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The Role of Science in Risk Regulation under the SPS Agreement

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ABSTRACT

This paper attempts to present a comprehensive and coherent picture of the role performed by science under the SPS Agreement and SPS case law. It argues that the approach adopted by the Appellate Body is predominantly based on a technical paradigm, supplemented, however, with some considerations arising from other paradigms.

The paper argues that the approach adopted in the case law is generally compatible with the text of the SPS Agreement and provides a coherent SPS system. However, it also identifies certain areas which lack coherence, as certain standards seem to violate the right of the member states to establish an appropriate level of protection. These are: ascertainability of the risk as a precondition for valid risk assessment; strict specifity of the risk assessment in low-risk situations; the proportionality between the risk identified and the SPS measure; the notion of negligible risks; and the concept of likelihood in the quarantine risk assessments. The paper claims that these standards cannot be generally applied in SPS disputes as, in certain situations, they will result in the violation of the right of member states to establish an appropriate level of SPS protection.

Finally, a number of specific issues are highlighted which require further clarification in case law, such as the issue of the quality of minority scientific opinions and the relationship between the insufficiency of scientific evidence and scientific uncertainty. The paper suggests that the ultimate role ascribed to science under the SPS Agreement can be assessed only after an interpretation of those issues is provided by future case law.

KEYWORDS

WTO, SPS Agreement, Risk Regulation, Science and Risk, Risk Assessment, Risk Management, Precautionary Principle, International Trade.

TABLE OF CONTENTS:

The Role of Science in Risk Regulation under the SPS Agreement

Lukasz Gruszczynski*

1. Introduction

The last fifty years witnessed an enormous expansion of international trade. The system created in 1947 by the General Agreement on Tariffs and Trade proved to be very successful in elimination of trade tariff barriers. By limiting tariffs, nations have gained access to foreign markets at considerably lower costs. As proposed by the theory of comparative advantage, nations should specialize in the production of those goods in which they have an advantage. Limited domestic resources, when invested in those activities, can provide the biggest gains and the total output and economic welfare can be increased. Thus, it is supposed that the development of international trade contributes to the increase of domestic and global welfare and the reduction of poverty.[1]

International trade liberalization coincided with the increase of national regulatory activism. This process was particularly visible in the area of risk regulation. Governments, responding to the fears and demands of their domestic constituencies, adopted a wide range of regulatory measures aimed at the protection of the environment and human health and safety. In the majority of the cases, the new regulatory initiatives served fully legitimate goals. However, it also appeared that those internal measures might take the place traditionally occupied by tariffs barriers and become an attractive vehicle for protectionism. The clash between international trade and national regulation seemed to be just a matter of time. Trading partners understood this potential danger, however the first efforts to avoid this danger proved to be unsuccessful.[2] It was only with the Uruguay Round that new sets of rules disciplining the regulatory activity of WTO member states were introduced. The Agreement on Technical Barriers to Trade[3] and the Agreement on Sanitary and Phytosanitary Measures[4] are particularly important in this respect. Both agreements were specifically designed to deal with the problem of non-tariff barriers to international trade. In other words, they intended to create standards for the establishment and maintenance of internal measures that might have an impact on international trade flows. Indeed, the second agreement had an almost immediate impact in disciplining environmental and food risk regulation of WTO member states.

The SPS Agreement ascribes a special role to science. WTO member states are obliged to ensure that their SPS measures have a scientific basis and are not maintained without sufficient scientific evidence. That general rule soon became a source of deep disagreement

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[1] For an extensive discussion on the relationship between trade liberalization, economic growth and poverty reduction, *see* Peter Van den Bossche *The Law and Policy of the World Trade Organisation. Text Cases and Materials* (Cambridge: Cambridge University Press, 2005), at 11-19.

[2] The operation of the Standard Code adopted during the Tokyo Round is generally perceived as a failure, *see e.g.* David Victor, *The Sanitary and Phytosanitary Agreement of the WTO: An Assessment after five Years*, 32 N.Y.U.J. Int'l L. & Pol. 865, 874 (2000).

[3] Agreement on Technical Barriers to Trade, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, available at http://www.wto.org [hereinafter **TBT Agreement**].

[4] Agreement on Sanitary and Phytosanitary Measures, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, available at http://www.wto.org [hereinafter **SPS Agreement**].

among WTO member states and scholars. What is the exact role of science under the SPS Agreement? Whose science should be taken into account; the majority view or also divergent opinions? If minority opinions are relevant, should they comply with certain requirements? What kind of relationship is required between the conclusions of risk assessment, scientific evidence and an SPS measure? Is there any place for other considerations, such as cultural, economical and political factors in the process of risk assessment? When exactly may a provisional measure be undertaken? Unfortunately, the SPS Agreement does not provide clear answers to these questions. Some of them have been already addressed in the case law; some still require clarification.

The examination presented below will analyze the text of the SPS Agreement as well as the relevant case law.[5] My main aim is to present a comprehensive and coherent picture of the concept of science as embodied in the SPS Agreement. This includes the analysis of SPS "scientific" provisions, their mutual relationships as well as relevant WTO case law. I also intend to identify the role played by science and discuss potential problems. This paper claims, contrary to some scholars, that the Appellate Body adopted a rather sensitive approach to SPS disputes, addressing most of the controversial issues in reasonable way. At the same time, I also submit that certain standards adopted in the case law (i.e. evaluating sufficiency of scientific evidence or appropriateness of the risk assessment) are questionable, as they may impair the right of the member states to adopt an appropriate level of SPS protection.

The paper proceeds as follows: Section 2 briefly describes the basic concepts in the field of risk regulation. It also provides a short description of the system established by the SPS Agreement. Section 3 analyzes in detail the "scientific" provisions of the SPS Agreement. Thus, the textual basis of the SPS Agreement is juxtaposed with the existing case law and literature. Section 4 attempts to generalize the findings of the preceding section and provide a coherent and comprehensive picture of the role that is played by science under the SPS Agreement. This section also offers a brief overview of the current scholarship in the field. Finally, Section 5 summarizes the previous findings and draws final conclusions.

2. General Remarks on Risk Regulation

2.1 Notion of Risk

Risk is indispensable part of our life. We are constantly forced to confront risk. Every substance or activity has a certain potential to cause harm. Driving a car, working, skiing and even simply walking is related to a certain degree of risk. So what exactly is meant by risk? The answer is not straightforward. Risk is a very complex phenomenon, which can be described from various perspectives.[6] Specifically, risk can be defined within technical, economical, psychological and sociological paradigms. Note that the summary presented below does not aspire to evaluate validity or the plausibility of the paradigms. It is provided, rather, as a useful background for further analysis of the provisions of the SPS Agreement.

The first group of definitions is derived from the technical paradigm which perceives risk as the "combination of the likelihood (probability) and the harm (adverse outcome, e.g. mortality, morbidity, ecological damage) resulting from exposure to an activity or substance

[5] For an extensive review of the facts and findings in disputes decided under the SPS Agreement, see Victor *supra* note 2; Joost Pauwelyn, *WTO Agreement on SPS Measures as Applied in the First Three SPS Disputes*, 4 J. Int'l Econ. L. 641 (1998); Joel P. Trachtman, *Decisions of the Appellate Body of the World Trade Organization*, (available at http://www.ejil.org/journal/curdevs/sr44.pdf last visited May 22, 2005).

[6] The subsequent discussion is based on Ortwin Renn *Concepts of Risk: A Classification*, in: Sh. Krimsky and D. Golding (eds.) *Social Theories of Risk* (Westport-London: Praeger Publishers, 1992), at 53.

(hazard)."[7] In other words, risk is a combination of "expected number of fatalities or injuries likely to arise in the event the risk materialized in harm."[8] Within that paradigm risk is assessed on the basis of statistical data, scientific information and probability techniques.

The second group relies on economic perspectives. Risk is also perceived as the combination of probability and harm. However, the harm is defined as a subjective utility (i.e. satisfaction and dissatisfaction). As pointed out by Renn, under the economic paradigm, "the relevant criteria are the subjective satisfaction with the potential consequences rather than predefined list of undesirable effects."[9]

The third group of definitions, which can be gathered within the psychological paradigm, defines risk as a function of individual perception. Consequently, risk is not absolute and varies from person to person. These theories stress the fact that the public perception of risk might differ significantly from the results reached by the experts within the technical paradigm. In short, the public perception of risk is different from the perception of technical experts. That phenomenon is partly caused by the lack of information on the side of the general public but also - which is stressed by advocates of this paradigm - by the fact that the popular perception of risk includes elements, which are excluded in scientific risk assessment. Those elements include: the catastrophic nature of risk, the controllability of risk, the permanent nature of loss, the equitable distribution of the danger and potential benefits from risk, the possibility of victims' identification, the voluntariness of exposure, and the gravity of potential outcome.[10]

The fourth group, covered by the sociological paradigm, consists of a great array of different definitions. The common feature is an emphasis on the phenomenon of "the social processing of the risk"[11] (i.e. risk is socially defined and subsequently socially filtered) as well as the problem of risk distribution. That group also stresses the role which is played by the media in shaping the perception of risks.[12] Closely related to the sociological paradigm, are cultural approaches to risk. Those approaches perceive risk as a social and cultural construct. Thus, they emphasize the importance of cultural factors in constructing the notion of risk.

2.2 Risk as a Subject of Regulation

In the majority of modern societies, the problem of risk is predominantly addressed through governmental regulation. That includes different types of risk, such as environmental, occupational, medicinal and the risk related to food and feedstuffs. State intervention is generally justified by the need to minimize the level of risk exposure and distribute the costs of risk in socially acceptable ways. At the same time, it is also stressed that the market alone cannot properly address the problem of risk. In consequence, risk regulation is perceived as an indispensable instrument for dealing with risk. The characteristic feature of modern risk

[7] Jonathan B. Wiener & Michael D. Rogers, *Comparing Precautions in the US and Europe*, 5 (4) Journal of Risk Research 317, 320 (2002).

[8] Jeremy Fraiberg & Michael J. Trebilcock, *Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform*, 43 McGill L.J. 835, 863 (1998).

[9] Renn *supra* note 6, at 62.

[10] Jan Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle*, 40 Colum. J. Transnat'l L. 323, 358 (2002); *see also generally*, Paul Slovic, *Perception of Risk*, 236 Science 280 (1987).

[11] Renn *supra* note 6, at 73.

[12] *See e.g.* Dorothy Nelkin, *Selling Science: How the Press Covers Science and Technology* (New York: WH Freeman, 1987), at 3.

regulation is that it tends to address risk before is materializes. Rather, it aims at prediction and prevention of risk than compensation for damages.[13] Consequently, risk regulation provides *ex-ante* solutions to risk situations.[14]

Risk regulation draws from technical, psychological and cultural paradigms. The theory of risk regulation usually makes a distinction between three elements of the risk regulatory process: risk assessment (based predominantly on the technical paradigm), risk management and risk communication (both based on the combination of all the above paradigms).[15] Again, all those terms can be defined in various different ways.[16] The prevalent view describes risk assessment as a process of probabilistic estimation of the potential adverse health or environmental effects of a substance, process, action or event, determined according to scientifically plausible methods. The goal of risk assessment is to provide risk managers with the information necessary for rational decision-making. Science plays a predominant role in that phase. It "identifies areas for regulatory action, while limiting the field of possible responses."[17] Science is deemed to provide neutral and rational advice to political bodies responsible for subsequent risk decisions.

Risk management is defined as "a process of identifying, evaluating, selecting and implementing actions to reduce risk."[18] Risk management reflects the preferences of a particular society for an acceptable level of risk exposure. It is based on a number of factors, such as the costs and benefits of regulation of the particular risk, societal values and preferences, and technical feasibility. Risk communication is understood as the two-way "flow of information and risk evaluation … between academic experts, regulatory practitioners, interests groups, and the general public."[19] The aim of risk communication is to influence the trust of the general public and increase support for regulatory decisions.

