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Precautionary Approach to Decision Making: The  
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## A PRECAUTIONARY APPROACH TO DECISION MAKING: THE EVOLVING JURISPRUDENCE ON ARTICLE 5.7 OF THE SPS AGREEMENT

**BRYAN MERCURIO\* AND DIANNA SHAO\*\***

*This article evaluates the evolving jurisprudence on the precautionary approach (Article 5.7 of the SPS Agreement) in World Trade Organization dispute settlement. While the jurisprudence demonstrates that panels and the Appellate Body have balanced a Member's precautionary autonomy with the WTO obligations of transparency and non-discrimination, this has not made for fluid jurisprudence and some of the interpretations taken in earlier disputes have not meshed well with the facts or circumstances of subsequent disputes. It is the view of the authors, however, that the interpretive framework developed by the Appellate Body in US/Canada—Continued Suspension could be applied to all circumstances arising from Article 5.7, providing for greater deference to regulatory authorities while at the same time also providing clear boundaries to the scope of Article 5.7. The Appellate Body decision does not answer all remaining questions regarding the scope, coverage and applicability of Article 5.7 or of the SPS Agreement more generally, but it is a step forward in the evolution of decision-making and one that will have continued prominence and importance in the years to come as panels are established in the next generation of SPS Agreement-related disputes.*

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## I. INTRODUCTION

The “precautionary principle”, at its very core, describes behaviour that is characteristically human - the idea that prevention, care and foresight are required in the face of an uncertain outcome is universal.<sup>1</sup> However, human response to risk varies infinitely depending on a myriad of contextual variables. Thus, some academicians in the field acknowledge the conceptual difficulties in calling this a precautionary “principle”.<sup>2</sup> It follows that it is perhaps more appropriate to refer to it as an “approach” as this imports a certain degree of flexibility.<sup>3</sup> This is, of course,

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<sup>1</sup> James Cameron, Will Wade-Grey & Juli Abouchar, *Precautionary Principle and Future Generations*, in *FUTURE GENERATIONS AND INTERNATIONAL LAW* 29 (Emmanuel Agius *et al.* eds., 1998).

<sup>2</sup> See for example *EVOLUTION AND STATUS OF THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL LAW* 8, (Daniel Bodansky ed., 2002) (hereinafter Bodansky); TRACEY EPPS, *INTERNATIONAL TRADE AND HEALTH PROTECTION: A CRITICAL ASSESSMENT OF THE WTO’S SPS AGREEMENT* 32 (2008) (hereinafter EPPS); JACQUELINE PEEL, *THE PRECAUTIONARY APPROACH IN PRACTICE: ENVIRONMENTAL DECISION MAKING AND SCIENTIFIC UNCERTAINTY* 83 (2005); *IMPLEMENTING THE PRECAUTIONARY PRINCIPLE: PERSPECTIVES AND PROSPECTS* 19 (Elizabeth Fisher, Judith Jones & Rene von Schomberg eds., 2006) (hereinafter Fisher *et al.*).

<sup>3</sup> Bodansky, *id.* at 3-5.

a controversial proposition in the field of international law (and perhaps heresy in the field of international environmental law). More importantly, for our purposes, it demonstrates the emotive nature of any discussion on the issue.

Regardless of the label, issues of precaution do not arise in World Trade Organization (WTO) dispute settlement because a Member is dissatisfied with the level of health and environmental protection of another Member. As a trade organization, disputes arise when environmental or health measures are put in place with the effect of undermining trade concessions afforded under the WTO regime. The precautionary approach, most aptly reflected in Article 5.7 of the *Agreement on the Application of Sanitary and Phytosanitary Measures*<sup>4</sup> operates as a shield (rather than a sword) in WTO policy-making.<sup>5</sup>

When forced to interpret the WTO-consistency of trade-restricting SPS measures, WTO panels and the Appellate Body have had little to say about the role of the precautionary approach.<sup>6</sup> For instance, the Appellate Body in *EC–Hormones* considered it “unnecessary” and “probably imprudent” to take a position on the status of the “precautionary principle” in public international law,<sup>7</sup> noting that the

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<sup>4</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 493 (hereinafter SPS Agreement), available at: [http://www.wto.org/english/docs\\_e/legal\\_e/15-sps.pdf](http://www.wto.org/english/docs_e/legal_e/15-sps.pdf). It should be noted that neither the term “precautionary approach” nor “precautionary principle” appear anywhere in the SPS Agreement.

<sup>5</sup> See Andrew Green & Tracey Epps, *The WTO, Science and the Environment: Moving Towards Consistency*, 10(2) J. INT'L ECON. L. 285, 292 (2006). To some commentators, this classification reflects a systematic and structural bias against precautionary measures within the WTO. Jan McDonald, *Tr(e)ading Cautiously: Precaution in WTO Decision Making*, in Fisher *et al.*, *supra* note 2, at 163 (hereinafter McDonald).

<sup>6</sup> For discussion, see Jan Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle*, 40 COLUM. J. TRANSNAT'L L. 323 (2002) (hereinafter Bohanes).

<sup>7</sup> Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, ¶123, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) (adopted Feb. 13, 1998) (hereinafter *EC–Hormones*). See also, Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, ¶¶ 7.87-7.89, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006) (circulated Sept. 26, 2006) (hereinafter *EC–Biotech*):

[T]he legal debate over whether the precautionary principle constitutes a recognized principle of general or customary international law is still ongoing... Since the legal status of the precautionary principle remains unsettled, like the Appellate Body before us, we consider that prudence suggests that we not attempt to resolve this complex issue, particularly if it is not necessary to do so ... Our analysis below makes clear that for the purposes of disposing of the legal claims before us, we need not take a position on whether or not the

*SPS Agreement* itself made no provision for the application of a precautionary approach to justify SPS measures, except as contained under Article 5.7 (and to a lesser extent article 3.3 and the preambular paragraphs).<sup>8</sup>

With this background in mind, it is important to understand that the operation of a precautionary approach within the *SPS Agreement* is subject to a number of important limitations.<sup>9</sup> First, while Members are permitted to select their own levels of protection, they are nonetheless encouraged to base their technical measures on relevant international standards.<sup>10</sup> Second, common to all of the WTO agreements is the stipulation that domestic regulations may only restrict trade to the extent necessary to achieve its legitimate policy objective. This is not to say that every WTO agreement has a ‘necessity’ test; as with other provisions and issues, the operation of such a principle operates differently in the various agreements. In this instance, the limitation takes the form of an exception in some agreements (i.e. Article XX of the GATT) and as a substantive obligation in other agreements (i.e. Articles 2.2<sup>11</sup> and 5.6 of the SPS Agreement; Article 2.2 of the TBT Agreement).<sup>12</sup> A corollary to this principle is the additional limitation that Members must seek to avoid arbitrary differences in the level of protection they apply in similar circumstances.<sup>13</sup> Finally, there is the overarching requirement that SPS measures which reflect a higher level of perceived risk be justified with

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precautionary principle is a recognized principle of general or customary international law ... [and therefore] refrain from expressing a view on this issue.

<sup>8</sup> *EC–Hormones* Appellate Body Report, *id.* ¶ 125. The Appellate Body stressed that the specific wording of the SPS Agreement prevails over any actual or supposed operation of the precautionary principle. *See further*, JOANNE SCOTT, *THE WTO AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES: A COMMENTARY* 126-128 (2007) (hereinafter SCOTT).

<sup>9</sup> McDonald, *supra* note 5, at 166-174.

<sup>10</sup> *See* SPS Agreement, *supra* note 4, art. 3.1. Although harmonization is neither a binding obligation nor a “general rule”, the Appellate Body decision in *US/Canada–Continued Suspension* clearly suggests that its influence is strong, *see* Appellate Body Report, *US – Continued Suspension of Obligations in the EC–Hormones Dispute*, ¶¶ 695-6, WT/DS320/AB/R (Oct. 16, 2008) (*adopted* Nov. 14, 2008) (hereinafter *US–Continued Suspension*).

<sup>11</sup> On ‘necessity’ and Article 2.2 of the SPS Agreement, see Lukasz Gruszczynski, *Risk Management Policies under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures*, 3 *ASIAN J. INT’L HEALTH L. & POL’Y* 261, 290-293 (2008).

<sup>12</sup> For more on Article 5.6 of the SPS Agreement, see Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, ¶ 194, WT/DS320/AB/R (Oct. 20, 1998) (*adopted* Nov. 6, 1998) (hereinafter *Australia–Salmon*). *See also*, Panel Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, ¶¶ 7.1096-7.1098, WT/DS367/R (Aug. 9, 2010).

