

**Committee on Sanitary and Phytosanitary Measures**

**ISSUES IN THE APPLICATION OF ARTICLE 6 OF THE AGREEMENT ON THE  
APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES**

**BACKGROUND DOCUMENT**

Note by the Secretariat<sup>1</sup>

**I. INTRODUCTION**

1. The Committee on Sanitary and Phytosanitary Measures (the SPS Committee) initiated substantive discussion of problems linked with the implementation of the provisions for recognition of pest- and disease-free areas at the June 2003 SPS Committee Meeting and held informal meetings on the issue in 2003, 2004, 2005 and 2006.<sup>2</sup>

2. Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) states that :

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 organizations.

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.

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<sup>1</sup> This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights or obligations under the WTO.

<sup>2</sup> See in particular meeting reports: October 2003 (G/SPS/R/31, paras 90-103); March 2004 (G/SPS/R/33, paras 108-119); June 2004 (G/SPS/R/34, paras 83-97); October 2004 (G/SPS/R/35, paras 120-137); March 2005 (G/SPS/R/36, paras 115-136); June 2005 (G/SPS/R/37, paras 98-114); February 2006 (G/SPS/R/38 and G/SPS/R/39).

3. Committee discussions have focused on two aspects of regionalization: the establishment of pest- or disease-free areas by exporters and the recognition of the pest- or disease-free status by importing countries, although some Members have recalled that Article 6 also addresses areas of low pest- or disease- prevalence. Members have submitted papers summarizing their experiences, and proposals for the work programme of the SPS Committee. The IPPC and the OIE have also submitted documents summarizing their activities which provide guidance for countries seeking to establish, or to be recognized for pest- or disease-free status.<sup>3</sup>

4. Within the context of the Committee's work in this area, there are indications that application of this concept poses difficulties to Members. Numerous issues raised as specific trade concerns within the SPS Committee relate to the process of recognition of pest- or disease-free status.<sup>4</sup> Furthermore, in the course of Committee discussions Members have specifically highlighted difficulties in obtaining prompt recognition of their pest- or disease-free status by importing countries. Other Members have stressed the need for confidence in their trading partners' health status and provision of accurate information in their evaluation of requests for recognition of free status.

5. The resolution of these challenges could involve consideration of the relationship between the work of the SPS Committee and the work of the international standards setting organizations (ISSBs). Members have noted the competent work of the ISSBs and stressed the need to avoid duplication of efforts in addressing this issue, as well as the need to consider expedited recognition procedures in cases where the ISSBs have already recognized free status.

6. In the January 2006 meeting of the SPS Committee, some Members requested that the Secretariat prepare a background document on the implementation of Article 6 of the SPS Agreement to further the discussions on this issue. This background document begins by summarizing Members' experiences in the implementation of regionalization. Next the document highlights the work of the IPPC and OIE in this area. The final section provides a synthesis of Members' proposals concerning administrative steps for implementing the concept of regionalization.

## **II. MEMBERS' EXPERIENCES**

7. In documents dating back to 1998, Members have provided descriptions of their experiences related to the implementation of Article 6 of the SPS Agreement. Members have highlighted the fact that the requirements for implementing the concept of regionalization differ across importing and exporting Members. Factors which influence an importing country's acceptance of free status of a trading partner include tangible and intangible characteristics of the exporting Members' regulatory system which can either generate or erode importing countries' trust. Four areas in particular have been highlighted in the context of Committee discussions: (a) the recognition of regions by international standards-setting bodies and by Members; (b) procedures and guidelines for the implementation of recognition of the concept of regionalization; (c) predictability (or undue delays) and (d) transparency.

### **A. RECOGNITION (INTERNATIONAL AND BILATERAL)**

8. The guidance from the OIE and IPPC is helpful for exporting countries seeking to establish and maintain disease- or pest-free areas in a manner that will give importing countries the assurances they seek.<sup>5</sup> However, recognition by the OIE as having achieved free status in particular diseases

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<sup>3</sup> A compendium of these documents can be found in document G/SPS/GEN/636 and Corr.1.

<sup>4</sup> See G/SPS/GEN/204/Rev.5.

<sup>5</sup> United States (G/SPS/GEN/477).

does not necessarily enhance the ability of WTO Members to gain bilateral recognition.<sup>6</sup> Some Members note that the procedures or information required for verification by the OIE do not fully meet their concerns. Alternatively, members note that lack of transparency in the process of international recognition makes it difficult to determine if these information requirements for bilateral recognition may in fact be met during the existing process of international recognition. Other Members emphasize the difficulty of investing adequate resources to meet requirements of both the OIE and importing Members, which appear different.

