ARTICLES

Science in the Process of Risk Regulation under the WTO Agreement on Sanitary and Phytosanitary Measures

By Lukasz Gruszczynski[*]

Abstract

This article attempts to present a comprehensive and coherent picture of the position occupied by science under the SPS Agreement and in the SPS case law. It claims 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.

The article argues that such an approach 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 article 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 the Member States to establish an appropriate level of SPS protection. Finally, a number of specific issues, which require resolution, are highlighted, namely the quality of minority scientific opinions, the relationship between the insufficiency of scientific evidence and scientific uncertainty. The article 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.

[*] Mag. Jur., Jagiellonian University (2000), LL.M., Central European University (2002), Ph.D. Candidate, European University Institute. Email: Lukasz.Gruszczynski@iue.it.

https://doi.org/10.1017/S2071832200004739 Published online by Cambridge University Press

A. 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, countries should specialize in the production of goods whereby limited domestic resources, when invested in specific activities, can provide the biggest gains and the total output and economic welfare can be increased. Thus, it is argued 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. 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 Member States were introduced. The Agreement on Sanitary and Phytosanitary Measures,[3] specifically designed to create standards for the establishment and maintenance of internal measures having an impact on international trade, is particularly important in this respect.[4]

+ This article was first published as Working Paper in Law 2006/13 at the European University Institute. The author would like to thank Prof. E.U. Petersmann and Prof. J. Scott for their valuable comments on earlier drafts of this article. All omissions and mistakes are author's sole responsibility.

[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 ORGANIZATION. TEXT CASES AND MATERIALS 11-19 (Cambridge University Press 2005).

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

[4] The SPS Agreement applies to measures, which may, directly or indirectly, affect international trade, 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.

The SPS Agreement ascribes a special role to science. 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 among Member States and scholars. 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 analyzes the text of the SPS Agreement as well as the relevant case law. The aim of this article is to present a comprehensive and coherent picture of the concept of science as embodied in the SPS Agreement and relevant WTO case law. This article claims contrary to some scholars, that the Appellate Body (the "AB") adopted a rather sensitive approach to SPS disputes, addressing most of the controversial issues in a proper way. At the same time, the article also submits 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 article proceeds as follows: Section B analyzes in detail the "scientific" provisions of the SPS Agreement. The textual basis of the SPS Agreement is juxtaposed with the existing case law and literature. Section C attempts to generalize those findings and provide a coherent and comprehensive picture of science under the SPS Agreement. Section D summarizes the previous discussion and draws final conclusions.

B. Science under the SPS Agreement

References to science appear in the different provisions of the SPS Agreement. SPS measures need to be "based on scientific principles" and "not maintained without sufficient scientific evidence" (Article 2.2). Unless the measures conform 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, SPS measures may be taken provisionally on the basis of "available pertinent information". In such a case a "Members shall seek to

obtain the additional information necessary for a more objective assessment of risk" (Article 5.7).

I. Scientific Principles and Sufficient Scientific Evidence (Article 2.2)

Article 2.2 requires to base SPS measures on scientific principles and does not allow Member States to maintain them without sufficient scientific evidence. As Article 2.2 employs conjunction ("and"), both obligations need to be met simultaneously. The AB 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.

The notion of "sufficient scientific evidence" has received far more attention in the case law. The word "scientific" was defined by the AB 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."[5] 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."[6] As noted by Peel, such a perception of scientific evidence may be understood as providing minimum methodological constraints.[7]

Sufficiency was as constructed a relational concept, which requires an "adequate relationship between two elements, … between the SPS measures and scientific evidence."[8] The adequate relationship was understood as a "rational or objective one"[9] and the rationality of the relationship should be determined on a case-by-case

[5] Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products*, WT/DS26/AB/R, WT/DS48/AB/R (*adopted* 13 February 1998) [hereinafter EC-Hormones], footnote 172, referring to the ordinary meaning of the word "scientific."

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

[7] Jacqueline Peel, *Risk Regulation under the WTO SPS Agreement: Science as an International Normative Yardstick?* (Jean Monnet, Working Paper 2002/04) footnote 213.

