

Precautionary Principle under the SPS Agreement: A Critical Exposition**¹Abdul Haseeb Ansari and ²Sri Wartini**¹*Professor, Ahmad Ibrahim Kulliyah of Laws, International Islamic University Malaysia, Malaysia*²*Lecturer, Fakultas Hukum, UII, Indonesia*

Abdul Haseeb Ansari and Sri Wartini: Precautionary Principle under the SPS Agreement: A Critical Exposition

ABSTRACT

The Sanitary and Phytosanitary Agreement of 1992, which is a part of the WTO legal regime, in order to ensure augment international trade in GMOs, provides for ensuring their safety so that they could be acceptable in international market, i.e. it prescribes for a kind of precautionary principle, which is supposed to be adhered to by the WTO Member States. This is well in practice. But some jurists and environmentalists find it trade friendly, which can be detrimental to human health and the environment. Moreover, states, which produce GMOs, like to introduce it quickly; and for that, they perform some kind of risk assessment, which were not be acceptable to some importing countries. This resulted in disputes, which were ultimately resolve, in most of the cases in favour of international trade rather than protection of the environment or ensuring human health, except for where the harm was eminent. Keeping this in mind, the paper conducts a critical appraisal of the PP provisions of the SPS Agreement and offers certain amicable suggestions for improvement on the existing provisions.

Key words: Genetically modified organisms, Biosafety, Biodiversity, risk assessment, Sanitary and phytosanitary measures.

Introduction

The paper examines the role and application of precautionary principle (PP) in the SPS Agreement on international trade in GMOs. It in specific addresses the question as to what extent the PP provisions are applicable under the SPS Agreement. The paper demonstrates that although the PP provisions are embodied in the provisions of the SPS Agreement, its application is ineffective and unenforceable. The unenforceability is characterised by the fact that the PP is not explicitly mentioned in the SPS Agreement. The ineffectiveness of the implementation is indicated by the fact that, among other things, the aim of the PP to improve the protection of human, animal, plant life and health is hampered by the SPS principles. However, PP based on risk assessment is enshrined in there.

The Cartagena Protocol, made under the Convention on Biological Diversity, also provides for some kind of precautionary principle to be applied by the GMO importing countries. This PP is considered to be stringent than that of the SPS Agreement. But this aspect the dichotomy of the international trade law and international environmental law is not within the scope of this paper (in order to have some insight in this aspect of

the precautionary principle pertaining to cross border movement of GMOs/LMOs, see [6,2,4,5,3].

First, the paper briefly gives an overview and the historical background of the SPS Agreement. This is followed by the scope of the SPS Agreement and the mechanism of transferring LMOs under the risk assessment, risk management, and control, inspection and approval procedures, and finally the role and application of the PP on transboundary movement of GMOs/LMOs under the SPS Agreement is analysed concisely.

An Overview of the SPS Agreement:

International trade in GMOs (GM crops, living and non-living, and GM food) has sharply increased [19]. With the rise of population in third world countries, the volume of trade will keep on increasing. This might give rise to larger number of cases at the WTO pertaining to human health and applicability of PP as biosafety measure [16,20]. The conflict traces back to choices made in the United States and Europe in the mid-1980s about how to regulate fast growing agricultural biotechnologies [26].

Since the growth of LMOs is at rise, using them without determining their safety their adverse effects

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may be serious on the biodiversity and human health [34]. It is for this reason that the SPS Agreement attempts to address the measures used by governments to ensure that human and animal food is safe from contaminants, toxins, disease-causing organisms and additives, and measures to protect human health from pests or diseases carried by plants and animals [70].

The SPS Agreement explicitly recognises the right (the basic rights and obligations of the Member States are stipulated in Article 2 of the SPS Agreement, which are then further elaborated in subsequent articles) of States to take measures to protect human, animal and plant life and health. However, where trade restrictions occur, these measures should be taken only to the extent necessary for health protection on the basis of sufficient scientific evidence: in absence of which, governments may temporarily impose precautionary restriction on imports while they seek further information. However, the PP incorporated in Article 5(7) of the SPS Agreement does not represent an overarching principle of the Agreement in its own right, nor can it be invoked outside the scope of Article 5(7) to override other provisions of the Agreement, in particular, the requirement of a scientific basis for a national health measure [31]. States are at liberty to determine the level of health protection they consider appropriate on the basis of an evaluation of the risks involved. It should be noted that it could be regarded as a SPS measure only when it addresses the specified types of corresponding SPS risks [21].

Forms of SPS measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements (Annex A (1) (d), the SPS Agreement) directly related to food safety. In other words, the SPS Agreement encompasses substantially diverse measures. Nonetheless, if a measure is not intended to protect against one of the risks mentioned in Article 1(a)-(d) of the SPS Agreement, then the measure is not an SPS measure.

The SPS Agreement does not contain any provision in line with advanced informed agreement (AIA) procedure of the Cartagena Protocol. It allows WTO Members to restrict trade in LMOs as necessary to protect human, animal or plant life or health in consistent with the Agreement. The SPS Agreement is presumed to be consistent with the legal regime of the GATT, if restricts Members' ability to create barriers to international trade.

Affording importance to unrestricted trade, WTO Members, under the SPS Agreement, "shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence" [62].

The basic objectives of the SPS Agreement is as follows: To maintain the sovereign right of any state to provide the level of health protection it deems appropriate, but to ensure that these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers to international trade [60]. Thus, the Agreement prohibits Members from imposing different levels of health protection, which cause arbitrary or unjustifiably discriminatory measures on other Member States.

On the other hand, the SPS Agreement also requires risk assessment to be based on an international standard or guideline [64,23] contained in the Codex Alimentarius Commission (Codex) [72] for standards relating to food; the International Office of Epizootics (OIE) for standards relating to animal health and zoonoses, and the International Plant Protection Convention (IPPC) [35] for standards relating to plant health and safety.