The risk analysis, as described above, is not free from legitimate criticism. The experts in this field indicate a number of inherited limitations in the scientific risk assessment.[20] It is pointed out that real-life situations are composed of a great number of variables. This is

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[13] Jacqueline Peel, *Risk Regulation under the WTO SPS Agreement: Science as an International Normative Yardstick?* Jean Monnet Working Paper 2002/04 (available at http://jeanmonnetprogram.org/papers/04/040201.html last visited May 20, 2005), at 5.

[14] Fraiberg & Trebilcock *supra* note 8, at 841.

[15] However, it should be noted that there are number of authors questioning the strict distinction between risk assessment and risk management, *see e.g.* Ellen K. Silbergeld *Risk Assessment and Risk Management: An Uneasy Divorce*, in: D. Mayo & R. Hollander (eds.) *Acceptable Evidence: Science and Values in Risk Management* (London: Oxford University Press, 1991).

[16] *See e.g.* William W. Lowrance *Of Acceptable Risk: Science and the Determination of Safety* (Los Altom: WM. Kaufmann, 1976), at 8; NRC/NAS Committee on the Institutional Means for Assessment of Risks to Public Health, Risk Assessment in the Federal Government (1983), at 18 (available at http://nap.edu/books/0309033497/html/R1.html, last visited on May 10, 2005); Vincent T. Covello & Miley W. Merkhofer *Risk Assessment Methods Approaches for Assessing Health and Environmental Risk* (New York: Plenum Press, 1993), at 210; David A. Wirth, The *Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, 27 Cornell Int'l L. J. 817, 833-34 (1994).

[17] Jeffery Atik, *Science and International Regulatory Convergence*, 17 Nw. J. Int'l L. & Bus. 736, 737 (1996/97).

[18] The Presidential/Congressional Commission on Risk Assessment and Risk Management 1 *Framework for Environmental, Health Risk Management* (1997), at 1.

[19] William Leiss, *Three Phases in the Evolution of Risk Communication Practice*, 545 Annals 85, 86 (1996), note that there are also one-way definitions of risk communication, for details *see* Baruch Fischhoff *Risk Perception and Communication Unplugged: Twenty Years of Process* in: R. Löfstedt & L. Frewer (eds.) *The Earthscan Reader in Risk and Modern Society* (London: Earthscan Publications, 1998), at 133-145.

[20] *See e.g.* Vern R. Walker, *The Myth of Science as Neutral Arbiter for Triggering Precaution*, 26 B.C. Int'l & Comp. L. Rev. 197 (2003).

particularly true in the case of ecological and health issues.[21] That complexity means that the results of the risk assessment are frequently uncertain.[22] That uncertainty results from the difficulty with the separation of different variables, lack of information, gaps in scientific theories as well as possible synergies of interactions between those elements. An additional difficulty is added by the imperfection of the scientific methods used in the process of risk assessment.[23] A separate set of problems arises in low-level risk situations (i.e. where a particular chemical or biological agent may be responsible for certain adverse health effects, but only with respect to small part of the population and over a long period of time) where causality is particularly difficult to identify. Finally, critics emphasize that risk assessment is not a purely scientific activity. Due to the problems indicated above, value judgments and non-scientific considerations frequently enter the process.

Despite those objections, scientific risk assessment seems to be an indispensable part of the modern risk regulation process. Arguably, it is capable, to a considerable extent, of identifying and ranking different risks. Scientific risk assessment seems to be also one of the most reliable enquiry processes available to regulators. In other words, it may not provide us with the perfect answers but is the best we have. Moreover, it is submitted that science leads to better-informed and more effective legislative and regulatory decisions. Simultaneously, it makes the regulatory process more transparent by providing the possibility of control and review, as well as eliminating some of the political biases.[24]

2.3 Risk Regulation under the SPS Agreement

The SPS Agreement entered into force on January 1, 1995 as part of the Marrakesh Agreement Establishing the World Trade Organization.[25] The adoption of the SPS Agreement was seen as a response to the ongoing dispute between the E.C. and U.S. relating to the importation ban on hormone treated beef. As the old system provided by the General Agreement on Tariffs and Trade (including the Tokyo Standard Code) proved unable to resolve that controversy, it became clear that only the creation of the new sets of rules regulating SPS measures might provide the answer.[26]

The old system of the General Agreement on Tariffs and Trade relied predominantly on three principles – most favored nation (Article I), national treatment (Article III) and prohibition of quantitative restrictions (Article XI), subjecting them to the general exception (Article XX). As pointed out by Sykes, under GATT, "regulators were otherwise free to adopt whatever regulations they wished, even if the regulations raised the costs of foreign suppliers disproportionately and thus had the effect of insulating domestic firms from foreign competition."[27] The SPS Agreement introduced a new set of requirements, particularly the requirement of regulatory rationality. According to the Agreement, an SPS measure should be based on science and supported by sufficient scientific evidence. In consequence, under the new system, even *bona fides* non-discriminatory measures could potentially violate the provisions of the SPS Agreement. In effect, the scientific basis, as required by the SPS

[21] Malcolm MacGarvin *Precaution, Science and the Sin of Hubris* in: T. O'Riordan & J. Cameron (eds.) *Interpreting the Precautionary Principle* (London: Cameron May, 1994), at 205-206.

[22] Fraiberg & Trebilcock *supra* note 8, at 849.

[23] Lester B. Lave *Quantitive Risk Assessment in Regulation* Washington 1982, at 23.

[24] Fraiberg & Trebilcock *supra* note 8, at 857-58.

[25] Marrakesh Agreement Establishing the World Trade Organization, available at http://www.wto.org [hereinafter **WTO Agreement**].

[26] Wirth *supra* note 16, at 824.

[27] Alan O. Sykes, *Domestic Regulation, Sovereignty and Scientific Evidence Requirements: A Pessimistic View*, 3 Chi. J. Int'l L. 353, 356 (2002).

Agreement, has become one of the important factors in the assessment of compatibility with international trade rules.

The scope of the SPS Agreement is rather narrow, as it only applies to measures intended for the protection, within the territory of the importing member state, of the life and health of people, animals, and plants from certain specified SPS risks. According to the definition provided in Annex A to the SPS Agreement, the relevant SPS risks consist of: (a) risks for animal or plant life or health arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; (b) risks for human or animal life or health arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (c) risks for human life or health arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; and (d) other risks related to the entry, establishment or spread of pests. As the list is exhaustive, if the particular type of risk does not fall within one of the above categories, the SPS Agreement does not apply.

Before analyzing the SPS Agreement in detail, it is worthwhile presenting a general overview of the system. Article 2, which defines the basic rights and obligations of member states under the SPS Agreement, may serve as a starting point of analysis. Paragraph 1 confirms the right of each WTO member state to adopt and maintain SPS measures necessary for protection of human, animal or plant life or health. For the purpose of further analysis, it is worth citing here Article 2.1 in full. It provides that "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"[28] [emphasis added]. That right is, however, qualified by the second and third paragraph, which provides some additional conditions. Thus, Article 2.2 requires an SPS measure to be both - necessary and founded on scientific basis, while Article 2.3 demands that the measure be non-discriminatory. Simultaneously, Article 3 of the SPS Agreement introduces the rebuttable presumption of SPS consistency, with those measures, which conform to international standards, guidelines or recommendations (Article 3.2).[29] The presumption covers all the above requirements, namely necessity, scientific basis and non-discriminatory character, as well as the other obligations provided in the SPS Agreement. The threshold is quite high, as an SPS measure should be substantially the same as the relevant standard, or in other words, should reflect the standard completely.

Measures not conforming to international standards do not benefit from the consistency presumption and require scientific justification. The Appellate Body has distinguished two types of such measures. First, a measure may be only based on the international standards (Article 3.1) without conforming to them.[30] The notion "based on" was understood as requiring a rather lax relationship. Such a measure incorporates some, but not all the elements of the relevant standard.[31] Second, a measure may differ from the international standard by providing a higher level of protection (Article 3.3). That possibility is available in situations

[28] Art. 2.2 of the SPS Agreement.

[29] The SPS Agreement enumerates standard setting bodies relevant for the purpose of the Agreement; those are Codex Alimentarius Commission, International Office of Epizootics and Secretariat of the International Plant Protection Convention.

[30] Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products*, WT/DS26/AB/R; WT/DS48/AB/R, adopted February 13, 1998 [hereinafter **EC-Hormones**], para. 171.

[31] As the Appellate Body stated "a measure that conforms to and incorporates a Codex standard is of course based on that standard; a measure however based on the same standard might not conform to that standard, as where only some, not all, of the elements of the standard are incorporated into the measure" (EC-Hormones *supra* note 30, para. 163).

when there is scientific justification or "as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5."[32]

Presumably, the Appellate Body did not differentiate between those two types. In consequence, a WTO member state does not gain anything by deciding to base its measure on international standards rather than deviating from them completely. It is submitted that the interpretation introduced by the Appellate Body conflicts with the goals of the SPS Agreement, as provided in its recitals.[33] Moreover, from the textual point of view, such an interpretation seems to be troublesome, as it reduces Article 3.1, and the mandatory language used there ("shall") into an "idealistic but wholly unenforceable objective."[34]

Articles 5.1 to 5.3 of the SPS Agreement elaborate on the requirement of a scientific basis as incorporated in Article 2.2. In other words, they translate the general obligation contained in Article 2.2 into practical duties. Article 5.1 requires member states to base their SPS measures on risk assessment. The article specifically provides that "[m]embers 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."[35]

Article 5.2 enumerates the elements that need to be taken into account when conducting risk assessment. Those elements are: "available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment."[36] The list is not exclusive and other elements may be taken into account as well.[37] Article 5.3, which applies to assessment of risk to animal or plant life, supplements that list with economic factors.[38]

Articles 5.4 and 5.6 introduce some discipline with respect to the establishment of an appropriate level of protection (the term used for risk management under the SPS Agreement). They require member states adopting SPS measures, to "take into account the

[32] Article 3.3 specifically provides that "[m]embers may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement."

[33] Particularly recital no 5 of the SPS Agreement which provides "desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations."

[34] Dale E. McNiel, *The First Case Under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban*, 39 Va. J. Int'l L 89, 125 (1998).

[35] Article 5.1 of the SPS Agreement.

[36] Article 5.2 of the SPS Agreement.

[37] EC-Hormones *supra* note 30, para. 187.

[38] Article 5.3 provides that "[i]n assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks."

objective of minimizing negative trade effects;"[39] "avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade;"[40] and "ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."[41]

Finally, Article 5.7 provides the right of WTO member states to adopt SPS measures, if scientific evidence is insufficient. Such measures should be based on available pertinent information and have a provisional character. Member states are obliged to look for additional information in order to perform risk assessment of the risk in question. The provisional SPS measures should also be reviewed within a reasonable period of time.[42]

Other articles of the SPS Agreement provide additional obligations, such as equivalency (Article 4), transparency (Article 7), special and differential treatment of developing countries (Articles 9 and 10), as well as establish rules for the administration of the Agreement (Article 12).

The SPS Agreement allocates the burden of proof in line with the practice adopted under general WTO law.[43] Thus, it is the complaining party who needs to establish a so-called *prima facie* case of inconsistency of a particular measure with the SPS Agreement.[44] A *prima facie* case is defined as one, "which, in the absence of effective refutation by the defending party, requires a panel, as matter of law, to rule in favor of the complaining party presenting the prima facie case."[45] When a *prima facie* case is established it is for the defending party to counter or refute the claim of the complainant. An additional rule, providing that "the party who asserts a fact, whether the claimant or the respondent, is responsible for providing proof"[46] of that fact, was also accepted under the SPS Agreement.[47]

A *prima facie* requirement was construed in the SPS case law as rather easy to satisfy, a WTO member state adopting an SPS measure needs to be prepared to present, during the panel proceeding, sufficient scientific backup.[48]

3. Science under the SPS Agreement

References to science appear in the different provisions of the SPS Agreement. As mentioned above, SPS measures need to be "based on scientific principles" and "not maintained without sufficient scientific evidence" (Article 2.2). Unless the measures conform

[39] Article 5.4 of the SPS Agreement.