[8] Appellate Body Report, *Japan–Measures Affecting Agriculture Products*, WT/DS76/AB/R, (*adopted* 19 March 1999) [hereinafter Japan-Agriculture Products], para. 73-74.

[9] *Id.*

basis.[10] There are, however, some clues of what could be important in such a determination. According to the AB, vital elements are: "the characteristic of the measure at issue, quality and quantity of scientific evidence."[11] Additionally, in the Japan-Apples case, the AB 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.[12] Thus, examining the rationality of the relationship involves a kind of proportionality test. If the risk is "negligible", while the SPS measure is strict, no rational relationship will be found. On the other hand, it seems that the AB 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."[13] 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."[14] Article 5.1 is "specific application of the basic obligations contained in Article 2.2," [15] and "'may be seen to be marking out and elaborating a particular route leading to the same destination set out in' Article 2.2."[16] Moreover, the AB introduced a negative presumption for measures not conforming to the requirements of risk assessment.[17] The nature of that

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

[11] Japan-Agriculture Products *supra* note 8, para. 84.

[12] Japan-Apples *supra* note 10, para. 164.

[13] EC-Hormones *supra* note 5, para. 124.

[14] *Id.*, para. 180.

[15] Japan-Agriculture Products *supra* note 8, para. 82.

[16] Panel Report, *Australia – Measures Affecting Importing of Salmon*, WT/DS18/R (*adopted* 6 November 1998) [hereinafter Panel Australia-Salmon], para. 8.52.

[17] Appellate Body Report, *Australia – Measures Affecting Importing of Salmon*, WT/DS18/AB/R (*adopted* 6 November 1998) [hereinafter Australia-Salmon], para. 137.

presumption is problematic. The language used by the AB 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. 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. Given the more general character of Article 2.2 the positive presumption is of course not available, as Article 5.1 does not exhaust the whole meaning of Article 2.2. The additional examination of the measure under Article 2.2 is not excluded, even if such a measure is found to be consistent with Article 5.1.[18] Therefore, a measure based on the formal risk assessment may still violate the more general rule of Article 2.2. A possible violation may relate either to the necessity requirement provided in Article 2.2 or validity of scientific information. The second situation may particularly happen if after conducting the risk assessment, new scientific data indicates that conclusions of that risk assessment are patently incorrect.

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 or health should satisfy the rationale, which lies behind the requirement of risk assessment. However, the case law does not seem to support that conclusion. First, the requirements provided in Article 2.2 do not exactly match those of Article 5.1. In the Japan-Apples case, the examination under Article 2.2 was limited to the following issues: (i) identification of the risk and (ii) comparison of identified risk with the SPS measure.[19] 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 specificity seems to be not contained in Article 2.2. In consequence, it may appear that the AB perceives those two provisions as related but separate sets of obligations. The practical consequences of such differentiation are far-reaching. Would it be possible to pass the examination under Article 2.2 and fail

[18] Japan-Agriculture Products *supra* note 8, para. 250.

[19] *See* review of the panel analysis by the Appellate Body in Japan-Apples *supra* note 10, para. 164.

because of deficiencies in the risk assessment? Presumably, future case law will need to provide clarification on that issue.

II. Scientific Justification (Article 3.3)

Article 3.3 allows the adoption of SPS measures, which result in a higher level of SPS 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."[20]

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 is possible even if not provided in the form of risk assessment.[21] The AB, 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."[22] The AB'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 AB, that also includes compliance with Article 5. Second, it 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." According to the AB, such evaluation and examination "would appear to partake of the nature of the risk assessment required in Article 5.1."[23] 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 AB 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."[24] As that statement is

[20] SPS Agreement, *supra* note 3, Article 3.3.

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

[22] EC-Hormones *supra* note 5, para. 176.

[23] *Id.*, para. 175.