Besides that, there are certain basic principles of the SPS Agreement that are necessary to be taken into account, namely: non-discrimination principle, the most favoured nation principle and transparency principle (Article 7, the SPS Agreement).

The SPS Agreement has a strong principle of non-discrimination. Under the agreement there are three warnings against discrimination contained in the "basic rights and obligations" namely: (i) not making a distinction between goods from different countries, unless this is provided for in the agreement; (ii) not discriminating against imported goods, in favour of locally-produced goods; and (iii) not to use SPS measures as a disguised restriction on international trade [7]. This concept is also elaborated elsewhere in the agreement, such as in Article 5 of the Agreement.

The most favoured nation principle: Based on the most favoured nation principle, importing countries must treat imports from different countries with the same treatment, unless there are valid health reasons for treating them differently. So if a country is importing the same commodity from country A and country B, and country A and country B do not have significantly different pest or disease statuses, the importing country must apply the same conditions to the commodity from the two countries [43].

The transparency principle: Members shall ensure that all sanitary and phytosanitary regulations, which have been adopted, are published promptly in such a manner as to enable interested Members to become acquainted with them (Paragraph 1 Annex B, the SPS Agreement). Except

in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member (Paragraph 2 Annex B, the SPS Agreement).

The SPS Agreement is administered by the Committee on Sanitary and Phytosanitary Measures (SPS Committee) that provides a regular forum for consultations and carries out the functions necessary to implement the provisions of the Agreement (Article 12 (1), the SPS Agreement; see also [14]. The Committee is to encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. Moreover, the Committee shall encourage the use of international standards, guidelines or recommendations by all Members and also increase coordination and integration between international and national systems and approaches for approving the use of food (Article 12(2), the SPS Agreement).

A Brief History of the SPS Agreement:

Before the Uruguay Round was put to negotiation, measures taken to deal with human, animal or plant life or health, were addressed mainly by GATT Article XX(b) and the Tokyo Round Standards Code. These instruments, however, could not successfully cope with trade restrictive effects of various intricate measures adopted for sanitary or phytosanitary purposes.

The rules under Article XX(b) of the GATT do not sufficiently clarify or specify how to deal with complicated SPS measures, nor does the Tokyo Round Standards Code squarely cover SPS measures that featured unique and distinctive characteristics on how to deal mainly with agricultural products in spite of more articulated obligations for technical regulations and standards. Accordingly, when the GATT Contracting Parties decided to launch the Uruguay Round, they agreed, as a subject for negotiation, to minimise “the adverse effects that sanitary and phytosanitary regulations and barriers can have on trade in agriculture, taking into account the relevant international agreements”.

In fact, this decision on SPS Measures constituted to be a foundation for articulated rules on SPS measures and their implementation. This draft was subsequently modified and included as Part C of

“Text on Agriculture” in the Dunkel Draft [17]. Unlike the Brussels Draft, the Dunkel Draft contained the provision that specified the relationship between the SPS and the TBT Agreements. It was the Dunkel Draft that clarified the exclusivity of the two Agreements [15].

The SPS Agreement came into force when the WTO came into existence. It constitutes an integral part of the 1994 treaty known as the “Uruguay Round Final Act” (of the GATT). The provisions of the Agreement are, therefore, binding on all Members of the WTO, and compliance is enforceable through the WTO dispute settlement mechanism, giving it hard law characteristics. Finally, the SPS Agreement entered into force for most WTO members on 1 January 1995 [68].

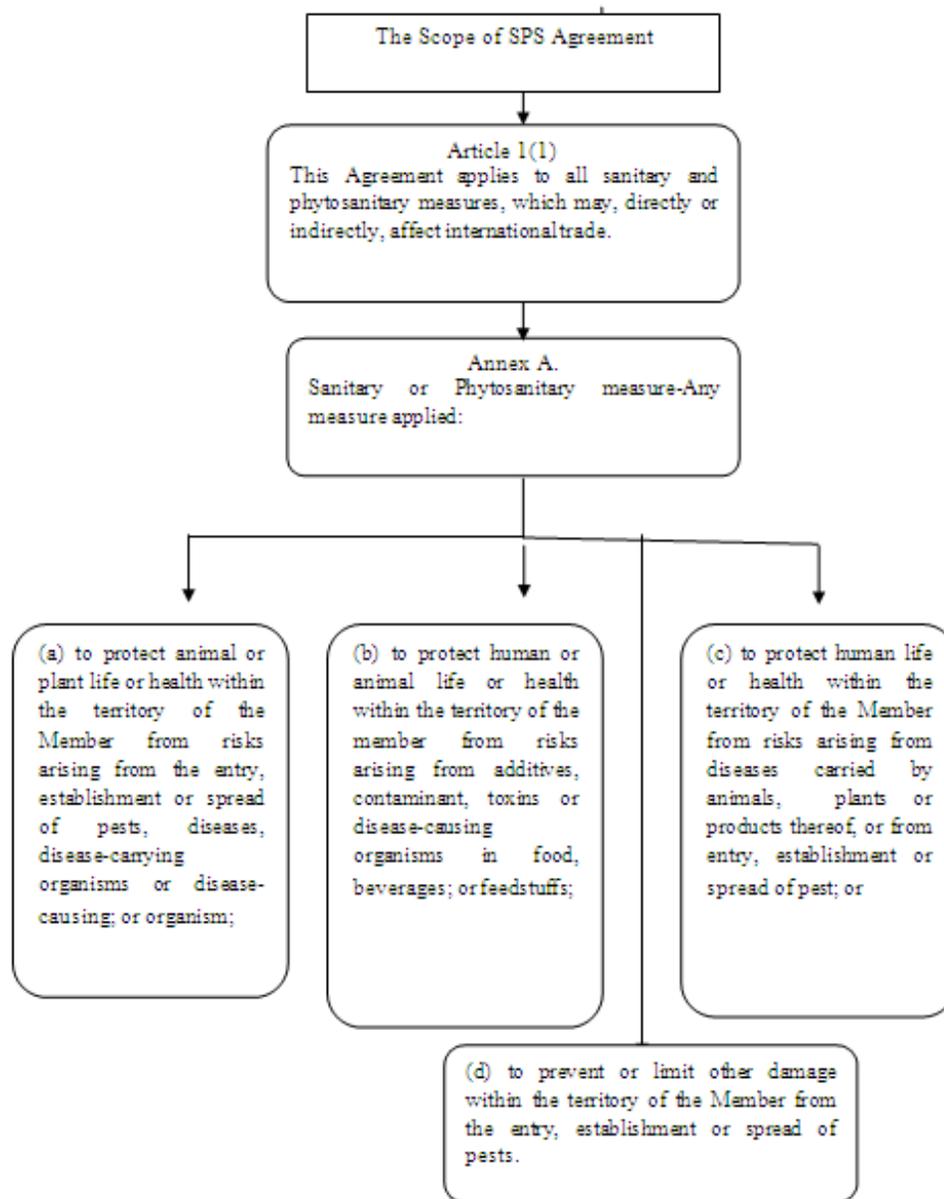
Undoubtedly, the SPS Agreement was a major achievement for agricultural exporters at the conclusion of the Uruguay Round. In the meantime, WTO Panels have dealt with disputes about alleged violations of the SPS Agreement in six cases [45]: (i) the *EC-Hormones* [50] (ii) the *Australia-Salmon* [48]; (iii) the *Japan-Agricultural Products* [53]; (iv) the *Japan-Apples* [54]; (v) and the *EC-Biotech* [49], and the *Australia-Apples* (Summary of the Panel and the Appellate Body Report on *Australia-Apples*. WT/DS367/R and WT/DS367/AB/R). In all these cases, the importing Member was found to have failed, in certain respects, to fully observe its obligations under the Agreement.

