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Scientific Principle under the SPS Agreement

Eun Sup Lee
Department of International Trade and Studies
Pusan National University
Busan, South Korea
lieunsup@pusan.ac.kr

Sun Ok Kim
Department of International Trade
Changwon National University
Busan, South Korea
ksok@pusan.ac.kr

Zhu Zhu
Department of International Trade and Studies
Pusan National University
Busan, South Korea
zhuzhu@pusan.ac.kr

***Abstract*—This paper assesses the science-based requirements of the SPS Agreement through reviewing the judicial interpretation and application of the provisions concerned. The WTO system has been substantially positive in response to the concerns about human health, particularly, through the judicially proper application and interpretation of the SPS provisions concerned. Judicial interpretations made by the Appellate Body stand mostly for the proposition that sanitary measures must be based on scientific evidence and risk analysis. Such interpretations imply that judicial interpretation and application can substantially function to protect the health-related interests of WTO member countries. Despite such positive achievements of the WTO dispute settlement body to judicially treat the public health under the SPS Agreement, however, member countries representing free trade supporters and environmentalists do not currently seem satisfied with such performance. Considering the serious criticism against the dispute settlement body's interpretation of the scientific principles and risk analysis so far and the well-recognized assumption in WTO societies that the WTO is the best tool to treat both free trade and the environment, a more flexible and reasonable attitude of the dispute settlement body to treat the scientific issues is required.**

Keywords-science-based requirements, scientific evidence, risk assessment, appropriate level of protection, scientific justification, disguised restriction on international trade

I. INTRODUCTION

The Agreement on the Application of Sanitary and Phytosanitary Measures(hereinafter SPS Agreement) of the World Trade Organization (hereinafter "WTO") regulates measures applied to protect against a range of specified risks to animals, plants and human health, including those arising from additives, contaminants, toxins or disease-causing organisms in food. Being different from the Article XX of GATT, which is a passitive exceptional clause, the SPS Agreement is no longer marginalizing the legitimate regulatory concerns as mere "exceptions," but is categorizing as a positive "right". It sets forth the rights and obligations of WTO Members in respect of these measures adopted by Members to protect the health or life of human, animals, or plants that may, directly or indirectly, affect international trade.

The Agreement, not creating any substantive SPS measures per se, sets forth a number of requirements mainly to reduce the possible arbitrariness of governments' decisions in the field of SPS measures, in particular, stressing the importance of the analysis and assessment of objective and accurate scientific evidences.

This paper reviews the science-based requirements of the SPS Agreement with careful attention to whether the dispute settlement body has been biased toward the free trade ideology through the strict and conservative interpretation of the substantive and procedural aspects embodied in science-based principle or not by reviewing the judicial interpretation and application of the provisions on the scientific principle and risk assessment under the SPS Agreement. This approach is projected in that the WTO dispute settlement system has functioned as a major part[1] in deciding the relationship between WTO provisions and the protection of public health-related interests, and that the efficiency and applicability of the WTO agreements have mainly been evaluated and discerned through the judicial interpretation and application of the specific provisions made by the dispute settlement body.

II. APPROPRIATE LEVEL OF PROTECTION

A. Science-based Obligation

WTO members may take risk reduction measures based on their own risk management objectives, referred to as the member's "appropriate level of protection" or "acceptable level of risk". WTO members are free to determine their "appropriate level of health protection," as long as this level does not constitute arbitrary or unjustifiable discrimination or a disguised restriction on international trade. After the sufficient evidence is established and a risk assessment is properly conducted, it is up to the member country to assess the level of risk which is interpreted to be a prerogative of the members concerned.

As such, members may impose measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant

[1] *See* Mattew D. Taylor (2000), "The WTO Panel Decision on Australia's Salmon Import Guidelines: Evidence That the SPS Agreement Can Effectively Protect Human Health Interests," *Pacific Rim Law & Policy Journal*, Vol. 9, p. 480.

international standards, guidelines or recommendations, if the measures are scientifically justified.[2]

Regarding the determination of the appropriate level of protections, the "level of protection" has judicially been interpreted not to need to be a quantitative one, but it has to be sufficiently precise to allow a determination whether it can be achieved by the application of certain measures.

