Application of the Precautionary Principle in the SPS Agreement

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Akawat Laowonsiri

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2 Lecturer of Public International Law and of Private International Law, Faculty of Law, Bangkok University, the Kingdom of Thailand.
Table of Contents

Introduction

I. Preliminary Issues
   1. Historical Background
   2. Definition of the Precautionary Principle
   3. Status of the Precautionary Principle
   4. Notion of Risk: Introductory Remarks prior to Analysing Coverage of the Precautionary Principle

II. Analytical Approach of the Scope of the Precautionary Principle
   1. Within the Scope of Article 5.7
      a. Insufficient Relevant Scientific Evidence
      b. Based on Available Pertinent Information
      c. Obligation to Obtain Necessary Additional Information
      d. Review within a Reasonable Period of Time
   2. Paragraph 6 of the Preamble
   3. The Scope of Article 3.3
   4. Outside the Scope of Article 5.7, Paragraph 6 of the Preamble and Article 3.3
      a. Possibility to Apply the Precautionary Principle in the Context of Arts 5.1 and 5.2
      b. Possibility to Apply the Precautionary Principle as an Unwritten Norm

III. Relation between the Precautionary Principle and Relevant Rules of International Law
   1. Rules of International Trade Protection
      a. Principle of Good Faith
      b. Transparency Requirement
      c. Necessity Test
   2. Countervailing Rules against International Trade Protection
      a. Principle of Self-Determination of Peoples in Economic Context
      b. Rules Established by the World Health Organisation
      c. Biosafety Protocol

IV. Dispute Settlement Concerning the Precautionary Principle
   1. Choice of Forum
   2. Roles of the SPS Committee
   3. Burden of Proof
      a. Arts 5.1 and 5.2
      b. Article 5.7
      c. Paragraph 6 of the Preamble and Article 3.3
   4. Review of Precautionary Measures

V. Precautionary Principle and Developing Countries
   1. Developing Countries as Exporting Countries
      a. Preoccupation on Configuration of the Precautionary Principle
      b. Preoccupation on Abusive Application of the Precautionary Principle
   2. Developing Countries as Importing Countries

Conclusion
Introduction

The application of the precautionary principle is a controversial issue in the field of international trade law. The principle has a significant role in striking a balance between international trade liberalisation and public health protection. In the past, the application of the principle was addressed in a comprehensive manner. There was no instrument which specifically endorsed the precautionary principle in the area of public health protection, until the concept was embraced into the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) as a result of the Uruguay Round Negotiations. The role of the principle is thus more apparent in the context of international trade, but even this configuration is still left unclear.

This thesis aims at addressing this problem. In doing so, it begins to characterise the precautionary principle in Part I, as basic notions of the precautionary principle are controversial. Without beginning with this, it would be difficult to advance on other problematic issues. Part II. will provide an analytical approach of the precautionary principle, which is the main topic for discussion amongst stakeholders. A restrictive version of the principle is supported by the Appellate Body. Its extensive version is not disregarded, as it is also considered thoughtful and deserves to be evaluated accordingly. For this thesis, the problem of how far the precautionary principle could be applicable is to be assessed along with the question of what is the yardstick which could feasibly provide the scope of the precautionary principle.

Application of the precautionary principle in the WTO context is subject to the methodology of public international law. It would not make sense to interpret the principle in technical isolation, rather than as an integral part of public international law, as once addressed by the

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4 Prévost, see note 3, 1 et seq.

Appellate Body in the *US-Gasoline* case.\(^6\) Therefore Part III. will demonstrate the relationship between the precautionary principle and relevant rules of public international law. Afterwards Part IV. will discuss significant procedural issues. Part V. will focus on issues concerning developing countries, as legal specialities appear to exist here.

I. Preliminary Issues

1. Historical Background

Although there a number of international instruments, which already existed in the early 1900s and would also accommodate the precautionary principle due to their language, for instance, the International Convention for the Abolition of Import and Export Prohibitions and Restrictions from 1927, surprisingly the precautionary principle was not invoked to justify trade restrictive measures authorised by relevant provisions thereof. Abstinence from imposing precautionary measures may result from the level of biological technology, which was not as developed as nowadays. Since imposition of precautionary measures deals directly with scientific matters, undoubtedly science has played a significant role in this area, as evidenced in legal texts in both domestic and international legal systems which have recognised this concept.

The concept of precaution did not, *per se*, originate in the international platform, but was pioneered in German national environmental law during the 1970s and 1980s, known as “Principle of Precautionary Action” or “Vorsorgeprinzip”. In the international legal context, it was partly included into the Preamble of the 1984 Bremen Ministerial Declaration of the International Conference on the Protection of the North Sea which provided that states “must not wait for proof of harmful effects before taking action”. The language, as written in the context of this Declaration, did not adequately emphasise the concept, until the release of the 1987 London Ministerial Declaration which clearly embraced the principle of precautionary action, thanks to the insistency by the Federal Republic of Germany. This explicit inclusion has made the principle obtain a clear standing in international law.

Afterwards, the concept became clearly prominent due to the UN Conference on Environment and Development in Rio de Janeiro in

The precautionary principle was embodied in Principle 15 of the Rio Declaration, in the following terms:

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

Since the Rio Declaration, the precautionary principle has been developed in several international conventions on the protection of the environment. For instance, the Preamble of the Convention on Biological Diversity, article 3 of the Framework Convention on Climate Change, article 2 (2)(a) of the Convention for the Protection of the Marine Environment of the North-East Atlantic. At this point, the principle was widespread in specific areas of environmental law. However the principle still lacked formulation in the area of public health especially in relation to international trade. Article XX (b) of GATT 1947 was insufficient to fulfil urgent needs of health protection when trade became trans-boundary. In the Uruguay Round of Ministerial Trade Negotiations, the topic was intensively discussed, resulting in the conclusion of the SPS Agreement.

Generally speaking, the precautionary principle was reflected in article 5.7 of the SPS Agreement, which allows Member States to provisionally impose precautionary measures in case of scientific uncertainty. Within the language of the SPS Agreement, the precautionary principle is considered merely as a part of the risk management and only allows

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7 Article XX (b) does not accommodate the precautionary principle, as clarified by the Appellate Body in the EC-Asbestos case. This case states that the particular exception contained in Article XX (b) of GATT demands sufficient evidence for the existence of a risk, thus excluding the application of the precautionary principle, which only applied in cases where there is scientific uncertainty. Furthermore, the examination of whether the measure in question is “necessary” to protect human health under this particular exception is essentially influenced by the principle of proportionality, Appellate Body Report, EC-Asbestos case, Doc. WT/DS135/AB/R, para. 167; P. Stoll/ L. Strack, “Article XX lit. b”, in: R. Wolfrum, WTO-Technical Barriers and SPS Measures, 2007, 106 et seq.; H. Priess, “Protection of Public Health and the Role of the Precautionary Principle under WTO Law: A Trojan Horse before Geneva’s Walls?”, Fordham Int’l L. J. 24 (2000), 519 et seq. (552).

precautionary measures for a temporary period. In the EC-Hormones case, the EC contended that the principle shall not be constrained as such, but rather be broadly applied also in risk assessment and thus can justify the adoption of non-provisional measures. Such non-compliance of the EC is significant in the development process of the SPS regime, since it does not represent a challenge of discipline, but rather insistency of thoughtful interpretation of the precautionary principle in the SPS context.

2. Definition of the Precautionary Principle

Despite the impressive number of both hortatory and binding international documents endorsing the precautionary principle, a precise definition of the precautionary principle does not exist therein. However, a definition has been proposed by Bohannes which reads:

“Generally speaking, the principle is advanced to help public authorities to make decisions in situations where claims of hazard are uncertain and decision-makers face the dilemma either to take immediate protective action or delay such action until scientific uncertainty concerning these hazards is eliminated or reduced. In these situations widespread public concerns about potential hazards often add to the pressure decision-makers face.”

The essence of the precautionary principle is that positive action, for example, a ban on certain activities in order to protect the environment or public health, may be required before the existence of a risk is scientifically established. The principle therefore accommodates the public authorities to legitimately impose precautionary measures in response to the situation.

However, it is stated that, with regard to SPS matters, there are a number of things that make us cautious. Routinely consumed food and beverages may contain substances which are significant factors for various kinds of diseases. Some kinds of seafood, especially scallops and squids, contain high proportions of cholesterol which could cause high blood pressure. French Fries, when fried at a very high temperature, generate acryl amide resulting in cancer. It is accepted that alcohol

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9 Ibid., para. 16.
10 Bohannes, see note 5, 331.
11 Available at <http://www.doctor.or.th/node/1926>.
causes various effects on brain, liver, etc. Does the precautionary principle has to deal with these problems?

This thesis finds that these problems are irrelevant to the application of the precautionary principle with regard to the SPS Agreement. Undeniably what we consume everyday may contain hazardous substances but anxiety caused by this is the result of consumer behaviour and decisions, rather than substances in the foods and beverages or their manufacturing process. People have studied at school that these food stuffs, if consumed too much, can cause illness. Scallops and squid cannot cause adverse effect if we eat them in moderation. Likewise with alcohol consumption. This thesis observes that anxiety about these circumstances is significantly provoked by behaviours and decisions of consumers, rather than substances of foodstuffs or their manufacturing processes.

In other words, the precautionary principle, in the SPS context, is to be considered as concerned with characteristics of organisms contained in beverages and foodstuffs, as the subject of the SPS Agreement according to Annex A.1. Risk assessment and risk management are determined under this Agreement to cope with these issues. Genetically modified food is definitely the object of the SPS Agreement. At this point, this thesis characterises the precautionary principle under the SPS Agreement as the principle dealing with circumstances where anxiety exclusively falls upon organisms or substances contained in/attached to an object at hand or its manufacturing process. Behaviours of consumers are outside the application of the SPS precautionary principle. Before making further analysis of the precautionary principle in the next part, it is important to recognise differences between the precautionary principle and the prevention principle. Differences between both doctrines have been observed by Jonas which reads:

“On sait que le principe de précaution se distingue de la prévention en ce qu’il tend à anticiper des risques simplement soupçonnés comme les risques résiduels ou reportés; ou totalement inconnus, comme les risques de développement, alors que le principe de prévention vise à empêcher les conséquences dommageables de risques connus, dont la survenance peut faire l’objet d’un calcul de probabilités et qui tombent pour cette raison dans le champ de l’assurance.”

His remark clarifies that the prevention principle contributes to protect damageable consequences of “known risks”, whereas the precautionary principle deals with “suspected risks, which could be totally unknown. The prevention principle is also reflected in the SPS Agreement,13 even more than the precautionary principle. However this thesis will focus on the precautionary principle, not the prevention principle.

3. Status of the Precautionary Principle

The status of the precautionary principle is a controversial issue as evidenced in the EC-Hormones case.14 The precautionary principle, in the view of the EC, has become a “general customary rule of international law” or at least a “general principle of law” and thus shall apply not only in risk management, but also in risk assessment. The argument was rebutted by the United States and Canada15 which share the common perspectives that the precautionary principle is not even a legal principle, but rather the so-called “precautionary approach”, which is reflected in article 5.7. However, the Appellate Body has made an important statement on this issue which reads:

“The precautionary principle is regarded by some as having crystallised into a general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. ... We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation.”

Argumentation on the precautionary principle of each side reflects that the discussion was taken merely on the status of the precautionary principle under general international environmental law, without considering that the objects of protection under the SPS Agreement consist of three main things, namely human beings, animals and plants, each of

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13 The case of melamine in China is an example of the application of the prevention principle in the area of public health, since risk of melamine contamination is evidently known.
14 EC-Hormones case, see note 8.
15 Ibid., paras 43 and 62.
which deserves a different level of protection. Definitely the priority shall go to the protection of human health and life. The main problem in this case is relevant to the issue of public (human) health. Surprisingly, the arguments of both sides were mixed in the topic of “general international environmental law”. If the status of the precautionary principle would be distinctly analysed with regard to the nature of public (human) health, a profound consideration would have been taken.

The precautionary principle in relation to the protection of health and life of human beings shall be carefully distinguished from “the protection of health and life of animals and plants”. When the precautionary principle is discussed in the context of general international environmental law, it appears that the controversy has not been settled, even though the precautionary principle is considered supplementary to the environmental legal context and is regularly advocated. Specifically, in the area of public health, the precautionary principle is not just a supplementary, but also a vital and inevitable tool which helps to prevent human beings from possible hazards. Due to the endless advancement of biotechnology, scientific outcomes are continuously generated and thus their risks sometimes are unpredictable. Genetically modified foods are evidence which affirms the anxiety resulting from advancement of biotechnology. When human beings get closer to the possible risk of science because of the food they consume, a sufficient legal framework shall be immediately established to protect human beings.