[24] Japan–Agriculture Products *supra* note 8, para. 79.

closer to findings made under Article 2.2, it may indicate the willingness of the AB 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 AB seems to be incompatible with the principle of effective treaty interpretation, already recognized in the previous WTO case law.[25] 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.

III. 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, while the second analyzes the implementation stage of risk assessment.

1. The Substantive Content of Risk Assessment

a) Distinction between Risk Assessment and Risk Management

The theory of risk regulation usually makes a distinction between three elements of the risk regulatory process: risk assessment, risk management and risk communication. 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.

[25] *See* Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (*adopted* 20 May 1996) para. 23.

Risk management is defined as "a process of identifying, evaluating, selecting and implementing actions to reduce risk."[26] 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."[27] The aim of risk communication is to influence the trust of the general public and increase support for regulatory decisions.

Initially, the risk assessment was defined in the SPS case law as a "scientific examination of data and factual studies;"[28] and "not a political exercise involving social value judgment made by political bodies."[29] The same panel confronted the concept of risk assessment with risk management, subscribing the scientific character only to the former, while perceiving the latter as non-scientific process, which "involves social value judgments."[30] However, the AB disagreed with that distinction, pointing to the lack of textual basis. It also added that the above resulted in excessive restriction of the notion of the risk assessment.[31]

It is submitted that the AB, 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.[32] Consequently, it is argued that the risk assessment was recognized as being not purely scientific, since political and value-related decisions may frequently enter this process. Without deciding whether risk assessment and management can be contrasted with each other, it seems that the above interpretation goes too far. If an integrated approach means equal consideration for scientific and nonscientific factors in the risk assessment, the

---

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

[27] William Leiss, *Three Phases in the Evolution of Risk Communication Practice*, 545 ANNALS 85, 86 (1996).

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

[29] *Id.*

[30] *Id.*, para. 8.160.

[31] EC-Hormones *supra* note 5, para. 181.

[32] Peel *supra* note 7, 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).

subsequent case law does not confirm it. As presented below, scientific considerations play under the SPS Agreement a superior role in risk assessment (prevailing over other factors), while non-scientific concerns dominate the risk management phase ("establishing the appropriate level of protection").

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 pests 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."[33] 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-causing organisms in food, beverages or feedstuffs."[34] 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)."[35] 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."[36] 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

[33] SPS Agreement *supra* note 3, Annex A, para. 4.

[34] *Id.*

[35] Australia-Salmon *supra* note 17, para. 12.

[36] *Id.*

have been potentially applied.[37] Presumably, such an interpretation makes it more difficult for 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."[38]

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."[39] The list is not exclusive and other elements may be taken into account as well.[40] Article 5.3, which applies to assessment of risk to animal or plant life, supplements that list with economic factors such as "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."[41]

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

As mentioned in the previous subsection, each type of risk assessment 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 AB, by referring to the ordinary meaning of those terms, equated likelihood

[37] Panel Japan-Apples *supra* note 6, para. 8.283; that finding was subsequently upheld by the AB.

[38] Panel EC-Hormones *supra* note 28, para. 8.98; although, the AB 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 5, para. 184.

[39] SPS Agreement *supra* note 3, Article 5.2.

[40] EC-Hormones *supra* note 5, para. 187.

[41] SPS Agreement *supra* note 3, Article 5.3

with probability,[42] while potential was understood as a mere possibility.[43] 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,"[44] a panel should rather look for the "'probability', of entry, establishment or spread of diseases."[45] Arguably, establishing a mere possibility should be an easier process than evaluation of probability.

It is not clear whether the drafters of the SPS Agreement introduced the above distinction deliberately. From a textual point of view, the interpretation proposed by the AB is fully acceptable. However, it also results in a strange outcome. The AB, 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. 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 AB 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).[46] The literature submits that "any quantifiable (or rather ascertainable - LG) risk – no matter how small – may serve a basis for sanitary measures."[47] The existence of risk may be expressed both in quantitative and qualitative figures. The quantitative measurement provides

[42] Australia-Salmon *supra* note 17, footnote 70.