[40] Article 5.5 of the SPS Agreement.

[41] Article 5.6 of the SPS Agreement.

[42] Article 5.7 provides that "[i]n 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. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

[43] Note, however, that there are some differences with respect to Article 3.3, for further discussion *see*: Section 3.3 of this paper.

[44] EC-Hormones *supra* note 30, para. 98.

[45] *Id.* para. 104.

[46] Appellate Body Report, *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R, adopted May 23, 1997 [hereinafter **U.S. – Shirts and Blouses**], para. 335

[47] Appellate Body Report, *Japan–Measures Affecting Agriculture Products*, WT/DS76/AB/R, adopted on March 19, 1999 [hereinafter **Japan-Agriculture Products**], para 121.

[48] Peel *supra* note 13, at 74.

to an international standard, the "scientific justification" (Article 3.3) in the form of formal risk assessment, is required (Article 5.1). The risk assessment should, among the others, take into account "available scientific evidence" (Article 5.2). In case of insufficiency of scientific data, an SPS measure may be taken provisionally on the basis of "available pertinent information". In such a case a "member shall seek to obtain the additional information necessary for a more objective assessment of risk" (Article 5.7).

The analysis presented below tries to systematize those provisions and corresponding case law. On that basis, an attempt to draw a comprehensive picture of the role of science under the SPS Agreement will be undertaken in Section 4. For the purpose of clarity, the subsequent analysis follows the structure of the SPS Agreement, rather than examining each of the SPS cases separately.

3.1 Scientific Principles and Sufficient Scientific Evidence (Article 2.2)

As already mentioned, Article 2.2 requires WTO member states to base their SPS measures on scientific principles and does not allow a member state to maintain them without sufficient scientific evidence. Note that Article 2.2 of the SPS Agreement employs conjunction ("and"), meaning that both obligations need to be met simultaneously. The Appellate Body has not yet defined the term "scientific principles". The ordinary meaning of the word "principle" denotes a general rule or law, which shows how a particular theory is put into practice. Thus, the requirement to base an SPS measure on scientific principles may be understood as requiring a certain scientific quality from both scientific evidence and risk assessment. As will be discussed in Section 3.3.2 (b) of this paper, the quality of scientific findings may play a pivotal role in the evaluation of divergent scientific opinions.

The notion of "sufficient scientific evidence" has received far more attention in the case law. The word "scientific" was defined by the Appellate Body as "having or appearing to have an exact, objective, factual, systematic or methodological basis and relating to, or exhibiting the methods or principles of science."[49] In another case, the panel used the tautology to define scientific evidence as "evidence gathered through scientific methods, excluding by the same token information not acquired through a scientific method."[50] As noted by Peel, such a perception of scientific evidence may be understood as providing minimum methodological constraints.[51]

In the Japan-Agriculture Products case, the Appellate Body constructed sufficiency as a relational concept, which requires an "adequate relationship between two elements, … between the SPS measures and scientific evidence."[52] The adequate relationship was understood as a "rational or objective one."[53] According to the Appellate Body, the rationality of the relationship should be determined on a case-by-case basis. In the Japan-Apples case, it repeated that the approach or methodology employed for examination of sufficiency would ultimately depend on the "particular circumstances of the case."[54]

Apparently, the Appellate Body refrained itself from creating any standard or test for the rational relationship. There are, however, some clues of what could be important in such a

[49] EC-Hormones *supra* note 30, footnote 172, referring to the ordinary meaning of the word "scientific."

[50] Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R, adopted December 10, 2003 [hereinafter **Panel Japan-Apples**], para. 8.92.

[51] Peel *supra* note 13, footnote 213.

[52] Japan-Agriculture Products supra note 47, para. 73-74.

[53] *Id.*

[54] Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted December 10, 2003 [hereinafter **Japan-Apples**], para. 164.

determination. According to the Appellate Body, vital elements are: "the characteristic of the measure at issue, quality and quantity of scientific evidence."[55] Additionally, in the Japan-Apples case, the Appellate Body upheld the finding of the panel that the disproportion between the risk identified by the scientific evidence and the SPS measure implies that there is no rational or objective relationship.[56] Thus, examining the rationality of the relationship involves a kind of proportionality test. If the risk is "negligible", while the SPS measure is strict, there is no chance that a rational relationship will be found. Moreover, it seems that the Appellate Body also implanted into the concept of sufficiency a certain margin of precaution or deference on the side of the national government (at least in all cases where risk is irreversible). It explicitly stated that "a panel charged with determination … whether 'sufficient scientific evidence' exists to warrant the maintenance by a Member of a particular SPS measure, may, of course and should, bear in mind that responsible, representative governments commonly act from the perspective of prudence and precaution where risks are irreversible."[57] However, the question how wide that margin is, may presumably only be answered on a case-by-case basis.

As already pointed out, Article 2.2 and 5.1 are closely related. However, the exact relationship between those two provisions is not entirely clear. As a general rule, it may be said that those provisions "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."[58] In another case Article 5.1 was described as the "specific application of the basic obligations contained in Article 2.2,"[59] However, Article 5.1 does not exhaust the whole meaning of Article 2.2. The Appellate Body did not exclude the additional examination of the measure under Article 2.2, even if such a measure is found to be consistent with Article 5.1.[60] Therefore, under the SPS Agreement, a measure based on the formal risk assessment may still violate the more general rule of Article 2.2. Arguably, a possible violation may only relate to the necessity requirement provided in Article 2.2. It is difficult to imagine a particular measure, which passes the muster of scientific risk assessment as provided in Article 5.1, as not being based on scientific principles or maintained without sufficient scientific evidence.[61]

The relationship between Article 2.2 and 5.1 was elaborated further in the Australia-Salmon case. First, the panel said that Articles 5.1-5.2 "'may be seen to be marking out and elaborating a particular route leading to the same destination set out in' Article 2.2."[62] The Appellate Body added a negative presumption for measures not conforming to the requirements of risk assessment. According to the Appellate Body, a measure that violates Article 5.1 should be "presumed … not to be based on scientific principles or to be maintained without sufficient scientific evidence."[63] Given the more general character of Article 2.2 the positive presumption is of course not available. The nature of that presumption

[55] Japan-Agriculture Products *supra* note 47, para. 84.
[56] Japan-Apples *supra* note 54, para. 164.
[57] EC-Hormones *supra* note 30, para. 124.
[58] *Id.* para. 180.
[59] Japan-Agriculture Products *supra* note 47, para. 82.
[60] *Id.* para. 250.
[61] Theoretically, such a situation may happen if after conducting the risk assessment, new scientific data indicates that conclusions of that risk assessment are patently incorrect. Presumably, a member state, while complying with Article 5.1, will violate a provision of Article 2.2. However, it also should be noted that the SPS Agreement does not require the member states to apply the best science available, the SPS measure should rather be rationally based on some scientific evidences, *see* discussion in Section 3.3.1 (d) of this paper.
[62] Panel Report, *Australia – Measures Affecting Importing of Salmon*, WT/DS18/R, adopted November 6, 1998 [hereinafter **Panel Australia-Salmon**], para. 8.52.
[63] Appellate Body Report, *Australia – Measures Affecting Importing of Salmon*, WT/DS18/AB/R, adopted November 6, 1998 [hereinafter **Australia-Salmon**], para. 137.

is problematic.[64] The language used by the Appellate Body may indicate that the presumption is rebuttable ("presumed" instead of "deemed" or "considered"). However, in practice it may appear that the presumption will operate as an irrebuttable one. In the majority of cases, finding that a measure is based on scientific principles or maintained with sufficient scientific evidence even if it fails to meet the requirements of the scientific risk assessment of Article 5.1 as construed in the case law, will be very difficult.

It is interesting to note how the relationship between those two provisions was construed in those cases where Article 2.2 was examined in the first place. Arguably, if the SPS measure is found to be consistent with Article 2.2, no examination under Article 5.1 should be required. Finding that the measure is based on scientific principles, supported by sufficient scientific evidence and applied only to the extent necessary to protect human, animal or plant life should satisfy the rationale, which lies behind the requirement of risk assessment.

The subsequent case law does not seem to support the above conclusion. First, when in the Japan-Agriculture Products case, the U.S. failed to establish before the panel a *prima facie* case under Article 2.2 with respect to a varietal testing requirement as applied to apricots, pears, plums and quince, the Appellate Body, found a violation of Article 5.1, based on the same factual findings.[65] Thus, it may be that establishing a *prima facie* case is easier under Article 5.1 than under Article 2.2.[66] It also seems that the requirements provided in Article 2.2 do not exactly match those of Article 5.1. In the Japan-Apples case, the panel limited its examination under Article 2.2 to the following issues: (i) identification of the risk and (ii) comparison of identified risk with the SPS measure.[67] Under Article 5.1 much more is required – i.e. evaluation of likelihood of entry, establishment or spread of disease according to the SPS measures that might be applied (actually and potentially). It is not clear whether that requirement may be written into the proportionality test invented by the panel under Article 2.2. In the same line, certain standards adopted under the SPS risk assessment provisions such as distinction between possibility and probability or requirement of specifity seems to be not contained in Article 2.2. In consequence, it may appear that the Appellate Body perceives those two provisions as related but separate sets of obligations. The practical consequences of such differentiation may be far-reaching. Would it be possible to pass the examination under Article 2.2 and fail because of deficiencies in the risk assessment? Presumably, future case law will need to provide clarification on that issue.

3.2 Scientific Justification (Article 3.3)

Article 3.3 allows the adoption of SPS measures, which result in a higher level of sanitary or phytosanitary protection than provided in the international standards, if there is scientific justification or "as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5."[68]

At first blush, it seems that Article 3.3 provides for the alternative ("or"), meaning that fulfillment of each of those conditions allows a member state to adopt a higher standard. Such a reading may have important consequences. As the first part of the above alterative does not explicitly refer to Article 5 of the SPS Agreement, it was submitted that scientific justification

[64] Pauwelyn also notes that problem, *see* Pauwelyn *supra* note 5, at 648.

[65] *See* discussion of the Appellate Body in Japan-Agriculture Products *supra* note 47, paras. 111-14.

[66] Note, however, that it may be legitimately argued that the conclusion of the Appellate Body was made only in this specific case.

[67] *See* review of the panel analysis by the Appellate Body in Japan-Apples *supra* note 54, para. 164.

[68] Art. 3.3 of the SPS Agreement.

is possible even if not provided in the form of formal risk assessment (as prescribed by Article 5).[69] The Appellate Body, however, interpreted the provision differently. It said that "distinction made in Article 3.3 between two situations may have very limited effects and may, to that extent, be more apparent than real."[70] The Appellate Body's argument was twofold. First, it made reference to the last sentence of Article 3.3, which provides that a measure may not be inconsistent with any other provision of the SPS Agreement. According to the Appellate Body, that also includes compliance with Article 5. Second, the Appellate Body found that the footnote to Article 3.3 defines scientific justification as "an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement."[71] According to the Appellate Body, such evaluation and examination "would appear to partake of the nature of the risk assessment required in Article 5.1."[72] In consequence, even under the first part of the alternative, a member state is obliged to follow the procedure prescribed by Article 5. That approach was subsequently confirmed in the Japan-Agriculture Products case. However, it is worth noting that in the same case, the Appellate Body also stated, without referring to Article 5.1, that "there is a scientific justification for an SPS measure, within the meaning of Article 3.3, if there is a rational relationship between the SPS measure at issue and the available scientific information."[73] As that statement is closer to findings made under Article 2.2, it may indicate the willingness of the Appellate Body to distinguish in the future between two parts of the alternative. In such a case, presumably, it will be possible to adopt an SPS measure that results in a higher level of protection than provided by the international standard without possessing appropriate risk assessment.

