

**THE IMPLEMENTATION OF ARTICLE 6 (REGIONALIZATION) OF THE
AGREEMENT ON THE APPLICATION OF SANITARY AND
PHYTOSANITARY MEASURES**

Submission by Japan

The following communication, received on 30 November 2005, is being circulated at the request of the Delegation of Japan.

I. BACKGROUND

1. Articles 2.2 and 5.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) require Members to ensure that their sanitary and phytosanitary measures are based on scientific principles and an appropriate risk assessment.

2. "Regionalization" is recognized in Article 6 of the SPS Agreement. At the same time, Article 6.3 stipulates that "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".

3. With regard to the relevant international standards:

The OIE has recommendations on the concept of "regionalization (zoning)" in the "Terrestrial Animal Health Code" and the "Aquatic Animal Health Code". Although the Codes admit that the steps generally depend on the circumstances existing within the Members involved, they have specified the recommended steps for the recognition of disease-free areas. However, the technical and administrative requirements for each step are not clearly distinguished. The Terrestrial Animal Health Code also establishes the concept of "compartmentalization". With regard to "compartmentalization", we understand that an explanatory paper is being prepared by the OIE in order to develop a mutual understanding among Members.

On the other hand, the IPPC has standards which describe the requirements for the establishment of pest-free areas or areas of low pest prevalence: "*Requirements for the establishment of pest-free areas*" (*International Standards for Phytosanitary Measures (ISPM No.4)*); "*Requirements for the establishment of pest-free places of production and pest-free production sites*" (*ISPM No.10*); and "*Requirements for the establishment of areas of low pest prevalence*" (*ISPM No.22*). The IPPC is also developing a technical standard on requirements for the establishment of free areas for a specific pest: "*Requirements for the*

establishment and maintenance of pest-free areas for tephritid fruit flies", and an administrative standard which will describe the recognition process of pest-free areas or areas of low pest prevalence, "Guidelines for the recognition of the establishment of pest-free areas and areas of low pest prevalence". The IPPC has developed technical guidelines and closely-related administrative guidelines in order to ensure the efficacy of implementing both types of guidelines.

4. In order to encourage discussions on the issue of "regionalization" in a well-balanced manner between importing and exporting Members, we would like to communicate the following experiences and views on this issue to the Committee and share them with other Members.

II. EXPERIENCE IN THE RECOGNITION OF PEST- OR DISEASE-FREE AREAS OR AREAS OF LOW PEST OR DISEASE PREVALENCE

5. In the area of animal quarantine, Japan has recognized disease-free areas primarily for classical swine fever (CSF) in light of the international standards. Currently CSF-free areas are recognized in three countries.

6. In the area of plant quarantine, Japan has recognized pest-free areas and pest-free places of production for Mediterranean fruit fly in three countries and a pest free area for the Melon fly in one country so far.

7. As for the establishment of pest- or disease-free areas and areas of low pest or disease prevalence, it is indispensable for the importing countries to understand the animal and plant quarantine system and the status of the enforcement of the system in the exporting countries. For that understanding, we think it important to accumulate experiences of recognition. With this in mind, we recognize that the international standards are important tools for "regionalization", i.e., pest- or disease-free areas or areas of low pest or disease prevalence.

III. JAPAN'S VIEW ON THE RECOGNITION OF PEST- OR DISEASE-FREE COUNTRIES OR AREAS

8. Article 6 of the SPS Agreement is an essential element of the scientific approach to trade-related regulations as well as to other provisions of the SPS Agreement. The introduction of the concept of "regionalization", on the basis of scientific evidence, makes it possible to enhance domestic health protection as well as to improve market access for products from regions which meet the appropriate level of protection.

9. We consider that the roles and responsibilities of the SPS Committee, the relevant international organizations and Members in the implementation of Article 6 are the following;

- (a) The SPS Committee is responsible for the interpretation of the SPS Agreement and the supplementary decisions in order for the Members to ensure that any sanitary and phytosanitary measure is not applied in a manner which constitutes a disguised restriction on international trade.
- (b) The relevant international organizations are responsible for developing technical and scientific criteria or guidelines regarding the establishment, assessment and recognition of pest- or disease-free areas and low pest or disease prevalence.
- (c) Members are responsible for applying the principle of Article 6, exchanging data between exporting and importing Members and determining the SPS measure that achieves the appropriate level of sanitary or phytosanitary protection.

10. In the discussions of the SPS Committee, some Members expressed the view that a Member should automatically observe the recognition of disease-free countries or areas by the OIE. However, Japan points out that it is difficult to support this view for the followings as reasons:

- (a) According to Article 3.3 of the SPS Agreement, a Member 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 standard, if there is a scientific justification, or other requirements are met. This is the case with the OIE standard, which is the international standard under the SPS Agreement, and Members need not necessarily follow the OIE standard in their adoption of sanitary and phytosanitary measures and recognition of disease-free countries or areas if there is a scientific justification.
- (b) Even if a Member adopted sanitary and phytosanitary measures identical to the OIE standard, the right should be accorded to the Member to make a final decision in its recognition of the disease-free countries or areas, since that decision is directly linked to sanitary and phytosanitary measures that are taken based on each Member's own risk assessment.
- (c) Furthermore, in the recognition of disease-free countries or areas, a Member's decisions, as the exercise of its right, should be fairly respected since they are based on the thorough research, including on-site inspection, of the applicant Member's actual condition of disease and its potential impact on trade, while the OIE's judgement is conducted merely in terms of its consistency with the OIE standard, on the basis of on-desk examination of documents/data submitted by the applicant Member. Therefore, it is appropriate that a Member use OIE's recognition of disease-free countries or areas as a good reference but not necessarily observe it unconditionally.

11. With regard to "regionalization", some Members share the view that the SPS Committee should develop administrative guidelines. However, we believe that Members should examine the following points.

- (a) Technical guidelines and administrative guidelines are closely interrelated in "regionalization".
- (b) If the SPS Committee starts to develop administrative guidelines on this issue, while various international standards on the same issue are developed by the international standard-setting bodies, duplication of work and confusion among Members could happen.

12. As we said in paragraph 5, the recognition of pest- or disease-free areas or areas of low pest or disease prevalence requires the understanding of the animal and plant quarantine system and the status of the enforcement of the system in the exporting countries. Therefore, as was the case with equivalence and Article 4 of the SPS Agreement, we believe that the international standard-setting bodies should develop guidelines including both technical and administrative aspects. Furthermore, we think it important to review these guidelines based on the experiences of Members.
