## Is It Possible to Provide Evidence of Insufficient Evidence? The Precautionary Principle at the WTO

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### **Abstract**

This Article aims to demonstrate that the WTO jurisprudence on science-related trade disputes has become imbued with a specific vision of science that has prevented any possible application of the precautionary principle. This situation is due both to the WTO's specific dispute settlement procedures and to the substantive nature of precautionary measures. Indeed, such measures' foundation on "insufficient scientific evidence" dramatically undermines the probative value of science in WTO adjudication and creates a seeming contradiction: The system requires defendants to provide legal evidence of the absence of sufficient scientific evidence. The reasoning of the Panel on the EC-Biotech case was riddled with this apparent paradox. For the first time, the US-Continued Suspension case has opened a gateway to address this fundamental issue.

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#### I. INTRODUCTION

The precautionary principle is an established principle of international law that is explicitly included in a number of international environmental agreements, such as the Convention on Biological Diversity<sup>1</sup> and the United Nations Framework Convention on Climate Change,<sup>2</sup> and is referred to in more general terms in other international agreements, such as the Marrakesh Agreement of 1994 establishing the World Trade Organization.<sup>3</sup>

Notwithstanding the frequency with which it is invoked, there exists no universally accepted statement of the precautionary principle,<sup>4</sup> nor is there consensus about its location within the sources of international law.<sup>5</sup> Despite

Convention on Biological Diversity (1992), 33 ILM 818 (1992).

United Nations Framework Convention on Climate Change, 1771 UN Treaty Ser 107, S Treaty Doc No 102-38 (1992).

Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Legal Instruments—Results of the Uruguay Round vol 1 (1994), 33 ILM 1125 (1994) (Final Act).

See, for example, David L. Vanderzwaag, *The Precautionary Principle in Environmental Law and Policy:* Elusive Rhetoric and First Embraces, 8 J Envir L & Practice 355, 360 (finding fourteen interpretations); Per Sandin, *Dimensions of the Precautionary Principle*, 5 Hum & Ecol Risk Assessment 889, 902–05 (1999) (finding nineteen interpretations).

In particular, most of the debate concerns its relevance as international customary law. For those who are in support of that thesis, see, for example, James Cameron and Juli Abouchar, The Status

this ambiguity, the precautionary principle is frequently invoked in treaties to ensure that, where there are threats of serious or irreversible damages to the environment, governments should take action even if scientific evidence of the risk is not conclusive. Indeed, the precautionary principle emerged from the concern that full scientific evidence is, for many issues of environmental law and policy, too strict a standard for undertaking action and that another form of rational justification should be found within the boundaries of science. For instance, instead of requiring that a risk be established in the form of probability before acting, its existence could be reflected upon plausible, reliable—even though not conclusive—explanations.<sup>6</sup> Once it is established that policymakers should not forgo acting when the informing science is incomplete, it remains a matter of policy discretion to decide the form of the intervention, either through protective measures or through delaying the implementation of certain projects whose risks have not been clearly identified.<sup>7</sup>

Including the precautionary principle in the WTO framework is highly controversial because of the discretion inherent in applying precautionary policies and the absence of definite standards of proof. Although Article XX of the 1994 General Agreement on Tariffs and Trade (GATT 1994)<sup>8</sup> provides for protection measures, such measures' adoption under the precautionary principle is problematic because they are based on reasons of "precaution" rather than of "strict necessity." For measures premised on precaution rather than necessity, no clear standards of proof exist because the science underlying any application of the precautionary principle is, by its nature, incomplete or inconclusive. The precautionary principle exposes the tension between the political nature of the decisions concerning environmental policies and the need for a reasonable relation with the underlying scientific evidence. Furthermore, the precautionary principle affects each member state's sovereign choice to set levels of protection for human, plant, and animal health. The second tension is thus between the need for interstate coordination, due to the global nature of environmental problems, and the sovereign right to act according to national preferences. Indeed, the lack of clear coordination benchmarks, such as scientific evidence

of the Precautionary Principle in International Law, in David Freestone and Ellen Hey, eds, The Precautionary Principle and International Law: The Challenge of Implementation 29, 36–37 (Kluwer Law International 1996); Theofanis Christoforou, The Precautionary Principle in European Community Law and Science, in Joel A. Tickner, ed, Precaution, Environmental Science, and Preventive Public Policy 241, 243 (Island 2003). For the views of those who oppose it, see, for example, P.W. Birnie and A.E. Boyle, International Law and the Environment 116 (Oxford 2d ed 2002).

Olivier Godard, et al, Traité des Nouveaux Risques: Précaution, Crise, Assurance 72–74 (Gallimard 2002).

See generally Nicholas de Sadeleer, ed, Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA (Earthscan 2007).

<sup>8</sup> Final Act, Art XX (cited in note 3).

<sup>&</sup>lt;sup>9</sup> For an explanation of the "necessary test," see note 15.

would provide, and the discretion of policy intervention under precautionary considerations are certainly problematic for promoting harmonization among member states' practices, which is one of the priorities at the WTO. Similarly, the use of protection measures that are politically discretionary and scientifically uncertain indicates that the precautionary principle may be used to disguise indirect barriers to trade.

No explicit reference to the precautionary principle is found in the WTO agreement; rather there are "gateway" provisions to it, 10 which have been interpreted through the WTO jurisprudence on science-related disputes to include the precautionary principle. However, I argue in this Article that despite some important changes, the status of the precautionary principle remains incompatible with WTO rules. This opinion is corroborated by one fundamental fact: Those states invoking the precautionary principle in support of protection policies have never succeeded in their claims. 11

This Article aims to outline an epistemological framework of science at the WTO in order to determine the proper application of the precautionary principle. This will be done by way of comparison with its supposed opposite, the science-based principle. In Section II, I provide a brief analysis of the Sanitary and Phytosanitary Agreement<sup>12</sup> (SPS Agreement) and the *EC–Biotech* dispute between the EU and the group composed of the US, Canada and Argentina. This analysis demonstrates that the precautionary principle is one

<sup>10</sup> Ilona Cheyne, Gateways to the Precautionary Principle in WTO Law, 19 J Envir Law 155, 158 (2007).

In the EC-Hormones case, the EC invoked the precautionary principle to justify its prohibition on marketing and importing meat and meat products treated with certain hormones. World Trade Organization, Report of the Appellate Body, EC Measures Concerning Meat and Meat Products (Hormones) ¶ 26, WTO Doc No WT/DS26/AB/R, WT/DS48/AB/R (Jan 16, 1998) (EC-Hormones). The Appellate Body concluded that, among other provisions, the EC had violated Article 5.1 of the Sanitary and Phytosanitary (SPS) Agreement, requiring that a member's SPS measures be based on a risk assessment. Id at ¶ 253. In the EC-Biotech case, the EC invoked again the precautionary principle and the Panel concluded that the EC member state safeguard measures violated Articles 5.1 and 2.2 of the SPS Agreement because they were not based on risk assessments and hence could be presumed to be maintained without sufficient scientific evidence. World Trade Organization, Report of the Panel, European Communities-Measures Affecting the Approval and Marketing of Biotech Products ¶¶ 4.290–4.291, WTO Doc No WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept 29, 2006) (EC-Biotech). Finally, in the US-Continued Suspension case, the EC invoked the precautionary principle to justify a temporary ban on meat and meat products treated with five specific growth promotion hormones. World Trade Organization, Report of the Appellate Body, United States-Continued Suspension of Obligations in the EC-Hormones Dispute ¶ 85, WTO Doc No WT/DS320/AB/R (Oct 16, 2008) (US-Continued Suspension). Though it did not fault the EC for its conduct, the Appellate Body was unable to determine whether the risk assessments performed by the EC supported a case of insufficient scientific evidence. Id at ¶¶ 207 - 08.

Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Legal Instruments—Results of the Uruguay Round vol 1, Annex 2 A, 1867 UN Treaty Ser 493 (1995).

justification for imposing restrictive measures on trade. In Section III, I argue that despite being given the status of an autonomous right by the EC-Biotech Panel, the principle's procedural and substantive qualifications make it operate in practice as an exception to the rule of performing a risk assessment. This precise allocation of the precautionary principle within the realm of policy as opposed to that of science creates a crucial legal problem, for which only scientific evidence is translated into legal evidence and only an "adequate" risk assessment is considered to be relevant for providing facts for the dispute. In Section IV, I address the situation in which a claim of precaution is severely impaired by "insufficient scientific evidence" or becomes even impossible to support when it has to counter a case of "sufficient scientific evidence." In these situations, the question arises whether the precautionary principle can still refer to the autonomous right of WTO Members to set their preferred level of protection as found by the EC-Biotech Panel. 13 In Section V, I address this seeming paradox through the analysis of another similar dispute, US-Continued Suspension. Analyzing this case opens the way for important changes to the epistemology of science maintained at the WTO. Section VI concludes.

### II. THE RELATION BETWEEN SCIENCE AND PRECAUTION AT THE WORLD TRADE ORGANIZATION

### A. The Sanitary and Phytosanitary Agreement

In order to shed light on the discourse on the applicability of the precautionary principle in WTO law, this Article will focus on the WTO SPS Agreement, since it strictly addresses the relation between the validity of scientific instructions to protect human, plant, and animal health and the legitimacy of member states' accordingly applying restrictive measures to trade.

Article 2.2 of the SPS Agreement states:

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.<sup>14</sup>

Therefore, the SPS Agreement requires that all possible less-restrictive solutions be exhausted before imposing protective measures, a requirement called the "necessary test."<sup>15</sup> It further states that those actions producing more trade-

Report of the Panel, *EC*–Biotech at ¶ 7.1389 (cited in note 11).

SPS Agreement, Art 2.2 (cited in note 12).

The "necessary test" was first formulated by the Panel Report on the Tuna/Dolphin case; in order to demonstrate that a trade-restrictive measure is consistent with Article XX(b) of GATT 1994, member states must have exhausted all possible less-restrictive alternatives, provided that the Panel determines whether any such alternative is "reasonably available." GATT Dispute Panel

restrictive effects than those generally expected from similar measures based on international standards<sup>16</sup> must be corroborated by scientific justification.

As specified in Article 5.1, this justification implies that a risk assessment of the product under protection be performed: "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>17</sup>

But the SPS Agreement also provides an exception to this rule, which is included in Article 5.7 and considers a situation where scientific evidence is insufficient to conclude that there is a definite risk: "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 Members." Does this mean that a case arising under Article 5.7 is exempt from scientific justification? As I shall demonstrate in the following paragraphs, the WTO jurisprudence up until the *EC-Biotech* dispute confirms precisely this approach, validating a dramatic dichotomy between science in Article 5.1 and precaution in Article 5.7. This situation has important consequences for the ability to justify precautionary measures in case of dispute. <sup>19</sup>

### B. The EC-Biotech Dispute: Legal Background

In the EC-Measures Affecting the Approval and Marketing of Biotech Products dispute (EC-Biotech),<sup>20</sup> the group composed of the US, Canada, and Argentina accused the EU of having imposed a de facto moratorium on the commercialization of genetically modified organisms (GMOs)<sup>21</sup> since 1998 by

Report, US-Restrictions on Imports of Tuna ¶ 5.22, DS21/R-BISD (39th Supp) 155 (Sept 3, 1991) (unadopted) (Tuna/Dolphin I).

SPS Agreement, Art 3.3 (cited in note 12). In the Japan–Agricultural Products case, the Appellate Body stated that it would have been wrong to convert an advantage (the presumption of legitimacy for those SPS measures based on international standards) into an obligation that members comply with such standards. World Trade Organization, Report of the Appellate Body, Japan–Measures Affecting Agricultural Products ¶ 102, WTO Doc No WT/DS76/AB/R (Mar 19, 1999) (Japan–Agricultural Products).

SPS Agreement, Art 5.1 (cited in note 12).

<sup>18</sup> Id at Art 2.2.

<sup>19</sup> See Section III.

Report of the Panel, *EC–Biotech* (cited in note 11).

In this paper, biotechnology products are also referred to as "genetically modified organisms" (GMOs), except where differently stated. GMOs are products that have been altered using recombinant DNA technologies.

"undue delay" in the approval procedure.<sup>22</sup> Besides accusation of procedural failures,<sup>23</sup> the complainants claimed that the European member states either never performed the risk assessments on GMOs or dismissed the positive results of risk assessments.<sup>24</sup> Thus, according to the complainants, the European behavior violated Article 5.1 of the SPS Agreement, which requires that SPS measures be based on scientific risk assessment.<sup>25</sup> In the absence of such an assessment, the European delay amounted to a non-necessary<sup>26</sup> and not science-based<sup>27</sup> restrictive measure to trade.<sup>28</sup>

In their defense, the European Communities (EC) argued that, to the extent that safeguard measures<sup>29</sup> on the import of certain GMOs were adopted by six EC member states,<sup>30</sup> the case of inconsistency was to be examined under Article 5.7 of the SPS Agreement instead of Article 5.1, the former contemplating the case of insufficient scientific evidence and better reflecting the precautionary principle.<sup>31</sup>

On September 29, 2006, the WTO Dispute Settlement Body issued its ruling on the complaints, on the one hand faulting the EC for "undue delay" in approving GMO products for a four-year period ending in 2003<sup>32</sup> and on the other accusing a number of EC member states of maintaining unjustified bans on genetically modified products already found safe by the European scientific committees.<sup>33</sup> Indeed, the justification of the six European states that scientific results were not "convincing" and needed further evaluation before allowing the

<sup>22</sup> Report of the Panel, EC-Biotech at ¶ 4.163 (cited in note 11).

The complainants accused the EU on two grounds: a general complaint related to the its incapacity to consider or complete the approval of certain GMOs under Community legislation; and a specific and more substantial complaint related to the obligation to provide scientific justification for maintaining the alleged ban.

<sup>&</sup>lt;sup>24</sup> Id at ¶¶ 4.220-4.221.

<sup>&</sup>lt;sup>25</sup> Id at ¶ 4.222.

SPS Agreement, Art 5.6 (cited in note 12) (defining "non-necessary" as "more trade restrictive than required").

Id at Art 2.2 (defining "not science-based" as "maintained without sufficient scientific evidence").

<sup>&</sup>lt;sup>28</sup> Report of the Panel, *EC*–*Biotech* at 1068 (cited in note 11).

Safeguard measures are trade-restrictive measures for the sale or use of GMOs that EC member states may adopt on a provisional basis, even if those products have already received consent for introduction into the European market. At the time of the dispute, the safeguard was laid down in Council Directive 90/220, Art 16 1990 OJ (L117) 15, 20, and Commission Regulation 258/97, Art 12, 1997 OJ (L 043) 1, 6.

<sup>30</sup> The six European states concerned are Austria, France, Germany, Greece, Italy, and Luxembourg.

Report of the Panel, EC-Biotech at ¶ 4.467 (cited in note 11).

<sup>32</sup> Id at 1068 (stating that the suspension of the approval procedure produced a de facto general moratorium inconsistent with the provisions of Article 8 and Annex C(1) of the SPS Agreement).