Rules of public international law normally take time to be crystallised. Their retardedness discourages efficiency to deal with “accelerated biotechnological advancement” as well as open-ended biological problems. The existence of conventional rules requires the expression of consent to be bound by the Member States. Customary international law needs constitution of physical (state practice) and mental (opinio juris sive necessitatis) elements. In this case, it is difficult to invoke the precautionary principle by referring to both sources, given that the SPS Agreement, as interpreted by the Appellate Body, only accommodates the precautionary principle in limited extent and its status as customary

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17 Genetically modified products or any other outcomes of technology.

international law is widely argued. However, there remains a hopeful source of international law, a general principle of law, which does not require such stringent criteria as the others and is expected to be applicable law at the time when non-liquet is almost envisioned.

If the object of argumentation, of whether the precautionary principle is applicable, were narrowed down into the matter of public (human) health, the Appellate Body should have deferred to the fact that non-liquet is almost envisioned and thus shall have recourse to the application of the general principle of law. Considering the SPS regime, the precautionary principle has not only been developed within the SPS Agreement, but also in other international hortatory and binding instruments.

The principle was pioneered in the German legal system and then was induced to be applied internationally in the field of general international environmental law. Manifestly the concept of precaution has already transferred to the field of public (human) health protection, as evidenced in the International Health Regulations (IHR) of the WHO and in the Cartagena Protocol on Biosafety. The precautionary principle as a general principle of law subsists in the IHR of the WHO and in the Cartagena protocol and could be applicable law within the WTO system, at least, referred to as a general principle of law recognised in response to the status of non-liquet.

Taking the experience of international space law, which was a new area of international law, states have solved the problems of gap-in-law by referring to general principles of law as applicable law. A number

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20 Brownlie, see note 16, 16-17; J. Thirawat, Public International Law, 85 et seq. (written in Thai).
21 A. Cassese, International Law, 2005, 189 et seq.
22 Article 43 of the International Health Regulations (IHR).
23 Para. 4 of the Preamble and article 16 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.
24 Actually the precautionary principle could be applied as conventional rule of different configuration, imported from other international agreements. This notion will be discussed in Part III.
25 As explained above.
of general principles of law have been applied in this field, regardless of the lack of conventional rules or customary international law. If the answer for international space law is yes, why is it not so for the international SPS regime?

4. Notion of Risk: Introductory Remarks prior to Analysing Coverage of the Precautionary Principle

When discussing the precautionary principle, it is important to refer to “risk assessment and risk management”. The notion of risk is closely related to the precautionary principle. Before continuing the analytical approach of the scope of the precautionary principle, the distinction between risk assessment and risk management is to be made and the “relationship between the principle and the notion of risk” is to be identified.

The SPS Agreement only provides a definition of risk assessment in Annex A4 thereof, but not for risk management. However, risk assessment is an employment of a scientific methodology to establish the probability of hazardous effects of a substance or an activity.27 Risk assessment entails laboratory testing procedures as well as other scientific methods necessary to provide configuration and probability of the risk of a substance and activity at hand,28 whereas risk management29 is concerned with activities rendered by the relevant authority to deal with potential hazards; it includes the process of identifying and evaluating a risk upon a decision to select and implement appropriate measures to

27 Bohannes, see note 5, 335.
28 The Panel elaborates risk assessment as a two-step process that “should (i) identify the adverse effect on human health (if any) arising from the presence of the hormones at issue when used as growth promoters in meat…, and (ii) if any such adverse effects exist, evaluate the potential or probability of occurrence of such effects”, EC-Hormones case, see note 8, para. 183.
29 The SPS Agreement recognises at least three types of actions that a member may take to manage risks, and sets certain minimal requirements for each. These three types of actions are: (i) selecting the level of protection deemed appropriate by the member; (ii) establishing sanitary measures to achieve that level of protection; and (iii) accepting measures established by other members as being equivalent to its own; V. Walker, “Keeping the WTO from Becoming the ‘World Trans-Science Organization’: Scientific Uncertainty, Science Policy, and Fact Finding in the Growth Hormones Dispute”, Cornell Int’l L. J. 31 (1998), 251 et seq. (268).
reduce such risks.30 In a risk management, the relevant authority is normally entitled to set forth what level of risk is acceptable in a particular society.31

Risk assessment and risk management are related to the application of the precautionary principle. It is widely accepted that application of the precautionary principle is a part of risk management, as evidenced, at least, in article 5.7 of the SPS Agreement.32 (Further elaboration on the application of the principle in the process of risk management will be discussed in Part II.) The problem of applicability of the precautionary principle in risk assessment, is rather a controversial issue especially after the interpretation of the Appellate Body in the EC-Hormones case. The argument of the EC, that states are entitled to take precaution in risk assessment,33 is also supported by academics in this field.

This thesis considers that the argument of the EC is thoughtful and should be taken into consideration, but also makes some observations. It also affirms that, by methodology of treaty interpretation, the precautionary principle, actually, is also a part of the risk assessment. Even if the jurisprudence of the WTO, in which science obtains a pertinent role, is pursued in this context, there remains a gateway to application of the precautionary principle since the scientific methodology also provides the concept of precaution in itself.34 Discussion will be made in Part II.35 However, in analysing the scope of the precautionary principle, relevant provisions of the SPS Agreement will be regarded and the notion of risk assessment and/or risk management, if necessary, will be additionally raised.

30 Bohannes, see note 5, 335.
31 Ibid.
32 Ibid., 336; however, some argue that it is more appropriate to use the word “precautionary approach” instead of “precautionary principle”. See arguments of the United States and Canada in the EC-Hormones case, see note 8, paras 43 et seq.
33 The EC argued that the precautionary principle also overrides arts 5.1 and 5.2 and thus a state is entitled to take precaution in risk assessment. In other words, regardless of the conclusion that there is no risk, states can take precaution on the scientific experiment. This topic will be discussed in detail in Part II.
34 Walker, see note 29, 266 et seq.
35 Ibid.
II. Analytical Approach of the Scope of the Precautionary Principle

It is recognised that the scope of the precautionary principle is not exhausted in article 5.7, as asserted by the Appellate Body in the EC-Hormones case, which reads:

“... We agree, at the same time, with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3 ...”

This finding has offered a significant interpretation for this topic, but has not provided, in detail, the configuration of the precautionary principle in the sixth paragraph of the preamble and in article 3.3. Also, for its reflection in article 5.7, the configuration of the precautionary principle has not been completely illustrated. In response to these ambiguities, this thesis will try to describe configurations of the precautionary principle within the scope of such provisions. Moreover it will analyse and evaluate the possibility of applying the precautionary principle outside the scope of the said provisions.

1. Within the Scope of Article 5.7

The precautionary principle is reflected in article 5.7 but in a restrictive manner: precautionary measures must be provisional and must fulfil four requirements given under article 5.7. That is to say, during/after

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36 Some issues were left unanswered; Prévost, see note 3, 37 et seq.
37 As mentioned in Part I., the precautionary principle is also related to the notion of risk, including risk assessment and risk management. The relationship between the precautionary principle and the notion of risk will also be demonstrated in this part. When discussing the notion of risk, it is unavoidable to take into consideration the role of science, given that in the context of the SPS Agreement, the precautionary principle is not purely a legal or policy matter. Science is considerably recognised in this Agreement in comparison with other fields of international law, which also endorse the precautionary principle, but do not accept the role of science as much as in this field.
precautionary measures are applied, measures must: (i) be imposed in respect of a situation where “relevant scientific information is insufficient”; (ii) be adopted “on the basis of available pertinent information”; (iii) not be maintained unless the member seeks to “obtain the additional information necessary for a more objective assessment of risk”; and (iv) be reviewed accordingly “within a reasonable period of time”. Its configuration as reflected in article 5.7 will be analysed as followed.

a. Insufficient Relevant Scientific Evidence

Clarification of this requirement had not been addressed until the Appellate Body, in *Japan - Measures Affecting the Importation of Apples* case, interpreted the phrase. It clarified that article 5.7 is not applied “in situation of scientific uncertainty”, as in other fields of international law, but rather in a situation where “scientific evidence is insufficient.” In other words, the SPS Agreement provides a more restrictive situation which entails application of the precautionary measures. Insufficiency of scientific evidence is referred to as a situation where scientific evidence has been, at least once, sought for, but eventually is considered insufficient, whereas scientific uncertainty loosely represents a wide range of doubftfulness. In this sense, the Appellate Body affirmed that these two phrases are not interchangeable. This reflects a character of the precautionary measures in the context of article 5.7.

So, under which circumstances is scientific evidence insufficient? In answering this question, the Appellate Body clarified that insufficiency should not exclude a “case where the available evidence is more than minimal in quantity, but has not led to reliable or conclusive results.” With regard to this clarification, reliability and conclusiveness are yardsticks to point out in which situation the scientific evidence, at issue, is considered insufficient. Assessment of reliability and conclusiveness should not be scientifically characterised in isolation, but rather in relation with the values of a particular community in a particular context. At this point, room is left for Member States to take into consideration non-scientific factors.

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39 Oxford Advanced Learner’s Dictionary.
41 Ibid.
42 Winickoff et al., see note 38, 113.
b. Based on Available Pertinent Information

The phrase “available pertinent information” has not been clarified in any WTO case. In order to interpret this requirement, we should employ methodology of treaty interpretation from article 31 (1) of the Vienna Convention on the Law of Treaties, which provides that “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.”

“Pertinent”, according to the Oxford English Dictionary, means “pertaining or relating to the matter at hand; relevant; to the point; apposite” and, according to the American Heritage Dictionary of the English Language, it means “having logical precise relevance to the matter at hand.” According to both dictionaries, in reliance with the object and the purpose of the SPS Agreement, the available information, referred to by Member States, shall obtain a logical linkage to the potential hazards alleged to occur.

In addition, according to article 31 (1) of the Vienna Convention, contextual language of article 5.7 should also be considered to further clarify the phrase “available pertinent information”. At this point, observation was made by Winickoff, which reads:

“The first sentence of Article 5.7 clearly differentiates pertinent information from relevant scientific information, implying that the former is a broader category than the latter. The term should be interpreted to include substantive inputs from officially recognized public deliberations, experiential data not available from the published scientific literature, and other information concerning public values such as consumer data on public attitudes.”

This thesis also finds it appropriate to interpret in this way, since the context actually confers the different meaning of the two phrases. The phrase “available pertinent information” is something not based on science anymore, but rather on “public values.” The question of what “public values” are will vary with each case and particularity in each Member State, given that Member States are only entitled to impose
SPS measures within their own jurisdictions. Such public values could thus vary thereupon.

For example, people in state A eat food X regularly. But food X is highly objected in state B, where people are afraid of possible risks resulting from consumption of food X. Even though the scientific experiment proves that no risk takes place, food X is still objected by people in state B. Objection to food X is considered as public value of state B. Thus, when referring to this element, state B could invoke that its people highly object food X. But, vice versa, if food X, is exported from state C to state A, state A cannot refer to the public value, since the same public value does not exist in state A. As mentioned above, the public value of state A does not object to consumption of food X.

c. Obligation to Obtain Necessary Additional Information

After a Member State has imposed precautionary measures on the basis of available pertinent information, it is required to seek for necessary additional information which “must be germane to the conduct of a more objective risk assessment.”47 Such information, as clearly characterised as additional, must be additional to the old information at hand.48 It is therefore not necessarily a new information in the sense of a new discovery.49 In addition Member States are not required to conduct their own research, but rather they have discretion to decide which means they may employ to obtain such additional information, i.e. consultation of scientific research, database, internal and external experts, since the phrase “seek to obtain” implies various means which could be employed to obtain such additional information.50

Moreover Member States are not obliged to achieve actual results. After Member States have made “plausible efforts to obtain the additional information”,51 it should be assumed that they have complied

48 Stoll/Strack, see note 46, 461.
49 Ibid.
50 Ibid.
51 At this point, Stoll and Strack have made a reasonable statement, which reads: “This, however, does not mean that half-hearted efforts in this regard will not have legal consequences. If they result in a lack of additional information, the duty to review will at some point require the Member to admit that efforts to produce sufficient scientific evidence and a more ob-
with article 5.7 accordingly. Member States are also required to perform the obligation pursuant to the principle of good faith in order that this provision is not abused. Non-compliance with this requirement results in an obligation to repeal the precautionary measures, as clarified by the Appellate Body that Member States could not maintain the precautionary measures at hand, unless this requirement is fulfilled.

d. Review within a Reasonable Period of Time

In addition to the previous obligation, after applying the precautionary measures, Member States are also required to review the measure at hand within a reasonable period of time. This requirement implies that Member States shall conduct their own “self-evaluation on such precautionary measures”, which may result in a decision to repeal or to sustain the measures. Regarding the reasonable period of time, the Appellate Body, in the Japan-Varietals case, clarified that such period had to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty to obtain additional information necessary for the review and the characteristics of the provisional SPS measures. The Appellate Body further clarified that the reasonable period of time starts only after the entry into force of the SPS Agreement.