The Scope of the SPS Agreement:

With regard to the scope of application of the SPS Agreement, this section distinguishes between: (i) the substantive *scope* of application, i.e., these types of measures to which the Agreement applies; (ii) the personal scope of application, i.e. the entities to which the Agreement applies; and (iii) the temporal scope of application of the Agreement [56].

The substantive scope of application: The disciplines referenced to the SPS Agreement do not cover all measures for the protection of human, plant or animal life or health but, rather, apply to a clearly circumscribed set of measures. The substantive scope of application of the SPS Agreement is set out in Article 1(1). It states: “This Agreement applies to all sanitary and phytosanitary measures, which may, directly or indirectly, affect international trade ...”. The below figure demonstrates the substantive scope of the SPS Agreement.

The Substantive Scope of the SPS Agreement:



The figure indicates that a measure that is subject to the SPS Agreement, therefore, must be: (i) a sanitary or phytosanitary measure; and (ii) a measure that may affect international trade. From the scope, which is articulated in Article 1(1) of the SPS Agreement and in the Annex A, it is clear that the question of whether a measure is an “SPS measure” depends on its purpose or aim (Article 1 and Annex A, the SPS Agreement).

In fact, in broad sense, an SPS measure is one that: (i) aims at the protection of human or animal life or health from food-borne risks; or (ii) aims at the protection of human, animal or plant life or health from risks from pests or diseases. In theory, GM organisms, which are “food-borne contaminant”, would fall within the scope of the SPS Agreement [45]. However, the scope in Annex A refers

specifically to the protection of human, animal or plant life or health “within the territory of the Member”, thus excluding measures aimed at extra-territorial health protection from the scope of application of the Agreement.

The personal scope of application: The adoption and implementation of SPS measures may sometimes be in the hands of bodies other than central government such as regulatory agencies, regional bodies and sub-federal governments [69]. The SPS Agreement takes this into account by providing, in Article 13 of the SPS Agreement, that Members are fully responsible for the implementation of the Agreement and must enact and implement positive measures to ensure the observance of its rules by bodies other than central bodies if any.

The temporal scope of application: The question whether the SPS Agreement is applicable to SPS measures adopted and/or applied before the entry into force of the agreement was raised by the European Communities in *EC-Hormones* [61] hereinafter *Beef Hormones-Case*). The Dispute Settlement Body adopted the Appellate Body's Report and the European Communities, thus, was bound to bring its hormone measures into conformity with the SPS Agreement [57]. It can be concluded that the SPS Agreement is also applicable to the measures that have been undertaken before the SPS Agreement came into force.

Furthermore the AB pointed to Article XVI:4 of the WTO Agreement which obliges Members to ensure the conformity of their laws, regulations and procedures with their obligations under the SPS Agreements. It is thus apparent that Members have to review their existing SPS measures in the light of the new disciplines of the Agreement [69].

The Mechanism of Transboundary Movement of Gmos/Lmos under the SPS Agreement:

The SPS Agreement is not intended to provide any direct provisions for transboundary movement of GMOs/LMOs, except for the requirement to provide necessary rules and procedures for LMOs. In addition, the SPS Agreement has not been adopted to address the transboundary movement of GMOs/LMOs and it does not establish international standards for biotechnology or other food-safety in questions [24]. Thus, there is no explicit mechanism of transboundary movement of GMOs/LMOs under the Agreement.

However, the SPS Agreement promotes conformity between national measures with international standards that has been mentioned in sub-chapter 5(2) and encourages countries to enact measures based on an international standard [27]. Thus, when states want to export or import LMOs (GM crops/seeds) in their territory, they have to comply with the provisions of the Agreement. The Agreement applies to all sanitary and phytosanitary measures which may directly or indirectly, affect international trade (Article 1(1), the SPS Agreement). Obviously, the SPS Agreement permits countries to maintain SPS measures necessary to protect human, animal, and plant life and health.

The SPS Agreement, however, requires the Member Countries of the WTO: (i) to base their SPS measures on science (Article 2(2), the SPS Agreement); (ii) not to use SPS measures as disguised barriers to trade (Article 2(3), the SPS Agreement.); (iii) to recognise the equivalency, where possible, of different procedures used by other members for protecting against similar risks (Article 4(1), the SPS Agreement); (iii) to base their SPS measures on risk assessments (Article 5(1), the SPS Agreement); (iv) to recognise the concepts of

disease- and pest-free areas; (v) to maintain transparent SPS regulations, and (vi) not to use control, inspection, and approval procedures as unjustified SPS barriers to imports [67].

