WORLD TRADE ORGANIZATION

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REVIEW OF THE SPS AGREEMENT

Adaptation to regional conditions – Equivalence

Submission by the European Communities

ARTICLE 6 - Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organisations.

2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

ARTICLE 4 - Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures

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I. INTRODUCTION

1. The purpose of this paper is to give an overall view of the regionalization policy that the European Communities has developed to prevent the spread of organisms and diseases potentially harmful for humans, animals and plants, with the aim of protecting both human, animal and plant life or health without creating unjustifiable trade restrictions and thus without unnecessarily interfering with either intra-Community trade or importation from third countries.

2. The completion of the Internal Market in the European Communities implied the abolition of controls, including veterinary and phytosanitary checks, at the borders between member States. Animals, products of animal origin, plants and plant products moving within the Community should be checked at origin to ensure compliance with health rules, and random checks may be made at their destination. Exports to the European Communities are required to meet health standards at least equivalent to those applied at EC level.

3. As human and animal diseases and plant pests have never respected national boundaries, the concept of regionalization or "zoning", had been present in EC sanitary and phytosanitary legislation long before the establishment of the internal market. With the abolition of border controls, policy was reinforced and extended to cover all the pests and diseases of major concern.

4. Similarly, when assessing the eligibility of a country to export live animals, products of animal origin, plants or their products to the European Communities, account may be taken of the sanitary or phytosanitary status of regions within the country as well as of the whole country.

5. This principle of regionalization has been internationally recognized, incorporated in the SPS Agreement and adopted by the relevant international standard-setting bodies. The application of regionalization for SPS measures, may contribute to meet the provisions of Article 5.6 of the SPS Agreement, i.e.: to choose the least trade-restrictive measures possible.

6. In EC legislation a distinction is made between the sanitary and the phytosanitary field.

II. SANITARY MEASURES

7. Adjacent countries or parts of countries which have the same animal health status and similar disease controls can be considered as a *region.*

8. The European Communities has applied this above definition in the recognition of regions free of certain diseases, infected regions and areas of high or low disease prevalence, as required by Article 6 of the SPS Agreement. Regionalization may take several forms:

- Free region: where a part of an affected territory is declared free of a disease, e.g.: Foot-and-Mouth Disease in Zimbabwe; African Swine Fever in Spain.[1]

- Infected region: part of a territory is declared infected.

- Protected area: where a particular zone of a territory has a special health status, e.g.: IBR in Denmark.

- Low- incidence area: where part of an infected territory is declared to have a higher health status, e.g.: Foot and Mouth Disease in part of Brazil.

[1] See Annexes I and II.

9. We consider regionalization for *infected regions* as the application of strict controls to a country or part of a country where a disease exists, in order to control and eradicate it while preventing the spread to other areas, thus permitting free movement of animals and products outside the affected areas, irrespective of the country's borders and without risk of extension of the disease to other areas.

10. Article 2.2 of the SPS Agreement requires Members to 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.

11. Optimally, before a decision to restrict a region is taken, a risk assessment should be carried out to identify all the factors relevant to the choice of sanitary measure or measures that best meet the chosen level of protection. An outbreak of an epidemic disease will require in most cases immediate emergency measures to be taken before a risk assessment can be completed.

12. The assessment should include risks linked with the country of origin, the commodity to be imported and the place of destination. This evaluation will help in reaching a final decision on trade of a given commodity. The following elements should also be considered:

- animal population, epidemiological data, such as disease history and pathogenesis, possible vaccination, surveillance and eradication programmes[2];
- controls on movements of animals, products and trade flows;
- animal identification and recording;
- ante- and post-mortem inspection systems;
- diagnostic capability;
- presence of vectors and possible reservoirs, e.g. in wild animals;
- presence of the harmful organisms in adjacent areas;
- geographical nature (presence of physical barriers) and meteorological conditions;
- possible use of buffer zones.

13. When assessing the application of regionalization in an exporting country, the primary element to be taken into consideration is the quality of the service in charge of implementation and control of the policy. Acceptance of trade when a decision on regionalization is taken requires full confidence in the certifying competent authority.

14. A region should be defined on the basis of geographical features, vector studies, meteorological conditions, epidemiological data and administrative boundaries. In the case of the European Communities, the area may cover territory in neighbouring member States. A restricted area must be adequately controlled by the national competent authority. In addition, in the European Communities, the Commission's Veterinary Inspectorate from the Food and Veterinary Office carries out inspection missions to check on the implementation of the rules by member States. Monitoring inside and outside the area should be carried out routinely by the competent authority. Surveillance must be maintained and, in some cases, serological surveys are necessary to assess the prevalence of a disease.

