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## STANDARD OF REVIEW UNDER THE SPS AGREEMENT AFTER *EC- HORMONES II*

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International and Comparative Law Quarterly / Volume 59 / Issue 02 / April 2010, pp 441 - 459  
DOI: 10.1017/S0020589310000072, Published online: 14 May 2010

Link to this article: [http://journals.cambridge.org/abstract\\_S0020589310000072](http://journals.cambridge.org/abstract_S0020589310000072)

### How to cite this article:

Michael M Du (2010). STANDARD OF REVIEW UNDER THE SPS AGREEMENT AFTER *EC- HORMONES II*. International and Comparative Law Quarterly, 59, pp 441-459 doi:10.1017/S0020589310000072

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# STANDARD OF REVIEW UNDER THE SPS AGREEMENT AFTER *EC- HORMONES II*

## I. INTRODUCTION

A recurring and delicate issue in the GATT/WTO dispute settlement processes is whether, and to what extent, WTO panels and the Appellate Body (AB) should defer to national government decisions.<sup>1</sup> If we agree that WTO panels should respect national government determinations up to some point, that point is the crucial issue that has sometimes been labeled the 'standard of review'.<sup>2</sup> In other words, standard of review in the WTO dispute settlement describes the nature and intensity of panels' scrutiny of the legal validity of a WTO Member's domestic regulatory decisions.<sup>3</sup> It marks the boundary of a Member State's discretion, and determines the power of WTO panels to investigate, evaluate and judge the acts of a Member State against its legal obligations.<sup>4</sup> While fundamentally a legal question, the issue of the standard of review encompasses broader political consequences in the WTO and relates to the allocation of power between Member States and the WTO. When the AB addressed standard of review for the first time in *EC-Hormones I* ten years ago, it cautioned that the applicable standard of review must reflect the 'balance established . . . between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves'.<sup>5</sup>

Since the WTO Agreements entered into force in 1995, one of the most heated debates surrounding WTO panels and the AB is whether they have exceeded their judicial power and inappropriately engaged in 'judicial activism'.<sup>6</sup> Most criticisms in this regard center on the WTO panels' and the AB's interpretation of the Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter the SPS Agreement).<sup>7</sup> WTO panels and the AB have been repeatedly charged with preventing WTO Members from offering to their citizens a desirable level of protection against unwanted harm.<sup>8</sup> The scientific evidence requirements, one of the core obligations

<sup>1</sup> M Oesch, *Standards of Review in WTO Dispute Resolution* (Oxford University Press, Oxford, 2003); J Durling, 'Deference, But Only When Due: WTO Review of Anti-Dumping Measures' (2003) 6 JIEL 125.

<sup>2</sup> SP Croley and JH Jackson, 'WTO Dispute Procedures, Standard of Review, and Deference to National Governments' (1996) 90 AJIL 194.

<sup>3</sup> C-D Ehlermann and N Lockhart, 'Standard of Review in WTO Law' (2004) 7 JIEL 493.

<sup>4</sup> DZ Cass, 'The "Constitutionalization" of International Trade Law: Judicial Norm-Generation as the Engine of Constitutional Development in International Trade' (2001) 12 EJIL 58.

<sup>5</sup> WTO *European Communities—Measures Concerning Meat and Meat Products (EC-Hormones I)*, Appellate Body Report (13 February 1998) WT/DS26/AB/R para 115.

<sup>6</sup> Eg, R Howse, 'The Most Dangerous Branch? WTO Appellate Body Jurisprudence on the Nature and Limits of the Judicial Power' in Thomas Cottier and PC Mavroidis (eds), *The Role of the Judge in International Trade Regulation* (The University of Michigan Press, Ann Arbor, 2003) 11–36.

<sup>7</sup> T Epps, *International Trade and Health Protection* (Edward Elgar Publishing, Cheltenham, 2008); J Bohanes, 'Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle' (2002) 40 Columbia Journal of Transnational Law 323, 325–389.

<sup>8</sup> JM Wagner, 'The WTO's Interpretation of SPS Agreement has Undermined Right of Governments to Establish Appropriate Level of Protection against Risk' (2000) 31 Law & Policy

under the SPS Agreement, are criticized as being so stringent that the promise of protecting regulatory sovereignty of WTO Members, at least with regard to risk tolerance, is in no small part illusory.<sup>9</sup> To solve the perceived problems, it has been suggested that a more deferential, less intrusive standard of review should be applied by WTO panels, especially in the SPS disputes where science plays a central role in deciding the legality of SPS measures.<sup>10</sup>

This essay intends to contribute to this discussion in the light of recent landmark *EC-Hormones II* case.<sup>11</sup> This case follows on from the notorious *EC-Hormones I* case in the 1990s and represents the second round clash between the United States and the European Community (EC) over safety of meat injected with artificial growth hormones to human health. Part II offers a critique of the status quo of standard of review in WTO dispute settlement processes in general, and its application in SPS disputes in particular. I argue, first, that ‘objective assessment’, as a nominal standard of review in GATT/WTO, does not provide any useful guidance as to what standard of review WTO panels should apply in reviewing disputed trade measures; second, that the AB has been persistently reluctant to intervene in WTO panels’ appreciation of facts even if it possesses adequate legal means to do so; and finally, the standard of review applied in the SPS disputes before *EC-Hormones II* was close to a standard of *de novo* review. Part III introduces the recent *EC-Hormones II* case and focuses on analyzing the standard of review articulated in the AB report. I propose that the AB in *EC-Hormones II* has reversed its previous position and endorsed a more deferential, procedurally-focused standard of review. This shift of position is likely to have profound impact on the outcome of future SPS disputes. Part IV concludes.

## II. STANDARD OF REVIEW BEFORE *EC-HORMONES II*: A CRITIQUE

### A. The Enigmatic ‘Objective Assessment’

Other than the Anti-dumping Agreement, nowhere in the WTO Agreements do drafters of this impressive international economic constitution specify the standard of review that WTO panels should apply in reviewing the legality of disputed national measures. In *EC-Hormones I*, the AB for the first time concluded that article 11 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU) ‘articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels reviewing the assessment of facts under the SPS Agreement’.<sup>12</sup> Article 11 of the DSU requires WTO panels to make an ‘objective assessment of the

in International Business 855, 855–859; T Christoforou, ‘Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty’ (2000) 8 NYU Env’t. L. J. 622, 622–623.

<sup>9</sup> AO Sykes, ‘Domestic Regulation, Sovereignty, and scientific Evidence Requirements: A Pessimistic View’ in George A Bermann and PC Mavroidis (eds), *Trade and Human Health and Safety* (Cambridge University Press, Cambridge, 2006) 257, 261.

<sup>10</sup> A Guzman, ‘Food Fears: Health and Safety at the WTO’ (2004) 45 Virginia Journal of International Law 1, 17–18; C Button, *The Power to Protect: Trade, Health and Uncertainty in the WTO* (Hart Publishing, Oxford, 2004) 212–225.

<sup>11</sup> WTO *United States—Continued Suspension of Obligations in the EC-Hormones Dispute* (*EC-Hormones II*) Appellate Body Report (14 November 2008) WT/DS320/AB/R.

<sup>12</sup> *EC-Hormones I* (n 5) paras 115 and 116.

matter before it, including an objective assessment of the facts of the case and the applicability of conformity with the relevant covered agreements. . .’.

