# Insufficiency of Scientific Evidence under Article 5.7 of the SPS Agreement: Some Remarks on the Panel Report in the EC – Biotech Products Case

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THE ARTICLE ADDRESSES THE PROBLEM OF INSUFFICIENCY of scientific evidence in the context of the WTO Agreement on Application of Sanitary and Phytosanitary Measures (SPS Agreement). The analysis is performed in the light of the panel's report in European Communities – Measures Affecting the Approval and Marketing of Biotech Products, a case that for the first time comprehensively analyzed the legal meaning of the notion of insufficiency of scientific evidence. The article recognizes that insufficiency serves under the SPS Agreement a two-fold function - it triggers the application of Article 5.7 but it also constitutes one of the consistency requirements. As far as the issue of applicability is concerned, the article identifies in the report a number of deficiencies of different nature (e.g. inconsistency with the previous case law, logical flows). This article argues that it was more appropriate to view Article 5.7 as a separate set of obligations that is applicable to the exclusion of other science-based provisions of the SPS Agreement. On the substantive level, the article questions the approach of the panel that conceptualizes insufficiency in absolute terms. The article argues that sufficiency implies relativity and its assessment may legitimately differ between scientists operating in different cultural settings. In this context, the article also disagrees with weighing of scientific opinions and deciding which science is better. Finally, the article criticizes the approach of the Biotech panel to the temporal assessment of insufficiency of scientific evidence (i.e. what is the relevant time for the assessment of insufficiency), noting that such approach leads to complicated practical problems.

DANS CET ARTICLE, ON TRAITE DU PROBLÈME DE L'INSUFFISANCE de preuves scientifiques dans le contexte de l'Accord sur l'application des mesures sanitaires et phytosanitaires de l'OMC (Accord SPS). L'auteur procède à cette analyse à la lumière du rapport du groupe spécial dans Communautés européennes — Mesures affectant l'approbation et la commercialisation des produits biotechnologiques, une affaire où, pour la première fois, on a analysé de façon exhaustive la notion d'insuffisance de preuves scientifiques. Dans cet article, on reconnaît que cette insuffisance occupe, en vertu de l'Accord SPS, une fonction à double volet – elle déclenche l'application de l'article 5.7 tout en constituant une des exigences de cohérence. En ce qui a trait à la question de l'applicabilité, l'article identifie dans le rapport un certain nombre de lacunes de différentes natures (par ex. l'incohérence par rapport à la jurisprudence antérieure, l'ordre logique). Dans cet article, on soutient qu'il serait préférable de considérer l'article 5.7 comme un ensemble d'obligations applicables distinct, à l'exclusion d'autres dispositions fondées sur une évaluation scientifique dans l'Accord SPS. Sur le plan du fond, l'article remet en question l'approche adoptée par le comité spécial qui conceptualise l'insuffisance en termes absolus. On soutient en outre que cette notion de suffisance de preuves implique la relativité et que son évaluation peut légitimement varier entre scientifiques qui œuvrent dans des milieux culturellement différents. Dans ce contexte, l'auteur de l'article désapprouve le fait d'évaluer le bien-fondé des opinions scientifiques en vue de déterminer quelle science est la meilleure. Enfin, il critique l'approche adoptée par le comité spécial sur les produits biotechnologiques en matière d'évaluation de l'insuffisance de preuves scientifiques dans son acception temporelle (c'est-à-dire le moment opportun de procéder à l'évaluation de cette insuffisance), faisant observer qu'une telle approche mène à des problèmes pratiques compliqués.

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# Insufficiency of Scientific Evidence under Article 5.7 of the SPS Agreement: Some Remarks on the Panel Report in the EC – Biotech Products Case

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## 1. INTRODUCTION

THE WORLD IS GETTING SMALLER AND SMALLER. The introduction of new technologies, the liberalization of international trade, lower transport and logistics costs, as well as the free flow of capital, truly shape the world of today. In consequence, consumers from different countries can benefit from access to cheaper goods and may select from a wider variety of products. However, the globalization process also raises a number of difficult legal and political problems. People are increasingly concerned with the health risks posed by this new globalized world. Concerns over the use of hormones for bovine growth and milk promotion purposes, "mad cow disease" (BSE) and the marketing of food produced from genetically modified organisms (GMOs), as well as the spread of infectious diseases, are central issues on many political agendas and subject to intense public debate. In response to these fears, national governments have adopted a wide range of regulatory measures aimed at the protection of the environment as well as human health and safety. However, it is also true that these measures are attractive vehicles for protectionism and often take the place traditionally occupied by tariff barriers.

The law of the World Trade Organization (WTO) was designed to address the above-mentioned concerns. The fundamental legal instrument in this context is the SPS Agreement,[1] which is intended to limit the impact of national sanitary and phytosanitary (SPS) measures on the international trade in agricultural goods. The introduction of the SPS Agreement was thus an important development in the international surveillance of SPS regulations. Its predecessor, the Standard Code adopted in 1979 during the Tokyo Round negotiations in 1979, failed to establish an operable system and no single SPS measure had been successfully challenged through the General Agreement on Tariffs and Trade (GATT) dispute settlement mechanism. The main reason for this failure was the nature of the

1. *Agreement on the Application of Sanitary and Phytosanitary Measures* (15 April 1994) in *Agreement Establishing the World Trade Organization, Annex 1A,* <http://www.wto.int/english/tratop_e/sps_e/spsagr_e.htm>, 1867 *United Nations Treaty Series* 493 [SPS Agreement].

Code: it was a plurilateral agreement with a limited number of parties that relied the consensus-based dispute settlement process allowing a losing party to block the adoption of a panel decision. This changed with the creation of the WTO. All future Members were expected to accept all agreements under discussion as a single package, which constituted one international treaty. At the same time, the new dispute settlement system was strengthened. It was no longer possible for one party to obstruct the adoption of a final decision, since the rejection of the panel ruling required the unanimity of all WTO Members.

As will be discussed below, the primary goal of the SPS Agreement is to promote the harmonization of SPS measures. In all cases where WTO Members deviate from international standards, measures are expected to be sufficiently supported by scientific evidence. This requires WTO Members to ensure that their SPS measures have a scientific basis and are not maintained without sufficient scientific evidence. The general obligation is translated into a more specific requirement of scientific risk assessment as a basis for an SPS measure. It is legitimate to say that the SPS Agreement employs science as a mechanism for eliminating "unnecessary" restrictions to international trade, by requiring a certain degree of rationality from domestic regulators. This obviously goes beyond the traditional WTO principle of non-protectionism, as it aims at the general elimination of obstacles to international trade, irrespective of whether or not they have a protectionist character.

At the same time, the SPS Agreement also recognizes that WTO Members frequently act in the absence of conclusive or reliable evidence. This possibility is contemplated by Article 5.7, which allows a Member to adopt and maintain SPS measures in the absence of the scientific evidence necessary for the performance of an adequate risk assessment. However, WTO Members willing to take advantage of this option are expected to comply with certain requirements. For example, such a measure must be provisional and based on pertinent information, and the WTO Member needs to actively seek to acquire new scientific data. Not surprisingly, this very laconic language in the SPS Agreement proved to be difficult to apply. What exactly triggers the application of the disciplines provided by Article 5.7? What does "insufficient scientific evidence" mean? Is it an absolute or a relative benchmark? What is the difference between scientific evidence and pertinent information? What is the legal meaning of the provisionality requirement?

The purpose of this article is to address some of the above questions. Due to the complexity of the issues arising under Article 5.7, the discussion is limited to one specific part of the provision.[2] Thus, the article focuses on the first and probably the most important condition of Article 5.7, which is the insufficiency of scientific evidence. The article recognizes the dual nature of this condition; it separately, rather than jointly, addresses the problems of insufficiency of scientific evidence as a determinant of Article 5.7's applicability, and as a requirement for consistency with Article 5.7. In this context, special attention is given to the panel report in *European Communities - Measures Affecting the Approval and*

2. For an extensive discussion of the other elements of Article 5.7, see Lukasz Adam Gruszczynski, "The SPS Measures Adopted in Case of Insufficiency of Scientific Evidence – Where do We Stand after EC-Biotech Products Case?" in Julien Chaisse and Tiziano Balmelli, eds., *Essays on the Future of the World Trade Organization* (Editions Interuniversitaires Suisses EDIS, 2008) 91–140, <http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=lukasz_gruszczynski>.

*Marketing of Biotech Products*.[3] The reasons for this approach are twofold. First, it is the first panel which comprehensively addressed the condition of insufficient scientific evidence. Second, as this article argues, some of its developments are disappointing and not well reasoned. The article intends to outline those deficiencies.

The article proceeds as follows. The first part briefly reviews the provisions of the SPS Agreement that are relevant to the subsequent discussion on the insufficiency of scientific evidence. This includes the concept of the appropriate level of protection, the scientific basis and formal risk assessment requirements (Articles 2.2 and 5.1), the harmonization obligations (Article 3) as well as the disciplines in Article 5.7. The second part provides a brief summary of the facts in *EC – Biotech Products*, together with the central findings in the panel's report. Against this background, the third part addresses the systemic issue regarding the applicability of Article 5.7, identifying insufficiency as a triggering factor. The fourth part turns to the substantive content of the "insufficient scientific evidence" formula. This analysis is divided into four problematic areas: (i) the relationship between the insufficiency of scientific evidence and uncertainty, (ii) the assessment of insufficiency, (iii) the timing of such assessment and (iv) the role of relevant international standards in the evaluation of insufficiency. The last part attempts to draw overall conclusions on the legal meaning of the first condition of Article 5.7.pass.

