

## **CHAPTER**

### **SANITARY AND PHYTOSANITARY MEASURES**

#### *Article 1*

##### **Objectives**

The objectives of this Chapter are:

1. To protect human, animal or plant life and health in the territory of the Parties while facilitating trade between the Parties under the scope of the implementation of the sanitary and phytosanitary (SPS) measures.
2. To establish a cooperation for further implementation of the WTO Agreement on the application of SPS measures.
3. To ensure that SPS measures do not create unjustified barriers to trade between the Parties.
4. To cooperate in technical and scientific issues related to the adoption and application of SPS measures.
5. To improve the exchange of information and consultation between the Parties.
6. To establish a working cooperation on multilateral fora.

#### *Article 2*

##### **Scope**

1. This Chapter shall apply to all SPS measures , as defined in Annex A to the WTO SPS Agreement that may, directly or indirectly, affect trade between the Parties.
2. This Chapter shall apply to matters related to cooperation on multilateral fora.

#### *Article 3*

##### **Definitions**

1. For the purposes of this Chapter, the following definitions apply:

- (a) the definitions in Annex A of the SPS Agreement;
- (b) the definitions adopted by the Codex Alimentarius Commission (the "Codex");
- (c) the definitions adopted by the World Organisation for Animal Health (the "OIE");
- (d) the definitions adopted by the International Plant Protection Convention (the "IPPC");
- (e) protected zone for a specific regulated pest means an officially defined geographical part of the territory of each Party in which that pest is known not to be established in spite of favourable conditions and its presence in other parts of the territory of the Party.

Protected zones are pest free areas under EU control in the EU territory. They are recognised under Regulation (EU) No 2031/2016. This concept is not applied out of the EU territory. For trade purposes the EU will not require MCS to establish protected zones in their territory. In this case the conditions of Pest Free Areas will apply. For the purposes of this Chapter and for the recognition of Protected Zones, the same conditions as for Pest-Free Areas shall apply.

2. In the event of an inconsistency between the definitions of the SPS Agreement and definitions agreed by both Parties or the definitions adopted by Codex, OIE and IPPC, the definitions set out in the WTO SPS Agreement shall prevail.

#### *Article 4*

### **Rights and obligations**

The Parties reaffirm their rights and obligations under the WTO SPS Agreement. Nothing in this chapter shall affect their rights and obligations that each Party has under the WTO SPS Agreement.

#### *Article 5*

### **Competent authorities**

1. For the purposes of this Chapter, the official competent authorities are the authorities of the Parties that according to the respective legislation have been empowered to enforce the domestic legislation of a Party falling within the scope of this Chapter to ensure compliance with the requirements of this Chapter, or any other authority to which such authority has delegated that power.

2. Upon entry into force of this Agreement, each Party shall provide the other Party the name of the competent authorities responsible for the implementation of the provisions included in this Chapter. This information shall be provided in writing, including the source where it is published.

The information shall also include a description of the distribution of competences between the respective authorities.

3. The Parties shall, in accordance with the Article 11 (Transparency and exchange of information), inform each other of any change of these competent authorities.

## *Article 6*

### **General obligations**

1. Products exported from a Party shall meet the applicable SPS requirements of the importing Party.

2. The SPS requirements of the importing Party shall be the same for the entire territory of the exporting Party, as long as the same sanitary and phytosanitary conditions prevail, without prejudice of Article 10 (Recognition of animal health and pest status and regional conditions).

The Parties shall ensure that their SPS measures are applied in a proportionate manner and do not arbitrarily or unjustifiably discriminate between Members of the EU or MERCOSUR Member States where identical or similar conditions prevail including between its own territory and that of the other Party. SPS measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

3. The procedures established in this Chapter shall be applied without undue delays and in a transparent manner, and information requested shall be limited to what is necessary for appropriate approval, control, inspection and verification purposes.

4. The Parties shall ensure that any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other WTO Member and shall not be higher than the actual cost of the service.

5. Except as provided for in the Article 14 (Emergency measures), when modifying SPS import requirements, each Party and, when appropriate MERCOSUR, shall allow for a transitional period, taking into account the nature of the modification, in order to avoid the unnecessary interruption or disruption of trade flows of products and to allow the exporting Party to adjust its procedures to such modification.

6. The implementation of the provisions of this Chapter shall not jeopardise the SPS trade related conditions between the Parties existing at the entry into force of this Agreement.