<sup>13</sup> *See in particular* SPS Agreement, *supra* note 4, arts. 2.3, 3.5 & 5.5. *See also*, Appellate Body Report, *Australia–Salmon*, *id.* ¶ 140.

scientific evidence.<sup>14</sup> In circumstances where this is not yet possible, Article 5.7 comes into play, although even then measures of precaution may only be temporary and transient in nature.<sup>15</sup> It should also be noted at the outset that Article 5.7 has been held to operate as a *qualified right* – not an exception from the obligation under Article 2.2 of not maintaining SPS measures without sufficient scientific evidence.<sup>16</sup>

While only a handful of disputes have been decided under the SPS Agreement, all of them have been controversial. The decisions have also been criticized in literature for so stringently applying the letter of the law so as to effectively prevent Members from offering the desired level of protection to its citizens and environment.<sup>17</sup> On the other hand, commentators also warn that too lenient a determination – that is, too much discretion – will fail to properly guard against protectionism.<sup>18</sup>

This article explores these issues by focusing on the operation and understanding of Article 5.7 of the SPS Agreement, with particular focus on how the recent decision of the WTO Appellate Body in *US/Canada–Continued Suspension* (also referred to by some as “*EC–Hormones IP*”) modifies the interpretative framework established throughout the first ten years of SPS jurisprudence.<sup>19</sup> More specifically, this article argues that the Appellate Body in *US/Canada–Continued Suspension* took positive steps towards establishing a more practical, less intrusive, approach to Article 5.7 which allows greater flexibility for those Member States genuinely concerned about the uncertain health effects of given products. Such an approach clarified unresolved interpretive issues and modified ill-advised findings of previous disputes. In doing so, the Appellate Body develops a framework to guide panels in future disputes.

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<sup>14</sup> In particular SPS Agreement, *supra* note 4, arts. 2.2 & 5.1.

<sup>15</sup> SPS Agreement, *supra* note 4, art. 5.7.

<sup>16</sup> See *EC–Biotech* Panel Report, *supra* note 7, ¶ 7.2973. This issue will be revisited in Section IV of the article.

<sup>17</sup> See, e.g., J. Martin Wagner, *The WTO’s Interpretation of SPS Agreement has Undermined Right of Governments to Establish Appropriate Level of Protection against Risk*, 31 LAW & POL’Y INT’L BUS. 855 (2000). It should be noted, however, that the criticism is not universal nor is it in regards to every aspect of each decision. For an overview, see CATHERINE BUTTON, *THE POWER TO PROTECT: TRADE, HEALTH AND UNCERTAINTY IN THE WTO* (2004) (hereinafter *BUTTON*); EPPS, *supra* note 2; Alexia Herwig, *Whither Science in WTO Dispute Settlement*, 21 LEIDEN J. INT’L L. 823 (2008).

<sup>18</sup> See, e.g., Jeffery Atik, *Science and International Regulatory Convergence*, 17 NW. J. INT’L L. & BUS. 736, 758 (1996-7).

<sup>19</sup> *US–Continued Suspension* Appellate Body Report, *supra* note 10; Appellate Body Report, *Canada – Continued Suspension of Obligations in the EC–Hormones Dispute*, WT/DS321/AB/R (Oct. 16, 2008) (*adopted* Nov. 14, 2008) (hereinafter *US/Canada–Continued Suspension*).

This article seeks to map out the path that panels and the Appellate Body have taken in balancing a Member's precautionary autonomy to the WTO obligations of transparency and non-discrimination. This balance is an extremely tenuous one, and will no doubt remain so given the steadily increasing threats posed to the natural environment by human activities and our inherently limited ability to discover these risks through scientific investigation. Part II briefly outlines the DSB's approach to interpreting Article 5.7 prior to the Appellate Body decision in *US/Canada—Continued Suspension*, focusing on both the procedural and substantive requirements of Article 5.7. Part III analyses the Appellate Body decision in *US/Canada—Continued Suspension* in light of the problems and inconsistencies inherent in the earlier interpretation of Article 5.7 by concentrating on four distinct aspects of the report which clarified and/or modified previous jurisprudence. Part IV reflects upon some general observations about the nature and ambit of the precautionary approach within the WTO, highlighting several of the remaining interpretive and substantive ambiguities. Part V concludes.

## II. THE 'TRADITIONAL APPROACH' TO INTERPRETING ARTICLE 5.7 OF THE SPS AGREEMENT

The purpose of the *SPS Agreement* is to alleviate concerns that Members' domestic regulations in the area of sanitary and phytosanitary protection could constitute non-tariff barriers to liberalised trade in agricultural goods.<sup>20</sup> As such, the Agreement seeks to eliminate disguised protectionism by requiring that all SPS measures be based on scientific justification. This is most clearly reflected in SPS Articles 5.1 and 2.2, which the Appellate Body has repeatedly affirmed should be read together.<sup>21</sup> These Articles state:

Article 5.1: 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.  
 Article 2.2: Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

Most importantly, Article 5.1 of the *SPS Agreement* requires Members to ensure

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<sup>20</sup> See SPS Agreement, *supra* note 4, pmb. and art. 1.1.

<sup>21</sup> See *EC—Hormones* Appellate Body Report, *supra* note 7, ¶ 194; *Australia—Salmon* Appellate Body Report, *supra* note 12, ¶ 180. For commentary, see SCOTT, *supra* note 8, at 82-84. See generally, Lukasz Gruszczynski, *Science in the Process of Risk Regulation under the WTO Agreement on Sanitary and Phytosanitary Measures*, 7 GERMAN L.J. 371 (2006).

that their SPS measures are “based on a risk assessment”. In addition, the risk assessment must be conducted in accordance with risk assessment techniques developed by the relevant international organizations.<sup>22</sup>

In addressing this issue, the panel in *Australia–Salmon* held that Members must fulfil two steps in order to satisfy Article 5.1.<sup>23</sup> First, the importing Member must have conducted a proper risk assessment evaluating the likelihood of the entry, establishment and spread of the pest or disease in question,<sup>24</sup> taking into consideration the effectiveness of SPS measures that might be applied.<sup>25</sup> Second, the importing Member must also have demonstrated that the SPS measure in question was “based on” a proper risk assessment.<sup>26</sup> In other words, the results of the risk assessment must “sufficiently warrant”, or “reasonably support”, the SPS measure at issue.<sup>27</sup> It therefore follows that Article 5.1 contains both a highly stringent *procedural* test requiring a scientific study to “tick the boxes” under the Annex A, paragraph (4) definition of a risk assessment, while also encompassing a *substantive* requirement that there be a rational relationship between the measure at issue and the risk assessment.<sup>28</sup>

The specific requirements under Article 5.1 derive from a more general obligation under Article 2.2 that SPS measures be “based on scientific principles and...not be maintained without sufficient scientific evidence, *except as provided for in [article 5.7]*” (emphasis added). Thus, while SPS measures must normally be scientifically justified, a potential safe haven is available under Article 5.7, which reads:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other

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<sup>22</sup> See SPS Agreement, Annex A(3).

<sup>23</sup> Panel Report, *Australia – Measures Affecting Importation of Salmon*, ¶ 8.77, WT/DS18/R (circulated on June 12, 1998) (hereinafter *Australia–Salmon* Panel Report).

<sup>24</sup> It is important to note that there is a crucial distinction between the risk assessment required for “food-borne” risks to human life or health (under Annex A(1)(c)) and that for disease or pest risks for animal and plant health (Annex A(1)(a), (b) or (d)). Risk assessment for “food-borne” risks requires only the evaluation of the *potential* for adverse effects on human or animal health; the risk assessment for disease or pest risks demands an evaluation of the *likelihood* of entry, establishment or spread of a disease, and of the associated potential biological and economic consequences.

<sup>25</sup> *Australia–Salmon* Panel Report, *supra* note 23, ¶ 8.73.

<sup>26</sup> *Id.* ¶ 8.73.

<sup>27</sup> *Id.* ¶ 8.94.

<sup>28</sup> See Gavin Goh, *Tipping the Apple Cart: the Limits of Science and Law in the SPS Agreement After Japan–Apples*, 40(4) J. WORLD TRADE 680 (2006).

Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.<sup>29</sup>

Section A evaluates the test under the four requirements of Article 5.7 and the resulting controversies. Section B discusses the jurisprudence pertaining to the threshold requirements of Article 5.7.

#### *A. Interpreting Article 5.7 – The Cumulative 4-Step Test*

In the first dispute to interpret Article 5.7, the panel in *Japan–Varietals*<sup>30</sup> was asked to decide whether Japanese measures which sought to prevent the introduction of “codling moth” through the importation of apples, cherries, peaches, walnuts, apricots, pears, plums and quince breached Article 2.2 and several other provisions of the *SPS Agreement*. In that case, Japan’s prohibition on the importation of the abovementioned products could be lifted if the exporting country imposed an alternative quarantine treatment (e.g. fumigation and/or cold storage) which provided the same level of protection to Japan as its import prohibition. Procedurally, once an alternative quarantine treatment with respect to a particular product category had been proposed, the prohibition would be lifted in two main stages. The first stage involved testing on a representative variety of the product (e.g. Granny Smith apples) leading to an initial lifting of the prohibition only on that particular variety.<sup>31</sup> The second stage necessitated that each additional variety of apples be similarly tested before those varieties could be imported. It is this second “varietal testing requirement” that was the subject of dispute, with the complainant (the United States (U.S.)) arguing that once one variety was demonstrated to be safe, there was no legitimate reason to believe other varieties would be any different.<sup>32</sup>

In determining the issue, the panel set out the four requirements contained in Article 5.7:

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<sup>29</sup> The difference between the sufficiency of scientific evidence under Article 2.2 and Article 5.7 should be noted. In the former, sufficiency of scientific evidence relates to whether the evidence is sufficient to support the measures whereas under Article 5.7 the question is whether there is even sufficient scientific evidence to perform a risk assessment.

