

## **PART THREE**

### **Technical Barriers to Trade**

#### **Chapter 8**

#### **Sanitary and Phytosanitary Measures**

##### **Article 8.01 Objectives**

The objectives of this Chapter are to protect human, animal, or plant life or health in the Parties' territories, enhance the implementation of the SPS Agreement, and establish a Committee for addressing and resolving issues on sanitary and phytosanitary matters.

##### **Article 8.02 General Provisions**

1. The Parties reaffirm the provisions under the SPS Agreement.
2. Those that are legally responsible for ensuring compliance with sanitary and phytosanitary requirements provided in this Chapter are deemed as the competent authorities.
3. Based on the SPS Agreement, the Parties establish this framework of rules and disciplines to guide the development, adoption and compliance with sanitary and phytosanitary measures.
4. The Parties, shall facilitate trade through mutual cooperation to prevent the introduction or spread of pests and diseases, and improve plant health, animal health, and food safety.

##### **Article 8.03 International Standards and Harmonization**

With the aim to harmonize sanitary and phytosanitary measures, the Parties shall follow the principles as described below:

- (a) each Party shall use international standards, guidelines or recommendations as reference guideline for its sanitary and phytosanitary measures;
- (b) each Party may adopt, implement, establish or maintain a sanitary or phytosanitary measure with a level of protection different from or stricter than that of international standards, guidelines or recommendations, provided that there is scientific justification for the measure;
- (c) with the aim of reaching a higher degree of harmonization, each Party shall follow the guidelines of the SPS Agreement, the IPPC for plant

health, the OIE for animal health and the Codex on food safety and tolerance limits; and

- (d) the Parties shall establish harmonized systems for the procedures of control, inspection and approval of the sanitary and phytosanitary measures for animals, plants, their products and by-products as well as food safety.

#### **Article 8.04 Equivalence**

For the purpose of applying sanitary and phytosanitary measures in the territories of the Parties, the Parties shall accept as equivalent the sanitary and phytosanitary measures of the other Party in accordance with the following principles:

- (a) a Party shall accept the sanitary or phytosanitary measures of the other Party as equivalent, even if these measures differ from its own in the same product, if the other Party objectively demonstrates to the Party that its measures, based on scientific information and risk assessment, achieve the Party's appropriate level of sanitary or phytosanitary protection. At the request of a Party, the other Party shall grant reasonable access for information related to inspection, testing and other relevant procedures; and
- (b) the Parties shall facilitate access to their territories for purposes of inspection, testing, and other relevant procedures in order to establish equivalence between their sanitary and phytosanitary measures.

#### **Article 8.05 Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection**

In accordance with the guidelines developed by relevant international organizations recognized by the WTO:

- (a) the Parties shall ensure that their sanitary or phytosanitary measures are, based on an assessment, as appropriate to the circumstances, of the existing risks to human (food safety), animal or plant life or health protection, taking into account the guidelines and risk assessment techniques developed by the relevant international organizations;
- (b) the Parties shall facilitate the necessary conditions for the evaluation of their sanitary or phytosanitary services, by using the procedures in force, for the assessment of controls, inspections and application of sanitary or phytosanitary measures and programs, taking into account the guidelines and recommendations of the relevant international organizations;
- (c) in assessing the risk that may exist in a commodity and establishing the appropriate level of protection, the Parties shall take into account the

following factors:

- (i) available technical and scientific information;
  - (ii) existence of pests or diseases, and recognition of pest or disease-free areas and areas of low pest or disease prevalence;
  - (iii) epidemiology of pests or diseases;
  - (iv) analysis of critical control points in sanitary (food safety) and phytosanitary aspects;
  - (v) physical, chemical and biological hazards in foods;
  - (vi) relevant ecological and environmental conditions;
  - (vii) production methods and processes, and the inspection, sampling and testing methods;
  - (viii) structure and organization of sanitary or phytosanitary services;
  - (ix) protection procedures, epidemiological surveillance, diagnosis and treatment to ensure food safety;
  - (x) loss of production or sales in the event of entry, establishment, or spread of a pest or disease;
  - (xi) applicable quarantine measures and treatments that shall satisfy the importing Party on risk mitigation; and
  - (xii) the cost of control or eradication of pests or diseases in the territory of the importing Party, and the cost-effectiveness of alternative approaches to reduce risks;
- (d) when establishing the appropriate level of protection, the Parties shall avoid arbitrary or unjustifiable distinctions, if such distinctions result in discrimination or disguised restriction on trade;
- (e) when a Party determines that relevant scientific evidence is insufficient for a risk assessment, it may adopt a provisional sanitary or phytosanitary measure on the basis of available information, including information from the relevant international organizations described in this Chapter. In such circumstances, the Parties shall seek to obtain the additional information necessary for a more objective risk assessment and review the sanitary or phytosanitary measure accordingly within a reasonable period of time. For this purpose, the following procedures shall be applied:

- (i) the importing Party provisionally applying the sanitary or phytosanitary measure shall, within 30 days of adopting the provisional measure, request the technical information necessary to complete a risk assessment from the other Party, which shall provide the required information. In case the information is not provided, the provisional measure shall be maintained, and if the information is not requested within the established period, the provisional measure shall be withdrawn;
- (ii) if the importing Party has requested the information, it shall be a period of 60 days from the date of provision of such information to revise, withdraw or maintain the provisional measure as definitive. If necessary, the Party may extend the period;
- (iii) the importing Party may request clarification of the information provided by the exporting Party;
- (iv) the importing Party shall allow the exporting Party to provide its comments and shall take these into account in the conclusion of the risk assessment; and
- (v) the adoption or amendment of a provisional sanitary or phytosanitary measure shall be immediately notified to the other Party through the notification authorities established under the SPS Agreement;
- (f) where the risk assessment results in non-acceptance of an import, the scientific basis for the decision shall be notified in writing; and
- (g) when a Party has reasons to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Party is restricting, or has the potential to restrict 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 Party maintaining the measure within 60 days from the date on which its competent authority receives the inquiry.

#### **Article 8.06 Recognition of Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence**

1. The Parties shall recognize, based on international standards, guidelines or recommendations, the pest- or disease-free areas and areas of low pest or disease prevalence. They shall take into account such factors as geographical situation, ecosystems, epidemiological surveillance, and the effectiveness of sanitary and phytosanitary controls in the area.

2. The Party declaring that an area within its territory is free of a specific pest or disease shall demonstrate such a condition objectively to the importing Party, and give assurances that the area shall remain free of that pest or disease on the basis of protection measures adopted by the authorities responsible for sanitary and phytosanitary services.

3. The Party interested in obtaining recognition of a pest- or disease-free area shall request such recognition and provide the relevant scientific and technical information to the other Party.

4. The Party from which recognition is requested, may carry out inspection, testing and other relevant procedures. In case of non-acceptance of the request, it shall provide the technical reasons for its decision in writing.

5. The Parties may initiate consultation in order to reach agreement on specific requirements for recognition of pest-or disease-free areas or areas of low pest or disease prevalence. In view of lack of international standards for the recognition of areas of low pest or disease prevalence, it is agreed by both Parties that the recognition of such areas shall be pending until the establishment of the international standards.

#### **Article 8.07 Control, Inspection and Approval Procedures**

1. The Parties shall, in accordance with this Chapter, apply the provisions in Annex C of the SPS Agreement, as regards control, inspection or approval procedures, including national systems for approving the use of additives or for establishing levels of tolerance for contaminants in foods, beverages or feedstuffs.

2. When the competent authority of the exporting Party files a first request to the competent authority of the importing Party for the inspection of a productive unit or productive processes in its territory, the competent authority of the importing Party, after full review and assessment of the required documents and data, shall conduct such an inspection within a period not to exceed 100 days. This period may be extended by mutual agreement between the Parties, when such extension is justifiable, for example, due to a product's life cycle. Once the inspection is carried out, the importing Party shall issue a decision based on the inspection results and notify the exporting Party within 90 days from the date on which the inspection is completed.