7. Without prejudice of similar provisions in other Chapters of this Agreement, nothing in this Chapter shall affect the rights and obligations of each Party to protect confidential information, according to each Party's relevant legislation. Each Party shall ensure that procedures are in place to prevent the disclosure of confidential information that is acquired during the process established in this Chapter.

8. The Parties shall avail themselves of the necessary resources to effectively implement this Chapter.

### *Article 7*

#### **Trade facilitation measures**

A – Approval of establishments for the import of animals, animal products, products of animal origin and animal by-products:

1. The importing Party may require the approval of the establishments for the import of animals, animal products, products of animal origin and animal by-products.
2. The approval shall be granted without prior inspection of individual establishments by the importing Party once the importing Party has recognised the official control system of the competent authority of the exporting Party and has authorised the import of the concerned products and if the exporting Party provides sufficient guarantee that they fulfil the sanitary requirements of the importing Party.
3. The exporting Party shall only authorise the exports from approved establishments. The exporting Party shall suspend or withdraw the export approval of those establishments that do not comply with the sanitary requirements of the importing Party and shall notify it to the importing Party.
4. The exporting Party shall propose the list of establishments to be approved. This list will be accompanied by the guarantees of the competent authority of the exporting Party that the establishments meet the sanitary requirements of the importing Party.
5. The importing Party shall approve the imports from the proposed establishments within 40 working days following the receipt of the request of the exporting Party accompanied by the sanitary guarantees. In case additional information is requested and as a result the request cannot be processed within the 40 working days deadline the importing Party shall inform the exporting Party and establish a new deadline for the approval that shall in no case exceed additional 40 working days after the receipt of the additional information.
6. The importing Party shall draw up lists of approved establishments and shall make these lists publicly available.
7. The importing Party may refuse the approval of establishments that are considered to be non-compliant with the import requirements. In these cases, the importing Party shall inform the exporting Party about the rejections to approve establishments, including the justification for the rejection.

8. The importing Party may carry out verifications in accordance with Article 15 (Verification of the official control system) of this Chapter. Based on the results of these verifications the importing Party may amend the list of establishments.

**B – Sanitary and phytosanitary import checks:**

1. Each Party shall adopt or maintain procedures allowing for the expedited release without undue delay.

2. The Parties shall agree, when appropriate, to simplify controls and verifications and reduce the frequency of the import checks made by the importing Party on products of the exporting Party. This decision will be based on: a) the risks involved; b) the controls carried out by the producers and/or importers validated by the Competent Authorities of the Parties; c) the guarantees given by the competent authority of the exporting country; and d) the international guidelines, standards and recommendations of the World Organization for Animal Health (OIE), or International Plant Protection Convention (FAO/IPPC) and Codex Alimentarius. Each Party may apply other criteria to simplify the controls if they do not undermine the common agreed criteria.

3. In case of rejected products or consignments as a result of non-compliances with SPS import requirements at the import check, the importing Party shall notify the exporting Party according to the procedure established in Article 12 (Notifications), the results of the import checks as soon as possible and normally within 5 working days from the date of the rejection.

4. If import checks reveal non-compliance with the relevant SPS import requirements, the action taken by the importing Party must be: justified, based on the identified non-compliance and not more trade-restrictive than required to achieve the Party's appropriate level of sanitary or phytosanitary protection.

**C – Simplification of import and approval procedures:**

The Parties recognise the different levels reached by regional integration processes within the European Union, on one hand, and MERCOSUR on the other. With a view to facilitate trade between their respective territories, MERCOSUR will make its best efforts to gradually adopt, if applicable:

- a) one single questionnaire;
- b) one single certificate, and
- c) one list of approved establishments.

MERCOSUR will make its best efforts to harmonize import requirements, certificates and import checks.

### **Alternative measures**

1. Upon request of the exporting Party, the importing Party shall examine whether exceptionally an alternative SPS measure ensures its appropriate level of protection. The alternative measure may be based on international standards, or on SPS measures of the exporting Party.
2. Alternative measures are not subject to the provisions of Article 9 (Equivalence).