Transboundary Movement of LMOs Based on Risk Assessment and Risk Management:

Risk assessment and risk management on transboundary movement of GMOs/LMOs have a significant role in order to achieve the objective of the SPS Agreement. However, it is essential to distinguish between risk assessment and risk management. The aim of this functional separation between risk assessment and risk management is to protect the scientific integrity of the risk assessment by distinguishing scientific findings from value judgments [10].

In the face of uncertainties, agencies responsible for setting safety standards should make science policy choices. Since virtually all scientific data are incomplete or ambiguous in some fashion, "risk-assessments must use general knowledge and policy guidance to bridge data gaps". Hence, risk assessment is primarily collection and evaluation of data from a multitude of scientific disciplines epidemiology, toxicology, statistics, and pathology, just to name a few [39].

The national regulatory process by means of which SPS measures are imposed typically involves risk analysis. For the purposes of the SPS Agreement, two elements of risk analysis are relevant, namely, risk assessment and risk management. The term "risk assessment" refers to the scientific process of identifying the existence of a risk and establishing the likelihood that the risk may actually materialise according to the measures that could be applied to address the risk.

On the other hand, risk management is the policy-based process of determining the level of protection, which a country wants to ensure in its territory and choosing the measure that will be used to achieve that level of protection. In risk management decision-making, not only are the scientific results of the risk assessment taken into account but also societal value considerations such as consumer preferences, industry interests, relative costs, etc. However, the distinction between risk assessment and risk management is a useful tool in enhancing the understanding of the regulatory process.

The risk assessment and risk management distinction is implicitly taken into account in those areas of the SPS Agreement that relate to the risk analysis process contained in Article 5. Articles 5(1) to 5(3) set strict scientific disciplines for risk assessments on which SPS measures must be based, whereas a Member's choice of an appropriate level of protection, an aspect of risk management, is largely respected by the provisions of Articles 5(4) to

Article 5(5). Thus, another aspect of risk management is subject to trade-related rather than scientific disciplines in Articles 5(3) and 5(6) (See Codex Alimentarius Commission-Procedural Manual, 2003). However, risk management is not mentioned explicitly in the provision of the SPS Agreement.

Transboundary Movement of GMOs/LMOs Based on Risk Assessment:

Import decisions of GMOs/LMOs must be based on a risk assessment that uses a scientific procedure. Risk assessment is generally described as the process of evaluating the likelihood of the entry, establishment, or spread of a pest or disease within a country and the potential consequences of such a spread. In the animal and animal products, past strategies of eliminating all risks have been replaced by determinations of “acceptable levels of disease-specific risk because zero risk is considered unattainable [71]. In plant product area, there is an assessment of the degree to which an area is pest free as well as the effectiveness of mitigation measures using approaches that reduce the risk of disease or pest infestation to a negligible level. A risk assessment focuses on a number of risk factors including prevalence of a pest or disease in and near the export area. A risk assessment goes beyond disease or pest information. Officials of the importing country also have an interest in judging or assessing the reliability of any pest or disease information and data. Therefore, the risk assessment also attempts to evaluate the quality of the surveillance system itself, including such things as the laboratory capabilities and other aspects of the exporting country’s quarantine programmes. Article 5(1) of the SPS Agreement states:

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

Article 5(1), thus, obliges Members to base their SPS measures on a risk assessment as deemed appropriate to the circumstances and suggests the Members to take into account risk assessment techniques developed by relevant international organisations, such as the Codex Alimentarius Commission. A “risk assessment” is defined in paragraph 4 of Annex A of the SPS Agreement as follows:

“The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on

human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”

Thus, there are two types of risk assessment, each with different requirements. The type of risk assessment required in a given case will depend on the type of SPS measure at issue. The first type of risk assessment is applicable to SPS measures aimed at risks from pests or diseases; the second type is applicable to SPS measures aimed at food-borne risks. The former involves not only an assessment of the risk of entry, establishment or spread of a pest or disease but also an assessment of the risk of the associated potential biological and economic consequences.

Thus, such a risk-assessment should: (i) identify the disease whose entry, establishment or spread a member wants to prevent within its territory . . . , (ii) evaluate the likelihood of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences, and (iii) evaluate the likelihood of entry, establishment or spread of these diseases according to the SPS measures which might be applied [1].

It is required that the second type of risk assessment should comply with the two prescribed requirements applicable to food borne risks. The two requirements are: (i) identify the adverse effects on human or animal health, if any, arising from the additive, contaminant, toxin or disease-causing organism in food/beverages/feedstuffs at issue; and (ii) if such adverse health effects exist, evaluate the potential of occurrence of these effects [12]. However, if a risk assessment is applied for food derived from biotechnology, the risk assessment should refer to Codex Guidelines on Foods derived from biotechnology [37].

Although the SPS Agreement does not lay down any methodology of risk assessment to be followed by Members, it does specify certain factors that Members must take into account in their risk assessments. Article 5(2) of the Agreement lists certain scientific and technical factors that Members must consider when assessing risks. These are:

“Available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.”

From this list, it is clear that a risk assessment for the purposes of the SPS Agreement is not purely scientific (in the sense of laboratory science), but includes a consideration of real world factors that affect risk such as climatic conditions, control mechanisms, etc. This was further supported in *EC-Hormones* [8] by the AB’s rejection of the Panel’s finding that the risks relating to control and detection of failure to observe good veterinary practices must

be excluded from risk assessments as they are non-scientific and thus outside the scope of Article 5(2) of the SPS Agreement.

