

RISK ASSESSMENT UNDER SANITARY AND PHYTOSANITARY MEASURES

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ABSTRACT

Sanitary and phytosanitary measures are not only required for protection of human life against hazardous substances, but also implemented for overall protection of the environment. The nations to this agreement must conform to the international standard specified for food items. The nations will be free to devise methods for assessing risks associated with such food products. This agreement also speaks of level of protection that the nations can decide upon based on risk assessment. However, the level of protection should not be so to lead to become arbitrary or unjustifiable. Under this agreement nations are free to take specific measures, but that should not act more than the normal trade restriction. Moreover, the protection measures are adopted, which are necessary to protect the human, animal or plant life and health.

INTRODUCTION

The sanitary and phytosanitary (hereinafter SPS) agreement protects the right of member nations of World Trade Organization to take health safety measures, otherwise known as SPS measures, to protect the human, animal or plant life and health. Any member nation who takes some measure which may affect trade at international level and the concerned measure is connected for the protection of life and health of human, animal or plant, the concerned nation will have to maintain such measures as per the conditions of SPS agreement. The definition of measure¹ is found in

¹ Sanitary or phytosanitary measure — Any measure applied: (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; (b) to protect human or animal life or health within the territory of

annex A of the SPS agreement. Under the definition clause the term ‘Measures’ means and includes that any measures are taken for the purpose of protection of life and health of human, animal or plant against certain pests, diseases or such organisms which carry diseases. Similarly, the measures which are taken for the purpose of protecting the life and health of human, animal or plants against the entry in the member nations of harmful additives, contaminants, toxins or disease-causing organisms found in food, beverage or any other kind of feedstuffs. At the same time, the member nations can take measures for the protection of life and health of human being against the entry of such animals which are carrying diseases or plant products which are harmful to human health. However, the member nations may have restrictions on their rights to impose SPS measures.

MEMBER’S RIGHTS TO IMPOSE SPS MEASURES AND RESTRICTIONS THEREOF

The rights of the members on putting SPS measures are not unlimited². The member nation will have to satisfy the ground that imposition of SPS measure is done on necessity and this extent is limited to protect the life and health of human, animal or plant. What should be the nature of measure has been established in *EC-Biotech*³ case. In this case the dispute settlement body of WTO specified that a general moratorium on Biotech approval cannot be considered as requirement or procedure, as per the provision of risk assessment⁴ under SPS agreement. In this connection, any SPS measure should be taken based on sufficient scientific evidences. Therefore, no member nation should use evidence as in the form of mere information to take SPS measure. In *Japan*

the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests. Sanitary or phytosanitary 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 labelling requirements directly related to food safety. Available at https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm (Last visited on 10.03.2017)

² See, Articles 2.2 and 2.3, Sanitary and Phytosanitary Agreement

³ DS291, 292, 293, the dispute settlement panel of WTO, circulated its report on September 29, 2006 and the report has been accepted on November 21, 2006. Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds291sum_e.pdf (last visited on 10.03.2017)

⁴ See, Article 5.1, Sanitary and Phytosanitary Agreement

*Apple*⁵ case the appellate body accepted the panel's report and clarified that substantial information which is insufficient can be considered as information only and not as evidence. Therefore, in case of scientific uncertainty member nations can take provisional measures. Risk assessment shall be successful, once, the assessment has been done based on efficient and sufficient scientific evidences. Another example can be cited from *EC-Hormones*⁶ case, where the European Communities restricted the entry of meat and meat products from America on the ground that it contains certain hormones which are harmful to life and health of human beings. Though, the panel found there are matters with regard to human health issue. However, the appellate body did not accept the plea and stated that the specific SPS measures can be taken by any member nation, provided the same measure is of international standard. Therefore, risk assessment would be successful if the scientific evidences show that the measures adopted by the member nation is of international standard. Moreover, conforming SPS measures and basing on SPS measures are different.

DIFFERENCE BETWEEN BASING AND CONFORMING OF SPS MEASURES

In a domestic law to follow the mandates of SPS agreement, cannot be called as based on SPS agreement, but one can say that the domestic law is in conformity with SPS agreement. Accordingly, when it is said that a measure is based on international standard, it means that such measures are supported by the international standard. More interestingly, it can be noted here that the parameters mentioned to maintain the international standard, have been followed, therefore, such measure is based on international standard. However, there may be scientific uncertainty to reach to quantum of level of international standard even if followed those parameters. In this regard, the expression 'conform' is more scientific and one can say that to conform to international standard, means completely at the quantum of level of such standard. Therefore, to conform with international standards are more specific in relation to SPS agreement and GATT. However, the burden of proof is with the complainant and not with the respondent. Since, the expression 'conform' enjoys more precision in terms of maintaining the quantum of level of international

⁵ DS245, the dispute settlement panel of WTO, circulated its report on July 15, 2003 and the report has been accepted on December 10, 2003. Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds245sum_e.pdf (last visited on 10.03.2017)

⁶ DS26, 48, the dispute settlement panel of WTO, circulated its report on August 18, 1997 and the report has been accepted on February 13, 1998. Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds48sum_e.pdf (last visited on 10.03.2017)

standard, therefore, the burden of proof is heavier. Under SPS agreement, there is a possibility of imposing higher level measures than that of international standard.

