The Precautionary Principle in the SPS Agreement

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A. Introduction

In the 1970s the use of hormones in cattle started to worry European consumers. Some organizations even promoted boycotts against hormone-treated products and politicians were therefore driven to take the concern seriously. As a result, several declarations regarding the use of hormones in livestock were adopted. Later on, in 1981, the European Communities (EC) imposed an internal ban on substances with hormonal action intended for use on livestock. The primal fear

behind the prohibition was that the effects of hormones had not yet been scientifically attested. In 1988, the EC extended the ban to imported meat produced with growth hormones. As a response, in 1996, the United States of America (USA) contested the measure set forth by the EC as inconsistent with World Trade Organization (WTO) law, bringing to life one of the most famous WTO disputes of all times.[1]

That is just one of several examples of a dispute where a WTO member has imposed a precautionary ban. In such cases, three factors usually play an important role. Firstly, the hazard associated with the particular product will not be clearly determinable by science.[2] Secondly, the measure in question is often related to a sensitive area of governmental policy, for example the protection of human health.[3] Thirdly, it is frequently an agricultural product which is the target of the measure, a sector where protectionism traditionally governs all trade relationships.[4] Therefore, when a WTO member imposes a precautionary measure, the question arises whether the ban is really precautionary or simply a protectionist measure.

In those disputes, the precautionary principle is a commonly used defense, entitling governments to take up measures in order to err on the side of caution where scientific evidence is inconclusive.[5] A minority group of WTO members, led by the EC, sustains that the concept is able to justify an import restriction. In opposition, a vast number of WTO members consider the principle a phony invention to disguise protectionism on inefficient agricultural markets. This discussion has prompted the polarization of sectors regarding the role, if any, of the precautionary principle in WTO law and, in particular, in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Consequently, WTO members have not yet been able to agree on what should be an adequate level of caution or to coincide on a precise procedure to adopt precautionary measures. This has caused clear distress, the fear being that members may undermine the dispute settlement system as a result of their inability to agree on transparent rules that govern this sensitive topic.[6]

It is widely understood that the precautionary principle poses many economic, scientific and political predicaments. The lack of agreement on clear procedures on

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1 See the "Factual Aspects" of *EC - Hormones*, Panel Report, *European Communities - Measures Affecting Meat and Meat Products*,WT/DS26/R, adopted 18/8/1997.

2 *Eggers*, The Precautionary Principle in WTO Law, 2001, p. 1.

3 *Van den Bossche*, The Law and Policy of the World Trade Organization, 2007, p. 462.

4 Ibid.

5 *Eggers*, (fn. 2), p. 1.

6 *Van den Bossche*, (fn. 3), p. 298.

the role of the principle and the silence of the SPS Agreement thereon, have put the WTO judiciary to test. Therefore, the main goal of this paper is to determine – according to WTO rules, doctrine and case law – the function of the precautionary principle in the SPS Agreement. Accordingly, the definition and the current status of the principle in international law will be ascertained. Subsequently, it will be discussed what factors influence the application of the axiom of precaution in the SPS Agreement. Thereafter, it will be established what the procedures for the enactment and review of precautionary measures are and what role the principle has played in trade disputes. Lastly, questions relating to the burden of proof and the applicable standard of review for precautionary measures will be dealt with.

B. The origin of the precautionary principle

I. Germany and the precautionary principle

The precautionary principle has its origin in the 1970s in Germany. It was called the *Vorsorgeprinzip* and is nowadays one of the fundamental pillars of German environmental policy. In broad terms, it aims at the prevention of any harmful effects, for example pollution, through prior care, foresight and forward planning – *Vorsorge*.[7]

The *Vorsorgeprinzip* makes a distinction between two types of human activities. A first category called *Gefahrenvorsorge* contains all those human behaviors posing a danger of a cataclysmic consequence, for example a nuclear disaster. Such actions should be stopped at any cost. The second category is called *Risikovorsorge*, and includes all human activity with potential negative consequences. In such cases, preventive measures should be imposed to preclude damage to the environment.[8]

In 1984, the German Federal Ministry of the Interior explained the meaning of the *Vorsorgeprinzip*: "The principle of precaution commands that the damages done to the natural world [...] should be avoided in advance and in accordance to opportunity and possibility. *Vorsorge* further means the early detection of dangers to health and environment by comprehensive synchronized [...] research, in particular about cause and effect relationships [...]. It also means acting when conclusively ascertained understanding by science is not yet available [...]".[9]

7 *Kogan*, The Precautionary Principle and WTO Law: Divergent Views toward the Role of Science in Assessing and Managing Risk, Seton Hall Journal of Diplomacy and International Relations, Vol. V (2004), p. 91. See also *Eggers*, (fn. 2), pp. 22 and 25.

8 *Kogan*, (fn. 7), p. 91.

II. The meaning of scientific uncertainty

It is important to understand the expression "scientific uncertainty" due to its close link to the precautionary principle. Although the term "scientific uncertainty" seems straightforward, the concept is not exempted from philosophical and scientific discussion. Many definitions can be found. One of them, for example, describes it as "a relative lack of consensus in the scientific community".[10] Notwithstanding this, "scientific uncertainty" should be explained from two points of view: firstly, from a scientific point of view and secondly, from a political perspective.

1. Scientific uncertainty from a scientific point of view

If events are theoretically possible but have not yet happened, only a limited explanation whether or not they will occur can be obtained.[11] Scientists believe uncertainty is a result of inappropriate data, mere ignorance or indeterminacy. Nevertheless, they recognize uncertainty as an intrinsic part of science and thus do not view it as a problem.[12] The outcome of this "ignorance" is obvious: scientists can only say that they do not have the answer.

The question then is what should be done in the absence of knowledge or consensus regarding the risks of a determined product or human action. The answer evidently cannot be provided by science, but usually by politics.[13]

2. Scientific uncertainty from a political point of view

Some political decisions must be based on scientific proof.[14] That is the case with environmental policy which requires an answer to specific questions that sometimes cannot be answered due to human limitations. This notion can be found, for example, in the Communication from the Commission on the Precautionary Principle, which defines scientific uncertainty as a situation where the public has

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9 German Federal Ministry of the Interior, Dritter Immissionsschutzbericht, 10/1345 (1984), quoted in: *Percival*, Who's Afraid of the Precautionary Principle?, University of Maryland Legal Studies Research Paper No. 62 (2005), pp. 5-6.

10 *Cameron/Abouchar*, The Status of the Precautionary Principle in International Law, in: Freestone/David (eds.), The Precautionary Principle and International Law, 1996, p. 45.

11 *Davies*, Morality Clauses and Decision-Making in Situations of Scientific Uncertainty: The Case of GMOs, 2006, p. 6.

12 *Costanza/Cornwell*, The 4P Approach to Dealing with Scientific Uncertainty, Environment Vol. 34 (1992), No. 9, p. 3.

13 *Davies*, (fn. 11), p. 7.

14 *Eggers*, (fn. 2), p. 61.

heard of a potential harm and has demanded from policymakers appropriate measures before scientists have been able to provide a conclusive answer.[15]

Therefore, for politicians, scientific uncertainty is a problem. Governmental leaders must respond to threats in the best way possible in order to protect their nationals. More than ever, those decisions are also influenced by the need of politicians to secure the votes of the public, therefore provoking the enactment of rules that might sometimes not be the most rational ones.[16]

C. The precautionary principle at international level

I. First steps of the precautionary principle at international level

As the father of the precautionary principle, Germany took over the task of introducing the concept at international level. The country was already successful in its enterprise in 1982, when the axiom of precaution received its first international recognition.[17] The United Nations World Charter for Nature included a provision remarking that: "Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed".[18]

The term was also pushed forward by Germany in conferences on the protection of the North Sea held in Bremen (1984), London (1987), The Hague (1990) and Esbjerg (1995).[19] By 1990, at The Hague conference, the parties agreed that they "will continue to apply the precautionary principle, that is to take action to avoid the potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even when there is no scientific evidence to prove a causal link between emissions and effects."[20]

Additionally, in Esbjerg (1995), it was recommended that the precautionary principle should be applied where fisheries management policies were concerned. This

15 See the Communication from the Commission on the Precautionary Principle, COM (2000) 1 final, para. 1.

16 *Van den Bossche*, (fn. 3), p. 25.

17 *Sunstein*, Beyond the Precautionary Principle, John M. Olin Law & Economics Working Paper No. 149, 2003, p. 4.

18 See Principle 11(b) of the United Nations World Charter for Nature, 1982.

19 *Percival*, (Fn. 9), p. 6.