<sup>33</sup> Id at ¶ 4.602.

import of these products was not upheld by the Panel, which found no GMO case where scientific evidence was insufficient to perform an adequate risk assessment.<sup>34</sup>

### C. The Role of Article 5.7 with Respect to Article 5.1 of the SPS Agreement

Despite the fact that the Panel managed to bypass substantial questions on the compatibility between European legislation on GMOs and WTO rules<sup>35</sup> and finally concluded by faulting the EC only on the procedural ground of "undue delay," some important issues of a substantive nature emerged at a variety of levels. The first substantive issue is the tension between a state's sovereign right to apply the level of protection it deems appropriate for its citizens on the one hand and the need to harmonize state practices by means of some neutral standard—science being the presumptive candidate—on the other. The second issue concerns the boundary between science and non-science, or "pertinent available information" under Article 5.7. The third and most important issue raised by EC–Biotech concerns the probative value of all pertinent information with respect to science.

To address these questions, we should begin by understanding why and how the EU invoked the precautionary principle in claiming that scientific evidence was insufficient. After all, some risk assessments had already been performed on certain GMOs and had concluded in favor of their safety. The complainants argued that since the EC's measures amounted to a ban, and since there was no reason for concern about these products, the EC's conduct was *not* rationally or objectively based on risk assessment, contrary to Article 5.1.<sup>36</sup>

The European legislation on GMOs contains the so-called "safeguard clause," which integrates the precautionary principle by allowing European states to derogate from the Commission's final approval of GMOs. Under the safeguard clause, member states may provisionally restrict GMOs' sale and use even after the Commission allows the introduction of certain GMOs into the European market. The European safeguard clause is compatible with the SPS Agreement for two reasons. As determined by the Appellate Body in the EC-Hormones case, Article 3.3 of the SPS Agreement confers upon WTO member states the right to choose their own level of protection, including a higher level

<sup>34</sup> See generally id.

Report of the Panel, *EC–Biotech* at 1067 (cited in note 11).

The requirement that SPS measures be "based on" risk assessment has been interpreted in other cases by the Appellate Body to be a substantive requirement that there be a rational or objective relationship between SPS measures and risk assessment. See Report of the Panel, *EC-Hormones* at ¶ 186 (cited in note 11); Report of the Appellate Body, *Japan–Agricultural Products* at ¶ 84 (cited in note 16).

<sup>&</sup>lt;sup>37</sup> Council Directive 90/220, Art 16 (cited in note 29).

of protection than that established by international standards.<sup>38</sup> Furthermore, Article 5.7 of the same agreement considers that "in cases where relevant scientific evidence is insufficient, a Member may *provisionally* adopt sanitary or phytosanitary measures."<sup>39</sup> But can Articles 3.3 and 5.7 override the requirement set out in Article 5.1 to base SPS measures on risk assessment?

An extensive part of the proceedings in *EC-Biotech* was devoted to precisely this point. Its discussion was undertaken as a matter of legal procedure. The issue was whether the complainants had to make their prima facie case on the basis of Article 5.1, as they themselves requested, or on the basis of Article 5.7, which was instead invoked by the EC. Since both are considered justification for protection measures under Article 2.2,<sup>40</sup> the EC called for a parallel: Inasmuch as Article 3.3 of the SPS Agreement granted member states the autonomous right to set their chosen standards of protection,<sup>41</sup> it was an autonomous right—and not an exception—for each member state to take precautionary actions under Article 5.7. According to this view, Article 5.7 gave precautionary actions the same legitimacy as Article 5.1 gave risk-based actions. As a matter of legal procedure, this would have implied that the complainants present their prima facie case of inconsistency on the basis of Article 5.7.

The Panel agreed with the EC's position and held:

[I]f a challenged SPS measure was adopted and is maintained consistently with the four cumulative requirements of Article 5.7, the obligation in Article 5.1 to base SPS measures on a risk assessment is *not* applicable to the challenged measure. Conversely, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7, the aforementioned obligation in Article 5.1 is applicable to that measure, provided there are no other elements which render Article 5.1 inapplicable.<sup>42</sup>

This interpretation set an important precedent for the precautionary principle within the WTO legal framework, conferring upon it the status of an *autonomous right*. Concerning the *EC-Biotech* case, this interpretation blessed the EC's invocation of the precautionary principle under Article 5.7, *in spite of* the conclusions of risk assessments. It therefore fell to the complainants to prove that there was not "insufficient scientific evidence" in this case and, once they

In the *EC–Hormones* case, the Appellate Body reversed the previous Panel finding on the same case that setting higher standards of protection represented an exception to the general objective of the SPS Agreement to promote international standards harmonization: "[The] right of a Member to establish its own level of sanitary protection under Article 3.3 of the SPS Agreement is an *autonomous* right and not an 'exception' from a 'general obligation' under Article 3.1." Report of the Appellate Body, *EC–Hormones* at ¶ 172 (cited in note 11).

<sup>&</sup>lt;sup>39</sup> SPS Agreement, Art 5.7 (cited in note 12) (emphasis added).

<sup>40</sup> See Section II.A.

<sup>&</sup>lt;sup>41</sup> Report of the Appellate Body, EC-Hormones at ¶ 172 (cited in note 11).

Report of the Panel, EC-Biotech at ¶ 7.2997 (cited in note 11) (emphasis added).

had discharged the burden of proof, it would have fallen to the EC to provide evidence for its claim of "insufficient scientific evidence."

But proceedings did not ultimately go this way. The *EC-Biotech* Panel failed to follow the logical implications of its own findings and decided to review the prima facie case of the complainant under Article 5.1.<sup>43</sup> This choice was explained as a matter of legal procedure: Since the two articles applied to exclusive situations (one of sufficient and the other of insufficient scientific evidence), if the European safeguard measures had been found consistent with Article 5.1, the Panel held, there would have been no need to assess their consistency with Article 5.7.<sup>44</sup> However, precisely because of this exclusivity between Articles 5.1 and 5.7, the opposite reasoning would have been equally valid: If the safeguard measures had been found consistent with Article 5.7, then there would have been no need to analyze further their consistency with Article 5.1.

What then is the real difference between the two legal procedures? I shall explain that, in practical terms, given the vision of mainstream science maintained by the Panel and confirmed by previous WTO jurisprudence on similar cases, the difference is negligible. Theoretically, if the WTO's vision of mainstream science changed, the difference between adjudication under Article 5.1 and under Article 5.7 could be substantial.

#### III. LEGAL AND SCIENTIFIC STANDARDS OF PROOF

The *EC-Biotech* Panel concluded that Articles 5.1 and 5.7 of the SPS Agreement applied to two mutually exclusive situations: cases with sufficient scientific evidence and cases with insufficient scientific evidence.<sup>47</sup> The mutual exclusivity of the two articles implies that, in theory, cases under either article should have equivalent legal procedures. However, the *EC-Biotech* Panel upheld the definition of Article 5.7 as "a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence." This description of Article 5.7 suggests that, in practice, cases under the two different articles might not receive equal treatment. Indeed, in terms of the relative probative values of science and precaution, science, corroborated by

<sup>43</sup> Id at ¶ 4.620.

<sup>44</sup> Id at ¶ 7.3006. This choice was explained as a matter of legal procedure. In fact, the Panel held that if the safeguard measures had been found consistent with Article 5.1, there would have been no need to assess their consistency with Article 5.7, given their exclusivity; that is, neither article takes precedence over the other.

<sup>45</sup> See Section III.B.

<sup>46</sup> See Section V.B.

Report of the Panel, EC-Biotech at ¶ 7.3006 (cited in note 11).