[43] The AB said in a different case that the ordinary meaning of "potential" relates to "possibility"; *see* EC-Hormones *supra* note 5, para. 184.

[44] Australia-Salmon *supra* note 17, para. 123.

[45] *Id.*

[46] EC-Hormones *supra* note 5, para. 186; Australia-Salmon *supra* note 17, para. 124.

[47] David R. Hurst, *Hormones: European Communities – Measures Affecting Meat and Meat*, 11 (*available at* http://www.ejil.org/journal/Vol9/No1/sr1g.rtf last visited 25 May 2005); *see,* however, discussion in the Section B.III.2.c) of this article.

information on the probability of adverse effect occurrence, while the qualitative one speaks only about possibility of casual link without indicating its likelihood. The AB 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."[48] The theoretical uncertainty was defined 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."[49] 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 AB came to this conclusion in the context of the notion "potential" as provided with respect to food-borne risk assessment. As mentioned in Section B.III.1.c) of this article, 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 necessary (due to the interpretation of the notion "likelihood"). Thus, the same finding of the AB in the Australia-Salmon case (relating to quarantine risk) seems to be incompatible with the structure of quarantine risk assessment. 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?[50]

The above does not mean that qualitative elements cannot be present in the assessment of quarantine risks. The AB confirmed, with respect to both types of risks, that assessment was not limited to the matters "that are susceptible of quantitative analysis by the empirical and experimental laboratory methods."[51] This observation was drawn from the wording of Article 5.2, which "enlist factors not wholly susceptible of investigation according to laboratory methods."[52] As

[48] EC-Hormones *supra* note 5, para. 186.

[49] Japan-Apples *supra* note 10, para. 241.

[50] A way out from this inconsistency is to simply disregard the distinction made by the AB between "potential" and "likelihood" and apply uniform standard of "potential" to both categories of risk assessment.

[51] EC-Hormones *supra* note 5, para. 187.

[52] *Id.*

Article 5.2 is applicable to both types of assessment, the AB's finding is equally relevant for pest and disease risks. The AB, 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."[53]

There is no agreement between commentators regarding the type of factors that may be included in risk assessment. Indeed, the AB 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).[54] Others claim that the AB "opened the door to the inclusion of such factors as cultural preferences and societal values in the risk assessment for SPS measures."[55] Consequently, according to them, it is possible to take into account subjective factors influencing both perception and risk itself.[56]

It seems 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 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 B.III.1.b) of this article, 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

---

[53] *Id.*

[54] Warren H. Maruyama, *A New Pillar of the WTO: Sound Science*, 32 INT'L LAWYER 651, 673 (1998).

[55] 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).

[56] M. Gregg Bloche, *WTO Deference to National Health Policy: Toward and Interpretative Principle*, 5 (4) J. INT'L ECON. L. 825, 836 (2002).

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 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 AB, 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.[57] 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"[58] was required. A general discussion on particular SPS risk cannot satisfy the specificity condition (i.e. evaluation of the entire categories of hormones or collection of various host plants). As was noted in the literature, the specificity requirement was construed by the AB more stringently than what was textually supported by the SPS Agreement.[59]

Indeed, it seems that such interpretation does not correctly balance the rights and obligations of Member States. The strict requirement of specificity may undermine the right of the Member to establish its appropriate level of protection. As observed by Sykes, the approach adopted by the AB is particularly troublesome in all cases that relate to low-level risk situations.[60] 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, for example, one in a million? According to the AB, 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

[57] The AB upheld this finding.

[58] Japan-Apples *supra* note 10, para. 200.

[59] Neugebauer *supra* note 55, at 1267.

[60] Alan O. Sykes, *Domestic Regulation, Sovereignty and Scientific Evidence Requirements: A Pessimistic View*, 3 CHI. J. INT'L L. 353, 356, at 364-65 (2002).

deducting carcinogenic effects of oestrogen present in beef from general studies on oestrogen),[61] it may appear that in low-risk situations the appropriate level of protection is an illusory right.