## B. PROCEDURES AND GUIDELINES

9. Given the goal of Members to have areas recognized as pest- or disease-free, the logical process to determine how to achieve recognition is to evaluate the underlying procedures and guidelines. Members' experiences indicate that difficulties in achieving recognition for free status by nature are associated with procedures, including the challenge of adjusting to the procedures of different trading partners, as well as delays in the recognition process.<sup>7</sup> This broad categorization of difficulty has not been considered in sufficient detail to determine common gaps or overlaps. All agree that recognition as free from pests and disease can generate economic benefits, but how much depends on the effectiveness and length of the process.<sup>8</sup> Substantial investments may be required to achieve and maintain this status.<sup>9</sup> Committing to these investments is difficult when the achieving trading partners' recognition is unpredictable. At the same time, trust established through repeated interactions between trading partners facilitates decisions to recognize free status.

### 1. Eradication<sup>10</sup>

10. Eradication procedures for specific animal disease often follow relevant provisions of the OIE's terrestrial code concerning the declaration of free status. Eradication programmes for animal diseases may include some or all of the following components: vaccination campaigns with certification of vaccination status by veterinarians, outreach programmes to educate the general public, epidemiological reporting systems, strengthening of biosecurity measures at the farm level, disinfection of meat packaging facilities (in the case of animal diseases), monitoring and surveillance, emergency plan for outbreaks, and the establishment of vaccine reserves. Eradication programmes for plant pests, may include similar activities such as disinfection of equipment and facilities, chemical or biological pesticide treatment, restriction of cropping and trapping, and lures or other physical control methods.

### 2. Control and emergency preparedness

11. Emergency preparedness enhances the ability to rapidly contain a disease. Rapid containment with strict controls on trade and animal movement can allow the policy of regionalization to continue throughout the course of an outbreak.<sup>11</sup> Emergency plans for animal disease may include containment procedures, including reinforcement of quarantine protection along country borders, control on movement of animals, the potential for boosted vaccinations, and epidemiological surveys.<sup>12</sup> Similar approaches to contingency planning that anticipate the likely introduction of particular plant pests or

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<sup>6</sup> Argentina (G/SPS/GEN/269/Rev.1); Brazil (G/SPS/GEN/584); Peru (G/SPS/GEN/607) and Chile (G/SPS/GEN/610).

<sup>7</sup> Chile (G/SPS/GEN/610).

<sup>8</sup> Peru (G/SPS/GEN/417 and G/SPS/GEN/418).

<sup>9</sup> Peru (G/SPS/GEN/607) and Colombia (G/SPS/GEN/612).

<sup>10</sup> Chile (G/SPS/GEN/81 and G/SPS/GEN/610); Argentina (G/SPS/GEN/315); Chinese Taipei (G/SPS/GEN/402 and G/SPS/GEN/419); European Communities (G/SPS/GEN/461); Costa Rica (G/SPS/GEN/527); and Peru (G/SPS/GEN/531).

<sup>11</sup> European Communities (G/SPS/GEN/461).

<sup>12</sup> Peru (G/SPS/GEN/531) and Chinese Taipei (G/SPS/GEN/419).

pest groups, may be particularly useful in enhancing the preparedness of groups that may need to cooperate in future eradication programmes. Systematic and permanent follow-up programmes engender trust in the importing country.<sup>13</sup>

### 3. Surveillance and maintenance

12. Surveillance systems may include both active surveillance, in which sampling of populations was conducted, and passive surveillance, in which reported disease activity triggered investigations.<sup>14</sup> Monitoring and surveillance strategies related to both animals and plant health activities often include testing of products from markets and farms, and may actively involve farmers.<sup>15</sup> For regionalization related to plant health, trapping can contribute to the efficient detection of the presence of pests in particular regions.<sup>16</sup> Flexible surveillance activities in the case of animal health can be important for detecting viral activity and quantifying the level of immunity provided by a vaccine.<sup>17</sup>

### 4. Public-private cooperation

13. Particularly in relation to animal health, effective regionalization could be enhanced through the involvement of producers, the processing industry, related professions and representatives of the public sector concerned in implementation and training related to achieving free status.<sup>18</sup> One approach to strengthening the private participation in public sector animal health plans would be through accreditation of veterinarians specializing in specific animal health areas.<sup>19</sup>