<sup>30</sup> Panel Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/R (circulated on Oct. 27, 1998); Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R (Feb. 22, 1999) (adopted Mar. 19, 1999) (hereinafter *Japan–Varietals II*).

<sup>31</sup> Maxwell Gregg Bloche, *WTO Deference to National Health Policy: Towards an Interpretative Principle*, 5(4) J. INT’L ECON. L. 538 (2002).

<sup>32</sup> For background, see Bohanes, *supra* note 6.

1. That the measure in question be imposed in respect of a situation where “relevant scientific information is insufficient”;
2. That the measure be adopted “on the basis of available pertinent information”;
3. That the Member in question “seek to obtain the additional information necessary for a more objective assessment of risk”; and
4. That the Member “review the SPS measure within a reasonable period of time”.<sup>33</sup>

Following this four-step approach, the Panel found that even if it could be assumed that Japan satisfied the first requirement of scientific insufficiency, it had nonetheless failed to seek additional information examining the appropriateness of the measure (step 3).<sup>34</sup> Further, the Japanese measure had been in effect for 50 years and thus “could hardly” be classified as a provisional measure that had been reviewed within a reasonable period of time (step 4).<sup>35</sup>

On appeal, the Appellate Body reaffirmed the Panel’s finding as it relates to the Article 2.2 claim. In doing so, the Appellate Body confirmed that the four conditions of Article 5.7 must be read cumulatively and are each “equally important” in determining the applicability of 5.7. Thus, if one of these conditions is not satisfied, then the exemption under Article 5.7 is not available.<sup>36</sup> Moreover, the Appellate Body confirmed that the SPS Agreement does not set an arbitrary time limit or method to be used in collecting relevant scientific evidence. Instead, there is a continuing obligation on the government concerned to actively seek to obtain the necessary scientific evidence needed to conduct a risk assessment.

#### B. “Insufficiency” of Relevant Scientific Evidence

While the *Japan–Varietals* decision clarified the requirements of Article 5.7, it did not address the issue of sufficiency of scientific evidence – that is, *when* Members can rely on Article 5.7. In the subsequent dispute of *Japan–Apples*, the Appellate Body was asked to determine the meaning of the threshold requirement in Article 5.7.<sup>37</sup> In this dispute, the Appellate Body made two important holdings

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<sup>33</sup> *Japan–Varietals II* Panel Report, *supra* note 30, ¶¶ 8.54–8.55.

<sup>34</sup> *Id.* ¶ 8.59.

<sup>35</sup> *Id.* ¶ 8.53, 8.57–8.59.

<sup>36</sup> *Japan–Varietals II* Appellate Body Report, *supra* note 30, ¶ 89.

<sup>37</sup> In this dispute, the U.S challenged certain Japanese quarantine requirements relating to the importation of apples. Japan contended that the requirements were necessary in order to protect against the risk of fire blight – a disease not present in Japan. See Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R (circulated on July 13, 2003); Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R (Nov. 26, 2003) (adopted Dec. 10, 2003) (hereinafter *Japan–Apples*).

relating to Article 5.7. First the Appellate Body explicitly stated that a link exists between the first sentence of Article 5.7 and the obligation to perform a risk assessment under Article 5.1.<sup>38</sup> With this link established, it follows that “relevant scientific evidence” will be “insufficient” within the meaning of 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 under Annex A(4) of the *SPS Agreement*”.<sup>39</sup>

Second, the Appellate Body distinguished the term “uncertainty” from that of “insufficiency”. Here, Japan argued that the Appellate Body should not narrow the applicability of Article 5.7 to only cover situations where “little or no reliable evidence was available on the subject matter at issue”.<sup>40</sup> Rather, Japan submitted that Article 5.7 should also apply in circumstances where existing scientific evidence is not able to resolve a Member’s concerns.<sup>41</sup> The Appellate Body dismissed this argument, stating that the application of Article 5.7 is “triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence”.<sup>42</sup> The Appellate Body pointed out that “[t]he two concepts are not interchangeable” before acknowledging that it is ultimately the *reliability* of available evidence (rather than its quantity) that will be determinative.<sup>43</sup>

Although seemingly simplistic in approach, the reasoning of the Appellate Body has been called ‘groundbreaking’ for clarifying the first sentence of Article 5.7,<sup>44</sup> which Prévost efficiently summarizes:

[The Appellate Body establishes that Article 5.7] is there to address situations where there is a true lack of sufficient scientific evidence regarding the risk at issue, either due to the small quantity of evidence on new risks, or due to the fact that accumulated evidence is inconclusive or unreliable. In either case, the insufficiency of the evidence must be such as to make the performance of an adequate risk assessment impossible. Thus Article 5.7 cannot be used to justify measures that are adopted in disregard of existing scientific evidence. It can also not be used in situations of scientific

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<sup>38</sup> *Japan–Apples* Appellate Body Report, *id.* ¶ 179.

<sup>39</sup> *Id.* ¶ 179. Applying this to the facts, the Appellate Body reaffirmed the panel’s finding that not only did a large quantity but also high quality scientific evidence exist which concludes the risk of transmission of fire blight through apple fruit as negligible. In light of these findings, Article 5.7 was held inapplicable because available scientific evidence permitted the performance of a risk assessment under Article 5.1; *Id.* ¶ 180-182.

<sup>40</sup> *Id.* ¶ 183.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* ¶ 184.

<sup>43</sup> *Id.* ¶ 185.

<sup>44</sup> Denise Prévost, *What Role for the Precautionary Principle in WTO Law After Japan–Apples?*, 2 *ECON. POLY & L.: J. TRADE & ENVTL. STUD.* 1, 9 (2005).

controversy, where proper risk assessments have been conducted, but are in conflict with each other. Provision is made for the latter situation by the interpretation by the Appellate Body in *EC–Hormones* of the requirement in Article 5.1 that SPS measures must be “based on” a risk assessment, discussed above, which allows for reliance on divergent, even minority, views.<sup>45</sup>

The Appellate Body decision can therefore be applauded for creating a limited exception for cases where there is truly a lack of relevant or reliable scientific evidence on the risk at issue instead of providing for a broader interpretation which could be seen (or used) as a loophole around the provisions and spirit of the SPS Agreement. But the value of the decision is limited; the Appellate Body provided no guidance as to what criteria would apply in determining the *reliability* of available scientific evidence. Indeed, as will be discussed hereinafter, it is questionable whether it is even appropriate for the Appellate Body to do so.

The panel decision in *EC–Biotech*<sup>46</sup> closely followed the interpretative approach established in *Japan–Apples* and *Japan–Varietals*. In that dispute, the U.S, Canada and Argentina complained, *inter alia*, that certain EC Member States adopted and maintained nine different “safeguard” measures prohibiting or restricting the marketing of genetically-modified products.<sup>47</sup> In each case, a relevant EC scientific committee found there was no risk to human health or the environment. However, for the products in question, some individual Member States considered that additional information existed which justified the imposition of their safeguard measures.

While the interpretive approach established in *Japan–Apples* and *Japan–Varietals* produced sensible results, the decision in *EC–Biotech* produced a rather unsettling and potentially problematic result. More specifically, while the Panel followed the line of reasoning established in *Japan–Varietals* by classifying Article 5.7 as a *qualified right* subject to the qualifications contained in the cumulative 4-step test,<sup>48</sup> it also followed the reasoning of *Japan–Apples* to find that since the EC previously performed a risk assessment that resulted in the products being approved for sale

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<sup>45</sup> *Id.*

<sup>46</sup> *EC–Biotech* Panel Report, *supra* note 7.

<sup>47</sup> The nine different safeguard measure at issues were: Austria – T25 maize, Austria – Bt-176 maize, Austria – MON810 maize, France – MS1/RFa oilseed rape, France – Topas oilseed rape, Germany – Bt-176 maize, Greece – Topas oilseed rape, Italy – Bt-11, MON810 maize, MON809 maize, T25 maize and Luxembourg – Bt-176 maize.

<sup>48</sup> This reasoning is virtually identical to the Appellate Body’s finding in *Japan–Varietals* that Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. See *Japan–Varietals II* Appellate Body Report, *supra* note 30, ¶ 80; *EC–Biotech* Panel Report, *supra* note 7, ¶ 7.2973.

in the European market, there was sufficient scientific evidence to preclude EC Member States from invoking Article 5.7.<sup>49</sup> The consequences of such an interpretation will be discussed in Part III, below.