2. Implementation of Risk Assessment Results

The SPS measure should be based on the risk assessment.[62] There is no procedural requirement to consider the conclusions of the risk assessment during the process of enactment of an SPS measure.[63] Therefore, a Member State may present scientific evidence, supporting its SPS measure, produced at the time of panel's proceeding.

a) Rational Relationship between the Risk Assessment and SPS Measure

According to the AB, 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."[64] 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.[65] As stressed by the AB, 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.

What, then, should be the level of compatibility between the results of the risk assessment and the SPS measure? The AB 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."[66] As may be suggested by the reasoning of the panel in the

---

[61] EC-Hormones *supra* note 5, para. 198.

[62]According to the AB, 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 5, para. 190.

[63] *Id.,* para. 189.

[64] *Id.*

[65] *Id.,* para. 192.

[66] *Id.,* para. 194; *see also* Japan–Agriculture Products *supra* note 8, para. 79 where the AB characterized in a similar way the relationship existing between the scientific information and the SPS measure under Article 3.3 of the SPS Agreement.

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.[67]

Additional guidance may be also deduced from the interpretation adopted by the AB 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.[68] 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 there will be no rational or objective relationship.[69] That interpretation under Article 5.1 needs to be, however, confirmed by the AB.

Scholars generally perceive the rational relationship required by the AB as easy to satisfy. Specifically, Hurst claims that the AB, 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.[70] Others label the rational relationship test as a deferential standard, which leaves great discretion to Member States and allows for inclusions of non-scientific considerations.[71] However, it was also submitted that "the AB is moving in the direction of substantive benchmark,"[72] 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

[67] Panel Australia-Salmon *supra* note 16, para. 8.98.

[68] For a more detailed discussion, *see* Section B.I. of this article.

[69] *See* Section B.V. for the discussion on the implication of those findings for the right of a Member State to adopt an appropriate level of protection.

[70] Hurst *supra* note 47, at 16; same Bloche *supra* note 56, at 837.

[71] 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).

[72] Joanne Scott, *European Regulation of GMOs: Thinking about 'Judicial Review' in the WTO* 20 (Jean Monnet, Working Paper 4/04).

The risk assessment may set out both the majority scientific opinion, as well as the opinions of scientists taking a divergent view.[73] The AB 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."[74]

The interpretation adopted by the AB is not, however, entirely clear. The above passage, particularly the notion "qualified and respected source", may be interpreted as requiring a divergent opinion with 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 AB 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,"[75] particularly if those other studies are more specific. Thus, the divergent opinion needs to be specific and supported by some evidence as well.[76] 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."[77] It was also suggested that if the measure were based on minority scientific opinion, the relationship between the measure and the risk assessment would be subject to more stringent review.[78] 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 AB may presume its plausibility; in case of divergent opinions 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 specificity may result in the practical exclusion of

[73] EC-Hormones *supra* note 5, para. 194.

[74] *Id.*

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

[76] Bloche *supra* note 56, at 83.

[77] 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, at 119 (1998).

[78] Hurst *supra* note 47, at 12 basing his argument on the AB statement that by itself reliance on a minority viewpoint does not necessary signal the absence of reasonable relationship.

divergent opinions, as those opinions are usually "based in the kind of suggestive but not definite scientific evidence."[79] There are, however, voices claiming that the requirement of sound science, as deducted from the statement of the AB, may be premature. The AB did not define what is understood by "qualified and respected sources". Moreover, it seems that in rejecting the opinion of Dr. Lucier, the AB rather required specificity of risk assessment than certain scientific quality. It is legitimate to say that final determination of that issue will have to wait for a future decision of the AB. 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,"[80] 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.

IV. Insufficiency of scientific evidence (Article 5.7)

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.[81] 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

[79] Peel *supra* note 7, at 71.

[80] Sykes *supra* note 60, at 366.

[81] Japan-Agriculture Products *supra* note 8, para. 80.

measure in the sense provided by Article 5.7.[82] 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.[83] That position was shifted in the Japan-Apples case. Japan argued that its measure might be justified under Article 5.7. The AB 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."[84] 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.