Transboundary Movement of GMO/LMOs Based on Risk Management:

Risk management uses the information gathered through risk assessment to create policies to deal with a hazardous environmental or health agent. Whereas, risk assessment is limited to scientific inquiries, risk management under the SPS Agreement only includes economic and political values, but it does not include social values. Risk assessors are responsible for determining risks of hazardous agents through scientific analysis, but risk managers are responsible for considering the results of risk assessments and competing societal goals and values and creating strategies for dealing with the hazardous agents.

Risk management, as explained above, entails policy decision-making regarding the level of protection that a country wants to secure in its territory and the measure it will use to achieve this level of protection. These choices are based on both scientific evidence and economic value judgments. The SPS Agreement gives national regulators substantial latitude in making risk management decisions, but there are certain non-scientific disciplines in place to ensure that the adverse trade effects of these decisions are limited as much as possible.

Risk management entails, in the first place, the decision on the “appropriate level of protection (ALOP)”, defined in paragraph 5 of Annex A of the SPS Agreement as: “The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory” (Article 5 (3), the SPS Agreement; see [58]). Thus, there is a clear recognition that it is the prerogative of the Member imposing the SPS measure to choose the level of protection of human, animal or plant life or health it will enforce in its territory. The SPS Agreement does not oblige Members to lower their level of protection, even where this would be most trade-efficient.

Two provisions in the SPS Agreement deal with the choice of an ALOP. Article 5(4) provides that Members should take into account the objective of minimising negative trade effects when choosing their level of protection (Article 5 (4), the SPS Agreement). The word “should” indicates that this provision is only rhetoric, containing no binding obligation. Obliging Members to choose the least trade restrictive level of protection would go against the underlying principle of the SPS Agreement, that is, the prerogative of the Member to determine the level of protection it deems appropriate in its territory. The discipline with regard to the ALOP is

contained in Article 5(5), which provides the relevant part:

“With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.”

Two elements of Article 5(5) discipline can be distinguished, namely: (i) the goal (for the future) of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection; and (ii) the legal obligation to avoid arbitrary or unjustifiable distinctions in the levels of protection deemed appropriate in different situations, if these distinctions lead to discrimination or disguised restrictions on trade.

Risk management is “the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health”. Risk managers decide what, if anything, to do about risk, by employing: (1) the results of risk assessment; (2) scientific information about the costs, benefits, and causal consequences of management choices; and (3) value judgments about societal goals and objectives. The resulting risk management decisions balance such competing societal goals as taking a conservative approach to protecting human health and maximising the net benefits of various forms of regulation [34].

In the case of foods derived from biotechnology, which is directly linked to the question of biosafety, the Codex Alimentarius adopted Codex Principles for Risk Analysis of Foods Derived from Biotechnology [11]. However, in order to conduct risk management in the SPS Agreement the Member States should refer to the guidelines that have been established officially in the Codex (Annex A, paragraph 3 (a), the SPS Agreement). The Codex and its subsidiary bodies, acting as risk managers in the context of these working principles [42]. They should ensure that the conclusion of the risk assessment is presented before making final proposals or decisions.

Control, Inspection and Approval Procedures of GMOs/LMOS:

The SPS Agreement recognises that the timely inspection of some agricultural products, especially perishable ones, such as GMOs/LMOs, is crucial. Any control, inspection, and approval procedures for imports must be executed without undue delay (Annex C, paragraph 1 (a), the SPS Agreement). Any such regulations imposed on imported products shall be reasonable and necessary. In order to comply with the mechanism, the Member states have to obey the notification procedure is stipulated in

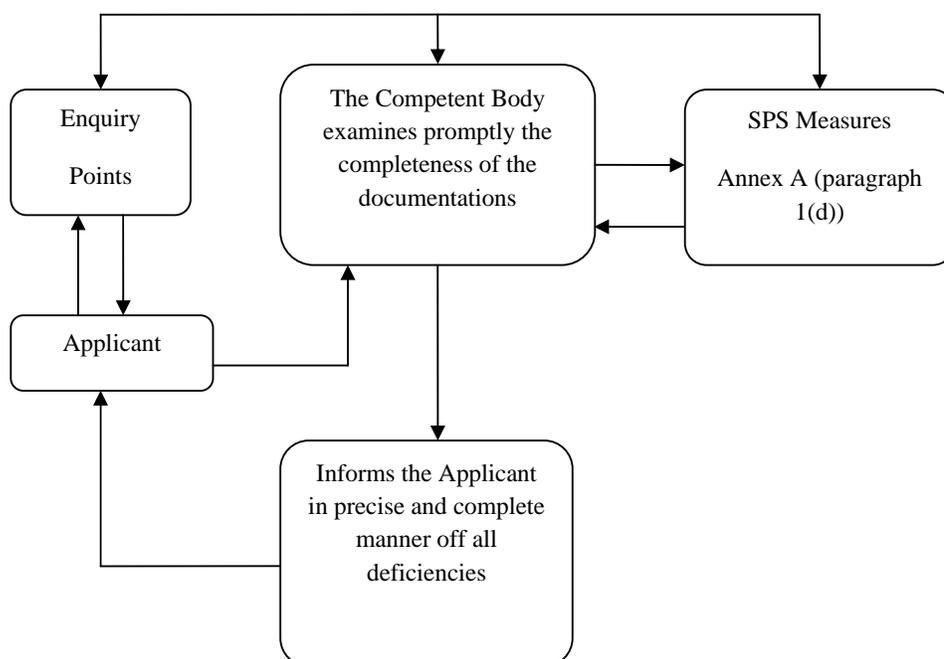
Annex B and the control, inspection and approval procedures in Article 8 and Annex C. Article 8 of the SPS Agreement states:

“Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.”

According to Article 8, Members must comply with Annex C as well as the other provisions on the SPS Agreement in the operation of their control, inspection and approval procedures.

In order to ensure that their SPS measures are complied with, States usually have control, inspection and approval procedures in place [69]. If these procedures are lengthy, costly or complex, they may effectively restrict market access. The SPS Agreement addresses this problem in Article 8 and Annex C. In addition, exporting Members are obliged to facilitate the work of other Member’s controlling authorities on their territories, where the SPS measure relates to control at the level of production. The figure below demonstrates a simple model of the control, inspection and approval procedures according to Annex C of the SPS Agreement.