#### C. PREDICTABILITY/TIME

14. The lack of predictability in recognition of regionalized measures by trading partners makes it difficult to commit to the significant medium and long-term investments necessary to achieve free status.<sup>20</sup> In some cases, the procedure for recognition by importing countries have been delayed without technical explanation.<sup>21</sup> Furthermore, as noted above, variations in the timing, requirements and procedures required by trading partners makes the application of Article 6 inefficient from the perspective of an exporting country.<sup>22</sup> Exporting Members may find the treatment of requests for recognition unpredictable due to lack of familiarity with the pest/disease status of the importing Member, or with their relevant health service. Importing Members may have difficulty handling requests for recognition due to high numbers of requests, lack of familiarity with the pest/disease status of the exporting Member, and lack of training for adequate analysis.

#### D. TRANSPARENCY

15. Some Members have suggested that Members periodically provide the SPS Committee with information on their experience in developing, applying, and implementing measures that are adapted to regional conditions.<sup>23</sup> One proposal suggested a procedure similar to that used for notifying equivalence agreements of the recognition, including a form for the notification of the recognition of pest- and disease-free zones, which in principle could be submitted by an exporting or an importing

<sup>13</sup> Honduras (G/SPS/GEN/362).

<sup>14</sup> Republic of Korea (G/SPS/GEN/348).

<sup>15</sup> Chinese Taipei (G/SPS/GEN/419) and Peru (G/SPS/GEN/417 and G/SPS/GEN/418).

<sup>16</sup> Mexico (G/SPS/GEN/440/Rev.1).

<sup>17</sup> Argentina (G/SPS/GEN/323 and G/SPS/GEN/377) and Nicaragua (G/SPS/GEN/575).

<sup>18</sup> Paraguay (G/SPS/GEN/413 and G/SPS/GEN/454).

<sup>19</sup> Peru (G/SPS/GEN/446).

<sup>20</sup> Peru (G/SPS/GEN/607).

<sup>21</sup> Argentina (G/SPS/GEN/433).

<sup>22</sup> Argentina (G/SPS/GEN/606); New Zealand (G/SPS/W/151).

<sup>23</sup> See in particular Canada (G/SPS/W/145) and Chile (G/SPS/W/144).

Member.<sup>24</sup> Provision of detailed information by importing Members to the Committee regarding their questionnaires and evaluation criteria could also enhance transparency and promote predictability.<sup>25</sup>

### III. WORK OF THE INTERNATIONAL STANDARDS-SETTING ORGANIZATIONS

16. The IPPC and the OIE have provided regular updates on their activities in this area. Both organizations have been responsive to requests from the SPS Committee for technical guidance on this subject.

#### A. IPPC

17. The IPPC currently has three standards addressing regionalization: ISPM 4 on requirements for the establishment of pest-free areas; ISPM 10 on the establishment of pest-free places of production and production sites; and ISPM 22 on requirements for the establishment of areas of low pest prevalence.

18. At the seventh Interim Commission on Phytosanitary Measures (ICPM) in April 2005, agreement was reached to urgently develop a concept standard on "Guidelines for the recognition of the establishment of pest free areas and areas of low pest prevalence". In October 2005, an Expert Working Group produced a draft standard "Guidelines for the recognition of the establishment of pest free areas and areas of low pest prevalence", which included a recommended procedure for recognition.<sup>26</sup> This procedure included the following series of steps:

- submission of a request by the National Plant Protection Organization (NPPO) of the exporting contracting party (CP) for recognition, together with relevant information on the area of concern;
- acknowledgement from the NPPO of the importing CP and identification of major omissions in the information supplied; description of the recognition process to be used by the NPPO of the importing CP, ideally with a provisional timetable;
- assessment of the technical information and, if necessary, requests for further information or site visits to verify pest status;
- communication of the result of the assessment to the NPPO of the exporting CP; and
- official recognition by the importing CP, if successful.

The draft ISPM is intended for consideration by the CPM Standards Committee in April/May 2006 and following modification will be sent out for country consultation. Approval may be possible at the CPM meeting in 2007.

19. The ICPM also decided that a feasibility study should be undertaken on the international recognition of pest free areas, which would take into account legal, technical and economic factors and assess the feasibility and sustainability of such system.<sup>27</sup>

20. In addition, the IPPC has a number of supporting standards, such as ISPM 6 "Guidelines for surveillance", ISPM 8 "Determination of pest status in an area", and ISPM 9 "Guidelines for pest eradication programmes".

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<sup>24</sup> Chile (G/SPS/W/181).