There is no clear guidance as to what constitutes an ‘objective assessment’ in article 11 of the DSU. According to the AB, so far as fact-finding is concerned, the ‘objective assessment’ standard is neither *de novo* review nor *deference*. The *de novo* standard of review would allow a panel complete freedom to come to a different view than the competent authority of the Member whose act or determination is being reviewed. A panel would have to verify whether the determination by the national authority was ‘correct’ both factually and procedurally.<sup>13</sup> The *de novo* review is inappropriate as panels are ‘poorly suited to engage in a *de novo* review’.<sup>14</sup> The *deference* standard, on the other hand, would not allow a panel to redo the investigation conducted by the national authority but instead examine whether the *procedure* required by the relevant WTO rules had been followed.<sup>15</sup> The *deference* standard was rejected by the AB on the basis that deference to the findings of the national authorities could not ensure an objective assessment of the matter before the panel.<sup>16</sup> As to questions of law, ‘objective assessment’ means that panel has to interpret the WTO Agreements in accordance with customary rules of interpretation of public international law, i.e., articles 31 and 32 of the Vienna Convention on the Law of Treaties (VCLT).<sup>17</sup>

The catch-all phrase ‘objective assessment’ that would apply to all disputes is singularly unhelpful. It is couched in rather broad terms that do very little to provide substantive guidance on the nature and intensity of the scrutiny that panels should apply in reviewing national measures.<sup>18</sup> For example, should the WTO panel review the cases involving a non-discriminatory measure aiming at protecting human health and safety with the same strict scrutiny as a clearly discriminatory measure? To what extent should a margin of error be excused on the part of WTO Members? When should WTO panels respect a national authority’s own risk assessment, if that risk assessment differs from panel-appointed experts’ evaluation? What, exactly, are the differences between ‘objectiveness assessment’ and the more familiar terms such as ‘*de novo*’ review or the ‘reasonable’ standard? The enigmatic ‘objective assessment’ does not provide useful answers to these questions. As a result, despite the apparent generality of article 11 as a universal standard of review to both questions of facts and questions of law across WTO Agreements (other than the Anti-dumping Agreement), the nature and intensity of WTO panels’ scrutiny on national measures remains unclear.

In *EC-Hormones I*, the EC submitted that, as to factual findings, the ‘deferential reasonableness standard’ embodied in article 17.6(i) of the Anti-dumping Agreement is applicable to ‘all highly complex factual situations, including the assessment of the risks to human health arising from toxins and contaminants’.<sup>19</sup> Article 17.6(i) of the Anti-dumping Agreement provides:

[I]n its assessment of the facts of the matter, the panel shall determine whether the authorities’ establishment of the facts was proper and whether their evaluation of those facts was unbiased and objective. If the establishment of the facts was proper and the evaluation

<sup>13</sup> *ibid* para 111.

<sup>15</sup> *ibid* para 111.

<sup>17</sup> Ehlermann and Lockhart (n 3) 497.

<sup>19</sup> *EC-Hormones I* (n 5) para 113.

<sup>14</sup> *ibid* para 117.

<sup>16</sup> *ibid* para 117.

<sup>18</sup> *ibid* 495; Button (n 10) 171.

was unbiased and objective, even though the panel might have reached a different conclusion, the evaluation shall not be overturned...<sup>20</sup>

Apparently, article 17.6(i) establishes a rather deferential standard of review of factual conclusions.<sup>21</sup> The AB has confirmed the deferential tone of the article by making it clear that the overarching purpose of this provision is to avoid having panels second-guessing the determinations of the national authorities when the facts have been properly established and subjected to an unbiased and objective evaluation.<sup>22</sup> In practice, this provision results in fairly deferential review; panels do not overturn simply because they think it would have been preferable for the authorities to have come to a different conclusion. Rather, it is only where things are obviously amiss that the panel will intervene.<sup>23</sup> The reason for a deferential standard of review with regard to questions of facts is usually explained from a capacity point of view, i.e., which party is better equipped to make factual determinations. It is generally argued that disputing parties who have made decisions facing a GATT/WTO challenge almost surely have vastly more factual information than reviewing panels do; because panels themselves lack many fact-gathering resources, they are ill-positioned to second-guess a party's factual determinations.<sup>24</sup>

In *EC-Hormone I*, the AB has explicitly rejected the EC's argument that a different standard of review other than article 11 of the DSU should apply to disputes involving human health and safety under the SPS Agreement. Instead, the AB ruled that article 17.6(i) is specific to the Anti-dumping Agreement only and textually, there is no indication in the SPS Agreement of intent to adopt or incorporate such a deferential standard.<sup>25</sup>

The AB is certainly correct in pointing out that the 'deferential reasonableness standard' is not mentioned in the SPS Agreement. However, it is an outright misunderstanding that 'objective assessment' in article 11 *a priori* excludes the possibility of certain deference to national decisions. It is totally reasonable to argue that the deferential reasonableness standard is a subset of 'objective assessment'. By no means does 'objective assessment' connote that WTO panels should review the facts and the legal characterization of facts with the same level of intensity across different Agreements and different provisions. Indeed, in *US-Hot-Rolled Steel*, the AB has said that 'it is inconceivable that article 17.6(i) should require anything other than that panels make an objective assessment of facts of the matter'.<sup>26</sup> The AB here has clearly agreed that an obvious deferential standard of review in the Anti-dumping Agreement can be categorized as 'objective assessment'. I would take this conclusion one step further and argue that any reasonable standard of review, be it highly deferential, marginally deferential or highly intrusive, can meet the 'objective assessment'

<sup>20</sup> Art 17.6 (i) of the Anti-dumping Agreement.

<sup>21</sup> Croley and Jackson (n 2) 208.

<sup>22</sup> *WTO Thailand-Anti-Dumping Duties on Angles, Shapes and Sections of Iron or Non-Alloy Steel and H-Beams from Poland* (5 April 2001) WT/DS122/AB/R para 117.

<sup>23</sup> *WTO US-Anti-Dumping Measures on Hot-Rolled Steel Products from Japan (US-Hot-Rolled Steel)*, Panel Report (23 August 2001) WT/DS184/R para 7.235. Button (n 10) 184–185. But see MG Bloche, 'WTO Deference to National Health Policy: Toward an Interpretative Principle' (2002) 5 JIEL 825, 831–832.

<sup>24</sup> Croley and Jackson (n 2) 208; Guzman (n 10) 23.

<sup>25</sup> *EC-Hormones I* (n 5) para 114.

<sup>26</sup> *WTO US-Hot-Rolled Steel* (23 August 2001) WT/DS184/AB/R para 55.

criterion, as long as the circumstances and the context of the underlying obligations contained in the WTO Agreements justify such a standard. The issue is therefore not whether WTO Agreements have explicitly allowed a deferential standard of review in their texts, but whether WTO panels and the AB are willing to grant any deference to national authorities in making factual determinations. As the standard of 'objective assessment' is not really operative, a more detailed, functional standard of review should be developed in the WTO dispute settlement system.