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## 2. OVERVIEW OF THE RELEVANT PROVISIONS OF THE SPS AGREEMENT

THE SCOPE OF THE SPS AGREEMENT IS RATHER NARROW, as it only applies to national measures intended to protect the life and health of people, animals and plants in the territory of the importing WTO Member against specified SPS risks.[4] Moreover, according to Article 1.1 of the SPS Agreement, the relevant measures are only those that may, directly or indirectly, affect international trade. Thus, SPS measures with an exclusively internal impact or without an international dimension are not covered by the Agreement.

As noted by the Appellate Body, the SPS Agreement reflects a "delicate and carefully negotiated balance [...] between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings (animals and plants respectively)."[5] More specifically, the SPS Agreement, while promoting free trade through harmonization of SPS measures on the basis of international standards, recognizes the right of each Member

3. Panel Report, WT/DS291/R, WT/DS292/R, WT/DS293/R, European Communities – Measures affecting the Approval and Marketing of Biotech Products (29 September 2006), <http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDFDocuments/t/WT/DS/293R-00.doc > [*Panel Report, EC – Biotech Products]*.
4. The relevant risks include: (i) risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms, (ii) risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs, (iii) risks arising from diseases carried by animals, plants or products, or from the entry, establishment or spread of pests, or (iv) other risks resulting from the entry, establishment or spread of pests. SPS Agreement, *supra* note 1 at Annex A(1).
5. Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, European Communities – Measures Concerning Meat and Meat Products (16 January 1998), <http://www.sice.oas.org/dispute/wto/hormecap.asp> at para. 177. [*Appellate Body Report, EC – Hormones*].

to deviate from them by adopting measures that aim at a higher level of SPS protection, that is, the appropriate level of protection (ALOP).[6] The ALOP as such is defined in the SPS Agreement as the level of protection deemed appropriate by a WTO Member adopting a particular measure.[7] In other words, the ALOP can be understood as the highest level of risk that a country is prepared to tolerate. The preamble to the SPS Agreement explicitly states that this determination is a prerogative of WTO Members.[8] This general statement is reflected in a number of provisions of the SPS Agreement.[9] The case law has also confirmed on several occasions that a WTO Member has considerable discretion in setting its ALOP.[10]

As was already mentioned, one of the major goals of the SPS Agreement is to promote the harmonization of diverse national SPS measures. To this end, the SPS Agreement requires WTO Members to base their SPS measures on international standards, guidelines or recommendations (Article 3.1).[11] Measures that conform to such standards, guidelines and recommendations, are subject to a rebuttable presumption that they are consistent with the relevant provisions of the SPS Agreement and GATT 1994[12] (Article 3.2). On the other hand, WTO Members may introduce and maintain SPS measures that result in a higher level of SPS protection than would be achieved by measures based on relevant international standards, only if there is a scientific justification or as a consequence of the level of SPS protection that a Member determines to be appropriate in accordance with the provisions of the SPS Agreement (Article 3.3).

The requirement of scientific justification is explained in Article 2.2, which demands that SPS measures be based on scientific principles and not maintained without sufficient scientific evidence. The case law interprets this language as requiring an "adequate relationship between two elements, […] between the SPS measures and scientific evidence."[13] The general obligation of Article 2.2 is translated into the more specific duty of basing SPS measures on formal risk assessment (Article 5.1). The SPS Agreement defines risk assessment as the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing WTO Member according to the SPS measures which might be applied, and of the associated potential biological

6. See generally, Lukasz Adam Gruszczynski, "Risk Management Policies under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures," (2008) 3:1 Asian Journal of WTO & International Health Law and Policy 261–308, <http://works.bepress.com/cgi/viewcontent.cgi?article=1002&context=lukasz_gruszczynski>.
7. SPS Agreement, *supra* note 1 at Annex A, para. 5.
8. The sixth paragraph of the SPS Agreement preamble provides that the Agreement "[*d*]*esir*[*es*] to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards [...] *without requiring Members to change their appropriate level of protection* of human, animal or plant life or health[,]" (emphasis added). SPS Agreement, *supra* note 1 at preamble.
9. See, e.g., Articles 3.3, 4.1, 5.4, 5.5, 5.6 and Annexes A(5) and B(3) of the SPS Agreement, *supra* note 1.
10. *Appellate Body Report, EC – Hormones*, *supra* note 5 at para. 124; Appellate Body Report, WT/DS18/AB/R, Australia – Measures Affecting Importation of Salmon (20 October 1998), <http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDFDocuments/t/WT/DS/18ABR.doc> at para. 199 [*Appellate Body Report, Australia – Salmon*].
11. The SPS Agreement identifies the relevant standards, guidelines and recommendations as those coming from the Codex Alimentarius Commission for food safety issues, the World Organization for Animal Health (formerly the International Office of Epizootics) for animal health and life, and the Secretariat of the International Plant Protection Convention for plant health and life.
12. *General Agreement on Tariffs and Trade* (15 April 1994) in *Multilateral Agreement on Trade in Goods, Annex 1A*, <http://www.wto.org/english/docs_e/legal_e/06-gatt_e.htm>, 55 *United Nations Treaty Series* 194, 1867 *United Nations Treaty Series* 187, [GATT 1994].
13. Appellate Body Report, WT/DS76/AB/R, Japan – Measures Affecting Agricultural Products (22 February 1999), <http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDFDocuments/t/WT/DS/76ABR.doc> at para. 73 [*Appellate Body Report, Japan - Agriculture Products II*].

and economic consequences, for example quarantine risks, or as the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs (food borne risks). This evaluation needs to take into account, among other things, scientific evidence, relevant processes and production methods, relevant ecological and environmental conditions (Article 5.2) and, as far as risks to animal or plant life or health are concerned, economic factors (Article 5.3). The case law makes clear that Article 2.2 and 5.1 "should (be) constantly read together. Article 2.2 informs Article 5.1: the elements that define the basic obligations set out in Article 2.2 impart meaning to Article 5.1."[14] This also means that Article 5.1 "'may be seen to be marking out and elaborating a particular route leading to the same destination set out in' Article 2.2."[15]

In all such situations when there is not sufficient scientific evidence to assess SPS risks, WTO Members may still act, however, subject to certain requirements (Article 5.7). The SPS Agreement stipulates that conformity with Article 5.7 requires the satisfaction of four conditions: (i) there needs to be a case of insufficient scientific evidence, (ii) an SPS measure must be based on available pertinent data, (iii) a WTO Member must seek to obtain additional scientific information, and (iv) the measure must be provisional, meaning that it is subject to review within a reasonable period of time.[16] These conditions are of a cumulative nature, meaning all of them need to be met in order to ensure the measure is consistent with Article 5.7.[17]

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## 3. THE EC - BIOTECH PRODUCTS DISPUTE

IN MAY 2003, THE US, CANADA AND ARGENTINA initiated a WTO dispute settlement proceeding against the European Communities (EC) regarding a deadlock in the authorization process for new biotech products at the European level, as well as because of certain measures adopted by EC Member States with respect to already-approved products.[18] More specifically, the complainants alleged that between 1999 and 2003 the EC imposed: (i) a general moratorium on the approval of all new products and (ii) specific moratoria on products which had already been in the authorization pipeline. In addition, the complainants identified a number of safeguard measures, for example, import bans, and the prohibition of marketing of biotech products, adopted by EC Member States Austria, France, Germany, Greece, Italy, and Luxembourg, which barred already-

14. *Appellate Body Report, EC – Hormones*, *supra* note 5 at para. 180.
15. Panel Report, WT/DS18/R, Australia – Measures Affecting Importation of Salmon, adopted as modified by the Appellate Body Report, WT/DS18/AB/R, and DSR 1998: VIII, 3407 (6 November 1998), <http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/WT/DS/18r00.doc>, at para. 8.52.
16. See *Appellate Body Report, Japan – Agricultural Products II*, *supra* note 13 at para. 89; Appellate Body Report, WT/DS245/AB/R, Japan – Measures Affecting the Importation of Apples (26 November 2003), <http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDFDocuments/t/WT/DS/245ABR.doc> at para. 176 [*Appellate Body Report, Japan – Apples]*.
17. See *Appellate Body Report, Japan – Agriculture Products II*, *supra* note 13 at para. 89.
18. Biotech products were defined for the purpose of the dispute as plant cultivars that have been developed through recombinant deoxyribonucleic acid (recombinant DNA) technology. *Panel Report, EC – Biotech Products*, *supra* note 3 at para. 2.2.

approved biotech products from entering the respective national markets. According to the US, Canada and Argentina, all of those measures violated certain obligations of the SPS Agreement, the Agreement on Technical Barriers to Trade (TBT) Agreement[19] and the GATT 1994. In this context, it is also worth noting that the complainants did not challenge the EC regulatory framework for the authorization of biotech products in itself.