### III. CHANGING TIDE? THE APPELLATE BODY REPORT IN *US/CANADA—CONTINUED SUSPENSION*

As briefly mentioned above, the panel decision in *EC—Biotech* uncovered several potentially problematic issues with respect to the existing approach to understanding the operation of Article 5.7 of the *SPS Agreement*. The sequel to *EC—Hormones*, the *US/Canada—Continued Suspension* dispute, goes some way in addressing and remedying the problematic approach. After initially raising the facts of the dispute, this section both raises the issues arising from *EC—Biotech* and the interpretive modifications by the Appellate Body in *US/Canada—Continued Suspension*.

#### A. *The Facts and Panel Decision*

In *US/Canada—Continued Suspension*, the U.S. and Canada complained about the EC's actions between 1998-2002 in initiating and funding a number of scientific studies with the purpose of producing a risk assessment which would bring it in compliance with the *SPS Agreement*. Overall, the EC conducted three risk assessments (in 1999, 2000 and 2002, respectively) into the potential risks to human health from hormone residues in bovine meats and meat products.<sup>50</sup> As a result of these risk assessments, EC Directive 2003/74/EC permitted (amongst other things) a provisional prohibition on animal meat products treated with five specific hormones.<sup>51</sup> The EC justified these provisional SPS measures under Article 5.7 on the grounds that its risk assessments "showed the existence of risks, but all the information and data necessary to conduct a more objective and complete risk assessment was insufficient or missing".<sup>52</sup>

The U.S and Canada disagreed with the EC interpretation and maintained their suspension of concessions. As a result, the EC filed the complaint at the WTO.<sup>53</sup>

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<sup>49</sup> *EC—Biotech* Panel Report, *supra* note 7, ¶ 7.3007.

<sup>50</sup> *US—Continued Suspension* Appellate Body Report, *supra* note 10, ¶¶ 18-23.

<sup>51</sup> These hormones were testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate.

<sup>52</sup> *US—Continued Suspension* Appellate Body Report, *supra* note 10, ¶ 44.

<sup>53</sup> In a rather unique set of circumstances, the EC filed the complaint after the US and Canada refused to initiate compliance proceedings under Article 21.5. Thus, the EC claimed the continued American and Canadian countermeasures violated Article 23 of the DSU. Rather bizarrely, the panel found that Canada and the US had violated Article 23 of

The EC, however, failed to convince the panel that its measures satisfied the requirements of Article 5.7. More specifically, the panel noted that four of the five hormones banned by the EC had been the subject of several scientific assessments performed by reputable regulatory agencies and international experts and none found a “critical mass” of new evidence and/or information which would call into question the “fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient evidence now insufficient”.<sup>54</sup>

Similar to the situation in *EC–Biotech* where there had been a pre-existing EC-level risk assessment, the issues in this dispute were: (1) to what extent does a Member’s level of SPS protection have an impact on the “sufficiency” of relevant scientific evidence; (2) what impact does the existence of an international standard have on the determination of sufficiency; and (3) under what circumstances can existing scientific evidence be put into question (and thus become “insufficient”) by the emergence of new information.

In determining the case, the panel continued the trend of prior dispute settlement determinations in narrowly interpreting Article 5.7. With respect to the first issue, the panel found that a Member’s level of protection has no bearing on the objective question of sufficiency. The panel concluded that the extent to which a Member determines whether its population should be exposed to a particular risk (or at what level) is irrelevant to determining whether that risk exists.<sup>55</sup>

Regarding the second issue, the panel explained that the existence of an international standard implies consistency with the *SPS Agreement*, and as such, is based on sufficient scientific evidence.<sup>56</sup> Finally, with respect to the third question, the panel held that where relevant evidence exists, there must be a “critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge so as to make previously sufficient evidence insufficient”.<sup>57</sup>

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the DSU and also that the EC had not removed the measure found to be inconsistent with the SPS Agreement. For brief discussion, see Fernando Piérola, *A Pandora’s Box in the Dispute Settlement Implementation Phase? Reflections on the outcome of the dispute Canada, United States–Continued Suspension of Obligations in the EC–Hormones Dispute*, 3 GLOBAL TRADE & CUSTOMS J. 327 (2008); Catharina E. Koops, *Suspensions: To Be Continued*, 36(4) LEGAL ISSUES ECON. INTEGRATION 353, 357-360 (2009).

<sup>54</sup> See *US–Continued Suspension* Appellate Body Report, *supra* note 10, ¶¶ 7.831-837.

<sup>55</sup> Panel Report, *US – Continued Suspension of Obligations in the EC–Hormones Dispute*, ¶ 7.611, WT/DS320/R (circulated on Mar. 31, 2008).

<sup>56</sup> *Id.* ¶ 7.644.

<sup>57</sup> *Id.* ¶ 7.648.

### B. *The Appellate Body Decision*

On appeal, the Appellate Body demonstrated a more nuanced approach to understanding the operation of Article 5.7. In reversing the panel's findings under Article 5.7, the Appellate Body went some way in alleviating some of the concerns and inconsistencies raised by the decision in *EC–Biotech*. This section discusses some of the Report's more important findings.

1. The Existence of an International Standard Does Not Preclude the Operation of Article 5.7 for States that Choose a Higher Level of Protection.

As previously described, the panel in *EC–Biotech* prohibited the application of Article 5.7 as a result of a pre-existing EC-level risk assessment. Two interconnected questions arise from this decision: first, would the result have been different if the individually determined desired level of protection of the EC Member States is higher than that at the EC-wide level? Second, what would be the result if available scientific evidence is sufficient to respond to a lower level of protection, but is not enough to assess concerns at a higher level of protection?

The Panel did not find it necessary to investigate the interaction between Articles 3.3 and 5.7.<sup>58</sup> However, the implication of the panel's decision is that a provisional measure could never be maintained by an EC Member, even if available scientific evidence (though sufficient to parlay concerns on an EC-wide level) is insufficient to address a Member's higher level of protection. In so holding, the panel essentially held that there is no link between a Member's appropriate level of protection and the assessment of potential health risks.<sup>59</sup> In effect, such a holding renders Article 3.3 defunct with respect to the operation of Article 5.7. Such an approach is contrary to the explicit wording of Article 3.3, which reads:

Members may introduce or maintain SPS measures which result in a higher level of SPS protection ... if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate *in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.* (emphasis supplied)

Despite the wording of Article 3.3, the panel in *US/Canada–Continued Suspension* agreed with the panel in *EC–Biotech*, stating 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>60</sup>

<sup>58</sup> *EC–Biotech* Panel Report, *supra* note 7, ¶ 7.3298.

<sup>59</sup> *See id.* ¶ 7.3238.

<sup>60</sup> *US–Continued Suspension* Panel Report, *supra* note 55, ¶ 7.612.

The Appellate Body in *US/Canada—Continued Suspension*, however, revisited the issue. Citing Article 3.3, the Appellate Body found no basis as to why the existence of an international standard must necessarily imply the existence of sufficient scientific evidence (and thus bar the application of Article 5.7) for States that do not wish to adhere to that standard (i.e. set an appropriate level of protection which is higher than an international standard).<sup>61</sup> In other words, it is wrong to assume that if one body finds available scientific evidence to be “sufficient” to conduct a risk assessment that other bodies must come to the same conclusion. The fact that a WTO Member has chosen to set a higher level of protection may require it to “perform certain research as part of its risk assessment that is different from the parameters considered in the risk assessment underlying the international standard”.<sup>62</sup>

The Appellate Body further stated that scientific evidence that may have been relied upon by an international body in formulating its international standard at a certain point in time “may no longer be valid, or may become insufficient in light of subsequent scientific developments”.<sup>63</sup> Therefore, the existence of a risk assessment performed by an international or regional body does not mean that the scientific evidence underlying it is necessarily sufficient within the meaning of article 5.7. Moreover, the Appellate Body further stated that although the evidence contained in the risk assessment underlying an international/regional standard may be highly probative,<sup>64</sup> it should not be “dispositive” and “non-rebuttable”,<sup>65</sup> if a State can objectively show that the said risk assessment does not adequately accord with their desired level of protection, and that as of yet, there exists insufficient evidence to undertake a revised assessment under Article 5.1.

This approach marks a tremendous step forward from the previous interpretation of Article 5.7. On one level, it acknowledges the evolving and inexact nature of scientific investigation. On another level, it rectifies the anomalous situation created in *EC—Biotech* wherein a more cautious EC Member State is barred from invoking provisional measures under Article 5.7 because it is effectively “bound” by an existing regional risk assessment. This new interpretive approach not only broadens the operation of Article 5.7, but it also gives Member States far greater freedom to legitimately pursue their desired levels of risk exposure and regulation.

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<sup>61</sup> *US—Continued Suspension* Appellate Body Report, *supra* note 10, ¶¶ 685, 695.

