

## **PART THREE: TRADE BARRIERS**

### **CHAPTER 8: SANITARY AND PHYTOSANITARY MEASURES**

#### **Article 8.01 Definitions**

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

- (a) the Agreement on the Application of Sanitary and Phytosanitary Measures, that forms a part of the WTO Agreement, hereinafter referred to as ASPS;
- (b) the World Organisation for Animal Health, hereinafter referred to as OIE;
- (c) the International Plant Protection Convention, hereinafter referred to as IPPC; and
- (d) the Codex Alimentarius Commission, hereinafter referred to as Codex.

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

1. The Parties reaffirm their existing rights and obligations with respect to each other under the ASPS.
2. The Parties, on the basis of the ASPS, establish this framework of rules and disciplines that shall guide the adoption and implementation of sanitary and phytosanitary measures.
3. The authorities legally responsible for ensuring the compliance with the sanitary and phytosanitary obligations provided in this Chapter shall be deemed as the competent authorities.
4. The Parties shall facilitate trade through mutual cooperation to prevent the introduction or spreading of pests or diseases and to improve plant health, animal health, and food safety.
5. The Parties shall use the relevant dispute settlement provisions of the WTO Agreement, instead of Chapter 15 (Dispute Settlement) of this Agreement, for any formal disputes related to their rights and obligations under the ASPS.

#### **Article 8.03 Rights of the Parties**

The Parties, according to the ASPS, may:

- (a) establish, adopt, maintain or implement any sanitary or phytosanitary measures in their territories, only to the extent necessary to protect human life and health (food safety) and animal life or to preserve plant health, even if they are stricter than international standards, guidelines or recommendations, provided that there is a scientific basis to justify them;

- (b) implement the sanitary and phytosanitary measures only to the extent necessary to reach an appropriate level of protection; and
- (c) ensure that plants, animals, products and by-products bound for export are subject to sanitary and phytosanitary monitoring to ensure conformity with the requirements of the sanitary and phytosanitary measures established by the importing Party.

#### **Article 8.04 Obligations of the Parties**

1. Sanitary and phytosanitary measures shall not constitute a disguised restriction to trade and shall not have the purpose or effect of creating an unnecessary obstacle to trade between the Parties.
2. Sanitary and phytosanitary measures shall be based on scientific principles, shall only be maintained if there are reasons to sustain them and shall be based on risk assessment.
3. Sanitary and phytosanitary measures shall be based on international standards, guidelines or recommendations.
4. Where conditions are identical or similar, sanitary and phytosanitary measures shall not discriminate arbitrarily or unjustifiably.

#### **Article 8.05 International Standards and Harmonization**

With the aim to harmonize sanitary and phytosanitary measures, the procedures of control, inspection and the approval of sanitary and phytosanitary measures of the Parties, shall be based on the following principles:

- (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 ASPS, the IPPC for plant health, the OIE for animal health and the Codex for 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 8.06 Equivalence**

With the purpose of implementing sanitary and phytosanitary measures in the territory of the Parties, the Parties shall implement control, inspection and approval procedures according to the following principles:

- (a) each 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, based on scientific information and risk assessment, its measures achieve the Party's appropriate level of sanitary or phytosanitary protection. Upon request by a Party, the other Party shall give reasonable access to information related to its inspection, testing and other relevant procedures; and
- (b) the Parties shall facilitate access to their territories for the purpose of inspection, testing and other relevant procedures in order to establish equivalence of sanitary and phytosanitary measures.

#### **Article 8.07 Assessment Risk and Determination of the Appropriate Level of Sanitary and Phytosanitary Protection**

According to the guidelines developed by relevant international organizations:

- (a) the Parties shall ensure that their sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the existing risk for the protection of human life and health (food safety) and animal health, or to protect plant health taking into account the guidelines and risk assessment techniques developed by relevant international organizations;
- (b) the Parties shall provide necessary access for assessing sanitary and phytosanitary services through the procedures in force for verification of control, inspections, approval procedures, measure implementation and programs on sanitary and phytosanitary matters, on the basis of the guidelines and recommendations of the international organizations recognized by the WTO;
- (c) in assessing the risk of a good and in establishing the appropriate level of protection, the Parties shall take into account the following factors among others:
  - (i) available scientific and technical information;
  - (ii) existence of pests or diseases;
  - (iii) epidemiology of pests and diseases of quarantine importance;
  - (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 processes and methods, and inspection, sampling and testing methods;
  - (viii) structure and organization of sanitary or phytosanitary services;
  - (ix) procedures for protection, epidemiological surveillance, diagnostic and treatment to ensure food safety;
  - (x) loss of production or sales in the event of the entry, establishment, spread or dissemination of a pest or disease;
  - (xi) applicable quarantine measures and treatments that shall satisfy the importing Party on risk mitigation; and
  - (xii) costs of controlling or eradication of pests or diseases in the territory of the importing Party and relative cost-effectiveness of other possible methods to reduce the risk;
- (d) for the purpose of establishing and harmonizing the appropriate level of protection, the Parties shall avoid arbitrary or unjustifiable distinctions that may result in discrimination or disguised restriction to trade;
- (e) where relevant scientific evidence is insufficient for carrying out risk assessment, the Party may provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information, including that from the relevant international organization described in this Chapter. In such circumstances, the Parties shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measures accordingly within a reasonable time frame, and with this aim, the following procedures shall be applied:
- (i) the importing Party that applies the provisional measure, shall request from the other Party, within thirty (30) days of adoption of the provisional measure, the necessary technical information to complete the risk assessment, and the other Party shall provide the information. If the information is not provided, the provisional measure shall be sustained, and if on expiration of this period the information has not been requested, the provisional measure shall be withdrawn;
  - (ii) if the importing Party has requested information, it shall have sixty (60) days from the date of provision of this information to review, withdraw or keep as final the provisional measure. If necessary, the Party may extend this time period;
  - (iii) the importing Party may request clarification about the information provided by the exporting Party after its receipt;

- (iv) the importing Party shall allow the exporting Party to make its comments and shall take them into account for its conclusion of the risk assessment; and
- (v) the adoption or revision of the provisional sanitary or phytosanitary measure shall be immediately notified to the other Party through the notification authorities established under the ASPS;
- (f) if the result of risk assessment involves non-acceptance of the importation, the scientific basis for the decision shall be notified in writing; and
- (g) when a Party has reasons to believe that a sanitary or phytosanitary measure established or maintained by the other Party restricts or may restrict its exports and that the measure is not based on relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, the Party may demand an explanation for the reasons of the sanitary and phytosanitary measures and the Party maintaining these measures shall provide the explanation within sixty (60) days from the date of receipt of the inquiry by the competent authority.

#### **Article 8.08 Recognition of Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence**

1. The Parties shall recognize the pest- or disease-free areas and the areas of low pest or disease prevalence according to international standards, guidelines or recommendations, taking into account geographical situation, ecosystems, epidemiological surveillance and the effectiveness of sanitary and phytosanitary controls in the area.
2. The Party claiming that an area within its territory is free from a specific pest or disease, shall demonstrate objectively to the importing Party this condition and ensure that it will be maintained as such, on the basis of the protection measures adopted and implemented by those in charge of the sanitary and phytosanitary services.
3. The Party interested in obtaining recognition that an area is free from a specific pest or disease shall send the request to the other Party and provide relevant scientific and technical information.
4. The Party that receives the request for recognition may carry out inspections, testing and other verification procedures. If the Party does not accept the request, it shall indicate in writing the technical basis for its decision.
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. Due to the 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 8.09 Control, Inspection and Approval Procedures**

1. The Parties, according to this Chapter, shall observe the provisions of Annex C to the ASPS on control, inspection and approval procedures, including approval of the use of additives or establishment of tolerances for contaminants in food, beverages and feedstuffs.

2. When the competent authority of the exporting Party requests for the first time to the competent authority of the importing Party to inspect a production unit or production process in its territory, the competent authority of the importing Party shall, upon completion of review and evaluation of necessary documents and information and risk assessment required by the importing Party, carry out the inspection within a period of one hundred (100) days. This period may be extended by mutual agreement between the Parties in those cases where it can be justified. When the inspection is completed, the competent authority of the importing Party shall issue a decision based on the results on the inspection and shall notify the exporting Party within ninety (90) days after the inspection.