### *Article 9*

#### **Equivalence**

1. An exporting Party may request a determination of equivalence regarding a specific SPS measure or measures related to a product or group of products or on a system-wide basis.
2. In order to implement this Article, the Subcommittee established in Article 18, will develop provisions and make recommendations to establish a procedure for the recognition of equivalence based on WTO/SPS Committee Decision G/SPS/19/Rev.2 (or its subsequent updates) and guidelines, standards and recommendations adopted in the framework of Codex, OIE and IPPC. This procedure should include the consultation process, the information to be required, responsibilities of the parties and the deadlines.
3. Upon receipt of a specific request, the Parties shall enter into consultations based on the procedure established in paragraph 2, with the aim of achieving an agreement on recognition of equivalence.
4. Upon request of the exporting Party, the importing Party shall inform the exporting Party of the state of play of the equivalence assessment.

### *Article 10*

#### **Recognition of animal health and plant pest status and regional conditions**

1. The Parties shall recognise concept of zoning and compartmentalization, including pests or disease free areas and low pest or disease prevalence area and agree to apply it in the trade between the Parties, in accordance with the WTO SPS Agreement, including the Guidelines to further the practical implementation of Article 6 of that SPS Agreement (WTO/SPS Committee Decision G/SPS/48) and the relevant recommendations, standards and guidelines of the OIE, or IPPC.
2. When determining pest and disease-free areas, areas of low pest and disease prevalence and compartments, whether for the first time or after an outbreak of an animal disease or plant pest, the importing Party shall base its own determination of the animal and plant health status of the exporting Party or parts thereof, on the information provided by the exporting Party in accordance

with the SPS Agreement and OIE and IPPC standards, and take into consideration the determination made by the exporting Party.

3. After finalisation of the procedure established in this Article and in the Annex (Procedure for recognition of zones and compartments and pest status) and without prejudice to Article 14 (Emergency measures), the importing Party shall take the decision to approve the requested zones or compartments and shall allow trade on that basis, without undue delay.

A. Animals, animal products, products of animal origin and animal by-products :

1. The procedure for the recognition of the disease-free zones or compartments is established in paragraph 3 of this title A and in the Annex (procedure for recognition of zones and compartments and pest status). The Subcommittee established in Article 18 of this Chapter, may define further details for this procedure, taking into account the WTO SPS Agreement and OIE guidelines, standards and recommendations.

2. When establishing or maintaining the zones or compartments referred to in point 2 the Parties shall consider factors such as geographical location, ecosystems, epidemiological surveillance and the effectiveness of sanitary controls.

3. Within 60 working days following the receipt of the information referred to in paragraph 2 of this Article, the importing Party may raise an explicit objection or request additional information, consultation or verification. The importing Party shall assess any additional information within 30 working days following its receipt. In case of consultation and/or verification, they shall take place according to Article 13 (Consultations) or Article 15 (Verification of the official control system) respectively. In the case of verifications required by the importing Party, the deadline for assess additional information will be interrupted.

4. The importing Party will expedite the procedure established in paragraph 3 of this title A, when the zones proposed by the exporting Party have the status of disease-free officially recognised by the OIE or when the status has been recovered after an outbreak.

5. In the event that the importing Party does not approve the requested zones or compartments it shall notify its decision to the exporting Party and explain the reasons for the rejection and, upon request, hold consultations, in accordance with Article 13 (Consultations).

B. Plants and plant products:

1. Each Party shall establish a list of regulated pests and regulated products. The importing Party shall make available to the other Party its list of regulated pests, regulated products and the

phytosanitary import requirements. The SPS import requirements shall be limited to what is necessary to protect plant health and/or safeguard the intended use. The importing Party shall inform the other Party about any required additional declaration.

The phytosanitary requirements of the importing Party shall be established considering the phytosanitary status in the exporting Party and, if required by the importing Party, the result of a pest risk analysis. The pest risk analysis shall be carried out in accordance with the relevant ISPMs. Risk analysis shall take into account available scientific and technical information as well as the intended use of the plants under consideration.

The importing Party will gradually update the lists mentioned in paragraph 1 on this title B when the exporting Party makes request to export new products to the other Party. When the importing Party requires a PRA to authorize this importation, in order to speed up the process, PRA already carried out for the same or similar products could be used as a basis, including additional information that the importing Party considers it necessary to be analysed.

The importing Party, when conducting the process for the determination of the pest status of the exporting Party, shall take into account the provisions in this Section (Section B plants and plant products) and in the Annex and the recommendations of the International Standards for Phytosanitary Measures (ISPMs) of the International Plant Protection Convention (FAO/IPPC).