In this context, it also should be noted that the interpretation adopted by the Appellate Body seems to be incompatible with the principle of effective treaty interpretation, already recognized in the previous WTO case law.[74] That principle requires that meaning should be given to every provision of the agreement(s). A reading of Article 3.3, which equates two parts of the alternative, can be hardly seen as reaching that standard.

3.3 Risk Assessment (Articles 5.1 – 5.3)

In order to satisfy the requirement of scientific justification as provided in Article 3.3, a member state is obliged to base its SPS measure on risk assessment. The subsequent analysis of relevant provisions is divided into two parts. The first concerns the substantive content of the risk assessment, particularly its nature and required components. The second part analyzes the implementation stage of risk assessment.

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[69] The appellant's (EC) submission in the EC-Hormones case, para. 88.

[70] EC-Hormones *supra* note 30, para. 176.

[71] Footnote to Article 3.3 of the SPS Agreement provides as follows "[f]or the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection."

[72] EC-Hormones *supra* note 30, para. 175.

[73] Japan–Agriculture Products *supra* note 47, para. 79.

[74] *See* Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted May 20, 1996, para. 23, where the Appellate Body has recognized the principle of effective treaty interpretation as "one of the corollaries of the 'general rule of interpretation' in the Vienna Convention."

3.3.1 The Substantive Content of Risk Assessment

a) Distinction between Risk Assessment and Risk Management

The panel in the EC-Hormones case defined risk assessment as a "scientific examination of data and factual studies;"[75] it also noted that risk assessment "is not a political exercise involving social value judgment made by political bodies."[76] Subsequently, the same panel confronted the concept of risk assessment with risk management, subscribing the scientific character only to the former, while perceiving the later as non-scientific process, which "involves social value judgments."[77] The Appellate Body disagreed with that distinction, pointing to the lack of textual basis. It also added that the above distinction resulted in excessive restriction of the notion of the risk assessment.[78]

It is submitted that the Appellate Body, by doing this, opted for an integrated approach to risk assessment and risk management. This approach recognizes that scientific and political considerations constantly infiltrate both phases of risk regulation - risk assessment and management.[79] Consequently, it is argued that the Appellate Body recognizes risk assessment as being not purely scientific, since political and value-related decisions may frequently enter this process. This does not mean, however, that both phases are indistinguishable. As pointed out by one of the scholars in risk assessment and management are demonstrable under the SPS Agreement.[80]

Indeed, irrespective of the nomenclature used for describing risk assessment and management activities under the SPS Agreement, it seems that those two phases can be generally identified. As noted above, risk assessment does not have an exclusively scientific character, while risk management ("establishing appropriate level of protection") relies only on political and value-related factors. Nevertheless, scientific considerations play a superior role in risk assessment (prevailing over other factors), while non-scientific concerns dominate risk management phase.

b) What Constitutes Risk Assessment under the SPS Agreement?

The SPS Agreement distinguishes between assessment of risks to the life and health of humans, animals and plants attributable to pest and disease (the pest and disease risks or quarantine risks) and risks to the life and health of humans and animals arising from the presence of certain substances in food, beverages and feedstuffs (food-borne risks). The first type of assessment is defined as an "evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures, which might be applied, and of the associated potential biological and economic consequences."[81] With respect to food-borne risks, the definition provides that risk assessment is an "evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-

[75] Panel Report, *EC - Measures Concerning Meat and Meat Products (Hormones) complaint by the United States*, WT/DS26/R/USA, adopted February 13, 1998 [hereinafter **Panel EC-Hormones (US)**], para. 8.94.

[76] *Id.*

[77] *Id.* para. 8.160.

[78] EC-Hormones *supra* note 30, para. 181.

[79] Peel *supra* note 13, at 66; similarly Robert Howse, *Democracy, Science and Free Trade - Risk regulation on Trial at the WTO*, 98 Mich. L. Rev. 2329, 2343 (1999-2000).

[80] Bohanes *supra* note 10, p. 339.

[81] Annex A paragraph 4 of the SPS Agreement.

causing organisms in food, beverages or feedstuffs."[82] The subsequent subsection will evaluate the importance of that distinction.

The structure of the risk assessment was conceptualized separately for each type of risk. In the first case, a risk assessment is structured as a three-steps analysis. Initially, a risk assessment needs to identify two sets of data: "the diseases (or pests - LG) whose entry, establishment or spread a Member wants to prevent within its territory and potential biological and economic consequences associated with the entry, establishment or spread of these diseases (or pests – LG)."[83] Subsequently, it should assess the likelihood with respect to each set of data. Finally, a risk assessment has to "evaluate the likelihood of entry, establishment or spread of these diseases (or pests – LG) according to the SPS measures which might be applied."[84] The last requirement was developed further in the Japan-Apples case. The panel adopted a rather broad interpretation and required not only an evaluation for a measure actually applied, but also for other measures that might have been potentially applied.[85] Presumably, such an interpretation makes it more difficult for WTO member states to adopt *ex-post* justification for already operating measures.

The assessment of food-borne risks was conceptualized as a two-step analysis. The first step consists in the identification of adverse effects to human or animal health and life arising from the presence of certain substances (additives, toxins, etc.) in food, feedstuffs and beverages. If such adverse effects are found, the second step of the analysis requires the evaluation of the "potential or probability (sic!) of occurrence of these effects."[86]

c) Likelihood and Probability v. Potential and Possibility – Two Different Concepts?

As mentioned in the previous subsection, the SPS Agreement distinguishes two types of risk assessment. According to the Appellate Body, each type requires its own level of "likelihood". Assessment of quarantine risks requires evaluation of the likelihood of entry, establishment or spread of a pest or disease. In the case of food-borne risk, the SPS Agreement speaks only about the potential for adverse effect. The Appellate Body, by referring to the ordinary meaning of those terms, equated likelihood with probability,[87] while potential was understood as a mere possibility.[88] Consequently, the Appellate Body found the first category required a higher level of "probability" than the second one (or in other words, it required a quantitative dimension). Therefore, in case of pest and disease risk assessment "it is not sufficient that a risk assessment conclude that there is a possibility of entry, establishment or spread of diseases,"[89] a panel should rather look for the "'probability', of

[82] *Id.*

[83] Australia-Salmon *supra* note 63, para. 12.

[84] *Id.*

[85] Panel Japan-Apples *supra* note 50, para. 8.283; that finding was subsequently upheld by the Appellate Body.

[86] Panel EC-Hormones *supra* note 75, para. 8.98; although, the Appellate Body said that the "utility of a two-step analysis may be debated" it also admitted that "it does not appear … to be substantially wrong," *see* EC-Hormones *supra* note 30, para. 184.

[87] Australia-Salmon *supra* note 63, footnote 70; the Appellate Body specifically said that "[i]n view of the very different language used in paragraph 4 of Annex A for the two types of risk assessment, we do not believe that it is correct to diminish the substantial differences between these two types of risk assessments."

[88] The Appellate Body said in a different case that the ordinary meaning of "potential" relates to "possibility", *see* EC-Hormones *supra* note 30, para. 184.

[89] Australia-Salmon *supra* note 63, para. 123.

entry, establishment or spread of diseases."[90] Arguably, establishing a mere possibility should be an easier process than evaluation of probability.

As noted by Pauwelyn, it is not clear whether the drafters of the SPS Agreement introduced the above distinction deliberately.[91] From a textual point of view, the interpretation proposed by the Appellate Body is fully acceptable. However, it also results in a strange outcome. The Appellate Body, by lessening the requirements of risk assessment with respect to food-borne risks, presumably provided importing countries with greater room for maneuver than in the case of quarantine risks. As both types of risk may relate to the life and health of humans and animals, it seems that there are no compelling reasons for differentiating between those two situations.[92] Moreover, as will be shown in the next subsection, the different levels of "probability" required under the two types of risk assessment may determine whether a minimum magnitude of risk needs to be ascertained.

d) Minimum Magnitude of Risk, Quantitative and Qualitative Elements of Risk Assessment

The Appellate Body said that no minimum magnitude of risk or threshold level of risk needed to be demonstrated in risk assessment (i.e. 1:1,000,000).[93] In the literature it was submitted that "any quantifiable (or rather ascertainable - LG) risk – no matter how small – may serve a basis for sanitary measures."[94] In consequence, there are no negligible *de minimis* risks under the SPS Agreement.[95] The existence of risk may be expressed both in quantitative and qualitative figures. The quantitative measurement provides information on the probability of adverse effect occurrence, while the qualitative one speaks only about possibility of casual link without indicating its likelihood.[96] The Appellate Body also stressed that risk needs to be ascertainable, as "theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed."[97] The Appellate Body defined theoretical uncertainty as the kind of 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."[98] Thus, identifiability of risk serves as a bottom line for the definition of risk under the SPS Agreement.

Note, however, that this interpretation, which does not require any minimum magnitude of risk or threshold level of risk in risk assessment, was given to the provision in the EC-Hormones case, thus, a case relating to food-borne risk. I claim that the Appellate Body came to this conclusion in the context of the notion "potential" as provided with respect to food-borne risk assessment. As mentioned in Section 3.3.1 (c) of this paper, the word "potential" was interpreted as a mere possibility, which does not require any quantitative dimension. Consequently, the assessment of food-borne risks does not require a minimum magnitude of risk, while in case of assessment of pest and disease risks such quantitative data will be required (due to the interpretation of the notion "likelihood"). Thus, the same finding of the Appellate Body in the Australia-Salmon case (case relating to quarantine risk) seems to be

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[90] *Id.*

[91] Pauwelyn *supra* note 5, at 647.

[92] *See* also the argument made by the EC in the Australia-Salmon case (Third participant's submission of the European Communities, para. 7).

[93] EC-Hormones *supra* note 30, para. 186; Australia-Salmon *supra* note 63, para. 124.

[94] David R. Hurst, *Hormones: European Communities – Measures Affecting Meat and Meat*, (available at http://www.ejil.org/journal/Vol9/No1/sr1g.rtf last visited May 25, 2005), at 11.

[95] However, *see* discussion in the Section 3.3.2 (c) of this paper.

[96] Walker *supra* note 20, at 200.

[97] EC-Hormones *supra* note 30, para. 186.

[98] Japan-Apples *supra* note 54, para. 241.

incompatible with the concept of risk assessment with respect to quarantine risks. The notion of "likelihood" in risk assessment of pest and disease requires presentation of quantitative figures of the risk probability. If the potential of occurrence of adverse effect needs to be established, how can it be done without demonstrating a minimum magnitude of risk?