2. Paragraph 6 of the Preamble

Paragraph 6 of the preamble reflects technical aspects of the SPS regime since application of the SPS measures can involve a conflict (or clash) between scientific and legal technicalities. The SPS Agreement, therefore, also provides significant roles upon relevant specialised organisations to establish international standards, guidelines and recommenda-

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52 Ibid.
53 Ibid.
54 Ibid., Japan-Varietals case, see note 47, para. 93.
55 They are sometimes called “three sisters organisations”, which are namely Codex Alimentarius Commission (CAC or Codex), International Office of Epizootics (OIE, Office International des Epizooties) and the Secretariat of the International Plant Protection Convention (IPPC).
tions in order that such technical matters be harmonised, which eventually favour international trade regimes.

With regard to international standard setting for precautionary measures, Charnovitz has remarked that “Normally when an international standard exists, it was written because there was scientific information available.” In his view, precautionary measures could not be harmonised with international standards, as international standards are set when available scientific information exists. According to him, application of the precautionary principle is not in the sphere of international standard setting.

However, this thesis envisions that the concept of precaution could also be inserted into international standards, as no substantive obstacle prohibits us from doing so. International standards, for instance, on genetically modified products, could be established by a specialised organisation. Harmonisation of precautionary measures, if rendered, could be a merit because, in doing so, we could decrease tension amongst Member States. It is known that the precautionary principle grants states a range of discretion, which tends to result in abusive application of the precautionary principle, but once Member States are encouraged to take precaution according to existing international standards, which are widely accepted, they are thus more likely to conform to such international standards, since presumption of compliance is to be granted in accordance with article 3.2.

Making reference to international standards is not obligatory and is flexible. Member States are entitled to select any works of relevant specialised organisations or of international organisations as identified by the SPS Committee in accordance with Annex A.3(d). However, it

56 S. Charnovitz, “Preamble SPS”, in: Wolfrum, see note 7, 373 et seq.
58 However, the question under which circumstances precautionary measures should be instructed by international standards should depend on the single situation.
59 International standards are not obligatory, but SPS measures in conformity with international standards result in the presumption of compliance with the SPS Agreement pursuant to article 3.2 of the SPS Agreement.
60 These specialised organisations are three sister organisations, as mentioned in note 55.
61 As yet, the SPS Committee has not identified international organisations under this provision.
Laowonsiri, Application of the Precautionary Principle  

is restrictive that international standards are established when “international concerns” are met. Sometimes circumstances are involved merely with “domestic concerns”, which will hardly provoke establishment of an international standard. Thus, Member States, in case of domestic concerns, have to employ the mechanism of article 5.7. and this is a weak point of international standard setting.

In addition to the notion of international standards, the precautionary principle is also reflected in the last part of the sixth paragraph of the preamble, which recognises the right of Member States to establish “their own appropriate level of SPS protection.” It should be noted that, in the sixth paragraph of the preamble, the level of SPS protection is not deemed appropriate not just in the opinion of Member States, but also in the spirit of the SPS Agreement. Without this regard, the relevant SPS measures may be repugnant to relevant SPS provisions. Concerning this issue, article 3.3 sets forth requirements as will be analysed later in this part.

However, the preamble itself does not provide obligations for Member States, but rather establishes general ideas of application of the SPS Agreement. According to the Vienna Convention on the Law of Treaties, the preamble could be regarded as to help interpret provisions. It does not principally oblige Member States, whereas provisions of the treaty actually do. When precautionary measures are applied in the context of the SPS Agreement, provisions in the SPS Agreement shall prevail and the sixth paragraph of the preamble could be employed to help interpret the relevant provisions of the SPS Agreement.

In conclusion, even though the precautionary principle is actually reflected in the sixth paragraph of the preamble, it does not play an indispensable role in respect of the application of the principle, as the preamble of the SPS Agreement is employed to interpret the relevant provisions according to article 31 of the Vienna Convention on the Law of Treaties.

3. The Scope of Article 3.3

The scope of the precautionary principle in article 3.3 is a controversial topic. The question of whether this article reflects the precautionary

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62 Article 3.3 provides the similar context which will be discussed later.
principle has not been settled. In analysing the applicability of the precautionary principle, this thesis will firstly draw attention to the unclear text of article 3.3 and then to the interpretation of the Appellate Body in the EC-Hormones case.

Article 3.3 reads:

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

According to the text, this article loosens the obligations of Member States under arts 3.1 and 3.2, which require Member States to base or to conform their SPS measures on or with international standards respectively. Article 3.3, instead, leaves room for Member States to decide not to use international standards, but to introduce or to maintain their SPS measures which result in a higher level of protection than would be achieved by measures based on the relevant international standards. The Appellate Body, in the EC-Hormones case, affirmed that “the right of a Member to establish its own level of sanitary protection under Article 3.3 of the SPS Agreement is an autonomous right and not an exception from a general obligation under Article 3.1.” It also asserted that this article reflects the precautionary principle, in the sense that Member States may take precaution on potential hazards by elevating the level of SPS protection.

Despite the finding of the Appellate Body in the EC-Hormones case that this article reflects the precautionary principle, interpretation by the Appellate Body, in the same case, shows that it seems impossible to apply the precautionary principle in the context of this provision. It seems strange that the same Appellate Body Report was written differently.

A number of commentators, including the author of this thesis expose their position against this finding of the Appellate Body. Bohannes, see note 5, 335 et seq.; Charnovitz, see note 56, 373 et seq.
Article 3.3 sets forth two situations either of which Member States could invoke to impose measures resulting in a higher level of protection: (i) if there is a scientific justification; or (ii) the measures are consequences of a level of protection that the Member State determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. By reading only these two conditions, we may imagine that the configuration of the precautionary principle subsists in the requirement of scientific justification, but the case is not that easy. The second sentence and footnote of this article have generated confusion amongst scholars and practitioners in this field around the world including the Appellate Body.

The second sentence of this provision additionally requires that all SPS measures in both situations shall not be inconsistent with any other provision of this Agreement. Due to this additional requirement, scientific justification could not play an independent role that would embrace applicability of the precautionary principle. Instead, the scientific justification is required not to be inconsistent with any other provisions of the SPS Agreement. In addition, the footnote to this article makes this requirement redundant as it clearly obliges Member States, which refer to the scientific justification, to conduct “an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement.”

At this point, the article is reluctant to say that, on the basis of scientific justification, Member States have to rely again on risk assessment. In other words, with the text and the WTO jurisprudence, we have to understand that relying on a scientific justification would not be considered different from conducting a risk assessment according to article 5.1, as asserted by the Appellate Body in the EC-Hormones case. It considered that risk assessment plays a countervailing factor with respect to the application of article 3.3, which reads as follows:

“Consideration of the object and purpose of Article 3 and of the SPS Agreement as a whole reinforces our belief that compliance with Article 5.1 was intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection. ... The ultimate goal of the harmonization of SPS measures is to prevent the

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66 Charnovitz, see note 56, 423 et seq.
67 EC-Hormones case, see note 8, para. 175.
68 Scientific justification is broader than risk assessment.
69 EC-Hormones case, see note 8, paras 172 et seq.
70 EC-Hormones case, see note 8, para. 177.
use of such measures for arbitrary or unjustifiable discrimination between Members or as a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are both ‘necessary to protect’ human life or health and ‘based on scientific principles’, and without requiring them to change their appropriate level of protection.”

At this point, we can see the contradiction between the two findings of the Appellate Body in the same case. On the one hand, it established that article 3.3 reflects the precautionary principle, but on the other hand, it emphasised that the application of the precautionary principle is subject to the “scientific justification” which, as it holds, is not different from the “process of risk assessment.” Thus, from its view, in elevating the level of SPS protection, Member States are called upon to rely on the relevant provisions of risk assessment in order to justify the higher level of SPS protection. In this regard, article 3.3 does not configure with the precautionary principle, as long as the provisions concerning risk assessment, per se, do not accommodate the precautionary principle, as will be discussed below.

4. Outside the Scope of Article 5.7, Paragraph 6 of the Preamble and Article 3.3

a. Possibility to Apply the Precautionary Principle in the Context of Arts 5.1 and 5.2

Even though the Appellate Body, in the EC-Hormones case, has already addressed that arts 5.1 and 5.2 do not accommodate the application of the precautionary principle, there have been consistent efforts, by academics, to make the precautionary principle applicable in the context of these articles. This thesis does not consider the notion merely academically, but rather logically thoughtful and complementary. In considering the coverage of the precautionary principle in the context of both articles, the provisions and their jurisprudence will be analysed and some proposals will also be made.

Article 5.1 requires Member States to ensure that their SPS measures are based on a risk assessment. In complying with article 5.1 Member States are required to examine risk factors as listed in article 5.2: “avai-
able 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.” However the Appellate Body, in the EC-Hormones case, affirmed that the list of risk factors in article 5.2 is not intended to be a closed list and has made a statement significant for a possible gateway to the precautionary principle which reads:

“It is essential to bear in mind that 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 effects on human health in the real world where people live and work and die.”

According to this interpretation, risk assessment, as required by arts 5.1 and 5.2, has been clearly in reliance with something outside the scope of pure science. The phrase “risk in human societies” indicates that “societal factors” could be included as well in the context of article 5.2. In the light of this interpretation, the precautionary principle accordingly finds its role within the context of risk assessment under the open list of article 5.2. However, consideration of societal risks within the context of article 5.2 is not unconditional, since the Appellate Body, in the Australia-Salmon case, has demarcated the role of societal factors, which reads: “the risk evaluated in a risk assessment must be an ascertainable risk; theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed.”

At this point, “risk in human societies”, as a part of risk assessment, must be an “ascertainable risk”. Risk in human societies, as merely a “theoretical uncertainty”, is not included in the context of arts 5.1 and 5.2.

“Ascertainable risk”, the second element, was not explicitly explained by the Appellate Body in the EC-Hormones case. The phrase “ascertainable risk” was used by the Appellate Body, in substitution of the phrase “scientifically identified risk” used by the Panel in the same

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72 The Appellate Body, in the EC-Hormones case, preferred the word ascertainable risk instead of “identifiable risk”, as used by the Panel; EC-Hormones case, see note 8, para. 186.

73 Appellate Body Report, Australia-Salmon case, Doc. WT/DS18/AB/R, para. 125, EC-Hormones case, see note 8, para. 186.
case. In seeking for its characterisation, the excerpt of the relevant text is to be considered as follows:

“It is not clear in what sense the Panel uses the term ‘scientifically identified risk’. The Panel also frequently uses the term ‘identifiable risk’, and does not define this term either. The Panel might arguably have used the terms ‘scientifically identified risk’ and ‘identifiable risk’ simply to refer to an ascertainable risk: if a risk is not ascertainable, how does a Member ever know or demonstrate that it exists? ...

In another part of its Reports, however, the Panel appeared to be using the term “scientifically identified risk” to prescribe implicitly that a certain magnitude or threshold level of risk be demonstrated in a risk assessment if an SPS measure based thereon is to be regarded as consistent with article 5.1. To the extent that the Panel purported to require a risk assessment to establish a minimum magnitude of risk, we must note that imposition of such a quantitative requirement finds no basis in the SPS Agreement. A Panel is authorized only to determine whether a given SPS measure is “based on” a risk assessment.

If the finding of the Panel in this case had been adopted by the Appellate Body, science would have played a highly intense role and no room would have been left for assessment of “risk in human societies”, subsequently making the WTO a “purely scientific organisation”? In making alignment with other previous findings, the Appellate Body has neutralised the element of risk assessment, by substituting the phrase “scientifically identified risk” with the phrase “ascertainable risk” and disregarded the qualitative requirement, magnitude or threshold, as proposed by the Panel. This could make Member States feel more comfortable, in the sense that they are entitled to make decisions on the basis of “risk in human societies”, taking into account “societal risk factors.” Therefore, when Member States would like to impose precautionary measures in the context of arts 5.1 and 5.2, they have to rely on this approach as well.