The Notification Procedure Model :



Based on the figure, the procedure can be summarised as follow: (i) the applicants request information relates to the SPS measures in the importing countries through the Enquiry Points; (ii) the applicant sends all the document that are required to the Competent Body; (iii) when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise manner of all deficiencies; (iv) the competent body transmits as soon as possible the result of the procedure in accurate and complete manner to applicant; and (v) the applicant may take corrective action, if it is necessary, then submit to the competent body. Finally the competent body will determine whether the application can be accepted or not.

The SPS Agreement establishes rules in Article 8 and Annex C that allow WTO members to control,

inspection, and approval procedures, but it prohibits Members from using control, inspection and approval procedures for arbitrarily or unjustifiably importation of foreign products. These procedures include inspecting products for pests, diseases, and toxins before they are permitted entry into a country and approving the presence, or maximum tolerance level, of a contaminant in an imported food product.

This procedure will become a useful instrument of PP if the Member States use it properly, because implementing the control inspection and approval procedure demonstrates the authority of the states to regulate the importing products, such as GMOs/LMOs based on their interest and the objective of the SPS Agreement, as far as these kinds of measures are not being used as disguise protectionism. Obviously, each state has its own

mechanism of control, inspection and approval procedures.

Precautionary Principle under the SPS Agreement:

It is submitted that risk assessment and risk management may not be sufficient to prevent the adverse impacts of transboundary movement of GMOs/LMOs, because there are some loopholes in the risk assessment and risk management to cope up with the adverse impacts of GMOs/LMOs. For example, risk assessment is mandatory to be based on scientific evidence that may be certain, while the impacts of GMOs/LMOs are not certain. Thus, the risk analysis in the risk assessment does not cover adverse impacts that cannot be foreseen exactly.

It is generally accepted that there are situations where governments need to take measures to prevent risks on health even when sufficient scientific evidence regarding the risk is lacking. Thus, governments may act with precaution in order to protect against risks without waiting for the conclusive results of scientific analyses. This is commonly referred to as acting in accordance with the PP. However, the SPS Agreement does not mention explicitly the PP in its provisions.

In fact, the SPS Agreement expressly allows WTO Members to restrict international trade by adopting measures necessary to protect human, animal or plant life or health. The same language in the body of the Agreement describes the obligations of Members under the Agreement. The use of the word “necessary” circumscribes the scope of permissible restrictions on trade (Article 2 (2), the SPS Agreement). Interpreted with a focus on the word necessary, a Member would have to justify its restrictions on trade under a strict level of scrutiny to show their necessity.

In the SPS Agreement, the PP is implicitly embodied in paragraph 6 of the Preamble, in Article 3(3) and Article 5(7) of the SPS Agreement. These provisions explicitly recognise the right of Members to establish their own appropriate level of sanitary protection (ALOP), which may be higher (i.e. more cautious) than that implied in existing international standards, guidelines and recommendations [38]. Thus, the PP is not named expressly in the WTO legal provisions [65] and the AB has refused to commit itself to a particular articulation of the principle’s precise content and scope [30].

Recognising that one of the basic elements of PP is scientific uncertainty, it seems contradictory with the requirement of the SPS measures, which demands scientific evidence [3]. The contradiction can be observed from the provisions of the SPS Agreement, such as Article 3 (3) and Article 5(7) of the SPS Agreement. Article 3(3) of the SPS Agreement states:

“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 [other provision of the agreement].”

Thus, the SPS Agreement allows Members to impose higher standard but only where there is sufficient scientific justification to support Member’s determination that there is a need for stricter standard (Marc Victor, Spring 2001), and should be in accordance with the other provisions of the Agreement. Article 3(3) of the Agreement reflects the PP.

On the other hand, according to Article 2(2) of the SPS Agreement, Members have an obligation not to maintain an SPS measure without sufficient scientific evidence. However, Members may provisionally adopt SPS measures under Article 5(7) if the measure is imposed with respect to a situation where relevant scientific evidence is insufficient. Article 5(7) of the Agreement states:

“In cases where relevant evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.”

Based on the Article, measures not based on scientific evidence can only be maintained temporally. Besides that, the measure, which is adopted, should be based on available pertinent information, provided additional information is sought for an objective assessment of risk within a reasonable period of time [18]. Thus, the PP can only be applied provisionally.

Under the PP, the Member States are entitled to adopt protective measures on the basis of incomplete scientific knowledge even where the measures may seriously harm legally protected positions. Therefore, this does not imply that the right to be heard in administrative proceedings, even in the absence of rules governing the procedure in question, may be transposed to the legislative context leading to adoption of rules of general application. Moreover, scientific risk assessment is carried out as thoroughly as possible on the basis of the principles of excellence, independence and transparency in order to ensure objectivity and to preclude arbitrary measures [33].

The Role of Precautionary Principle under the SPS Agreement:

The use of the PP in the regulatory process is gaining acceptance at the international level where countries cope with risk assessment decisions in the face of substantial scientific uncertainties or where public health is potentially implicated. The PP encourages governmental authorities to err on the side of environmental or public health protection in formulating public policy in the contexts characterised by the conditions of scientific uncertainty.

One of the principles of the SPS Agreement is sound science (Article 3 (3), the SPS Agreement), in the sense that SPS measures, which are conducted by the importing states, must be based on scientific evidence. The provision is compatible with the PP, since the PP is actually part and parcel of sound science. Science is an active knowledge system in which new discoveries are made almost every day. However, scientific evidence is always incomplete and uncertain. The responsible use of scientific evidence, therefore, is to set precaution. This is more important for technologies such as GMOs/LMOs can either be controlled or recalled.