Even though the level of protection does not have to be quantitatively determined, considering the fact that the level is always going to be expressed in qualitative terms such as "negligible risk," the determination on the achievement of the adjectival description of the risk objective from the imposed sanitary and phytosanitary measure at issue would depend on getting a sufficient number of reputable scientists to testify it.

In determining the specified appropriate level of protection, prior to the Japan-Apples case, it has been thought that member governments are free to choose the "lowest level of risk" or even a "zero risk" as its appropriate level of protection, provided that the governments can show the scientific evidence establishing that there is some risk, however small.

In the EC-Hormones case, the Appellate Body addressed that there shall be a "rational relationship" between the SPS measure at issue and the corresponding risk. Following that, in the Japan-Apples case, the Panel determined, regarding a measure attempting to control negligible risk, that the requirement of maintaining such an appropriate SPS measure adopting with the "negligible" risk is very strict.

And finally, the Panel in the case did not approve Japan's measure due to unsatisfied scientific evidence. It indicated that Japan's SPS measure was "clearly disproportionate to the risk identified on the basis of the scientific evidence available". The panel's conclusion seems to be contrary to the traditionally recognized view that member countries can choose such negligible level of risks, provided that they can be proven to exist.

Thus the panel in the Japan-Apples case has been indicated to guard the strictness of the scientific justification criterion even though it did not explicitly introduce any minimum risk criterion.

Therefore, although member countries are allowed to determine their "appropriate" level of protection, members would not be permitted to adapt a level of protection greater than that which would result in the SPS measure being based on international standards, unless the setting of a stricter appropriate level of protection is scientifically justified, and the protection level is obtained and maintained only by means of the least-trade-restrictive measures.[3] As such, for the member countries' right to maintain their level of protection to be exercised properly, the science-based obligation should be supplemented by additional obligations regarding non-discrimination and "least trade-restrictive measures."

B. Non-discrimination Principle

The non-discrimination principle is stipulated in the Article 2.3 of SPS Agreement. It provides that member countries imposing SPS measures should not make an arbitrary or unjustifiable discrimination between members and should not constitute a disguised restriction on international trade. In addition, Article 5.5 provides that member countries should avoid arbitrary or unjustifiable distinctions resulting in discrimination or a disguised restriction on international trade. The contents of the non-discrimination principle provided in Article 5.5 are more or less overlapped by drawing upon the same core concepts to those in Article 2.3.

There have not yet been judicially clear interpretations about the meaning of the core concepts in Article 2.3, notably the concept of arbitrary or unjustifiable discrimination, and that of a disguised restriction on international trade. The determination about discrimination provisioned in Article 2.3, contrary to the GATT most-favored-nation and national treatment rules, is not made on the basis of the comparability of the products between member countries, but on the basis of comparability of the prevailing conditions in those countries, which is shared with the Article XX "chapeau" of GATT.

Establishment of the "acceptable level of risk" by the member countries should not constitute "arbitrary and unjustifiable distinctions," if such distinctions result in discrimination against/between imported good or a disguised restriction on international trade. As such, even though it is clearly provisioned that it is up to each member to determine the appropriate level of protection, these protection measures should be in some relation with an assessment of health-related risk that takes available scientific evidence into account.

The compatibility of the requirement demanding comparable levels of SPS protection has judicially been required. The Appellate Body ruled in EC-Hormones and the Australia-Salmon case under Article 5.5: i) comparable levels of protection are not required in comparable situations; ii) not applying comparable measures in comparable situations is arbitrary and unjustifiable; and iii) such measures constitute discrimination or a disguised restriction on international trade.[4]

As such the provision of Article 5.5 encompasses three constituent elements which cumulate in the presence of all three being required for a breach. First, for satisfying the consistency requirement, different levels of SPS protection are required to be adopted in situations which are different, but not so different to preclude meaningful comparison. Regarding the interpretation of the term "comparable," the Appellate Body, in the EC-Hormones, emphasized that

[2] Andrew, P. Thomson (2002), "Australia-Salmon and Compliance Issues Surrounding the SPS Agreement," *Law & Policy in International Business*, Vol. 33, p. 722.