### *B. Panels' Wide Discretion in Appreciation of Facts*

WTO panels possess wide discretion with regard to questions of fact. Under article 17.6 of the DSU, appellate review is limited to 'issues of law covered in the panel report and legal interpretations developed by the panel'. The AB has interpreted this provision to mean that, '[f]indings of fact, as distinguished from legal interpretations or legal conclusions, by a panel are, in principle, not subject to review by the Appellate Body.'<sup>27</sup> In practice, the AB has consistently refused to reverse a panel finding where an appellant alleged disagreement with a panel's factual findings.<sup>28</sup> This discretion afforded to WTO panels covers not only the establishment of facts, but also the evaluation of facts. The AB has stated:

[T]he determination of whether or not a certain event did occur in time and space is typically a question of fact. ... The determination of the credibility and weight properly ascribed to a given piece of evidence is part and parcel of the fact-finding process and is, in principle, left to the discretion of a panel as the trier of facts.<sup>29</sup>

In *EC-Asbestos*, the AB reiterated that the panel enjoys 'a margin of appreciation in assessing the value of the evidence, and the weight to be ascribed to that evidence.'<sup>30</sup>

Even if there is a clear division of labour between panels and the AB with regard to questions of fact or questions of law, the AB still possesses adequate legal power to determine the outcome of a case if it disagrees with panels as to their factual findings, without violating article 17.6 of the DSU. To begin with, the demarcation between questions of fact and questions of law is not always clearly drawn.<sup>31</sup> A single issue will often involve both legal and factual questions, and an issue that is factual in one context may be 'legal' in another.<sup>32</sup> As a result, frequently the panel is engaging simultaneously in an assessment of the facts and an interpretation of the WTO rules.<sup>33</sup> Moreover, even if some findings are categorized as facts and thus not reviewable by the AB, the AB has held that 'consistency or inconsistency of a given fact or set of facts

<sup>27</sup> *EC-Hormones I* (n 5) para 132.

<sup>28</sup> See eg, *WTO Australia-Measures Affecting Importation of Salmon*, Appellate Body Report (6 November 1998) WT/DS18/AB/R para 276.

<sup>29</sup> *EC-Hormones I* (n 5) para 132.

<sup>30</sup> *WTO European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, Appellate Body Report (5 April 2001) WT/DS135/AB/R para 161.

<sup>31</sup> R Allen ad M Pardo, 'The Myth of the Law-Fact Distinction' (2003) 97 *Northwestern University Law Review* 4, 1768; T Voon and A Yanovich, 'The Facts Aside: The Limitation of WTO Appeals to Issues of Law' (2006) 40 *Journal of World Trade* 239, 244–245.

<sup>32</sup> *ibid* 245.

<sup>33</sup> J Bohanes & N Lockhart, 'Standards of Review in WTO law' in D Bethlehem, D McRae, R Neufeld and I Van Damme (eds), *The Oxford Handbook of International Economic Law* (OUP, Oxford, 2009) 391.

with the requirements of a given treaty provision is. . . a legal characterization issue. It is a legal question.<sup>34</sup> Finally, whether panels have made an *objective assessment* of facts in accordance with article 11 of the DSU is a question of law.<sup>35</sup> The AB's legal power to check panels' evaluation of facts, directly or indirectly, is highly important in SPS disputes. Due to the inherent uncertainty of and controversies in science, scientific experts frequently give divergent and even contradictory opinions to some vitally important questions, such as whether a dreaded risk indeed exists or has potential to be introduced to a Member's territory. Scientific evidence is usually taken as facts and thus not reviewable by the AB,<sup>36</sup> however, whether WTO panels have properly evaluated these scientific facts, including scientific opinions of the experts, is a question of law and falls under the AB's review.

Even though the AB has adequate legal power to check panels' evaluation of facts (such as scientific evidence supporting/refuting potential of risk) in dispute settlement processes, in practice it has been remarkably reluctant to exercise its power. Nowhere can this point be made clearer than the AB's understanding of when the duty of 'objective assessment' is breached by WTO panels. In *EC-Hormones I*, the AB stated that 'not every error in the appreciation of evidence may be characterized as a failure to make an objective assessment'. The AB further limited the breach of this obligation on the part of the panel to 'deliberate disregard of, or refusal to consider, or willful distortion or misrepresentation of the evidence before the panel'.<sup>37</sup> According to the AB, 'disregard' and 'distortion' and 'misrepresentation' of the evidence, in their ordinary signification in judicial and quasi-judicial processes, imply not simply an error of judgment in the appreciation of evidence but rather an egregious error that calls into question the good faith of a panel.<sup>38</sup> The AB further explained in *EC-Poultry* that 'an allegation that a panel has failed to conduct the objective assessment of the matter before it required by Article 11 is a very serious allegation. Such an allegation goes to the very core of the integrity of the WTO disputes settlement process itself. . .'.<sup>39</sup>

The test established in *EC-Hormones I* by the AB is unsatisfactory. Apparently, it would be extremely challenging for a WTO Member to question the 'good faith' of the panel. Nearly all panelists are experienced and distinguished international trade experts and the rigor of their reports has won enormous respect from the international economic law community. To discuss the 'good faith' of WTO panelists is, however, beside the point. The real issue is that these panelists are likely to make mistakes in evaluating and weighing facts, such as scientific evidence. These mistakes may be a result of 'deliberate disregard' or 'willful distortion' of certain evidence, or, more likely, are made out of negligence or good faith. It is entirely plausible that a panel may misrepresent certain scientific evidence, fail to consider certain scientific evidence with no good reason, or mistakenly dismiss certain important evidence as irrelevant, while a panel may, at the same time, honestly believe that they have fairly evaluated all evidence at hand. The 'willful distortion' or 'good faith' test is difficult to establish in

<sup>34</sup> *EC-Hormones I* (n 5) para 132.

<sup>36</sup> Voon and Yanovich (n 31) 256–257.

<sup>38</sup> *ibid* para 133.

<sup>39</sup> WTO *European Communities-Measures Affecting the Importation of Certain Poultry Products*, Appellate Body Report (23 July 1998) WT/DS69/AB/R para 133.

<sup>35</sup> *ibid*.

<sup>37</sup> *EC-Hormones I* (n 5) para 133.

practice. Thus the AB seems to leave too much discretion to non-expert, non-specialized panelists to judge issues of tremendous scientific complexity in SPS disputes.

This problem has been compounded by two additional factors. The first is the highly technical nature of SPS disputes, as evidenced by the heavy reliance on scientific experts in such disputes. The highly technical and complex nature of disputes means that panels are more likely to make mistakes. The practice of appointing scientific experts to inform panels helps mitigate the problem but cannot resolve it, since it is not the experts who must make a final decision.<sup>40</sup> Secondly, the AB lacks power to remand cases to the panel whose decision has been appealed.<sup>41</sup> After the AB modifies or reverses a panel's legal finding, or concludes that the panel has failed the 'objective assessment' test, the AB frequently needs to engage in fact finding in order to rule on whether the challenged measure violates WTO law. Sometimes the AB may proceed to complete the analysis if there is a sufficient factual basis or the legal issue to be addressed is closely connected to the legal issues addressed by the panel.<sup>42</sup> More often than not, however, the AB declines to complete the panel's analysis because there are insufficient factual findings.<sup>43</sup> If the AB cannot complete the analysis, the dispute will remain unsolved.

The fact that 'objective assessment' as a criterion does not provide any real guidance to the panels and that the AB has been persistently reluctant to intervene in panels' evaluation of facts causes serious problems with systemic repercussions in the SPS disputes. I argue that, despite WTO panel and the AB claim to the contrary, with regard to questions of fact, WTO panels have actually adopted a standard of review close to *de novo* review in SPS disputes. Indeed, before *EC-Hormones II* WTO panels showed a disturbing tendency to act as if they were in the business of risk assessment, rather than in the business of assessment of risk assessment performed by the national regulators. This criticism will be fully developed in the following part.