IS IT POSSIBLE TO IMPOSE HIGHER LEVEL OF PROTECTION ON SCIENTIFIC GROUND?

There is a possibility of imposing higher level of measures by the member nation than that of international standard as mentioned under Article 3.3⁷ of SPS agreement. First, higher level of measures can be imposed provided that there is scientific justification for such imposition of higher level of measures for the protection of life and health of human, animal or plant. Second, it is left to the member nation to take a separate high level of measures which is the consequence with the level of protection adopted by the member nation as per the requirement of Article 5.1⁸ read with Article 5.8⁹ of SPS agreement. Therefore, it is the wish of the member nation that they can choose a higher level of measure than that of international standard, but there must be scientific justification or at least the member nation should show that the level of protection implemented as per the requirement of assessment of risk. It is interesting to note here that, the appellate body of WTO clearly mentioned in *EC-Hormones*¹⁰ case that these two conditions as mentioned above are not very clearly depicted under Article 3.3 of SPS agreement.

PROCEDURE TO ASSESS RISK FROM PESTS OR DISEASES

⁷ 3.3, SPS Agreement-Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.(2)Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

⁸ 5.1, SPS Agreement-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.

⁹ 5.8, SPS Agreement-When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

¹⁰ See, *Supra* Note. 6

SPS agreement is very particular on procedure regarding risk assessment. The three conditions which are required to be followed as mentioned in *EC-Salmon*¹¹ case, where the European Communities imposed ban on entry of farmed Salmon from Norway, which is also an international issue of anti-dumping law. The WTO panel stated that there are three requirements which should be fulfilled to determine this kind of risk assessment from pests or diseases. First, identification of pests or diseases by the member nations would like to stop the entry of such food product consisting of risk of diseases. Along with this, potential health hazard and loss of economy should also be shown in the report. Second, the member nation who would take steps to stop the entry of such product must examine the situation and state that the possible entry and spread of disease will contribute significantly the biological and economic negative consequences of such nation. Third, the member nation should also evaluate the spread of pests and disease in the concerned nation and how that will affect the SPS agreement and measures thereof.

RISK ASSESSMENT ON FOODBORNE RISK

There should not be difficulty to make a conclusion that how risky would be to take such food items or beverages which are consisting of harmful additives or contaminants or toxins or even microorganism causing diseases. This has bearing not only on health but on life of human as well. Under SPS agreement, there are two requirements to be fulfilled for assessing the risks measures. According to *EC-Hormones*¹² case, first, the member nation should focus and identify the adverse effect on animal or human health because of consumption of such food items which are consisting of harmful additives or contaminants or toxins or bearing microorganism carrying serious diseases. Once, it is proved that in taking this food item will have serious health issue to animal or human, then the second condition will come to play. Second condition is to examine the potential of hazards of such health effects. In the other words, it is the member nation, who will have to prove that consuming such food items consisting of the above-mentioned harmful elements will substantially damage the health of the human or animal. However, SPS agreement also speaks of other requirements, where one can assess risk factors from such food items.

¹¹ DS337, the dispute settlement panel of WTO, circulated its report on November 16, 2007 and the report has been accepted on January 15, 2008. Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds337sum_e.pdf (last visited on 10.03.2017)

¹² See, Supra Note. 6

OTHER REQUIREMENTS FOR CONDUCTING RISK ASSESSMENT

Regarding, other requirements that the member should keep in mind while conducting risk assessment, are not mentioned extensively under SPS agreement. However, the findings of the appellate body and panel under WTO, both have made many observations, which may be considered as other requirements. According to the appellate body of WTO, under the *EC-Hormones*¹³ case, the other requirements would be, first, the risk assessment may be of distinct type, therefore, this risk assessment should be of a specific type of a particular case and should not be considered in generic sense. Second, member nations should not conduct their own risk assessment. Rather they should depend on the risk assessments conducted by international organization. This similar provision is also available under Article 5.1 of SPS agreement. Third, to understand the real picture of adverse effects on human health the risk assessment should not be limited to laboratory test, rather it should go beyond and examine the actual or potential adverse effect in the real world where people live and die. Fourth, risk assessment should not lead to theoretical knowledge and practices, it would be effective if the risk assessment shows the field proof of substantial risk associated with food item containing hazardous elements which would impair the natural health and life of human and animal. Another requirement was developed by the dispute settlement panel of WTO in *Japan Apple*¹⁴ case. According to this case SPS measures are the consequences of sufficient scientific evidences. However, as scientific technologies are progressing and in future more advanced technologies will be witnessed, therefore, the scientific evidences based on which risk assessments are being done currently, also cannot be stable and cannot address the future crisis, therefore, such risk assessment should be reviewed with the new advanced technologies in future.