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 a Member State seeks to obtain additional scientific information, (iv) that the provisional measure is the subject of review within a reasonable time.[85] 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."[86] However, the concept of insufficiency does not exclude "cases where the available evidence is more than minimal in quantity but has not led to reliable or conclusive results."[87] Thus, both quantity and conclusiveness of scientific data play an important role in triggering the application of Article 5.7. At the same time, insufficiency cannot be equated with uncertainty.[88] The distinction made is between lack of scientific evidence and uncertainty about the validity of scientific conclusions on the cause of harm. In the words of the AB "existence of unknown and uncertain elements does not justify a departure from the requirements of Articles 5.1, 5.2 and 5.3."[89] Thus, existing uncertainty in the presence of scientific

[82] Panel Report, *Japan – Measures Affecting Agriculture Products*, WT/DS76/R (*adopted* 19 March 1999), paras. 4.187, 8.48.

[83] *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."

[84] Japan-Apples *supra* note 10, para. 175.

[85] *See* Japan-Agriculture Products *supra* note 8, para. 89; Japan-Apples *supra* note 10, para. 176.

[86] Japan-Apples *supra* note 10, para. 179.

[87] *Id.*, para. 185.

[88] *Id.*, para. 184.

[89] Australia-Salmon *supra* note 17, para. 130.

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."[90] In such a case, a Member State should rather perform risk assessment according to the provision of Articles 5.1-5.3. Of course, a Member State may use conservative assumptions and qualitative elements in such assessment or base 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 have 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."[91] If the threshold for pertinent information is established at a high level, clearly it will limit the possibility to invoke Article 5.7 (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.
A Member State is obliged to "seek to obtain the additional information necessary for the more objective assessment of risk."[92] The AB confirmed that Article 5.7 does not require any specific kind of information to be collected or collection procedures to be used.[93] This information needs to be, however, relevant for both the risk in question and the risk assessment itself.

---

[90] 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).

[91] 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).

[92] SPS Agreement *supra* note 3, Article 5.7.

[93] Japan-Agriculture Products *supra* note 8, 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.[94] The AB 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.[95] 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).[96] 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.

V. 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 Member State. The AB on several occasions also recognized that this was a prerogative of national governments[97] and that Member States are free to adopt any level of protection they deem to be appropriate. As already mentioned that also includes zero risk level.[98] 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."[99] Other considerations such as societal values, cultural acceptance of risk, technical and economical feasibility influence the governmental decision in this respect.

---

[94] *Id.*, para. 93.

[95] *Id.*

[96] Winickoff, Jasanoff, Busch, Grove-White & Wynn *supra* note 91, at 115-16.

[97] EC-Hormones *supra* note 5, para. 124.

[98] Australia-Salmon *supra* note 17, para. 125.

[99] Peel *supra* note 7, at 14.

There are, however, some troublesome findings in the case law, which bring the right of Member States to establish an appropriate level of protection into question. First, according to the AB, 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 AB, which excludes this category of risks as a legitimate subject of regulation, effectively deprives states of the possibility to regulate them. 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 specificity of risk assessment required by the AB may result in an impossibility to regulate low-risk situations. As indicated in Section B.III.1.c) of this article, these 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 a 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.[100] 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 Member States. If a country is

[100] 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 6, Annex 3, para. 332.

entitled to establish its appropriate level of protection, the panel may not classify risks as negligible or require proportionality between the risk and measure.[101]

Forth, as discussed in Section B.III.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.

C. Science as a Benchmark in International SPS Disputes

Before drawing any conclusions on the role of science under the SPS Agreement, 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. 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 a 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 AB 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 do they need to be? What level of reliability should they bear? Will "a measure inconsistent with the current dominant paradigm will fall the SPS scrutiny."[102] Finally, the notion of "available pertinent information" requires further investigation by panels and the AB.

On the basis of existing case law, it is legitimate to say that within the SPS context, risk is conceptualized in accordance with the technical paradigm. Under that paradigm risk is perceived as a combination of "expected number of fatalities or injuries likely to arise in the event the risk materialized in harm."[103] It is assessed on

[101] *But see* Panel Japan-Apples *supra* note 6, 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."