### C. *De Novo* Review in the SPS Agreement

To discuss the appropriate standard of review in the SPS Agreement, it is worth noting that a health or quarantine risk assessment- and the identification and selection of risk management measures- is a detailed scientific process undertaken by governments over a period of time. The process of scientific inquiry entailed by a risk assessment is not one that can be meaningfully replicated by a WTO panel and its scientific advisors. These sensitivities were recognized by the panel in *Japan-Varietals*:

To determine whether or not the Japan's measures are maintained without scientific evidence, we need to refer to the opinions we received from the experts advising the panel. We recall that these expert opinions are opinions on the evidence submitted by the parties.

<sup>40</sup> Guzman (n 10) 23.

<sup>41</sup> D Palmeter, 'The WTO Appellate Body Needs Remand Authority' (1998) 32 *Journal of World Trade* 41, 43; F Pierola, 'The Question of Remand Authority for the Appellate Body' in Andrew Mitchell (ed), *Challenges and Prospects for the WTO* (Cameron & May, London, 2005) 193.

<sup>42</sup> A Yanovich and T Voon, 'Completing the Analysis in WTO Appeals: The Practice and Its Limitations' (2006) 9 *JIEL* 933, 936.

<sup>43</sup> Eg, *WTO United States—Countervailing Duty Investigation on Dynamic Random Access Memory Semiconductors (DRAMs) from Korea* (20 July 2005) WT/DS296/AB/R para 208; *EC-Hormones II* (n 11) para 735.

We are not empowered, nor are the experts advising the panel, to conduct our own risk assessment.<sup>44</sup>

Although the AB explicitly rejected the *de novo* review as a proper standard to be applied by WTO panels, I concur with several other commentators who note that it is this standard of review which panels are close to applying under the SPS Agreement.<sup>45</sup> Granted, the line between ‘objective assessment’ and a *de novo* review is a fine one. ‘Objective assessment’ allows the panel to determine the existence, quality and sufficiency of scientific evidence supporting the SPS measure in question. This would arguably entitle the panel to impose its own view on the scientific evidence.<sup>46</sup> Such a reading assumes a rather intrusive standard of review which is not significantly deferential to national authorities’ findings. In evaluating the threshold issue of whether there is a risk, for example, it is easy to substitute the risk sensibility of the adjudicator or of the expert witness for that of the administrative agency of the importing state. ‘If,’ the panel implicitly reasons, ‘it has not been proven to our satisfaction that there is sufficient scientific evidence to establish a real danger, then *ipso jure* the state measure is non SPS-compliant’.<sup>47</sup>

This danger has unfortunately been demonstrated in the WTO case law. In *Japan-Apples*, Japan contended that the panel erred in interpreting article 2.2 of the SPS Agreement because the panel failed to accord ‘a certain degree of discretion’ to the importing Member in the manner in which it chooses, weighs, and evaluates scientific evidence. Japan suggested that the panel should have evaluated the scientific evidence in the light of Japan’s approach, which reflects ‘the historical facts of trans-oceanic expansion of the bacteria’ and the rapid growth of international trade and the fact that the pathways of transmission of the bacteria are still unknown in spite of several efforts to trace them.<sup>48</sup> Remarkably, the AB flatly rejected Japan’s contention that a WTO panel is *obliged* to give precedence to the importing Member’s approach to scientific evidence and risk when analyzing and assessing scientific evidence, because such deference would not ensure an objective assessment as required by article 11 of the DSU.<sup>49</sup> Here the panel relied heavily upon the views of its scientific experts, looking to these expert views to evaluate the credibility of the scientific evidence presented by the parties and reached its own findings, including the characterization of the risk. Where the evidence advanced by the parties was in conflict, the panel relied upon its scientific experts’ assessments to resolve such conflict, and criticized the methodology and conclusions that could be drawn from the studies cited by Japan.<sup>50</sup> The AB’s stance in *Japan-Apples* explicitly allowed the panel to sidestep Japan’s approach to

<sup>44</sup> WTO *Japan—Measures Affecting Agricultural Products* (Japan-Varietals) Panel Report (27 October 1998) WT/DS76/R, para 8.32.

<sup>45</sup> Bohanes and Lockhart (n 33) 412; J Peel, ‘Risk Regulation under the WTO SPS Agreement: Science as an International Normative Yardstick?’ Jean Monnet Working Paper (02/2004) 95–97.

<sup>46</sup> N Covelli and V Hohots, ‘The Health Regulation of Biotech Foods under the WTO Agreements’ (2003) 6 JIEL 773, 783.

<sup>47</sup> DJ Neven and JHH Weiler, ‘Japan- Measures Affecting the Importation of Apples: One Bad Apple?’ in H Horn and PC Mavroidis (eds), *The WTO Case Law of 2003* (Cambridge University Press, Cambridge, 2006) 291–294.

<sup>48</sup> *Japan-Measures Affecting the Importation of Apples* (Japan-Apples), Appellate Body Report, WT/DS245/AB/R (10 December 2003) para 161.

<sup>49</sup> *ibid* 165.

<sup>50</sup> WTO *Japan-Apples*, Panel Report (15 July 2003) WT/DS245/R paras 8.123–8.127.

risk regulation and second guess the reasonable interpretation of scientific evidence from the national regulator. Accordingly, the panel's role seems to have shifted to finding out what the 'correct science' is, as opposed to whether Japan's interpretation of scientific evidence is an honest, reasonable, and coherent account, even if it differs from the opinions given by the panel's scientific experts. Instead, the panel largely focused on the scientific experts' views to reach its conclusion and nowhere do we find that the panel accorded a certain degree of discretion to Japan.

In *Japan-varietyals*, the panel did not even bother to lay out Japan's scientific basis for the varietyals requirements measure, or discuss whether the Japan's opinion is from a qualified and respected source. Instead, the panel started its analysis of article 2.2 with the sentence 'to determine whether or not the varietyals requirement is maintained without sufficient scientific evidence, we need to refer to the opinions we received from the experts advising the panel.'<sup>51</sup> Then the panel extensively discussed and analyzed the expert opinions, with little regard to Japan's risk assessment. Despite the fact that there remained some uncertainty in the scientific evidence, the panel ruled against Japan because its scientific experts stated that there was not sufficient scientific evidence in support of the measures at issue.

Let me clarify that I am not arguing that WTO panels and the AB were wrong in ruling against Japan in both cases. What I do argue, however, is that WTO panels could do better if they first lay out Japan's approach to risk assessment and examine, *in light of Japan's approach*, whether scientific evidence is sufficient to support the SPS measures at issue unless such an approach is ridiculous and unreasonable. If WTO panels are able to sidestep WTO Members' approach, together with their underlying regulatory philosophy and legitimate concerns, and go directly to scientific experts who evaluate independently the potential risk at issue, it is *de novo* review, even though it can be claimed as an 'objective assessment'.