<sup>25</sup> Brazil (G/SPS/W/185).

<sup>26</sup> G/SPS/GEN/626.

<sup>27</sup> See Annex 1 of document G/SPS/GEN/626 for a description of the elements to be covered in this feasibility study.

## B. OIE

21. The OIE has a mandate to examine, upon request from a member country, its claims for a particular status with regard to four of the OIE listed diseases: foot and mouth disease, rinderpest, contagious bovine pleuropneumonia and bovine spongiform encephalopathy.<sup>28</sup>

22. The OIE Terrestrial Animal Health Code describes the requirements for obtaining disease free status, including requirements for surveillance and monitoring based on the concept of geographic zones. At the 73<sup>rd</sup> General Session of the OIE in May 2005, member countries of the OIE adopted a revised chapter of the Terrestrial Animal Health Code on zoning and compartmentalisation. This includes procedures for implementing zoning and compartmentalisation and a description of the process for trading partners to follow in achieving recognition of the health status of animal subpopulations.<sup>29</sup> For zoning, the recommended steps are as follows:

- the exporting country identifies a geographical area within its territory which it considers to contain an animal subpopulation with a distinct health status with respect to a specific diseases, based on surveillance and monitoring;
- the exporting country identifies the procedures which are being, or could be, employed to distinguish such an area epidemiologically from other parts of its territory, in accordance with the measures stipulated in the Terrestrial Code;
- the exporting country provides the information above to the importing country, and explains that the area can be treated as an epidemiologically separated zone for international trade purposes;
- the importing country determines whether it may accept such an area as a zone for the importation of animals and animal products, taking into account:
  - an evaluation of the exporting country's Veterinary Services;
  - the result of a risk assessment based on the information provided by the exporting country and its own research;
  - its own animal health situation with respect to the disease(s) concerned; and
  - other relevant OIE standards;
- the importing country notifies the exporting country of the result of its determination and the underlying reasons, within a reasonable period of time, being either:
  - recognition of the zone;
  - request for further information; or
  - rejection of the area as a zone for international trade purposes;
- an attempt should be made to resolve any differences of opinion over the definition of the zone, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism);
- the importing country and the exporting country may enter into a formal agreement defining the zone.

23. The OIE has developed a concept paper on compartmentalisation to be discussed at the General Session of the OIE International Committee in May 2006.<sup>30</sup> This concept paper includes description of seven factors for the evaluation and recognition of a compartment, as well as a section on the recommended sequence of steps to be taken in defining a compartment, which are similar to those steps identified for zoning.

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<sup>28</sup> Details of the OIE's evaluation and approval procedure are available in G/SPS/GEN/542 and Add.1.

<sup>29</sup> See G/SPS/GEN/552 for text of the revised standard.

<sup>30</sup> G/SPS/GEN/625.

24. The OIE notes that the application of zoning and compartmentalisation is not mandatory, and should only be used when appropriate, taking into account the epidemiology of the disease and the particular factors applying in each situation. These particular factors may include environmental factors, the level of surveillance for the disease, the quality of veterinary services or other competent authorities, and the ability to apply appropriate biosecurity measures.

#### **IV. TYPICAL STEPS FOR ADMINISTRATIVE PROCEDURES FOR RECOGNITION: SUMMARY OF PROPOSALS<sup>31</sup>**

25. As previously noted, a number of Members have submitted proposals regarding the administrative process for recognizing pest- or disease-freedom. Although these proposals vary in a number of requests, there are some common or recurrent elements. This section of the paper identifies these common elements.

26. The administrative process for achieving bilateral recognition is typically preceded by a country eradicating the disease or pest in question and obtaining a particular sanitary or phytosanitary status within part or all of its territory.

##### **A. EXPORTING MEMBER REQUESTS ISSB RECOGNITION**

27. Following this, a country may seek recognition of its status by the competent international organization. Upon obtaining the status of pest- or disease-free area or area of low prevalence, a Member officially declares this status (see step K for discussion of expedited procedure).

##### **B. EXPORTING MEMBER REQUESTS BILATERAL RECOGNITION**

28. Once achieved, the free status is communicated to relevant trading partners along with a formal request for recognition of this status, initiating the bilateral process of recognition.<sup>32</sup> This request for the recognition of a pest- or disease-free area or an area of low pest or disease prevalence may be accompanied by science-based and technical information to support the exporting Members' objective demonstration of its sanitary or phytosanitary status, including reference to relevant international recognition of free status. Alternatively, the initial request could relate to requirements and procedure specific to the importing Member, and the technical information could be sent later (see step D).