Report of the Appellate Body, *Japan–Agricultural Products* at ¶ 80 (cited in note 16).

a risk assessment in the form of "sufficient scientific evidence," certainly has an advantage over precaution, marked by "insufficient scientific evidence." After all, what is more "evident" than science?

To answer this question, we should first distinguish precaution ("insufficient scientific evidence") from science ("sufficient scientific evidence"), before identifying the consequences this distinction has on the relation between *scientific* evidence and *legal* evidence.

To begin with, the wording of Article 2.2 rephrases the essence of the two realms denoted by Articles 5.1 and 5.7 as "scientific principles" on the one hand and "available pertinent information" on the other.<sup>49</sup> This rephrasing deprives the notion of "insufficient scientific evidence" of its *scientific* and *evident* nature, creating a problem that is both *scientific*<sup>50</sup> and *legal*.<sup>51</sup>

### A. The Relationship between Sufficient Scientific Evidence and Adequate Risk Assessment

The wording of the SPS Agreement conveys the idea that only scientific evidence that is "sufficient" remains scientific, whereas scientific evidence that is insufficient loses its scientific character and becomes "available pertinent information."

But what makes scientific evidence insufficient? According to the Appellate Body Report in *Japan–Apples*,<sup>52</sup> which the *EC–Biotech* Panel followed, "relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate risk assessment."<sup>53</sup>

In the *EC-Biotech* case, assessments of the risk entailed by certain GMOs were already available, therefore providing "sufficient scientific evidence." But we know that the EC actually claimed to have "insufficient scientific evidence" *despite* the availability of those risk assessments. If the ability to perform an "adequate risk assessment" is the bright line between the two situations, how could the EC invoke the precautionary principle? In terms of legal procedure, we already know the answer; but in terms of legal substance, this creates a true

<sup>49</sup> See Section II.

<sup>50</sup> See Section III.A.

<sup>51</sup> See Section III.B.

World Trade Organization, Report of the Appellate Body, *Japan–Measures Affecting the Importation of Apples* ¶ 179, WTO Doc No WT/DS245/AB/R (Dec 10, 2003) (*Japan–Apples*).

<sup>53</sup> Id at ¶ 179.

Report of the Panel, EC-Biotech at ¶ 4.216 (cited in note 11).

<sup>55</sup> Id at ¶ 4.379.

<sup>&</sup>lt;sup>56</sup> Id at ¶ 7.2939.

<sup>57</sup> See Section II.C.

problem, whose origins are to be found in the epistemology of science maintained by the Panel.

According to the Panel's view, an "adequate risk assessment" is one that follows the standards contained in Annex A(4) of the SPS Agreement and is able to demonstrate the existence of a risk in terms of the probability, and not just possibility, so that an event may induce another event. Going back to the definition of insufficient scientific evidence as one where "the body of available scientific evidence does not allow... the performance of an adequate risk assessment, Go the correspondence between the "adequacy" of risk assessment and the "sufficiency" of scientific evidence can be summarized through the following syllogism: Risk assessment is adequate when it builds on the Annex A(4) standards; to follow Annex A(4) standards implies that scientific evidence is sufficient; therefore, an adequate risk assessment is one where scientific evidence is sufficient.

The epistemological problem with this interpretation is that the transitivity between the adequacy of risk assessment and the sufficiency of scientific evidence is incorrect: Risk assessment is certainly the defining feature of "science," but it does not provide any guarantee of producing sufficient scientific evidence. Indeed, it is a matter of ontological and epistemological correctness to distinguish between the information that is processed in a risk assessment (input) and the conclusions that can result from it (output). As with any decision, the evidence is not produced by facts (the collection of sufficient data), but by the moment when knowledge is closed. 61 When this does not happen, for example when a cause-effect relationship between two events cannot be established, knowledge remains open to alternative possible conclusions, which in any case are the product of a scientific analysis. This means that sufficient scientific evidence is not the inevitable product of processing all the information relevant and available to a subject, but is the product of interpretation. Most importantly, scientific evidence does not lose its scientific character if it is inconclusive as to the existence of a risk.

As maintained by the Appellate Body in the *Australia–Salmon* case, the risk assessed in the court should be a probable and not a possible one, for it must be ascertainable and verifiable and must allow for an objective risk assessment. World Trade Organization, Report of the Appellate Body, *Australia–Measures Affecting Importation of Salmon* ¶ 123, WTO Doc No WT/DS18/AB/R (Oct 20, 1998) (*Australia–Salmon*).

This position is confirmed by the Appellate Body report in *Japan–Apples*, stating that the adjective "insufficient" attached to scientific evidence indicates a relational concept, as it is "adequate" for risk assessment. Report of the Appellate Body, *Japan–Apples* at ¶ 179 (cited in note 52).

<sup>60</sup> Id at ¶ 179 (emphasis added).

Brian Wynne, Establishing the Rules of Laws: Constructing Expert Authority, in Roger Smith and Brian Wynne, eds, Expert Evidence: Interpreting Science in the Law 23, 44–45 (Routledge 1989).

### B. Legally Locked-In Scientific Evidence

The previous paragraph has shown that the legal operation of linking the sufficiency of scientific evidence to the adequacy of risk assessment is not supported by a modern understanding of the epistemology of science. <sup>62</sup> This flawed epistemology applies even less to the case of GMOs, where the supporting sciences of biology and ecology are by nature anything but complete, objective, or undisputed. <sup>63</sup>

The dichotomy between science and precaution, between "sufficient scientific evidence" and "insufficient scientific evidence," creates a serious legal problem. It is common knowledge that before a court (or a legal panel such as the WTO), the parties in dispute must provide some evidence in support of their case. Putting aside the question of allocating the burden of proof,<sup>64</sup> the issue is establishing which obligations are relevant to proving a case of inconsistency. Indeed, determining whether Article 5.1 or Article 5.7 is the controlling provision affects the evidentiary burden of the parties.

In case of litigation, the defendant must provide scientific explanation in support of its stricter protection policies under Article 2.2 of the SPS Agreement. Legally, this justification corresponds to providing scientific evidence of some threat to human or animal health or to the environment, which is meant to qualify a situation of "necessity" under Article 5.1. For cases where no evidence of risk is available—in other words, cases of insufficient scientific evidence—Article 5.7 considers another kind of justification, which is apparently "less scientific" because it is not supported by conclusive evidence, but only by "available pertinent information," calling for "precaution" instead of strict necessity.

These preliminary considerations already suggest that, even if the fundamental characteristic of legal evidence is reasonableness and rationality, the kind of science intended by the Panel (always sufficient, complete, and objective) is more apt, if not automatically apt, to provide evidence for a case than is precaution. Indeed, the kind of rationality behind the latter is much less evident and much more difficult to disclose before a court. In short, science, if conclusive and temporarily undisputed, creates a legal advantage for whomever wants to use it as evidence for his case and, conversely, imposes a huge burden

<sup>62</sup> For further discussion on this point, see generally Elisa Vecchione, Science for the Emironment: Examining the Allocation of the Burden of Uncertainty, 2 Eur J Risk Reg 227 (2011).

<sup>63</sup> Interview with Antoine Méssean, Head of Unit, Ecological Impacts of Innovations in Crop Production, Institut National de la Recherche Agronomique (INRA) France, in Paris, France (Apr 16, 2008).

<sup>64</sup> Indeed, there is nothing to discuss, since legal procedure prescribes that it falls to the complainant to form a prima facie case of inconsistency between the defendant's behavior and his obligations. See Section II.

on whomever wants to provide a case to the contrary. This is the characteristic of scientific knowledge per se and these are its legal implications when used in a tribunal. This situation risks automatically translating scientific standards of proof into legal standards of proof. If "science" means only complete scientific knowledge establishing cause-effects relationships in factual terms through risk assessment, then there could not be any competing legal evidence, much less any based on a case of "insufficient scientific evidence."