The EC authorization system was composed at that time of different pieces of legislation, including the EC Directive 2001/18 and its predecessor, EC Directive 90/220, which regulated the deliberate release into the environment of GMOs, (the term used by the EC for biotech products), and EC Regulation 258/97 regulating novel foods and novel food ingredients. According to this law, the marketing of biotech products on the EC market required prior authorization, which was granted or denied only after a case-by-case evaluation of the potential risks that a biotech product might pose to human health and the environment. National measures prohibiting the use and sale of an approved biotech product were also linked to the EC regulatory approval regime. EC law provided the possibility of adopting so-called provisional safeguard measures in respect of biotech products that had obtained approval for EC-wide marketing. Such an option was available if an EC Member State had scientific evidence that the product constituted a risk to human health or the environment. When a safeguard measure was adopted, a Member was obliged to simultaneously inform the EC Commission, which was supposed to make the ultimate decision regarding whether such action was justified or not.[20]

In its report, issued on 29 September 2006, the panel found that there had been indeed a *de facto* moratorium on the approval of biotech products, which was applied both generally and with respect to specific product applications. However, contrary to the arguments of the complainants, the panel held that neither the general moratorium nor the specific moratoria were SPS measures. Instead, the panel considered them as an "undue delay" in the application of an SPS measure as part of the EC authorization process. In consequence, the panel found that the EC had acted inconsistently with its WTO obligations provided by Article 8 and Annex C of the SPS Agreement. As far as the national safeguard measures were concerned, the panel concluded that, since the relevant scientific committee on the EC level had evaluated the objections raised by the EC Member States and had not found potential risks to human health and/or to the environment, it was not possible anymore for Member States to rely on the exemption of Article 5.7 of the SPS Agreement. The safeguards were therefore inconsistent with the requirements of WTO law.

19. *Agreement on Technical Barriers to Trade* (15 April 1994) in *Multilateral Agreements on Trade in Goods, Annex 1A*, <http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf>, 1868 *United Nations Treaty Series* 120.
20. *Panel Report, EC – Biotech Products*, *supra* note 3 at paras. 2.4-2.5.

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## 4. INSUFFICIENCY OF SCIENTIFIC EVIDENCE AS A DETERMINANT OF THE APPLICABILITY OF ARTICLE 5.7

AS PRESENTED IN SECTION II, ARTICLES 2.2 AND 5.1, on the one hand, and Article 5.7, on the other, establish two distinct sets of obligations. Under Article 2.2 and 5.1, an SPS measure needs to be based on scientific principles and to not be maintained without sufficient scientific evidence. In practical terms, this obligation is explained by the requirement of scientific risk assessment. On the other hand, Article 5.7 allows a Member, in certain situations, to adopt and maintain measures which are not supported by scientific evidence and risk assessment. What is the relationship between these two sets of obligations? When do we apply the disciplines established by Article 2.2 and 5.1 and those established by Article 5.7?

When addressing the above questions, the panel in *EC - Biotech Products* observed that Article 5.7 is applicable in every case where relevant scientific evidence is insufficient.[21] This interpretation mirrored the approach of previous case law, which saw insufficiency of scientific evidence as a triggering factor for the application of Article 5.7.[22] Elaborating on this issue, the *EC - Biotech Products* panel noted that "first it would need to be established that […] measures were adopted in respect of situations where relevant scientific evidence was insufficient."[23] According to the panel, this point results from the textual structure of Article 5.7, which provides the "if-then" rule of conditionality, that is, "if p, then q."[24] On this basis, the panel concluded that in all cases where scientific evidence is insufficient, a WTO Member may adopt a provisional measure. This conclusion allowed the panel to reject the EC argument that the demarcation line between Article 5.1 and, by implication, Article 2.2, and Article 5.7 was the provisionality of the SPS measure.[25] In the context of its analysis, the panel also made a distinction between the issue of applicability and that of consistency. According to the panel, the former addresses the question as to "what triggers the application of Article 5.7," while the latter concerns the conditions that must be fulfilled in order to find an SPS measure consistent with that article.[26] The provisionality element was seen as part of the consistency requirements.

The panel also addressed the question of whether Article 5.7 is an exception from the general obligation in Articles 2.2 and 5.1, or rather an independent right of WTO Members.[27] Although this issue was relevant primarily for the allocation of the burden of proof between the parties to the dispute, it also had, as discussed below, an implication with regard to applicability. The panel

21. *Ibid.* at para. 7.2939, noting that "Article 5.7 is applicable whenever the relevant condition is met, that is to say, in every case where relevant scientific evidence is insufficient."
22. *Ibid.* at para. 7.2940; see also Appellate Body Report, Japan – Apples, *supra* note 16 at para. 184.
23. *Ibid.* at para. 7.2944.
24. *Ibid.* at para. 7.2939. The panel understood the if-then rule of conditionality as follows: "if a certain condition is met (*in casu*, insufficiency of relevant scientific evidence), a particular right is conferred (*in casu*, the right provisionally to adopt an SPS measure based on available pertinent information)."
25. *Ibid.* at para. 7.2939.
26. *Ibid.* at para. 7.2942.
27. As far the allocation of burden of proof is concerned, qualifying a particular provision as a right requires a complainant to establish that a measure is *prima facie* inconsistent with a relevant provision. On the other hand, in case of an exception, it is a defendant who needs to prove that its measure is justified by such an exception.

based its analysis on the test introduced by the Appellate Body in *EC – Tariff Preferences*, which required three cumulative conditions for establishing that a particular provision constitutes a right, rather than an exception. This particularly includes the following elements: (i) the provision permits what would otherwise be inconsistent with an obligation of another provision, (ii) there is a cross-reference between these two provisions, and (iii) one of the provisions suggests that its obligation is not applicable to a measure.[28] Applying the above test, the panel found that Article 5.7 "permits, in certain circumstances, behaviour […] that would otherwise be inconsistent with […] the obligation in Article 2.2[…]."[29] Two other conditions were also met, namely the existence of cross-reference, "except as provided for in paragraph 7 of Article 5[,]" and the exclusion of applicability, "except as."[30] This conclusion was also supported by reference to the case law where such a relationship was already found. The panel identified Articles 3.1 and 3.3 of the SPS Agreement as possible examples in this respect and observed that the language used in Article 3.1 is substantially identical to that of Article 2.2.[31] The panel noted that Article 3.3 was characterized in the case law as a right of a WTO Member and that the consistent interpretation of the SPS Agreement required the same conclusion with respect to Article 5.7.[32] Consequently, Article 5.7 was recognized as a right and it was for the complainants to demonstrate that the challenged SPS measure was inconsistent with at least one of the four requirements set forth in Article 5.7. The same approach was followed with respect to the relationship between Article 5.1 and 5.7. The panel, referring again to the test of *EC – Tariff Preferences*, found that the relationship between Article 5.1 and 5.7 is one of exclusion.[33] Thus, when Article 5.7 permits in certain circumstances behavior otherwise inconsistent with Article 5.1,[34] there is a reference between two provisions,[35] and there is a suggestion that the obligations of one provision are not applicable to such a measure.[36] The panel therefore concluded that, as in the case of Articles 2.2 and 5.7, it is for the complainants to establish a *prima facie* case of inconsistency of the SPS measure with Article 5.7.[37]

The panel report, up to this moment, is more or less clear. Following the logic of applicability, one would expect that after establishing the applicability

28. The Appellate Body stated that "[i]n cases where one provision permits, in certain circumstances, behavior that would otherwise be inconsistent with an obligation in another provision, and one of the two provisions refers to the other provision, [...] the complaining party bears the burden of establishing that a challenged measure is inconsistent with the provision permitting particular behaviour *only* where one of the provisions suggests that the obligation is not applicable to the said measure. Otherwise, the permissive provision has been characterized as an exception, or defence, and the onus of invoking it and proving the consistency of the measure with its requirements has been placed on the responding party." Appellate Body Report, WT/DS246/AB/R, European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries, (7 April 2004) <http://docsonline.wto.org/DDFDocuments/t/WT/DS/246ABR.doc> at par. 88 [*Appellate Body Report EC – Tariff Preferences*].
29. *Panel Report, EC – Biotech Products*, *supra* note 3 at para. 7.2968.
30. *Ibid.* at para. 7.2968. Cf Tomer Broude, "Genetically Modified Rules: The Awkward Rule-Exception-Right Distinction in EC – Biotech," (2007) 6:2 World Trade Review 215–231, <http://ssrn.com/abstract=949623>, who also notes the confusion introduced by the panel in *EC – Biotech Products* between substantive and procedural implications of characterizing particular provision as a right or an exception.
31. Article 2.2 uses the expression, "except as provided for," while Article 3.1 states, "except as otherwise provided for." SPS Agreement, *supra* note 1.
32. *Panel Report, EC – Biotech Products*, *supra* note 3 at para. 7.2967.
33. According to the panel, only if four requirements provided by Article 5.7 are met.
34. *Panel Report, EC – Biotech Products*, *supra* note 3 at para. 7.2993.
35. *Ibid.* at para. 7.2994.
36. *Ibid.* at paras. 7.2995-96.
37. *Ibid.* at para. 7.3000.

of a provision, non-compliance with one of the requirements of that provision does not remove a measure from its scope. This conclusion would also be in line with the distinction made by the panel between applicability and consistency. As rightly observed by the EC with respect to different WTO agreements, the applicability "does not and cannot depend on whether or not [a measure] is consistent with one or other substantive provisions of that Agreement."[38] Thus, a finding that evidence is sufficient should trigger the applicability of the regime provided by Articles 2.2 and 5.1. In consequence, Article 5.7 will be deemed inapplicable, rather than violated. The opposite is also true: a finding in favor of the applicability of Article 5.7 makes the disciplines of Articles 2.2 and 5.1 irrelevant for the assessment of a measure. Of course, in such case, a WTO Member needs to comply with the other three requirements of Article 5.7. However, finding that one of them is not met leads only to an instance of the violation of Article 5.7, and not to a case of inapplicability. If applicability is understood in such a manner, deciding what serves as a triggering factor is of prime importance. Should this factor be provisionality, as argued by the EC, a mere characterization of an SPS measure by a WTO Member as provisional[39] will allow that Member to escape the disciplines of Articles 2.2 and 5.1. Should it be insufficiency of scientific evidence, much more would then be required. This is probably the scenario that the panel had in mind when it rejected the EC argument on provisionality as a demarcation line between the disciplines of Articles 2.2 and 5.1 and those of Article 5.7.