2. The Parties shall recognise the concepts of Pest Free Areas, Pest Free Places of Production and Pest Free Production Sites, as well as areas of low pest prevalence as specified in the FAO/IPPC ISPMs, and of Protected Zones which they agree to apply in their trade.

3. When establishing or maintaining phytosanitary measures, the importing Party shall take into account Pest Free Areas, Pest Free Places of Production, Pest Free Production sites, and areas of low pest prevalence, as well as Protected Zones if they are established.

4. The exporting Party shall communicate Pest Free Areas, Pest Free Places of Production, Pest Free Production Sites, Protected Zones or areas of low pest prevalence to the other Party and, upon request, provide an explanation and supporting data as provided for in the relevant ISPMs or otherwise deemed appropriate. Unless the importing Party raises an objection or requests additional information or consultations within 150 working days after receiving the information, the recognition of the determination of the status of the exporting Party shall be understood as accepted by the importing Party.

5. The importing Party shall assess additional information requested within 90 days after receipt. If consultations are required by the Parties, they shall be conducted according to Article 13 (Consultations). Any verification the importing party may request shall be carried out in accordance with Article 15 (Verification of the official control system) taking into account the biology of the pest and the crop concerned. In the case of verifications required by the importing Party, the deadline for assess additional information will be interrupted.

C. The Subcommittee established in Article 18 of this Chapter, may define further details for this procedure, taking into account the SPS Agreement and OIE and IPPC guidelines, standards and recommendations.

*Article 11*

**Transparency and exchange of information**

1. Upon request of a Party and within 15 working days following the date of such request, the Parties shall exchange information on:

- a) SPS procedures for the import approval of a product, including, if possible, expected timelines;
- b) The requirements that apply for the import of specific products, including as appropriate the model of certificate;
- c) Information on the pest status, including surveillance, eradication and containment programs and their results in order to support such pest status and import phytosanitary measures;
- d) The state of play of the procedure for import approval of specific products;
- e) The relation of the SPS measure to the international standards, guidelines and recommendations and, in case that a measure is not based on international standard, the scientific information on which the SPS measure is not in conformity with and an explanation of the reasons of such measure.
- f) In cases where relevant scientific evidence is insufficient, a Party adopting a provisional measure shall provide the available pertinent information on which the measure is based and, when available the additional information for a more objective assessment of the risk and will review the SPS measure accordingly in a reasonable period of time.

2. The Parties shall make publically available, by the means they decide, updated information of their:

- a) SPS import requirements and authorisation procedures for the products covered by this chapter.
- b) List of regulated pests.

3. The Parties shall inform each other of:

- a) Any change in the sanitary and phytosanitary status that may affect trade between the Parties.
- b) Matters related to the development and application of SPS measures that may affect trade between the Parties.
- c) Any pertinent information for the adequate implementation of this Chapter.

4. Without prejudice of paragraph 1 when the information referred has been made available by notification to the WTO or to the International Standard Setting Body, in accordance with the relevant rules, or on publicly accessible and fee free web-sites of the Parties, the information shall be considered communicated to the other Party.

5. Each Party shall designate a contact point and inform the other Party no later than one month after the entry into force of this Agreement.

## *Article 12*

### **Notifications**

1. Any serious or significant risk to human, animal or plant life or health, including any food or feed control emergencies, shall be notified to the contact points designated in Article 11 (Transparency and exchange of information), within two working days.

2. Non serious risks shall also be notified to the other Party within a reasonable period of time sufficient to avoid threatening human, animal or plant life or health or jeopardising existing trade.

3. Such notifications shall be done through a permanent established system of notifications or through specific ad hoc notifications, in accordance with the legislation of the notifying Party. In both cases, the notification shall be sent to the competent authorities of the concerned Parties.

4. If the notifying Party takes any action in relation to the notification (including the rejection of a product or consignment), that notification shall be accompanied by an explanation of the reasons justifying the measures adopted.

5. The notifying Party shall withdraw any alert notification if the information upon which it is based proves to be unsubstantiated or if it is transmitted erroneously. This withdrawal shall take place as soon as possible, and notified to the exporting Party, in order to avoid negative trade impacts.

6. The Parties shall identify and inform the contact points for the notifications under this Article in case they are not the same as those identified according to point 5 of Article 11 (Transparency and exchange of information).