The above does not mean that qualitative elements cannot be present in the assessment of quarantine risks. The Appellate Body confirmed, with respect to both types of risks, that risk assessment was not limited to the matters "that are susceptible of quantitative analysis by the empirical and experimental laboratory methods."[99] This observation was drawn from the wording of Article 5.2*,* which "enlist factors not wholly susceptible of investigation according to laboratory methods."[100] As Article 5.2 is applicable to both types of risk assessment, the Appellate Body's finding is equally relevant for pest and disease risks. The Appellate Body, in its famous sentence, summarized the above, by saying:

> the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effect on human health in the real world where people live and work and die.[101]

There is no agreement between commentators regarding the type of factors that may be included, on the basis of the above considered, in risk assessment. Indeed, the Appellate Body findings are very enigmatic and leave great room for interpretation. Some scholars argue that these factors should be limited to control and enforce concerns (i.e. actual enforcement of SPS measure).[102] Others claim that the Appellate Body "opened the door to the inclusion of such factors as cultural preferences and societal values in the risk assessment for SPS measures."[103] Consequently, according to them, it is possible to take into account subjective factors influencing both perception and risk itself.[104]

I argue that any interpretation, which allows for the broad inclusion of cultural preferences and values does not have a sufficient grounding neither in the SPS Agreement nor in the case law. On the textual level, Article 2.2 assigns the special role to science by requiring WTO member states to base their SPS measures on scientific principles, and not maintain them without sufficient scientific evidence. That role is subsequently highlighted in Article 3.3, which speaks about scientific justification as a condition *sine qua non*. The definition of risk assessment, as provided in Annex A to the SPS Agreement, also strongly refers to the technical paradigm. In consequence, inclusion of non-scientific factors in the risk assessment, to the extent that they will prevail over scientific evidence, seems to be incompatible with the explicit language of the SPS Agreement. The case law also supports this position. As mentioned in Section 3.3.1 (b) of this paper, the risk assessment was conceptualized as either a two or three-steps analysis. Note that in both cases, the individual steps of the analysis relate to scientific considerations. Identification of risk as well as an evaluation of probability (or possibility) has a strong scientific character. In consequence, the implementation of non-scientific considerations may only have a supplementary character and

[99] EC-Hormones *supra* note 30, para. 187.
[100] *Id.*
[101] *Id.*
[102] Warren H. Maruyama, *A New Pillar of the WTO: Sound Science*, 32 Int'l Lawyer 651, 673 (1998).
[103] Regine Neugebauer, *Fine-Tuning WTO Jurisprudence and the SPS Agreement: Lessons from the Beef Hormone Case*, 31 Law & Pol'y Int'l Bus. 1255, 1267 (2000).
[104] M. Gregg Bloche, *WTO Deference to National Health Policy: Toward and Interpretative Principle*, 5 (4) J. Int'l Econ. L. 825, 836 (2002).

cannot counter-balance the scientific findings. However, the acceptable input of non-scientific considerations in risk assessment can presumably only be ascertained on a case-by-case basis.

e) Specifity of Risk Assessment

Risk assessment needs to be specific. According to the Appellate Body, it should evaluate the specific potential of harm arising from the presence of specific SPS risk. Thus, in the EC-Hormones case, the panel required evaluation of the carcinogenic potential of residues of hormones used for growth promotion purpose, which were present in meat and meat products.[105] Similarly in the Japan-Apples case, evaluation of "entry, establishment or spread of fire blight through [U.S.] apple fruit as a separate and distinct vector"[106] was required. Consequently, a general discussion on particular SPS risk cannot satisfy the specifity condition (i.e. evaluation of the entire categories of hormones or collection of various host plants). As was noted in the literature, the specifity requirement was construed by the Appellate Body more stringently than what was textually supported by the SPS Agreement.[107]

Indeed, it seems that such interpretation does not correctly balance the rights and obligations of WTO member states. The strict requirement of specifity may undermine the right of the WTO member state to establish its appropriate level of protection. As observed by Sykes, the approach adopted by the Appellate Body is particularly troublesome in all cases that relate to low-level risk situations.[108] How does one provide the specific risk assessment, which will evaluate the risk connected with the presence of a particular substance in a particular product, if the presumed effect is e.g. one in a million? According to the Appellate Body, a member state is free to regulate any ascertainable risk and adopt any level of protection it deems to be appropriate. It also includes the zero risk policy and clearly encompasses the situation when the risk ratio is one to million. However, if the extrapolation from the more general studies and findings does not satisfy the specifity requirement (e.g. in the EC-Hormones case deducting carcinogenic effects of oestrogens present in beef from general studies on oestrogen),[109] it may appear that in low-risk situations the appropriate level of protection is an illusory right. Sykes summarizes that "the effect is to make it impossible for national regulators to elect to eliminate low-level risks that are not susceptible to rigorous demonstration."[110]

3.3.2 Implementation of Risk Assessment Results

The SPS measure should be based on the risk assessment.[111] There is no procedural requirement to consider the conclusions of the risk assessment during the process of enactment of an SPS measure.[112] Therefore, a member state may present scientific evidence, supporting its SPS measure, produced at the time of panel's proceeding.[113] It is argued that denial of a procedural requirement may result in gambling over SPS measures, as most of

[105] The Appellate Body upheld this finding.
[106] Japan-Apples *supra* note 54, para. 200.
[107] Neugebauer *supra* note 103, at 1267.
[108] Sykes *supra* note 27, at 364-65.
[109] EC-Hormones *supra* note 30, para. 198.
[110] Sykes *supra* note 27, at 365.
[111] According to the Appellate Body, a member state is not obliged to conduct its own risk assessment; an assessment may be carried out by another country or international organization and only used by the particular member; *see* EC-Hormones *supra* note 30, para. 190.
[112] *Id.* para. 189.
[113] Pauwelyn *supra* note 5, at 649.

them will never be challenged (due to the costs of proceeding). According to that argument, the procedural requirement may serve harmonization goals of the SPS Agreement, as member states will be obliged to make a scientific assessment for all measures and not only for those, which are disputed.[114] Note, however, that such an approach will result in the exclusion of new scientific evidence produced after the adoption of the measure. In effect, a member state will be precluded from presenting state-of-the-art scientific data. In disputes concerning such sensitive areas like health and environment, it is not a plausible solution. Moreover, if the violation of the SPS Agreement related to procedural deficiencies alone, member states might be encouraged to employ time-delay strategies. In some cases, it might be tempting to find against a defendant on the basis of procedural defects, without substantial issues being decided. Subsequent procedural compliance will provide a defendant with the additional time necessary for substantive examination of the measure in the second potential case. As a consequence, I believe, that the approach of the Appellate Body seems to be appropriate.

a) Rational Relationship between the Risk Assessment and SPS Measure

According to the Appellate Body, the relationship between risk assessment and an SPS measure should be perceived as an "objective relationship between two elements", or in other words "an objective situation that persists and is observable between an SPS measure and a risk assessment."[115] In practice, the examination of an objective relationship should consist of a comparison of the scientific conclusions reached in the risk assessment with the conclusions embedded in the SPS measure, in order to examine their compatibility.[116] As stressed by the Appellate Body, those conclusions do not need to conform with each other, but rather the scientific conclusions of the risk assessment must reasonably support the SPS measure under the examination. Apparently, the Appellate Body used both terms, objective and rational, interchangeably. This again reflects the technical paradigm followed by the Appellate Body - the rationality and rational reasoning delimits the objectivity.

What, then, should be the level of compatibility between the results of the risk assessment and the SPS measure? The Appellate Body did not provide a clear definition of the rational relationship. It rather preferred a case-by-case approach, in which "account is taken of all considerations rationally bearing upon the issue of the potential adverse health effects."[117] As may be suggested by the reasoning of the panel in the Australia-Salmon case, the risk assessment cannot be considered as a rational basis for the SPS measure if it does not evaluate risk and risk reduction related to the SPS measure at stake.[118] Additional guidance may be also deduced from the interpretation adopted by the Appellate Body under Article 2.2. Note that the language used under the both Articles is very similar. The relationship between the SPS measure and the risk identified by the scientific evidence under Article 2.2 was described as a rational or objective one.[119] The very same language was used for the characterization of the relationship between the conclusions of the risk assessment and the SPS measure. Thus, by analogy, it can be said that the relationship between the SPS measure and the findings of the risk assessment should be proportional. Consequently, if the risk assessment identifies "negligible risks", while the SPS measure introduces a stringent regime

[114] Hurst *supra* note 94, at 14.
[115] EC-Hormones *supra* note 30, para. 189.
[116] *Id* para. 192.
[117] EC-Hormones *supra* note 30, para. 194; *see also* Japan–Agriculture Products *supra* note 47, para. 79 where the Appellate Body characterized in a similar way the relationship existing between the scientific information and the SPS measure under Article 3.3 of the SPS Agreement.
[118] Panel Australia-Salmon *supra* note 62, para. 8.98.
[119] For a more detailed discussion, *see* Section 3.1 of this paper.

there will be no rational or objective relationship.[120] That interpretation of rational relationship under Article 5.1 needs to be, however, confirmed by the Appellate Body.

Scholars generally perceive the rational relationship required by the Appellate Body as easy to satisfy. Specifically, Hurst claims that the Appellate Body, by allowing member states to base their SPS measure on the minority science and not requiring a minimum magnitude of risk, created a rather undemanding test to pass.[121] Others label the rational relationship test as a deferential standard, which leaves great discretion to WTO member states and allows for inclusions of non-scientific considerations.[122] However, it was also submitted that "the Appellate Body is moving in the direction of substantive benchmark,"[123] which requires a more intense relationship. Indeed, if the above findings on the required proportionality are relevant, such statement seems to be justified.

b) Majority and Minority Scientific Opinions

The risk assessment may set out both the majority scientific opinion, as well as the opinions of scientists taking a divergent view.[124] The Appellate Body also said that

> [i]n most cases, responsible and representative governments tend to base their legislative and administrative measures on 'mainstream' scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources.[125]

In consequence, according to the Appellate Body, the SPS measure may rely on either of them.

The interpretation that was adopted by the Appellate Body is not, however, entirely clear. The above passage, particularly the notion "qualified and respected source", may be interpreted as requiring from divergent opinion a sound basis in science. Presumably, not every divergent view may amount to scientific opinion. The phrase "qualified and respected sources" indicates a certain level of reliability and quality. The Appellate Body confirmed that position when it rejected one of the experts' opinions in the EC-Hormones case. It said that "single divergent opinion … is not reasonably sufficient to overturn the contrary conclusions reached in the scientific studies,"[126] particularly if those other studies are more specific. Thus, the divergent opinion needs to be specific and supported by some evidence as well.[127] As pointed out by McNiel, a country "maintaining a purported SPS measure must be able to adduce evidence that prominent scientists would accept as scientific."[128] It was also suggested that if the measure were based on minority scientific opinion, the relationship between the

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[120] *See* Section 3.5 for the discussion on the implication of those findings for the right of member state to adopt an appropriate level of protection.

[121] Hurst *supra* note 94, at 16; same Bloche *supra* note 104, at 837.

[122] Ryan D. Thomas, *Where's the Beef? Mad Cows and the Blight of the SPS Agreement*, 32 Vand. J. Transnat'l L. 487, 507 (1999).

[123] Joanne Scott, *European Regulation of GMOs: Thinking about 'Judicial Review' in the WTO*, Jean Monnet Working Paper 4/04 (available at http://www.jeanmonnetprogram.org/papers/040040401.html last visited May 28, 2005), at 20.

[124] EC-Hormones *supra* note 30, para. 194.

[125] *Id.*

[126] *Id.* para. 198, rejecting the opinion of Dr. Lucier.

[127] Bloche *supra* note 104, at 83.

[128] McNiel *supra* note 34, at 119.

measure and the risk assessment would be subject to more stringent review.[129] I would claim, rather, that the more stringent review would be applied to minority opinion itself. While in case of a majority scientific view, the Appellate Body may presume its plausibility; in case of divergent opinion it may be necessary to examine the substance of the evidence.

The above approach to minority opinions is subject to legitimate criticism. It is submitted that requirement of specifity may result in the practical exclusion of divergent opinions, as those opinions are usually "based in the kind of suggestive but not definite scientific evidence."[130] There are, however, voices claiming that the requirement of sound science, as deducted from the statement of the Appellate Body, may be premature. The Appellate Body did not define what is understood by "qualified and respected sources". Moreover, it seems that in rejecting the opinion of Dr. Lucier, the Appellate Body rather required specifity of risk assessment than certain scientific quality. As argued by Charnovitz, neither the case law nor the SPS Agreement provides for such a requirement and the issue still requires resolution.[131]

It seems that final determination of that issue will have to wait for a future decision of the Appellate Body. However, it should be stressed that acceptance of any kind of divergent view, irrespective of its quality, is not advisable. As noted by Sykes, unlimited reliance on the scientific minority view transforms the risk assessment requirement into "minimal procedural hurdles,"[132] as it will be always possible to find an expert with a dissenting scientific opinion. In consequence, a certain threshold of scientific reliability is necessary in order to guarantee the operation of the SPS system.