At this point, it is conclusive that the jurisprudence allows the precautionary principle to be applied as long as a relevant unlisted risk fac-

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74 According to the American Heritage English Dictionary (electronic source), “ascertain” means: (i) to discover with certainty, as through examination or experimentation; (ii) (Archaic) to make certain, definite, and precise.

75 Walker, see note 29, 252.
tor has been embraced into article 5.2 with regard to the fulfilment of two requirements, as mentioned, ascertainability and exclusion of theoretical uncertainty.

However, this approach does not leave room for argumentation of the EC to prevail. As the EC argued in the *Hormones* case, that the precautionary principle overrides arts 5.1 and 5.2 and thus precaution could be taken as the result of the risk assessment, *per se*. This thesis considers that this argument, even though it finds some logical basis, is not practical as an argument, since it is easy to be attacked and significantly offends WTO jurisprudence.

Instead of stating that the precautionary principle overrides arts 5.1 and 5.2, the argument may have been that the precautionary principle overlaps with such provisions and is applicable in conjunction with article 5.1 because a relevant unlisted risk factor definitely provides a gateway to its application. The ruling of the Appellate Body does not imply inapplicability of precautionary measures in risk assessment un-

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76 Moreover the fulfilment of these two requirements is the gateway to the application of the precautionary principle in article 3.3, as the author of this thesis has analysed in the previous part.

77 In this regard, it is worth remembering a well-known statement of Socrates which is relevant to this discussion: “so when I went away, I thought to myself, ‘I am wiser than this man: neither of us knows anything that is really worth knowing, but he thinks that he has knowledge when he has not, while I, having no knowledge, do not think that I have. I seem, at any rate, to be a little wiser than he is on this point: I do not think that I know what I do not know.’” Plato Euthyphro, *Apology*, Crito 26 (F.J. Church trans., 2nd edition 1956) cited in: Walker, see note 29, 267. This statement reflects the reality of scientific knowledge which cannot perfectly provide absolute certainty. In response to this problem, Walker has suggested that scientists should have a role in making a decision on the issue. He says: “Science policies should be formally adopted and risk assessment scientists should be required to disclose and explain inherent scientific uncertainties. In this way, those who make decisions based on a particular risk assessment will understand the limits of the underlying scientific knowledge. Absent such disclosure and explanation, decision-makers will not be able to distinguish guesswork from well-supported findings”, ibid.

78 It was foreseeable that adjudicatory organs of the WTO did not agree on the argument of the EC, given that WTO jurisprudence significantly gives importance to its institutional framework. The written texts of its covered agreements normally prevail over an unwritten notion, such as the precautionary principle.
der article 5.1, but only rejects the argument of the EC that significantly
promoted the role of precaution over article 5.1.

b. Possibility to Apply the Precautionary Principle as an Unwritten Norm

As proposed by academics in numerous publications that the precau-
tionary principle is also a part of the risk assessment and thus Member
States may take precaution as result of a risk assessment, taking into ac-
count that the precautionary principle overrides arts 5.1 and 5.2, as also
invoked by the EC, this thesis does not oppose to this notion but will
support that the concept of precaution should also be developed out-
side the framework of the SPS Agreement. As experienced in many
cases, when the precautionary principle or precautionary approach is
applied in the context of the WTO, it is unable to exercise its role natu-
really, but rather subjugates itself to the overarching rules of the SPS re-
gime,79 which always prioritises the object and purpose of trade.

States obtain their jurisdiction within their own territory to impose
SPS precautionary measures in order to protect human, animal and
plant’s life and health. The precautionary principle, when considered
outside the SPS context, also plays its role independently in the area of
international environmental law. The principle deserves to be highly re-
garded when its configuration in environmental law is overlapping with
that of international health law, resulting in the configuration of the
precautionary principle aimed at international (human) health protec-
tion, which is quite new, but indispensable. Biological development is
always unforeseeable. Keeping with the mode of the SPS Agreement
would not be able to deal with potential hazards resulting from such
development.80

The precautionary principle may find some difficulties in being con-
sidered as customary international law as the principle seems to con-

79 EC-Hormones case, see note 8; Australia-Salmon case, see note 73.
80 Concerning this point, Walker has made a statement: “On the one hand,
Members obtain jurisdiction to introduce and maintain measures to protect
health and life within their territories; on the other hand, they may do so
only if such measures are not inconsistent with the provisions of the SPS
Agreement, and in particular, are not arbitrarily or unjustifiably discrimi-
natory and do not constitute disguised restrictions on international trade”,
Walker, see note 29, 253.
front persistent objection from at least the United States, Canada and especially developing countries, the economies of which significantly depend on agricultural products. Another choice left to us, as mentioned in Part I., is that the principle could be applied as a general principle of law recognised by developed countries. The precautionary principle in international (human) health protection deserves to be regarded as a general principle of law to prevent a legal vacuum or non-liquet within the field. This thesis finds that we are approaching non-liquet in this field, as a consequence of the subjugation process, by the trade regime, which has promoted the role of science and does not leave room for appropriate formulation of the principle. Even though the precautionary principle, according to the Appellate Body, subsists in some provisions, it has already been eviscerated by their own texts.

The principle, therefore, should also be developed outside the SPS regime of the WTO, but in circumstances where the subject matter is overlapping with trade context, Member States shall ensure that the measures neither result from arbitrary or unjustifiable discrimination, nor are characterised as disguised restrictions to international trade. Strictly speaking, all requirements, as set forth in the SPS Agreement, are intended to prevent Member States from imposing arbitrarily or unjustifiably discriminatory measures and disguised restriction to international trade. If precautionary measures, when applied outside the scope of the SPS Agreement, are double checked as such, both regimes, trade and health protection, could reach consistency resulting there from.

III. Relation between the Precautionary Principle and Relevant Rules of International Law

It is important to note that when Member States apply the precautionary principle, they shall rely on other relevant rules of international law.

81 EC-Hormones case, see note 8, paras 43 and 60.
82 D. Prévost/ M. Matthee, “The SPS Agreement as a Bottleneck in Agricultural Trade between the European Union and Developing Countries: How to Solve the Conflict”, Legal Issues of Economic Integration 29 (2002), 43 et seq. (43-45); Perspectives of developing countries on the precautionary principle will be discussed in Part V.
83 This thesis also takes into consideration overlapping areas concerning the precautionary principle between the SPS Agreement and relevant international agreements, as mentioned in Part III.
On the one hand, rules of international law help to clarify the configuration of the precautionary principle in the context of the SPS Agreement so that the concept of precaution will no longer be abstract, but rather practical and tangible. On the other hand, rules of international law could prevent Member States from arbitrarily exercising their jurisdiction resulting in a disguised violation. A pure application of the precautionary principle is also dangerous, not less than potential hazards of biotechnological food, as the precautionary principle provides states with discretion and thus states can easily evade international obligations. Rules of international law therefore are important in this regard.

1. Rules of International Trade Protection

a. Principle of Good Faith

The Principle of Good Faith is, at least, a general principle of law as recognised by developed nations and has crystallised to be customary international law. The Vienna Convention reflects the role of the principle of good faith in arts 31(1) and 26. Article 31(1) requires that treaty interpretation shall be “interpreted in good faith”, whereas article 26 emphasises “the performance of obligation under a treaty, by Member States, in good faith.” Both provisions must be considered in the application of the precautionary principle in order to prevent Member States from avoiding compliance with obligations by arbitrarily relying on the precautionary principle. The principle of good faith therefore not only regulates Member States to interpret relevant provisions, but also requires them to perform their obligations in good faith.

The role of the principle, therefore, is not independent, but rather attached to other obligations of Member States. Concerning this point, the ICJ has addressed that the principle is applied to regulate an existing substantive obligation at hand, as affirmed in the following text:

“The principle of good faith is one of the basic principles governing the creation and performance of legal obligations, ... it is not in itself a source of obligation where none would otherwise exist ... Good faith does not exist as an abstract notion that could be determined

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without looking at the same time at the substantive obligation to which it refers. 85

Not only the ICJ, but also the Appellate Body has recognised the application of the good faith principle in its jurisprudence. The principle of good faith, in its view, is considered as “an organic and pervasive general principle ... that underlines all treaties.” 86 It is employed in conjunction with the application of the WTO Agreements, including the SPS Agreement. This principle shall also be regarded when relevant provisions of the precautionary principle are applied. In this regard, Member States are accordingly required to apply SPS precautionary measures in good faith, although good faith is not written down in the Agreement.

In the SPS Agreement, it is also necessary to analyse article 2.3, as the provision partially reflects the principle of good faith. It provides a general obligation that SPS measures shall not arbitrarily or unjustifiably discriminate between Member States and shall not be applied in a manner which would constitute a disguised restriction on international trade. Definitely Member States, when applying precautionary measures, have to perform the obligation under this article. But this article, alone, could not provide a sufficient mechanism which enhances Member States to comply with their obligations. The article could not be a substitute for the principle of good faith and thus Member States shall eventually comply with the principle of good faith as well.

b. Transparency Requirement

The Transparency requirement is considered as an essential mechanism to enhance “fair trade”. Lack of transparency could unavoidably result in trade barriers. 87 The SPS Agreement embraces this recognition in article 7 and Annex B which set forth obligations for Member States to fulfil the notion of transparency. For example, Member States are required to publish their SPS measures for a reasonable period before the measures enter into force in order that producers in exporting countries adapt their products and methods of production to the requirements of

87 M. Böckenförde, “Article 7 and Annex B SPS”, in: Wolfrum, see note 7, 478 et seq.
the importing country. In case that SPS measures are different from international standards, guidelines or recommendations, Member States are required to allow a reasonable time for other members to make written comments, discuss these comments upon request, and take the comments and the results of the discussion into account.88

However, article 7 and Annex B reflect the international character of the notion of transparency, whereas domestic participation is also needed to render appropriate SPS measures.89 Domestic stakeholders are directly affected by the imported products so that they, also, should have a role in making decisions. Participation of domestic stakeholders could be observed in two referenda made in Austria in 199790 and in Switzerland in 1998,91 in both of which the majority of the voters voted against importation of genetically modified organisms into their territories. It is necessary that “domestic participation” is a part of the SPS Agreement, even in the case of domestic issues, that Member States could manage within their own territories, because domestic stakeholders are a group of people who are directly affected by importation of such products.92

This thesis considers that the “result of domestic participation should entail effect at international level and thus could render precautionary measures legitimate.” Practically speaking, if the importation of a kind product provokes great public concern in a country, it makes no sense to continue introducing such product into the country. This regard should be recognised in the name of domestic transparency, which grants participatory role upon domestic stakeholders.93 However, we may be confronted with difficulties to introduce this concept into the SPS Agreement, since SPS measures are required to be based on risk assessment. This thesis suggests that we should step back to view article

90 Available at <http://www.netlink.de/zeitung/970414a.htm>.
91 Available at <http://www.gmo-free-europe.org/de/node/126>.
92 The notion of domestic participation, as proposed, will be elaborated when discussing the principle of self-determination.
93 The notion responds to the principle of self-determination as will be discussed later in this part.
5.2 and include public concern as one factor in the open list of the article.

At this point, Bohannes suggested that the transparency mechanism should also embrace a participatory role of “non-domestic economic actors” apart from Member States which have obtained their role pursuant to the relevant provisions. He explains that “the rationale is to counterbalance with any bias of the scientific findings or of the opinions of the domestic stakeholders”.94 This thesis supports this suggestion, taking into account that, in adopting precautionary measures, Member States should gather relevant information and comments as much as possible in order to make precautionary measures an objective which could favour stakeholders in the context of international trade and international health protection.

c. Necessity Test

When SPS measures are applied, a necessity test is normally required, otherwise relevant SPS measures are not legitimate under the SPS Agreement. The application of the precautionary principle is not exempted from this requirement. Even though provisions which accommodate the application of the precautionary principle do not explicitly link to the requirement of the necessity test, Member States are obliged to perform a necessity test as well. Such performance of the obligation could ensure that the application of the precautionary principle is objective in the sense that the precautionary principle is not invoked to abusively generate disguised restriction in international trade. In analysing the necessity test in the scope of the SPS precautionary principle, arts 5.6 and 2.2 will be observed as follows.