##### **C. IMPORTING MEMBER CLARIFIES REQUIREMENTS**

29. At the request of the exporting Member, the importing Member explains the requirements and procedures for recognition of sanitary or phytosanitary status with respect to a given pest or disease. The importing Member, upon receiving this information, may request answers to a specific questionnaire.

##### **D. EXPORTING MEMBER PROVIDES DOCUMENTATION**

30. The exporting Member sends the technical file establishing compliance with the requirements laid down by the importing Member, accompanied by an official declaration from the national regulatory body attesting that the ecosystem is a pest- or disease-free area or an area of low pest or disease prevalence. Alternatively, the exporting Member provides supporting information showing

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<sup>31</sup> See in particular Argentina (G/SPS/GEN/606); Brazil (G/SPS/W/185); Chile (G/SPS/W/129, G/SPS/W/140/Rev.2 and G/SPS/W/144); Colombia (G/SPS/GEN/611); Mexico (G/SPS/GEN/388); Peru (G/SPS/W/148).

<sup>32</sup> Chile (G/SPS/W/129).

that the procedures used to obtain recognition are based on an international standard, guideline or recommendation established by competent bodies under the SPS Agreement. The exporting Member also supplies any further information that could help the importing Member to reach its decision on recognition.

E. IMPORTING MEMBER EVALUATES DOCUMENTATION/ADDITIONAL INFORMATION

31. The importing Member provides feedback to the exporting Member regarding whether the documentation is in order. In addition, the importing Member can provide information regarding the necessity of additional information, the necessity of on-site auditing, and suggestion of dates for the on-site auditing. The importing Member may take into consideration whether the recognition has been accorded previously by an international body or by another Member when scheduling a technical inspection visit.

32. If the response from the importing Member is negative, the importing Member issues a decision rejecting the request and providing reasons. This allows the exporting Member to modify and adapt its system with a view to seeking recognition in the future.

33. If the response from the importing Member is positive, the importing Member indicates comments where they exist.

F. EXPORTING MEMBER RESPONDS TO COMMENTS

34. If the evaluation report contains comments, the exporting Member provides the relevant clarifications, additions or modifications.

G. IMPORTING MEMBER EVALUATES DOCUMENTATION

35. The importing Member provides feedback to the exporting Member regarding responses and indicates whether further clarification is necessary. If further clarification is needed the process repeats steps F and G.

H. IMPORTING MEMBER CONDUCTS ON- SITE EVALUATION

36. If necessary the importing Member carries out a visit in order to verify the information provided in support of the request for recognition of a pest- or disease-free area or area of low prevalence. This technical inspection could consider, *inter alia*, the administrative structure of the regulatory bodies and the programmes they implement with a view to prevention, control and eradication. The strength and credibility of the veterinary or phytosanitary infrastructure of the exporting region(s) would also be part of this evaluation.

37. The importing Member indicates comments relating to the inspection visit in an inspection report.

I. EXPORTING MEMBER RESPONDS TO INSPECTION REPORT

38. If the report of the visit contains comments, the exporting Member provides the relevant clarifications, additions or modifications.

J. IMPORTING MEMBER REJECTS OR AUTHORIZES

39. Where its evaluation and verification of the information provided by the exporting country leads to an unfavourable conclusion, the importing Member provides technical grounds for the



decision, so that the exporting Member may modify and adapt its system with a view to future recognition requests.

40. Where its evaluation and verification of the information provided by the exporting country leads to a favourable conclusion, the importing Member launches its internal administrative procedures to eliminate the restrictions relating to the pest or disease associated with the recognition, to facilitate trade from the exporting Member that requested recognition. The importing Member modifies existing regulations or elaborates new ones to support official recognition of free status. In addition, the importing Member may circulate the modified or new regulation for public comment. The recognition of free status by the importing Member would not preclude the importing Member from taking emergency actions if the status of the exporting Member changes.

#### K. EXPEDITED PROCESS

41. An expedited process for recognition of sanitary status could be applied in the following situations:

- (a) When there has been official recognition following verification by one of the SPS Agreement's international reference organizations;
  - (b) When there has been an outbreak in a previously recognized area which, once the problem was eliminated, was restored to its former status;
  - (c) When the infrastructure and operation of the responsible veterinary or phytosanitary service of the exporting Member are sufficiently familiar to the importing Member owing to sanitary or phytosanitary recognition with respect to other pests or diseases, or to existing trade relations.
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