Those who support the PP tend to endorse precautionary measures in the face of any risk to the environment or public health without further engaging in an evaluation of the seriousness of the actual risk. They cite the difficulty of establishing scientific "certainty" on a particular biological health threat as justification for erring on the side of caution. Furthermore, this principle is seemingly endorsed by the very terms of the SPS Agreement permits Members to choose their own level of sanitary or phytosanitary measures (Article 3 (3), the SPS Agreement).

Those who oppose the PP tend to focus on the adverse implications of excessive cautious regulation in the absence of conclusive scientific evidence of the actual risk. These countries generally tend to endorse a wait and see philosophy that endorses scientific certainty as a precondition to adopting policy responses. Furthermore, these countries specifically reject the influence of "consumer anxieties rather than any actual adverse effects on human health" when conducting risk assessments of a particular health threat [29].

Thus, the adoption or acceptance of the PP, in the context of the SPS Agreement, would allow for potentially more trade-restrictive regulations than are necessary for the protection of human health. This would defeat the stated goal of the SPS Agreement of minimising the negative regulatory effects on international trade. The goals of protecting public health and minimising the adverse impacts of sanitary and phytosanitary regulations on international trade, within the context of the SPS Agreement, are frequently contradictory in nature, and present a terrible obstacle in the path of any attempt at harmonization [63].

Based on the Article 3(3) of the SPS Agreement, the Member States have a right to take SPS measures, which are higher than the international standard, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5 which establish procedures for determining whether scientific evidence of a health risk exists (Article 5, the SPS Agreement).

This provision is compatible with the protection of human, animal, or plant life or health relating to transboundary movement of GMOs/LMOs. The purpose of this requirement is to ensure that where a Member adopts a food-safety regulation provides more protection than the pertinent international standard, the measure in question has a genuine scientific basis and is not in actuality a form of trade protection. To this end, the SPS Agreement bars the imposition of food-safety measures that amount to "discrimination or a disguised restriction" (Article 2 (3) of the SPS Agreement) on trade based on arbitrary or unjustifiable distinctions. Similarly, the Agreement mandates that Members ensure that measures are not more trade-restrictive than necessary to achieve the appropriate level of protection [25].

On the other hand, Article 5(7) of the SPS Agreement obviously operates in such a way as to allow for precautionary responses to risks. It is interesting to note the degree to which public appreciation of risks may be relevant in the interpretation and application of Article 5(7). In this respect, it can be suggested that determinations of whether the scientific evidence in a case is insufficient for a risk assessment should take into account the seriousness of the risk in question.

For example, where a risk is understood to be particularly serious and to threaten highly valued interests, and yet relatively little information about the risk is available, then these factors must surely contribute to a determination of whether it should be possible to rely on Article 5(7). Under Article 5(7), this would be a temporary measure, but nowhere is there any indication of the length of time that a temporary measure can endure. The implication from the language of this article is that such a temporary measure could last until the scientific debate is resolved.

The Application of Precautionary Principle under the SPS Agreement:

Like the Cartagena Protocol, the SPS Agreement includes precautionary language. That language provides that in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent

information. However, in such circumstances, a Member has a continuing obligation both to obtain the additional information necessary for a more objective assessment of risk and to review the sanitary or phytosanitary measure accordingly within a reasonable period of time (Article 5 (7), the SPS Agreement).

The SPS Agreement prohibits discrimination. Article 2(3) reiterates the threshold requirement of the GATT that SPS measures may not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail and may not be applied in a manner would constitute a disguised restriction on international trade [32]. Certainly, efforts to embody the content and mechanism of the PP can be observed in both the literature as academic theory and in governmental guidelines for practice. This reflects the argument that the PP might have been incorporated into the international trade regime as a consequence of the preamble to the Agreement establishing the World Trade Organisation [41].

Therefore, it may be a certain theoretical basis that can be used to justify the implementation of PP in the SPS Agreement. Because of the potential impact of certain commodities in international trade such as GMOs/LMOs to some extent, the commodities may create serious or irreversible impacts to human, animal or plant life or health. Consequently, it is significant to protect human, animal or plant health and also the environment in general.

The general idea of Article 5(7) is very similar to the PP. This issue also appeared in the WTO *EC-Hormones* (Panel Report, *EC-Hormone*, WT/DS26/R/USA), *Australia-Salmon* (Panel Report on *Australia Salmon*, WT/DS18/RW), *Japan-Agriculture Products* (Panel Report on *Japan - Agricultural Products*, WT/DS76/R), *Japan-Apples* (Panel Report on *Japan -Apples*, WT/DS245/R) and *EC-Biotech* (*EC-Biotech*, United States (WT/DS291/R); Canada (WT/DS292/R); Argentina (WT/DS293/R) 29 September 2006). Article 5(7) of the SPS Agreement provides that Members may introduce provisional measures where there is insufficient scientific evidence. In *EC- Hormones*, the AB recognised that this provision reflected the PP [9]. It declined to make any findings on the status of the principle in the international law but emphasised that it had not been written into the SPS as an exception and that it could not be used to avoid normal interpretation of the provisions of the SPS. As a result, the version of the PP contained in Article 5(7) must be applied in the context of the SPS and subject to its conditions.

In particular, the right to introduce provisional measures is excluded if sufficient evidence exists to make an adequate assessment of risk. Members must also seek further information and review provisional measures within a reasonable period of time. A reasonable period of time depends on the

circumstances of each case, including the difficulty of obtaining additional information. The obligation to seek further scientific evidence and to carry out regular reviews is not part of the PP as generally expressed, for example, in the Rio Declaration [28]. Even though agreed research programmes usually accompany specific applications of the PP, they do not constitute legal conditions for its use.

However, requiring further research is inconsistent with the need to protect the interests of other States whose rights are affected by trade-restricting measures. Article 5(7) therefore acts as a gateway by incorporating its own version of the PP, which may constitute a *sui generis* application in trade law. On the other hand, Article 3(3) permits Members to impose measures leading to a higher standard of protection than granted by international standards, recommendations and guidelines. Members may introduce such measures if there is scientific justification for doing so, or if the higher level of protection can be justified according to the conditions contained in Article 5(1-8). Article 5(1) requires that national measures be based on a risk assessment, taking account of risk assessment techniques developed by relevant international organisations, and Article 5(2) requires the risk assessment to take into account, *inter alia*, available scientific evidence.