20 *Eggers*, (fn. 2), p. 119.

decision was taken due to the lack of complete scientific understanding on the impact of fisheries on ecosystems.[21]

Meanwhile, the idea of a precautionary principle also fought its way into EC law, once again promoted by Germany.[22] In February 1992, the Treaty of Maastricht was signed, bringing to life the European Union. The Treaty adopted the principle as a pillar of its environmental policy. A definition, however, was not provided.[23]

Shortly after, in June 1992, the United Nations Conference on the Environment and Development adopted the Rio Declaration on Environment and Development (Rio Declaration).[24] Principle 15 of this declaration contains the most widely known recognition of the precautionary principle:[25] "In order to protect the environment, the precautionary approach shall be widely applied by all States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[26]

Nonetheless, Principle 15 has not been exempted from debate. Some scholars see it as a permissive approach toward the adoption of measures even when there is no certainty that these measures will actually prevent environmental damage.[27] It is also interesting to mention that while the official English translation of Principle 15 of the Rio Declaration refers to a "precautionary approach", different official translations into other languages expressly use "precautionary principle".[28] This difference might have been influenced by the opposition of the USA to the principle.[29]

Finally, as a follow-up to the Rio Declaration, in 1996 a new conference called Codifying Rio Principles in National Legislation took place and resulted in the

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21 Ibid., pp. 91 and 119.

22 *Kogan*, (Fn. 7), p. 92.

23 See Art. 174 (2) of the Treaty Establishing the European Community which states: "Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle".

24 http://www.un.org/geninfo/bp/enviro.html (26/8/2009).

25 *Eggers,* (fn. 2), p. 49; see also *Kogan*, (fn. 7), p. 92; *Percival*, (fn. 9), p. 6.

26 See principle 15 of the 1992 Rio Declaration on Environment and Development adopted by the United Nations Conference on the Environment and Development.

27 *Kogan*, (fn. 7), p. 92.

28 *Percival*, (fn. 9), p. 7.

29 *Shaw/Schwartz*, Trading Precaution: The Precautionary Principle and the WTO, UNU-IAS Report, 2005, p. 5. See more on USA's position in section C.II.3.

adoption of The Hague Declaration on Principles of Environmental Law. The purpose of the declaration was to integrate the precautionary principle into national and international legal systems. As a consequence, the principle has been directly or indirectly recognized in a number of multilateral environmental agreements, grasping the principle as a sort of "underlying rationale".[30]

II. The status of the precautionary principle in international law

As a result of the Rio Declaration, the precautionary principle was firstly used as guidance in the interpretation of international environmental law in situations where scientific uncertainty existed.[31] Thereafter, some authors considered that the principle evolved into a general principle of international environmental law. Consequently, the principle started being mentioned in various multilateral environmental agreements and statements.[32] This provided a justification to many environmental experts to sustain that the principle evolved into customary international law or even into a general principle of international law.[33] However, as will be explained in the following paragraph, such consideration is strongly debated.[34]

1. Evolving into customary law or into a general principle of international law

Legally speaking, a principle becomes a general principle of international law when it is applied universally in various legal systems. As such, it requires a certain level of consistency.[35]

Furthermore, a principle may become a part of customary international law if it complies with two cumulative requirements. The first one relates to state practice and demands an invariable *modus operandi* to treaty negotiations. Equally important, the application of the principle in national law and domestic court decisions is also required. The second requisite can be observed through *opino juris*, where-

30 Ibid., p. 4; *Nash*, Standing and the Precautionary Principle, Chicago Working Paper No. 178, 2007, p. 5.

31 *Sands*, Principles of International Environmental Law I, 2nd ed. 2003, p. 208.

32 See for example Conference on the Protection of the North Sea (Esbjerg), 1995; The Hague Declaration on Principles of Environmental Law, 1996; Wingspread Statement on the Precautionary Principle, 1998; Cartagena Protocol on Biosafety, 2000; Communication from the Commission on the Precautionary Principle, COM (2000) 1 final.

33 *Nash*, (fn. 30), p. 5.

34 *Eggers*, (fn. 2), p. 233.

35 http://www.law.berkeley.edu/library/classes/iflr/customary.html (26/8/2009).

by states act as if they are bound by the principle. For example, when there are persistent objections from states refusing to be bound by a determined practice.[36] It is also necessary for the principle to be harmoniously defined and consistently applied in international agreements. Finally, its recognition should be equally steady in decisions of international courts.[37]

2. The definition of the precautionary principle

The essence of the precautionary principle rests upon caution in the face of a risk which is still scientifically uncertain.[38] Yet to be satisfied with that simple formulation may be misleading.[39]

Many environmental experts claim that one of the biggest strengths of the principle, is the flexibility of its definition. This elasticity can be observed in the different formulations of the principle in the various agreements in which it has been included.[40] Nevertheless, this strength is at the same time its biggest weakness. Its flexibility has caused a lack of an internationally agreed definition. Several scholars even maintain that some definitions are incompatible with each other.[41]

To illustrate, two similar definitions that experts normally refer to will be compared. The first description is the one found in the already mentioned Principle 15 of the Rio Declaration.[42] The second one is contained in the Bergen Ministerial Declaration on Sustainable Development in 1990: "In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of sci-

36 *Nash*, (fn. 30), p. 4.

37 *Shaw/Schwartz*, (fn. 29), p. 4.

38 *Nash*, (fn. 30), p. 4.

39 Ibid., p. 6.

40 Compare for example Bergen Ministerial Declaration on Sustainable Development, 1990; Rio Declaration on Environment and Development, 1992; Conference on the Protection of the North Sea (Esbjerg), 1995; The Hague Declaration on Principles of Environmental Law, 1996; Wingspread Statement on the Precautionary Principle, 1998; Cartagen Protocol on Biosafety, 2000; Communication from the Commission on the Precautionary Principle, COM (2000) 1 final.

41 *Sunstein*, (fn. 17), p. 3; see also *Shaw/Schwartz*, (fn. 29), p. 4; *Percival*, (fn. 9), p. 10.

42 Which declares: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

entific certainty should not be used as a reason for postponing measures to prevent environmental degradation."[43]

Although the two definitions look quite similar, they present a perfect example of the lack of a generally recognized definition. Both formulations are congruous regarding what may give rise to a precautionary measure, namely a threat of serious or irreversible harm. Nevertheless, the description in the Rio Declaration considers that only measures that are "cost-effective" must be pursued. Thus the concept includes a careful analysis of the economic impact of a decision. This economic approach was not considered in the Bergen Ministerial Declaration.[44]

All these issues have been a major cause for some WTO members to protest the principle's full integration into WTO law.[45] This scepticism has been taken into account by the Appellate Body, which has emphasized that "at least outside the field of international environmental law, [the precautionary principle] still awaits authoritative formulation".[46] In *EC - Biotech Products*, the panel acknowledged that a unified formulation of the principle has not been found yet and, accordingly, refused its application.[47]

All in all, the current debate on the definition of the precautionary principle does not permit the establishment of a universally accepted formula. Instead, it shows the contrary, namely the difficulty of considering the principle customary law or a general principle of international law.

3. International perspectives

Given that the EC already incorporated the concept into its own law,[48] the precautionary principle has gained solid ground in European environmental treaties, policy and law.[49] Consequently, the EC is of the position that the principle is already part of customary international environmental law.[50] Moreover, decisions

43 See Paragraph 7 of the Bergen Ministerial Declaration on Sustainable Development in the ECE Region, 1990.

44 *Shaw/Schwartz*, (fn. 29), p. 4.

45 See the Report of the meeting of the WTO Committee on Trade and Environment held on 5-6/7/2000, WT/CTE/M/24, Trade and Environment Bulletin No. 33. See also *Shaw/Schwartz*, (fn. 29), p. 4.

46 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 123.

47 *EC - Biotech Products*, Panel Report, *European Communities - Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, adopted 29/9/2006, para. 7.88.