According to Ehlermann, a renowned former WTO Appellate Body member, the reason why the standard of review in SPS disputes differs from article 17.6(i) in the Anti-dumping Agreement is that the structure of the SPS Agreement differs markedly from the Anti-dumping Agreement.<sup>52</sup> In *EC-Hormones I*, the AB explicitly rejected the existence of 'minimum procedural requirements' in the WTO Members' domestic risk regulation process.<sup>53</sup> Thus, there is no requirement for WTO Members to conduct their own risk assessment, or to publish a report explaining how SPS measures are justified in light of such a risk assessment in making regulatory decisions.<sup>54</sup> In contrast, the Anti-dumping Agreement sets out in great detail how the investigation is to be conducted by the authority, including publication and notification requirements; specific issues to be examined; a duty to seek out and examine information; and opportunities for interested parties to be heard. It also provides a series of procedural guarantees to protect the interests of parties likely to be affected by an anti-dumping measure.<sup>55</sup> As a result, the facts of the matter referred to in article 17.6(i) are 'the facts made available in conformity with appropriate domestic procedures to the authorities of the importing

<sup>51</sup> *Japan-Varietyals* (n 44) para 8. 32.

<sup>52</sup> Ehlermann and Lockhart (n 3) 517.

<sup>53</sup> *EC-Hormones I* (n 5) paras 188–191.

<sup>54</sup> *ibid* para 190. *Australia-Salmon* (n 28) para 121.

<sup>55</sup> Ehlermann and Lockhart (n 3) 506.

member.<sup>56</sup> Since there is no corresponding formal investigation stage in the SPS Agreement, there is no basis for panel deference in SPS cases.

I find this explanation unsatisfactory from a number of perspectives. It is true that, under certain circumstances, a WTO Member may have never performed any formal risk assessment. As a result, the panel may be the trier of first impression of the facts. However, what if a WTO Member voluntarily elects to adopt SPS measures on the basis of a formal risk assessment process and incorporates a range of procedural guarantees as provided in the Anti-dumping Agreement? Will the panel accord a certain degree of deference to the factual findings from such an elective process? As Ehlermann and his co-author admit, the answer is far from being clear and chances are probably that such voluntary formal procedural guarantees are not helpful at all.<sup>57</sup> Second, let's take one step back from the alleged structural differences between the SPS Agreement and the Anti-dumping Agreement: is it truly reasonable that the WTO panels should defer to a Member's factual determinations in Anti-dumping Agreement, where only economic benefits (or arguably only protectionism) are involved, while perform a *de novo* review of highly complex scientific facts relating to values of the highest order- human safety and health?

WTO panels may have decided to adopt a *de novo* standard of review in the SPS disputes simply because they prefer to follow an overly strict textual approach to interpret WTO Agreements. As a more deferential standard is explicitly included in the Anti-dumping Agreement but not mentioned in other WTO Agreements, WTO panels seem to take the absence as a justification for a more intrusive standard of review at the expense of domestic regulatory autonomy. However, this understanding is questionable. As explained above, 'objective assessment' does not spell out any exact standard of review and may include a range of subcategories of standards, each of which may be properly regarded as 'objective assessment' depending on the circumstances.

### III. STANDARD OF REVIEW IN *EC- HORMONES II*

Some of the most striking features in our discussion of standard of review in the SPS disputes are that, firstly, there is no principled way to check the panel's consideration and weighing of scientific evidence. On some occasions, the panel seems to give more weight to some evidence with no adequate explanation for why divergent opinions were not accepted. Secondly, scientific experts played a prominent role in the SPS dispute settlement processes. The panel and the AB relied heavily on their opinions and judgments to evaluate sometimes competing scientific evidence before them.<sup>58</sup> As SPS cases tend to focus on the threshold issue of whether there is a real risk to justify the SPS measures, there is the danger that panels and scientific experts will take the approach of exploring the scientific 'truth' vigorously and independently, with no or little regard to the WTO Member's risk assessment approach. Panels then compare the

<sup>56</sup> WTO *Thailand-Anti-dumping Duties on Angles, Shapes and Sections of Iron or Non-alloy Steel and H Beams from Poland*, Appellate Body Report (5 April 2001) WT/DS122/AB/R paras 114–118; Art 17.5(2) of the Anti-dumping Agreement.

<sup>57</sup> Ehlermann and Lockhart (n 3) 514.

<sup>58</sup> J Pauwelyn, 'Expert Advice in WTO Dispute Settlement' in GA Bermann and PC Mavroidis (eds), *Trade and Human Health and Safety* (Cambridge University Press, Cambridge, 2006) 251–252.

scientific conclusion they believe to be the best science with the WTO Member's alleged scientific justifications and strike down the national SPS measures.<sup>59</sup> Arguably, this is what has happened in *Japan-Apples*.

The AB report of the recent *EC-Hormones II* has provides us with more guidance on the standard of review in SPS disputes. *The EC-Hormones II* is a natural consequence of the *EC-Hormones I* case. After *EC-Hormones I*, the EC refused to bring its measures in compliance with the WTO DSB report; instead, it initiated and funded 17 scientific studies to evaluate the potential for adverse effects to human health from the use of six hormones for growth promotion purposes. These studies concluded that oestradiol-17 $\beta$  had to be considered as a complete carcinogen, as it exerts both tumour-initiating and tumour-promoting effects and that the data currently available do not make it possible to give a quantitative estimate of risk. Based on these studies, the EC adopted Directive 2003/74/EC in 2003 providing for the permanent prohibition on the importation of meat from cattle treated with oestradiol-17 $\beta$  for growth promotion purposes, as well as a provisional ban on meat treated with the other five hormones.<sup>60</sup> However, the US and Canada raised questions as to the validity of the new evidence submitted by the EC and disagreed with the EC as to the safety of meat treated with artificial hormones in light of the new evidence. This fresh disagreement led to *EC-Hormones II*, of which the AB report was adopted on 14 November 2008.

The AB in *EC-Hormones II* clarified and modified a number of important issues on standard of review in SPS disputes. These clarifications and modifications indicate that the AB is in the process of formulating a new and arguably more deferential standard of review than it previously adopted. In this part I will summarize these clarification/modifications and explain how they differ from our conventional understandings of the SPS Agreement.

#### A. Panels' Limited Mandate

Commenting on the standard of review in determining the consistency of SPS measures with article 5.1, the AB in *EC-Hormones II* observed that the panel's task is limited to review of the risk assessment performed by the WTO Member. Where a panel goes beyond this limited mandate and acts as a risk assessor, it would be substituting its own scientific judgment for that of the risk assessor and making a *de novo* review. Consequently, the panel would exceed its functions under article 11 of the DSU. In other words, the review power of a panel is not to determine whether the risk assessment undertaken by a WTO Member is correct, but to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable.<sup>61</sup> In the AB's words:

[I]t was not the panel's task, much less that of the experts that the panel consulted, to determine whether there is an appreciable risk of cancer arising from the consumption of meat from cattle treated with oestradiol-17 $\beta$ . Instead, the panel was called upon to *review the European Communities' risk assessment*.<sup>62</sup>

<sup>59</sup> *Japan-Apples*, panel report (n 50); *EC-Hormones II*, Panel Report (31 March 2008) WT/DS320/R.

<sup>60</sup> *EC-Hormones II* (n 11) para 488.

<sup>61</sup> *ibid* para 590.

<sup>62</sup> *ibid* para 614 (emphasis added).