[3] Jan Bohanes (2002), "Risk Regulation in WTO Law: A Procedure-Based approach to the Precautionary Principle," *Columbia Journal of Transnational Law*, Vol. 40, pp. 375-386.

[4] David G. Victor (2000), "The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years," *New York University Journal of International Law and Politics*, Vol. 32, p. 902. (footnote omitted)

"comparable" would not be interpreted "in the narrowest possible manner".

The Appellate Body, in the Australia-Salmon Case, illustrated that, when Australia adopted a "high or very conservative level of sanitary protection aimed at reducing risks to very low levels for ocean-caught pacific salmon, while the level of sanitary protection was definitely lower for herring and ornamental," the former salmon could acceptably be "compared" both to herring used as bait and to live ornamental fish. As such, the unique qualification in the SPS Agreement to specifically constrain the domestic level of SPS protection of the member country is the requirement of "the comparable levels of SPS protection in comparable situations" to be sought under Article 5.5.

Second, the differences in the levels of protection should not be either arbitrary or unjustifiable. The panel's notion that the presence of a "higher risk" would be such to justify the adoption of a higher level of protection seems to be accepted by the Appellate Body in the Australia-Salmon case. The concept of "higher risk," instead of not being defined, is treated as pertaining to the relative likelihood of disease introduction, which means if there is a higher probability or possibility, understood in quantitative or qualitative terms, of the emergence of a hazard, this will be regarded as a higher risk.

Regarding the relevance of higher risk to the "comparableness" required in Article 5.5, the Appellate Body, making assessment of the justifiability of differences in the level of protection with respect to natural and synthetic hormones used for growth promotion on the one hand, and natural hormones occurring endogenously in meat and other foods on the other hand, produced a conclusion that these differences in levels of protection were not arbitrary or unjustifiable. In doing so, the Appellate Body emphasized that there exists a "fundamental distinction" between "added hormones" and those "naturally-occurring."

Third, regarding the discrimination or disguised restriction on international trade, the concept of arbitrary or unjustifiable discrimination on the one hand, and a disguised restriction on the other hand, appear to be similar to the text of the chapeau of Article XX. However, there are "structural differences" between the chapeau and Article 5.5. The panel in the Australia-Salmon case interprets the concept of a "disguised restriction on international trade" to include, among other things, "restrictions constituting arbitrary or unjustifiable discrimination between products," however, the Appellate Body considers that all arbitrary or unjustifiable distinction in levels of protection will give rise to discrimination among production. As such, discrimination between products is not, in its own terms, relevant in assessing the existence of a disguised restriction on international trade.

C. Least Trade-Restrictive Measures

With relation to the "least trade-restrictive measures" in determining the appropriate level of protection, according to Articles 5.4 and 5.6, the objective of minimizing negative trade effects should be taken into account and the members' SPS measures are required not to be more trade-restrictive than required to maintain the appropriate level of sanitary or phytosanitary measures, which is, however, interpreted to be a restriction on the "choice of measure," not on the "level of protection." Article 5.4 requires a member country to take into account the objective of minimizing negative trade effects in determining their appropriate level of protection. However, this provision is construed as falling short of imposing legal obligation. Article 5.6 is, by contrast, forceful in nature by imposing a "least trade-restrictive measures obligation."

For the legitimacy under Article 5.6: i) The alternative must be reasonably available, taking into account technical and economic feasibility; ii) The measure must achieve the Member's appropriate level of SPS protection; and iii) The measure must be significantly less trade-restrictive than the alternative SPS measure. For legitimacy under Article 5.6, these three requirements should be satisfied accumulatively. Regarding the meaning of the term "more trade-restrictive than required," it will be interpreted so when there is another measure that is reasonably available when taking into account technical and economic feasibility, and that other measures achieve the appropriate level of sanitary or phytosanitary protection and is significantly less trade restrictive to trade. For proving a violation of the requirement that sanitary and phytosantary measures should not be more trade-restrictive than required to achieve their appropriate level of protection, an alternative measure to achieve the appropriate level of protection and to be significantly less trade-restrictive must be reasonably available.

