

CHAPTER 7

SANITARY AND PHYTOSANITARY MEASURES

ARTICLE 7.1

Scope

This Chapter applies to all sanitary and phytosanitary measures of the State Parties, that may, directly or indirectly, affect trade between the Parties.

ARTICLE 7.2

General provisions

1. Unless otherwise provided for in this Chapter, the SPS Agreement applies between the State Parties and is incorporated into and form part of this Agreement, *mutatis mutandis*.
2. In implementing this Chapter, each State Party shall take into account the relevant guidance of the WTO Committee on Sanitary and Phytosanitary Measures (hereinafter referred to as "WTO SPS Committee") and base its SPS measures on international standards, guidelines, and recommendations adopted by the international organisations identified in the SPS Agreement.

ARTICLE 7.3

Objectives

The objectives of this Chapter are to:

- (a) facilitate trade between the Parties within the scope of sanitary and phytosanitary measures while protecting human, animal or plant life or health in the territories of the State Parties;

- (b) reinforce and build on the SPS Agreement and cooperate on the further implementation of the SPS Agreement;
- (c) strengthen communication, consultation and cooperation between the Parties, and particularly between the State Parties' competent authorities and contact point;
- (d) ensure that sanitary or phytosanitary measures implemented by a State Party are science-based, taking into account risk analysis principles;
- (e) ensure that sanitary or phytosanitary measures implemented by a State Party do not create unjustified obstacles to trade;
- (f) enhance transparency in and understanding of the application of each State Party's sanitary and phytosanitary measures;
- (g) encourage the development and adoption of international standards, guidelines and recommendations, by the international organisations identified in the SPS Agreement and promote their implementation by the State Parties; and
- (h) provide effective means to resolve any sanitary and phytosanitary concerns that may affect trade between the Parties.

ARTICLE 7.4

Definitions

1. For the purposes of this Chapter, the following apply:
 - (a) the definitions contained in Annex A of the SPS Agreement;
 - (b) the definitions adopted by the Codex Alimentarius Commission (hereinafter referred to as the "Codex");

- (c) the definitions adopted by the World Organisation for Animal Health (hereinafter referred to as the "WOAH");
 - (d) the definitions adopted by the International Plant Protection Convention (hereinafter referred to as the "IPPC");
 - (e) "import check" means an inspection, examination, sampling, review of documentation, test or procedure, including laboratory, organoleptic or identity, carried out at the border by an importing State Party or its representative to determine if a consignment complies with the sanitary and phytosanitary requirements of the importing State Party; and
 - (f) "international standards, guidelines and recommendations" means documents adopted by the relevant international organisations identified in the SPS Agreement.
2. In the event of an inconsistency between the definitions of the SPS Agreement and the definitions agreed by both Parties or the definitions adopted by Codex, WOAHA and IPPC, the definitions set out in the SPS Agreement shall prevail.

ARTICLE 7.5

Adaptation to regional conditions, including pest- or disease-free areas and areas of low pest or disease prevalence

1. The State Parties shall act in accordance with Article 6 (Adaption to Regional Conditions, Including Pest-or Disease- Free Areas and Areas of Low Pest or Disease Prevalence) of the SPS Agreement, guidelines adopted by the WTO SPS Committee by Decision G/SPS/48 and the standards, guidelines and recommendations of the IPPC and WOAHA, to facilitate the recognition of the pest- or disease-free areas and areas of low pest or disease prevalence.
2. The State Parties shall accept their respective disease-free areas, zones or compartments recognised by the WOAHA, expeditiously and without undue delay.
3. The exporting State Party shall provide appropriate science-based and technical information to objectively demonstrate to the importing State Party that its territory, or any region or regions of

its territory, are pest or disease-free areas or areas of low pest or disease prevalence and that such condition is likely to remain.

4. When an importing State Party receives a request for the recognition of a pest- or disease-free area or an area of low pest or disease prevalence from the exporting State Party, it shall initiate an assessment and present a timeframe for the recognition process.

5. If the assessment results in recognition, the importing State Party shall communicate this recognition to the exporting State Party in writing without undue delay, and shall apply these conditions to trade within a reasonable period of time.

