientific evidence to make a regulatory decision – that is, they are not interchangeable legal concepts. In this regard, the Panel distinguished, as a matter of law, between the narrowly defined standard of ‘insufficient scientific evidence’ referenced in SPS Articles 5.1 and 5.7 (indicating a Precautionary Approach), and the broader Precautionary Principle-based notion of ‘scientific uncertainty’, which the EC and the EU Member States endeavoured to have read into SPS Article 5.7.21

The Panel supported this distinction by referencing the Appellate Body’s conclusion in the prior EC – Hormones case.22 In EC – Hormones, the Appellate Body ruled that, although Article 5.7 may reflect a Precautionary Approach, ‘the [P]recautionary [P]rinciple, as such, was not written into the SPS Agreement as a ground for justifying an SPS measure that is otherwise inconsistent with the Agreement’ (emphasis added).23

V. THE IRRELEVANCE AND INAPPLICABILITY OF THE PRECAUTIONARY PRINCIPLE TO WTO LAW

A. Passing on the Status of the Precautionary Principle as a Matter of Customary International Law

Moreover, the Panel refused to embroil itself in the continuing international debate over the legal status of the Precautionary Principle. That debate has persisted since at least January 1998, when EC – Hormones was decided. Advocates have argued that the Precautionary Principle has evolved into a general principle of customary international law, while others have expressed scepticism that it has evolved into anything more than domestic, and perhaps, international environmental law.24 As the EC – Biotech Products decision noted, ‘there has, to date, been no authoritative decision by an international court or tribunal which recognizes the [P]recautionary [P]rinciple as a principle of general or customary international law’.

The Panel also noted that there was not even a single, definitive formulation of the principle.25 After finding that the principle’s legal status outside the boundaries of international trade law was irrelevant to the case at hand, the Panel passed on offering its own opinion on this matter.26

B. Inferred UN Treaty ‘Precaution’ Norms Do Not Govern Interpretation of WTO Law for Non-UN Biosafety Protocol Treaty Parties

Lastly, the WTO Panel, in EC – Biotech Products, rejected the EC’s and EU Member States’ efforts to invoke the Precautionary Principle as an applicable non-WTO treaty norm that could serve as a viable defense of its regulatory system. The EC had alleged, for example, that the Precautionary Principle plays a central role within the 2000 Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity (commonly known as the Biosafety Protocol), even though language referring to a ‘Precautionary Approach’ rather than the ‘Precautionary Principle’ appears within the text of the Protocol.27

Consequently, according to the EC, the Panel should have interpreted and taken into account those Convention and Protocol provisions as requiring the application of the Precautionary Principle in the face of scientific uncertainty surrounding the safety of imported biotech products.28 The WTO Panel, however, relying on a sensible interpretation of Article 31(3)(c) of the Vienna Convention,29 refused to take into account and bind the US to either the Convention or the Biosafety Protocol, which it had not signed.30 It then

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23 EC – Biotech Products decision, para. 7.3220, pp. 1008–1009.
28 Ibid., para. 7.55.
determined that the Biosafety Protocol was also inapplicable to nonparties Argentina and Canada.\textsuperscript{33} The Panel, therefore, concluded that neither multilateral treaty was ‘applicable in the relations between all parties to the treaties (i.e., the relevant WTO agreements) which were being interpreted’.

\textbf{VI. The Last Word}

Given the 2005 speech made by EU Enterprise and Industry Commissioner Gunter Verheugen, before EuropaBio, the European association for bio-industries, it would appear that some EU Commission officials believe that the successful promotion of biotechnology depends on the regulatory debate remaining ‘science-based’.\textsuperscript{32} However, neither Commissioner Verheugen, the WTO, nor the plaintiffs in EC – Biotech Products are likely to have the last word. At least one NGO, the Institute for Agriculture and Trade Policy (IATP), has already alleged that the Panel’s final decision, which the EC wisely elected not to appeal,\textsuperscript{33} had been substantively revised from its earlier interim (February 2005) decision, as the result of strong political pressure applied by the United States, Canada and Argentina. And, in an effort to confuse policymakers, the IATP has claimed that these changes will expose ‘the precautionary approach to regulation’ (what they really mean to say, is the Precautionary Principle) to an indefinite ‘threat of further litigation’\textsuperscript{34}. Considering certain EU Member States’ maintenance of nation-wide biotech bans and support for other Member State bans in defiance of the WTO ruling,\textsuperscript{35} and the growing trade distortions that the EU’s new regulatory regime for food biotech products has triggered, both within and outside the European region, this is far from a remote possibility.

Anticipating the WTO Panel’s decision and the continuing uncertainty over the relationship between the Precautionary Principle and WTO law,\textsuperscript{36} Precautionary Principle supporters, including both activist groups and governments, have enlisted the assistance of the United Nations University Institute of Advanced Studies. Their goal is plainly and simply to incorporate the broad-based Precautionary Principle within WTO jurisprudence. The UNU-IAS, for example, has undertaken a series of studies, the first of which was released during November 2005, ‘to explore the role of precaution in the WTO Agreements … [in an effort] … to shed light on proposals to enhance the incorporation of this principle in the rules of the multilateral trading system and to diminish tensions in this regard between the WTO and MEAs.’\textsuperscript{37} In particular, these reports seek to define precisely under what circumstances the extra-WTO Precautionary Principle would constitute disguised trade protectionism, and which party bears the scientific burden of proof when there is a disagreement about a product’s safety, within the WTO regime. In other words, they aim to develop a common international definition of the

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31 Ibid., para. 7.75, p. 336.

According to A.H. Zakri, Director of the UNU-IAS, “[T]he [first of these] report[s] warns that disputes over biotechnology products, founded in part on cultural differences, are creating a ‘trans-Atlantic divide.’ It highlights similarities and differences between agreements and organizations with respect to precaution – and the consequences of those differences . . . ‘How a society chooses to manage the risks of biotechnology will be affected by such factors as confidence in the regulators, acceptance of new technologies, the need for the new benefits and general levels of awareness,’ says Dr. Zakri (emphasis added).\footnote{Ibid.}

Based on these remarks, however, it is more likely than not, that such calls to avoid the international acrimony and debate triggered by Precautionary Principle sceptics alleging disguised protectionism are themselves actually intended as a disguised effort to weave divisive cultural differences (preferences) into the WTO Agreements.
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