#### **Article 8.08 Transparency**

1. Each Party, in recommending adoption or amendment of a sanitary or phytosanitary measure of general application, shall notify the following:

- (a) the adoption of and amendment of measures. Furthermore, it shall facilitate relevant information in accordance with provisions in Annex B of the SPS Agreement and implement the pertinent adaptations;
- (b) changes or amendments of sanitary or phytosanitary measures that

have a significant effect on trade between the Parties, within 60 days prior to the effective date of the new provision, to allow for comments from the other Party. The 60 day period shall not apply to emergency situations, as established in Annex B of the SPS Agreement;

- (c) changes occurring in the status of animal health, such as the occurrence of exotic diseases, and those on list in the Animal Health Code of the OIE, within 24 hours from the time the disease is confirmed;
- (d) changes occurring in the status of phytosanitary, such as the occurrence of quarantine pests and diseases or spread of quarantine pests and diseases under official control, within 72 hours following their verification;
- (e) disease outbreaks which are scientifically shown to be caused by the consumption of imported food and food products, natural or processed; and
- (f) the causes or reasons for rejecting a commodity of the exporting Party.

2. The Parties shall designate notification authorities and enquiry points established under the SPS Agreement as a communication channel. In case urgent measures are adopted, the Parties shall immediately notify the other Party in writing, briefly indicating the objective and reason of the measure as well as the nature of the problem.

3. Each Party shall respond to reasonable requests for information from the other Party and provide the relevant documentation in accordance with the principles established in paragraph 3 of Annex B in the SPS Agreement.

#### **Article 8.09 Committee on Sanitary and Phytosanitary Measures**

1. The Parties hereby establish the Committee on Sanitary and Phytosanitary Measures, as set out in Annex 8.09

2. In a period not to exceed 30 days after the entry into force of this Agreement the Parties, through an exchange of notes, shall identify their representatives to the Committee.

3. Each Party shall ensure that the Committee is made up of representatives with an adequate level of responsibility for the development, implementation and enforcement of sanitary and phytosanitary measures.

4. The Committee shall hear matter relating to this Chapter and shall carry out the following functions:

- (a) Promoting the means necessary for the training and specialization of technical staffs;

- (b) Promoting the active participation of the Parties in international bodies; and
- (c) Creating and updating a database of specialist qualified in the fields of food safety, plant and animal health.

5. The Committee may establish *ad hoc* work groups.

6. Issues related to the development or application of sanitary or phytosanitary measures that affect or may affect trade between the Parties shall be consulted between them.

7. The Committee shall meet as mutually agreed.

#### **Article 8.10 Technical Cooperation**

Each Party, upon request from the other Party, may cooperate in research, technology, information exchange, technical assistance and other sanitary and phytosanitary related matters under mutually agreed terms and conditions to strengthen the sanitary and phytosanitary measures and activities related to the other Party.

#### **Article 8.11 Definitions**

For purposes of this Chapter, the Parties shall apply the definitions and terms set out in:

**SPS Agreement** means the WTO Agreement on the Application of Sanitary and Phytosanitary Measures;

**OIE** means the World Organisation for Animal Health;

**IPPC** means the International Plant Protection Convention; and

**CODEX** means the Codex Alimentarius Commission,

such definitions and terms are incorporated to and form part of this Agreement.

## **Annex 8.09**

### **Committee on Sanitary and Phytosanitary Measures**

The Committee on Sanitary and Phytosanitary Measures established in Article 8.09 and shall be composed of:

- (a) In the case of the Republic of Nicaragua, the Ministerio de Fomento, Industria y Comercio (MIFIC), the Ministerio Agropecuario y Forestal (MAGFOR), and the Ministerio de Salud (MINSA); and
- (b) In the case of the Republic of China (Taiwan), the Council of Agriculture, represented by the Bureau of Animal and Plant Health Inspection and Quarantine; the Department of Health, represented by the Bureau of Food Safety; and the Ministry of Economic Affairs, represented by the Bureau of Standards, Metrology and Inspection,

or their successors.