48 See Art. 174 (2) of the Treaty Establishing the European Community.

49 *Nash*, (fn. 30), p. 5.

by the European Court of Justice have proved that there are elements pointing toward a general application of the principle in EC Law.[51] These elements include uncertainty, risk and a direct causal link between a risk and a potential injury.[52] The EC has also pursued, as one of its objectives, the drafting of guidelines for the use of the principle, aiming at more transparency in its application. Such efforts, though commendable, have been ineffective and highly criticized.[53] For example, *Shaw* and *Schwartz* concentrate their criticism on the wide discretion of policy makers in the application of the principle and how it may have the effect of taking priority before other principles such as proportionality or non-discrimination.[54]

Despite its appreciation in EC law, the discussion of the principle in the USA has been everything but favorable.[55] The country holds the opinion that precaution is not a formal principle, but simply an approach. This position has greatly influenced many multilateral environmental agreements, resulting in the use of terms like "precautionary approach" or "precautionary measures" instead of "precautionary principle". Perhaps the most well-known cause of criticism in the USA toward the principle is the genuine concern on the potential economic costs of applying it.[56] It has been further criticized that the application of the precautionary principle leads to a paralyzing regulation while not taking into account a cost-benefit analysis.[57] Additionally, there has been strong opposition to litigation in the USA based on the implementation of the "principle".[58] Courts expressly avoid using the term "precautionary principle" and prefer just the term "precaution".[59]

It should be added that several scholars do not consider important the debate between "approach" and "principle". For them, the real problem is the disagreement between governments regarding the underlying values.[60] Simultaneously, however, for other authors there is an important difference since only the term

50 Communication from the Commission on the Precautionary Principle, COM (2000) 1 final.

51 ECJ, case C-157/96, *BSE*, Rec. 1998, I-2211; CFI, case T-13/99, *Pfizer*, Rec. 2002, II-3305; CFI, case T-70/99, *Alpharama*, Rec. 2002, II-3945.

52 *Shaw/Schwartz*, (fn. 29), p. 4.

53 Ibid.

54 Ibid., p. 5.

55 *Nash*, (fn. 30), p. 5.

56 *Shaw/Schwartz*, (fn. 29), p. 5.

57 *Sunstein*, (fn. 17), p. 2.

58 *Percival*, (fn. 9), p. 8.

59 *Sunstein*, (fn. 17), p. 3.

60 *Eggers*, (fn. 2), p. 64.

"principle" can create obligations. Accordingly, the word "approach" does not impose any duty, which is the reason why the USA prefers it.[61]

Canada's point of view is a bit more indulgent. Domestically speaking, the country has accepted the existence of the principle. Even the Supreme Court of Canada has seen it as part of international custom. However, Canada has internationally opposed the EC's invocation of the principle, claiming that it is still an "emerging principle of international law".[62] The Canadian Government has even published a discussion paper explaining the difficulties of formally introducing the principle into its international policy. The major concern lies, as in the case of the USA, on the negative economic effect of its application through the unfair imposition of costs in sectors where there is scientific uncertainty.[63]

With regard to developing countries, some courts have also recognized the existence of the principle. As an example, the Supreme Court of India has granted the precautionary principle the level of customary international law.[64] Notwithstanding this, most developing countries have serious concerns that the application of the principle might have adverse export consequences through disguised protectionism.[65]

Finally, the International Court of Justice has not yet elaborated on whether the precautionary principle is customary law or a general principle of international law, even though the question has been brought up in more than one case.[66]

4. Conclusions

On the whole, it is clear that the precautionary principle has neither a unified definition, nor that there is agreement as to its status in international law. This discrepancy could not even be solved by an international court, which proves that the status of the precautionary principle in international law remains uncertain. Therefore, the precautionary principle cannot be considered, at this point, as customary law or as a general principle of international law.

61 *Shaw/Schwartz*, (fn. 29), p. 5.

62 Ibid., p. 5.

63 Ibid.

64 Ibid.

65 Ibid., p. 10.

66 Ibid., p. 5.

D. Protectionism versus precautionism in WTO law

Being an organization for the international liberalization of trade, the WTO is charged with handling accusations of exporting members that precautionary measures are disguised protectionist measures of inefficient agricultural markets. The WTO dispute settlement system has consequently had the tedious duty to establish a reasonable equilibrium between the right of members to pursue their national policy aims and the right of other members to trade freely at an international level.[67] Connected disputes have revealed that it is extremely burdensome to draw a clear line between precaution and protectionism.

I. The underlying rationale of the conflict

To date, all trade conflicts related to the precautionary principle have involved agricultural products. Agriculture has been a sector which has been especially known for being protectionist and difficult to fully open to international trade.[68] Therefore, when a WTO member imposes an import restriction based on the precautionary principle, most agricultural exporters will argue that the measure is protectionist.

Protectionism is often explained as an intentional restriction on imports seeking to allow inefficient domestic producers to compete with alien producers which are more efficient than them.[69] Particularly, in trade disputes concerning measures aiming to protect human health or the environment, there are two forms of protectionism: regulatory protectionism and agricultural protectionism.[70]

1. Regulatory protectionism

Regulatory protectionism has been described as "any cost disadvantage imposed on foreign firms by a regulatory policy that discriminates against them or that otherwise disadvantages them in a manner that is unnecessary to the attainment of some genuine, non-protectionist regulatory objective".[71] In other words, this kind of protectionism raises the costs for foreign producers in comparison to expenses of national producers, hence provoking unnecessary discrimination.[72]

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67 *Eggers,* (fn. 2), p. 74.

68 *Van den Bossche*, (fn. 3), p. 28.

69 *Hinkelman*, Dictionary of International Trade, 2nd ed. 1998, p. 164.

70 *Eggers*, (fn. 2), p. 76.

71 *Sykes*, Regulatory Protectionism and the Law of International Trade, University of Chicago Law Review 1999, p. 3.

72 *Eggers*, (fn. 2), p. 77.

This type of protectionism can be seen in two ways. The first is through open discrimination, for example where foreign products must comply with additional requirements or are subject to restrictions that are not compulsory for national products.[73] The second case covers measures applying to both national and foreign products, which in appearance look non-discriminatory. Nevertheless, the measure may still be found burdensome for foreign products if they are not required to comply with that regulation in their own legal system. This definition varies from the normal understanding of protectionism, because it also includes those measures that are not deliberately implemented to the detriment of foreign producers.[74]

2. Agricultural protectionism

The application of protectionist measures to agricultural products is one of the most wide-spread forms of protectionism in the world. As an example, in 2007 approximately US$ 365 billion were paid in all member states of the Organization for Economic Cooperation and Development (OECD) in support for the agricultural sector.[75] The underlying rationale of those subsidies is that a country should be able to trust its own farmers to meet a basic level of food security.[76]

Furthermore, it is commonly understood that farmers are a well-organized sector of the economy, with a strong influence in governmental decisions. This allows them to use their lobbying power to set up measures to protect the national production of agricultural products to the detriment of international trade.

II. The role of the SPS Agreement in WTO law

The SPS Agreement was promoted by two events during the Uruguay Round. Firstly, the hormones dispute between the USA and the EC was expected to be a never-ending story.[77] A number of tries to solve the conflict already proved to be ineffective. Analysts concluded that the rules supplied by the General Agreement on Tariffs and Trade (GATT) 1947 and the Agreement on Technical Barriers to Trade (TBT Agreement) were insufficient to effectively solve the dispute.[78]

73 Ibid.

74 Ibid.

75 http://www.oecd.org/document/59/0,3343,en_2649_33727_39551355_1_1_1_1,00.html (26/8/2009).

76 *Van den Bossche*, (fn. 3), p. 28.

77 See for further details *Meng*, The Hormone Conflict between the EEC and the United States within the Context of GATT, Michigan Journal of International Law 11 (1990), pp. 819-839.

78 *Eggers*, (fn. 2), p. 96.

Secondly, the negotiation on the Agreement on Agriculture brought up the concern that governments might apply a "regulatory compensation" to counterbalance the considerable liberalization accomplished by the agreement. Therefore, the Agreement on Agriculture expressly specified the compromise of members to conclude an agreement covering sanitary and phytosanitary measures (SPS measures).[79]

When the SPS Agreement was being negotiated, the precautionary principle was already known and discussed internationally, but nevertheless, there is no reference of it in the negotiations on the SPS Agreement. Strangely enough, it was not even mentioned by the EC.[80]

In its preamble, the SPS Agreement recognizes the right of members to decide on the level of health protection which they consider appropriate, as the agreement is not intended to affect this. Notwithstanding, it is also settled that this right should not be abused for protectionist purposes.[81]

Furthermore, the agreement seeks in Art. 3.1 to harmonize SPS measures as far as possible. Using a "stick effect",[82] it obliges members to base their measures on international standards, guidelines or recommendations whenever these exist.[83] On the other hand, Art. 3.2 of the SPS Agreement uses a "carrot effect",[84] presuming SPS measures respecting international standards, guidelines or recommendations to be compatible with the SPS Agreement and the GATT 1994. Annex A.3 to the SPS Agreement contains a list of such standards, guidelines and recommendations. However, Art. 3.3 further allows the application of stricter rules than those contained in international standards as long as one of two conditions is respected: a scientific justification is provided, or alternatively, a risk assessment under Art. 5 is conducted.[85]

Lastly, the task of the SPS Agreement is a specific one and thus its scope of application extends only to SPS measures.[86] These are defined by an Annex to the Agreement as any measure designed "to protect human, animal or plant life or health within the territory of the Member from certain food-borne risks and pest-

79 Ibid., pp. 96-97.

80 *Prévost*, What Role for the Precautionary Principle in WTO Law after Japan-Apples?, EcoLomic Policy and Law, Journal of Trade & Environment Studies Vol. 2 (2005), p. 3.