This risk explicitly materialized in the *EC—Biotech* case, which is why there would have been practically no difference if the Panel had maintained its own findings and reviewed the complainant's case on the basis of Article 5.7 instead of Article 5.1.66 Indeed, if that had been the case, the complainants would have had to demonstrate that scientific evidence was *not* insufficient (in other words, that it was sufficient) and, as a second step, that evidence would have rationally called for a different (in other words, zero or less stringent) level of protection.

If we retain the vision of science emerging from WTO jurisprudence and confirmed by the *EC-Biotech* Panel, we can conclude that this burden is relatively easy to discharge. Not only risk assessments but also international standards, such as the Codex Alimentarius, <sup>68</sup> were in place in the case of *EC-Biotech* to demonstrate that scientific evidence was in fact sufficient. The burden of proof would have then shifted to the defendant, which would have had to prove that the scientific evidence was, on the contrary, insufficient. This proof requires disrupting already existing international standards or already available risk assessments by providing *new* scientific evidence. But this very condition means that the justification for precautionary actions is difficult to exercise. First, the evidence required is burdensome in scientific terms because it corresponds to a paradigm shift. Second, this condition relies on the requirement in Article 5.1, despite the fact that the case of precaution should instead be made on the basis

The science used for informing legal trials and instructing policy decisions—which are eventually contested within legal trials—is a form of knowledge that is "frozen," contingent upon consensus of the majority of the scientific community. This means that it can be contested, but to do so imposes a heavy burden on whomever wants to confute the state of the art.

<sup>66</sup> See Section ILC

<sup>67</sup> Specifically, as per the Appellate Body's findings in the Japan–Agricultural Products case, compliance with Article 5.7 was to be determined upon four requirements. Measures shall be: (1) imposed in respect of a situation where "relevant scientific information is insufficient"; and (2) adopted "on the basis of available pertinent information." Members shall (3) "seek the . . . measure accordingly within a reasonable period of time"; and (4) review the . . . measure accordingly within a reasonable period of time." Thus, the complainants would have discharged their burden by simply demonstrating the inconsistency of EU measures with at least one of these requirements. See Report of the Appellate Body, Japan–Agricultural Products at ¶ 90 (cited in note 16).

The Codex Alimentarius is one of the so-called "three sisters" organizations explicitly referred to by the SPS Agreement for providing international standards, guidelines, and recommendations. See SPS Agreement, Annex A, ¶ 3 (cited in note 12).

of Article 5.7—in other words, on the basis of "insufficient scientific evidence." The trap in which the precautionary principle falls is clear: demonstrating "insufficient" scientific evidence through the provision of new, hence "sufficient," scientific evidence. However, even without that, it is unlikely that already available scientific evidence (contained in international standards) will be countered by insufficient scientific evidence or "pertinent available information."

The vicious cycle of incessantly searching for scientific truth is caused by the strict dichotomy maintained between "sufficient science" as the only science and "insufficient science" as something else: less scientific, less evident. And indeed in the actual proceedings the Panel tried to evaluate, with the help of a scientific panel specially appointed for the case, <sup>69</sup> whether the scientific studies conducted by the European states could account for *new* scientific evidence capable of counteracting previous science. As such, new scientific evidence should have been able to demonstrate the existence of a probable rather than just a possible risk. <sup>70</sup> No matter how minimal the risk found, it had to be proven as a matter of fact. In other words, it had to be "ascertainable" in terms of a cause-effect relationship. <sup>71</sup> But this position again dismisses the fact that a case of precaution originates from the exact opposite situation, which is the inability to prove a cause-effect relationship.

<sup>69</sup> A scientific panel was established to distinguish science, truth, and certain information from everything else. However, the recourse to the scientific panel was more a procedural artifice than the expression of a true consciousness of the complexity of the science-law interface. Interview with Eric Schoonejans, Legal Counsel for the delegation of the European Communities to the EC-Biotech dispute, in Paris, France (Sept 1, 2008). The complexity and accuracy of this part of the report is both undeniable and useless to the purpose of legal proceedings. Moreover, the five scientists appointed to the scientific panel were definitely not enough to handle commentaries on more than forty GMOs.

For instance, for the Austrian ban on T-25 maize, the probabilities of specific risks were not reported, just the possibility of risks generally. With respect to the potential adverse effects on human and animal safety, only reservations on risk assessment procedures were advanced, which did not persuasively counsel for the ban's adequacy.

The EC-Biotech panel maintained the Appellate Body findings in the Australian-Salmon case that, if Article 3.3 confers upon a member state the right to set the preferred level of protection, then each member state had, in principle, the right to ban a product even if the risk of dangerous effects from its usage was minimal: "As stated in our Report in European Communities – Hormones, the 'risk' evaluated in a risk assessment must be an ascertainable risk; theoretical uncertainty is 'not the kind of risk which, under Article 5.1, is to be assessed.' This does not mean, however, that a Member cannot determine its own appropriate level of protection to be 'zero risk.'" Report of the Appellate Body, Australian-Salmon at ¶ 125 (cited in note 58).

### IV. A QUESTION OF RIGHTS: HOW TO PROVIDE LEGAL EVIDENCE OF INSUFFICIENT SCIENTIFIC EVIDENCE

The previous Section demonstrates that the dichotomy between science and precaution translates into a dramatic overlap between scientific and legal standards of proof, the standard for both of which is risk assessment. As a consequence of the dichotomy between science and precaution, a perfect and dangerous conceptual match emerges between scientific evidence and legal evidence, while an oxymoron seems to dominate the relationship between uncertainty, in the form of insufficient scientific evidence, and legal evidence. How is it in fact possible to provide evidence of uncertainty?

The consequence of such an approach is that precautionary measures cannot find any defense in case of dispute, simply because the legal issue of providing evidence of a case (in other words, a case of insufficient scientific evidence) is discarded as almost a contradictory operation. But if we suppose that the existence of a right (in other words, the right to set preferable levels of protection under Article 3.3) depends on the ability of the party invoking that right to demonstrate the legitimacy of its conduct, then we might wonder whether this right subsists for the case of precautionary measures.

As in any international organization, within the WTO tension always exists between national states' sovereignty and their international obligations. In the context of SPS measures, the WTO obligation to provide scientific justification for restrictive trade measures is a necessary coordination rule for a multilateral trade system in which each member state has in principle the right to choose its own level of protection. The risk is that SPS measures become a de facto "disguised restriction to international trade" and devolve into the right to undertake unilateral action. How can a balance be struck between this right and scientific obligations?

There is no WTO jurisprudence on science-related disputes clearly defining this relationship. Until the *EC-Biotech* case, WTO jurisprudence had never defined it more than in terms of a unilateral relationship between science and policy, where science served as a pivot for national governments to fine-tune policies according to their degree of risk aversion.

Indeed, the dichotomy between science and precaution makes the relationship between scientific analysis and policy decisions a unilateral one, where the former instructs the latter: Once the risk is set in probabilistic terms—that is, once it has provided scientific justification—the legislator's autonomous right to set the level of protection is reduced to its degree of aversion to this risk. In this sense, the legislator only has the autonomous right to be more or less risk averse, provided there is a risk, established through a cause-effect relationship, justifying its aversion. Therefore, in terms of the *EC-Biotech* case, it is clear that the examination of whether the EC measures were "based on" risk assessment could only be straightforwardly concluded with a negative finding once it was

determined that scientific evidence was sufficient: If the risk assessments already available showed no concern regarding GMOs, and if the studies provided by European states could not amount to scientific findings, the EC ban became "irrational" since it was based on no "objective" relationship<sup>72</sup> with the results of risk assessments.