WHAT SCIENTIFIC AND TECHNICAL FACTORS TO BE CONSIDERED DURING ASSESSING THE RISKS?

Under Article 5.2¹⁵ of the SPS agreement while assessing the risks of food items certain technical and scientific factors should be kept in mind. Such as, relevant product and process methods and

¹³ See, Ibid.

¹⁴ See, Supra Note 5

¹⁵ 5.2, SPS Agreement-In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of

techniques; scientific evidences which are currently available; existence of pests or disease-free areas; identify the areas where pests and diseases are prevalent; identify the ecological and environmental condition which are relevant for such risk assessment; proper method for inspection, testing method and collection of samples and facilities connected with quarantine and other treatment.

LEVEL OF PROTECTION BY MEMBER NATION ON SPS MEASURES

Based on international standard, the member nation is free to choose its own level of protection. Accordingly, the nation concerned shall be at liberty to fix its own level of protection for healthy life of human, animal or plant. According to Article 5.4¹⁶ of SPS agreement, the purpose of fixing level of protection is basically to minimize negative trade effects, therefore, a nation when is going to choose its own level of protection should keep in mind that the action should not distort the international trade. Similarly, under Article 5.5¹⁷ of SPS agreement, there should be effort of the nation to bring consistency in the level of protection in conformity with international standard. However, to counter this observation about consistency as per the findings of *EC-Hormones*¹⁸ case, where the WTO appellate body clearly mentioned that a member nation can fix the level of protection by its own as *ad hoc* measure, which will be temporary only. Therefore, the other meaning of the same article would be getting consistency with regard to level of protection is not practically possible. Another requirement under the same Article is that a member nation should avoid legal obligation because of fixing its own level of protection, if that level of protection amounts to discrimination and preferential treatment, which will act as trade distortion.

GROUND FOR VIOLATION OF ARTICLE 5.5 OF SPS AGREEMENT

specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

¹⁶ 5.4, SPS Agreement-Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

¹⁷ 5.5, SPS Agreement-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. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

¹⁸ See, *Supra* Note. 6

The violation of Article 5.5 of the SPS agreement is possible under three grounds. First, the member nation has fixed different level of protection under different situations. Merely, claiming different situation will not be enough the concerned nation will have to show comparable data on this issue. Second, as soon as the member nation has fixed its own level of protection that must lead to arbitrary or unjustifiable situation on the ground that differences in the treatment of different situations. Third, member nations own level of protection which are shown as the arbitrary or unjustifiable now leads to discrimination or distinguished trade restrictions. This situation is possible when there is absence of scientific justification.

INSUFFICIENT SCIENTIFIC EVIDENCE AND SPS MEASURES

There is a difference between scientific uncertainty and insufficient scientific evidence. In the first case, the result is uncertain because the experiment is not properly concluded. In the second case, it shows that scientific evidences are not sufficient to take a call on risk assessment. Under Article 5.7¹⁹ of SPS agreement the member nation can take provisional SPS measures, where scientific evidences are not sufficient. In *Japan-Agricultural Products II*²⁰ case it was clarified by the appellate body of WTO that a member can take provisional measures in case of insufficiency of scientific evidences. However, the provisional measure cannot continue for long, accordingly, there will be certain conditions to be fulfilled by such member nation. For example, provisional SPS measure can be imposed only in relation to a situation, which is comparable, where scientific evidences are available insufficiently. Such provisional SPS measure can be adopted on the basis of relevant information, by which one can conclude that there will be no possible adverse effect to human health or life. This provisional SPS measure will be successful once the member nation who is imposing so, also making effort to obtain additional and pertinent information which is necessary to assess the risk associated in such food items. Finally, as the provisional SPS measure

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

²⁰ DS76, the appellate body of WTO, circulated its report on February 22, 1999 and the report has been accepted on March 19, 1999. Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds76sum_e.pdf (last visited on 10.03.2017)

cannot go for long period, therefore, such measures shall be reviewed in a time bound fashion so that the risk associated with the human health of life can be delayed.

CONCLUSION

It is true that food items are traded internationally and any risk associated with such food item, because of presence of harmful additives or contaminants or toxins or such microorganisms which are carrying harmful diseases, cannot be traded internationally because of presence of potential hazards to the life and health of human, animal or plants globally. SPS agreement provides ample opportunity to member nations to assess the risk and fix the level of protection so that there could be protection to life and health of human beings. International standards have been fixed, so that national level of protection can be in conformity with such standard and maintaining such parity will not act as trade distortion. However, under SPS agreement there is scope for fixing own level of protection by the member nation, but that should not go against the interest of other member nations too. In case of absence of proper scientific evidences regarding the risk assessment, the member nation can take provisional SPS measures. This is a temporary facility available to the interested nations but cannot go for a long period of time. It can be concluded here that no nation will take any risk with the agricultural products which are consisting of harmful elements by which the life and health of the human, animal or plants can be put at danger. Therefore, scientific level of protection, which is compatible to international standard must be practiced by the member nations to promote the life and health of human beings.