## **Article 8.10 Transparency**

1. Each Party, when proposing adoption or modification of a sanitary or phytosanitary measure of general application, shall notify the following:

- (a) adoptions and modifications of these measures, it shall also provide information on measures according to the provisions of Annex B to the ASPS, and shall implement the relevant adjustment;
- (b) changes or revisions in sanitary or phytosanitary measures that have a significant effect on trade between the Parties, within sixty (60) days prior to the entry into force of the new provisions, to allow the other Party to comment; such requirement shall be exempted for emergencies, according to the provisions of Annex B to the ASPS;
- (c) changes in the status of animal health, as the occurrence of exotic diseases and listed diseases in List A of the OIE, within twenty-four (24) hours after confirming the disease;
- (d) changes in the phytosanitary status, as the occurrence of quarantine pests and diseases or spread of quarantine pests and diseases under official control, within seventy-two (72) hours of their verification; and
- (e) disease outbreaks which are scientifically shown to be caused by the consumption of imported food and food products, natural or processed.

2. The Parties shall use the notification authorities and enquiry points established under the ASPS as communication channels. When emergency measures are needed, the Party shall immediately notify the other Party in

writing, indicating briefly the purposes and basis of the measure, and the nature of the problem.

3. According to the provisions of Article 13.02 (Information Center), each Party shall answer any reasonable request for information from the other Party and shall provide relevant documentation according to the principles of paragraph 3 of Annex B to the ASPS.

#### **Article 8.11 Technical Consultations**

1. A Party, when necessary, may request consultations with the other Party regarding the application or interpretation of the content in this Chapter.

2. The Party that considers that the sanitary and phytosanitary measures of the other Party are interpreted or implemented inconsistently with this Chapter, shall have the burden to establish the inconsistency.

3. If the Party requests consultations, it shall notify the Committee. The Committee shall facilitate the consultations, and if necessary, forward to an ad-hoc working group for technical recommendations.

#### **Article 8.12 Committee on Sanitary and Phytosanitary Measures**

1. The Parties hereby establish the Committee on Sanitary and Phytosanitary Measures ("the Committee"), as set out in Annex 8.12.

2. The Committee shall hear matters regarding this Chapter and, without prejudice to Article 14.05(2) (Committees), shall carry out the following functions:

- (a) monitoring the fulfilment and correct application of the provisions in this Chapter;
- (b) promoting the means necessary for the training and specialization of technical staff;
- (c) promoting the active participation of the Parties in international bodies;
- (d) creating and updating a database of specialists qualified in the fields of food safety, plant and animal health, for the purpose of the provisions of Article 14.06 (Groups of Experts);
- (e) enhancing mutual understanding of each Party's sanitary and phytosanitary measures and the regulatory processes that relate to those measures;
- (f) consulting on matters related to the development or application of sanitary and phytosanitary measures that affect, or may affect, trade between the Parties; and

(g) addressing sanitary and phytosanitary matters with a view to facilitating trade between the Parties.

3. The Parties shall establish the Committee through an exchange of letters identifying the primary representative of each Party to the Committee.

4. The Committee shall seek to promote communication and enhance present or future relationships between the Parties' ministries with responsibility for sanitary and phytosanitary matters.

5. The Committee shall seek to facilitate a Party's response, in reasonable time, to a written request for information from another Party. The Committee shall endeavor to ensure that the responding Party communicates to the requesting Party the steps involved in responding to the request.

6. The Committee shall meet if necessary as requested by the Parties.

7. All decisions of the Committee shall be taken by consensus, unless the Committee otherwise decides.



## **ANNEX 8.12**

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

The Committee on Sanitary and Phytosanitary Measures, established in Article 8.12 shall be composed of:

- (a) 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 Sanitation, and the Ministry of Economic Affairs, represented by the Bureau of Standards, Metrology and Inspection;
- (b) in the case of the Republic of El Salvador, the Ministerio de Economía, the Ministerio de Agricultura y Ganadería and the Ministerio de Salud Pública y Asistencia Social; and
- (c) in the case of the Republic of Honduras, the Secretaría de Industria y Comercio, the Secretaría de Agricultura y Ganadería and the Secretaría de Salud;

or their successors.