According to article 5.6, Member States are obliged to reduce negative effects to international trade. SPS measures, or precautionary measures in this regard, shall “not be more trade-restrictive than required to achieve” a Member’s appropriate level of SPS protection. It should be noted that article 5.6 requires necessity tests in a manner different from Article XX (b) of GATT 1994, which sets forth a “least trade restrictive requirement,”95 that makes necessity tests more stringent.

94 Bohannes, see note 5, 368.

95 Thailand-Cigarettes case, BISD 37S/200, para. 74.; Stoll/Strack, see note 7, 108 et seq. In this regard, Desmedt has remarked: “WTO Agreements and corresponding case law are indeed sprinkled with substantive rules and concepts that are close to a full-fledged proportionality principle known in
In the *Australia-Salmon* case, the Appellate Body has illustrated the proper configuration of the necessity test under article 5.6, in a negative proof as an SPS measure is more trade restrictive than necessary if there is another SPS measure that (1) is reasonably available, taking into account technical and economic feasibility; (2) achieves the member’s appropriate level of sanitary or phytosanitary protection; and (3) is significantly less restrictive to trade than the SPS measures contested. These three elements of this negative test are cumulative so that, if one of these elements is not fulfilled, the SPS measure is consistent with article 5.6.97

Moreover, a relationship between the arts 5.6 and 2.2 should be made, as both articles appear to similarly require a necessity test. In the *Japan-Varietals* case, the Panel clarified that article 2.2 does not swallow article 5.6 at all, even though article 2.2 also requires a necessity test. The Panel remarked that article 5.6 further requires a necessity test, even after an SPS measure is already consistent with article 2.2, as it stated that: “findings under Article 5.6 would stand even if the measures in dispute were not in violation of Article 2.2.” This clarification of the Panel not only shows that a necessity test under article 5.6 is performed when article 2.2 is applied, but also that the necessity test shall be regarded when a precautionary measure is applied under article 5.7.98

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96 For example, an absolute ban on genetically modified products is considered more trade restrictive than necessary, since there are other available means.

97 Stoll/Strack, see note 46, 456 et seq.

98 Knowingly article 5.7 is the exception of article 2.2.
2. Countervailing Rules against International Trade Protection

a. Principle of Self-Determination of Peoples in Economic Context

As mentioned in the second part, application of precautionary measures also deals with public values, but results from a decision of the incumbent authority of the Member State. The authority of the Member State, in performing its role, has to enhance domestic values of its society, which is a difficult task, since such determination of public values in conjunction with an assessment of societal risk factors may not be internationally recognised and thus would be a subject of dispute before WTO adjudicatory organs. Is it possible that public values prevail on the international platform?

This thesis proposes to employ the principle of self-determination to promote recognition of public values on international platforms. Self-determination has been recognised not only as customary international law,\(^9\) but also as *ius cogens*\(^10\) which prevails here over rules of international trade protection. Here, it is named “Principle of Self-Determination in Economic Context”.\(^11\) The principle of self-determination is often applied in cases of genetically modified organisms. As aforementioned, referenda in Austria and Switzerland are not only examples of domestic participation, but also of exercising self-determination. Once public values have been expressed via referendum or other substantive means, the action shall result in preponderance of public values over international trade law and thus be internationally recognised in pursuance with the principle of self-determination.

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\(^9\) The principle has been recognised in legal instruments, i.e., the UN Charter, the 1966 International Covenant on Civil and Political Rights, the Universal Declaration of Human Rights, the Declaration on the Granting of Independence to Colonial Countries and Peoples (A/RES/1514 (XV) of 14 December 1960), and the Friendly Relations Declaration (A/RES/2625 (XXV) of 24 October 1970), which have precipitated the formation of the first element, state practice. *Opinio iuris*, the mental element, was also affirmed in judicial decisions, i.e., the Namibia case, the Western Sahara case, the East Timor case, etc.


\(^11\) Brownlie, see note 16, 582 et seq.
However, expression of public values should be relevant to the determination of measures for health protection, since public values are not always absolute, that is, people in a single society may think differently. If the result of a referendum is quite definite, for example 80-90 per cent of voters vote against genetically modified organisms, this should entail a total ban of those products. If the result of the referendum is not so clear cut, a total ban is not reasonable and could be deemed illegitimate under the relevant provisions of the SPS Agreement.

b. Rules Established by the World Health Organisation

The World Health Organisation (WHO) has objectives to promote and protect health internationally. Since its foundation in 1946, the WHO has significantly contributed to global health protection, as evidenced in its numerous active works in formats of regulations, recommendations, resolutions, etc. However, protection of international health is not an isolated field, but correlates with others; the WHO has acknowledged this trait. The WTO collaborates with other relevant institutions, for instance, ILO, UNESCO, FAO, etc., in search of achieving common goals. Although international health protection, by nature, has a close relationship with international trade, the collaboration with the WTO is surprisingly not as explicit as with other institutions.

Despite the lack of explicit collaboration between the two regimes, relevant provisions of International Health Regulations (IHR) give insights about several subjects in which consistency between both regimes can be found. It appears that, even though the WHO enjoys a primary competence to elaborate rules and standards on human health, “its regulations were surprisingly made subordinate to relevant provisions of international trade.” In this context, arts 43 and 57 of the

102 D. Fidler, International Law and Public Health, 2000, 87 et seq.
104 Available at <http://www.who.int/crs/ihr/en>.
105 Von Tigerstrom, see note 103, 55 et seq. These include, for example, the WTO agreements on air and marine pollution, nuclear safety conventions, human rights agreements and the law on diplomatic relations.
IHR have echoed some significant notions of the precautionary principle, which are quite similar to the concept set forth in the SPS Agreement, for instance, the role of science and the necessity test. Therefore conflict between the WHO and IHR concerning the SPS precautionary principle does indeed look weak.

Article 43.1 of the IHR sets forth a necessity test, which resembles article 5.6 of the SPS Agreement, by requiring that additional measures106 “shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.” Thus, when a precautionary measure is inconsistent with article 5.6 of the SPS Agreement, it appears to be inconsistent also with article 43.1 of the IHR. Even though, configuration of the necessity test under article 43.1 of the IHR has not been identified, it is expected not to be different from that of article 5.6 of the SPS Agreement, since the former is designed107 and called upon to be compatible with the latter, in accordance with article 57.1 which reads:

“States Parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible. The provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements.”

It is important to note that the word “should” is used in the first sentence, calling upon compatible interpretation between the IHR and relevant agreements applicable to analogous subjects. But, in the second sentence, the word “shall” is used instead to require that rights and obligations of States Parties not be affected by the IHR provisions. What can we deduce from this article?

Since there are two sentences in the provision which are separable, this thesis suggests to firstly read both sentences separately, but, in the end, link them together. The first sentence contains a recommendatory condition. The word “should” indicates that States Parties are merely encouraged to interpret relevant agreements to be compatible with the IHR. On the other hand, it could be interpreted as the possibility that states could adopt incompatible views with regard to two or three agreements, under consideration, as long as the incompatibility does not result in significant alteration of the rights and obligations of the

106 Member States are obliged to implement health measures as required by the IHR. Nevertheless, they are also entitled to apply additional health measures in accordance with article 43.

107 Von Tigerstrom, see note 103, 55 et seq.
concerning States Parties. Even though the compatibility between the IHR and other international agreements is something expected, the WHO shall have an appropriate standing to elaborate its own regime, when necessary, regardless of emerging conflicts with other conventions. For the WHO, health protection is characterised as a prudent framework, as Gostin has remarked:

“Certainly, international commerce is a social good, and overreaction without scientific evidence can cause economic harm by diminishing trade, travel, and tourism. However, the international community cannot have it both ways – unimpeded travel and trade, with full public health protection ... The WHO’s mission should unequivocally be expressed as global health protection and promotion... That is the vision of the WHO Constitution. Neither the preamble nor Article 21 mention commerce protection, let alone minimization of barriers to commercial intercourse.”

This thesis considers that this opinion could serve as a counterbalance to the pretension that the IHR is subordinated to other relevant agreements. Article 1 of the WHO Constitution sets forth the WHO’s objective as “the attainment by all peoples of the highest possible level of health.” The WHO, therefore, shall perform its actions to achieve and make possible this objective. Compatibility with other relevant agreements could be enhanced as long as such compatibility does not pertinently deprive the WHO from its objective. This notion is quite helpful in analysing IHR relevant provisions concerning the precautionary principle, namely arts 43.1(a) and 43.1(b) of the IHR, which go with arts 3.3 and 5.7 of the SPS Agreement respectively.

The SPS precautionary principle, as asserted by the Appellate Body, is reflected in article 3.3 of the SPS Agreement, but its scope is restricted by the phrasing of the provision and the related footnote, as mentioned in the previous Part. Article 43.1(a) of the IHR also recognises application of the precautionary principle in similar circumstances by allowing States Parties to adopt “the greater level of health protection than WHO recommendations ... in response to specific public health risks or health emergencies of international concern”, without putting onerous

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109 Ibid.

110 Ibid.
requirements like article 3.3 of the SPS Agreement. An SPS precautionary measure of higher level of health protection which is legitimate under article 43.1(a) of the IHR could be held to contradict article 3.3 of the SPS Agreement, as a result of its inconsistency with the additional text and the footnote.

Article 3.3 of the SPS Agreement is deemed to contain a definition of the precautionary principle, as asserted by the Appellate Body in the EC-Hormones case, but the preoccupation that it might lead to an abusive application results in the insertion of the additional text, which renders article 3.3 confusing, as mentioned in Part II., and leaves little room for application of the precautionary principle. Article 43.1(a) of the IHR seems to accommodate the applicability of the SPS precautionary principle more than article 3.3 of the SPS Agreement as it does not add other requirements in its text. At this point, we acknowledge a degree of conflict between the two configurations of the precautionary principle. Is the concept of the precautionary principle under article 43.1(a) of the IHR to be interpreted or applied in a subordinated position in relation to the SPS Agreement?

As mentioned earlier, in accordance with article 57.1, WHO States Parties are allowed to interpret article 43.1(a) of the IHR in a different way as compared to article 3.3 of the SPS Agreement, as long as the rights and obligations of the concerned states are not affected. The configuration of article 43.1(a) of the IHR is therefore legitimate in the context of the IHR and the WHO Constitution. Nevertheless, with regard to the WTO jurisprudence, this configuration is hardly to be introduced when it is exposed to the WTO legal system, given that the law which is applicable under it is rather limited and that article 3.3 seems restrictive, as the footnote seems to clarify. Unfortunately, the WTO legal system does not leave room for reconciling article 3.3 of the SPS Agreement with article 43.1(1) of the IHR.

Article 43.2(b) of the IHR is a provision which also reflects the precautionary principle by reiterating some elements of article 5.7 of the SPS Agreement. However, it does not set forth more stringent requirements than the latter. According to the provision of article 43.2(b) of the IHR, where scientific evidence is insufficient,111 “States Parties shall base their determinations upon ... ... the available information.” Like-

111 “Sufficiency of scientific evidence”, the requirement under article 43.1 (a), is the same element for application of the precautionary principle as article 5.7 of the SPS Agreement. The drafters of the IHR rejected to use the word “scientific uncertainty”.
wise, if the precautionary principle is invoked before the WTO, the configuration of provisions of less stringent character under article 43.2(b) will not affect the SPS regime of the WTO.

In the elaboration of this thesis, the author has reached the conclusion that the SPS Agreement provides elements which are possibly connected to the WHO regime, as can be seen in article 3.2 and Annex A.3(d). According to article 3.2, precautionary measures that conform to international standards, guidelines or recommendations are presumed to be consistent with the Agreement. This presumption only applies to “relevant international organisations as identified by the SPS Committee” as Annex A.3(d) points out.

Until now, the WHO has not been included in the list of such relevant international organisations of the SPS Committee. In the future, if it is included in the list, the channel will be open to its recommendations and guidelines concerning the SPS precautionary principle, in the sense they have been exposed, amongst others, by arts 43.1(a) and 43.2(b).

c. Biosafety Protocol

The relationship between the SPS Agreement and the Biosafety Protocol is a controversial topic in the SPS context. Relevant provisions of both instruments are indicative of the existence of overlapping areas regarding the applicability of the SPS precautionary principle. The Biosafety Protocol was designed to cope with problems of possible hazards resulting from cross-border transfer of the so-called Living Modified Organisms (LMOs), by establishing rights and obligations upon States Parties, with the aim of reducing possible hazards. This concern is considered important in the SPS Agreement which allows Member States to introduce and maintain SPS measures, as long as the measures do not imply trade restrictions inconsistent with the relevant provisions of the Agreement.