6. If the assessment does not result in recognition, the importing State Party shall provide the exporting State Party with the rationale for its decision including any scientific and technical reasons in writing without undue delay. The importing State Party will allow the exporting State Party to provide more information or clarifications with the purpose of reviewing the decision.

7. The State Parties shall promote cooperation of their competent authorities in order to facilitate the implementation of this Article.

ARTICLE 7.6

Equivalence

1. The State Parties recognise equivalence as an important means to facilitate trade.

2. The determination of equivalence between the State Parties shall be established in accordance with the Decisions adopted by the WTO SPS Committee and based on the standards, guidelines and recommendations adopted by the relevant international organisations of the SPS Agreement.

3. The State Parties may recognise the equivalence of a measure, a group of measures, or a system for a product or group of products.

4. The importing State Party shall recognise the equivalence of a sanitary or phytosanitary measure if the exporting State Party objectively demonstrates to the importing State Party that the exporting State Party's measure:

(a) achieves the same level of protection as the importing State Party's measure; or

(b) has the same effect in achieving the objective as the importing State Party's measure.

5. On request of the exporting State Party, the importing State Party shall explain the objective and rationale of its sanitary or phytosanitary measure and clearly identify the risk the sanitary or phytosanitary measure is intended to address.

6. The exporting State Party shall communicate its interest in an equivalence determination and provide appropriate science-based and technical information with a view to objectively demonstrating the equivalence.

7. When an importing State Party receives a request for an equivalence assessment and determines that the information provided by the exporting State Party is sufficient, it shall initiate the equivalence assessment according to a timeframe established between the importing and exporting parties.

8. When an importing State Party commences an equivalence assessment, that State Party shall promptly, on request of the exporting State Party, explain its equivalence process and timetable for making the equivalence determination and, if the determination results in recognition, for enabling trade.

9. In determining the equivalence of a sanitary or phytosanitary measure, an importing State Party shall take into account available knowledge, information and relevant experience, as well as the regulatory competence of the exporting State Party.

10. Upon request of the exporting State Party, the importing State Party shall inform the exporting State Party of the status of the equivalence assessment.

11. If the importing State Party requires an "on-site" inspection to verify the equivalence, and this request is duly justified, the exporting State Party shall organise such inspections.

12. When an importing State Party recognises the equivalence of an exporting State Party's specific sanitary or phytosanitary measure, group of measures or a system for a product or group of products, the importing State Party shall communicate this to the exporting State Party in writing without undue delay and shall apply this recognition within a reasonable period of time.

13. If an equivalence determination does not result in recognition by the importing State Party, the importing State Party shall provide the exporting State Party with the rationale for its decision including any scientific and technical reasons for the decision, in writing and without undue delay.

ARTICLE 7.7

Risk analysis

1. The State Parties recognise the importance of ensuring that their respective sanitary and phytosanitary measures are based on scientific principles.
2. Each State Party shall base its sanitary and phytosanitary measures on international standards, guidelines, and recommendations unless no applicable international standards, guidelines and recommendations exist, or if a State Party has established a higher level of sanitary or phytosanitary protection. In such cases, the State Party shall ensure that its sanitary or phytosanitary measure is based on an assessment, as appropriate to the circumstances, of the risk to human, animal or plant life or health.
3. Recognising the State Parties' rights and obligations under the relevant provisions of the SPS Agreement, nothing in this Chapter shall be construed to prevent a State Party from:
 - (a) establishing the level of protection it determines to be appropriate;
 - (b) establishing or maintaining an approval procedure that requires a risk analysis to be carried out before the State Party grants a product access to its market; or
 - (c) adopting or maintaining a sanitary or phytosanitary measure on a provisional basis.

4. When conducting its risk analysis, each State Party shall:
 - (a) take into account relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations;
 - (b) ensure that its sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between State Parties where identical or similar conditions prevail, including between its own territory and that of other State Parties;
 - (c) ensure that each risk assessment it conducts is appropriate to the circumstances of the risk at issue and takes into account reasonably available and relevant scientific information; and
 - (d) ensure that it is documented.

