

## CHAPTER 6

### SANITARY AND PHYTOSANITARY MATTERS RELATED TO ANIMALS AND ANIMAL PRODUCTS, PLANTS AND, PLANT PRODUCTS

#### Article 6.1

##### Objective

1. The objective of this Chapter is to safeguard public, animal and plant health in the territory of the Parties whilst facilitating trade in animals and animal products, plants, plant products and other goods between the Parties, by:
  - a- improving transparency, communication and cooperation between the Parties on sanitary and phytosanitary measures
  - b- establishing mechanisms and procedures for trade facilitation; and
  - c- further implementing the principles of the WTO SPS Agreement
2. The Parties agree to establish a working cooperation on multilateral fora and on food safety, animal health and plant protection science.
3. The Parties agree to establish a working cooperation on any other SPS matter or fora jointly agreed.

#### Article 6.2

##### Multilateral obligations

The Parties reaffirm their rights and obligations under the WTO Agreement and, in particular, the WTO SPS Agreement. These rights and obligations shall underline the activities of the Parties under this Chapter.

#### Article 6.3

##### Scope

This Chapter shall apply to:

1. All sanitary and phytosanitary measures as defined in Annex A to the WTO SPS Agreement in so far as they affect trade between the Parties.
2. The cooperation on multilateral fora recognised in the framework of the WTO/SPS Agreement.
3. Bilateral Cooperation on Food Safety, Animal Health and Plant Protection Science.

4. The cooperation in any other SPS matter or in any other fora that the Parties may jointly agree.

#### Article 6.4

##### Definitions

For the purposes of this Chapter the following definitions apply:

- definitions in Annex A of the SPS Agreement, as well as those of *Codex Alimentarius* (Codex), the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC).<sup>1</sup>
- ‘Protected zone’: for a specific regulated pest means an officially defined geographical part of the territory of a 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;

#### Article 6.5

##### Competent authorities

1. The competent authorities of the Parties are the authorities responsible for the implementation of the measures referred to in this Chapter, as provided for in Appendix I.
2. In accordance with Article 6.12, the Parties shall inform each other of any significant changes in the structure, organisation and division of competency of their competent authorities.

#### Article 6.6

##### Recognition for trade of animal health and pest status and regional conditions

##### A. Recognition of status for animal diseases, infections in animals or pests

1. As regards animal diseases and infections in animals (including zoonoses), the following shall apply:

- (a) The importing Party shall recognise for trade the animal health status of the

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<sup>1</sup> Nota de los negociadores: El acuerdo actual incluye definiciones como “Acuerdo de Asociación” “día hábil”, intr. Alia, que deberían ser consideradas en los capítulos transversales.

exporting Party or its regions as determined by the exporting Party in accordance with Appendix III.A., with respect to animal diseases specified in Appendix II.A.

(b) Where a Party considers that it has, for its territory or a region, a special status with respect to a specific animal disease other than those in Appendix II.A., it may request recognition of this status in accordance with the criteria set out in Appendix III.C. The importing Party may request guarantees in respect of imports of live animals and animal products, which are appropriate to the agreed status of the Parties.

(c) The status of the territories or regions, or the status in a sector or sub-sector of the Parties related to the prevalence or incidence of an animal disease other than those in Appendix II.A. or infections in animals, and/or the associated risk, as appropriate, as defined by the international standard setting organisations recognised by the WTO SPS Agreement, is recognised by the Parties as the basis between them. The importing Party may request guarantees in respect of imports of live animals and animal products, which are appropriate to the defined status in accordance with the recommendations of the standard setting organisations, as appropriate.

(d) Without prejudice to Articles 6.8 and 6.14, and unless the importing Party raises an explicit objection and requests supportive or additional information or consultations and/or verification, each Party shall take without undue delay the necessary legislative and administrative measures to allow trade on the basis of the provisions of subparagraphs (a), (b) and (c).

2. As regards pests, the following shall apply:

a) The Parties recognise for trade their pest status in respect to pests specified in Appendix II.B.

b) Without prejudice to Articles 6.8 and 6.14, and unless the importing Party raises an explicit objection and requests supportive or additional information or consultations and/or verification, each Party shall take without undue delay the necessary legislative and administrative measures to allow trade on the basis of the provision of subparagraph (a).

## B. Recognition of regionalisation

1. The Parties recognise the concept of regionalisation, which they agree to apply to trade between them.

2. The Parties agree that regionalisation decisions for animal and fish diseases listed in Appendix II.A and for pests listed in Appendix II.B. must be taken in accordance with the provisions of Appendix III.A. and Appendix III.B, respectively.

3. (a) As regards animal diseases and in accordance with the provisions of Article 6.13, the exporting Party seeking recognition of its regionalisation decision by the importing Party shall notify its measures with full explanation and supporting data for its determinations and decisions. Without prejudice to Article 6.14, and unless

the importing Party raises an explicit objection and requests additional information or consultations and/or verification within 15 working days following receipt of the notification, the regionalisation decision so notified shall be considered as accepted.