# V. THE *US-Continued Suspension* Dispute: Opening the Gateway for a New Epistemology of Science at the WTO

Despite the fact that the relationship between scientific obligations and sovereign rights was dismissed in the *EC–Biotech* case, the question remains as to the margin of risk aversion allowed to the legislator to set higher standards of protection than those set by international organizations.

Considering the ideal situation where science is conclusive and complete, we know that there would be no challenge to legitimately setting higher standards of protection. But once scientific evidence is provided, how high can the level of protection be? Or, put differently, if two member states adopt two different levels of protection based on the same scientific evidence, can both be judged to be "based on" risk assessment as required by Article 5.1? What is the maximum difference allowed between their degrees of risk aversion that would keep intact their right to set their own standards of protection?

If the Panel's view of science and precaution in the *EC-Biotech* case prevented any discussion on the relationship between the right to protect and the obligation to provide scientific justification, the *US-Continued Suspension of Obligations in the EC-Hormones Dispute* case of 2008 (*US-Continued Suspension*)<sup>73</sup> made important changes to this point. By dismantling the unilateral treatment of scientific assessment and policy measures for protection pursuant to Article 5.1, the Appellate Body distanced itself from the mainstream view of science—in other words, from the view that scientific conclusions must be complete and objective—that was initially adopted by the Panel. By reversing the most salient findings of the latter, the Appellate Body put forward the idea that on the one hand scientific conclusions may be multiple and equally legitimate, and, on the other, that they may be inconclusive but still legally relevant to corroborate a case of precaution.

<sup>72</sup> See note 36.

World Trade Organization, Report of the Panel, US—Continued Suspension of Obligations in the EC—Hormones Dispute, WTO Doc Nos WT/DS320/R (US) and WT/DS321/R (Canada) (Mar 21, 2008); World Trade Organization, Report of the Appellate Body, US—Continued Suspension of Obligations in the EC—Hormones Dispute, WTO Doc No WT/DS320/AB/R (Sept 19, 2008).

<sup>&</sup>lt;sup>74</sup> Report of the Panel, *US–Continued Suspension* at ¶¶ 7.609–7.611 (cited in note 73).

### A. The Factual Background of the Hormones Dispute

The dispute between the EU and the group composed of the US and Canada on hormone-treated meat is long-standing. It dates back to 1996, when the US and Canada held formal consultations with the EU regarding the latter's legislation covering the ban on six hormones for growth promoting purposes in livestock. The Appellate Body on the original Hormones case (*EC–Hormones*) concluded by faulting the EU for maintaining a ban inconsistent with Article 5.1 of the SPS Agreement. The EU failed to conduct a proper risk assessment that provided evidence of a specific risk from residues in meat treated with hormonal growth promoters.

Later, since the EU failed to comply with the WTO decision on the dispute and did not lift its ban, the US and Canada, pursuant to Article 22.2 of the Dispute Settlement Understanding<sup>77</sup> (DSU), adopted retaliatory measures against the EU in the form of 100 percent *ad valorem* duty on selected food products from European countries. The EU responded by commissioning seventeen new scientific studies to reaffirm its position that there were possible risks to human health associated with hormone-treated meat, given the available scientific data.

In 2003, in conjunction with Directive 2003/74/EC, the EU notified the Dispute Settlement Body that it had brought its previously inconsistent measures into compliance. For the case of the hormone 17 beta-oestradiol, the requirements under Article 5.1 were met by establishing a clear and definite risk, whereas for the other five hormones in question, a temporary ban was invoked under Article 5.7. By virtue of these assessments, the EU asserted that it had fulfilled its WTO obligations and asked for the immediate lifting of the sanctions imposed by Canada and the US in accordance with the provisions of Article 22.8 of the DSU. As the two countries refused to withdraw their retaliatory measures, a Panel was established in February 2005.

Despite the fact that the *US-Continued Suspension* case was premised on the alleged infringement of certain provisions of the DSU, the current dispute settlement text lacks an explicit post-retaliation complaint procedure. This is why the Panel decided to base the proceedings not only on the DSU, <sup>78</sup> but also on

Council Directive 96/22/EC prohibited administering to farm animals substances having a thyrostatic, oestrogenic, androgenic, or gestagenic action, as well as marketing meat from such animals. Council Directive 96/22/EC, 1996 OJ (L 125) 3, 3–8. The six hormones concerned are 17 beta-oestradiol, progesterone, testosterone, zeranol, trenbolone, and melengestrol acetate.

Report of the Appellate Body, EC–Hormones (cited in note 11).

Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Legal Instruments—Results of the Uruguay Round vol 1, Annex 2 A, 1869 UN Treaty Ser 441 (1994).

The Panel held that the US and Canada had violated the DSU by maintaining their retaliatory measures rather than initiating WTO proceedings after the EU had notified the Dispute Settlement Body of the enactment of Directive 2003/74/EC. Report of the Panel, US–Continued

the provisions of the SPS Agreement to determine whether the EC had fully complied with the ruling in the *EC-Hormones* case. This decision, though highly disputable, makes the *US-Continued Suspension* case particularly instructive on the evolution of WTO jurisprudence for science-related disputes.

Whereas the majority of the *EC-Biotech* case revolved around the relationship between Articles 5.1 and 5.7 in determining whether one took precedence over the other,<sup>80</sup> in the *US-Continued Suspension* case, the provisions relevant to the dispute are clear, as are the procedures of the Panel to review the compliance of European studies on 17 beta-oestradiol with Article 5.1 on the one hand, and the compliance of the other studies covering the five remaining hormones with Article 5.7 on the other.<sup>81</sup>

Using this distinction, two different questions were addressed by the *US-Continued Suspension* Panel: Whether the scientific reviews on the hormone 17 beta-oestradiol could account for risk assessment under Article 5.1; and whether, as regards the five remaining hormones temporarily banned based on precautionary considerations, "relevant scientific evidence can *become* insufficient within the meaning of Article 5.7 in the presence of international standards." Therefore, the EC had to demonstrate that previously accepted scientific studies had become outdated either due to new scientific evidence or to new findings raising concerns about the validity of their conclusions. In short, the EC needed to prove that scientific evidence had evolved since the 1998 Appellate Body decision, that it had overridden previous scientific examinations, and that it rationally supported new SPS measures.

#### B. How to Override Scientific Evidence

Conceptually, overriding previous scientific evidence consists of two phases. The first is one of *disruption*, where doubts and concerns are raised for

Suspension at ¶ 7.245 (cited in note 73). See European Parliament and the Council of the European Union, Directive 2003/74/EC, 2003 OJ (L 262) 17. The Panel's decision was then reversed by the Appellate Body. Report of the Appellate Body, US–Continued Suspension at ¶ 736 (cited in note 73).

Tt clearly emerges from the Panel report that the EC had done its utmost to avoid such a situation, probably based on the memory of similar disputes in the past, such as EC-Hormones in 1998 and EC-Biotech in 2006, where friction was evident between the epistemology of science made by the SPS Agreement and its own doctrine on the precautionary principle. See generally Report of the Panel, US-Continued Suspension (cited in note 73).

<sup>80</sup> See Section III.B.

<sup>81</sup> Unlike the EC-Biotech case, where a dispute settlement panel was requested, in the US-Continued Suspension case the complainant (the EC) initiated compliance panel proceedings, where it was in its interest to prove (and determine the relevant provisions for its case) that the respondent failed to bring itself into compliance with WTO obligations. Report of the Panel, US-Continued Suspension at ¶ 4.32 (cited in note 73).