After the conclusion of the Protocol, rights and obligations of the WTO Member States need to be clarified, since a considerable number of the WTO Member States are also States Parties to the Biosafety Protocol. Whether or not their rights and obligations under both in-

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112 Scott, see note 3, 53 et seq.
Instruments are complementary to each other is being debated. Some scholars consider that the Protocol was intended to be complementary to the SPS Agreement. A number of scholars argue that both accords are rather contradictory. This thesis will not analyse the Protocol as a whole, but will select relevant provisions concerning the precautionary principle separately, as we find that some provisions are actually complementary to the SPS Agreement, but not all of them.

The Biosafety Protocol sets forth different mechanisms, establishing rights and obligations upon Member States. Requirements under the Protocol do not always imply a rejection of the SPS Agreement. Whether or not this reaction takes place depends on relevant provisions of the Biosafety Protocol. For example, requirements of notification according to article 8 of the Protocol do not challenge the SPS Agreement, as it is the consequence of a duty imposed on importing countries to acknowledge the transfer of LMOs. But when a decision under article 10 of the Protocol has been taken, a challenge to the SPS Agreement may arise, especially concerning the level of protection of human health. There is also the question of risk assessment pursuant to article 15, which is less stringent than in the relevant provisions of the SPS Agreement.

Many examples may be exposed to demonstrate contradictions between both treaties although this thesis will not analyse all of them. It prefers to focus on general resolutions to overcome contradictions between both instruments.

The first possibility, proposed by this thesis, to resolve the conflict between both instruments, is the principle of effective treaty interpretation (ut res magis valeat quam pereat) which is also recognised in WTO jurisprudence, as evidenced by the US-Gasoline case. This principle

115 Stewart/ Johanson, see note 113, 21 et seq.
116 It is possible that some provisions are not complementary to the SPS Agreement because the Biosafety Protocol prioritises protection of public (human) health, rather than protection of international trade.
provides that a treaty shall be interpreted in the light of applicability and enforceability of rights and obligations of States Parties. Concerning provisions on risk assessment, it is clear that requirements applicable to it under the SPS Agreement are more stringent by nature. Consistency between both systems could be attained if States Parties, when performing risk assessment under article 15 of the Protocol, also perform their obligations under relevant provisions of the SPS Agreement.

By doing so, the purpose of the Protocol is still maintained. That means obligations of States Parties, including the duty to notify, reception of notification and the decision making procedure, etc., are still required under relevant provisions. But enforcement of these requirements is a difficult issue in the light of WTO mechanism, since these rules are not considered as applicable law according to the DSU and its jurisprudence. They could be just “interpretative supplements” employed by adjudicatory organs to interpret particular WTO provisions under consideration. Actually this is clearly reflected in article 3.2 which provides that applicable law of the WTO is composed of “covered agreements” and “customary rules of interpretation of public international law.”

Notwithstanding article 3.2 of the DSU, Customary International Law (CIL) and General Principles of Law (GPL) are recognised as applicable law within the context of the WTO as well. Some provisions under the Protocol could be invoked as applicable law before Panels or the Appellate Body, if such provisions are considered as CIL or GPL.

Potential conflicts between the Protocol and the SPS Agreement could be solved by recourse to some other rules of treaty interpretation, especially arts 30 and 31 of the Vienna Convention on the Law of Treaties. Article 30 is related to the application of successive treaties relating to the same subject matter, that is, the Biosafety Protocol is considered as a successive treaty to the SPS precautionary principle of the same subject matter. But, in similar circumstances as the Biotech case, the Panel did not apply article 30, but instead article 31, which establishes general rules of treaty interpretation. It should be noted that article 30 of the Vienna Convention deals with application of successive treaties, while article 31 thereof merely refers to the general rule of interpretation. Both situations are significantly different.

118 US-Gasoline case, see note 6, para. 16.
119 Stewart et al., see note 113, 35.
The application of article 30 of the Vienna Convention, by the Panel, in the Biotech case, demonstrates that applicable law in the WTO context is restricted in the light of article 3.2 of the DSU. The application of article 30 of the Vienna Convention could entail importation of rules outside the WTO, resulting in the modification of its institutional legal framework, whereas article 31 is applicable, since it does not imply modification as such, but rather suggests that certain provisions of the Protocol, as in this case, be employed as supplementary interpretive tools. For this thesis, article 31 (3)(c) is to be taken into account, as it employs “any relevant rules of international law applicable in the relations between the parties.” Thus, when provisions of the SPS Agreement are applied, relevant rules of the precautionary principle under the Biosafety Protocol shall be employed as just “supplementary interpretative tools”, even though both parties ratified the Protocol.

However, as mentioned above, article 3.2 of the DSU does not make the WTO deny the concept of public international law, as CIL and GPL are also applicable law that adjudicatory organs could apply in cases as well. The rules in the successive treaty could thus be applied if they are CIL or GPL.120

IV. Dispute Settlement Concerning the Precautionary Principle

Dispute settlement concerning the application of the precautionary principle is a significant topic, apart from the substantive issues. As mentioned in previous Parts, substantive issues are quite complicated and have not yet been sufficiently addressed. We could say, in other words, that the precautionary principle, at this moment, is in a legal vacuum. Substantive issues are problematic as such, so the dispute settlement dimension is not less problematic. Procedural issues or dispute settlement concerning the precautionary principle should therefore be approached in this thesis.

1. Choice of Forum

Application of the precautionary principle is not only available in the SPS Agreement, but also in other international instruments, namely the

120 US-Gasoline case, see note 6, para. 16.
Free Trade Agreements (FTA), the IHR of the WHO, and the Biosafety Protocol. These instruments also provide mechanisms for dispute settlement. Member States of the SPS Agreement, which are also parties to these instruments, can select one of them for dispute settlement. Applicable provisions regarding the precautionary principle, as mentioned in previous Parts, may differ from those embodied in the SPS Agreement, and that could lead to inconsistencies of the findings of adjudicatory organs according to each institution. The precautionary principle may be subject to variations according to the forum activated in a specific case.

It should be noted that conflicts of procedural dimension are rarely found between mechanisms of WTO and FTA. Most of the FTA are influenced by the SPS Agreement of the WTO, as the entirety of the SPS Agreement is directly referred to in those FTA. In the view of the FTA drafters, rules on SPS matters, as established in the SPS Agreement, are considered perfect, as well, for bilateral relations. Such reference-making could be found in, article 6.1 of the Chile-United States free trade agreement, article 6.3 of the one between Chile-Japan, article 7.3 of the Australia-United States free trade agreement, article 6.1 of the Bahrain-United States and article 4 of the Peru-Thailand free trade agreement. Differences to the text of the SPS Agreement also exist, but only in a few cases, such as the Association Treaty between Chile and the EC which establishes certain special rules for the SPS Agreement. Since conflicts between a FTA and the SPS Agreement are quite rare as such, due to the same substantive legal basis, conflicts between both systems will rarely happen.

If a dispute arises in relation to the application of the precautionary principle, the claimant may decide to submit the claim to one of the two systems, as the same law (SPS Agreement in most cases) is applicable in both mechanisms. However, the submission of a claim to an adjudicatory function of the FTA may be beneficial for both, in the sense that the procedure could be faster compared with the WTO’s adjudicatory mechanism. But a disadvantage of the FTA is that other states cannot participate in the proceedings. Application of the precautionary principle normally does not affect the interest of only one state, but often of Member States as a whole. In this regard, dispute settlement before FTA mechanisms is not very practical.

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121 A. Frohmann, Lecture on the Chile-United States Free Trade Agreement (Dumping and Safeguards), Heidelberg Centre for Latin America, 20 August 2008.
Conflicts of dispute settlement mechanisms between the WTO and the Biosafety Protocol, could be found more easily than the previous examples. The WTO mechanism seems to obtain more advantages than those of the Biosafety Protocol. Panels and the Appellate Body of the WTO work with an adjudicatory function. In the Biosafety Protocol, dispute settlement mechanisms work in the format of conferences in which States Parties discuss how to solve non-compliance, according to article 27 of the Protocol. The latter lacks institutional framework and thus faces great difficulties in respect of the enforcement, whereas the former contains significant mechanisms for enforcement, which makes it more advantageous. In this regard, states prefer to invoke and defend their rights concerning SPS measures before the WTO mechanism.

Comparing the dispute settlement mechanisms of WTO and WHO, both organisations have their own adjudicatory organs. Slightly similar to the WTO mechanism, WHO States Parties shall seek in the first instance to settle the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation in accordance with article 56.1 of the IHR. If the dispute could not be settled by any of such means, a State Party may declare in writing to the WHO Director General that it accepts arbitration in accordance with article 56.3 of the IHR. If both States Parties have agreed to accept arbitration, this will be the procedure to be followed.

At this point, we can see that the mechanism of the WHO is parallel to the mechanism of the WTO in the sense that both systems render judicial decisions binding and final. How can we deal with such overlapping jurisdiction? Actually with regard to this issue, the question was

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122 With regard to dispute settlement mechanisms, Stewart has made a remark as follows: "If two parties to the Protocol seek to resolve a dispute involving LMOs under the auspices of the Protocol, they could conceivably do so, but as a practical matter, the dispute settlement process of the Protocol remains undefined." Stewart et al., see note 113, 33.

123 The implementation process of the WTO is instructed by the principle of prompt compliance. The responding Party is required to implement the adopted report within a reasonable period of time. If the recommendations and rulings of the DSB are not implemented within a reasonable period of time, the complaining party may seek for “compensation or the suspension of concessions or other obligations” with regard to authorisation of the DSB; E. Kessie, The Course on Dispute Settlement in International Trade, Investment and Intellectual Property: World Trade Organisation, 3.4 Implementation and Enforcement, 2003, 3 et seq. and 25 et seq.
already answered in article 56.4 of the IHR and article 11.3 of the SPS Agreement.

Article 56.4 of the IHR sets forth that “nothing in these Regulations shall impair the rights of States Parties under any international agreement to which they may be parties to resort to the dispute settlement mechanisms of other intergovernmental organizations or established under any international agreement.” The phrase “nothing ... shall impair the rights” is significant in this context. Especially, if disputes concerning SPS precautionary principles have been brought before adjudicatory organs of the WTO. The DSU has eventually released a recommendation, with regard to article 56.4 of the IHR according to which States Parties cannot repeatedly bring the claim before the WHO mechanism.

If, vice versa, the States Parties decide to bring a dispute before the WHO arbitration and the arbitral award has already been given, can the losing party bring the claim again before the WTO? To answer this question this thesis suggests to apply article 11.3 of the SPS Agreement which reads: “Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.” Likewise article 56.4 of the IHR, article 11.3 of the SPS Agreement provide solutions for possibly overlapping jurisdiction, that is, adjudicatory organs of the WTO shall also recognise the final decision from the other system.124

2. Roles of the SPS Committee

The SPS Committee was established to serve as a regular forum for consultations and to be in charge of performing functions necessary to achieve the objectives of the SPS Agreement.125 The Committee does

124 Article 56.4 of the IHR and article 11.3 of the SPS Agreement reflect a general principle of procedural law, recognised in various domestic jurisdictions. The concept is that the moment a dispute has been settled by a competent judicial organ, the dispute concerning the same substantive issue cannot be repeatedly adjudicated. F. Schorkopf, “Article 11”, in: Wolfrum, see note 7, 523 et seq.
125 Scott, see note 3, 48 et seq.; V. Röben, “Article 12”, in: Wolfrum, see note 7, 526 et seq.
not only obtain a “role of administration”, but also a “role of norm elaboration”, as it is competent to address concerns relating to SPS issues, including application of precautionary measures. If SPS issues have been appropriately elaborated by the Committee, Member States will envisage such elaborated norms, which help to reduce a number of disputes brought before WTO adjudicatory organs. However, in order to cope with the SPS precautionary issues, the SPS Committee and states concerned need to do something more.

It appears that the Committee has to carry out plenty of work, but its own structure does not enable it to efficiently pursue its functions. The Committee is a big institution, which consists of representatives of all Member States. It makes decisions on the basis of consensus; that is, all members have to agree upon an issue raised before them. Regularly it organises meetings three times a year, where problematic SPS issues are addressed. Annex A.2.3 of the SPS Agreement helps to reduce the work of the Committee by referring to capacities of the three sister organisations, making international standards, recommendations and guidelines applicable in the context of the SPS Agreement. Member States therefore do not have to submit issues to the Committee, but directly refer to such instruments.