## *Article 13*

### **Consultations**

1. Without prejudice to the Dispute Settlement Chapter of this Agreement, if the SPS measures or draft measures of the importing Party, or their implementation, are considered to be inconsistent with this Chapter, both Parties shall enter into consultations within 60 days after the exporting Party has introduced a motivated request.
2. Notwithstanding paragraph 1, in the case of notification exchange in accordance with Article 12 (Notifications), or where a Party has serious concerns regarding a risk to public, animal or plant health, affecting products being traded between the Parties, consultations regarding the situation shall, on request, take place as soon as possible. Each Party shall endeavour, in such conditions, to provide all the information necessary to avoid trade disruption or to avoid limiting trade.
3. At the request of the exporting Party, the importing Party shall provide all the information necessary to avoid trade disruptions or to avoid limiting trade. This information will include that indicated in point 1 of Article 11 (Transparency and exchange of information).
4. Consultations may be held for a reasonable period of time to review and suggest any procedure to resolve the difficulties.
5. Consultations may be held by e-mail, video or audio conference. The requesting Party should ensure the preparation of the minutes which shall be formally approved by the Parties.
6. If the Parties do not reach a satisfactory solution after the consultation, the case may be submitted to the Subcommittee established in Article 18 that may meet in special session.

### *Article 14*

#### **Emergency measures**

1. Should a Party take domestic measures to control any serious risks to human, animal and plant life or health, these measures shall, without prejudice to the provisions of paragraph 2, also aim to prevent the introduction of any sanitary and phytosanitary risk into the territory of the other Party.
2. The importing Party may, in case of serious human, animal or plant life or health risk, take emergency measures against these risks.
3. For products in transit between the Parties, the importing Party shall consider the most suitable and proportional solution in order to avoid unnecessary disruptions to trade.
4. Measures referred to in paragraph 2 could be adopted without previous notification. However, the Party adopting the emergency measures shall notify the measures to the other Party as soon as possible and, in any case, no later than 48 hours following its adoption.

5. Each Party may request any information related to the sanitary and phytosanitary situation and the emergency measures adopted. Each Party shall answer as soon as the requested information is available.

6. Upon request of either Party and in accordance with the provisions of Article 13 (Consultations), the Parties shall hold consultations regarding the situation within 15 working days of the notification. The Parties may consider options for the facilitation of the implementation or the replacement of the measures.

### *Article 15*

#### **Verification of the official control system**

1. Each Party, within the scope of this Chapter, has the right:
  - a) To carry out verification of the official control system of the other Party, including verification visits.
  - b) To receive information about the control system of the other Party and the results of the controls carried out under that system.

The nature and frequency of audits and verifications shall be determined by the importing Party taking into account the import requirements, inherent characteristics of the product, the track record of past import checks and other available information, such as audits and inspections undertaken by the competent authority of the exporting Party.

The objective of the verifications will be to evaluate the capacity of the Competent Authorities of the exporting Party to ensure that the commodities exported or to be exported meet the requirements of the importing Party.

2. The verification visits shall be carried out without undue delay and notified to the exporting Party at least 60 working days before such verifications are carried out, except in emergency cases or if the Parties decide differently. Any modification to the date of the visit shall be agreed by the Parties.
3. Verifications shall be conducted in accordance with the audit plan agreed by the Parties concerned, based on the international guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems. Any modification to the audit plan of the visit shall be justified by the importing Party.
4. The expenses incurred by the Party carrying out the verification shall be borne by this Party.
5. The Party carrying out the verification shall send a draft report of the verification to the Party receiving the verification within 60 working days after the end of the visit. The Party receiving the verification may comment on the draft report within 60 working days after the receipt of the report; comments and action plan, when required, shall be attached to the final report. The

Party carrying out the verification shall send the final report within 30 working days after the receipt of the comments on the draft report.

Any measure taken as a consequence of audits and verifications shall be proportionate to shortcomings or risks identified. If so requested, technical consultations regarding the situation shall be held in accordance with Article 13 (Consultations).

6. Where a significant public, animal or plant health risk has been identified during the verification, the Party being verified shall be informed as quickly as possible and in any case within 10 working days following the end of the verification.

#### *Article 16*

##### **Cooperation in multilateral fora**

1. The Parties shall promote the cooperation in all the multilateral fora relevant for SPS issues, in particular in international standard setting bodies recognised in the framework of the WTO/SPS Agreement.