[2] In the occurrence of a disease in wild animals, the size of the area, the control/eradication measures and the eventual restrictions to trade, should be established in relation to the risk that the disease may persist in the infected population and be transmitted from the infected animals to other wild and domestic animals

III. PLANT HEALTH

15. In the plant health legislation, the regionalization principle is introduced through the concept of "protected zones", exposed to particular plant health risks, and to which special protection is accorded. There, special arrangements are necessary to take account of differing pest and disease situations and differing crop and growing conditions within the European Communities**.**

16. Two types of protected zones can be identified:

(a) Zones in which pests and diseases established in one or more part of the European Communities are not endemic or established; e.g.:

Bark beetles and woodborers of the genera Scolytus and Ips affecting wood of conifers with bark or isolated bark of conifers. Protected zone are recognised for:

- Ips aminutus in Greece, France (Corsica), Ireland and United Kingdom;

- Ips typographus in Ireland and United Kingdom;

- Ips cembrae in Greece, Ireland, United Kingdom (Isle of Man and Northern Ireland).

(b) Zones in which there is a danger that certain harmful organisms will establish, due to ecological conditions, despite the fact that the organisms are not endemic or established in the European Communities.

17. Both the border of the protected zone and the type of special protection must be specified on a case-by-case basis, taking into account, *inter alia,* the specific biological interaction of the host plant and harmful organism concerned.

18. The area of a protected zone in the European Communities may cover an entire country, whereby the limits of the zone may coincide with natural borders of the member States, different countries, or may be an uninfested part of a country situated within a generally infested area of that country.

19. The recognition of a particular protected zone within the European Communities based:

- on a request of a member State(s);

- an official confirmation by the responsible official body of the member State introducing the above request, that the relevant pest or disease, in respect of which the zone is to be recognized as a protected zone, is not endemic or established there, and

- an approval under the EC procedure involving the monitoring and evaluation of inspections carried out following the above official confirmation, by the Plant Health Inspection Unit of the EC Food and Veterinary Office.

20. Absence of the pest or low prevalence must be confirmed by appropriate monitoring and surveillance. EC legislation lays down rules for surveys to be carried out. EC member States must take action in order to prevent the entry into the zone, the spread within the zone, or in order to eradicate a pest or disease of unknown origin. Upon detection, the presence of the harmful organism

must be notified and a risk assessment undertaken by the Commission together with the member States in the framework of the Standing Committee on Plant Health.

21. The concept of regionalization is also applied for import of specific plant products from some third countries. Similar criteria as for the recognition or the abolition of protected zones in the European Communities are taken into consideration.

IV. EQUIVALENCE

22. When assessing the possibilities for trade where one or more of the Members concerned operate a regionalization policy, it will be necessary to apply the principles of equivalence because the prevailing conditions in the exporting country, being adapted to its particular circumstances as described above, will be different from those in the importing country. Nevertheless, it may be possible to decide that the different measures applied in the exporting country still meet the level of health protection chosen by the importing country.

23. In accordance with the provisions of Article 4 of the SPS Agreement, it is incumbent upon the exporting country to demonstrate objectively to the importing country that the measures applied meet the importing country's chosen level of protection. Furthermore, reasonable access must be given to the importing country to check on the effectiveness of the measures. In the case of regionalization for disease control, it is essential for the Member operating the policy to give rapid and comprehensive information to its trading partners and to up-date this information regularly. As the circumstances of each disease outbreak or for the establishment or spreading of a pest are different, the actual measures applied must be adapted to those circumstances. Measures will also be different in each case, even though they are based on the same principles. For this reason, it is advisable to facilitate access for visits by importing countries from an early stage, in order to protect trade by demonstrating the effectiveness of the different measures in each case.

24. In the medium and long term, a Member operating a regionalization policy may seek to negotiate an agreement as provided for in Article 4.2 of the SPS Agreement, in order to have a framework of mutual trust and understanding. This will avoid having to renegotiate access with trading partners each time a regionalization decision is applied. An agreement should set out the principles under which regionalization will be operated, allowing the importing country to be satisfied that its interests are protected without having to make inspections in every case before trade can be allowed.

25. Where equivalence is acknowledged and embodied in an Agreement, special standardised sanitary and phytosanitary certificates might be used. In addition, Members may envisage to reduce the frequency of controls on specific imported goods.

26. In the absence of an agreement, it is necessary to determine whether a sanitary or phytosanitary measure implemented and maintained by an exporting Member achieves the importing Member's appropriate level of protection. The general steps outlined below provide a structured approach based on risk assessment:

(a) request from the exporting Member and identification of SPS measures for which recognition of equivalence is sought;

(b) explanation by the importing Member of the objective of its SPS measures, including an assessment, as appropriate to the circumstances, of any risks that the relevant measures are intended to address, and identification by the importing Member of its appropriate level of protection;

(c) provision of information by the exporting Member supporting its view that its sanitary or phytosanitary measures achieve the importing Member's appropriate level of protection;

(d) evaluation by the importing Member of whether the exporting Member's SPS measures achieve the importing Member's appropriate level of sanitary protection; this step may include an evaluation of:

(i) the risks identified by the importing Member and evidence provided by the exporting Member that its SPS measures effectively address those risks;

(ii) the legislative authority, standards, practices and procedures including those of laboratories, as well as the programmes in place to ensure that the domestic requirements of the exporting Member and the importing Member's requirements are met;

(iii) the documented structure of the relevant responsible authorities, their command chain, their authority, their operational procedures and the resources available to them; and

(iv) the performance of the relevant responsible competent authorities in relation to the control programme and assurances.