With regard to the member country's autonomy in establishing its appropriate level of protection, as the requirements in Article 5.6 are construed as the weak proportionality requirements not implying a balancing of the value of the objective being pursued against the trade-restrictive effects of measure, there is no demand for a trade-off between trade restrictiveness and the level of protection. In such analysis, the one thing that is remained to fixed is the level of protection, which was affirmed by the Appellate Body in the Australia-Salmon case, stating that it was not established scientifically that the regulatory alternatives identified would be capable of achieving Australia's appropriate level of protection.

III. SCIENTIFIT EVIDENCE

A. Substantive and Procedural Requirements

Measures that "conform to" international standards, however, are deemed to be in compliance with this requirement. From this, a general obligation is induced to base the member countries' domestic SPS measures either on international standards or on a scientific justification either in the absence of an international standard or if a risk assessment has evidenced that a higher level of protection than the one established by international standards is appropriate.[5]

[5] Ilaria Filippi (2005), "Food Safety in the WTO: Where Do

The scientific justification discipline has substantively been analyzed in the Japan-Agricultural Products and Japan-Apples cases, where Japan's measures were determined to be maintained without sufficient scientific evidence.

The Appellate Body in the Japan-Agricultural Products case, noting the Japan's prerogative to adopt a stricter standard than an international standard subject to a scientific justification for such a high standard, stated that for a scientific justification to be secured, there should be a "rational or objective relationship" between the concerned measure and the available scientific justification, which was followed by the later case where it was interpreted that for the requirement of "sufficient science evidence" to be met there must be an "objective and rational relationship" between the SPS measure and the science evidence.

The Appellate Body, avoiding the creation of any standard for "sufficient" or "rational relationship," found that the rational relationship should be determined on a case-by-case basis and would depend on the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence. The Appellate Body found that the panel's reliance on expert's views on this question was within the panel's discretion on assessing the weight and value of the evidence, which implies that, while willing to defer substantially to panel assessments of the facts, the Appellate Body was not willing to defer to the member government's determination in the same way.

Regarding the procedural requirement of a risk assessment to be considered at the time of the enforcement of the SPS measure at issue, the Appellate Body stated that an objective relationship between the measure and scientific evidence is required because of an "objective situation that persists and is observable between the SPS measure and a risk assessment." As long as the scientific evidence can be showed at the time of the dispute on the concerned measure, then such evidence is presumed to be considered in development of the measure. As such, the "objective and rational relationship interpretation" of the "sufficient scientific evidence" criterion is not necessarily intrusive. Focusing on the logical relationship between the evidence and measure, such interpretation would make the member governments remain free to make regulations based on what they considered to be sufficient evidence, provided that there was a rational relationship between the evidence and the measure.

The Appellate Body's elaboration of the rational relationship test in the Japan-Agricultural Products case does, however, hint at more intrusive scrutiny by listing the "quality and quantity of the scientific evidence" as factors that are relevant to whether there is the requirement for an "objective and rational relationship." These interpretations are to solidify the importance of scientific evidence as a requirement of the SPS measures to be justified without being based on international standards[6] and to block the chance of being used as non-tariff barriers to international trade in the name of the protection of public health.

B. Relationship with Risk Assessment

In all of the SPS-related dispute cases, the question of whether the importing country used a proper risk assessment and provided scientific justification in imposing its preferred level of sanitary and phytosanitary protection has been fundamental to the determination of whether the measure constituted arbitrary or unjustifiable discrimination.

In the EC-Hormones case, the Appellate Body, upholding the decision of the Panel, agreed that Article 5.1 is a "specific application" of the basic obligation contained in Article 2.2. In other words, Article 2.2 and Article 5.1 should be "constantly read together". Article 2.2 focuses on the basic obligations of the SPS Agreement, while Article 5.1 construes the specific application of Article 2.2.