The panel's approach was, however, different. After discussing the applicability of Article 5.7 and making a distinction between applicability and consistency, it added in a footnote that:

> when we refer to applicability of Article 5.7 we address the issue of whether or not the right conferred by the first sentence of Article 5.7 is, in principle, available to a Member. In a specific case a Member must, of course, satisfy the various requirements set forth in Article 5.7 if it wishes to benefit from the right conferred by Article 5.7.[40]

The expressions, "in principle" and "benefit from the right conferred by Article 5.7," appear to be of critical importance. Expanding on these terms, the panel noted that:

> if a challenged SPS measure was adopted and is maintained consistently with the four cumulative requirements of Article 5.7, the situation is "as provided for in paragraph 7 of Article 5" (Article 2.2), and the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence is not applicable to the challenged measure.[41]

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38. Second Written Submission of the European Communities in *EC – Biotech Products*, 19 July 2004, DS291, DS292, DS293, <http://www.gmfreeireland.org/coexistence/WTO/Second_EU_Submission_to_WTO.pdf> at para. 83.
39. Even if the panel had evaluated the provisionality of a measure in a more objective fashion, i.e. through examination of the real intent of a WTO Member, it would have been relatively easy for a WTO Member to escape the scrutiny of the SPS Agreement's scientific provisions.
40. *Panel Report, EC – Biotech Products*, *supra* note 3 at footnote 1807.
41. *Ibid.* at paras. 7.2974-7.2975.

This meant to the panel that the violation of any requirement of Article 5.7 removes a measure from its scope and results in the applicability of Article 2.2. Thus, according to the panel, Article 2.2 is not applicable only if all four requirements of Article 5.7 are met.

The above reasoning of the panel is disappointing. First, note that according to this understanding of applicability, the distinction between applicability and consistency becomes pointless. A measure needs to be consistent with all requirements of Article 5.7 in order to fall within the scope of Article 5.7. Moreover, the approach of the panel also makes its very extensive discussion as to what constitutes a demarcation line between Article 2.2 and 5.7 – provisionality as argued by the EC, or insufficiency of scientific evidence as ultimately found by the panel – meaningless. Does it really matter if a violation of any conditions provided in Article 5.7 results in referring a measure back to Article 2.2? Even if provisionality is supposed to serve as a demarcation line, a provisional SPS measure will need to comply with all the other requirements provided by Article 5.7. A measure that does not meet one of the requirements of Article 5.7, including adoption in the case of insufficiency of scientific evidence, is referred back to Article 2.2 anyway. In other words, Article 5.7 will not be applicable in such a situation. Consequently, according to the panel's interpretation, even if provisionality is the triggering factor, sufficiency will remove a measure from the scope of Article 5.7.

Second, the logic adopted by the panel in *EC – Biotech Products* is even more surprising, if one considers the case law referred to by the panel. Thus, in *EC – Hormones*, when examining the relationship between Articles 3.1 and 3.3 – the relationship which served as a model for the examination of Articles 2.2 and 5.7 in *EC – Biotech Products* – the Appellate Body reversed the panel's conclusion that "the EC by maintaining without justification under Article 3.3 SPS measures which are not based on existing international standards, acted inconsistently with 3.1 of the SPS Agreement."[42] This finding is striking; these two provisions apply to different situations, as Article 3.1 "simply excludes from its scope of application the kind of situations covered by Article 3.3."[43] Similarly, in *EC – Tariff Preferences*, referring to the same finding, the panel confirmed that

> Article 3.3 excludes the application of Article 3.1 of the SPS Agreement. Where a Member has projected for itself a higher level of sanitary protection than would be achieved by a measure based on international standards, Article 3.3 applies and Article 3.1 does not apply at all.[44]

Consequently, if one of the obligations provided by Article 3.3 is violated it does not mean that a measure violates Article 3.1. Articles 3.1 and 3.3 are provisions which govern different situations. Almost identical language in Article 2.2 did not lead the panel to the same conclusion with respect to the relationship between Articles 2.2 and 5.1 and Article 5.7.

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42. *Appellate Body Report, EC – Hormones*, *supra* note 5 at para. 253.
43. *Ibid.* at para. 104.
44. Panel Report, WT/DS246/R, European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries, (1 December 2003), <http://docsonline.wto.org/DDFDocuments/t/WT/DS/246R-00.doc> at para. 7.50. [*Panel Report, EC – Tariff Preferences*].

Why the panel did not follow the logic of Articles 3.1 and 3.3 in *EC – Biotech Products*, is not clear. Perhaps the panel was uncomfortable with the fact that existing case law makes it possible to examine conformity with Article 5.7 without prior assessment of its applicability. Note that the panel in *Japan – Agriculture Products II*, when analyzing the conditions provided by Article 5.7, assumed for the sake of its subsequent analysis that there was insufficient scientific evidence and concentrated its analysis on the third condition, an obligation to seek to obtain the additional information necessary for a more objective assessment of risk. It found that the condition was not met and concluded that the Japanese measure violated Article 2.2 of the SPS Agreement.[45] On appeal, Japan argued that the phrase "except as provided for in paragraph 7 of Article 5" refers only to the first sentence of Article 5.7, which includes the requirement of insufficient scientific evidence. The Appellate Body rejected this argument, finding no textual basis for such limitation.[46] It also confirmed the panel's approach and upheld the finding that the SPS measure violated Article 2.2.[47] A similar approach was taken in *Japan – Apples*. The panel noted that it might have "[begun] examination with either the requirements of the first sentence or of the second sentence of Article 5.7."[48] Although the Appellate Body expressed some reservation with respect to the allocation of the burden of proof in the panel analysis, it did not change the logic of the panel's reasoning in respect to applicability.

Third, note that the panel's reasoning on applicability in *EC – Biotech Products* is much more similar to another part of the Appellate Body Report in *EC – Tariff Preferences*. It is worth citing the relevant passage in full. As noted by the Appellate Body, "the Enabling Clause 'does not exclude the applicability' of Article I:1 in the sense that, as a matter of procedure […], the challenged measure is submitted successively to the test of compatibility with the two provisions."[49] The Appellate Body continued by saying that

> as a matter of final determination–or *application* rather than *applicability*–it is clear that only one provision applies at a time. This is what the panel itself found when, after stating that "as an exception provision, the Enabling Clause applies concurrently with Article I:1," it added "and *takes precedence* to the extent of the conflict between the two provisions."[50]

Note that this is exactly the type of analysis performed by the panel in *EC – Biotech Products*. The SPS safeguard measures were tested for compatibility with two provisions in succession: first an examination under Article 5.1,[51] and then a subsequent analysis under Article 5.7. The final determination specified that only one set of provisions applied at a time, namely Articles 2.2 and 5.1. However, if all the conditions of Article 5.7 had been met, Article 5.7 would have

45. Panel Report, WT/DS76/R, Japan – Measures Affecting Agricultural Products, (27 October 1998), <http://docsonline.wto.org/DDFDocuments/t/WT/DS/76R.DOC> at paras. 8.59-8.61.
46. See *Appellate Body Report, Japan – Agriculture Products II*, *supra* note 13 at para. 90.
47. *Ibid.* at paras. 94 and 143.
48. Panel Report, WT/DS245/R, Japan - Measures Affecting the Importation of Apples, (15 July 2003), <http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDFDocuments/t/WT/DS/245R.doc> at para. 8.214 [*Panel Report, Japan – Apples*]
49. *Appellate Body Report EC – Tariff Preferences*, *supra* note 28 at para. 102.
50. *Ibid.*
51. See *Panel Report, EC – Biotech Products*, *supra* note 3 at para. 7.3396.

taken precedence over the requirement of Articles 2.2 and 5.1, and only this provision would apply. The surprising thing about this unconscious application of the reasoning in *EC – Biotech Products* is the fact that the analysis in *EC – Tariff Preferences* was performed with respect to the provisions that were characterized as providing for a general rule/exception relationship. However, this is not the type of relationship which was identified by the *EC – Biotech Products* panel. As discussed above, the panel made clear that Article 5.7 is a provision that does not operate as an exception to other obligations of the SPS Agreement, specifically Articles 2.2 and 5.1.[52]

Fourth, the conclusion reached by the *EC – Biotech Products* panel seems to be incompatible with the requirements set forth in the test of *EC – Tariff Preferences*. Recall the statement of the Appellate Body that a measure is qualified as a right only if "one of the provisions suggests that the *obligation is not applicable* to the said measure[,] [o]therwise, the permissive provision has been characterized as an exception[,]"[53] while the panel in the same dispute observed "the relationship between exceptions provisions and provisions setting out basic GATT obligations is not one [...] where the application of one provision excludes the application of the other."[54] Note, however, that, under the panel's analysis in *EC – Biotech Products*, actually all of the provisions, Articles 2.2 and 5.1 and Article 5.7, were applicable. The evaluation of any condition of Article 5.7 requires first that this provision be applicable. Consequently, the conceptualization of applicability, which was introduced by the panel, necessitated the conclusion that Article 5.7 is an exception from the general obligation of Articles 2.2 and 5.1, rather than an independent right.