<sup>62</sup> *Id.* ¶ 686.

<sup>63</sup> *Id.* ¶¶ 695-6.

<sup>64</sup> *Id.* ¶ 708.

<sup>65</sup> *Id.* ¶ 679.

## 2. Established Scientific Evidence Can Become “Insufficient” if New Evidence Questions the Soundness of Previous Conclusions

The panel in *EC–Biotech* suggested that an EC Member State would never be able to impose provisional measures under Article 5.7 of the *SPS Agreement* due to the existing EC-level risk assessment.<sup>66</sup> In other words, since a risk assessment has already been undertaken, “sufficient scientific evidence” (as per Articles 2.2 and 5.1) exists *and will always exist*.<sup>67</sup> This decision essentially extends the holding by the Appellate Body in *Japan–Apples* that Article 5.7 is available in situations where there is insufficient scientific research, not in situations where a large body of existing scientific research could be used in a risk assessment.<sup>68</sup>

Such an interpretation is problematic, as it means that new evidence demonstrating a greater degree of risk than that which was previously understood could never trigger a provisional measure under Article 5.7 of the *SPS Agreement*.<sup>69</sup> This interpretation not only has the effect of drastically diminishing a Member State’s authority to be responsive to evolving health risks, but it also fundamentally fails to reflect the inherently discursive nature of scientific knowledge. It is, of course, entirely possible that new evidence which was either previously unknown or otherwise unavailable could radically change an understanding of an identified risk, identify a new risk or simply reveal inadequacies of the previously completed risk assessment. In this regard, scientific evidence which had been considered ‘sufficient’ could become ‘insufficient’ in light of the new evidence.

In finding that such situations fall within the scope of Article 5.7, the Appellate Body in *US/Canada–Continued Suspension* reversed the position taken by the panel in *EC–Biotech*.<sup>70</sup> The new approach, which essentially requires that a previously conducted risk assessment must be reviewed in light of new evidence, means that new evidence could be used either to perform another risk assessment (in accordance with Annex A(4) of the *SPS Agreement*) or simply to render ‘insufficient’ a body of scientific evidence which was previously considered ‘sufficient’.

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<sup>66</sup> *EC–Biotech* Panel Report, *supra* note 7, ¶ 7.3260.

<sup>67</sup> Caroline Henckels, *GMOs in the WTO: A Critique of the Panel’s Legal Reasoning in EC–Biotech*, 7 MELB. J. INT’L L. 295 (2006).

<sup>68</sup> *Japan–Apples* Appellate Body Report, *supra* note 37, ¶¶ 180-182. But see the panel decision in *US/Canada–Continued Suspension*, Panel Report, *US/Canada – Continued Suspension of Obligations in the EC–Hormones Dispute*, ¶¶ 7.597-7.599, WT/DS31/R (circulated on Mar. 31, 2008) stating that “scientific evidence which was previously deemed sufficient could subsequently become insufficient”.

<sup>69</sup> See *Japan–Apples* Appellate Body Report, *supra* note 37, ¶¶ 180-182.

<sup>70</sup> *US–Continued Suspension* Appellate Body Report, *supra* note 10, ¶ 701.

The difficult question for the Appellate Body was not in holding that sufficient scientific evidence can be rendered insufficient through new evidence (a proposition which all parties to the dispute seemed to accept), but rather under what circumstances could this shift occur. The Appellate Body started its analysis by recognizing that the mere supplementation of existing scientific knowledge is not enough to render information insufficient, before determining that the panel's "critical mass" standard for determining insufficiency under Article 5.7 – requiring "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>71</sup> – as far too onerous and inflexible.<sup>72</sup> Instead, the Appellate Body determined that Members should be permitted to take a provisional measure where new evidence from a "qualified and respected source" casts doubts as to whether the previously existing body of scientific evidence "still permits a sufficiently objective assessment of risk".<sup>73</sup> In other words, existing scientific evidence can become "insufficient" if new evidence casts into doubt the soundness of previous conclusions.<sup>74</sup>

This re-evaluation of the standard of proof is more practical than the previous approach; indeed, one wonders why a Member would ever need to invoke a provisional measure under Article 5.7 if they in fact possess a "critical mass" of evidence to discredit existing scientific evidence.

### 3. Implicit Recognition that the "Research and Review" Obligations under Article 5.7 are both *Supplementary* and *Conditional*

As discussed above, the Appellate Body has repeatedly held that the four-step test under Article 5.7 is cumulative insofar as if one of the four requirements does not meet the measure at issue, it will be inconsistent with Article 5.7.<sup>75</sup> Such an approach seems logical, and as mentioned when applied in the first two Article 5.7-related disputes, produces sensible outcomes.

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<sup>71</sup> *Id.* ¶ 704.

<sup>72</sup> *Id.* ¶¶ 699-702.

<sup>73</sup> *Id.* ¶ 703. The Appellate Body stated that a WTO Member should be permitted to take a provisional measure 'where new evidence from a qualified and respected source puts into question the relationship between the pre-existing body of scientific evidence and the conclusions regarding the risks'.

<sup>74</sup> For criticism of the panel's "critical mass" standard, see Andrew T.F. Lang, *Provisional Measures Under Article 5.7 of the WTO's Agreement on Sanitary and Phytosanitary Measures: Some Criticisms of the Jurisprudence So Far*, 42 J. WORLD TRADE 1085, 1096-1097 (2008) (hereinafter Lang).

<sup>75</sup> See, e.g., *Japan-Varietals II* Appellate Body Report, *supra* note 30, ¶ 89; *Japan-Apples* Appellate Body Report, *supra* note 37, ¶ 176; *EC-Biotech* Panel Report, *supra* note 7, ¶¶ 7.2973-7.2974.

On the other hand, such an approach ignores the nature of the four obligations contained in the two sentences of Article 5.7. Andrew Lang of the London School of Economics proposes an alternative interpretation, arguing that the existing approach of reading the first and second sentence of Article 5.7 cumulatively ignores the fact that the two requirements contained in the *first sentence* of Article 5.7 (i.e. step 1 and 2 of the four-step test) relate to the *adoption* of an Article 5.7 measure while step 3 and 4 (found in *second sentence* of 5.7) relate to the *maintenance* of an Article 5.7 measure.<sup>76</sup> Lang proposes that a more satisfactory approach would be to characterize the “research and review” obligations in the second sentence of Article 5.7 as *supplementary obligations* triggered by the exercise of an Article 5.7 right – rather than *conditions* attached to the provisional right itself.<sup>77</sup>

Lang’s approach is preferable to the current approach for two reasons.<sup>78</sup> First, the existing approach has the perverse effect of, in some circumstances, denying Members the opportunity to take provisional measures even where such measures are clearly legitimate. For example, if a country genuinely adopts provisional protection on the basis of available pertinent evidence, but fails for one reason or another to seek further science in a timely manner,<sup>79</sup> then the protective measures themselves become unlawful – even if the objective justification for provisional protection remains as strong as it was upon adoption.<sup>80</sup>

Second, following on from the above example, the existing interpretation is also logically problematic. Currently, a failure to seek additional information bars the application of Article 5.7, since SPS Articles 2.2 and 5.1 automatically apply, and the government is required to perform a risk assessment in order to justify its SPS measure. However, logically, this is an impossibility, as “there is *ex hypothesi* insufficient evidence to do so” (i.e. assuming that a Member is able to satisfy steps 1 and 2 but cannot satisfy step 3).<sup>81</sup> Lang concludes that “Article 5.1 logically can *never* (without absurdity) apply in a situation where there is insufficient scientific evidence to perform a risk assessment”.<sup>82</sup>

Although the Appellate Body in *US/Canada–Continued Suspension* was not asked

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<sup>76</sup> Lang, *supra* note 74, at 1091-1095.

<sup>77</sup> *Id.* at 1091.

<sup>78</sup> Lang also argues that such an approach is both truer to the text of the provision and also more helpful in that it will provide more guidance to WTO Members as to how to abide by their WTO commitments. See *id.* at 1091, 1093.

<sup>79</sup> Note that this may particularly be the case for developing countries as continued scientific investigation may be resource intensive.

<sup>80</sup> Lang, *supra* note 74, at 1092.

<sup>81</sup> *Id.* at 1093.

<sup>82</sup> *Id.*

to specifically address the nature of the four obligations in Article 5.7, its general discussion of the four-step test contained a hypothetical example which may alleviate our concerns. More specifically, the Appellate Body stated that “in emergency situations, a Member will take a provisional SPS measure on the basis of limited information, and the steps it takes to comply with its obligation to seek to obtain additional information and review the measure, will be assessed in light of the exigencies of the emergency”.<sup>83</sup> A close reading of this sentence suggests a presumption that the legitimacy of the *imposition* of the emergency measure is clearly separate from the question of whether it has been legitimately *maintained ex post facto*. Thus it seems (although it is not altogether clear) that the Appellate Body accepts that the “research and review” obligations under the second sentence of Article 5.7 can be characterized as supplementary obligations.