2. The Subcommittee established in Article 18 shall be the forum to exchange information and cooperate in the field of matters covered by paragraph 1.

#### *Article 17*

##### **Cooperation and technical assistance**

1. The Parties shall endeavour to strengthen cooperation so as to further the implementation of this Chapter and optimise its results with a view to expand opportunities and obtaining the greatest benefits for the Parties. This cooperation shall be developed within the legal and institutional framework governing cooperation relations between the Parties.

2. To achieve these objectives, the Parties shall give consideration to the cooperation needs identified by the Subcommittee established in Article 18.

#### *Article 18*

##### **Subcommittee**

1. The Parties hereby establish a Subcommittee on SPS matters. This Subcommittee shall meet for the first time within one year after the entry into force of this Agreement. Subsequently, the Subcommittee shall meet at least once a year, and if necessary in special session at the request of one of the Parties. The Subcommittee may meet in video or audio-conference and may also address issues electronically between sessions.

2. The Subcommittee shall have in particular the following responsibilities and functions:

- a) Establish the necessary arrangements to resolve the problems raised by the implementation of this Chapter.
  - b) Monitor the progress in the implementation of this Chapter.
  - c) Provide a forum to discuss the problems arising from the application of the SPS measures with a view to reaching mutually acceptable solutions. This forum may also discuss the information exchanged according to Article 11 (Transparency and exchange of information).
  - d) Promote the collaboration on multilateral fora.
  - e) Perform any other function or consider any matter referred to it expeditiously, as agreed by the Parties.
  - f) Exchange the lists of Contact Points to share information related to this chapter.
  - g) Recommend the amendment of the Annex.
3. The Subcommittee shall be comprised of representatives of the Parties with responsibility for SPS.
4. The Subcommittee may establish ad hoc working groups.

#### *Article 19*

##### **Special and differential treatment**

1. In application of article 10 of the SPS Agreement, when Paraguay has identified difficulties with a proposed measure notified by the EU Party, Paraguay may request, in its comments submitted to the EU, pursuant to Annex B to the SPS Agreement referred to in Article 7 of the SPS Agreement, an opportunity to discuss the issue. The EU Party and Paraguay shall enter into consultation in order to agree on:
- a) alternative import conditions to be applied by the importing Party according to Article 7 (alternative measures); or
  - b) technical assistance according to Article 18 cooperation and technical assistance; or
  - c) a transitional period of 6 months for proposed measures to apply to goods from Paraguay, which could be exceptionally extended for another period of no longer than 6 months.

## **ANNEX**

### **PROCEDURE FOR RECOGNITION OF ZONES, COMPARTMENTS AND PEST STATUS**

1. In accordance with the provisions of Article 12 (Notifications), the exporting Party, seeking recognition by the importing Party of its zones and compartments, including pests or disease-free areas and low pests or disease prevalence areas or a protected zone if applicable, shall notify its measures to the importing Party.
2. The Parties shall notify each other of any change in the measures specified in paragraph 1 which relate to the disease or pest. The additional guarantees may, in the light of such notification, be amended or withdrawn.
3. Notification shall include explanation and supporting data setting out in particular:
  - 3.1. In the case of animal health:
    - a) the nature of the disease and the history of its occurrence in its territory;

- b) the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation. It shall also be considered if the disease must be notified by law to the competent authorities;
- c) the period over which the surveillance was carried out;
- d) where applicable, the period during which vaccination against the disease was prohibited and the geographical area concerned by the prohibition;
- e) the measures to verify the absence of the disease.

3.2. In the case of plant health:

3.2.1. Each Party shall establish a list of regulated quarantine and regulated non-quarantine pests including:

- a) Quarantine Pests: Pests of potential economic importance not known to occur within any part of its own territory;
- b) Quarantine Pests: Pests of potential economic importance present but not widely distributed in its own territory and under official control;
- c) Regulated non-quarantine Pest.
- d) Where applicable, pests not known to occur within officially demarcated pest-free areas where legal requirements are in place to keep the pest-free status (protected zones), including movement and import requirements for host plants.

3.2.2. Any change to the list established in point 3.2.1 of regulated pests shall be based on pest risk analysis or relevant technical information and communicated to the other Party in accordance with Article 11 (Transparency and exchange of information).