

**REVIEW OF THE SPS AGREEMENT**

Update on adaptation to regional conditions

Submission by the European Communities

The following submission is being circulated at the request of the Delegation of 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.*

**I. INTRODUCTION**

1. On 23 November 1998, the SPS Secretariat issued G/SPS/GEN/101 on "Adaptation to regional conditions – Equivalence" as submitted by the European Communities. This paper outlined the overall view of the regionalization policy that the European Communities had developed. In view of the present discussion on the difficulties in the application of the regionalization policy, the EC has

submitted this document to amplify its earlier document and provide updated information on the implementation of this concept by the European Union.

2. Regionalization/zoning is a risk management option which is applied within the European Union in a flexible manner, reflecting the complexity of the factors involved in the occurrence and spread of disease agents, and in the context of other risk management measures aimed at guaranteeing an appropriate level of protection against 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 unnecessary trade restrictions. In the same manner and in accordance with the same principles, the European Union recognises the application of this concept by third countries wishing to export to the European Union.

3. The completion of the Internal Market in the European Communities in 1992 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 are 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. This policy will continue to apply also in the enlarged European Union, which will include ten new Member States as at 1 May 2004.

4. 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, this policy was reinforced and extended to cover all the pests and diseases of major concern.

5. 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, or even beyond the borders of one single country.

6. 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.

7. In EC legislation sanitary and the phytosanitary measures are treated separately.

## **II. ANIMAL HEALTH MEASURES**

8. As outlined in G/SPS/GEN/101, definitions 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, still remain valid. All necessary elements to assess the animal health status of a country, including the appropriate risk assessment, and hence on which the decision to apply or not the concept of regionalization equally remain valid as referred to in the cited document.

9. In recent years the application of regionalization/zoning has had a very substantial impact, in particular on the animal health policy of the European Union, leading to positive results both in terms of disease control and reducing trade barriers. Indeed, the possibility to reduce trade barriers through regionalization/zoning is a major stimulus to improve disease control and surveillance both in the affected and the free areas. It also has a positive effect on developing countries' trade.

10. The success of the implementation of regionalization/zoning is strictly linked to the appropriateness and effectiveness of the disease control and surveillance measures applied both in the

infected and the free zone of the country(ies) concerned. These measures must ensure both that the risk of spread of the disease from the infected zone to the free zone is minimised and that, if such an event occurs, the disease agent is rapidly detected and adequate control measures are immediately applied, so that this situation does not pose unacceptable risks for the importing country(ies).

11. In the case of animal diseases, the European Union applies this concept for highly contagious and easily spreading contagious diseases such as Foot-and-Mouth Disease, Classical swine fever and Avian Influenza, and for less contagious diseases, such as Aujeszky's disease or IBR. (A more detailed examination of the regionalization applied during the Foot-and-mouth epidemic in the European Union in 2001 can be found in Annex II). According to the characteristics of the disease and the local epidemiological situation, the European Union may identify other zones around, or in the vicinity of, infected zones which cannot be considered as free because of the high risk that the disease may spread into these zones. However, from these non-infected/non-free zones certain trade may take place under certain conditions. This trade may only be allowed following the application of special control measures and/or only for those commodities posing a limited risk as regards the spread of the disease agent in question (e.g. trade in products like meat from these zones may be allowed, whilst trade in live animals is forbidden).

12. In a similar manner, within an infected zone "compartments" may also be identified from which a certain trade can take place under certain conditions (e.g. in case of classical swine fever in the wild boar, trade in domestic pig meat may be authorised from the infected areas if certain specific surveillance and control measures are applied both on feral and domestic pigs in the zone).

13. Mitigating factors including specific treatments and time periods can also be introduced for added security. This is done for certain commodities from some third countries e.g. meat from Southern Africa.

14. Examples of the implementation of this concept within the European Union and of the recognition of the policy applied for third countries are given in Annex I. The European Union deems that its approach as regards regionalization/zoning is fully in line with the SPS agreement and the OIE and other international standards.

15. 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.

### **III. PLANT HEALTH**

16. 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. Within protected zones, special arrangements are necessary to take account of differing pest and disease situations and differing crop and growing conditions within the European Community.

17. Two types of protected zones can be identified:

- (a) Zones in which pests and diseases established in one or more parts of the European Community 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 Community.

18. 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.

19. The area of a protected zone in the European Community 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.

20. The recognition of a particular protected zone within the European Community is based:

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

21. 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 relevant Regulatory Committee.