However, practically speaking, this is somewhat a moot point. The very basis of Article 5.7 is that it provides a *provisional* right to impose SPS measures due to a lack of evidence. What precisely constitutes a “reasonable period of time” will inevitably vary from case-to-case,<sup>84</sup> but the point is that Article 5.7 should not be seen as an alternative to the general obligation to base one’s SPS measures on a risk assessment. Thus the only way that a Member can maintain a provisional measure for an extended period of time is to continually establish that evidentiary insufficiency continues to prevail.

Overall, it could be said the Appellate Body decision sought to reconcile the underlying tensions within Article 5.7. On the one hand, it must ensure that Article 5.7 is not given too broad an application because it was only meant to apply in exceptional circumstances.<sup>85</sup> On the other hand, it must also give States the ability to take necessary measures of precaution in line with their legitimately perceived level of risk.

#### 4. Standard of Review

The standard of review defines the role of an adjudicative body in relation to the other actors within its legal institution, and the limits of its authority to apply and enforce the legal rules for which it has been entrusted with jurisdiction.<sup>86</sup> While this is fundamentally a legal question, the standard of review assumes broader political consequences in the WTO (and especially in SPS disputes) as they

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<sup>83</sup> *US/Canada—Continued Suspension* Appellate Body Report, *supra* note 19, ¶ 680.

<sup>84</sup> See *Japan—Varietals II* Appellate Body Report, *supra* note 30, ¶ 93.

<sup>85</sup> See *Japan—Varietals II* Appellate Body Report which specifically warned against a “too broad or flexible” interpretation of Article 5.7. See *id.* ¶ 80.

<sup>86</sup> Holger Spamann, *Standard of Review for World Trade Organization Panels in Trade Remedy Cases: A Critical Analysis*, 38(3) J. WORLD TRADE, 511 (2004) (hereinafter Spamann).

relate to the competence and sovereignty of national authorities in their policy-making.<sup>87</sup> What is ultimately required is a balancing of rights and obligations – i.e. the sovereignty of national governments in implementing and justifying measures versus the rights of other Members to benefit under the WTO Agreements.<sup>88</sup> The Appellate Body in *EC–Hormones* summarized the situation by stating that the applicable standard of review must take account of 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>89</sup>

Striking the balance has been a recurring issue (and some would say problem) for panels and the Appellate Body. The Appellate Body in *EC–Hormones* provides a useful illustration of the difficulties in formulating and maintaining an appropriate standard of review. In this dispute, the EC complained that the panel should have applied a standard of review more deferential to EC actions and submissions. In determining the issue, the Appellate Body concluded that the appropriate standard of review is neither a “*de novo* review”, which would allow a panel complete freedom to differ from the competent authority of a Member whose act or determination is being reviewed, or complete ‘deference’, whereby a panel should not seek to redo the investigation conducted by the national authority but instead examine whether the procedural rules required by the WTO had been followed.<sup>90</sup> Noting that the *SPS Agreement* itself is silent on the matter, the Appellate Body referred to Article 11 of the *Dispute Settlement Understanding* (DSU), which requires a panel to “make an objective assessment of the facts of the case”,<sup>91</sup> in order to substantiate its holding that the appropriate standard of review is the “objective assessment of the matter ... including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements”.<sup>92</sup> Therefore, the appropriate standard of review lies within an ill-

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<sup>87</sup> *Id.*

<sup>88</sup> See generally, Steven P. Croley & John H. Jackson, *WTO Dispute Procedures, Standard of Review, and Deference to National Governments*, 90 AM. J. INT’L L. 193 (1996); MATTHIAS OESCH, STANDARDS OF REVIEW IN WTO DISPUTE RESOLUTION (2003); Claus-Dieter Ehlermann & Nicolas Lockhart, *Standard of Review in WTO Law*, 7 J. INT’L ECON. L. 491 (2004); Spamann, *supra* note 86, at 511; James Durling, *Deference, But Only When Due: WTO Review of Anti-Dumping Measures*, 6 J. INT’L ECON. L. 125 (2003).

<sup>89</sup> *EC–Hormones* Appellate Body Report, *supra* note 7, ¶ 115.

<sup>90</sup> *Id.* ¶ 111-119.

<sup>91</sup> Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125 (1994) (hereinafter DSU) at art. 11.

<sup>92</sup> *EC–Hormones* Appellate Body Report, *supra* note 7, ¶ 118. In so doing, the Appellate Body ignored the more deferential language of Article 17.6(i) of the *Anti-Dumping Agreement*, finding no indication in the SPS Agreement of intent on the part of the

defined middle ground between the two extremes of *de novo* review and complete deference.<sup>93</sup>

Such an approach is initially attractive, but problems can arise with its practical application.<sup>94</sup> For instance, it is sometimes not immediately apparent where the line is between a panel undertaking an objective assessment of the matter (e.g. the scientific evidence by a competent authority of a Member State) and a *de novo* risk assessment.<sup>95</sup>

The compliance panel decision in *Japan–Apples* demonstrates the difficulty in drawing a distinction between an objective assessment and a *de novo* review. In *Japan–Apples*, following its unsuccessful appeal Japan commissioned a series of additional scientific studies indicating that fire blight could: (1) be present in maturing or mature apple fruit; (2) that ‘completion of the pathway’ through carriage by common flies could be shown.<sup>96</sup> Relying on these new studies, Japan produced a subsequent risk assessment (“2005 PRA”) and correspondingly revised its SPS measures in line with its new risk assessment. The compliance panel, however, found that Japan’s revised measures remained inconsistent with its WTO obligations, ruling that the new measures were not based on “sufficient scientific evidence” as per Article 2.2 since the studies reflected a result that had little practical basis under natural (as opposed to laboratory) conditions.<sup>97</sup> What is interesting is that the compliance panel made the point of emphasizing that its approach was consistent with the Appellate Body decision in *EC–Hormones*. A key finding in *EC–Hormones*, however, was that a Member may choose to rely on a minority scientific opinion in crafting SPS measures.<sup>98</sup> Of course, while it can easily be argued that the scientific studies relied on by Japan could not credibly be attributed to a minority opinion because they could not *reliably* be deemed to be scientific in nature,<sup>99</sup> a question remains as to the ascertainable difference between

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Members to adopt or incorporate into that Agreement the standard set out in Article 17.6(i) of the *Anti-Dumping Agreement*. See *id.* ¶¶ 113-114, 118-119.

<sup>93</sup> *Id.* ¶ 123.

<sup>94</sup> See BUTTON, *supra* note 17, at 171.

<sup>95</sup> See Jacqueline Peel, *Risk Regulation under the WTO SPS Agreement: Science as an International Normative Yardstick?* 95-97. (Jean Monnet Working Paper No. 02, 2004).

<sup>96</sup> *Japan–Apples* Panel Report, *supra* note 37, Article 21.5, ¶ 8.41-42.

<sup>97</sup> *Id.* ¶ 8.45-8.72.

<sup>98</sup> *EC–Hormones* Appellate Body Report, *supra* note 7, ¶ 19: stating

[I]n most cases, responsible and representative governments tend to base their legislative and administrative measures on ‘mainstream’ scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources.

<sup>99</sup> *Japan–Apples* Panel Report, *supra* note 37, Article 21.5 ¶ 8.45-8.71.

a ‘*valid*’ minority scientific study and a ‘*flawed*’ scientific study that lacks corroboration by scientific experts.<sup>100</sup>

The Appellate Body in *Japan–Apples* also arguably engaged in a *de novo* review in its determination of the reliability and sufficiency of scientific evidence under Article 2.2, and by implication, Article 5.7 by finding that “as a matter of fact” it is not likely that apple fruit would serve as a pathway for the entry, establishment and spread of fire blight in Japan (based on what it perceived to be “reliable” evidence), the Appellate Body discounted Japan’s approach to risk regulation and its scientific evidence. Alternatively, the Appellate Body relied on other scientific evidence in an attempt to ascertain the “correct science”. In doing so, the Appellate Body performed (or at the very least was *seen* to perform) a *de novo* risk assessment in substitution of that envisaged under SPS Article 5.1.