The AB's explicit emphasis that WTO panels have only a limited mandate in reviewing SPS measures has profound implications for WTO dispute settlement proceedings. First, it directs WTO panels how to evaluate the disputed SPS measures against article 5.1 of the SPS Agreement.<sup>63</sup> According to the AB, a panel must begin with identification of the scientific basis upon which SPS measures were adopted. This scientific basis need not reflect the majority view within scientific community but may reflect divergent or minority views. Then, although the scientific basis does not need to represent mainstream views, the panel must verify that it comes from a respected and qualified source. In other words, it must have the necessary scientific and methodological rigor to be considered reputable science according to the standards of the relevant scientific community. A panel should also assess whether the reasoning articulated on the basis of the scientific evidence is objective and coherent. Finally, the panel must determine whether the results of the risk assessment 'sufficiently warrant' the SPS measure at issue.<sup>64</sup>

Second, the limited mandate of Panels also constrains the role of scientific experts in SPS disputes. Panel consultations with experts is proper only to the extent that it helps the panel to dispense with its limited mandate, i.e., identify the scientific basis of the SPS measures, verify whether the scientific basis is from a qualified source and decide whether the reasoning articulated on the basis of scientific evidence is objective and coherent. The experts may also be consulted on the relationship between the risk assessment and the SPS measure in order to assist the panel in determining whether the risk assessment sufficiently warrants the SPS measure. The AB stressed, however, that it is important to understand that the function of consultation with experts is not to perform their own risk assessment to see if they could reach the same conclusion as a risk assessor, nor whether the experts would have done a risk assessment in the same way as the national authorities.<sup>65</sup> In other words, *disputed SPS measures must be evaluated and verified in light of the WTO Member's own risk assessment and chosen level of protection.*

Based on this new approach of standard of review under article 5.1 of the SPS Agreement, the AB criticized the panel's analysis of whether the EC specifically assessed the risks arising from the consumption of meat treated with oestradiol-17 $\beta$ . The AB noted:

[A] significant portion of the Panel's reasoning consists of summaries of the responses of the experts. It is only after summarizing the experts' responses that the Panel describes some of the issues discussed in the [EC's risk assessment report]. Given the applicable standard of review and the role of the Panel that is determined by it, the Panel's analysis should have proceeded differently. . . [T]he Panel should have first looked at the EC's risk assessment. . .<sup>66</sup>

Indeed, the EC's risk assessment report revealed that the EC has articulated clear justifications on which its permanent ban was based. The studies showed that certain metabolites of oestradiol-17 $\beta$  have been found to be directly or indirectly genotoxic

<sup>63</sup> Art 5.1 provides: 'Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.'

<sup>64</sup> *EC-Hormones II* (n 11) para 598.

<sup>66</sup> *ibid* para 598.

<sup>65</sup> *ibid* para 592.

and this implies that any excess exposure to oestradiol 17- $\beta$  and its metabolites resulting from the consumption of meat and meat products presents a potential risk to public health, particularly to groups identified as particularly sensitive to exposure such as pre-pubertal children. The report also explained that a threshold cannot be established for these genotoxic metabolites.<sup>67</sup>

Following the approach outlined by the AB regarding the applicable standard of review, the panel's analysis should first identify the scientific basis for the conclusions on the genotoxicity of oestradiol 17- $\beta$ ; verify whether this scientific basis came from a qualified source; and determine whether the reasoning articulated on the basis of that scientific evidence is objective and coherent. In this context, the panel would have sought the experts' view as whether the conclusions reached by the EC can find support in the scientific evidence relied upon by the EC, even if the expert was of a different scientific view.<sup>68</sup>

After outlining the correct approach of standard of review, the AB criticized that the panel has gone beyond its limited mandate as it adopted the wrong approach to standard of review:

[T]he panel seems to have conducted a survey of the advice presented by the scientific experts and based its decisions on whether the majority of the experts, or the opinion that was most thoroughly reasoned or specific to the question at issue, agreed with the conclusion drawn in the EC's risk assessment [rather than a discussion of the evidence relied upon in the European Communities' risk assessment]. This approach is not consistent with the applicable standard of review under the SPS Agreement.<sup>69</sup>

In essence, the AB in *EC-Hormones II* has articulated a new standard of review roadmap for scientific experts and panels in SPS disputes settlement. Recall that in the section C of part II, I discussed the *de novo* standard of review adopted by the panels and the AB in *Japan-Apples* and *Japan-Varietals*. In both cases, the AB did not first consider Japan's approach of risk assessment and the underlying scientific evidence supporting the SPS measures. Rather, the AB relied heavily on the opinions from scientific experts and then tried to decide whether Japan's measures fit into these experts' scientific opinions. The new approach suggested by the AB in *EC-Hormones II* is likely to make scientific experts and panels more aware of their limited mandate.

### B. Duty to Provide Explanation in Appreciation of Facts

As we discussed in Part II, the AB has been consistently reluctant to challenge the panel's evaluation of the scientific evidence, be it from the parties or the panel-appointed scientific experts. Whenever the defendant complained that the more probative value was given to some evidence while other contrary evidence was neglected, the AB avoided the issue either by stating that it is within the panel's discretion or the error has not been so serious as to put the panel's objective assessment in question. In *EC-Hormones I*, the EC claimed, inter alia, that the panel disregarded in effect or distorted the scientific evidence presented by the EC and its scientific advisors, and systematically considered the scientific views of the panel-appointed experts or even a minority of those experts, of higher probative value than the scientific evidence presented by the EC scientists or other panel-appointed experts.<sup>70</sup> For

<sup>67</sup> *ibid* para 599.

<sup>69</sup> *ibid* para 598.

<sup>68</sup> *ibid* para 601.

<sup>70</sup> *EC-Hormones I* (n.5) para 110.

example, in the evaluation of relevant evidence with regard to MGA, the panel did not address the differing opinions expressed by Dr. Andre and Dr. Lucier who suggested that MGA is a 'real risk' or it is an 'extraordinary potent progestant'.<sup>71</sup> With regard to five other hormones, the panel incorrectly quoted Dr. Lucier who suggested that a risk is caused by the small fraction of oestrogens that is added for growth promotion purpose.<sup>72</sup> However, without addressing the implication and significance of these divergent opinions, the AB stated that these errors did not constitute a deliberate disregard of evidence or gross negligence amounting to bad faith, since it is generally within the discretion of the panel to decide which evidence it chooses to utilize in making findings.<sup>73</sup>

Such a conservative stance adopted by the AB has changed with *EC-Hormones II*. The AB is now much more willing to step into the panel's fact-weighting territory and flesh out the meaning of 'objective assessment'. Specifically, the AB appears to have added an '*obligation to provide explanation*' as a new element to the 'objective assessment' standard. In *EC-Hormones II*, Dr. Guttenplan's response seemed to accept the EC's position on the genotoxicity of oestradiol-17 $\beta$  and recognize that the EC's risk assessment specifically examined the risk arising from the hormone-treated meat.<sup>74</sup> For example, Dr Guttenplan agreed with the EC that the endogenous levels of hormones in pre-pubertal children were lower than previously thought. As a result, 'more accurate methods of analysis could now be used to measure the effects of eating hormone-treated beef on blood levels of estrogen in children and post-menopausal women. If practical, this experiment would be important in establishing or refuting the arguments of the EC.'<sup>75</sup> Moreover, in response to the panel's question on the specificity of the EC's risk analysis, Dr Guttenplan said that 'I believe the EC has done a thorough job in identifying the potential for adverse effects on human health of oestradiol-17 $\beta$  found in meat derived from cattle to which this hormone had been administered...'.<sup>76</sup> However, the panel failed to address Dr Guttenplan's written responses in its report. The AB stated that 'given that the European Communities was entitled to rely on minority views, the panel was required to explain why it did not consider that Dr. Guttenplan's testimony supported the European Communities' position'.<sup>77</sup> In addition, a number of relevant studies relied upon by the EC in its risk assessment to support the genotoxicity of oestradiol-17 $\beta$  were not mentioned in the panel's analysis. The AB criticized the panel for 'not give any reasons why it did not consider them relevant'.<sup>78</sup> In other words, the AB effectively stated that the panel must give reasoned and adequate explanation as to why it did not consider divergent opinions and relevant scientific evidence. After *EC-Hormones II*, at least the plaintiff can expect that WTO panels will need to address divergent opinions more fully, explain clearly why they decide not to accept these divergent opinions, and the AB will be more willing to intervene in this regard. It is no longer true that the AB will simply endorse the panel's appreciation and weighing of evidence and refuse to consider whether the panel indeed made some mistakes in its evaluation of facts, either substantively or procedurally.