5. Each State Party shall consider and select risk management options that are not more trade restrictive¹ than required to achieve the level of protection that the State Party has determined to be appropriate, including taking no measure if that would achieve the State Party's appropriate level of protection.

6. When the importing State Party makes a risk analysis for a new product, if there are similarities with other products and associated risk from the same exporting State Party or the other State Parties, the importing State Party shall be able to take into account previous risk assessments where applicable, in order to simplify the process.

7. If an importing State Party requires a risk analysis to evaluate a request from an exporting State Party to authorise importation of a good of that exporting State Party, the importing State Party shall provide, on request of the exporting State Party, an explanation of the information required for the risk assessment. On receipt of the required information from the exporting State Party, the importing State Party shall endeavour to facilitate the evaluation without undue delay.

¹ For greater certainty, a risk management option is not more trade restrictive than required unless there is another option that is reasonably available, taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

8. On request of the exporting State Party, the importing State Party shall inform the progress of a specific risk analysis request, and of any delay that may occur during the process.

9. If the importing State Party, as a result of a risk analysis, adopts a sanitary or phytosanitary measure that allows trade to commence or resume, the importing State Party shall implement the measure within a reasonable period of time.

10. If a State Party adopts or maintains a provisional sanitary or phytosanitary measure, in case where relevant scientific evidence is insufficient, the State Party shall without undue delay and in any case no longer than 6 (six) months:

- (a) seek to obtain the additional information necessary for a more objective risk assessment;
- (b) take into consideration any information provided by the other State Party in response to the provisional measure;
- (c) complete the risk assessment after obtaining the requisite information; and
- (d) review and, if appropriate, revise the provisional measure in light of the risk assessment.

11. Without prejudice to Article 7.12 (Emergency measures), a State Party shall not stop the importation of a good of another State Party solely for the reason that the importing State Party is undertaking a review of its sanitary or phytosanitary measure, if the importing State Party permitted the importation of that good of the other State Party when the review was initiated.

ARTICLE 7.8

Audits²

² For greater certainty, nothing in this Article prevents an importing State Party from performing an inspection of a facility for the purposes of determining if the facility conforms with: (i) the importing State Party's sanitary or phytosanitary requirements; or (ii) sanitary or phytosanitary measures that the importing State Party has determined to be equivalent.

1. To determine an exporting State Party's ability to provide required assurances and meet the sanitary and phytosanitary measures of the importing State Party, the importing State Party shall have the right, subject to this Article, to audit the exporting State Party's competent authorities and associated or designated inspection systems. That audit may include an assessment of the control systems and programmes including, if appropriate, reviews of the inspection and audit programmes; and on-site inspections of facilities or establishments.
2. In undertaking an audit, a State Party shall take into account relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations.
3. An audit shall be systems-based and designed to check the effectiveness of the regulatory controls of the competent authorities of the exporting State Party.
4. When an exporting State Party receives a request for an audit to verify compliance with sanitary or phytosanitary requirements by an importing State Party, the importing State Party shall provide the rationale for the said audit.
5. In the case of an on-site inspection, it shall be limited exclusively to the verification of what is technically necessary, without causing undue delays and unnecessary costs.
6. Prior to the commencement of an audit, the importing State Party and exporting State Party involved shall discuss the rationale and decide: the objectives and scope of the audit; the criteria or requirements against which the exporting State Party will be assessed; and the itinerary and procedures for conducting the audit. The exporting State Party shall facilitate the organisation and the itinerary to the audit.
7. The importing State Party shall provide a report setting out its conclusions in writing to the exporting State Party within 90 (ninety) working days. The report shall clearly document any corrective actions, timeframes, and follow-up procedures. The importing State Party shall take into consideration, without undue delay, any information provided by the exporting State Party. Comments made by the exporting State Party shall be attached to and, where appropriate, included in the report, without undue delay.
8. A decision or action taken by the importing State Party as a result of the audit shall be supported by objective evidence and data that can be verified, taking into account the importing

State Party's knowledge of, relevant experience with, and confidence in, the exporting State Party. This objective evidence and data shall be provided to the exporting State Party on request.

9. The costs incurred by the importing State Party shall be borne by the importing State Party, unless both parties agree otherwise.