It is worth further noting that similarly, at the compliance stage in *Australia–Salmon*, Canada (with the backing of one particular scientific expert) asserted that methodological flaws and inconsistencies in Australia’s 1999 revised risk assessment were such that the study did not constitute a proper risk assessment. In that case, however, the compliance panel expeditiously disposed of this argument by stating that even if the absence of these flaws might have led to a lower assessment of risk, it was nonetheless unconvinced that the flaws were “so serious as to prevent us from having reasonable confidence in the evaluation made and the levels of risk assigned”.<sup>101</sup> The question thus becomes whether the compliance panel in *Australia–Salmon* would have reached a different result than the compliance panel in *Japan–Apples*. More directly, did the compliance panel in *Japan–Apples* overstep its mandate by undertaking a *de novo* review of the scientific evidence?<sup>102</sup>

Fortunately, the Appellate Body in *US/Canada–Continued Suspension* clarified the ambiguous situation and provided a roadmap for panels to follow. Foremost, the Appellate Body stressed that it is the Member’s task to perform a risk assessment and the “panel’s task is to review that risk assessment”.<sup>103</sup> It cautioned that a panel which “acts as a risk assessor... would be substituting its own scientific judgement for that of the risk assessor and making a *de novo* review and, consequently, would exceed its functions under Article 11 of the DSU”.<sup>104</sup> In

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<sup>100</sup> For detailed analysis, see LUKASZ GRUSZCZYNSKI, REGULATING HEALTH AND ENVIRONMENTAL RISKS UNDER WTO LAW: A CRITICAL ANALYSIS OF THE SPS AGREEMENT Ch. 4 (2010) (hereinafter GRUSZCZYNSKI).

<sup>101</sup> Panel Report, *Australia – Measures Affecting Importation of Salmon—Recourse to Article 21.5 of the DSU by Canada*, ¶ 7.57, WT/DS18/RW (adopted 20 March 2000).

<sup>102</sup> A similar question can be asked in the *Japan–Measures Affecting Varietals* dispute.

<sup>103</sup> *US/Canada–Continued Suspension* Appellate Body Report, *supra* note 19, ¶ 590.

<sup>104</sup> *Id.*

essence, the Appellate Body confirmed that it is not in the panel's mandate to determine whether the Member's risk assessment is "correct", but to "determine whether th[e] risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable".<sup>105</sup>

The Appellate Body then expanded upon its reasoning and set out a clear test to be used by a panel in reviewing the consistency of an SPS measure with Article 5.1:

1. [I]dentify the scientific basis upon which the SPS measure was adopted. This scientific basis need not reflect the majority view within the scientific community but may reflect divergent or minority views.
2. Having identified the scientific basis underlying the SPS measure, the panel must then verify that the scientific basis comes from a respected and qualified source. Although the scientific basis need not represent the majority view within the scientific community, it must nevertheless have the necessary scientific and methodological rigour to be considered reputable science. In other words, while the correctness of the views need not have been accepted by the broader scientific community, the views must be considered to be legitimate science according to the standards of the relevant scientific community.
3. A panel should also assess whether the reasoning articulated on the basis of the scientific evidence is objective and coherent. In other words, a panel should review whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the scientific evidence relied upon.
4. Finally, the panel must determine whether the results of the risk assessment "sufficiently warrant" the SPS measure at issue. Here, again, the scientific basis cited as warranting the SPS measure need not reflect the majority view of the scientific community provided that it comes from a qualified and respected source.<sup>106</sup>

The Appellate Body then relied upon its four-part test to determine that the panel inappropriately gave too much weightage to the opinion of the majority of scientific experts. In so deciding, the Appellate Body decision corresponds with previous interpretations: panels should not determine whether a risk assessment corresponds to the majority scientific opinion, but rather panels must only make an objective assessment of the manner in which the factual determinations were made during the risk assessment. The difference, however, is that now there is a clear

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<sup>105</sup> *Id.*

<sup>106</sup> *Id.* ¶ 591. The recent panel report in *Australia–Apples* attempts to carefully follow this test. See *Australia–Apples* Panel Report, *supra* note 12, ¶¶ 7.225–7.229. See also *id.* ¶ 7.790.

standard by which to guide panels in their review. In this regard the Appellate Body has more clearly defined standards, both for the limits of panels' mandate (i.e. to review the Member's risk assessment against the standard set in Article 5.1) as well as on scientific experts (i.e. the standard is not whether the scientific expert would have conducted the risk assessment in the same manner and/or reached the same result, but only if it is objective, coherent and appropriate to the circumstances). In doing so, the Appellate Body has ensured that panels will now explicitly apply a standard of review which first considers and responds to the risk assessment and underlying scientific evidence presented by the Member concerned.<sup>107</sup> While this should go some way in clarifying the issue, the standard does leave unresolved some uncertainties as to the scale of deference to be given to a Member's risk assessment (e.g. to what degree of deference should be provided).

Although discussion of the appropriate standard of review in SPS disputes may be more directly relevant to Articles 5.1 and 2.2, any such standard could have implications for Article 5.7. The point here is that it is dangerous for panels and the Appellate Body to make determinations of scientific sufficiency or insufficiency for the purpose of triggering Article 5.7 based on some ill-defined and inconsistently applied notion of reliability. Furthermore, it is not the role of the panel/Appellate Body to impose its own view on the scientific evidence; instead, it is merely to determine the existence, quality and sufficiency of the scientific evidence presented by the Member concerned supporting the SPS measure in question. Indeed, when assessing the applicability of Article 5.7 the panel/Appellate Body must determine whether the complaining party has met its burden of demonstrating that there is sufficient science to conduct a risk assessment. This is an altogether different and more difficult task as it requires the panel/Appellate Body to make a ruling on the respondent's assertion that the science is insufficient to complete a risk assessment.<sup>108</sup> That being the case, the test set out by the Appellate Body in *US/Canada—Continued Suspension* remains relevant as it could be adapted and applied in the context of Article 5.7, where a

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<sup>107</sup> This is in contradistinction to both the panels in *Japan—Varietals*, *Japan—Apples* and the panel decision in *US/Canada—Continued Suspension*. The Appellate Body stated:

[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.

See *US/Canada—Continued Suspension* Appellate Body Report, *supra* note 19, ¶ 598.

<sup>108</sup> The authors are grateful to Tracey Epps for raising this important issue.

panel/Appellate Body must determine whether a responding party has successfully made the claim that the science is insufficient to perform a risk assessment.

#### IV. REMAINING AMBIGUITIES RELATING TO ARTICLE 5.7

Although we have argued that the most recent Appellate Body decision in *US/Canada–Continued Suspension* clarified and rectified some of the anomalies inherent within the existing interpretation of Article 5.7, there remain some important interpretive and substantive aspects of this provision that require further development. As such, the precise ambit of the operation of Article 5.7 remains unclear. This section discusses both the interpretive and the substantive uncertainties.

##### A. Interpretative Issues

The first interpretive uncertainty that warrants further discussion is the precise relationship between Article 2.2 and Article 5.7.<sup>109</sup> The panel in *EC–Biotech* explicitly characterized Article 5.7 as a “qualified right” – that is, a right qualified by the four cumulative requirements of Article 5.7.<sup>110</sup> Thus, the Appellate Body held that “Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7”.<sup>111</sup> In holding so, the panel strengthened – and some may say essentially departed from – the finding of the Appellate Body in *Japan–Varietals* that stated Article 5.7 is a “qualified exemption” from the obligation under Article 2.2 that should not be given an “overly broad and flexible interpretation”.<sup>112</sup> With the decision in *EC–Biotech*, it is clear that not only is the burden of proof on the complaining party,<sup>113</sup> but also that where a challenged SPS measure is adopted and maintained consistently with the four cumulative requirements of Article 5.7, Article 2.2 is not immediately applicable to the measure.<sup>114</sup> That is to say, the

<sup>109</sup> See further, SCOTT, *supra* note 8, at 111-113.

<sup>110</sup> See *EC–Biotech* Panel Report, *supra* note 7, ¶¶ 7.2962-7.2983. See also, Appellate Body Report, *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries*, ¶ 88, WT/DS246/AB/R (Apr. 7, 2004) (hereinafter *EC–Tariff Preferences*) (for similar analysis on whether the Enabling Clause is a right or exception to Article I:1 of the GATT).

<sup>111</sup> *EC–Biotech* Panel Report, *supra* note 7, ¶ 7.2969.

<sup>112</sup> *Japan–Varietals II* Appellate Body Report, *supra* note 30, ¶ 80. It should be noted that the panel in *EC–Biotech* engaged with the Appellate Body decision in *Japan–Varietals* and certainly did not believe its decision was a departure from existing jurisprudence. For general discussion on the relationship between Article 2.2 and Article 5.7, see SCOTT, *supra* note 8, at 111-113.

<sup>113</sup> *EC–Biotech* Panel Report, *supra* note 7, ¶¶ 7.2977-7.2979. See also *EC–Tariff Preferences* Appellate Body Report, *supra* note 110, ¶ 88.

<sup>114</sup> *EC–Biotech* Panel Report, *supra* note 7, ¶ 7.3298.

consistency of the respondent's measure will be judged on the four corners of Article 5.7, and not with reference to Article 2.2. Conversely, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7, then the situation is not "as provided for in paragraph 7 of Article 5" (as per Article 2.2), and the relevant obligations contained in Article 2.2 and/or 5.1 are applicable to the challenged measure.<sup>115</sup>

As previously mentioned, a problem thus could arise in a situation where a challenged SPS measure satisfies the first requirement of scientific insufficiency but fails on one (or all) of the remaining three – as was the case in *Japan–Varietals*.<sup>116</sup> In such a circumstance, it does not seem possible for a Member to show that its SPS measure was "not maintained without sufficient scientific evidence" when it has already been recognized that there is insufficient scientific evidence upon which to conduct a risk assessment. Given that it is impossible to perform a risk assessment pursuant to Articles 2.2 and 5.1, the necessary conclusion must be that the SPS measure will be in breach of Article 2.2 – as well as Article 5.7. However, it is logically absurd to assert a breach of Articles 2.2 and 5.1 when the underlying assumption (e.g. that there is sufficient scientific evidence) has been disproven.