22. The concept of regionalization is also applied for import of specific plant products from some third countries. For instance, the following areas in certain third countries have been recognised as being free of some specific diseases affecting Citrus fruits:

- as regards Citrus canker:
  - in Australia: New South Wales, Queensland, South Australia and Victoria;
  - all areas of Brazil, with the exception of the States of Rio Grande do Sul, Santa Catarina, Paraná, São Paulo, Minas Gerais and Mato Grosso do Sul;

- in the United States: Arizona, California, Guam, Hawaii, Louisiana, Northern Mariana Islands, Puerto Rico, American Samoa, Texas and the United States Virgin Islands;
  - all areas of Uruguay, with the exception of the Departments Salto, Rivera and Paysandu – north of River Chapicuy
- as regards Citrus black spot:
- in South Africa: Western Cape;
  - in Australia: South Australia, Western Australia and Northern Territory;
  - in China: all areas with the exception of Sichuan, Yunnan, Guangdong, Fujian and Zhejiang;
  - in Brazil: all areas with the exception of the States of Rio de Janeiro, São Paulo and Rio Grande do Sul.

23. Similar criteria as for the recognition or the abolition of protected zones in the European Community are taken into consideration.

#### **IV. CONCLUSIONS**

24. The European Communities has applied the concepts of regionalization 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. Unfortunately, very few other WTO Members apply this policy to other Members, including the EC. It should be recognised that recognition of disease- or pest-free areas within a larger geographical territory is both logic and necessary and provides for continuity in trade, without the importer's sanitary or phytosanitary status being at stake.

25. 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 can meet the objective of maintaining a high health status while minimizing barriers to trade.

## V. EXAMPLES OF CURRENT REGIONALIZATION FOR PRODUCTS FROM THIRD COUNTRIES

### ANNEX I

#### SANITARY MEASURES

##### Application of regionalization within the European Communities

Country	Decision No	Disease	Product	Comment
Southern African Countries	1999/283/EC	FMD	Fresh meat from Bovine, ovine, caprine,	General regionalization with certification
Botswana	2003/163	FMD	Fresh meat from Bovine, ovine, caprine, farmed and wild ungulates	Regionalization within Botswana to ensure imports are not from zones directly affected with FMD, or surrounding zones
South Africa	2001/164	FMD	"	Regionalization following outbreak
South Africa	2000/739	FMD	"	Regionalization following outbreak
South America	93/402/EEC	FMD	Fresh meat from Bovine, ovine, caprine,	General regionalization with certification
Brazil	2002/908	FMD	Bovine, ovine and caprine animals and swine, fresh meat or meat products	Regionalization of a border area following an FMD outbreak in Paraguay
Paraguay	2002/908	FMD	Bovine, ovine and caprine animals and swine, fresh meat or meat products	Regionalization following an FMD outbreak <i>(Subsequently repealed by 2003/137 which banned the whole country following unfavourable FVO Mission)</i>

Country	Decision No	Disease	Product	Comment
Argentina	2002/338	FMD	Bone-in ovine, caprine and bovine fresh meat	Further regions approved for export following OIE proposal to recognise certain provinces as FMD free without vaccination.
Argentina	2002/198	FMD	Bone-in ovine, caprine and bovine fresh meat	Following an outbreak of FMD in 2002, approval for certain regions to export due to improving FMD situation.
Argentina	2002/338	FMD	Bone-in ovine, caprine and bovine fresh meat	Further regions approved for export following OIE proposal to recognise certain provinces as FMD free without vaccination.
Bulgaria	1999/538	FMD	Bovine, ovine and caprine fresh meat	Removal of general regionalization in Bulgaria, but maintenance of regionalization in buffer zone next to Turkey
Bulgaria	1999/541	FMD	Live sheep and goats	Maintenance of regionalization in buffer zone next to Turkey
Bulgaria	2001/600	Bluetongue	Live Bovines, sheep and goats	Following outbreak of Bluetongue in July 1999, Bulgaria was regionalized to prevent imports of live animals from affected areas and surrounding regions
Slovakia	2002/940	Classical Swine Fever (CSF)	Fresh pig meat	Authorised from territories not under restriction due to CSF infection in wild boars.
Czech Republic	1999/538	CSF	Fresh pig meat	Regionalization to take account of CSF in feral pig populations.

Country	Decision No	Disease	Product	Comment
Brasil, Costa Rica, Columbia, Turkey, Venezuela (also see below)	92/160/EEC	General health conditions	Horses	Several countries have regionalized areas for the import of horses. This is due to outbreaks of specific equine disease, or more general health concerns.  There are also specific additional safeguards in relation to regionalization in certain countries. e.g. in some cases, importation is restricted to registered horses, or limited to re-importation of EC horses back into the EC.
Saudi Arabia	1999/228 (92/160/EEC)	African Horse sickness	Horses	
Kyrgyzstan	1999/236 (92/160/EEC)	Dourine	Horses	
Mexico	2001/611 (92/160/EEC)	Venezuelan equine encephalomyelitis	Horses	
Russia	92/161 (92/160/EEC)	General health conditions	Horses	
Egypt	95/536 (92/160/EEC)	General health conditions	Horses	
South Africa	97/10/EC (92/160/EEC)	General health conditions	Horses	
Peru	2001/619 (92/160/EEC)	General health conditions	Horses	
Australia	1999/549/EC	Newcastle Disease	Live poultry and hatching eggs, live ratites and hatching eggs, fresh meat of poultry, ratites, farmed and wild feathered game.	
United States	2003/67/EC	Newcastle Disease	Live poultry and hatching eggs, live ratites and hatching eggs, fresh meat of poultry, ratites, farmed and wild feathered game.	Regionalization to allow imports from unaffected states, and prevent imports from California, Nevada and Arizona.
United States	2003/337/EC	Newcastle Disease	Live poultry and hatching eggs, live ratites and hatching eggs, fresh meat of poultry, ratites, farmed and wild feathered game.	Following addition cases of ND, regionalization was restricted to prevent imports from newly affected counties in Texas and New Mexico.