<sup>71</sup> *ibid* para 135.

<sup>73</sup> *ibid*, paras 138, 135.

<sup>75</sup> *ibid* para 611.

<sup>77</sup> *ibid* para 613.

<sup>72</sup> *ibid*, para 138.

<sup>74</sup> *EC-Hormones II* (n 11) paras 603–613.

<sup>76</sup> *ibid* para 612.

<sup>78</sup> *ibid* para 610.

C. *Loosening the Specificity Requirement in Risk Assessment*

In *EC-Hormones II*, one scientific expert, Dr Cogliano, seemed to agree with the EC's position on the genotoxicity of oestradiol-17 $\beta$ . In his written responses, Dr Cogliano stated that the identification of oestradiol-17 $\beta$  as a human carcinogen indicates that there are potential adverse effects on human health when oestradiol-17 $\beta$  is consumed in meat from cattle treated with hormones for growth promotion purposes. However, the panel rejected the relevance of Dr Cogliano's statement. The panel reasoned that Dr Cogliano's analysis only identifies the potential adverse effect, while 'the SPS Agreement requires that the analysis must include an examination of the potential for that adverse effect to come into being, originate, or result from the presence of the specific substance under review in food, beverages, or food stuffs, in this case oestradiol-17 $\beta$  in meat and meat products derived from cattle treated with the hormone for growth promotion purpose.'<sup>79</sup> Here, the panel is actually repeating a well-established rule for risk assessment under article 5.1 of the SPS Agreement, i.e., risk assessment must identify and address a risk with a high degree of specificity, including a specified form of harm, a specified mechanism by which that harm might be caused, and a specific degree of likelihood of harm.<sup>80</sup> In *EC-Hormones I*, Dr Lucier's statement was rejected on the similar basis.<sup>81</sup> Surprisingly, the AB in *EC-Hormone II* held, with no further explanation, that the specificity requirement does not explain how to reconcile Dr Cogliano's statement with the panel conclusion that the scientific evidence does not support the EC position.<sup>82</sup> The panel's rejection of Dr Cogliano's opinion is actually straightforward—the opinion fails to establish a specific link between oestradiol-17 $\beta$  and the alleged adverse health effects.

I would submit that the fact that the AB found fault with the panel in rejecting Dr Cogliano's opinion may be explained by the AB's willingness to *reduce somewhat the rigor of the specificity requirement in risk assessment* under the SPS Agreement. In *EC-Hormone II*, the AB reiterated that the EC had to evaluate whether a causal relationship exists between the consumption of meat from cattle treated with oestradiol-17 $\beta$  and the possibility of adverse health effects. However, this does not mean that the EC had to establish a direct causal relationship between the two. It was sufficient for the EC to demonstrate that the additional human exposure to residues of oestradiol-17 $\beta$  in meat from treated cattle is *one of the factors* contributing to the possible adverse health effects. The European Community was not required to isolate the contribution made by residues of oestradiol-17 $\beta$  from other possible sources.<sup>83</sup> In other words, where multiple factors may contribute to a particular risk, a risk assessor is not required to differentiate the individual contributions made by each factor. The AB stressed that article 5.1 of the SPS Agreement only requires a risk assessment 'as appropriate to the circumstances', which suggests that the scientific inquiry involved in a risk assessment must take due account of particular methodological difficulties posed by the nature and characteristics of the particular substance and risk being evaluated.

This accommodating explanation needs to be compared with the AB's previous rulings. In *Japan-Varietals*, while there was scientific evidence indicating different test

<sup>79</sup> *ibid.*, para 605.

<sup>80</sup> *EC-Hormones I* (n 5) paras 186, 199; *Japan-Apples* (n 48) paras 200–206.

<sup>81</sup> *ibid.* para 198.

<sup>83</sup> *ibid.* para 562. <sup>82</sup> *EC-Hormones II* (n 11) para 606.

results for different varieties, the panel ruled that there was no evidence before the panel that differences in test results were *due to* varietals differences. The panel reasoned that these differences could have been caused by other factors and no attempt had been made to determine cause and effect in terms of varietals differences and differences in test results.<sup>84</sup> In *Japan-Apples*, the AB noted that Japan's discussion of possible pathways to have 'intertwined' the risk of entry through apple fruit with that of other possible vectors, including vectors considered more likely to be potential sources of contamination than apple fruit. Hence the AB held the position that in order to fulfill the scientific requirements, an evaluation of 'entry, establishment or spread of fire blight through apple fruit as a *separate and distinct vector*' was required.<sup>85</sup> After *EC-Hormones II*, it suffices that the substance at issue can be scientifically demonstrated to be one of the factors contributing to the risk. A separate, specific causal relationship between the substance and risk is no longer required.

#### D. The Relative Nature of 'Insufficient Scientific Evidence' in Article 5.7

The AB report in *EC-Hormones II* also sheds light on the AB's refined approach to Article 5.7 of the SPS Agreement. Under article 5.7, a WTO Member has an 'autonomous right', though not absolute or unqualified, to take provisional measures when there is 'insufficient scientific evidence'.<sup>86</sup> The AB in *Japan-Apples* reviewed the relationship of article 5.1 and article 5.7 and concluded that article 5.7 refers to the situation in which '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'.<sup>87</sup> Thus, article 5.7 contemplates situations where there is some evidentiary basis indicating the possible existence of risk, but not enough to permit the performance of a risk assessment.

The AB in *EC-Hormones II* highlighted the relative nature of 'insufficient scientific evidence' in article 5.7. To begin with, the AB held that the determination of 'insufficiency of scientific evidence' must be understood in the light of a WTO Member's predetermined appropriate level of protection ('ALOP'). It is possible that scientific evidence that is sufficient to conduct a risk assessment when a lower ALOP is set will become 'insufficient' when a WTO Member has set a higher ALOP.<sup>88</sup> This is because different levels of protection may require analysis of different risk parameters and this in turn affects the scope and method of the risk assessment. For example, it is possible that the available evidence sufficient to perform a risk assessment for international standards is not enough for a risk assessment aiming at a protection level higher than international standards.<sup>89</sup> The existence of a risk assessment does not necessarily mean that the scientific evidence is absolutely sufficient, therefore excluding the application of article 5.7. Such risk assessment only has probative value, but is not dispositive.<sup>90</sup>

The AB's position reversed the previous panel rulings. In *EC-Biotech*, the panel stated that there is no apparent link between a legislator's protection goals and the task

<sup>84</sup> *Japan-Varietals* (n 44) paras 8.37– 8.41.