3.4 Insufficiency of scientific evidence (Article 5.7)

According to the Appellate Body, Article 5.7 of the SPS Agreement operates as qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence.[133] Arguably, Article 5.7 exempts only the obligations contained in Articles 2.2 and 5.1-5.3. Consequently, it seems that Article 2.3, 5.5 and 5.6 of the SPS Agreement are fully applicable to measures adopted in the case of insufficiency of scientific evidence. That conclusion may be deducted from the formulation of Article 2.2, which establish certain disciplines and subject them to the exemption of Article 5.7. As Articles 5.1-5.3 provide the elaborations of the requirement of scientific basis as incorporated in Article 2.2, presumably they are also subjects of the exemption. Neither Article 2.3 nor 5.5-5.6 contains comparable language. Thus, provisional measures adopted under Article 5.7 should *inter alia* comply with a consistency requirement and be no more trade restrictive than required.

Since Article 5.7 establishes a form of affirmative defence, presumably, it is for the defending party to provide a panel with a *prima facie* case. Unfortunately, the case law is rather ambiguous in this respect. In the Japan-Agriculture Products case, Japan claimed that a varietal testing system could be considered as a provisional measure in the sense provided by

[129] Hurst *supra* note 94, at 12 basing his argument on the Appellate Body statement that by itself reliance on a minority viewpoint does not necessary signal the absence of reasonable relationship.

[130] Peel *supra* note 13, at 71.

[131] Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade Rules*, 13 Tul. Envtl L.J. 271, 279 (2000).

[132] Sykes *supra* note 27, at 366.

[133] Japan-Agriculture Products *supra* note 47, para. 80.

Article 5.7.[134] Logically, it should be for Japan to prove that the conditions of that article are fulfilled. Surprisingly, the panel reversed the burden of proof by requiring the U.S. to present a *prima facie* case of inconsistency.[135] In consequence, Charnovitz, commenting on the case, pointed out that "Article 5.7 should not be thought of as an exception because such reasoning might imply that the defendant government would have the burden of proof."[136] That position was shifted in the Japan-Apples case. Japan argued that its measure might be justified under Article 5.7. The Appellate Body said that "in this particular context that the Panel assigned the burden of proof to Japan to make a *prima facie* case in support of its position under Article 5.7."[137] Note, however, that the context was the same as in the Japan-Agriculture Products case. In both cases, it was Japan that relied on Article 5.7. That inconsistency of the case law should be addressed and clarified in future disputes. I claim that the interpretation proposed in the Japan-Apples case better reflects the language of the SPS Agreement. Article 5.7 should be seen as a form of the affirmative defence. The Appellate Body in its land-mark case stated that "the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a particular claim or defence. If that party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption."[138] Thus, following the reasoning of the Appellate Body in the US –Shirts and Blouses case, it should be for the defendant to come up with the appropriate evidence, unless it is a complaining party who asserts the violation of Article 5.7.

It this context, it is also interesting to note the additional inconsistency of the case law. With respect to Article 3.3, the Appellate Body required from the complainant a *prima facie* case of non-compliance.[139] Cleary, the Appellate Body considered the same textual basis differently ("except as" in Article 2.2 with respect to 5.7 and Article 3.1 with respect to 3.3), arguing that Articles 3.1 and 3.3 apply to dissimilar situations. The same language in 2.2 of the SPS Agreement, without any broader explanation, was interpreted in the Japan-Apples case as requiring the affirmative defence from defending party.[140]

Application of Article 5.7 requires cumulative satisfaction of the following requirements: (i) insufficiency of scientific data, (ii) that the measure is based on available pertinent information, (iii) that the member seeks to obtain additional scientific information, (iv) that the provisional measure is the subject of review within a reasonable time.[141] 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 or risks as required under Article 5.1."[142] In the same case, the Appellate Body also added that the concept of insufficiency should not exclude "cases where the available evidence is more than minimal in quantity but has not led to reliable or conclusive results."[143] Thus, both quantity and conclusiveness of scientific data play an important role in triggering the application of Article 5.7. The Appellate Body emphasized that insufficiency should not be equated with

[134] Panel Report, *Japan – Measures Affecting Agriculture Products*, WT/DS76/R, adopted March 19, 1999, [hereinafter **Panel Japan-Agriculture Products**], paras. 4.187 and 8.48.

[135] *Id.* para. 8.58, the panel particularly said that "we consider, therefore, that the United States has established a presumption that Japan did not comply with the requirements in the second sentence of Article 5.7. We also consider that Japan has not been able to rebut this presumption."

[136] Charnovitz *supra* note 131, at 289.

[137] Japan-Apples *supra* note 54, para. 175.

[138] U.S. – Shirts and Blouses *supra* note 46, para. 14.

[139] EC-Hormones *supra* note 30, paras. 104-108.

[140] Pauwelyn also points out that inconsistency, *see* Pauwelyn *supra* note 5, at 657.

[141] *See* Japan-Agriculture Products *supra* note 47, para. 89; Japan-Apples *supra* note 54, para. 176.

[142] Japan-Apples *supra* note 54, para. 179.

[143] *Id*. para. 185.

uncertainty.[144] The distinction made by the Appellate Body is between lack of scientific evidence and uncertainty about the validity of scientific conclusions on the cause of harm. 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."[145] Thus, existing uncertainty in the presence of scientific evidence cannot lead to application of Article 5.7. This may suggest that Article 5.7 will not apply to situations "when scientific uncertainty endures long after the risk has been identified."[146] In such a case, a member state should rather perform risk assessment according to the provision of Articles 5.1-5.3. As indicated in the EC-Hormones case, the existence of scientific uncertainty does not release a member state from the obligation to conduct a risk assessment.[147] To remedy this, WTO member state may uses conservative assumptions and qualitative elements in risk assessment or bases its SPS measure on divergent scientific opinions. The question remains, however, how to distinguish the situations in which there is "no reliable or conclusive results" from those which are characterized by certain level of uncertainty. Proper qualification will trigger the application of either Article 5.1 or 5.7 of the SPS Agreement. Is the amount of scientific evidence in a particular case to be decisive? Further guidelines are definitely required in this respect.

To date, none of the panels has reached the requirement of "available pertinent information". The "pertinent information" presumably provides for a lower level of conclusiveness than required from scientific data. However, it is not clear how big the difference between those two types of information is. It is argued that this type of information should include *inter alia* substantive "inputs from officially recognized public deliberation, ... other information concerning public values such as consumer data and public attitudes."[148] It should be noted that a future interpretation of that term has a capital importance for the scope of application of Article 5.7. If the threshold for pertinent information will be established at a high level, clearly it will limit the possibility to invoke the exemption (i.e. by excluding non-scientific data).

Presumably, the notion "based on" should, as understood under Article 2.2 or 5.1 of the SPS Agreement, require a rational or objective relationship between pertinent information and an SPS measure. Thus, using the reasoning provided in Article 5.1, "available pertinent information" with respect to the risk must reasonably support the SPS measure under the examination. In a similar way, the notion of negligible risk and proportionality test may also play a role under Article 5.7.

The member state is obliged to "seek to obtain the additional information necessary for the more objective assessment of risk."[149] The Appellate Body confirmed that Article 5.7 does not require any specific kind of information to be collected or collection procedures to be used.[150] This information needs to be, however, relevant for both the risk in question and the risk assessment itself.

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[144] *Id.* para. 184.

[145] Australia-Salmon *supra* note 63, para. 130.

146 J. Martin Wagner, *The WTO's Interpretation of the SPS Agreement has Undermined the Right of Governments to Establish Appropriate Level of Protection Against Risk*, 31 Law & Pol'y Int'l Bus. 855, 859 (2000).

[147] EC-Hormones *supra* note 30, para. 194; as noted by Howse the Appellate Body statement may suggest that "*uncertainty* does not in itself prevent a measure from being based on a scientific assessment of risk" (Howse *supra* note 79, at 2342).

[148] David Winickoff, Sheila Jasanoff, Lawrence Busch, Robin Grove-White, Brian Wynn, *Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law*, 30 Yale J. Int'l L. 81, 115 (2005).

[149] Article 5.7 of the SPS Agreement.

[150] Japan-Agriculture Products *supra* note 47, para. 92.

A measure under Article 5.7 needs to be provisional and subject to subsequent review. The review should take place within a reasonable time. Such a formulation leaves considerable discretion to a panel. The reasonable period of time is to be defined on a case-by-case basis.[151] The Appellate Body enumerated some of the elements, which may influence what will be considered a reasonable time in a particular case. Thus, the level of difficulty in gathering new information and the characteristic of a provisional measure play an important role in that judgment.[152] The second element may indicate that a stringent SPS measure will be subject to deeper scrutiny. If an SPS measure establishes an absolute ban, presumably that fact should be taken into account when examining reasonableness of time. It was also suggested in the literature that in low certainty and low consensus situations that time should be considerably long (i.e. in case of a novel risk situation related to new technologies such as GM crops).[153] Indeed, Article 5.7 seems to be capable of addressing properly that problem. However, the actual approach is still requires clarification in future case law.

3.5 The Role of Science in the Establishment of the Appropriate Level of Protection (Articles 5.4 – 5.6)

The SPS Agreement explicitly recognizes that establishment of appropriate level of SPS protection is an independent right of each WTO member state. The Appellate Body on several occasions also recognized that this was a prerogative of national governments.[154] Thus, member states are free to adopt any level of protection they deem to be appropriate. As already mentioned that also includes zero risk level.[155] The process of establishing appropriate level of protection is subject to some requirements of the SPS Agreement (i.e. consistency requirement as provided by Article 5.5), "but not to science-based criteria."[156] Other considerations such as societal values, cultural acceptance of risk, technical and economical feasibility to influence the governmental decision in this respect.

There are, however, some troublesome findings in the case law, which bring the right of the WTO member states to establish an appropriate level of protection into question. First, according to the Appellate Body, the risk that is regulated needs to be ascertainable. Consequently, hypothetical risks will not withstand scrutiny under the SPS Agreement. However, taking into account the limitations of scientific methods and science itself, what is hypothetical today may not necessarily be tomorrow. Presumably, among hypothetical risks there are a number of genuine risks which have yet to be verified. Thus, the approach of the Appellate Body, which excludes this category of risks as a legitimate subject of regulation, effectively deprives WTO member states of the possibility to regulate them.[157] In consequence, member states are unable to establish the level of protection, which they deem to be appropriate with respect to those risks. Article 5.7 of the SPS Agreement is able to address that problem only to certain limited extent. As noted above, the application of Article 5.7 is not generally triggered by the existence of uncertainty but rather because of lack of scientific data. Moreover, the requirements of available pertinent information may also constitute a constraint, particularly if data about the risk are very limited.

Second, the specifity of risk assessment required by the Appellate Body may result in an impossibility to regulate low-risk situations. As noted in Section 3.3.1 (c) of this paper, these

[151] *Id.* para. 93.
[152] *Id.*
[153] Winickoff, Jasanoff, Busch, Grove-White & Wynn *supra* note 148, at 115-16.
[154] EC-Hormones *supra* note 30, para. 124.
[155] Australia-Salmon *supra* note 63, para. 125.
[156] Peel *supra* note 13, at 14.
[157] A similar argument is made by Peel, *see* Peel *supra* note 13, at 70.

types of risks are very elusive and easily escape scientific examination. In effect, it may appear that in low-risk situations the right to establish appropriate level of protection is rather illusory.