Fifth, the approach of the panel is incorrect from the logical point of view. Imagine a situation where there is insufficient scientific evidence to assess a particular SPS risk. A WTO Member nevertheless adopts a measure and fails to observe one of the remaining conditions of Article 5.7, for example, to review a measure within a reasonable time or to seek to obtain additional scientific information. Under the panel's analysis, such a measure will not be saved under Article 5.7 and, in consequence, it will be sent back to be governed by Articles 2.2 and 5.1. Thus, the WTO Member will violate the requirement in Article 2.2 not to maintain an SPS measure without sufficient scientific evidence in a situation where there is no such evidence.[55] The same is true with respect to Article 5.1. The panel approach causes WTO Members to violate the requirement of risk assessment, even in a situation where existing scientific evidence is insufficient to perform such an assessment.

The author of this article believes that it is more appropriate to view the SPS Agreement as providing for three mutually distinctive paths available to

52. *Ibid.* at para. 7.2969.
53. *Appellate Body Report, EC – Tariff Preferences, supra* note 28 at para. 88.
54. *Panel Report, EC – Tariff Preferences, supra* note 44 at para. 7.44.
55. The panel seems to recognize such a problem, without, however, drawing any conclusions: "in cases where the relevant scientific evidence is insufficient, e.g., because none is available, a Member who wishes nonetheless to take a precautionary SPS measure could not meet the requirement in Article 2.2 to ensure that this measure 'is not maintained without sufficient scientific evidence'." *Panel Report, EC – Biotech Products, supra* note 3 at para. 7.2983.

WTO Members.[56] The first path consists in following international standards, and, strictly speaking, conforming to those standards. In such cases, an SPS measure is presumed to be in conformity with scientific requirements, as well as with the other provisions of the SPS Agreement. If a Member wishes to reach a higher level of SPS protection than would be achieved by measures based on the relevant international standard, or if there is no standard at all, the second path becomes available. In such a case, a WTO Member is required to base its SPS measure on scientific evidence and risk assessment. Finally, the third path applies to all those cases where scientific evidence is insufficient to perform risk assessment. Logically, in such situations a Member cannot be required to follow the scientific requirements of Articles 2.2 and 5.1; it can instead adopt a measure on the basis of pertinent information and observe the other requirements of Article 5.7. The relationship between these paths is one of exclusion, meaning that an SPS measure inconsistent with the provisions applicable to a particular path does not remove it from that path. If a WTO Member decides to depart from international standards, its measure is assessed against those provisions that are relevant for that path, Articles 2.2, 3.1 and 5.1–5.3. Thus, if an SPS measure is not based on risk assessment, this does not mean that the requirement of Article 3.1, to base a measure on international standards, is violated. Along the same lines, where scientific evidence is insufficient, failure to meet some of the requirements of Article 5.7 does not mean that a WTO Member also violates the requirements of Article 2.2, to base a measure on sufficient scientific evidence, and 5.1, to have appropriate risk assessment. Such an understanding of the SPS Agreement is definitively more logical than the one which is present in the current case law. It recognizes Article 5.7 as a right and, at the same time, it is compatible with the test provided in *EC – Tariff Preferences*.

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## 5. INSUFFICIENCY OF SCIENTIFIC EVIDENCE AS A CONDITION OF CONSISTENCY WITH ARTICLE 5.7

AS NOTED ABOVE, THE FIRST CONDITION OF ARTICLE 5.7 serves a twofold purpose. First, it triggers the application of Article 5.7. Second, insufficiency is, together with other requirements, one of the consistency requirements. According to the case law, insufficiency of scientific data exists if "[a] 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."[57] The case law also makes clear that insufficiency under Article 5.7 encompasses both a quantitative and a qualitative dimension. The first one refers to the amount of scientific data relating to a particular SPS problem.[58] The second is less concerned with the size of the scientific body of evidence, but more with its quality and conclusiveness. Using

56. Note that mutual exclusivity refers to available paths to be followed by a WTO Member under the SPS Agreement and not to the exclusivity of circumstances. In a particular case a Member can claim that scientific evidence is insufficient even if a relevant international standard exists.
57. *Appellate Body Report, Japan – Agricultural Products II*, *supra* note 13 at para. 179.
58. See *Panel Report, Japan – Apples*, *supra* note 48 at paras. 7.8 and 8.219.

the words of the Appellate Body, the concept of insufficiency also includes "cases where the available evidence is more than minimal in quantity, but has not led to reliable or conclusive results."[59] The panel, in the same case, was even more explicit when it stated that "[i]t is possible that, in a given situation, a lot of scientific research may have been carried out on a particular issue without yielding sufficiently 'relevant' - within the meaning of Article 5.7 - or reliable evidence."[60] The above indicates that the quality of scientific data plays an independent and important, if not a leading, role in the assessment of insufficiency. Thus, the existence of scientific evidence which does not provide decisive answers or is inconclusive may equally meet the requirement of insufficiency. As will be discussed below, these findings are of fundamental importance when addressing a problem of uncertainty under the SPS Agreement.

The section below evaluates in detail some specific problems that arise under the first condition of Article 5.7.

### *5.1. Insufficiency of Scientific Evidence versus Uncertainty*

The first problem concerns the relationship between the concepts of insufficiency of scientific evidence and scientific uncertainty. Does the notion of insufficiency include uncertainty, or are they two distinct concepts under the SPS Agreement? Before going into the details of the case law, it is worthwhile to look at how the concept of uncertainty is understood in risk science. A brief overview provided by Klinke and Renn summarizes the current state of art in this field and provides a useful typology of uncertainty for the subsequent discussion of the SPS disciplines.[61]

The authors stress that uncertainty is not a monolithic phenomenon. There are different types of uncertainty, which arise in the process of assessing risks, or in other words, there are different components of uncertainty *sensu largo*. The first type of uncertainty results from the nature of science, scientific research and the reality of risk regulation. Science does not provide "true" answers; it rather supplies certain coherent, within a predefined paradigm, and reasoned descriptions of natural phenomena. These descriptions are valid as long as they are not falsified. Epistemic uncertainty is therefore an indispensable feature of every scientific claim. The second type of uncertainty results from the variability problem, that is, the "variation of individual responses to an identical stimulus among the individual targets within [the] relevant population such as humans, animals [and] plants[…]."[62] The variation may result from the target's age, for example, children and elderly people are usually more sensitive, or from the target's sex and individual characteristics, for example diet and metabolism. The third type of uncertainty is caused by systemic and random measurement

59. *Appellate Body Report, Japan – Agricultural Products II, supra* note 13 at para. 185.
60. *Panel Report, Japan – Apples, supra* note 48 at para. 7.9.
61. There are other typologies of uncertainty, the US National Research Council distinguishes between aleatory uncertainty (random variations and chance outcomes in the physical world), epistemic uncertainty (lack of knowledge), indeterminacy (resulting from the choice of risk-generating process) and ignorance (unrecognized uncertainty). See, Paul C Stern, Harvey V Fineberg, eds., *Understanding Risk: Informing Decisions in a Democratic Society* (National Academy Press, 1996) <http://books.nap.edu/openbook.php?record_id=5138&page=R1> at p.107.
62. Andreas Klinke and Ortwin Renn, "A New Approach to Risk Evaluation and Management, Risk-Based, Precaution-Based, and Discourse-Based Strategies," (2002) 22:6 Risk Analysis Journal 1071-1094 at p. 1079.

errors, including problems such as imprecision or imperfection of measurements and extrapolations, for example, from animal data to humans or from large to small doses. The fourth type is caused by indeterminacy, which Klinke and Renn describe as "[r]esulting from a genuine stochastic relationship between cause and effect(s), apparently noncasual or noncyclical random events, or badly understood nonlinear chaotic relationship."[63] Finally, the last type of uncertainty is a consequence of a lack of knowledge that may result from "ignorance, [of] the deliberate definition of system boundaries and hence exclusion from external influences, measurement impossibilities, and others."[64]

The first type of uncertainty is, by its nature, disregarded in the risk analysis. If the scientific risk assessment is to be an operable tool, one needs to assume that science has the capacity to describe and measure the existence of real life phenomena such as hazards, probability and the extent of damages. All the strategies used to address the problem of uncertainty, as discussed below, are based on this assumption. The second and the third type of uncertainty are usually addressed through the application in the process of risk assessment of so-called safety factors, conservative assumptions or worst-case scenario approaches. A safety factor is a figure by which an observed or estimated toxic concentration or dose is divided to arrive at a criterion or standard that is considered to be without effect. In the process of establishing acceptable daily intake (ADI) for a particular substance,[65] the Codex Alimentarius typically applies an overall safety factor of 100, which consists of a safety factor of 10 for diversity within the human population[66] and a safety factor of 10 for extrapolation from animal test results to humans. The conservative assumptions that are adopted in the process of risk assessment consist of, for example, assuming a daily intake of a particular substance at much higher levels than statistically supported, ingestion of a substance over a whole lifetime, which in reality is rarely the case, or the absence of a safe threshold, exposure to a particular chemical, for example, the assumption that a genotoxic chemical substance causes harm at any level of concentration.[67] Other strategies include the employment of uncertainty analysis, qualitative or quantitative examination of uncertainties and assessment of the probability distribution between different possible outcomes usually in the form of a continuum.[68] Such data are subsequently transferred to risk managers, who decide on risk strategies on the basis of selected estimates including the worst-case scenario.