Indeed, in the case of a sanitary measure not to be based on a risk assessment in accordance with Article 5.1, this measure would be presumed, more generally, not to be imposed on the basis of scientific principles or to be maintained without sufficient scientific evidence. Therefore, if there is a violation of the more specific obligations set out in Articles 5.1, such violation would be presumed to imply a violation of the more general obligations under Article 2.2. The substantive threshold of "sufficient" scientific evidence provisioned in SPS Article 2.2 is also closely related to the procedural obligations requiring a proper risk assessment as stipulated in Articles 5.1-5.3.

IV. RISK ASSESSMENT

A. Substantive and Procedural Requirements

Although member countries have the right to decide their own appropriate level of protection, their decisions are subject to the requirements under Article 5.1 that address the requirements for the imposed measures to be based on risk assessments. In particular, if an appropriate level of protection adopted by a member is determined to possess higher level than would be achieved through the implementation of the measures imposed under acceptable international standards.

A risk assessment is defined as "the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of the importing member according to the sanitary or phytosanitary measures which might be applied, and of the associated biological and economic consequences" in the case of the risk assessments required for food-born risk, or "the evaluation of the potential for adverse effects on human and animal health" in the case of the risk assessments required for diseases or pest risks. Three elements for a valid risk assessment related to pest or disease risks have judicially been indicated: i) identify the disease or consequences on human and animal health associated with the entry, establishment or spread of the disease; ii) evaluate the likelihood of the occurrence of these effects; and iii) evaluate the probability or potential of

We Stand?,"*International Trade Law Review*, Vol. 11, p. 71.

[6] James D. Thayer (2005), "The SPS Agreement: Can It Regulate Trade in Nanotechnology?," *Duke Law Technology Review*, Vol. 2005, p. 32.

the occurrence of these effects according to the SPS measure which might be applied.

The first requirement for a valid risk assessment is satisfied when it identifies concerned diseases and the potential economic and biological impact that would result from contamination of local plants or animals. The second requirement is satisfied when either qualitative or quantitative assessment of the probability of contamination or damage is made and only "some evaluation of the likelihood" is not enough. The third requirement is met when it evaluates the relative risks associated with the SPS measures imposed "in any substantial way."

As such, the risk assessment is interpreted as the "scientific process" to examine the magnitude and distribution of possible risks, which is different from "risk management" to employ risk assessment as well as many other factors in determining and attaining the appropriate level of risk. This risk assessment should find evidence of an "ascertainable risk that is, it is not sufficient for governments to impose regulations simply on the basis of the "theoretical risk" that underlines all scientific uncertainty. To be precise, the "evaluation of risk" in a "risk assessment" should be distinguished from the "determination of the appropriate level of protection" and the theoretical uncertainty is "not the kind of risk" to be assessed under Article 5.1.

Herewith, the term "likelihood" is synonymous with the term "probability," which means that a proper risk assessment would evaluate "the probability of the entry, establishment or spread of diseases" as well as the associated potential biological and economic consequences and the probability of entry, establishment or spread of these diseases, according to the SPS measures that might be applied. Risk assessment should include an account for economic factors, such as potential loss in production or sales, if a pest or disease enters the country, as well as the cost-effectiveness of different measures that could limit such risk.

The requirement of a risk assessment itself, besides the procedural requirement to obtain a risk assessment, is a "substantive requirement" to require a relationship between the measure and the risk assessment. In addition, the risk assessments should not to be based entirely on research in the physical sciences or examined only as a quantitative risk.

Regarding the interpretation "based on a risk assessment," according to the Panel's interpretation, the competent EC authorities actually had to take into account risk assessment studies at the time they promulgated their SPS measures in order to satisfy the "minimum procedural requirement" imposed by Articles 5.1 and 5.2. The Appellate Body, however, rejected the Panel's "minimum requirement" and emphasized the "substantive requirements" for the regulation of the adoption of SPS measures and concluded that a member might rely on risk assessment studies performed by another member in making its risk assessment.

The requirement of "base on risk assessment" is satisfied if the "conclusions of the SPS measure and a risk assessment are comparable," which means that whether the implementing member actually considered the risk assessment at the time of implementation is thus irrelevant. As such, the Agreement identifies the substantive issues to be addressed in the risk assessment. However, it does not stipulate any procedures of the risk assessment to be conducted, just like in the case of the procedural requirement of scientific evidence.