[102] Atik *supra* note 17, at 753.

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

the basis of statistical data, scientific information and probability techniques. Accordingly, risk under the SPS Agreement is a combination of probability or possibility and adverse outcome resulting from the exposure to the hazard, while risk assessment is construed as predominantly scientific evaluation. An 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 a measure. The AB, while accepting divergent scientific opinions, also required from them a certain level of scientific plausibility. In the same line, the AB 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. Thus, under the SPS Agreement, science aims at the elimination of the internal barriers to international trade, irrespective of whether such barriers have a protectionist character.

The above does not mean, however, that the AB adopted the orthodox technical standpoint on the role of science. The case law proves just the opposite. The AB tries to find an equilibrium between competing objectives, namely trade liberalization and the need to protect life and health. As indicated previously, the notion of "science" was understood liberally. The AB 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 hypotheses. At the same time, science is not able to provide with absolute certainty that a particular substance will not have an adverse effect.[104] 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."[105] 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 and does not require employing the best science available. Member States are not required to construe a risk assessment as a purely quantitative procedure and the qualitative elements may play a vital role in the process of identification and evaluation of possible risks.

It also seems that on several occasions, the AB went beyond the technical paradigm of risk assessment. Arguably, the AB recognized that risk assessment is not a purely

[104] EC-Hormones *supra* note 5, para. 186.

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

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. The risk assessment is not limited to the matters that are "susceptible of quantitative analysis by the empirical and experimental laboratory methods."[106] That is particularly true if the risks are irreversible. Moreover, in the EC-Hormones case the AB recognized that the government might act from the perspective of prudence and precaution.[107] 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 AB did not require a substantial relation or full conformity. Thus, it is not necessary for a 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.[108] Clearly, it was possible within the language of the SPS Agreement to adopt a more stringent interpretation.

In that context, it also should be noted that the possible room of maneuver for WTO adjudicating bodies is limited. 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."[109] Both the panel and the AB 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 AB adopted a rather moderate interpretation of SPS provisions, however, further lessening of the role of science, i.e. the broad inclusion of non-scientific considerations in risk assessment or the implantation of non-technical paradigms into the SPS Agreement, seems to go too far. It will be incompatible with Article 19.2 of the DSU, as it will change completely the explicit language of the SPS Agreement.

The approach adopted in the case law seems to be generally compatible with the textual basis of the SPS Agreement and provides a coherent SPS system. Nevertheless, there are some specific findings in the case law, which seem to be inconsistent with the explicit language of the SPS Agreement. As discussed in

---

[106] EC-Hormones *supra* note 5, para 187.

[107] *Id.,* para 124.

[108] 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.

[109] Article 19.2 of the Understanding and Procedures Governing the Settlement of Disputes as incorporated by the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994 *available at* http://www.wto.org [hereinafter DSU].

Section B.V of this article, the SPS Agreement clearly provides that Member States have a right to establish and maintain their appropriate level of SPS. The AB on several occasions also has confirmed that right. Nevertheless, certain standards such as the requirement of risk ascertainability, high demands with respect to the specificity of risk assessment, the introduction of a proportionality test and the concept of "negligible risks", as well as quantitative 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. 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. 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. 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.

D. Conclusions (this section reads as an introduction not a conclusion because it talks of the article in the present tense and not in the past tense…Not a huge problem)

This article, 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 have tried to assess the role, which is assigned to science in international SPS disputes. I argue that the approach adopted by the AB 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 submitted that an examination of the case law reveals a recognition by the AB that risk situations are very complex in their nature. Thus, science is not perceived as a monolithic structure but rather as a constant process of inquiry. In consequence, the AB 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.).

This article has argued 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, it also identifies 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, the article submitted 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 specificity 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. The article claimed 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 the Member States to establish an appropriate level of SPS protection.

Finally, this article highlighted 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 5.1; 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 article suggested 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.