The fourth and fifth types of uncertainty are more problematic. The application of safety factors, conservative assumptions and uncertainty analysis

63. *Ibid.*
64. *Ibid.*
65. ADI (acceptable daily intake) is defined by the Joint Expert Committee on Food Additives (JECFA) as the highest quantity of residue that can be ingested on a daily basis over a lifetime without having any adverse effects on human health. Report JECFA/66/SC, (15 March 2006), Joint FAO/WTO Expert Committee on Food Additives, <ftp://ftp.fao.org/ag/agn/jecfa/jecfa66_final.pdf> at p. 10.
66. Sometimes additional safety factors are applied where there is an identifiable sub-group that might reasonably be expected to be more sensitive than the group in which data were obtained.
67. John D Graham and Lorenz Rhomberg, "How Risks Are Identified and Assessed," (1996) 545 *Annals of the American Academy of Political and Social Science* 15–25 at pp.15 & 20, noting the example of formaldehyde, which is considered as non-safety threshold substance, despite the fact that there is no conclusive evidence to support that conclusion.
68. Committee on Risk Assessment of Hazardous Air Pollutants, Commission on Life Sciences, National Research Council, eds., *Science and Judgment in Risk Assessment* (National Academy Press, 1994) <http://books.nap.edu/openbook.php?record_id=2125&page=R1> at p.167.

may limit the impact of those types of uncertainty only to a certain extent, as there is always a risk of under- or over-inclusion.[69] If the nature of the relationship between cause and effect, the probability of occurrence, or the extent of the possible damage are unknown, it is not really possible to address uncertainty through the application of traditional tools. In such cases, it seems advisable to leave a decision on how to address these uncertain risks to the risk managers, as science is not able in these instances to provide the required information.[70]

As might be expected, the WTO case law excludes the first type of uncertainty as not having any relevance for the purpose of the SPS Agreement. The Appellate Body stressed in the context of Article 5.1 that risk needs to be ascertainable and "theoretical uncertainty is not the kind of risk which [...] is to be assessed."[71] This also implies that theoretical uncertainty cannot satisfy the requirement of insufficiency of scientific evidence.[72] The Appellate Body defined theoretical uncertainty as uncertainty that is "inherent in the scientific method and which stems from the intrinsic limits of experiments, methodologies, or instruments deployed by scientists to explain a given phenomenon."[73] This is a reasonable approach. Recognizing this type of uncertainty as a legitimate ground for national risk decisions would result in the inoperability of the whole system established by the SPS Agreement.

As far as Article 5.7 is concerned, the case law provides that insufficiency should not be equated with uncertainty.[74] In the words of the Appellate Body, "existence of unknown and uncertain elements does not justify a departure from the requirements of Articles 5.1, 5.2 and 5.3[…]."[75] In another case, the Appellate Body added that these "two concepts are not interchangeable."[76] Thus, uncertainty existing in the presence of scientific evidence cannot lead to the application of Article 5.7. In such a case, a WTO Member should instead assess risk according to the provision of Articles 5.1–5.3. Of course, a Member may use conservative assumptions and qualitative elements in risk assessment or base its SPS measure on divergent scientific opinions.[77] This approach seems to be a workable solution for the second and third types of uncertainty.

It seems that although the Appellate Body rejected the consideration of uncertainty under Article 5.7, the case law shows that some types of uncertainty

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69. I presume that the existence of uncertainty is recognized, otherwise there would be no regulatory response at all.
70. It seems that the precautionary principle is aimed at such situations, although its legal value is contested as it does not really provide the criterion for its applications. See Cass R Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press, 2005). It may be useful as a tool in those situations where risk managers recognize the need for regulation.
71. *Appellate Body Report, EC – Hormones*, *supra* note 5 at p. 186.
72. Panel Report, WT/DS320/R, United States – Continued Suspension of Obligations in the EC – Hormones Dispute, (31 March 2008), <http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDFDocuments/t/WT/DS/320R-01.doc> at para. 7.631 [*Panel Report, US – Continued Suspension*], observing that "we should exclude theoretical uncertainty, which is the uncertainty that always remains because science can never provide absolute certainty about the safety of a given substance [.] In the Panel's view, theoretical uncertainly therefore should also not determine the applicability of Article 5.7."
73. *Appellate Body Report, Japan – Apples*, *supra* note 16 at para. 241.
74. *Ibid.* at para. 184.
75. *Appellate Body Report, Australia – Salmon*, *supra* note 10 at at para. 130; *Appellate Body Report, EC – Hormones*, *supra* note 5 at at para. 194.
76. *Appellate Body Report, Japan – Apples*, *supra* note 16 at para. 184.
77. On minority scientific opinions and qualitative elements in the process of risk assessment, see, Lukasz Gruszczynski, "Science in the Process of Risk Regulation under the WTO Agreement on Sanitary and Phytosanitary Measures," (2006) 7:4 German Law Journal 371-398 <http://www.germanlawjournal.com/pdf/Vol07No04/PDF_Vol_07_No_04_371398_Articles_Gruszczynski.pdf> at pp. 388-389.

are in fact addressed under that article, at least if we understand the concept as presented by Klinke and Renn. Arguably, the Appellate Body understood the notion of uncertainty quite narrowly, and as discussed above, excluded from its scope those cases that fall into the fourth and fifth type. Thus, indeterminacy, that is, the inability to explain the phenomenon, and a recognized lack of knowledge, seem to fall into the legal category of unreliable or inconclusive results, which, according to the case law are examples of insufficiency of scientific evidence. Consequently, the Appellate Body's refusal to equate uncertainty with insufficiency of scientific evidence cannot be taken literally. If uncertainty is understood broadly, at least some types will qualify as insufficient scientific evidence.

### *5.2. Assessment of Insufficiency*

The case law does not establish any general rules as to how to assess the existence of sufficiency or insufficiency of scientific evidence, including its reliability and conclusiveness. In fact, this would probably be impossible and each case needs to be examined separately. Ultimately, it will be a panel and indirectly the experts advising the panel who decide whether the body of scientific evidence is sufficient or insufficient, including the question of whether evidence is reliable and conclusive. Note, however, that from the epistemological point of view the sufficiency of scientific evidence is not an absolute term. As observed in the literature, "there is no scientific definition of terms such as acceptable, reasonable, and sufficient."[78] The same set of information can be sufficient for one scientist to assess risk and not sufficient for another. This depends not only on the available body of scientific information but also on other factors including: judgments of the experts reflecting their attitude toward particular risks, that is, whether they are less or more cautious, values of the particular community in which the expert is acting, as well as the nature of the risk assessment itself. As far as the last element is concerned, note that scientific risk assessment requires answering a number of questions which are not purely scientific. What weight should be assigned to positive and negative studies? What is statistical significance?[79] Can uncertainties be addressed through conservative assumptions and safety factors or is additional research needed? There are no absolute answers to these questions and expert responses may legitimately differ. Assessing the sufficiency of scientific evidence in a particular area is therefore not a straightforward scientific task, but includes a normative dimension.[80] As noted by a group of eminent scholars in the field of risk science, "evidence deemed reliable enough to generate a sufficient risk assessment in one regulatory context may fail in other contexts because of the different concerns, risk frames, and particular circumstance."[81] As science develops, an increasing number of scientists will agree that the available body

78. Douglas Crawford Brown, Joost Pauwelyn and Kelly Smith, "Environmental Risk, Precaution and Scientific Rationality in the context of WTO/NAFTA Trade Rules," (2004) 24:2 Risk Analysis Journal 461-467.
79. Carl F Cranor, "Science Courts, Evidentiary Procedures, and Mixed Science Policy Decisions," (1993) 4:2 Risk: Issues in Health and Safety 113-132, <http://www.piercelaw.edu/risk/vol4/spring/cranor.htm> at pp.113 and 119.
80. *Ibid.* Note that it could be debated whether scientists alone could decide on such normative choices.
81. David Winickoff, Sheila Jasanoff, Lawrence Busch, Robin Grove-White and Brian Wynne, "Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law," (2005) 30 Yale Journal of International Law 81–122.

of scientific information allows risk assessment.[82] However, if a particular field of research is novel and complex, it may be that no uniformity exists.[83] As summarized by one of the panel's experts in *EC – Biotech Products*,

> [w]hen additional scientific knowledge is needed to evaluate new GM crops, each nation's regulators and scientific advisory committees are placed in the difficult position of choosing between expediency and greater certainty. It is not always clear where the distinction lies between what regulators "need to know" vs. what is merely "nice to know.[84]

The above concerns are reflected in the answers provided by the experts who advised the panel in *EC – Biotech Products.* Two national safeguard measures may serve as useful examples, the French safeguard measure on oilseed rape, MS1xRF1, and the German measure on maize, Maize Bt-176. The panel asked the experts whether in the light of evidence before it, there was any reason to believe that the scientific evidence available to Germany and France had not been sufficient to permit them to undertake an appropriate assessment of potential risks to human, plant and animal health, and the environment, from the importation and use of the relevant GMOs.[85] This question also distinguished between two temporal moments, which were relevant for the assessment of sufficiency: the date of adoption of the national safeguard measure and the date of fixing the panel's terms of reference.