10. The importing State Party and the exporting State Party shall each ensure that procedures are in place to prevent the disclosure of confidential information that is acquired during the audit process.

11. For animal products, animal by-products, live animals and genetic materials, when the result of the audit of the official control system of the competent authority of the exporting State Party is favourable, the importing State Party shall notify to the exporting State Party, without undue delay, the specific category or categories of products, facilities and establishments, which the importing State Party has authorised. The import of such products shall be based on one of the following approval procedures of facilities or establishments, along with the rationale for its choice:

- (a) individual facilities or establishments are approved without prior inspection. The exporting State Party shall inform the list of facilities or establishments to be approved. The competent authority of the exporting State Party shall guarantee that the facilities or establishments from the list meet the sanitary requirements of the importing State Party. The importing State Party shall notify the exporting State Party of its acceptance or rejection of any facility or establishment without undue delay. The exporting State Party shall suspend or withdraw the export approval of those facilities or establishments that do not comply with the sanitary requirements of the importing State Party and shall promptly notify it to the importing State Party; or
- (b) only specific facilities or establishments are approved to export to the importing State Party upon compliance with its sanitary import requirements. For additional facilities or establishments to be considered for approval, the exporting State Party shall provide the relevant information as required by the importing State Party for further assessment. The importing State Party may conduct on-site inspections where necessary. The evaluation procedure shall be done in a reasonable period of time, and the exchange of information between the State Parties including the outcome of the evaluation shall be done without undue delay.

12. After a reasonable period of time, as it gains more confidence in the exporting State Party's system, the importing State Party may unilaterally change the approval procedure from subparagraph (b) to subparagraph (a) of paragraph 11. Alternatively, the exporting State Party may request this reassessment from the importing State Party and provide any relevant information to support its request. In this reassessment, the rationale used for the original decision, the existing risks, the number of establishments already approved and notifications that have occurred since the original assessment and the additional information provided by the exporting State Party should be considered.

13. In accordance with international standards, guidelines and recommendations, when the result of the audit of the official phytosanitary system of the competent authority of the exporting State Party is favourable, the exporting State Party may provide the list of places of production registered for export, whenever available.

14. When the result of the audit of the official control system of the competent authority of the exporting State Party is unfavourable, the importing State Party shall inform without undue delay the exporting State Party of any denial of approval of places of production facilities or establishments, providing the scientific justification and indicating the corrective actions and timeframe for implementation, which the exporting State Party should implement for the re-evaluation of the importing State Party.

ARTICLE 7.9

Import checks³

1. The application of import checks by the importing State Party shall not become disguised restrictions on trade between the Parties and shall be carried out in accordance with the SPS Agreement and the international standards, guidelines and recommendations.

³ For greater certainty, the State Parties recognise that import checks are one of many tools available to assess compliance with an importing Party's sanitary and phytosanitary measures.

2. Each State Party shall ensure that its import programmes are based on the risks associated with importations, and that import checks are carried out without undue delay⁴.
3. A State Party shall make available to another State Party, upon request, information on its import procedures.
4. An importing State Party shall provide to another State Party, upon request, information regarding the analytical methods, quality controls, sampling procedures and facilities that the importing State Party has used to test a good. The importing State Party shall ensure that any testing is carried out using appropriate and validated methods in a facility that operates under a quality assurance programme that is consistent with international laboratory standards. The importing State Party shall maintain physical or electronic documentation regarding the identification, collection, sampling, transportation and storage of the test sample, and the analytical methods used on the test sample.
5. In the event that import checks demonstrate that products do not conform with the relevant import requirements of the importing State Party, any action taken by the importing State Party should be proportionate to the sanitary and phytosanitary risk associated with the import of the non-compliant product.
6. Unless otherwise provided for in this Chapter, an importing State Party normally shall not suspend trade with another State Party on the basis that one consignment has failed to conform to its SPS requirements.
7. If an importing State Party takes an action regarding the importation of a good of another State Party on the basis of an adverse result of an import check, the importing State Party shall provide a notification, where practicable by electronic means, about the adverse result to at least one of the following: the importer or its agent; the exporter; the manufacturer; or the exporting State Party.
8. If an importing State Party determines that there is a significant non-conformity with a sanitary or phytosanitary measure; or a sustained, or a recurring pattern of non-conformity with a

⁴ For greater certainty, nothing in this Article prohibits a State Party from performing import checks to obtain information to assess risk or to determine the need for, develop or periodically review a risk-based import programme.

sanitary or phytosanitary measure, the importing State Party shall notify the exporting State Party of the non-conformity.