B. Appropriate Role of Science

There have been the Appellate Body's judicially progressive stances towards a more intensive review of the scientific evidence supporting the imposed measures and underlying risk assessment, as well as struggling with defining an "appropriated role for science" in a context where competing values are in play. Flexibility has sometimes judicially suggested to the member countries in emphasizing sound scientific evidence as a basis for appropriate risk assessment, with allowance of greater room for social considerations to inform risk assessment.

For example, the Appellate Body stated: "The risk assessment does not have to quantify risks in the sense of assigning risks numerical values. Instead, risks can be expressed in qualitative terms which allow a much greater scope for subjective judgments"; "There is no minimum level of risk that must be demonstrated in the risk assessment. Moreover any level of risk above zero could potentially justify SPS measures"; "A member's risk assessment can be based on what may be a divergent opinion coming from qualified and respected sources".

As such a broad room appears to be suggested in making risk assessment, even in the case that a substantive standard of review is required, then, in practice, the Appellate Body appeared to maintain a much narrower notion of risk assessment relying much more closely upon the majority scientific opinion about the health-related environmental measures at issue. For example, the Appellate Body, refusing to give one scientist's opinion any weight, stated that the scientist's opinion on the issues does not purpose to be the result of scientific studies, and accordingly that single divergent opinion appears not to be reasonably sufficient to overturn the contrary conclusions reached in the scientific studies on the issues. The Appellate Body's statement has, however, been evaluated to be a somewhat ambiguous statement.

The Appellate Body further, disapproving the EC-relied scientific studies, reasoned that the specificity to the case on the issue was not sufficient and the general association between exposure to increased hormone levels and the development of cancer was only treated without addressing the more specific situation of cancer risk posed by consuming hormone residues in beef.

The Appellate Body's rulings towards a narrower notion of risk assessment have two effects in doing risk assessment. One is that some minimum quantum of positive scientific evidence is required to support the identification of a risk and the other one is that the type of scientific evidence supporting the risk assessment should be "direct" scientific evidence establishing a link between the product of concern and a particular health-related environmental risk, rather than "indirect" evidence.

As such, the scientific principles have judicially been treated narrowly and strictly, however, a substantial degree of flexibility would be allowed to the member countries in determining their protection level and measures even though they are based on the objective minority scientific viewpoints, particularly in the case where serious or irretrievable damages to a human being's health are concerned. It implies that the science-based requirements of the SPS Agreement have not been too strictly or improperly interpreted and applied by the Appellate Body.

V. CONLUCSION

Conventional environmentalists has been seriously made against the WTO and the SPS Agreement that the WTO system has improperly treated human health concerns and that the rulings and decisions made by the dispute settlement body has hurt the member governments' ability to settle down their own standards of health-related environment issues by imposing on the governments the burdensome onus of proof to support the scientific validity of the SPS-related measures concerned. There have also been seriously expressed concerns about the SPS Agreement which would lead to a global "race to the bottom" in relation to public health standards.

However, the WTO system has been substantially positive in response to the concerns about human health, particularly through the judicially proper application and interpretation of the SPS provisions concerned. Even though the Appellate Body's decisions on the cases appear to make little account of public health by stating the SPS-related measures to be inconsistent with the SPS Agreement, such decisions just declare that the sanitary measures should be based on scientific evidence and proper risk assessment by disapproving the sanitary measures with no rational basis in science.

Member countries representing free trade supporters and environmentalists do not currently seem satisfied with such performance. Contrary to the conservative environmentalist's assertion on the "overall race to the bottom," free trade supporters have worried about the positive role of scientific principles at the expense of free trade expansion or the manner of the science-based provisions to be judicially interpreted and applied.

Considering the serious criticism against the dispute settlement body's interpretation of the scientific principles and risk analysis so far and the well-recognized assumption in WTO societies that the WTO is the best tool to treat both free trade and the environment, a more flexible and reasonable attitude of the dispute settlement body to treat the scientific issues is required under the condition that the body is well equipped with the capacity to read the health-related scientific aspects of international trade. This is because the literally strict interpretation and application of the science based provisions would not be sufficient to cover the newly emerging food and health-related risks.

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