As far as the first measure is concerned, Dr Nutti, one of the experts, was confident that the scientific evidence was sufficient to perform risk assessment. She particularly pointed out the positive assessment of the scientific body that had performed the risk assessment at the European level, the EC Scientific Committee on Plants (ECSCP), and the competent British authority, which was responsible for the evaluation of the initial application for approval of oilseed rape MS1xRF1.[86] On the other hand, when asked the same question, a second expert, Dr Andow, identified a number of instances where the evidence was insufficient. His view was that information on the dispersal of oilseed rape pollen was insufficient to complete an accurate assessment of dispersal probability,[87] "that the molecular characterization was insufficient to identify all transgene products, […] that the risk of evolution of resistance in weeds not related to the Brassicaceae [was] incompletely assessed […]"[88] and that data on non-target effects were insufficient.[89] He also expressed his concern with the assumption of the ECSCP that proper agriculture practices were being observed. [90] A third expert, Dr Snow, agreed with Dr Andow, and, following an evaluation of available

82. *Ibid.*
83. This is particularly visible in the case of biotechnology, sometimes referred to as science at the frontiers, which is both novel and complex.
84. WT/DS291/R/Add, WT/DS292/R/Add, WT/DS293/R/Add Annex H, "Replies by the Scientific Experts Advising the Panel to Questions Posed by the Panel" to *Panel Report, EC – Biotech Products* <http://docsonline.wto.org/DDFDocuments/t/WT/DS/293RA6-01.doc> [*Panel Report, EC – Biotech Products – Annex H, Scientific Experts*] at para. 14.
85. *Ibid.* at para. 171.
86. *Ibid.* at para. 780.
87. *Ibid.* at para. 785.
88. *Ibid.* at para. 789.
89. *Ibid.*
90. *Ibid.* at para. 786.

evidence, confirmed that "France had valid reasons [...] to carry out more research to 'supplement existing scientific knowledge and validate methods for managing the cultivation of genetically modified oilseed rape.'"[91] He also identified one particular instance of insufficiency of scientific evidence with regard to the rate at which the transgene for glufosinate tolerance would spread to volunteer plants, including the seed bank, and related weeds.[92] The fourth expert, Dr Squire, added that, "[t]here was insufficient knowledge [...] to predict accurately [...] what the rates of spread and cross pollination would be (GM to non-GM) if a large part of the rapeseed areas were GM."[93] Thus, three out of four experts advising the panel confirmed that there was insufficient scientific evidence. The same opinion was expressed by the Biomolecular Engineering Committee, a committee which assessed data on MS1xRF1 for the French competent authority. Note also that the above opinions were provided by the experts in the context of a very specific question posed by the panel. This additionally indicates that the experts saw deficiencies in knowledge to be serious enough as to prevent France from performing risk assessment.

When addressing the same question with respect to the German safeguard measure on Maize Bt-176, Dr Nutti once again confirmed that the available data allowed for the performance of risk assessment.[94] The other expert, Dr Andow, was less optimistic. He noted that although the ECSCP had concluded that the scientific information provided by the German authorities did not alter the original risk assessments, that opinion was only "one possible scientific opinion that can be reached from the information available at the time, [and] that new information also allows several other scientifically valid opinions."[95] He also added that the ECSCP had not considered all the scientific perspectives, and in some cases had even ignored prevailing scientific opinions. According to him, the ECSCP opinion did not invalidate the scientific opinion of Germany.[96] Note also that Dr Andow was conscious that some gaps in scientific knowledge could have been addressed through traditional risk assessment techniques, such as using the worst case scenario or conservative assumptions.[97] In this context, he explicitly identified non-target risks as an example of such a case (however, only in 2003 when the panel proceeding was initiated and not when a measure was adopted).[98] In the context of other questions, however, he did not make such a reservation.[99] Arguably, this indicates that other gaps in knowledge were of such a character as to prevent Germany from performing adequate risk assessment. Dr Andow concluded his answer by saying that "the scientific evidence available to Germany […] was not sufficient to permit it to undertake an appropriate

91. *Ibid.* at para. 791.
92. *Ibid.* at para. 793.
93. *Ibid.* at para. 795.
94. *Ibid.* at para. 921.
95. *Ibid.*at para. 933. This statement should be compared with the statement of Dr Snow who observed that "several […] papers challenged widely held assumptions about pollen, gene flow, or herbicide-tolerant crops[,]" at para. 15.
96. *Ibid.* at para. 937.
97. Compare with the opinion of Dr Andow on sufficiency of scientific evidence relating to Maize MON 810, where he noted that "it could be argued that a risk assessment could be conducted using scientifically justified worst-case assumptions." *Ibid.* at para. 998.
98. *Ibid.*at para. 941.
99. *Ibid.* at paras. 933–937. This particularly included data on the development of resistance and effects of Bt toxin in soil.

assessment of potential risks to plants and the environment […]."[100]

The above indicates that even among the experts advising the panel there was no uniformity of views. The panel, however, disregarded these opinions and found that since the ECSCP was able to perform the risk assessment of Maize Bt-176 and oilseed rape MS1xRF1 and, subsequently reviewed the concerns that had been raised by France and Germany finding that they did not alert the finding of original risk assessment, it was no longer possible for these countries to claim that there was insufficiency of scientific evidence.[101] Thus, the panel's approach may indicate that if one WTO Member is able to perform the risk assessment, no other Member may rely on Article 5.7. There are three distinct problems with this finding. First, it is incorrect from the point of view of risk science, as sufficiency is not an absolute term. Consequently, what may be sufficient for some scientists may be equally insufficient for others. As indicated above, the assessment of sufficiency of scientific evidence is not simply a scientific task, but also has a normative dimension with the judgments of the experts reflecting their attitudes toward particular risks, that is, whether they are less or more cautious, and the values of a particular community playing an important role. Second, and what this article considers to be more important, the panel decided to disregard some of the opinions of its own experts, as well as scientists that advised France and Germany. Thus, what the panel did was give more weight to some scientific opinions rather than to others. The immediate question that arises is whether a panel should decide which science is better. This is hardly the case, as panelists are not equipped with sufficient knowledge and resources to do so. Moreover, such an approach is clearly inconsistent with the existing case law. According to the Appellate Body, a WTO Member may rely on the majority scientific opinion as well as on those opinions of scientists who take a divergent view.[102] If the sufficiency of scientific evidence under Article 5.7 is to be assessed by scientists, the same standard should apply. The purpose of the WTO is not to impose on its Members one uniform vision of science; it is rather to eliminate national measures affecting international trade that are not supported by scientific evidence (plausible data and not the best available science). Third, note that the EC and its Member States are separate sovereign entities. All of them are, in fact, WTO Members. Despite that fact, the panel found that if the EC was able to perform the risk assessment, the EU Member State in question could no longer rely on Article 5.7. That interpretation interferes, however, with the sovereign right of each WTO Member to establish its ALOP. As sufficiency of scientific evidence is not an absolute term, its assessment may legitimately differ from one country to another. Thus, preventing one WTO Member from relying on Article 5.7 when risk assessment has been conducted somewhere else, deprives that Member of the opportunity to review scientific material, to assess it, and, consequently, to establish a level of protection which it deems appropriate.

The article argues that the task of a panel under Article 5.7 should be limited to assessing the plausibility of scientific opinions on the sufficiency of scientific evidence, rather than deciding which scientific view is better. This approach

100. *Ibid.* at para. 938.
101. *Panel Report, EC – Biotech Products, supra* note 3 at para. 7.3300.
102. *Appellate Body Report, EC – Hormones, supra* note 5 at para. 194.

closely corresponds with the case law on the assessment of scientific evidence for the purpose of Articles 2.2 and 5.1, which recognizes that an SPS measure may be based on both mainstream science as well as divergent opinions coming from qualified and respected sources. Applying that standard in the context of Article 5.7 would mean that a WTO Member may conclude on the basis of such minority opinions that scientific evidence is insufficient for the performance of risk assessment. The fact that another WTO Member takes a different view, based on mainstream or other minority opinion, and considers evidence as sufficient for the assessment of risk, would not have any consequences.