Third, the proportionality test applied by the panel in the Japan-Apples case also impairs the right of the member states to establish any level of protection they deem to be appropriate. According to the panel, disproportion between the risk identified by the scientific evidence and the SPS measure implies that there is no rational or objective relationship. In the same line the panel also introduced the notion of "negligible risk", risk whose probability of occurrence is very low.[158] If an adopted SPS measure is strict (presumably aiming at zero risk level), while the risk is negligible (which does not mean that it does not exists) no rational or objective relationship between the measure and the relevant scientific evidence will be found. Lack of such a relationship indicates that a measure is maintained "without sufficient scientific evidence" and violates Article 2.2 of the SPS Agreement. Note, however, that both concepts of proportionality and negligible risks reflect rather the political considerations, which are reserved to the WTO member states. If a member state is entitled to establish its appropriate level of protection, the panel may not classify risks as negligible or require proportionality between the risk and measure.[159]

Forth, as discussed in Section 3.3.1 (c) and (d), the interpretation of the notion of "likelihood" in the assessment of pest and disease risks seems to require a quantitative dimension. In such cases mere qualitative data cannot serve as a basis of proper risk assessment. In consequence, finding a quarantine risk, which is not reducible to quantitative dimensions, does not allow a member state to adopt an SPS measure.

3.6 Standard of Review in SPS Disputes

The last issue that requires clarification is the standard of review employed by the panels in the SPS disputes. The applicable standard has an essential role in the process of assessment of scientific evidence submitted by the parties during proceedings. The deferential standard results in the inability of a panel to review the scientific evidence. Instead, the panel may only examine whether a member state followed the procedures required by the SPS Agreement (i.e notifications requirements). On the other hand, a *de novo* standard allows a panel to review the determination made by the national authority and substitute it with its own judgments. That also includes evaluation of the validity of scientific evidence, as well as appropriateness of the SPS measure to address a specific risk situation. Of course between those two extremes, there is a great array of more or less deferential approaches.

As the SPS Agreement does not provide for any specific rules in this respect, the Appellate Body referred to Article 11 of the Understanding and Procedures Governing the Settlement of Disputes.[160] The Appellate Body found that "the applicable standard is neither *de novo* review as such nor 'total deference', but rather the 'objective assessment of the

[158] The negligible risk was defined by one of the experts in the Japan-Apple case as the "likelihood of between zero and one in a million," *see* Panel Japan-Apples *supra* note 50, Annex 3, para. 332.

[159] *But see* Panel Japan-Apples *supra* note 50, para. 4.64, where the U.S. observed that "in describing the risk of transmission as 'negligible' rather than 'zero', the scientific reports merely reflected 'the uncertainty that theoretically always remains [that an event may occur] since science can never provide absolute certainty' that an event may never occur."

[160] Understanding and Procedures Governing the Settlement of Disputes as incorporated by the Marrakesh Agreement Establishing the World Trade Organisation of April 15, 1994 available at http://www.wto.org [hereinafter **DSU**].

facts'."[161] Thus, in the EC-Hormones case, the Appellate Body refused the argument of the E.C. that the panel was obliged to apply deferential judicial review of the national regulatory authority's determinations. Likewise, in the Japan-Apples case, the Appellate Body confirmed that favoring "Japan's approach to risk and scientific evidence over the views of the experts conflicts with the Appellate Body's articulation of the standard of 'objective assessment of the facts.'"[162]

The objective standard allows the panel to determine the existence, quality and sufficiency of scientific evidence supporting the SPS measure in question. Consequently, the panel may review the scientific justification and determine whether evidence is sufficient for the justification of the measure. Indeed, in all four disputes the panels made such a determination. As noted by some commentators the "line between an objective standard and a *de novo* review appears blurry, as an objective assessment of the facts would arguably entitle the panel to impose its own views on the scientific evidence."[163] Certainly, the standard that was adopted by the Appellate Body is closer to *de novo* review than deference.[164] However, as noted by another scholar "where exactly the middle ground is to be found between de novo review and total deference will only become clear through adjudication of further cases."[165] That statement has not lost its strength.

4. Science as a Benchmark in International SPS Disputes

What kind of observations on the role of science under the SPS Agreement can be drawn from the above analysis? Theoretically, there are at least three distinctive roles, which may be performed by science under the SPS Agreement. First, science can be seen as an element of harmonization efforts pursued within the WTO. Presumably, science is one of the most universal discourses available to humans. This is particularly true with respect to hard science such as mathematics and physics, and to some extent biology, chemistry, and toxicology. Thus, the employment of science may result in greater convergence between the different regulatory systems than in the case of any other criteria.[166] However, acceptance of minority scientific opinions as well as recognition of the right of member states to establish its own level of protection seems to indicate that this function plays a rather limited role. Moreover, it may be legitimately argued that only those provisions of the SPS Agreement, which relate to international standards, may be seen as a reflection of harmonization goals.

Second, science can be seen as a sophisticated instrument for the detection of those measures which have a protectionist character. In other words, science may serve as an objective criterion for determination whether the particular SPS measure is protectionist or not. As noted by Sykes the requirement of scientific evidence "aids in motive review, and helps to sort regulations between those that are protectionists and those that seek to promote some legitimate, non-protectionist regulatory objective."[167] Consequently, the role of science

[161] EC-Hormones *supra* note 30, para. 117, the Appellate Body based its argument on the wording of Article 11 of the DSU.

[162] Japan-Apples *supra* note 54, para. 165.

[163] Nick Covelli & Viktor Hohots, *The Health Regulation of Biotech Foods under the WTO Agreement*, 6 (4) J. Int'l Econ. L. 773, 783 (2003).

[164] Peel *supra* note 13, at 95-97.

[165] G. Axel Desmedt, *Hormones: 'Objective Assessment' and (or as) Standard of Review*, 1 J. Int'l Econ. L. 695, 697 (1998).

[166] However, Atik argues that science may lead to fragmentation rather than convergence due to "influences exerted by particular scientific centers of authority" or as an alternative to procedural convergence as opposed to a substantive one, Atik *supra* note 17, at 755.

[167] Sykes *supra* note 27, at 355.

is limited to determining whether an SPS measure is genuine or constitutes disguised protection.[168] As one scholar put it, the role of science is limited to the task of circumscribing "the regulatory activity of national governments so as to limit the abuse of putatively scientific claims for protectionist purposes."[169]

Finally, science may be perceived as a mechanism for elimination of SPS restrictions to international trade, by requiring certain rationality from domestic regulations. That goal goes beyond the pure non-protectionism principle. It aims at the general elimination of the obstacles to international trade, irrespective of whether they have or not a protectionist character.[170] As stressed by one commentator, the SPS Agreement aims at "the prevention of unjustified regulation per se, whether or not such a regulation creates a competitive disadvantage for foreign goods vis-à-vis domestic goods."[171] Again it was submitted that the Appellate Body refused to recognize fully that function. As Hurst criticized, the Appellate Body "denied proper recognition to a fundamental premise underlying the SPS Agreement that even non-discriminatory measures have the clear potential to hamper the international trade."[172]

The approach adopted in the case law seems to indicate that the Appellate Body is still in the process of defining the exact role of science under the SPS Agreement. Arguably, the Appellate Body tries to find an equilibrium between competing objectives, namely trade liberalization and the need to protect life and health. In the words of the Appellate Body:

> [t]he requirements of a risk assessment under Article 5.1 as well as of 'sufficient scientific evidence' under Article 2.2, are essential for maintenance of the delicate and carefully negotiated balance in the SPS Agreement between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings.[173]

As a general observation, it may be said that the Appellate Body relied predominantly on the technical paradigm of risk. The Appellate Body, following the language of the SPS Agreement, conceptualized risk as a combination of probability or possibility and adverse outcome resulting from the exposure to the hazard. Likewise, risk assessment was perceived as predominantly scientific evaluation. Under that approach, the principal role needs to be assigned to science. Consequently, the SPS measure needs to be based on scientific principles, rationally related to scientific evidence (Article 2.2) and supported by the conclusions of risk assessment (Article 5.1). A mere consideration of scientific evidence is not sufficient; findings of risk assessment need to be reflected in an SPS measure. An SPS measure will be found incompatible with the SPS Agreement if not supported by sufficient scientific data and evidence. Presumably, the Appellate Body, while accepting divergent scientific opinions, also required from them a certain level of scientific plausibility. In the same line, the Appellate Body introduced the objective standards of review. This standard allows panels to determine the existence, quality and sufficiency of scientific evidence supporting the SPS measure in question. Science's role seems closer to the third function rather than the second one. Thus, science aims at the elimination of the internal barriers to international trade, irrespective of whether such barriers have a protectionist character. In the words of one commentator,

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[168] John J. Barceló III, *Product Standards to Protect the Local Environment – the GATT and the Uruguay Round Sanitary and Phytosanitary Agreement*, 27 Cornell Int'l L.J. 755, 768 (1994).

[169] Wirth *supra* note 16, at 818.

[170] Bohanes *supra* note 10, at 326.

[171] Robert Hudec, *Science and Post-discriminatory WTO Law*, 26 B.C. Int'l & Comp. L. Rev. 185, 187 (2003).

[172] Hurst *supra* note 94, at 31.

[173] EC-Hormones *supra* note 30, para. 177.

science is employed as a criterion for distinguishing the between legal and illegal SPS measures.[174]

The above does not mean, however, that the Appellate Body adopted the orthodox technical standpoint on the role of science. The case law proves just the opposite. As indicated previously, the notion of "science" was understood liberally. The Appellate Body recognized that science is not a static or determined set of knowledge; it is rather a constant process of inquiry on the nature and behavior of natural things, characterized by continuous verification of subsequent hypothesis. At the same time, science is not able to provide with absolute certainty that a particular substance will not have an adverse effect.[175] Such an understanding of science has far-reaching practical implications. As science is not perceived as constituting a monolithic view, divergent scientific opinions may constitute a valid basis for the SPS measure. What constitutes a divergent opinion today may become a majority view tomorrow; in consequence "the call for a scientific basis may be satisfied by one or multiple mutually exclusive sciences."[176] Likewise, a panel, when evaluating whether the SPS measure is based on sufficient scientific evidence, limits its examination to the plausibility of the evidence provided. It does not require a member state to employ the best science available. The Appellate Body recognized the imperfections inherent in scientific methods. In consequence, it did not require member states to construe a risk assessment as a purely quantitative procedure. The qualitative elements may play a vital role in the process of identification and evaluation of possible risks. It also seems that the Appellate Body went beyond the technical paradigm of risk assessment. Arguably, the Appellate Body recognized that risk assessment is not a purely scientific process and other considerations may play an important role. That finding is supported by the refusal to strictly distinguish the risk assessment from the risk management as well as interpretation of Article 5.2 of the SPS Agreement. The risk assessment is not limited to the matters that are "susceptible of quantitative analysis by the empirical and experimental laboratory methods."[177] That is particularly true if the risks are irreversible. Moreover, in the EC-Hormones case the Appellate Body recognized that the government might act from the perspective of prudence and precaution.[178] Thus, the national governments enjoy certain a degree of deference when adopting their SPS measures. In the same line, the relationship between scientific evidence or conclusions of the risk assessment and SPS measure was conceptualized as a rational or objective one. The Appellate Body did not require a substantial relation or full conformity. Thus, it is not necessary for the member state to mirror the findings of the risk assessment, as the SPS measure needs only to be rationally related to the conclusions of assessment.[179] Clearly, it was possible within the language of the SPS Agreement to adopt a more stringent interpretation. Note however, that the introduction of a proportionality test regarding risk and the SPS measure may also indicate that the case law tends to require a more substantial relationship.

On the other hand, there are some findings in the case law, which seem to be inconsistent with the explicit language of the SPS Agreement. As discussed in Section 3.5 of this paper, the SPS Agreement clearly provides that WTO member states have a right to

[174] Vern R. Walker, *Keeping the WTO from Becoming the "World Trans-Science Organization": Scientific Uncertainty, Science Policy, and Factfining in the Growth Hormones Dispute*, 31 Cornell Int'l L.J. 251, 254 (1998).