<sup>82</sup> Id at ¶ 7.619 (emphasis added).

different reasons, such as the scientific approach, methodologies, disciplines included, objective of the study, and so on. The second is one of *counter-evidence*, where the scientific void is replaced by new concluding evidence, confirming the errors, incompleteness, and inconclusiveness of previous scientific studies. In the *EC-Biotech* case, we saw that the Panel was concerned only with new scientific evidence despite the fact that the case for the GMO ban had been built upon precautionary justifications: It bypassed the first stage and asked only for counter-evidence. But in the *US-Continued Suspension* case, the two phases were kept separate for the first time according to whether the parties based their case upon Article 5.1 or 5.7. Indeed, the question emerged in clear terms whether the occurrence of the first stage alone, that of disruption, is sufficient to provide legal evidence for a case of insufficient scientific evidence.

1. Article 5.1 of the SPS Agreement: The appropriateness of risk assessment.

In examining whether the new European studies accounted for scientific evidence, the Panel sought to determine "whether scientific evidence supported the conclusions in the Opinions provided by the EU." The reason for putting the question of sufficient scientific evidence in those terms is that, with the favorable presumption that European analysis amounted to a risk assessment, the situation was, unlike in the *EC-Biotech* case, one of competing risk assessments (that of the Joint Expert Committee on Food Additives and other "old" safety assessments, and that of the EU), that were both supposedly conclusive. Therefore, the Panel went on to determine whether the new risk assessment provided by the EU could directly challenge the old ones through scientific counter-evidence.

The procedure consisted of a legal examination of whether the EU risk assessment was "appropriate to the circumstances" as prescribed by Article 5.1, 85 which actually translated into testing whether the transformation of the input (scientific evidence) into an output (conclusions) occurred in the right way. The Panel appointed a scientific panel to determine whether it would have been rational to achieve certain results starting from certain elements. The approach was exactly the same as in the *EC-Biotech* case. The Panel maintained that the

<sup>83</sup> Id at ¶ 7.552

The US's position was based on different safety assessments of national and international origin, such as those of the US Food and Drug Administration, the Codex Alimentarius Commission, and the Joint Expert Committee on Food Additives. Id at ¶ 4.85.

The Panel agreed with the reasoning of the Panel in *Japan–Apples* that "the scientific evidence which is being evaluated must support the conclusions of the [risk assessment]. Therefore, if the conclusions of the risk assessment are not sufficiently supported by the scientific evidence referred to in the [risk assessment], then there cannot be a risk assessment appropriate to the circumstances, within the meaning of Article 5.1." Report of the Panel, *US–Continued Suspension* at ¶7.538 (cited in note 73).

relationship between the adequacy of risk assessment and the sufficiency of scientific evidence is a matter of procedural and linear evolution from empirical evidence to theoretical probabilities. In this view, scientific controversies cannot exist or should be easily settled. Given this view, it is not surprising that the same overlap between scientific standards of evidence and legal standards of evidence occurred as had occurred in the *EC-Biotech* case. Indeed, in its attempt to obtain *objective* information from scientific experts, the Panel finally translated the supposed objectivity of science from laboratories to the courtroom and concluded that the EC ban on 17 beta-oestradiol was not based on a risk assessment "appropriate to the circumstances."

The simplicity of the Panel's interpretation of Article 5.1 was sharply overturned by the Appellate Body. The Appellate Body confirmed the drawbacks of searching for an objective science that sheds light on legal argumentation and decisions. The Appellate Body commented on the Panel's decision to consult scientific experts, saying that "the review power of a panel is not to determine whether the risk assessment undertaken by a WTO Member is correct, but rather to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable."87 In this sense, it continued, "a panel should review whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the scientific evidence relied upon."88 Hence, the appropriateness of risk assessment should not be judged on objectivity, but on the coherence of its reasoning and the rigor of its scientific methodologies, which refer to a legal operation rather than to legal faith in scientific advocacy. Given this interpretation, the Appellate Body overturned the Panel's previous findings and concluded that the European study on 17 beta-oestradiol amounted to a risk assessment.89

2. Article 5.7 of the SPS Agreement: How to provide legal evidence of insufficient scientific evidence.

The question of whether the temporary ban imposed by the EC on five hormones was justifiable because of "insufficient scientific evidence" pursuant to Article 5.7 was, as expected, a harbinger of controversy.

We saw that the *EC-Biotech* dispute clearly revealed the difficulty of justifying SPS measures according to the precautionary principle. And, indeed, to provide legal evidence of insufficient scientific evidence seems almost a

<sup>86</sup> Id at ¶ 7.573.

<sup>87</sup> Report of the Appellate Body, US-Continued Suspension at ¶ 590 (cited in note 73) (emphasis added).

<sup>88</sup> Id at ¶ 591 (emphasis added).

<sup>89</sup> Id at ¶ 619.

contradictory process, all the more so when it involves disrupting previously accepted scientific knowledge. This is also true in the *US–Continued Suspension* case, in which numerous studies and reports from international scientific organizations responsible for food quality standards<sup>90</sup> had raised no concerns until then about the hormones in question used as growth-promoting agents in livestock.

The core question of the proceedings as set by the Panel was to what extent "relevant scientific evidence can *become* insufficient within the meaning of Article 5.7 in the presence of international standards." First, the Panel revised the meaning of "insufficient scientific evidence," confirming previous jurisprudence that the qualification of insufficient was to be given with respect to the capability of performing risk assessment. Specifically, insufficient scientific evidence was to be judged retrospectively on the *adequacy* of the risk assessment. The Panel held that a risk assessment was adequate when it was complete and had established a cause-effect relationship between an event and an outcome in terms of risk. If the risk assessment was not adequate, then scientific evidence should have been found insufficient to fully reveal "the potential for the identified adverse effects."

Decisions in previous science-related trade disputes have never before stated that precautionary measures are justified in cases where risk assessment fails to establish a cause-effect relationship. In addition to its novelty, this interpretation is the closest to the most common international formula of the precautionary principle: the lack of full evidence of cause-effect relationships on the one hand, and the requirement to provide some tentative scientific explanation of the possibility of a severe risk on the other, are indeed the most important tenets of the principle. Therefore, the question turned out to be whether the impossibility of concluding on the evidence of a risk raised by the European inquiries could be retained as legal proof that international scientific standards had become outdated. What would have made previous cause-effect relationships unsustainable?

<sup>&</sup>lt;sup>90</sup> See note 84.

Panel, US-Continued Suspension at ¶ 7.597 (cited in note 73) (emphasis added).

The Panel held the Appellate Body's interpretation in the Japan-Apples case that "relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement." Id at ¶ 7.598. See note 52.

<sup>&</sup>lt;sup>93</sup> Report of the Panel, US-Continued Suspension at ¶ 7.507 (cited in note 73).

<sup>94</sup> Id at ¶ 7.628.

<sup>95</sup> See generally David Freestone and Ellen Hey, Implementing the Precautionary Principle: Challenges and Opportunities, in Freestone and Hey, eds, The Precautionary Principle and International Law 249 (cited in note 6)

According to the Panel's interpretation, the complainant should have shown "a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge" contained in international standards. He acritical mass, as later recognized by the Appellate Body, represents a paradigm shift in the scientific community. In other words, it is a requirement to provide something close to sufficient scientific evidence, which again confirms the presence of a locked-in situation where precautionary measures are finally justified upon grounds of scientific conclusiveness instead of scientific uncertainty.