(b) Consultations referred to in subparagraph (a) shall take place in accordance with Article 6.13(3). The importing Party shall assess the additional information within 15 working days following receipt of the additional information. The verification referred to in subparagraph (a) shall be carried out in accordance with Article 6.10 and within 25 working days following receipt of the request for verification.

4. (a) As regards pests, each Party shall ensure that trade in plants, plant products and other goods takes account of the pest status in a region recognised by the other Party. A Party seeking recognition of its regionalisation decision by the other Party shall notify its measures and decisions, as guided by the relevant FAO International Standards for Phytosanitary Measures, including No 4 ‘Requirements for the establishment of Pest Free Areas’, No 8 ‘Determination of Pest Status in an area’, and other International Standards for Phytosanitary Measures as the Parties deem appropriate. Without prejudice to Article 6.14, and unless a Party raises an explicit objection and requests additional information or consultations and/or verification within three months following the notification, the regionalisation decision so notified shall be considered as accepted.

(b) Consultations referred to in subparagraph (a) shall take place in accordance with Article 13(3). The importing Party shall assess the additional information within three months following receipt of the additional information. The verification referred to in subparagraph (a) shall be carried out in accordance with Article 6.10 and within 12 months following receipt of the request for verification, taking into account the biology of the pest and the crop concerned.

5. After finalisation of the procedures of paragraph 2, 3 and 4, and without prejudice to Article 6.14, each Party shall take, without undue delay, the necessary legislative and administrative measures to allow trade on that basis.

## Article 6.7

### Determination of equivalence

1. Equivalence may be recognised in relation to an individual measure and/or groups of measures and/or systems applicable to a sector or sub-sector.
2. In the determination of equivalence, the Parties shall follow the consultation process of paragraph 3. This process shall include the objective demonstration of equivalence by the exporting Party and the objective assessment of this demonstration by the importing Party with a view to possibly recognising equivalence by the latter.

3. Upon request of the exporting Party concerning a measure or measures affecting one or more sector(s) or sub-sector(s), the Parties shall, within three months after receipt by the importing Party of such request, initiate the consultation process which includes the steps set out in Appendix V. However, in case of multiple requests from the exporting Party, the Parties, on request of the importing Party, shall agree within the Sub-committee referred to in Article 6.15 on a time schedule in which they shall initiate the process referred to in this paragraph.

4. Unless otherwise mutually agreed, the importing Party shall finalise the assessment of equivalence within 180 days after having received from the exporting Party its demonstration of equivalence, except for seasonal crops when it is justifiable to delay the assessment to permit verification of phytosanitary measures during a suitable period of growth of a crop.

The sectors or sub-sectors of priority of each Party for which this process may be initiated, are to be set out, where appropriate, in order of priority in Appendix V.B. The Sub-committee referred to in Article 6.15 may amend, by means of decision, this list, including its order of priority.

5. The importing Party may withdraw or suspend equivalence on the basis of any amendment by one of the Parties of measures affecting equivalence, provided that the following procedures are followed:

(a) In accordance with the provisions of Article 6.12, the exporting Party shall inform the importing Party of any proposal for amendment of its measures for which equivalence of measures is recognised and the likely effect of the proposed measures on the equivalence which has been recognised. Within 30 working days of receipt of this information, the importing Party shall inform the exporting Party whether or not equivalence would continue to be recognised on basis of the proposed measures.

(b) In accordance with the provisions of Article 12, the importing Party shall inform the exporting Party of any proposal for amendment of its measures on which recognition of equivalence has been based and the likely effect of the proposed measures on the equivalence which has been recognised. Should the importing Party not continue to recognise equivalence, the Parties may agree on the conditions to re-initiate the process referred to in paragraph 3 on the basis of the proposed measures.

6. Without prejudice to Article 6.14, the importing Party may not withdraw or suspend equivalence before the proposed new measures of either Party enter into force.

7. The recognition or withdrawal or suspension of equivalence rests solely with the importing Party acting in accordance with its administrative and legislative framework including, as regards plants, plant products and other goods, appropriate communications in accordance with FAO International Standard for Phytosanitary Measures No 13 'Guidelines for the notification of non-compliances and emergency action' and other International Standards for Phytosanitary Measures, as appropriate. That Party shall provide to the exporting Party in writing full explanation and supporting data used for the determinations and decisions covered by this Article. In case of non-recognition, withdrawal or suspension of equivalence, the importing Party shall indicate to the exporting Party the required

conditions on which the process referred to in paragraph 3 may be reinitiated.