81 See paras. 1 and 6 of the Preamble to the SPS Agreement.

82 *Eggers*, (fn. 2), p. 102.

83 See Art. 3.1 of the SPS Agreement.

84 *Eggers*, (fn. 2), pp. 102-103.

85 See Art. 3.3 of the SPS Agreement.

86 See Art. 1.1 of the SPS Agreement.

and disease-related risks".[87] Further, the character of the agreement as a *lex specialis* is recognized by the fact that it takes precedence over the TBT Agreement.[88] With respect to the GATT 1994, there is no exclusivity, but the SPS Agreement disposes of a presumption of consistency with the GATT 1994 for those measures that are in harmony with the referred agreement.[89]

E. The right to precaution and its limits in the SPS Agreement

As noted previously, the SPS Agreement respects the right of WTO members to decide on their desired level of protection.[90] The Appellate Body has affirmed that members have the right to choose their "own appropriate level of sanitary protection which level may be higher (i.e. more cautious) than that of other members or international standards".[91] Members may even impose a "zero risk" tolerance level,[92] which goes well beyond the precautionary principle. It has also been accepted that choosing an appropriate level of protection is a prerogative of governments and such decisions cannot be criticized by panels or the Appellate Body.[93] Therefore, it seems that members have a particularly mighty right to precaution.

Nevertheless, the Appellate Body has stressed that the privilege of selecting a level of protection is not absolute.[94] The right is limited by other rules under the agreement, for example the science test, which is a key tool for maintaining the equilibrium between international trade on one hand, and the protection of life, health and environment on the other hand.[95] Consequently, it is rather important

87 *Eggers*, (fn. 2), p. 101. See also Annex A.1 to the SPS Agreement.

88 See Art. 1.5 of the TBT Agreement.

89 *Van den Bossche*, (fn. 3), pp. 462-463.

90 See paras. 1 and 6 of the Preamble to the SPS Agreement.

91 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 124.

92 *Australia - Salmon*, Appellate Body Report, *Australia - Measures Affecting Importation of Salmon* WT/DS18/AB/R, adopted 6/11/1998, para. 132.

93 Ibid., para. 198; see also *Thailand - Cigarettes*, Panel Report, *Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes*, DS10/R – 37S/200, adopted 7/11/1990, para. 74; *US - Gasoline*, Panel Report, *United States - Standards for Reformulated and Conventional Gasoline*, WT/DS2/R, adopted 20/5/1996, para. 6.22; *EC - Asbestos*, Panel Report, *European Communities - Measures Affecting Asbestos and Asbestos Containing Products*, WT/DS135/R, circulated 18/9/2000, para. 8. 179.

94 Ibid., para. 132.

95 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 177.

to determine the conditions set forth by the SPS Agreement and its case law for the application of precautionary measures, whether permanent or provisional.

I. Precautionary measures

In general terms, to set up an SPS measure, firstly, the measure must be based on sufficient scientific evidence of a potential risk.[96] Secondly, it must not discriminate where similar conditions between members prevail, nor may it be a disguised restriction on international trade.[97] Thirdly, a risk assessment must be performed according to the rules described in Arts. 5.1, 5.2 and 5.3 and Annex A.4 to the SPS Agreement. Lastly, the measure must not be more trade-restrictive than required to achieve the desired level of protection. In other words, a necessity test must be applied.[98] Case law has pointed toward considering a precautionary measure to fall within the category of SPS measures, as long as the precautionary measure aims, at least in part, at the prevention of any of the risks described under Annex A to the SPS Agreement.[99]

1. Relationship between Arts. 2.2 and 5.1 of the SPS Agreement

Under Art. 2.2[100] of the SPS Agreement, SPS measures must be based on a scientific examination performed with sufficient scientific evidence. According to the Appellate Body, this article is a reflection of the precautionary principle.[101] Nevertheless, it is not clear how this "reflection effect" works in practice. On the other hand, Art. 5.1[102] of the SPS Agreement establishes that a risk assessment[103]

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96 See Art. 2.2 of the SPS Agreement.

97 See Art. 2.3 of the SPS Agreement.

98 See Art. 5.6 and footnote to the Art. 5.6 of the SPS Agreement.

99 *Eggers*, (fn. 2), p. 129. See also Panel Report, *EC - Hormones*, (fn. 1), para. 8.22 (US) and para. 8.25 (CAN); Panel Report, *Australia - Salmon*, (fn. 92), paras. 8.32 and 8.34 - 8.37.

100 The relevant content of this article is: "Members shall ensure that any sanitary or phytosanitary measure [...] is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

101 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 124.

102 This article states: "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

103 In Annex A.4 to the SPS Agreement, risk assessment is defined as: "The 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; or the evaluation of the

must be executed with respect to a possible danger to human, animal or plant life or health.

The Appellate Body has acknowledged that Art. 2.2 is a general obligation which finds particular application in Art. 5.1. This implies that a violation of the latter article automatically indicates violation of Art. 2.2. Yet not all violations of Art. 2.2 will imply a violation of Art. 5.1.[104] Therefore, both articles should be read together since Art. 2.2 refers to Art. 5.1 directly.[105] Consequently, when examining a precautionary measure, the logical course of action is to start with an analysis of Art. 2.2 and then continue to Art. 5.1.[106]

2. The meaning of "sufficient scientific evidence"

The term "sufficient scientific evidence" used in Art. 2.2 was tackled by the Appellate Body in *Japan - Agricultural Products*, in which the Appellate Body concluded that "sufficiency" is a relational term "of quantity, extent, or scope adequate to a certain purpose or object" and requires a link between the SPS measure and the scientific evidence.[107] Panels have basically asked for that same connection, although with different terms such as "actual causal link" or "reasonably warrant".[108]

Additionally, the Appellate Body has accepted that the required scientific support does not have to be the prevailing current of thought, but can also be a minority opinion.[109] Thus, the existence of a minority report can suggest the presence of a rational relationship.[110] In other words, it is incorrect to think that "sufficient scientific evidence" means "sound scientific evidence", since the second term refers to precautionary measures based on the predominance of scientific thinking.[111] This opinion has been majorly attacked as it can seduce members to simply "buy"

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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."

104 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 180; see also Appellate Body Report, *Australia - Salmon*, (fn. 92), para. 137.

105 Ibid.; see also *Japan - Agricultural Products*, Appellate Body Report, *Japan - Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19/3/1999, para. 75.

106 Ibid., para. 250.

107 Ibid., para. 73.

108 *Eggers*, (fn. 2), pp. 133-134; see also Panel Report, *Australia - Salmon*, (fn. 92), para. 8.94; Panel Report, *Japan - Agricultural Products*, (fn. 105), para. 8.42.

109 Appellate Body Report, *EC - Hormones*, (fn. 1), paras. 186 and 194; Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 77.

110 *Eggers*, (fn. 2), p. 135.

111 Ibid., p. 143.

scientific studies which have been done by "puppet scientists".[112] The technique has also been extremely criticized as a "we know it when we see it" stance that does not offer true guidance for WTO members.[113] These critics are not well supported however. The Appellate Body has explained that such scientific examinations must come from "qualified and respected sources, who have investigated the particular issue at hand".[114] The term "sources" seems to point that just one study might not be enough and the phrase "who have investigated" appears to require that the investigation has to be based on a representative number of cases. Therefore, a little experimental information will not suffice.[115]

3. Assessment of risk through scientific examination

The Appellate Body defined risk assessment as "a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions".[116] It was concluded that the assessment must "reasonably support" the contended SPS measure, requiring a "rational relationship" between the measure and the examination.[117] It was further settled that this standard can only be analyzed on a case-by-case basis.[118]

Moreover, Annex A.4 to the SPS Agreement presents two substantially different constructions of the term "risk assessment", depending on whether the risk emerges from a food-borne risk or from diseases or pests.[119] On one side, food-borne risk assessments only require an examination of the potential negative effects on human or animal health.[120] The term "potential" refers to the "possibility of occurrence of adverse effects, which implies a lower degree of potentiality than probability".[121] On the other hand, disease or pest-related risk assessments require an evaluation of the probabilities of entry and spread without ignoring the biological and economic consequences.[122]

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112 *McNiel*, The First Case under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban, Virgina Journal of International Law No. 39 (1998), p. 134.

113 *Eggers*, (fn. 2), p. 130.