Even though these three similar organisations play a role in the assistance of the Committee, each year there remain pending issues to be addressed by the Committee. Such pending issues are abundant and deal with various topics concerning SPS matters. In responding to those issues Annex 2.3(d) provides that the Committee may invite other international organisations to participate in international standard setting. As yet, no international organisation participated in the process except the so-called three sister organisations. If functions of other relevant international organisations were embraced into the SPS context, SPS issues of international concern could also be addressed by such relevant organisations, leading to the reduction of SPS concerns brought before the Committee. Member States, therefore, do not need to present single issues to the Committee.

126 Concerning this point, Scott stated “... the committee not only elaborates norms for its own operation. It serves also to give shape and meaning to Members' obligations under the agreement. Formally, its powers are constituted in only the vaguest and weakest terms. In practice, it is hardly an exaggeration to conceive the committee as performing something approaching a legislative function”, Scott, see note 3, 49 et seq.

127 It can even make a proposal to amend the SPS Agreement; ibid., 48 et seq.
It should be noted that the Committee is sometimes reluctant to do so, since reference to international standards determined by certain specialised international organisations may lead to fragmentation\textsuperscript{128} of SPS regulations, since some international organisations are also responsible for the SPS area, but prioritise their objective differently to the WTO. The WHO, if determined as a specialised organisation under Annex A.3 (d), would be an example of an international organisation, which would be difficult to align with the spirit of the SPS Agreement, since it prioritises health protection rather than trade. Reliance on guidelines or recommendations, as established by the WHO, may constitute inconsistency with the SPS Agreement.\textsuperscript{129}

However, it is not only the SPS Committee that has the role to address SPS issues of international concerns, but also Member States should exercise their role, provided in the SPS Agreement, hand-in-hand seeking for common understanding with other Member States through a process of negotiation, consultation or any other peaceful means, instead of directly bringing cases before adjudicatory organs. Especially, with regard to the application of precautionary measures, affected Member States should actively respond to the problems.

3. Burden of Proof

The configurations of the precautionary principle, as mentioned in Part II., are reflected in three circumstances: (i) Member States perform risk assessment obligations under article 5.1 in reliance with unlisted risk factors under article 5.2, (ii) Member States introduce and maintain provisional measures under article 5.7 and (iii) Member States impose precautionary measures in conformity with international standards. In analysing rules for burden of proof of both configurations, we should take into account the statement of the Appellate Body, in the \textit{EC-Hormones} case, which reads:

“The initial burden of proof lies on the complaining party, which establishes a prima facie case of inconsistency with a particular provision of the SPS Agreement on the part of the defending party, or more precisely, of its SPS measure or measures complained about.


\textsuperscript{129} Scott, see note 3, 53 et seq.
When that prima facie case is made, the burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency. This seems straightforward enough and is in conformity with our ruling in United States-Shirts and Blouses, which the Panel invokes and which embodies a rule applicable in any adversarial proceedings. However, rules on the burden of proof are not fully restricted to this fundamental assertion. In some cases, it is impossible, for a complaining Party, to establish a prima facie case, while asserting inconsistency with relevant provisions. Proceedings concerning the application of the precautionary principle are one example. The responding Party regularly plays the role of the “affirmative defence” in the proceedings to assert that precautionary measures are justified under the SPS Agreement. In analysing this issue, this thesis will take into consideration elements of each configuration of the precautionary principle.

130 The Appellate Body has remarked “... it is a generally-accepted canon of evidence in civil law, common law and, in fact, most jurisdictions, that the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a particular claim or defence. If that party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption”, Appellate Body Report, US-Wool Shirts and Blouses case, Doc. WT/DS33/AB/R, para. 335.

131 At this point, it is worth a comparison with the burden of proof under the Biosafety Protocol, which sets different tasks on the Parties. Vallely stated: “The precautionary principle contained in Article 10 of the Protocol suggests a great amount of deference to the state imposing restrictions on trade in justifying the restriction. When combined with the detailed notification requirements imposed on exporters, the Protocol appears to impose a burden on the exporting country to demonstrate the safety of a given LMO export. The actual evidentiary burdens imposed on parties in a dispute under the Protocol are not yet known, as the Protocol defers agreement on specific procedural issues to a later date, but the text implied that the burden lies with the exporter. This directly conflicts with the assertion in Apples that the burden lies on the trade-restricting country to prove its side of the argument, further complicating reconciliation of the two treaties. Such an allocation of burdens, as a procedural matter, will significantly weaken the protections afforded to trade-restricting states under the Protocol”, P. Vallely/ J. Patrick, “Tension between the Cartagena Protocol”, Chi. J. Int’l L. 5 (2004), 369 et seq. (376).
a. Arts 5.1 and 5.2

As mentioned in Part II., the precautionary principle is reflected in risk assessments, taking into account “risk factors” under article 5.2, which must not constitute just a “theoretical uncertainty” but rather an “ascertainable risk”. (In the EC-Hormones case, the Appellate Body affirms that a “societal risk” is also recognised in the context of article 5.2)

At the beginning of the case, it may appear impossible for the complaining Party to demonstrate that there is no risk, as the burden of proof is characterised negative *per se*. With regard to this problem, the Appellate Body, in the Japan Varietals case has addressed this issue by considering the provision of article 5.8, according to which the complaining Party may have already requested an “explanation of reasons” for the precautionary measures, imposed by the responding Party. It is not required that the complaining Party proves a negative assertion, but merely raises a presumption on the basis of such explanation. The burden of proof, with regard to arts 5.1 and 5.2, still falls upon the responding Party as an affirmative defence.

b. Article 5.7

The burden of proof in case of invoking the precautionary principle under article 5.7 is also characterised as a form of affirmative defence, as the responding Party bears the burden to adduce evidence to demonstrate legitimacy of its provisional measures. However, the establishment of the *prima facie* case for article 5.7 is different to arts 5.1 and 5.2, as clarified by the Panel in the Japan - Measures Affecting the Importation of Apples case, which affirmed that the member imposing the provisional measure is to make a *prima facie* case. This finding was not reviewed by the Appellate Body.

This thesis considers that the findings of the Panel were not consistent with the WTO jurisprudence, as asserted by the Appellate Body in the Japan-Varietals case, that the complaining party has to rely on article 5.8 and thus to set off the *prima facie* case on the basis of the explanation it had already obtained from the responding Party. If the complaining Party is entitled to request for such an explanation of reasons for SPS measures, it could do so as well for explanations of applications of precautionary measures. However, whether the burden to establish

132 EC-Hormones case, see note 8, paras 181 et seq.
prima facie cases falls upon the complaining or the responding Party, the responding Party shall definitely obtain the burden to demonstrate legitimacy of its precautionary measures.

c. Paragraph 6 of the Preamble and Article 3.3

When the responding Party imposes its precautionary measures in conformity with international standards, recommendations or guidelines related to the precautionary principle, it is deemed that its measures have been in compliance with the SPS Agreement. This, however, does not exclude the responding Party from the burden of proof. The presumption of compliance just shifts the burden of proof on the complaining Party to adduce evidence to demonstrate that the measures at hand “are not in conformity with international standards” and then the responding Party has to rebut the argument of the complaining Party.

4. Review of Precautionary Measures

A function of Panels is to perform objective assessment of facts. Specifically, in proceedings concerning the application of precautionary measures, panels have to review precautionary measures, taking into account risk assessment and risk management, as, in the view of this author, the precautionary principle reflects both areas.

When precautionary measures are applied in the context of risk assessment, the Panel has to review the measures in regard to the elements justifying the precautionary measures, taking into account evidence adduced by both Parties, as mentioned in the previous Part. As mentioned in Part II., the precautionary principle is applied in the context of risk assessment when an unlisted risk factor fulfils the criteria: (i) ascertainability and (ii) exclusion of theoretical uncertainty. The Panel is fully entitled to re-examine whether such risk factor fulfils these criteria. In doing so, the Panel has to make an objective assessment of the facts concerned, as obtained by its capacity.

After reviewing the risk assessment of the responding Party, the Panel, then, has to review the risk management decisions of the responding Party. The keyword in this review is “evaluating measures selected by the responding Party.” The Panel has the capacity to examine

133 As mentioned in Part II., this thesis considers that precautionary measures could be instructed by international standards.
whether the precautionary measures, invoked by the responding Party are legitimate under the SPS Agreement. Basically, it has to check compliance of the measures with the relevant provisions that may be invoked by the responding Party, namely article 5.7 on provisional measures or article 3.2 for precautionary measures based on international standards.

After doing so, the Panel has to assess the legitimacy of the measures at hand, referring to other relevant provisions, for instance, article 5.6, for a necessity test, article 2.3, for evaluating whether the measures are characterised as disguised restrictions to international trade. Moreover, this thesis would like to make further remarks that the Panel shall take into account unwritten rules applicable to the case as those rules also intrude into the SPS precautionary matter. As mentioned in Part III., countervailing rules to international trade protection shall be regarded also in the WTO context. This idea was included in the WTO jurisprudence, as supported by the Appellate Body in the *US-Gasoline* case, which affirms that the WTO “... is not to be read in clinical isolation from public international law.”134

V. Precautionary Principle and Developing Countries

Application of the precautionary principle for developing countries,135 could be characterised as two sides of a coin. It could discourage as well as benefit developing countries. It depends which side of the coin we take into account. Firstly, this part will focus on developing countries when playing a role as exporting countries and secondly on developing countries when playing a role as importing countries.

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134 *US-Gasoline* case, see note 6, para. 16.
135 There is no definition of the term developing country in the SPS Agreement, nor has such a definition been adopted by the WTO members. Article XVIII:1 GATT 1994 which refers to developing countries as those economies which can only support low standards of living and are in the early stage of development can be used as guidance. In practice classification as a developing country is predominantly a matter of self-determination, Scott, see note 3, 505.
1. Developing Countries as Exporting Countries

Preoccupation of developing countries, as exporting countries, relating to the application of the precautionary principle is quite high, since, speaking in general, their economies rely on agricultural products, which are subject to the SPS Agreement. Applicability of the precautionary principle within the scope of the SPS Agreement is a significant cause for their anxiety since the principle provides that Member States are entitled to exercise a range of discretion to impose precautionary measures. On the one hand, such preoccupation has resulted from the nature of the precautionary principle, which entails “legitimate trade restriction”, and, on the other hand, from the potential that other states may “abusively apply the precautionary principle.”

a. Preoccupation on Configuration of the Precautionary Principle

Preoccupation on configuration of the precautionary principle has stemmed from the text of the relevant provisions in the SPS Agreement. In particular, article 5.7 was criticised by Prévost which reads:

“The allowance made in Article 5.7 for precautionary measures gives developing countries cause for concern. The terms used in Article 5.7 are rather vague and undefined. It is not clear what would constitute ‘pertinent information’ sufficient to justify a provisional measure, how long such a measure may be maintained while keeping its character as ‘provisional’ or what the obligation to ‘seek to obtain ... additional information’ entails. This creates the possibility that insufficiently justified measures could be maintained for long periods of time.”

It actually appears, as asserted by Prévost, that the wording of article 5.7 does not provide, in detail, specific requirements. But, in the view of

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136 At this point, Jensen has remarked: “The difficulties in exporting under increasingly strict SPS measures are manifold and particularly acute for many developing countries. The costs involved included both the production costs of respecting the SPS requirements and the conformity costs of making sure they are respected. When SPS requirements increase production costs do too as new inputs may be required or technologies changed”, M. Jensen, “Reviewing the SPS Agreement: A Developing Country Perspective”, 2002, 3 et seq.

137 Ibid., 1 et seq.; Prévost/ Matthee, see note 82, 43.

138 Prévost/ Matthee, ibid. 49
this thesis, the precautionary principle obtains its proper nature, that is, it deals with scientific loopholes, where even configuration of potential risk itself is difficult to identify, as mentioned in Part III.\textsuperscript{139} Drafters of the SPS Agreement basically seemed to obtain no choice in writing this article. Thus the configuration of the precautionary principle under article 5.7, by its own character, contains loose wording as such, which provides Member States with a wide range of discretion.

Despite the said character of article 5.7, developing countries are less concerned, since application of precautionary measures shall, nevertheless, be subject to substantive rules of international trade protection, including the principle of good faith, the transparency requirements, the necessity test, etc., as mentioned in Part III. Incompliance with these rules certainly renders the precautionary measures illegitimate.