In the above scenario, it would make more sense to conclude that despite the breach of Article 5.7, Article 2.2 is *inapplicable* – it simply would not be automatically triggered. However, such a conclusion is predicated upon a fundamental assumption – namely, that the third and fourth requirements under the four-step test operate as supplementary (rather than cumulative) obligations once a *threshold* requirement of "insufficiency of scientific evidence" has been established.

A second point of clarification is necessary when conceptualizing the relationship between Article 2.2 and Article 5.7. Article 2.2 provides three distinct obligations: a measure must be: (i) necessary, (ii) based on scientific principles, and (iii) not be maintained without sufficient scientific evidence. Given that there is a relationship of qualified exclusion between Articles 2.2 and 5.7, the question is whether a measure adopted in conformity with Article 5.7 is exempted from all the requirements of Article 2.2 or only from its last element.<sup>117</sup> Arguably the text of the

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<sup>115</sup> *Id.*

<sup>116</sup> Here, the Panel was willing to "assume" that Japan satisfied the first requirement of scientific insufficiency, but had nonetheless failed to seek additional information examining the appropriateness of their SPS measure (step 3).

<sup>117</sup> Lukasz Gruszczynski, *SPS Measures Adopted in Case of Insufficiency of Scientific Evidence – Where Do We Stand After EC–Biotech Products Case?*, in *ESSAYS ON THE FUTURE OF WORLD TRADE ORGANIZATION 91-140* (Julien Chaisse & Tiziano Balmelli eds., 2008) (hereinafter Gruszczynski).

provision makes available both interpretations and the existing case law does not provide a clear answer. Although it is highly unlikely that a Panel would accept the imposition of a measure beyond what is *necessary* to protect human, animal or plant life or health, a clarification is nonetheless welcome.

### B. Substantive Issues

In terms of substantive issues, three uncertainties are worth discussion. First, although panels have defined the ambit and operation of the first requirement under the four-step test in great detail, very little has been said about the remaining three requirements. For example, the meaning of the second requirement mandating that a provisional SPS measure be adopted “on the basis of *available pertinent information*” has yet to be explored. The difference (if there is one) between “pertinent information” and “scientific evidence” remains undefined and unclear. Gruszczynski argues that “on the continuum from no information to scientific data, pertinent information is to be found somewhere between these two extremes”.<sup>118</sup> While that may be the case, the extent of the difference between these two types of data is still unclear. For example, it remains uncertain whether “pertinent information” could be interpreted to include scientific opinions that have not been subject to peer review or are not fully consistent with existing theory. Furthermore, it is unclear whether the term even encompasses information concerning public values such as consumer data and surveys of public attitudes. The importance of this terminology, and the meaning therein, cannot be understated – an unduly restrictive interpretation could severely hinder a Member’s ability to impose a provisional SPS measure.

Similarly the scope of the third and fourth requirements under the four-step test is also ambiguous. For instance, under the third requirement, a Member is obliged to “seek to obtain additional information necessary for a more objective assessment of risk”. In exploring this provision, the Appellate Body in *Japan–Varietals* confirmed that there is no requirement for any specific type of information to be collected, nor is the method through which additional information is to be obtained specified.<sup>119</sup> Accordingly, Members are free to choose whatever methodology they consider appropriate – provided that this information is “necessary for a more objective assessment of risk”. It follows that the ultimate goal under this requirement of Article 5.7 is to encourage the performance of a risk assessment that ultimately satisfies the requirements under Annex A(4) and Article 5.1 (or is substantially closer to that standard than a mere consideration of available pertinent information).<sup>120</sup>

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<sup>118</sup> *Id.* at 119.

<sup>119</sup> *Japan–Varietals II* Appellate Body Report, *supra* note 30, ¶ 92.

<sup>120</sup> See Gruszczynski, *supra* note 117, at 123.

However, it is unclear whether the economic and technological capabilities of a Member have any bearing on its performance under the third requirement of the four-step test. In essence, the question is whether the standard is flexible enough to take account of the economic and technical situation of the Member concerned. As all SPS disputes to date have thus far exclusively concerned industrialized country Members, no panel or the Appellate Body has addressed this issue.

In evaluating the issue, the first point to make is that the preamble to the *SPS Agreement* does explicitly recognize that developing Members may encounter special difficulties in the formulation and application of SPS measures.<sup>121</sup> It therefore seems feasible to consider that panels may be willing (perhaps on a case-by-case basis) to consider factors such as a Member's research capacity, their national priorities or their ability to allocate funds to different areas of research – provided that the Member concerned can provide evidence of a genuine effort in obtaining further scientific evidence.

The final substantive issue to be addressed is the obligation to review a provisional SPS measure within a *reasonable* period of time under the final requirement of the four-step test. The wording of the provision provides panels and the Appellate Body with a considerable amount of discretion. To date, the Appellate Body has used the discretion provided to conclude that what constitutes a reasonable period of time is to be determined on a case-by-case basis, taking account of certain factors.<sup>122</sup> For example, the level of difficulty in gathering new information and the characteristics of a given provisional measure may play an important part in decision-making.<sup>123</sup> Scholars have also suggested that in circumstances where there is low certainty and low consensus with respect to a particular risk, the reasonable period of time should be considerably longer.<sup>124</sup> The EC raised a similar argument in *EC–Biotech*, noting that “GMO technology is still at the frontiers of science and its future consequences (compared to fire blight for example) are highly uncertain”.<sup>125</sup> As such, when long-term effects need to be

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<sup>121</sup> See SPS Agreement, *supra* note 4, arts. 9, 10 & 14. Although it is important to note that Articles 9 and 14 are not directly relevant to the operation of Article 5.7. Article 9 concerns technical assistance that is to be afforded to developing and least developed country Members while Article 14 concerns longer time frames for the implementation of the SPS Agreement for developing and least developed Members.

<sup>122</sup> *Japan–Varietals II* Appellate Body Report, *supra* note 30, ¶ 93.

<sup>123</sup> *Id.*

<sup>124</sup> David Winickoff, Shiela Jasanoff, Lawrence Busch, Robin Grove-White & Bryan Wynne, *Adjudicating the GM Food Wars: Science, Risk and Democracy In World Trade Law*, 30 *YALE J. INT'L L.* 81, 114 (2005) (hereinafter Winickoff *et al.*).

<sup>125</sup> *EC–Biotech* Panel Report, *supra* note 7, ¶ 7.3230.

assessed and their impact may have a permanent character, it seems “reasonable” that the reasonable period of time should be longer.<sup>126</sup> Although such an interpretive approach to Article 5.7 is available to the panel, it is perhaps more probable that in circumstances of low certainty and low consensus, the panel would concentrate more on the difficulty in gathering new information (under the third requirement) rather than introducing the issue as a “special case” under the fourth requirement.<sup>127</sup>

## V. CONCLUSION

This article sought to evaluate the evolving jurisprudence on the precautionary approach in WTO dispute settlement. In doing so, it is readily apparent that panels and the Appellate Body actively seeks to balance a Member’s precautionary autonomy with the WTO obligations of transparency and non-discrimination. To date, panels and the Appellate Body determinations have proven that the SPS Agreement is capable of being flexibly interpreted so as to both protect policy space and national regulations and at the same time protect against creeping protectionism.<sup>128</sup> This has not made for fluid jurisprudence, however, and as this article has demonstrated some of the interpretations taken in earlier disputes have not meshed very well with the facts or circumstances of subsequent disputes.

The Appellate Body decision in *US/Canada–Continued Suspension* goes some way in providing a sound interpretive framework to be applied to all circumstances arising from Article 5.7. Rather skilfully, it has done so in a manner which recognizes and understands the delicate balance between health/policy space and protectionism. The framework, if properly applied, should provide for greater deference to regulatory authorities while at the same time also providing clear boundaries to the scope of Article 5.7. The Appellate Body decision does not answer all remaining questions regarding the scope, coverage and applicability of Article 5.7 or of the SPS Agreement more generally, but it is a step forward in the evolution of panel/Appellate Body decision-making and one that will have continued prominence in the years to come as panels are established in the next generation of SPS Agreement-related disputes.

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<sup>126</sup> Winickoff *et al.*, *supra* note 124, at 115-116.

<sup>127</sup> Gruszczynski, *supra* note 117, at 127.

<sup>128</sup> See EPPS, *supra* note 2, who makes this point after an extensive review of the WTO decisions, even prior to the most recent decision. See also GRUSZCZYNSKI, *supra* note 100.