9. When the importing State Party provides a notification pursuant to paragraph 8, it shall:

(a) include:

(i) the reason for the non-conformity and the action taken;

(ii) the legal basis or authorisation for the action; and

(iii) information on the status of the affected goods and, if appropriate, on their disposition;
and

(b) transmit the notification by electronic means, if practicable and not already been provided through another channel.

10. Upon request, an importing State Party shall provide to the exporting State Party available information on goods from the exporting State Party that were found not to conform to a sanitary or phytosanitary measure of the importing State Party.

ARTICLE 7.10

Certification

1. The State Parties recognise that assurances with respect to sanitary or phytosanitary requirements may be provided through means other than certificates.

2. In applying certification requirements, an importing State Party shall take into account relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations.

3. If an importing State Party requires certification for trade in a good, that State Party shall ensure that the certification requirement is applied only to the extent necessary to protect human,

animal or plant life or health. The importing State Party shall limit the attestations and information it requires on the certificates to what is essential to provide assurances to the importing State Party that its sanitary or phytosanitary requirements have been met.

4. An importing State Party should provide to another State Party, upon request, the rationale for any attestations or information that it requires to be included on a certificate.

5. The State Parties may agree to work cooperatively to develop model certificates to accompany specific goods traded between the Parties, taking into account relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations.

6. The State Parties shall promote the implementation of electronic certification and other technologies to facilitate trade, taking into account the international standards, guidelines and recommendations, when applicable.

ARTICLE 7.11

Transparency⁵

1. The State Parties recognise the value of sharing information about their sanitary and phytosanitary measures on an on-going basis. The State Parties shall exchange information on issues related to the development and application of sanitary and phytosanitary measures affecting trade between them as well as on scientific evidence or new scientific information available that is relevant to this Chapter, upon request.

2. Each State Party shall observe the notification provisions of the SPS Agreement and the relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations. A State Party shall be deemed to have fulfilled their notification obligations pursuant to this Article if it has met their WTO notification obligations.

⁵ For greater certainty, this Article applies only to a sanitary or phytosanitary measure that constitutes a sanitary or phytosanitary regulation for the purposes of Annex B of the SPS Agreement.

3. A State Party shall notify a proposed sanitary or phytosanitary measure that may have an effect on the trade of another State Party, including any that conforms to international standards, guidelines or recommendations, by using the WTO SPS notification submission system as a means of notifying the other State Parties.
4. Unless urgent problems of human, animal or plant life or health protection arise or threaten to arise, or the measure is of a trade-facilitating nature, a State Party shall normally allow at least 60 (sixty) days for interested persons and other Parties to provide written comments on the proposed measure after it makes the notification pursuant to paragraph 3. If feasible and appropriate, the State Party should allow more than 60 (sixty) days.
5. The State Party, in accordance with its own internal procedures, shall make available to the public, by electronic means in an official journal or on websites, the proposed sanitary or phytosanitary measure notified pursuant to paragraph 3, as well as the adopted measures.
6. If a State Party proposes a sanitary or phytosanitary measure which does not conform to an international standard, guideline or recommendation, the State Party shall provide to another State Party, upon request, and to the extent permitted by the confidentiality and privacy requirements of the State Party's laws and regulations, the relevant information that the State Party considered in developing the proposed measure.
7. A State Party that proposes to adopt a sanitary or phytosanitary measure shall discuss with another State Party, upon request and if appropriate and feasible, any scientific or trade concerns that the other State Party may raise regarding the proposed measure and the availability of alternative, less trade-restrictive approaches for achieving the objective of the measure.
8. An exporting State Party shall notify the importing State Party through the contact points referred to in Article 7.16 (Competent authorities and contact points) or the already established communication channels with the competent authority of the importing State Party without undue delay:
 - (a) if it has knowledge of a significant sanitary or phytosanitary risk related to the export of a good from its territory;

- (b) of urgent situations where a change in animal or plant health status in the territory of the exporting State Party may affect current trade;
- (c) of significant changes in the status of a regionalised pest or disease;
- (d) of new scientific findings of importance which affect the regulatory response with respect to food safety, pests or diseases; and
- (e) of significant changes in food safety, pest or disease management, control or eradication policies or practices that may affect current trade.