114 Ibid., p. 142.

115 Ibid., pp. 142-143.

116 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 187.

117 Ibid., para. 193; see also Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 84.

118 Ibid., para. 194.

119 Appellate Body Report, *Australia - Salmon*, (fn. 92), paras. 123-124.

120 See Annex A.4 to the SPS Agreement, second sentence.

121 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 184.

122 See Annex A.4 to the SPS Agreement, first sentence.

In *US - Continued Suspension*, the Appellate Body considered that the purpose of a risk assessment is to prove that a negative effect could arise and not to demonstrate that an unfavorable outcome will actually happen.[123] That makes the difference between an "ascertainable risk" and uncertainty.[124] However, the examination is neither required to be presented in numerical terms, nor must a a minimum threshold of risk be demonstrated.[125] It was further recognized that a risk assessment cannot be isolated from the chosen level of protection. Thus the level of protection can influence the way an assessment is performed. Nevertheless, such an impact cannot overthrow the objectivity with which the risk assessment must be conducted.[126]

With regard to the question of how to conduct a risk assessment, a certain level of flexibility has been shown by the Appellate Body. In *US - Continued Suspension*, it overturned a strict distinction drawn by the panel between "risk assessment" and "risk management". Based on that differentiation, the panel had excluded important factors from its analysis on the examination of risk performed by the EC. On appeal, the Appellate Body stressed that components taken into consideration in a "risk management" can also be part of a "risk assessment".[127] Another example of elasticity shown by the WTO judiciary is accepting that a member may base its SPS measure on a risk assessment executed by another member, or by an international organization.[128]

Nonetheless, the Appellate Body has also been firm on other issues. It affirmed that the conclusion that there is a slight spread of a disease or pest is not enough for a proper risk assessment. It further explained that the probability of this spread must be thoroughly evaluated and that only "some evaluation" of this likelihood is not sufficient.[129]

Moreover, Art. 5.2 orders members to take into consideration the available scientific evidence in order to run their risk assessment. In that examination, attention should be paid to:

- Relevant processes and production methods;
- Relevant inspection, sampling and testing methods;

123 *US - Continued Suspension*, Appellate Body Report, *United States - Continued Suspension of Obligations in the EC - Hormones Dispute*, WT/DS320/AB/R, adopted 16/10/2008, para. 559.

124 Ibid., para. 569.

125 Ibid.

126 Ibid., para. 534.

127 Ibid., para. 545.

128 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 190.

129 Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 78.

- Prevalence of specific diseases or pests;
- Existence of pest or disease-free areas;
- Relevant ecological and environmental conditions;
- Quarantines or other treatments.

The Appellate Body has added that the list of elements contained in Art. 5.2 of the SPS Agreement is not exhaustive and that other factors outside a science laboratory can be taken into consideration in an examination of risk.[130] This interpretation has been widely criticized because of the broad scope given to the risk assessment by allowing WTO members to take into account elements outside science for the completion of their risk evaluations. *Quick* and *Blüthner* thereby consider that this construction undermines the requirement for scientific support contained in the SPS Agreement.[131] In spite of the Appellate Body's position, in *EC - Biotech Products*, the Panel found that members cannot rely on non-expert civil society reports, such as the ones published by non-governmental organizations, because such sources are not adequate for the conduction of a risk assessment.[132]

Lastly, Art. 5.3 obliges WTO members to consider relevant economic factors in their assessment. For instance, one such factor is "the potential damage in terms of loss of production or sales in the event of entry or spread of a pest or disease". Contrary to some constructions on the precautionary principle, this means that a cost-benefit analysis should be performed.

4. The necessity test

The necessity test has played a very important role in the resolution of disputes related to the exceptions of Art. XX of the GATT 1994.[133] Although the term "necessary" is not used in the SPS Agreement, Art. 5.6 contains a prohibition tantamount to the test. Specifically, the rule prohibits SPS measures that are more trade-restrictive than essential to attain a desired level of protection. A footnote to that same article provides further explanations on the test.[134]

130 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 187.

131 *Quick/Blüthner*, Has the Appellate Body Erred?, An Appraisal and Criticism of the Ruling in the WTO Hormones Case, JIEL 2 (1999), p. 616.

132 Panel Report, *EC - Biotech Products*, (fn. 47), para. 8.10.

133 See e.g. Appellate Body Report, *US - Gasoline*, (fn. 93), pp. 17-18; Panel Report, *EC - Asbestos*, (fn. 93), para. 8.194.

134 Footnote 3 to Art. 5.6 of the SPS Agreement states: "a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and

This is illustrated by the following example: if a biotech food product presents a risk of an allergic reaction for a small group of consumers, evidently a labeling requirement, instead of a ban, will be the least restrictive resort. Nevertheless, a labeling requirement based only on the application of a biotechnological process, may be considered as a discriminatory measure if there is no proof of an increased risk linked to the biotech food.[135]

II. Provisional measures

Article 5.7[136] of the SPS Agreement deals with scenarios where the shortage of scientific evidence does not allow for the performance of an objective risk examination.[137] In those cases, the precept recognizes that WTO members may adopt provisional SPS measures based on the available information. Hence, Art. 5.7 sets a lower standard than the one laid down in Arts. 2.2 and 5.1 of the SPS Agreement, an affirmation also acknowledged by the Appellate Body.[138]

Moreover, the Appellate Body stressed that Art. 5.7 of the SPS Agreement sets forth four cumulative requirements for the adoption of a provisional SPS measure.[139] The first two preconditions are, firstly, that there must be insufficient scientific information regarding the pertinent risk, and secondly that the measure is based on the available information. The other two requisites require members to try to obtain additional information for a better assessment of risk and to review the measure within a reasonable period of time.[140]

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economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade."

135 *Bergkamp*, Biotech Food and the Precautionary Principle under EU and WTO Law, 2001, p. 34.

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

137 Appellate Body Report, *US - Continued Suspension*, (fn. 123), para. 677.

138 Ibid., para. 678.

139 Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 89. This opinion was also shared by the panel in Panel Report, *EC - Biotech Products*, (fn. 47), para. 7.3218.

140 Ibid., para. 89.

1. Art. 5.7 of the SPS Agreement and the precautionary principle

Article 5.7 of the SPS Agreement does not expressively mention the precautionary principle. However, the scope and application of the rule is an extremely contentious point. Some environmental experts claim that Art. 5.7 shows quite clearly the presence of the precautionary principle in WTO law. However, the Appellate Body in *EC - Hormones* only acknowledged that the article is a "reflection" of the principle. This "reflection" calls upon the WTO judiciary to take into consideration that governments habitually err on the side of prudence and precaution where future harmful consequences might be irreversible.[141] It added, however, that the precautionary principle is not expressively included in the SPS Agreement as a justification for an SPS measure that is otherwise inconsistent with WTO law.[142]

Furthermore, the Article has been equally criticized by both contenders and supporters of the precautionary principle. Contenders regard the item as a dangerous loophole for the phony prevention of unreal risks. Supporters of the principle worry, on the other hand, that the referred rule does not wrap up all precautionary measures, especially those related to biotechnology products. For them, the problem is that measures under Art. 5.7 can only be adopted temporarily, whereby the main concern with biotechnology products is the long term risks involved. Thus, they demand the incorporation of the precautionary principle in its full form into the agreement.[143]

2. Art. 5.7 as an escape clause from Art. 2.2 of the SPS Agreement

An examination of Art. 2.2 of the SPS Agreement reveals that Art. 5.7 is an escape clause from the obligations set forth in the first mentioned precept. However, Art. 5.7 is not titled an "exception". When the provision was first mentioned in *Japan - Agricultural Products*, the Appellate Body called it a "qualified exemption" to Art. 2.2.[144] It appears that the choice of "exemption" instead of "exception" has a meaning since the Appellate Body overruled the panel's finding in *Australia - Salmon* which spoke of Art. 5.7 as an "exception".[145] Nonetheless, the term "qualified exemption" is not entirely clear since the Appellate Body has not elaborated on it and the literature has not been able to agree on a precise meaning.[146]

141 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 124.

142 Ibid.

143 *Eggers*, (fn. 2), p. 162.

144 Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 80.

145 Ibid.; see also Panel Report, *Australia - Salmon*, (fn. 92), para. 8.57.

146 *Eggers*, (fn. 2), pp. 164 and 167.