Application of the precautionary principle in arts 5.1 and 5.2 provokes preoccupation also upon developing countries because, as asserted by the Appellate Body, article 5.2 is not intended to be a closed list, which could provide a gateway to applicability of the precautionary principle, as long as risks invoked are ascertainable and not just theoretical ascertainable. It has not provided further explanation regarding “ascertainability”. Thus, in practice, at the beginning, determination of what risk is ascertainable falls upon Member States, which impose the measures\textsuperscript{140} as long as their application of precautionary measures are not counter to rules of international trade protection, as mentioned in the previous paragraph.

Application of the precautionary principle under paragraph 6 of the preamble and article 3.2, in the context of international standards,\textsuperscript{141} could also provoke preoccupation of developing countries, if international standards include instructions for precautionary measures. The problem of international standard setting is not usually about the level of protection itself, but rather the lack of participation of developing countries, even though they are affected by international standards.\textsuperscript{142} In response to this preoccupation, developing countries should be en-

\textsuperscript{139} This could be compared with the configuration of the precautionary principle in article 5.1, that the Appellate Body preferred to use the word “ascertainable” instead of “identifiable”.

\textsuperscript{140} Nevertheless determination of risk is still governed by relevant rules of international trade protection, as mentioned in the previous paragraph.

\textsuperscript{141} As mentioned in Part II., it is possible that precautionary measures are instructed by international standards.

\textsuperscript{142} Scott, see note 3, 269 et seq.
couraged to participate in international standard setting in order to express their concerns on precautionary measures harmonised by international standards. Actually developing countries have certain platforms to expose, but do not actively use this opportunity.

The configuration of the precautionary principle, as shaped by its own text in the SPS Agreement and WTO jurisprudence, is not problematic for developing countries, since application of the precautionary principle is countervailed by scientific requirements and relevant rules of international trade protection, including the principle of good faith, transparency requirements and necessity tests, as mentioned in Part III. The first preoccupation, concerning legitimate trade restriction, is nevertheless inevitable, since the precautionary principle has been endorsed to fulfil the spirit of the SPS Agreement. The principle itself does not aim at protectionism, but rather provides opportunity to Member States to protect public health within their own territories via SPS measures.

b. Preoccupation on Abusive Application of the Precautionary Principle

The SPS Agreement actually provides a doctrinal framework to counter abusive application of the precautionary principle. For example, “prohibition of arbitrary or unjustifiable discrimination and of disguised restriction to international trade” is underlined in article 2.3, in parallel to the Chapeau of Article XX of the GATT 1994. Also, as mentioned in the previous Part, relevant rules of international trade law play a significant role in regulating the application of precautionary measures. Despite the existence of these rules, preoccupation of developing countries and least developed countries still prevails. But, it appears that the preoccupation should focus on the question of how to implement these rules in order to effectively counter the abusive application, rather than how to change such rules.

The proposal of this thesis is that developing countries, altogether, should actively deal with the issue, rather than wait for help. In doing so, it is important to obtain enough information which manifests that arbitrary or unjustifiable discrimination and disguised trade restriction take place, since these problems are mostly related to fact findings. Without sufficient evidence, they could not bring claims against countries which impose the measures both before judicial and non-judicial

143 Ibid.
mechanisms. Gathering evidence is not a simple work and is difficult to be done alone. Therefore developing countries, which share the same interests, should begin to actively collaborate.

The collaboration may be achieved by various means, including exchange of information relating to their concerns in common, collective submission of requests for explanation under article 5.8, proceedings of collective consultation under article 11.1.

The first proposal of this thesis, “exchange of information”, may be achieved when developing countries communicate with each other. A developing country should neither feel insignificant, nor hesitate to help, when other developing countries ask for information, which is already available. Exchange of information between developing countries themselves could provide a useful means for each other. Two developing countries, which share the same concern, have investigated facts. The facts at hands of both countries may be complementary to each other, and if exchanged, could make fact finding more profound and then the process of investigation will be a lot faster.

It should be noted that this proposal is different to paragraph 7 of the preamble, since the former requires “self-collaboration amongst developing countries”, whereas the latter calls upon more prosperous countries to recognise the limitations of developing countries. This thesis forecasts that if current framework for developing countries under the SPS Agreement is complemented by this proposal, those rules of international trade law designed to prevent arbitrary or unjustifiable discrimination and disguised trade restriction will be implemented and thus importing countries will be discouraged from abusively applying precautionary measures with the real aim of trade restriction.

The second proposal of this thesis is to “employ Article 5.8 of the SPS Agreement in a collective manner.” According to article 5.8, a developing country could ask for an explanation from importing countries with regard to precautionary measures imposed. This thesis proposes that the submission of request for an explanation under article 5.8 will contribute to the interest of developing countries if developing countries, which share the same interests, make collective submissions of request. In doing so they should make observations on the explanation provided by the importing countries. With this proposal, the application of article 5.8 will not just be an inactive transfer of information, but rather a collaborative investigation of facts. Since no provision prohibits this collective submission, it is therefore possible to do so.
The third proposal of this thesis deals with the process of consultation, as the prerequisite for a dispute settlement proceeding. In the view of this thesis, the consultation process, if done collectively, could reconcile the interests of developing countries, affected by measures of importing countries. That is, developing countries, whose rights have been affected by precautionary measures, proceed together in the consultation process with the importing country. This could, on the one hand, help the importing country to get to know the full consequences of the application of the precautionary measures. On the other hand, developing countries feel more confident about undergoing the process of consultation, especially if the importing country is a big economy, namely the EC or the United States.

2. Developing Countries as Importing Countries

When developing countries exercise the role of importing countries, applying precautionary measures, they have much less preoccupation than they would have when exercising the role of exporting countries. Rights of developing countries with regard to the application of SPS measures, are established quite clearly in the SPS Agreement, namely in paragraph 7 of the preamble and article 10 of the SPS Agreement. In this regard, developing countries are also granted the capacity of imposing precautionary measures to protect public health within their territories.

Before further analysing special rules for developing countries, it is important to draw attention to the question, under what circumstances special rules could be applied for developing countries? The basic notion of special and differential treatment is that rules on special and differential treatment are designed to compensate disadvantages144 that developing countries may encounter when SPS measures are applied due to their limited capacity. Special and differential treatment shall not be interpreted as to diminish fundamental rules of international trade law.

For example, importation of genetically modified products entails application of precautionary measures which are intended to protect public health. However, the importation also significantly affects developing countries. That is, employment of genetic science accelerates and improves productions by providing herbicide resistance to plants, enlarging the size, making the taste better. Genetically modified prod-

144 A. Seibert-Fohr, “Article 11”, in: Wolfrum, see note 7, 504 et seq.
ucts therefore could quantitatively respond to demands of people a lot more than ordinary production, generally employed by developing countries. Even though this may be disadvantageous to developing countries, it is not a reason for differential treatment. If developing countries maintain their precautionary measures by this motive, it could be deemed that the precautionary principle is being invoked to justify a disguised restriction to international trade, which is not permitted under article 2.3 of the SPS Agreement.

As mentioned in Part II, the application of the precautionary principle under article 5.7 requires four elements, that is, during/after precautionary measures are applied, measures must: (i) be imposed in respect of a situation where relevant scientific information is insufficient; (ii) be adopted on the basis of available pertinent information; (iii) not be maintained unless the member seeks to obtain the additional information necessary for a more objective assessment of risk; and (iv) be reviewed accordingly within a reasonable period of time. With regard to relevant rules of special and differential treatment for developing countries, elements of article 5.7 are to be construed as long as each of them leaves room for special interpretation for developing countries.

The first element of article 5.7 does not entail special interpretation for developing countries, since determination of insufficiency of scientific evidence is based on the same standard for Member States, which deals with determination of “reliance and conclusiveness”, as clarified by the Appellate Body. Equally, the second element does not entail special interpretation because the question of whether the measures concerned are based on available pertinent information depends on “relevant information” and “public values of a single State”, which are not relevant to particular rights of developing countries.

The third and fourth elements entail special interpretation for developing countries. As mentioned in Part II, the third element leaves room for Member States to decide “what means to employ in order to obtain additional information which must be germane to the conduct of a more objective risk assessment.” In searching for information, developing countries may confront difficulties. The means, which they may employ to get information, shall depend on their capacities in the light

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145 However, before article 5.7 is applied, developing countries may enjoy special rights. That is, in seeking for scientific evidence, they obtain rights to get technical assistance. But this technical assistance is not relevant for article 5.7 at all, but rather for relevant provisions on risk assessment.

146 This issue has already been discussed in Part II.
of paragraph 7 of the preamble. Special interpretation is to be made, as well, for the last element of article 5.7, “review (the measures) within a reasonable period of time”. As the capacity of developing countries is generally limited, a reasonable period of time therefore could be construed in a more extensive manner than for developed countries.

Developing countries, when applying precautionary measures under arts 5.1 and 5.2, also find an opportunity to obtain special interpretation in accordance with article 9, which provides for the possibility of developing countries to obtain technical assistance. This thesis considers that article 9 not only provides special treatment for developing countries, but also fosters transparency when precautionary measures are imposed by developing countries. When Member States apply precautionary measures alone, the measures are contingent on discretion thereof, which sometimes may be abused. Whether the risk in question is ascertainable or not is still an abstract issue and is potentially interpreted by virtue of the state which imposes the measures. But when risk assessment is supported by technical assistance, the possibility of abused discretion is reduced, since the result of risk assessment is the output of collaboration between at least two countries.

Special rights of developing countries for application of the precautionary principle also include a “special right to determine relevant measures to reach an appropriate level of protection.” For example, developing countries basically have less capacity than developed countries in terms of equipment and materials necessarily used for checking entrance of suspected goods, as part of precautionary measures. Developed countries may use equipment of highly advanced technology to check significant substances contained in the products, whereas developing countries may not have the capacity to do this. In the light of article 10.1 and paragraph 7 of the preamble, they therefore could employ measures of lower technology or low costs to investigate the imported products.

However, in doing so, developing countries shall ensure that their measures are consistent with basic obligations, as mentioned in previous parts. Low cost measures shall conform to the principle of good faith. In imposing the measures, they have to perform the transparency obligations. The necessity test is also to be regarded to ensure that such low cost measures are not more trade restrictive than absolutely required.
Conclusion

Approaching the precautionary principle is a considerable challenge, since the principle contributes to the so-called suspected risks “des risques soupçonnés.” Once it has been exonerated from being suspected, the precautionary principle does not continue its role. The principle, in the SPS sphere, is definitely intended to protect life and health of living beings, including humans, animals and plants, but there is a fear that it may be abused by a state invoking it, since the principle gives a wide range of discretion to Member States. Despite its character it is required to exist in order to counterbalance rules of international trade protection. In the view of this thesis, the principle is not just a theoretical notion, but rather something we need in practice.

As mentioned in the relevant Parts, the principle obtains its standing in the SPS sphere both as a written provision, underlined in the SPS Agreement, and as unwritten principle, which is also applicable before adjudicatory organs of the WTO. The principle has not yet been crystallised as customary international law, but could be invoked as a general principle of law, when employed to protect human health. The scope of application of the precautionary principle is unclear and highly arguable. However, findings of the WTO provide relevant answers to questions concerning its scope of application in the SPS Agreement, although these findings are themselves contradictory. The configuration of the precautionary principle has not only been exhausted in article 5.7, but also reflected in certain provisions in a restrictive style.

Moreover, the precautionary principle is not isolated, but intermines with relevant rules of international trade law and other relevant areas. In this regard, application of the principle shall take into account other relevant rules. This thesis has split such relevant rules into two groups, rules of international trade protection and countervailing rules of international trade protection. The precautionary principle shall always be applied in conjunction with these rules, otherwise public health would not be ultimately protected or the application of the principle may result in protectionist tendencies.

After analysing the doctrinal framework of the precautionary principle, this thesis also took into consideration dispute settlement concerning the application of the precautionary principle, since there are significant issues which deserve to be approached. The topic is therefore included in this thesis in order to make the work complete. In the last Part, the thesis narrowed down the scope to relevant issues on developing countries. Generally speaking, developing countries do not appreci-
ate the application of the precautionary principle, since a considerable number of developing countries rely on revenues from agricultural products. Solutions to reduce this preoccupation have been proposed in the same Part. However, when developing countries play a role as importing countries, there are relevant issues to be regarded as well. In exercising this role, they enjoy certain special rights, which were also analysed in this thesis.