9. If feasible and appropriate, a State Party should provide an interval of more than 6 (six) months between the date it publishes a final sanitary or phytosanitary measure and the date on which the measure takes effect, unless the measure is intended to address an urgent problem of human, animal or plant life or health protection or the measure is of a trade-facilitating nature.

10. A State Party shall provide to another State Party without undue delay, upon request, all sanitary or phytosanitary measures related to the importation of a good into that State Party's territory.

ARTICLE 7.12

Emergency measures

1. If a State Party adopts an emergency measure that is necessary to address an urgent problem of human, animal or plant life or health protection that arises or threatens to arise, the State Party shall promptly notify the affected State Party of that measure through the relevant contact point referred to in Article 7.16 (Competent authorities and contact points) or the already established communication channels with the competent authority of the affected State Party. The State Party that adopts the emergency measure shall take into consideration any information provided by other State Parties in response to the notification.

2. If a State Party adopts an emergency measure, it shall review the scientific basis of that measure within 6 (six) months and make available the results of the review to any State Party upon request.

ARTICLE 7.13

Cooperation

1. The Parties shall explore opportunities for further cooperation, collaboration and information exchange between the State Parties on sanitary and phytosanitary matters of mutual interest, consistent with this Chapter. Those opportunities may include trade facilitation initiatives and technical assistance. The State Parties shall cooperate to facilitate the implementation of this Chapter. Such cooperation shall be based on mutually agreed terms and conditions.

2. The State Parties shall cooperate and may jointly identify work on sanitary and phytosanitary matters with the goal of eliminating unnecessary obstacles to trade between the Parties.

ARTICLE 7.14

Information exchange

A State Party may request relevant and reasonable information from another State Party on any matter arising under this Chapter. A State Party that receives a request pursuant to this paragraph shall provide that information, within a mutually agreed timeframe, in English and preferably by electronic means.

ARTICLE 7.15

Technical consultations

1. Where a State Party has serious concerns regarding a risk to human, animal or plant life or health, affecting commodities for which trade takes place, consultations regarding the situation

shall, upon request, take place as soon as possible. In this case, each State Party shall endeavour to provide in due time all necessary information to avoid disruption in trade.

2. Consultations referred to in paragraph 1 may be held by e-mail, video or telephone conference, or any means agreed between the State Parties. The requesting State Party shall ensure the preparation of the minutes of the consultation.

ARTICLE 7.16

Competent authorities and contact points

1. Competent authority means a government body of each State Party responsible for the implementation of the provisions included in this Chapter.
2. Each State Party shall designate a contact point which shall have the responsibility for coordinating the operation of this Chapter.
3. Within 60 (sixty) days after the date of entry into force of this Agreement for each State Party, that State Party shall notify to the other State Parties:
 - (a) the contact points for information exchange in accordance with this Chapter; and
 - (b) their designated competent authorities and the areas of responsibility of such competent authorities.
4. The State Parties shall inform each other of any change to their contact points or any significant change in the structure or competence of their competent authorities.
5. The functions of the competent authorities and the designated contact points shall include:
 - (a) monitoring the implementation and administration of this Chapter;
 - (b) when necessary, reviewing this Chapter and recommending any potential amendments;

- (c) addressing any issue that any State Party raises on matters covered by this Chapter in a timely manner;
- (d) encouraging cooperation among the State Parties on matters covered by this Chapter;
- (e) exchanging information on matters covered by this Chapter;
- (f) facilitating technical discussions on matters covered by this Chapter and trade-facilitating initiatives; and
- (g) exchanging information in the field of private standards in order to facilitate the understanding of private standards between the State Parties.