<b>Country</b>	<b>Decision No</b>	<b>Disease</b>	<b>Product</b>	<b>Comment</b>
Canada	88/212 (subsequently 2002/199)	Bluetongue	Bovine animals	Okanagan Valley- British Columbia
Canada	88/212 (subsequently 2002/199)	Bluetongue	Sheep and goats	Okanagan Valley- British Columbia

## ANNEX II

### REGIONALIZATION IN THE EUROPEAN UNION IN 2001 IN RESPONSE TO THE FOOT-AND-MOUTH EPIDEMIC

#### **Introduction**

1. The European Union adopted a regionalized approach during the outbreaks of FMD in 2001. This allowed trade to continue both within the unaffected areas of the member States, and with third countries. The regionalized approach was taken in parallel with severe safeguard measures to contain the disease within the infected areas within each affected country. This was of fundamental importance from a practical disease control aspect, but also to ensure that trading partners could be confident in the disease free status of the unaffected areas.

#### **Method**

2. Following the first cases of FMD in the UK in February 2001, the first Commission Decision (2001/145/EC) prohibited the exports of live animals, fresh meat and meat products, milk and milk products and other animal products from all parts of the UK to other parts of the Community. However the Decision set out the basis on which areas of UK territory could be regionalized subsequently if this was considered appropriate.

3. Following confirmed outbreaks in France, the Netherlands and Ireland, similar provisions for regionalization were set out (in Decisions 2001/208/EC, 2001/223/EC and 2001/234/EC respectively). This ensured that restriction on the trade in animal products was limited to those regions that were directly affected or considered at high risk. Because the disease was initially well contained and generally restricted to specific areas in these 'secondary' outbreaks, the balance of risk ensured that regionalization could be introduced for non-affected areas from the outset. Hence in principle meat etc from the majority of areas in France, the Netherlands and Ireland could continue to be placed on the market.

4. The containment of disease in France and Ireland allowed the policy of regionalization to continue throughout the course of the epidemic. However, in the Netherlands, infection spread to areas outside the initial restricted zones. Hence regionalization was suspended and restrictions were introduced for the whole of the Netherlands in April 2002 (Decision 2001/306/EC) for a short time. However the Netherlands reintroduced regionalization for unaffected areas when the epidemiological situation improved.

5. As the epidemic was brought under control, the affected Member States were able to repeal restrictions and expand regionalized areas as the epidemiological conditions became more favourable. However the Commission, in co-operation with the Member States was careful to ensure that restrictions were only repealed when the disease evolution would allow. Expanded regionalization was therefore introduced following a risk assessment approach, and was supplemented by additional measures such as physical checks at border regions, and appropriate marking of products to differentiate meat etc that had been produced within the regionalized areas that were therefore eligible to be placed on the market.

#### **Result of regionalization**

6. Member States recognised, and supported the need to control disease, and prevent the spread of infection, and hence in infected areas, strict controls were put in place. Regionalization provided a focus for targeted measures in areas affected by disease, but allowed disease control and prevention

strategies to be gradually repealed without impacting areas that were already free of disease. Hence the regionalization of affected MS could be expanded as the epidemic progressed.

7. Member States also supported the principle of regionalization as it allowed products to be placed on the market. This ensured that trade could continue between unaffected Member States that remained disease free, and unaffected regions within the infected countries. Subsequently, as the epidemic began to subside, Member States supported the affected countries in the reopening of areas that were directly affected by infection, again on a regionalized basis. Reopening of previously restricted areas was based on a risk assessment approach, and was carried out gradually with appropriate and proportional risk reduction measures in order to ensure that the release of restrictions did not cause new outbreaks. Member States embraced the wider regionalization as the epidemic declined, and through the SVC, supported the process of opening previously restricted regions up to the internal market.

8. Although necessary restrictions continued to apply in the worst affected areas for several months, the majority of areas within the affected Member States were able to recommence trade within a much shorter time period. This ensured that both farmers and customers could continue to maintain safe trade to the benefit of both parties. It also provided capacity within the market.

#### **Future provisions for regionalization in the event of an FMD outbreak**

9. The new FMD Directive recently proposed by the Commission will strengthen the principles of regionalization that were used successfully in the 2001 epidemic. The Directive gives clear obligations for member States to regionalise their territory into restricted zones and free zones. The Directive further outlines measures to be applied in the restriction zones, including the tracing of potentially infected animals and products dispatched to other member States.

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