[175] EC-Hormones *supra* note 30, para. 186.

[176] Atik *supra* note 17, at 749.

[177] *Id.* para 187.

[178] EC-Hormones *supra* note 30, para 124.

[179] Note, however, that the introduction of a proportionality test regarding risk and an SPS measure may indicate that the case law tends to require a more substantial relationship.

establish and maintain their appropriate level of SPS protection of human, animal or plant life and health. The Appellate Body on several occasions also has confirmed that right. Nevertheless, certain standards adopted for the purpose of evaluating the sufficiency of scientific evidence or the appropriateness of the risk assessment put that right in question. Particularly with respect to the requirement of risk ascertainability, specifity of risk assessment, proportionality between the SPS measure and risk probability, as well as the qualitative and quantitive dimension of risk assessment. Those standards are not inappropriate *per se.* Clearly, they worked properly in the SPS cases that were decided. Nonetheless, they seem to be incapable of universal application in the SPS disputes. As indicated above, there are borderline situations, in which the application of those standards, will result in the violation of the right of the member states to establish a level of SPS protection they deem to be appropriate. The additional problems relate to the issue of the burden of proof allocation under Article 5.7 as well as an interpretation of the alternative as provided by Article 3.3.

It also should be noted that there are a number of specific issues under the SPS Agreement still to be decided. The clarification of those matters will ultimately determine the role, which is played by science under the SPS Agreement. Thus, the relationship between Article 2.2 and 5.1 needs to be elucidated. Particularly, it is important to clarify whether it is possible for the member state to lose the case because of deficiencies in the risk assessment, even if scientific evidence showed the reasonableness of the SPS measure. The Appellate Body should also explain to what extent non-scientific considerations might be taken into account when conducting risk assessment. The additional clarification is also required with respect to the status of minority scientific opinions. How plausible they need to be? What level of reliability should they bear? Whether "a measure inconsistent with the current dominant paradigm will fall the SPS scrutiny"?[180] Finally, the notion of "available pertinent information" requires further investigation by panels and the Appellate Body.

The role that has been assigned to science under the SPS Agreement, through the Appellate Body's interpretation, is subject to both, strong criticism and genuine appraisal. Critics argue that the aim of the WTO system is the promotion of socio-economic welfare. Such welfare consists of both material and nonmaterial elements, including popular safety perception. In effect, reliance on purely scientific criteria does not guarantee the maximization of social welfare.[181] Popular fear in itself is a social cost. Thus, the adoption of risk regulation based on purely the popular perception of risk, may have sense, even if scientifically unfounded. Howse points out that "if citizens believe they need a certain regulation, however 'deluded' such belief is, their utility will be reduced if they do not get it, in the sense they will believe themselves exposed to a risk they believe to be significant."[182] Other authors make their arguments with reference to democratic values. Bohanes claims, on the basis of a subjective welfarism approach,[183] that the government should not override the preferences of its own citizens. Therefore, the ultimate decision should be taken in accordance with general public preferences rather than science. It is also submitted that democracy requires that the ultimate decision rests on citizens. As Howse puts it: "not to honor the citizens' choice is in fact to favor an artificial and cryptically elitist conception of democratic deliberation."[184] From a pragmatic point of view, it is argued that the application of the SPS Agreement, which favors scientific findings over the popular perception of the risk possibly "endangers public

[180] Atik *supra* note 17, at 753.
[181] Bohanes *supra* note 10, at 355.
[182] Howse *supra* note 79, at 2337.
[183] The subjective welfarism approach claims that "government, even, or perhaps especially in a democracy, should attend exclusively to conception of welfare as subjectively held by its citizens," Bohanes *supra* note 10, at 360, citing C. Sunstein *Free Markets and Social Justice* (1997).
[184] Howse *supra* note 79, at 2337.

support for the trade regime" in general.[185] Finally, critics stress that science is not a neutral criterion and, thus, is incapable of serving as an objective benchmark in international SPS disputes.[186]

Advocates indicate that the presence of science in the SPS Agreement may help national governments to maintain their autonomy in the field of health and environmental regulation. The scientific requirement may serve as a shield against the pressure from other states to weaken national regulations. In effect, the SPS Agreement does not undermine national sovereignty but rather plays a supportive role.[187] The criticism based on the concept of socio-economic welfare and social costs may be tried with three types of counterarguments. First, it should be noted that this concept does not take into account the external costs of the regulation (i.e. costs borne by the foreign traders, producers). It also underestimates the ancillary costs borne by the nationals (i.e. costs of consumers due to increase of prices or limitation of possible choices) as well as long term costs (i.e. *ex post* costs of maintaining regulation in force).[188] Second, it may be argued that fear can be reduced through less stringent means than regulation (i.e. information and education of general public). Third, regulatory responses to unfounded fears may create incentives for interests groups to promote new fears. Those new fears will of course entail additional costs.[189] In consequence, "deciding whether regulation would minimize social costs would entail a complex calculation."[190] Democratic criticism is addressed on three different levels. First, it is submitted that the "democratic" decisions may result not from the genuine preferences of citizens but rather reflect the interests of narrow but powerful interests groups.[191] Consequently, by relying on international rules (or science in case of the SPS Agreement) governments become more immune from those pressures and therefore closer reflect the real preferences of citizens. Other arguments indicate that democratic decisions need to be based on knowledge. Thus, science-based provisions may be seen as "enhancing the quality of rational democratic deliberation about risk and its control."[192] Third, science may be seen as actually re-enforcing democracy by providing the external accountability of states.[193] The pragmatic argument may be countered by the procedural history of SPS disputes. Out of four decided SPS cases, three were fully complied with by the loosing parties. The EC-Hormones case seems to constitute rather the exception than the general rule. Moreover, it may be argued that the possibility of the compensation and the suspension of concessions instead of compliance serves as a safety valve. Advocates of the SPS Agreement also stressed that the Appellate Body recognized the imperfection of science and scientific methods.

Instead of assessing the validity or plausibility of the above arguments, I would rather like to make four additional remarks. Firstly, it should be noted that the SPS case law is still in its infancy. Four cases decided up to date, have provided member states with some indication on the role of science under the SPS Agreement. However, as discussed above, there is also a number of important issues yet to be decided. Presumably, their interpretation

[185] Charnovitz *supra* note 131, at 302.
[186] *See e.g.* Walker *supra* note 174.
[187] Atik *supra* note 17, at 741.
[188] Howard F. Chang, *Risk Regulation, Endogenous Public Concerns, and the Hormones Dispute: Nothing to Fear but Fear Itself*, 77 S. Cal. L. Rev. 743, 762 (2004).
[189] *Id.* at 763-64.
[190] *Id.* at 763.
[191] Ernst-Ulrich Petersmann, *Trade Policy as a Constitutional Problem. On the 'Domestic Policy Functions' of International Trade Rules,* 41 Aussenwirtschaft 405, 426 (1986).
[192] Howse *supra* note 79, at 2330.
[193] Scott *supra* note 123, at 13, citing R. Keohane who defined external accountability as "accountability to people outside of the acting entity, whose lives are affected by it."

will shed more light on the exact role performed by science in the SPS Agreement. In consequence, some of the objections as well as the praise of the scientific-based system established by the SPS Agreement may be premature.

Secondly, the Appellate Body seems to be conscious of the inherited limitations of the science-based system established by the SPS Agreement. Recognizing those limitations, it approached issues such as scientific justification and risk assessment in very sensitive manner. By doing this, the Appellate Body was able to address some of the most controversial issues relating to the role of science under the SPS Agreement. In effect, the approach, which is emerging from the case law, seems to be far from scientific orthodoxy. This paper attempts to present the specific findings of the SPS case law, which illustrate that trend.

Thirdly, it should be noted that the SPS Agreement in different provisions explicitly recognizes science as a crucial factor for the determination of the legality of domestic SPS measures. [194] According to Article 19.2 of the DSU, "the panel and Appellate Body cannot add to or diminish the rights and obligations provided in the covered agreements."[195] Of course, both the panel and the Appellate Body have a certain margin of discretion in the interpretation of the provisions of WTO agreements (i.e. due to ambiguity or general language used in the text of the agreements). Nevertheless, that margin is not unlimited. That situation is clearly visible in case of the SPS Agreement. The Appellate Body adopted a rather moderate interpretation of SPS provisions. However, further lessening of the role of science, i.e. by the broad inclusion of non-scientific considerations in risk assessment or the implantation of psychological or sociological paradigms into the SPS Agreement, seems to go too far. I believe that such approach will be incompatible with Article 19.2 of the DSU, as it will change completely the explicit language of the SPS Agreement.

Finally, it seems that, in certain borderline situations, there is an inherent tension between the right of a member state to establish an appropriate level of protection and certain standards of risk assessment process. The requirement of risk ascertainability, high demands with respect to the specifity of risk assessment, the introduction of a proportionality test and the concept of "negligible risks", as well as quantitive dimensions in the assessment of quarantine risk through the interpretation of "likelihood" casts serious doubts on the right of the member states to establish its level of SPS protection. If the system created by the SPS Agreement is to operate as a coherent one, those issues require further elaboration and adjustment in the future case law.

5. Conclusions

This paper, by examining the text of the SPS Agreement and the relevant case law, attempts to present a comprehensive and coherent picture of science in the process of risk regulation as provided by the SPS Agreement. Thus, the interrelations between different "scientific" provisions of the SPS Agreement are presented and discussed. On this basis, I try to assess the role, which is assigned to science in international SPS disputes. I argue that the approach adopted by the Appellate Body reflects the explicit language of the SPS Agreement and is predominantly based on a technical paradigm. In consequence, science plays a critical role in distinguishing between legal and illegal SPS measures. However, I also submit that an examination of the case law reveals a recognition by the Appellate Body that risk situations are very complex in their nature. Thus, science is not perceived as a monolithic structure but

[194] As noted by one of the scholars "the core provision of the SPS Agreement establishes the role of science as a fundamental part of the basic obligations assumed by WTO Members with respect to sanitary and phytosanitary measures," McNiel *supra* note 34, at 117.

[195] Article 19.2 of the DSU.

rather as a constant process of inquiry. In consequence, the Appellate Body does not require adoption of the "best science available", and also recognizes divergent scientific opinions as a valid basis for an SPS measure. In the same line, the technical paradigm, as embodied in the SPS Agreement, is supplemented with a number of considerations arising from the other paradigms (i.e. non-scientific considerations in the risk assessment, rational relationship between the results of the risk assessment and an SPS measure etc.).

I argue that the approach adopted in the case law is generally compatible with the textual basis of the SPS Agreement and provides a coherent SPS system. However, I also identify certain areas where its coherence seems to be doubtful. Thus, the interpretation of Article 3.3 that equates two alternatives as well as the allocation of burden of proof under Article 3.3 and 5.7 is questioned. Moreover, I submit that certain standards adopted in the course of the interpretation of the SPS Agreement seem to violate the right of the member states to establish the appropriate level of protection. These are: ascertainability of the risk as a precondition for valid risk assessment; strict specifity of the risk assessment in low-risk situations; the proportionality requirement between the risk identified and the SPS measure; the notion of negligible risks; and the concept of likelihood in the quarantine risk assessments. I claim that the above standards seem to be incapable of general application in SPS disputes as, in certain situations, they will result in the violation of the right of member states to establish an appropriate level of SPS protection.

Finally, this paper highlights a number of specific issues under the SPS Agreement still to be decided. In particular it points out the relationship between Article 2.2 and 5.5; the problem of quality required from minority scientific opinions; the relationship between insufficiency of scientific evidence and scientific uncertainty; and the requirements of Article 5.7 (particularly the meaning of "pertinent information"). The paper suggests that the ultimate role ascribed to science under the SPS Agreement can be assessed only after interpretation of those issues is provided by future case law.