<sup>85</sup> *Japan-Apples* (n 48) para 200.

<sup>86</sup> WTO *European Communities—Measures Affecting the Approval and Marketing of Biotech Products* (EC-Biotech), Panel Report (29 September, 2006) WT/DS/291R para.7.2969.

<sup>87</sup> *Japan-Apples* (n 48) para 179.

<sup>88</sup> *EC-Hormones II* (n 11) para 685.

<sup>89</sup> *ibid* para 688–698.

<sup>90</sup> *ibid* para 697.

of assessing the existence and magnitude of potential risks, and refused to evaluate whether the scientific information is insufficient in the light of the WTO Member's chosen level of protection.<sup>91</sup> In *EC-Hormones II*, the panel quoted *EC-Biotech* approvingly and concluded that the 'determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be *disconnected* from the intended level of protection.'<sup>92</sup>

Moreover, 'insufficient scientific evidence' should also be evaluated in consideration of the evolving nature of science. New evidence that was previously unavailable or unknown may become available and change our understanding of an already-identified risk. The new evidence may relate to a newly identified risk that was not covered in the prior risk assessment. Alternatively, risk regulators may now simply know better the substantial inadequacies and limitations of earlier risk assessment. As a result, the scientific evidence used to be considered sufficient may become insufficient in view of the new evidence. In turn, the risk assessment upon which the SPS measure is based may become obsolete or no longer reliable. The AB in *EC-Hormones II* ruled that such situations also fall within the scope of article 5.7.<sup>93</sup> Again, this is a modification of the previous jurisprudence. In *EC-Biotech*, the panel suggested that once a risk assessment is actually performed, then that will at the very least raise a presumption that scientific evidence is sufficient in the relevant sense.<sup>94</sup> In *Japan-Apples*, the AB held that article 5.7 is an option primarily available to Members mainly in circumstances where there is inadequate scientific research about a particular risk, but not in a situation where there is a large body of existing scientific research that could be used in risk assessment.<sup>95</sup> Thus, the previous jurisprudence may be criticized as having neglected the possibility of scientific development since the previous risk assessment such that the earlier risk assessment has to be reviewed in light of the new evidence.

The new scientific evidence may permit a new risk assessment to be performed in accordance with Annex A.4 of the SPS Agreement. However, it is also possible that the new scientific developments themselves are not sufficient and do not permit the performance of a new risk assessment that is sufficiently objective. A critical question is how much new evidence is required to render insufficient a body of scientific knowledge that was previously considered sufficient. Granted, not any new evidence will be enough to overthrow the former risk assessment. The body of scientific evidence underlying a risk assessment can always be supplemented with additional information. The possibility of conducting further research or of analyzing additional information, by itself, should not mean that the relevant scientific evidence is or becomes insufficient.<sup>96</sup> On the other hand, the panel in *EC-Hormones II* developed the 'critical mass' standard, which requires 'a critical mass of new evidence that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient'.<sup>97</sup> This is a very high threshold as it would require a very significant piece of new evidence to call into question the fundamental precepts of previous knowledge. The AB rejected this critical

<sup>91</sup> *EC-Biotech* (n 86) para 7.3238.

<sup>92</sup> *EC-Hormones II* (n 11) para 7.612.

<sup>94</sup> *EC-Biotech* (n 86) para 7.3260.

<sup>95</sup> *Japan-Apples* (n 48) paras 180–182.

<sup>96</sup> *EC-Hormones II* (n 11) para 702.

<sup>93</sup> *ibid* para 701.

<sup>97</sup> *ibid* para 699–712.

mass standard as too inflexible an approach. Instead, a WTO Member should be permitted to adopt provisional measures ‘where new evidence from a qualified and respected source *puts into question the relationship between the preexisting body of scientific evidence and the conclusions regarding the risks*’.<sup>98</sup> The insufficiency requirement in article 5.7 does not imply that new scientific evidence must entirely displace the scientific evidence upon which the old risk assessment relies. It suffices that new scientific developments call into question whether the body of scientific evidence still permits of a sufficiently objective risk assessment.<sup>99</sup>

#### IV. CONCLUSION

The standard of review has long been believed to be a touchstone regarding the relationship of ‘sovereignty’ concepts to the GATT/WTO rule system.<sup>100</sup> The AB’s ruling in *EC-Hormones II* reversed the tide of *de novo* review in SPS disputes. First, WTO Panels’ mandate is limited to the assessment of the risk assessment performed by the WTO Members, and not to find the scientific ‘truth’. WTO panels’ review of national SPS measures must be conducted in light of the Member’s regulatory objectives and risk assessment approach. As long as a Member’s risk assessment meets the minimum scientific validity requirement, WTO panels are expected to respect the Member’s decision even if WTO panels and scientific experts prefer another scientific ‘truth’. Second, the panel is expected to consider all relevant facts and an adequate explanation should be given if some divergent opinions are dismissed. In other words, the appreciation of facts and weighing of scientific evidence will no longer be a *de facto* exclusive zone for panels. The AB is willing to play a more active role in making sure that panels have adequately considered divergent scientific opinions. Third, the AB has quietly loosened the specificity requirement in risk assessment. It suffices to show that the substance at issue is one of the factors contributing to the risk. A separate, causal relationship between the substance and risk is no longer required. Finally, the AB made it clear that ‘insufficient scientific evidence’ must be evaluated in light of the WTO Members’ chosen level of protection and new scientific evidence. An existing risk assessment only has probative value, but is not dispositive.

It is submitted that these new developments indicate that the AB is in the process of formulating a new standard of review for SPS disputes. The new standard will likely be more procedurally focused and less intrusive into the domestic regulatory order. Given the inherent scientific uncertainty and the latitude of WTO Members in conducting risk assessments, the new changes established in *EC-Hormones II* seem to provide more policy space for a WTO Member to justify its SPS measures.

Still, *EC-Hormones II* left many uncertainties. It is a long-running case which has generated enormous political difficulties between the two largest trading entities in the world. Indeed, *EC-Hormones I* is one of a very few cases where the AB’s ruling has never been complied with.<sup>101</sup> As this is the first SPS case where the AB has departed from its previous jurisprudence, it is not entirely clear whether the AB is willing to change the standard of review only for this difficult case where enormous scientific

<sup>98</sup> *ibid*, para 703.

<sup>99</sup> *ibid* para 725.

<sup>100</sup> Croley and Jackson (n 2) 194.

<sup>101</sup> B Wilson, ‘Compliance by WTO Members with Adverse WTO Dispute Settlement Rulings: The Record to Date’ (2007) 10 *JIEL* 397, 397–403.

uncertainty and human health and safety are entangled or, alternatively, for all future SPS disputes or even all WTO disputes. I have argued elsewhere that the standard of review exercised by the panels and the AB differs among WTO Agreements and even among provisions.<sup>102</sup> I therefore believe that this new standard of review will only be applicable to future SPS disputes where human health and safety are at issue. At best, it will apply to all future SPS disputes, but not all WTO disputes. For now, it remains to be seen how *EC- Hormones II* will guide future SPS disputes.

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<sup>102</sup> MM Du, 'Domestic Regulatory Autonomy under the TBT Agreement' (2007) 6 Chinese Journal of International Law 2, 269–302.

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