Normally speaking, the word "exemption" is used in WTO law to allow members to maintain certain measures without violating their obligations.[147] In contrast, an exception is a way of justifying a violation of an obligation. All this seems to hint that Art. 5.7 cannot be used as an affirmative defense because it is not an exception.[148]

3. The meaning of "insufficient scientific evidence"

The phrase "insufficient scientific evidence" as employed in Art. 5.7 should be read as a negation of the expression "sufficient scientific evidence" used in Art. 2.2 of the SPS Agreement. This proposal is based on the link existing between the two articles: Art. 2.2 states that SPS measures cannot be "maintained without sufficient scientific evidence except, as provided for in paragraph 7 of Article 5".[149] Thus, for the application of Art. 5.7, an inconsistency of the SPS measure with Art. 2.2 or 5.1 of the SPS Agreement must first be found.[150]

In this context, the Appellate Body made clear that "insufficient scientific evidence" does not entitle members to overlook a risk assessment under Arts. 5.1 and 5.2 of the SPS Agreement.[151] Therefore, firstly, it has to be determined if the available scientific evidence is sufficient to allow, either in quantitative or qualitative terms, the execution of a risk assessment.[152] The existence of different scientific opinions on the same issue does not automatically mean that there is "insufficient scientific evidence".[153] Moreover, in cases where a stricter level of protection than the one contemplated in an international standard has been chosen, the Appellate Body has maintained that the test to corroborate the insufficiency of information cannot be made more burdensome.[154]

It has further been settled that when a respected scientific opinion questions the link between existing scientific data and a resolution with regard to a risk, and this opinion does not allow the execution of an objective risk assessment, a provisional

147 See Art. II.2 and Annex on Art. II Exemptions of the General Agreement on Trade in Services (GATS); see also Art. 13 (a)(ii-iii), (b)(i-iii), (c)(ii) of the Agreement on Agriculture.

148 *Eggers*, (fn. 2), p. 168.

149 Ibid., p. 173.

150 Ibid., p. 174.

151 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 125.

152 Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 179; see also Panel Report, *EC - Biotech Products*, (fn. 47), para. 7.3233.

153 Appellate Body Report, *US - Continued Suspension*, (fn. 123), para. 677.

154 Ibid., para. 708.

measure may be adopted.[155] The panel in *US - Continued Suspension* required this contending opinion to include a "critical mass of new evidence".[156] The Appellate Body, upon appeal, read "critical mass of new evidence" as a paradigm shift, therefore considering that the Panel had set a rather high threshold. Consequently, the Appellate Body further clarified that such information need not present a "paradigm shift", but only to question the relationship between the existing scientific information and the conclusions of the risk assessment.[157] On the whole, both approaches seem significantly extreme and a more equilibrated criterion should be found.

Finally, in *EC - Biotech Products*, the panel rejected the EC's argument that the precautionary principle permitted them to ignore their own scientific risk assessments because of the existence of scientific uncertainty.[158] It added that the narrow standard of "insufficient scientific evidence" used in the SPS Agreement is different from the wide concept of "scientific uncertainty" employed in the precautionary principle.[159]

4. The meaning of "available pertinent information"

The second requirement to adopt a provisional SPS measure is that it should be taken "on the basis of available pertinent information", a condition which is less strict than the ones imposed under Arts. 2.2 and 5.1 of the SPS Agreement. It must be noted that the adjective "scientific" is not even included.[160] The Appellate Body has admitted that such information may be obtained from related international organizations or from SPS measures implemented by other States. Nevertheless, there has to be a rational relationship between the information and the SPS measure.[161]

155 Ibid., paras. 677 and 703.

156 Ibid., para. 705.

157 Ibid.

158 Panel Report, *EC - Biotech Products*, (fn. 47), para. 7.3240.

159 Ibid., para. 7.2941. See also *Kogan*, A World Trade Organization Biotech Decision Clarifies Central Role of Science in Evaluating Health and Environmental Risks for Regulation Purposes, Global Trade and Customs Journal 2007, p. 153. This position is also shared by *Wirth*, The Transatlantic GMO Dispute against the European Communities: Some Preliminary Thoughts, Boston College Law School Faculty Papers, 2006, p. 200.

160 *Eggers*, (fn. 2), p. 176.

161 Appellate Body Report, *US - Continued Suspension*, (fn. 123), para. 678.

5. The obligation to seek additional information

Because of its transitory nature, a WTO member enforcing a provisional SPS measure should "seek to obtain additional information necessary for a more objective assessment of risk".[162] Therefore, the imposing member is obliged firstly to identify the loopholes in the pertaining scientific data, and secondly to make a real effort to obtain additional information that will lead towards a more objective risk assessment. Otherwise, the Appellate Body warned, the provisional nature of the Article would be undermined.[163] This task, however, does not require a member to promise or foresee any particular result.[164]

Additionally, it should be pointed out that this precondition seems to allow a more "subjective" assessment of risk than that one described in Arts. 5.1, 5.2 and 5.3. That is because Art. 5.7 stresses that after the measure has been imposed, the government has the obligation to "seek to obtain the additional information necessary for a more objective assessment of risk".[165]

With respect to what information should be sought, the Appellate Body has stressed that Art. 5.7 does not regulate "explicit prerequisites regarding the additional information to be collected or a specific collection procedure".[166] Nonetheless, it enunciated that the information must "germane to conducting" a more objective assessment of the risk.[167] Hence, the data should be both pertinent and fitting.[168]

6. Reviewing the measure

The last condition to set up a provisional SPS measure is to "review the [SPS measure] [...] within a reasonable period of time". This requisite is directly related to the one of collecting additional information. That is because a member is required to review the provisional SPS measure based on the additional information that has been gathered. This stipulation is also strictly linked to the fact that Art. 5.7 only allows members to "provisionally adopt" SPS measures, a phrase that was not considered by the Appellate Body as a fifth element.

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162 See Art. 5.7, second sentence of the SPS Agreement.

163 Appellate Body Report, *US - Continued Suspension*, (fn. 123), para. 679.

164 Ibid.

165 *Eggers*, (fn. 2), p. 176.

166 Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 92.

167 Ibid.

168 According to http://www.answers.com/topic/germane (26/8/2009), the meaning of "germane" is "being both pertinent and fitting".

As was previously mentioned, the apparent short margin of provisional measures has concerned many environmentalists because it does not cover the whole range of precautionary measures, particularly those where long term risks are suspected, for example those with regard to biotechnology products.[169] This problem has been tackled by the Appellate Body, which has ruled that what is a "reasonable period of time" has to be established on a case-by-case basis depending on individual circumstances.[170] Thus, an average cannot be established since the time length of a measure may very well depend on the difficulties of gathering the additional information.[171] Hence, under Art. 5.7 of the SPS Agreement, long-term provisional measures may be taken. However, such an interpretation brings up the obvious problem that members may seek to disguise permanent measures as "long-term provisional measures"[172] and that requires an accurate inspection by panels and the Appellate Body.

III. Standard of review and burden of proof

The burden of proof and the standard of review are two particularly important issues in the context of implementing precautionary measures under the SPS Agreement.[173] Obviously, the scientific facts encompassed in disputes regarding SPS measures are extremely controversial. Therefore, it is meaningful to understand who must provide what evidence and in what quantity, as well as who takes the decision whether or not there is in fact a risk, and how the existing regulations should be interpreted.

1. Standard of review

The SPS Agreement does not contain specific rules regarding the standard of review. Consequently, Art. 11 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) takes precedence here. In broad terms, the rule obliges panels to make an objective assessment of facts and applicable law.[174] The Appellate Body further insisted in *EC - Hormones* that the applicable standard is the completion of the objective assessment of facts in accordance

169 *Eggers*, (fn. 2), p. 188.

170 Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 93.

171 Ibid.

172 *Quick/Blüthner*, (fn. 131), p. 625.

173 *Eggers*, (fn. 2), p. 197.