Thus, Members have discretion to apply the PP in two ways. Firstly, Members may choose to introduce provisional measures under Article 5(7), subject to the accompanying conditions. The PP is explicitly incorporated even if in a *sui generis* form. Secondly, Members may exercise discretion when choosing their level of protection, provided that a risk assessment has been carried out which supports the claim that there is an identifiable risk and the measure has a reasonably objective relationship with the risk assessment. Within those limits, the use of the PP to identify a risk and respond to it is complete and protected. Thus, the PP is also relevant under the SPS as a matter of legitimate discretion. The SPS therefore contains two apparent gateway provisions.

Though there are two gateways of the PP in the SPS Agreement, the application of the PP should satisfy the requirements, which are established in the provisions of the SPS Agreement. For example, those who want to apply PP under Article 5(7) should fulfill the requirements stated therein. There are four cumulative requirements [31] that must be met in order to adopt and maintain a provisional SPS measure under Article 5(7). Under the first sentence, the measure must be: (i) imposed in respect of a situation “where relevant scientific information is insufficient”; and (ii) adopted “on the basis of available pertinent information.” On the other hand, under the second sentence, the Member must: (iii) seek to “obtain the additional information necessary for a more objective assessment of risk”; and (iv)

review the measure accordingly “within a reasonable period of time.”

One important advantage to use the four requirements of the Article 5(7) to initiate precautionary measures is the feasibility of this mechanism. The first two requirements can be regarded as preconditions. They help the policy-makers to determine when to trigger precautionary management and how to initiate precautionary measures to handle the uncertainty. In the SPS Agreement, the precondition limits the adoption of the exceptional SPS measures to conditions where relevant scientific evidence is not clear or insufficient.

The other two requirements can be considered as obligations to the countries that take a PP. These two requirements, to obtain the additional information necessary for a more objective assessment of risk, and to review the SPS measures within a reasonable period of time, substantially match the nature of the precautionary measures. In fact, precautionary measures, by their very nature, should be temporary. The precautionary measure is an expedient measure that is only justifiable when the scientific evidence about a risk remains uncertain.

Theoretically, the use of the four requirements of Article 5(7) of the SPS Agreement for a precautionary decision or measures is apparent. It is a mechanism written in the context of the SPS Agreement, thus, each WTO Member has a right to enact. Firstly, Article 5(7) requirements are applicable to the practices of the WTO Members. Secondly, one of the aims that these four requirements achieve is to make sure the adopted provisional SPS measure is necessary to protect human, animal or plant life, or health, and will not constitute a disguised restriction on international trade.

However, the mechanism, which is based on the four cumulative requirements of Article 5(7) of the SPS Agreement to apply PP, is very difficult to apply. Since the risk assessment has started to justify SPS measure, the step will be continued by the adoption of available pertinent information, so it will be time-consuming and costly. This condition will be worse when the risk assessment has to be done by developing countries where the countries lack requisite knowledge, expertise and financial support.

Moreover, if the Member States failed to adopt pertinent information, the application of PP under the SPS agreement is not justified. On the other hand, if the two requirements have been carried out by the Member States, the other two requirements have to be accomplished too. Thus, it is mostly impossible to apply PP under Article 5(7), because the requirements of Article 5(7) are cumulative. It means when the Member States failed to comply with one of the four requirements of Article 5(7),

their SPS measure will not be justified under the SPS Agreement.

Conclusion:

The above discussion demonstrates that there are significant roles of risk assessment, risk management and control, inspection and approval procedure of the SPS Agreement on transboundary movement of GMOs/LMOs, though the SPS Agreement is not specifically aimed to regulate their transboundary movement. However, risk assessment and risk management in the Agreement are not sufficient to mitigate the adverse impacts of GMOs/LMOs. Therefore, the necessity to implement PP is reflected in paragraph 6 of the preamble, in Article 3(3) and in Article 5(7) of the SPS Agreement.

The PP cannot in any case override the explicit wording of Articles 5(1) and 5(2) of the SPS Agreement. The examination of the role and application of the PP reveals that despite the fact that the Agreement has accommodated PP provision implicitly, these provisions are mostly unenforceable in nature, and are applied ineffectively. The unenforceable nature of the provisions has been, to a large extent, caused by the formulation of the provisions are stringently based on the scientific evidence and the cumulative requirements of Article 5(7) that must be fulfilled by the Parties.

Consequently, the PP, which is reflected in the SPS Agreement, is generally unenforceable. Since the SPS Agreement is strictly based on scientific evidence and economic consideration; whereas, the PP is based on scientific uncertainty. However, it is fundamental to propose some solutions as to how the Member States can apply PP under the SPS Agreement.

The application of PP under the SPS Agreement should relate to the objective of the Agreement, which is to maintain the sovereign right of any government to provide the level of health protection it deems appropriate, but must ensure that these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers to international trade. Thus, by referring to the objective of the SPS Agreement, Member States have discretionary power to determine ALOP, which reflects the PP.

The application of PP under Article 5(7) can be materialised if the requirement as the precondition to apply PP under Article 5(7), for instance, “insufficient scientific evidence”, is substituted with “scientific uncertainty”. It will be very challenging, since the notion of insufficient scientific evidence is different from lack of full scientific certainty. However, if it is accepted by the Member States of the SPS Agreement and the DSB, the difficulty to apply Article 5(7) can be overcome.

The European Union has been very proactive in applying PP against imports from outside EU, especially from the United States. Nevertheless, at the inception of the proposed negotiations between them for a free trade agreement, which will weaken the multilateralism about international trade, the EU has clarified that the free trade agreement will not cover GMOs/LMOs [44]. It means that there will be no policy shift on the part of EU on the value of PP within the premises of the SPS Agreement. It is a good sign.

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