When the EC appealed to the Appellate Body and raised this very concern, the Panel's interpretation was overturned. In the Appellate Body's words:

Limiting the application of Article 5.7 to situations where scientific advances lead to a paradigm shift would be too inflexible an approach. WTO Members 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. We are referring to circumstances where new scientific evidence *casts doubts* as to whether the previously existing body of scientific evidence still permits of a sufficiently objective assessment of risk.<sup>97</sup>

In this sense, the Appellate Body implicitly acknowledged the existence of two phases in scientific research, one of disruption and one of counter-evidence. Even if not conclusive, the former has the potential to provide some evidence, scientific and then legal, of a threat, which means the results of previous scientific analysis are now outdated and no longer reliable.

### C. Questions Left Open

The findings of the Appellate Body Report on the *US–Continuous Suspension* case paved the way for a new epistemology of science at the WTO.

First, with respect to Article 5.1, the Appellate Body destabilized the unilateral relationship between scientific evidence and legal evidence by specifying that the scientific "objectivity" pursued in laboratories translates into the search for "coherence" in the courtroom. Therefore, it implicitly acknowledged that there is no unique rationality between processing scientific data and drawing conclusions about the process. The legitimacy of scientific interpretations is tested according to their coherence. Second, once the separation between legal and scientific standards of evidence has been determined, the Appellate Body broke the coterminous application of sufficient

Report of the Panel, US-Continued Suspension at ¶ 7.648 (cited in note 73).

<sup>97</sup> Report of the Appellate Body, US-Continued Suspension at ¶ 703 (cited in note 73) (emphasis added).

<sup>98</sup> See Section V.B.

scientific evidence and sufficient legal evidence and, conversely, between insufficient scientific evidence and insufficient legal evidence.

Without these two fundamental changes in the epistemology of science, the issue of providing legal evidence for a case of insufficient scientific evidence would have never been raised as relevant for the application of the precautionary principle within the WTO legal framework; the issue would have persisted in the form of providing sufficient scientific evidence, with no distinction between the legal and scientific nature of the two standards of proof.

Despite the fact that the Appellate Body deserves credit for setting a new precedent on the relationship between science and law, it did not conclude whether the EU measures were based on scientific risk assessment under Article 5.1, on the one hand, or were justified under conditions of insufficient scientific evidence under Article 5.7, on the other. This is due to the nature of the appeals, which are supposed to re-interpret points of law contained in the Panel's final decisions and not to re-examine existing evidence or to examine new evidence.

Some fundamental questions were then left open. Should the EU have opted for a different level of protection? After having found that the European study on 17 beta-oestradiol amounted to a risk assessment—in other words, that scientific evidence was legally sufficient under Article 5.1—the Appellate Body concluded that it was not in a position to determine whether the conclusions of the scientific studies were objectively "based on" the ensuing policy measures, and recommended that the parties initiate new proceedings on the issue. Therefore, the Appellate Body left open the question of the relation between the standard of evidence and the degree of risk aversion. Once science indicates the probability or the possibility of a risk, what is the maximum degree of risk aversion that would be allowed to governments legitimately to maintain their right to protect human, animal, and environmental health?

Concerning the five other hormones for which the EC invoked the precautionary principle, the Appellate Body failed to determine whether the doubts raised by European studies were enough to form legal proof of insufficient scientific evidence. It follows that the Appellate Body did not even reach the question of whether the corresponding policy measures—in this case, a temporary ban—were consistent with the available scientific evidence, even if insufficient.

Report of the Appellate Body, *US–Continued Suspension* at ¶ 620 (cited in note 73).

It may be presumed that the issue is addressed in terms of proportionality between restrictive measures to trade and scientific evidence, whether sufficient or insufficient. The principle of proportionality, indeed, is not new in cases of scientific warnings. As it is founded on the principles of a common and integrated market, the EU knows this principle well, and it is also included in its doctrine on the precautionary principle. See Commission of the European Communities, Communication from the Commission on the Precautionary Principle COM (2000) 1 final at

#### VI. CONCLUSION

This Article has tried to elucidate some fundamental features of the WTO's legal approach to science-related controversies in order to outline a specific epistemological framework. The purpose of this operation is to determine a precise application of the precautionary principle within the WTO legal framework in order to test whether its applicability is ever admissible.

The *EC-Biotech* dispute is instructive in this sense. It confirms that the only way to bring evidence of a risk before a WTO panel is by demonstrating it in factual terms, which is equivalent not only to performing a risk assessment, but most importantly to performing an "adequate" risk assessment capable of concluding that a risk exists in the form of a cause-effect relationship.

Given this situation, the European defense based on the precautionary principle was annulled, for two reasons: first, because providing evidence of a case of "insufficient scientific evidence" is anything but an easy legal operation, whereas providing evidence of "sufficient scientific evidence" through a risk assessment seems almost automatic; second, because the (non-)evidence of "insufficient scientific evidence" should have counteracted the evidence provided by those risk assessments that had already been performed on certain GMOs.

This situation, which this Article has denounced, corresponded de facto to overlapping scientific and legal standards of proof, where the only legal evidence was that of science, or "sufficient scientific evidence."

If this overlap has prevented any application of the precautionary principle in the WTO legal framework, it also called into question the autonomous right of WTO member states to set their chosen levels of protection. Indeed, if this right can only be maintained when there is hard evidence provided by conclusive scientific findings, it certainly cannot be sustained through precautionary considerations. But even without that, the WTO jurisprudence fails to uncover another important question: Considering an ideal situation where science can always provide justification for protection measures, how dissimilar can the levels of protection chosen by two member states be, given the same science?

This question has never been addressed in WTO disputes because the relationship between the obligation to provide scientific justification and the right to choose among policy measures has never been developed in more than unilateral terms, where the only right for member states was to fine-tune their degree of risk-aversion to the risk in question.

The open and unresolved questions that the EC-Biotech case raised reemerged in different forms in the US-Continued Suspension case. After the US-Continued Suspension Panel's decision confirmed the same approach as in the EC-Biotech dispute, the Appellate Body's findings paved the way for a new epistemology of science at the WTO. It broke the unequivocal relationship between objective science and objective policy by denouncing the gravity of

testing the adequacy of risk assessment in terms of its capability to provide one objective result. Therefore, the Appellate Body not only admitted that different legitimate interpretations of data analysis could exist, but it also sanctioned the separation between the legal and the scientific search for evidence.

This separation occurred in the case of "sufficient scientific evidence," but it opened up the opportunity to discuss whether it is ever possible also to provide legal evidence of "insufficient scientific evidence." The Appellate Body's decision defined precaution as a case where new scientific evidence, even if insufficient because inconclusive, casts doubt on previous scientific assessments so as to invalidate their conclusions.

The Appellate Body's findings on the US-Continued Suspension case make it possible to overcome the contested dichotomy between science and precaution, opening up a way to apply the precautionary principle within the WTO legal framework. However, the question remains open as to the relationship between the right of member states to set their own appropriate standards of protection and the obligation to maintain these according to scientific principles. Indeed, once it had been determined that scientific obligations had been fulfilled to provide a case of "sufficient scientific evidence," the Appellate Body could not conclude whether the EU policy actions (the ban on 17 beta-oestradiol) rationally corresponded to this scientific evidence, nor, for the case of "insufficient scientific evidence" concerning the other hormones under examination, did it conclude on whether the amount of doubt cast by European studies actually invalidated previous scientific analysis on the safety of those hormones. Therefore, despite the fact that the Appellate Body on US-Continued Suspension deserves credit for advancing a far more complex view of science that re-established the autonomy of legal proceedings concerning any case of science, whether conclusive or inconclusive, the complexity raised by the sub-case of precaution nevertheless marked the limitations of science as a neutral arbiter for dispute settlement.