174 See Art. 11 of the DSU. See also Appellate Body Report, *EC - Hormones*, (fn. 1), para. 116; *van den Bossche*, (fn. 3), pp. 238-240.

to Art. 11 and neither total deference nor a *de novo* review.[175] It was also explained that the threshold for finding that a panel did not conduct an objective assessment is considerably elevated. As such, not every error in the appreciation of proof means that a failure to carry out an objective assessment was made.[176]

Accordingly, a panel's standard of review as to the consistency of an SPS measure with Art. 5.1 of the SPS Agreement firstly includes pinpointing the scientific fundament upon which the measure was based. Following this, a panel must verify that such scientific basis is supported by reputable, objective and coherent sources.[177] When different scientific approaches exist on an issue, such examination does not include the prerogative to decide which opinion is more reliable, since WTO members are entitled to rely on minority views.[178]

Finally, a panel has to resolve whether the risk assessment "sufficiently warrants" the SPS measure at stake.[179] Hence, a "rational relationship" between the measure and the examination must be established.

a) A "total deference" standard of review for risk assessments

Notwithstanding what has been explained, the Appellate Body seems to have taken a "total deference" standard of review for risk assessments in *US - Continued Suspension*. In its decision, the Appellate Body stressed that a panel's task is to adjudicate whether a risk assessment is sustained by objective well-justified thinking and commendable scientific proof. It was further sustained that a panel cannot evaluate whether a risk assessment's conclusion is correct because it would then become a "risk assessor" and therefore performing a *de novo* review, going beyond its powers under Art. 11 of the DSU.[180] Likewise, it illustrated that a panel's task is not to repeat an investigation already performed by a member, but only to verify it from a procedural and factual point of view.[181]

In this explanation, the Appellate Body is basically following the EC's position in *EC - Hormones*, whereby a deference standard of review should be used to examine a risk assessment and thus a panel should not aim to repeat the investigation already conducted by a WTO member, but only to review whether the procedure

175 Appellate Body Report, *EC - Hormones*, (fn. 1), paras. 116-117.

176 Ibid., para. 133.

177 Appellate Body Report, *US - Continued Suspension*, (fn. 123), para. 591.

178 Ibid., paras. 612-613.

179 Ibid., para. 591.

180 Ibid., para. 590.

181 Ibid.

in the risk assessment is correct.[182] Therefore, in a contradictory way, the Appellate Body has applied a total deference review standard, which according to the Appellate Body itself is not in line with Art. 11 of the DSU.[183]

b) The influence of public international law on the SPS Agreement

Article 3.2 of the DSU clarifies that the dispute settlement system of the WTO aims to "clarify the existing provisions of the agreements in accordance with customary rules of interpretation of public international law". This rule is a clear indication that the SPS Agreement is not isolated from public international law.[184] This was also recognized in *EC - Hormones* when the Appellate Body insisted on the importance of the application of customary rules of interpretation of public international law.[185]

The Appellate Body has also accepted the use of the "General Rule of Interpretation"[186] contained in Art. 31 of the Vienna Convention on the Law of Treaties. In harmony, panels and the Appellate Body interpret WTO rules in conformity with the normal meaning of the words of the provision, taking into consideration their context and the aim and function of the respective agreement.[187] To illustrate, the Appellate Body in *EC - Hormones* overruled a panel's finding, warning that: "the fundamental rule of treaty interpretation requires a treaty interpreter to read and interpret the words actually used by the agreement under examination, not words the interpreter may feel should have been used."[188]

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182 See the EC's position in Appellate Body Report, *EC - Hormones*, (fn. 1), para. 111.

183 Ibid., para. 117.

184 *Van den Bossche*, (fn. 3), p. 206.

185 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 118.

186 This rule states: "1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. 2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes: (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty; (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty. 3. There shall be taken into account, together with the context: (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) any relevant rules of international law applicable in the relations between the parties. 4. A special meaning shall be given to a term if it is established that the parties so intended."

187 *Van den Bossche*, (fn. 3), p. 207.

188 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 181.

On the other hand, in *Japan - Apples*, the Appellate Body was asked whether the precautionary principle can be relevant to determine the fulfillment of a panel's obligation to make an objective assessment under Art. 11 of the DSU.[189] It was settled that a panel's discretion is not guided by the precautionary principle. Hence, it is not obliged to err on the side of caution in its factual findings.[190]

Likewise, the Appellate Body has acknowledged the difficulty of considering the precautionary principle as a tool to interpret the SPS Agreement. In *EC - Hormones*, it underlined that the lack of a unified position on the status of the precautionary principle in international law restrains the WTO judiciary from considering it as part of international law, and hence it cannot be used to give meaning to existing WTO rules.[191] That position was followed by the Panel in *EC - Biotech Products* whereby it was pointed out that "there has, to date, been no authoritative decision by an international court or tribunal which recognizes the precautionary principle as a principle of general or customary international law".[192]

c) The "in dubio mitius" principle and the standard of review

Furthermore, the standard of review is shaped by the Appellate Body's constant use of the *in dubio mitius* principle, which is defined as "a supplementary means of interpretation in public international law, whereby in cases of ambiguity that meaning is to be preferred which is less onerous to the party assuming an obligation".[193] As an example, in *EC - Hormones*, the Appellate Body was asked to interpret Art. 3.1 of the SPS Agreement.[194] In particular, the meaning of the rule requiring SPS measures to be "based on" international standards was in dispute. The panel had understood "based on" as "conform to", granting therefore a *de facto* binding effect to international standards.[195] The Appellate Body, using the *in dubio mitius* principle, sustained it cannot be assumed that members intend to impose upon themselves the most burdensome obligation. In accordance, it was

189 *Japan - Apples*, Appellate Body Report, *Japan - Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10/12/2003, para. 231.

190 *Prévost*, (fn. 80), p. 12.

191 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 123.

192 Panel Report, *EC - Biotech Products*, (fn. 47), para. 7.88.

193 *Eggers*, (fn. 2), p. 217.

194 Art. 3.1 of the SPS Agreement reads: "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3".

195 *Eggers*, (fn. 2), p. 216.

ruled that when a term is ambiguous or unclear, the less restrictive meaning should be preferred.[196]

The Appellate Body has also applied the *in dubio mitius* principle in other interpretations of the SPS Agreement, although without quoting it. For example, it reversed the interpretation given by a panel to the phrase "based on" in Art. 5.1. It stressed that a measure must have only a rational relationship with the risk assessment and not full conformity.[197] That means that WTO members have more flexibility on how to handle precaution since they do not have to strictly follow the findings of a risk assessment.[198]

Another illustration of the preference for the less-restrictive interpretation can be seen in *Australia - Salmon*. Regarding how to perform a risk assessment, the Appellate Body granted members the freedom to decide whether they wish to perform a qualitative or a quantitative assessment. However, the term "evaluate" was understood strictly and the conduction of only "some evaluation" did not satisfy the Appellate Body.[199]

Concerning the interpretation of Art. 5.7 of the SPS Agreement, the Appellate Body has also used the *in dubio mitius* principle when flexibly construing the requirement to "seek to obtain the additional information necessary for a more objective assessment of the risk".[200] While the SPS Agreement does not provide any light on the quantity and manner in which that additional information should be collected, the Appellate Body insisted that the information need only "be relevant" to the conduction of the risk assessment, imposing a requirement which is not very demanding.[201]

2. Burden of proof

The precautionary principle forces the producer to prove his product is safe. On the other hand, in WTO law, the producer is not obliged to do that. The responsibility rather lies on the members, who have to base their precautionary measures on reliable scientific proof.[202]

196 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 165.

197 Ibid., para. 193.

198 *Eggers*, (fn. 2), p. 217.

199 Appellate Body Report, *Australia - Salmon*, (fn. 92), para. 124.

200 *Eggers*, (fn. 2), p. 217.

201 Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 92.

202 *Eggers*, (fn. 2), p. 200.

In spite of the importance of the burden of proof, the SPS Agreement is silent on it and this constitutes one of the main problems of allocating it in cases of scientific uncertainty. This serious difficulty has been recognized by panels and the Appellate Body, leading them to ascertain that the allocation of the burden of proof under the SPS Agreement is an issue of great significance.[203] The question is, however, how much and what kind of evidence must be presented to satisfy the WTO judiciary.

a) The parties and the "prima facie" case

The DSU also lacks provisions related to the burden of proof.[204] Nonetheless, because of the antagonist nature of the system, the responsibility of collecting and presenting evidence rests, at least in principle, upon the parties.[205] The parties themselves are therefore the first source of information. In this respect, the Appellate Body has maintained, in an interpretation of Art. 13.1, in the third sentence of the DSU, that members have the duty to provide particular information requested by a panel.[206] A party's refusal to supply the requested information grants panels the right to draw inferences from these actions.[207]

In particular, the Appellate Body has noted that the burden of proof lies on the party that asserts a particular claim or defense. It only shifts to the other party when enough evidence has been presented to set a presumption that what is claimed is true. When that presumption has been achieved, the party has a *prima facie* case.[208] Thereafter, the burden of proof shifts to the defending party which must now refute the inconsistency. It has been further noted that a *prima facie* case is one where no refutation from the defending party will lead to a ruling in favor of the party with the *prima facie* case.[209]

The Appellate Body also established that how much and what kind of evidence is required to establish a *prima facie* case will depend on the SPS measure and the particular case.[210] Thus, it will be decided on a case-by-case basis. This poses the evi-

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203 Appellate Body Report, *EC - Hormones*, (fn. 1), para. 97; see also Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 122.

204 *Van den Bossche*, (fn. 3), p. 210.

205 *Eggers*, (fn. 2), p. 197.