Note that the Appellate Body stated that in the examination of sufficiency of scientific evidence under Article 2.2, "a panel […] should […] bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned."[103] This approach indicates the recognition by the Appellate Body that risk decisions are context dependent and that there is no absolute threshold. Thus, the degree of required accuracy and quality of scientific evidence depends on the type of risk, i.e. its potential severity and reversibility. The same standard under Article 5.7 would mean that in the case of risks which are irreversible or potentially serious, a higher level of confidence may be required by a WTO Member to conclude that scientific evidence is sufficient for the assessment of risk.

### *5.3. Time for Assessing Insufficiency of Scientific Evidence*

Another problematic issue under the first condition of Article 5.7 is the question of the time at which insufficiency of scientific evidence is to be assessed. Is it the time of adoption of an SPS measure by a WTO Member, or rather, the time at which the panel's terms of reference are fixed? Note that the panel in *EC – Biotech Products* distinguished between the obligations of Article 5.7 that refer to the adoption of an SPS measure, in the first sentence, and those concerning the maintenance of such a measure, in the second sentence. On that basis, the panel found that the insufficiency requirement, which is contained in the first sentence, should be determined by reference to the time when a relevant SPS measure was adopted.[104] According to the panel, the question of whether scientific evidence is still insufficient is to be addressed under the second sentence of Article 5.7, as it may

> shed light on whether the Member […] has complied with the requirement to "seek to obtain the additional information necessary for a more objective risk assessment" [and] whether the Member […] has conducted a "review" of its provisional measure "within a reasonable period of time."[105]

Following this logic, the existence of pertinent information also needs to be ascertained as of the day of adoption of an SPS measure.[106]

103. *Appellate Body Report, EC – Hormones*, *supra* note 5, at para. 124.
104. *Panel Report, EC – Biotech Products*, *supra* note 3 at para. 7.3253.
105. *Ibid.* at para. 7.3255.
106. The phrase "available pertinent information" is also included in the first sentence of Article 5.7. Note that according to the panel the verb "to adopt" indicates that the relevant time is the moment of adoption of a measure.

The panel's argument, although textually correct, leads to complicated problems. It may be difficult to prove a particular state of science in a certain moment of the past. Such a problem will be exacerbated if there is a long period of time between the adoption of a measure and a panel proceeding. Moreover, as the existence of insufficiency is to be established as of the moment of adoption of an SPS measure,[107] it is not clear how to address all those cases where after the adoption of a measure, "false" initial insufficiency turns out to be real. Under which condition of Article 5.7 should these new scientific developments be taken into account? The panel report in *EC – Biotech Products* does not provide the answer. The panel's interpretation also creates systemic problems, as far as interrelations of different SPS provisions are concerned. A particular measure may be found compatible with the sufficiency requirement of Article 2.2, as the relevant moment for the assessment of sufficiency is when the panel is fixing its terms of reference, and with the insufficiency requirement of Article 5.7, as the relevant moment is the adoption of a measure. If, as it is argued in this article, each provision applies to the exclusion of the other, which provision will be applicable in such a case?[108] Finally, note that the panel's findings in *EC – Biotech Products* are inconsistent with previous case law. The panel in *Japan – Apples* did not make any temporal distinctions in its assessment of the scientific evidence. It did not ask the experts about the sufficiency of scientific evidence at the time of the adoption of the Japanese SPS measure. More importantly, it explicitly rejected Japan's argument that evidence, which became available after adoption of the measure, should be disregarded for the purpose of Article 5.7.[109] In particular, the panel said that

> [w]e do not see in the text of Article 5.7, or of Article 2.2 for that matter, any reason to limit our assessment of the "relevant scientific evidence" to evidence available before 1995. On the contrary, since Article 5.7 provides for an exception to Article 2.2, and an assessment of the compatibility of a measure with Article 2.2 is made at the time the matter is reviewed by the Panel, there is no justification for assessing any alleged provisional measure at a different date.[110]

Note that the panel in *Japan – Apples* referred to the notion of "relevant scientific evidence," a phrase that is found in the first sentence of Article 5.7. Indeed, its finding could only refer to the first sentence, as it did not examine the obligations imposed by the remaining part of Article 5.7 at all.

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107. Although the panel stated (in a different context) that its interpretation "leave[s] room for the possibility that even if at a given point in time relevant scientific evidence is sufficient to perform a risk assessment, a situation might subsequently arise where the relevant scientific evidence could be considered insufficient to perform a risk assessment as required under Article 5.1 and as defined in Annex A(4) of the SPS Agreement." WT/DS291/R/Add.9, WT/DS292/R/Add.9, WT/DS293/R/Add.9 Annex K "Letter of the Panel to the Parties of 8 May 2006" to *Panel Report, EC – Biotech Products*, <http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDFDocuments/t/WT/DS/293RA9.doc> at p. K-3(d); it is not clear how under the panel's analysis the change of circumstances with respect to insufficiency of scientific evidence could be taken into account.
108. Of course this problem will not arise under the existing interpretation of the relationship between Articles 2.2 and 5.7.
109. To be precise, the specific date in that case was the date of entry into force of the SPS Agreement, as the SPS measure itself had been adopted earlier.
110. *Panel Report, Japan – Apples*, *supra* note 48 at para. 7.10.

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## 6. CONCLUSION

THE CASE LAW HAS CLARIFIED THE VERY GENERAL and rather enigmatic language of Article 5.7 of the SPS Agreement. The ruling of the panel in *EC – Biotech Products* seems to be of particular importance, as it addressed for the first time a number of issues, which arise under Article 5.7. Unfortunately, some of the developments in the panel report are disappointing, while others seem to be poorly reasoned. This article concentrates on one particular issue – the meaning of the term "insufficient scientific evidence." This article recognizes that a dual function is performed by this condition, as an applicability determinant and a consistency requirement, and analyzes each of them separately. As far as the issue of applicability is concerned, this article identifies a number of deficiencies in the reasoning of the panel. First, the conclusions reached by the panel make a distinction between applicability and consistency, as well as the discussion on what triggers the applicability of Article 5.7, namely provisionality versus insufficiency of scientific evidence, meaningless. Second, despite the textual similarities between Articles 2.2 and 3.1 and the explicit reference in the report to the example of Article 3, the panel ultimately failed to apply the same approach in the context of Articles 2.2 and 5.7. Third, the substantive analysis of the panel's reasoning shows that it is closer to the logic of the general rule and exception rather than to one of autonomous rights. This, however, contradicts the language of the other parts of the report. Fourth, the conclusion reached by the panel seems also to be incompatible with the requirements set forth in the test in *EC – Tariff Preferences*, as in *EC – Biotech Products*, both provisions, Articles 2.2 and 5.1, and Article 5.7, were actually applicable. Fifth, the panel's conclusion is logically flawed. A WTO Member is required not to maintain a measure without sufficient scientific evidence even if the evidence is objectively insufficient.

This article argues that it is more appropriate to view the SPS Agreement as providing for mutually exclusive paths of compliance. The first path consists of following the international standards. If a Member wishes to reach a higher level of SPS protection than would be achieved by following the relevant international standard, or if there is no standard at all, the second path becomes available. Finally, the third path applies to all those cases where scientific evidence is insufficient to perform risk assessment. The relationship between these paths is one of exclusion, meaning that conduct inconsistent with the provisions applicable to a particular path does not remove an SPS measure from that path.

On the substantive level, this article criticizes the panel's approach that suggests that if one WTO Member is able to assess the risk, no other WTO Member may rely on Article 5.7. This article identifies three distinct problems with such a finding. First, it is incorrect from the point of view of risk science, as sufficiency is not an absolute term. Consequently, what may be sufficient for some scientists can be insufficient for others. The article stresses that assessing the sufficiency of scientific evidence is not simply a scientific task, but also has a normative dimension, where judgments of the experts reflecting their attitude toward particular risks, that is, less or more cautious, and the values of their community play an important role. Second, the panel's analysis results

in weighing scientific opinions against each other and deciding which science is better. However, as the article argues, this is not a proper role for a WTO panel. Moreover, such an approach is inconsistent with the established case law decided in the context of sufficient scientific evidence, Article 2.2, and adequate risk assessment, Article 5.1. In particular, this article notes that the Appellate Body recognized that an SPS measure may be based on both mainstream science and divergent opinions. There are no reasons not to apply the same standard under Article 5.7. Third, the article points out that this approach deprives WTO Members of the opportunity to review scientific material, to assess it, and, in consequence, to establish a level of protection that they deem appropriate. This article argues that the task of the panel under Article 5.7 should instead be limited to the assessment of the plausibility of scientific opinion on the sufficiency of the scientific evidence, rather than deciding which scientific view is better. This would mean that the panel should accept scientific minority opinions and the contextual character of risk situations where the degree of required accuracy and quality of scientific evidence depends on the type of risk, that is, its potential severity and reversibility. Finally, this article disagrees with the approach of the panel to the temporal assessment of the insufficiency of scientific evidence, i.e., what is the relevant time for the assessment of insufficiency. It points out that the panel's approach leads to complicated practical and systemic problems. In this context, the article also stresses inconsistency in the existing case law with respect to this issue.