The importing Member may carry out audit and verification procedures, in accordance with Articles 4.1 and 6.3 of the SPS Agreement, to assist this assessment. In carrying out the process described above, trading Members should consider experience and information already acquired.

V. CONCLUSIONS

27. The European Communities has applied the concepts of regionalization and equivalence in recognizing, both in its own territory and in the territory of certain exporting countries, regional disease control policies as foreseen by the relevant international standards and Article 6 of the SPS Agreement.

28. These concepts should also be applied in a transparent and consistent manner, taking into account existing international standards, guidelines and recommendations and available scientific data. The experience gained by the European Communities in operating this policy has demonstrated that it meets the objective of maintaining a high health status while minimizing barriers to trade.

29. Equivalence in SPS measures between trading partners is beneficial and should be pursued, taking into account the available resources. This would guarantee that imported animals or products do not pose risks to both the human and animal population or to the flora.

ANNEX I

SANITARY MEASURES

APPLICATION OF REGIONALIZATION WITHIN THE EUROEPAN COMMUNITIES

1. Before a decision to regionalize part of the European Communities is taken, certain factors should be considered:

- A detailed enquiry must have been carried out which resulted in sufficient information to enable the geographical limits of the region to be clearly defined;
- The limits of the region must be easy to define, identify and control;
- Controls must be in place to prevent prohibited movements of animals and products;
- A crisis unit must be established with all the necessary powers to take charge of the eradication campaign;
- Restriction should be applied within the region as well as to movements out of the region.

In the occurrence of a disease, EC legislation foresees the creation of :

1. Restricted areas
2. Surveillance zones
3. Buffer zone

Minimum rules are set out in EC legislation. These conditions are applied directly by member States, but evaluated as soon as possible by the Commission.

2. The above-mentioned areas are defined on the basis of geographical features, vector studies, meteorological conditions, epidemiological data and administrative boundaries. The buffer zone adds extra security against spread outside the surveillance zone.

3. Restricted areas are patrolled by the appropriate authorities, under an agreed plan that involves cooperation between the police and the veterinary authorities. The plans are discussed in the framework of the Standing Veterinary Committee, composed of experts of the Commission and the member States, that meets in Brussels at least monthly. Checks by the Commission Food and Veterinary Office are made regularly on the implementation of the rules applied to the areas concerned. Serological monitoring outside and inside the area is routinely carried out as well. Products which could carry the infection may not leave the area, either for use within the country or for export to other member States.

4. In the absence of disease outbreaks, surveillance is maintained through routine investigations of herd and flocks.

This consists of:

- Reporting of diseases by the herd owner;
- Presence of the veterinary practitioner on the farm;
- Provision of diagnostic laboratories;
- Surveillance in the abattoir (ante/post-mortem);
- Herd Health Programmes, either voluntary or on a compulsory basis;
- Serological surveys. These have been used to assess the prevalence of certain diseases.

Minimum restrictions to be applied in the case of appearance of an epizootic disease

Restricted zone , within a radius of 3 km[3]

- Census and veterinary inspection of all holdings;
- Prohibition on movements and transport of animals, except for emergency slaughter under license;
- Control of vehicle movements;
- Restrictions on milk, meat, semen, manure, etc., as appropriate;
- Prohibitions of animal gatherings.

Surveillance zone, within a radius of 10 km

- Census of all holdings;
- Prohibition on movements and transport of animals, except for pasture and emergency slaughter;
- Prohibition of markets, fairs, shows;
- Control of vehicle movements.

Buffer zone

5. This may be established in order to give a certain degree of safety between an infected area and a free area. There, controls and inspections are maintained, though at a reduced level, and animal movements are limited. It is established taking into account geographical, meteorological and epidemiological factors.

[3] Restrictions are maintained for at least 15 days after slaughter, cleansing and disinfection. After that, the rules for the surveillance zone apply to the whole area for at least a further 15 days.

ANNEX II[4]

AFRICAN SWINE FEVER IN SPAIN

1. When Spain joined the European Communities (1985), a programme for the eradication of African swine fever was enforced throughout the country, where the disease was endemic (≈ 9,000 outbreaks in 1977-78).

2. Due to the results of this programme, in 1989 it was possible to adopt the Commission Decision 89/21/EEC by which Spain was divided into a free area and an infected area. From the free area, trade of pigs and pig products was allowed without restriction to the other member States of the European Communities, while the control/eradication activities continued in the infected area.

3. In the following years, in accordance with the progress in the disease eradication, this Decision was amended several times and the infected area was progressively reduced. In addition, a surveillance area was identified from which intra-Community trade in pigs and pig products was allowed if a number of additional controls and precautions were taken in accordance with the current scientific knowledge concerning disease prevention.

4. Following the eradication of the disease from the whole country, Commission Decision 95/493 lifted all restrictions on trade of pigs and pig products from Spain.

5. The regionalization policy adopted in Spain has been successfully applied and has allowed for a remarkable increase in trade of pigs and pig products from Spain, without the risk of spreading the disease to importing countries.

[4] Further comprehensive data are available on request from the European Commission.