206 *Canada - Aircraft*, Appellate Body Report, *Canada - Measures Affecting the Export of Civilian Aircraft*, WT/DS70/AB/R, adopted 20/8/1999, para. 187.

207 Ibid., para. 202.

208 *Eggers*, (fn. 2), p. 202; *van den Bossche*, (fn. 3), p. 210.

209 Appellate Body Report, *EC - Hormones*, (fn. 1), paras. 98 and 104.

210 *Eggers*, (fn. 2), p. 202; *van den Bossche*, (fn. 3), p. 210.

dent problem that it remains dubious what must be done to accomplish a *prima facie* case. For instance, in *EC - Hormones*, the Appellate Body sustained that the USA and Canada had presented a *prima face* case since they had recourse to international standards and scientific studies which suggested that the use of hormones is, in principle, a safe practice. To rebut this, the EC would have had to demonstrate that the practice of using hormones posed a risk for human health. This position could have been sustained with specialized studies on the field.[211] However, the general studies or the opinion of an expert presented by the EC were not enough to persuade the Appellate Body that the measure was based on a risk assessment.[212]

It is also interesting to mention with regard to the *EC - Hormones* case that the dispute involved the use of six hormones in cattle. The above mentioned standards and studies referred to five of them. Regarding the sixth one – Melengestrol Acetate (MGA) – there were no international standards or available studies at the time. The USA sustained that there was no risk assessment related to MGA performed by the EC. On the other hand, the EC argued that there were studies suggesting that MGA is an anabolic agent which imitates the action of progesterone. The Appellate Body found these studies not to be good enough. Therefore, the Appellate Body had to rule as to the consequences of the use of MGA in complete ignorance. At the end, the Panel's finding that there was no risk assessment conducted with regard to MGA was upheld.[213] In other words, the Appellate Body inferred that the absence of data revealed the import ban was not based on a proper risk assessment.[214] Consequently, instead of insisting that MGA is tantamount to progesterone, the EC should have invoked Art. 5.7 of the SPS Agreement since there was insufficient scientific information on the consequences of using MGA. However, it remains dubious why the EC did not recourse to this line of argument.

In another example, Canada also successfully established a *prima facie* case, as a complainant, in *Australia - Salmon*. The country raised a presumption that the Australian measure was not based on a proper risk assessment.[215] Canada considered that the Australian risk assessment only dealt with a very limited scope of salmon products while the measure at stake was of a much wider scope. In any case, even in relation to the products actually covered by the study, the panel found that there was no rational link between the measure and the so-called risk

211 Appellate Body Report, *EC - Hormones*, (fn. 1), paras. 195-209.

212 Ibid.

213 Ibid.

214 *Eggers*, (fn. 2), p. 203.

215 Panel Report, *Australia - Salmon*, (fn. 92), para 8.59.

assessment. In other words, Canada was not required to prove that its salmon products posed no threat to health, but only that Australia undertook an improper risk assessment.[216]

Furthermore, in *Japan - Agricultural Products*, the Appellate Body held that when a complainant proposes a less-restrictive alternative measure, a member is not relieved from its obligation to establish a *prima facie* case.[217] Instead, the complainant should seek expert opinions on the topic and present them before the panel to achieve the presumption of a violation.[218]

On the whole, the standard of proof varies from case to case. No predictable rules exist on how much and what kind of proof a party must present to have a *prima facie* case. The decisions in *EC - Hormones* and *Australia - Salmon* implicate that a proponent is, contrary to the precautionary principle, not required to prove that his product is safe but only to prove that a risk assessment is lacking. Also, the case law indicates that the complainant's burden to establish a *prima facie* case is not that hard to accomplish, while trying to rebut one is a harder task.

b) The burden of proof in provisional measures

The panel in *Japan - Agricultural Products*, while not directly addressing the issue, referred to the general burden of proof established in Art. 2.2, to determine whether the requisites of Art. 5.7 had been satisfied.[219] Accordingly, the Panel decided that the USA established a *prima facie* case of inconsistency with Art. 5.7 of the SPS Agreement because there was neither proof that Japan had sought to obtain the required information, nor that had it carried out a review of the measure. Thus, a presumption that Japan failed to act in line with its obligation under Art. 5.7, second sentence was established.[220]

The Appellate Body firstly elaborated on the burden of proof with regard to provisional measures in *US - Continued Suspension*. It proclaimed that a proponent must also construct a *prima facie* case of violation of Art. 5.7 of the SPS Agreement. Once that presumption is corroborated, the burden will shift to the member enacting the provisional SPS measure.[221]

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216 *Eggers*, (fn. 2), p. 204.

217 Appellate Body Report, *Japan - Agricultural Products*, (fn. 105), para. 129.

218 Ibid., para. 130.

219 Panel Report, *Japan - Agricultural Products*, (fn. 105), para. 8.59.

220 Ibid., para. 8.58.

221 Appellate Body Report, *US - Continued Suspension*, (fn. 123), paras. 580-583.

The Appellate Body further admitted that a WTO member can rely on risk assessments and scientific studies supporting international standards to contest a provisional SPS measure. With this proof, the member will substantiate that the existing scientific data is not insufficient to perform a risk assessment. Nevertheless, such evidence is not absolute and may be rebutted.[222]

F. Conclusion

It has been established that the application of the precautionary principle in the SPS Agreement is notably influenced by the underlying conflict between precautionism and protectionism. That is because trade conflicts dealing with the principle are related to the agricultural sector, which is particularly known for being protectionist. Furthermore, it has been demonstrated that the WTO judiciary has refrained from recognizing the precautionary principle as part of international law. That decision has been prompted by the lack of agreement between scholars whether the precautionary principle has achieved the status of customary law or of a general principle of international law. Its application has become even more troublesome since a uniform definition of the principle has also not been achieved. Consequently, the International Court of Justice is called upon to elaborate on the status and definition of the principle in order to bring some light to this heated debate.

Regardless of the uncertainty on the status and the absence of a precise definition of the precautionary principle, the Appellate Body has found a "reflection" of the principle in Arts. 2.2 and 5.7 of the SPS Agreement but, nevertheless, stressed that the principle cannot overrule any of the obligations contained in the agreement. Therefore, it remains clouded whether this "reflection" has any practical use at all. The Appellate Body should then set out transparent rules on how this "reflection" exactly works in practice. Nonetheless, the Appellate Body's formulations on provisional SPS measures – Art. 5.7 of the SPS Agreement – seem to suggest that a small space is being left for the eventual introduction of new considerations related to the principle. But then again, the issue would be whether it is possible to make the precautionary principle work without violating WTO rules.

Moreover, for disputes related to SPS measures, it can be concluded that the applicable standard of review is the realization of an objective assessment of facts and neither total deference nor a *de novo* review. It was further deduced that the minimum threshold for finding that a panel did not conduct an objective assessment is reasonably high. In spite of what was explained, the Appellate Body, in

222 Ibid., para. 696.

US - Continued Suspension, seems to have taken a total deference approach regarding the assessment of risks, which according to itself does not respect WTO rules.

In addition, it was shown that the *in dubio mitius* principle has been regularly used to interpret legal concepts in a more flexible way, sometimes perhaps being too flexible. This has generated constructions that are quite controversial. Perhaps more balanced interpretations between the right of members on one side, and precaution on the other side, should be developed.

Likewise, it was determined that the burden of proof lies on the party that asserts a particular claim or defense. It only shifts to the other party when a *prima facie* case has been established. The extent and type of evidence which must be presented will depend on the measure and the case and is thus to be evaluated on a case-by-case basis. This poses the evident problem that what is required to establish a certain *prima facie* case is unclear. Nonetheless, the case law shows that the complainant's obligation to establish a *prima facie* case is not that difficult to accomplish, whilst trying to rebut one is more troublesome.

Finally, WTO decisions have implicated that, contrary to the precautionary principle, a proponent must prove that the other party failed to undertake a correct risk assessment, rather than showing that his product is safe. This proves the limited influence of the principle in WTO law.

In summary, the precautionary principle has not been able to achieve with success the task of playing a significant role in WTO law. The case law regarding the SPS Agreement and its link with the principle is still insufficient. For now, the Appellate Body has rejected all SPS measures that have been based on the principle. Therefore, the answer to the question of what role should be played by the precautionary principle in WTO law depends on WTO members. A conclusive decision as to whether the precautionary principle fits within the WTO realm should be reached. Until then, the Appellate Body will have the word, with the aggravating factor that to date, it has not been able to set clear rules. Therefore, until a steady decision is taken, the present and future of the precautionary principle in WTO law is blurry. In the meantime, the debate between promoters of the precautionary principle and its opponents continues and in the short-term perspective, it does not seem that a solution will be found.