## Article 6.8

### Transparency and trade conditions

1. The Parties agree to apply general import conditions. Without prejudice to the decisions taken in accordance with Article 6.6, the import conditions of the importing Party shall be applicable to the total territory of the exporting Party. Upon entry into force of this Chapter and in accordance with the provisions of Article 6.12, the importing Party shall inform the exporting Party of its sanitary and phytosanitary import requirements. This information shall include, as appropriate, the models for the official certificates or attestations, as prescribed by the importing Party.

2. (a) For the notification by the Parties of amendments or proposed amendments of the conditions referred to in paragraph 1, they shall comply with the provisions of the SPS Agreement and subsequent decisions, as regards notification of measures. Without prejudice of the provisions of Article 6.14, the importing Party shall take into account the transport time between the Parties to establish the date of entering into force of the amended conditions referred to in paragraph 1.

(b) If the importing Party fails to comply with these notification requirements, it shall continue to accept the certificate or attestation guaranteeing the previously applicable conditions until 30 days after entering into force of the amended import conditions.

3. Once Chile grants access to one or more European Union sector(s) or sub-sector(s) in accordance to the conditions referred to in paragraph 1, Chile shall approve the subsequent European Union Member States export requests on the basis of a comprehensive dossier of information available to the European Commission (the Country profile), unless Chile requests additional information in limited specific circumstances when deemed appropriate.

4. (a) Within 90 days after recognition of equivalence, the Parties shall take the necessary legislative and administrative measures to implement the recognition of equivalence in order to allow on that basis trade between them in sectors and sub-sectors, for which all respective sanitary and phytosanitary measures of the exporting Party are recognised as equivalent by the importing Party. For these commodities, the model for the official certificate or official document required by the importing Party may, then, be replaced by a certificate drawn up as provided for in Appendix VIII.B.

(b) For commodities in sectors or sub-sectors for which one or some but not all measures are recognised as equivalent, trade shall continue on the basis of compliance with the conditions referred to in paragraph 1. Upon request of the exporting Party, the provisions of paragraph 5 shall apply.

5. Import shall not be subject to import licenses by the importing party.

6. For conditions affecting trade, upon request of the exporting Party, the Parties shall enter into consultations in accordance with the provisions of Article 6.15, in order to agree

on alternative or additional import conditions of the importing Party. Such alternative or additional import conditions may, when appropriate, be based on measures of the exporting Party recognised as equivalent by the importing Party. If agreed, the importing Party shall take the necessary legislative and/or administrative measures to allow import on that basis, within 90 days.

7. Approval of establishments for the import of animals, animal products, products of animal origin and animal by-products: for the import of animal products, upon request of the exporting Party accompanied by the appropriate guarantees, the importing Party shall approve establishments referred to in Appendix IV(2) which are situated on the territory of the exporting Party, without prior inspection of individual establishments. Such approval shall be consistent with the conditions and provisions set out in Appendix IV. Unless additional information is requested, the importing Party shall take the necessary legislative and/or administrative measures to allow import on that basis within 30 working days after the importing Party has received the request and guarantees.

The initial list of establishments shall be approved in accordance with the provisions of Appendix IV.

8. Upon request of a Party, the other Party shall provide full explanation and supporting data for the determinations and decisions covered by this Article.

#### Article 6.9

##### Certification procedures

1. For purposes of certification procedures, the Parties shall comply with the principles and criteria set out in Appendix VIII.A.
2. Certificates or official documents referred to in Article 6.8(1) and (4) shall be issued as set out in Appendix VIII.C.
3. The Sub-committee referred to in Article 6.15 may agree on rules to be followed in case of electronic certification, withdrawal or replacement of certificates.

#### Article 6.10

##### Verification

1. In order to maintain confidence in the effective implementation of the provisions of this Chapter, each Party, within the scope of this Chapter, shall have the right:

- (a) to carry out, in accordance with the guidelines of Appendix VI, verification of all or part of the other Party's authorities' total control programme. The expenses of such verification shall be borne by the Party carrying out the verification;

(b) from a date to be determined by the Parties, to receive on its request from the other Party submission of all or part of that Party's total control programme and a report concerning the results of the controls carried out under that programme;

(c) that, for laboratory tests related to commodities of animal origin, on request of one Party, the other Party shall participate in the periodical inter-comparative test programme for specific tests organised by the reference laboratory of the requesting Party. Such participation shall be borne by the participating Party.

2. Either Party may share the results and conclusions of its verifications with third countries, and make them publicly available.

3. The Sub-committee referred to in Article 6.15 may modify, by means of a decision, Appendix VI, taking due account of relevant work carried out by international organizations.

4. The results of verification may contribute to measures by the Parties or one of the Parties referred to in Articles 6.6, 6.7, 6.8 and 6.11.

#### Article 6.11

##### Import checks and inspection fees

1. The Parties agree that import checks on importation by the importing Party of consignments from the exporting Party shall respect the principles set out in Appendix VII.A. The results of these checks may contribute to the verification process referred to in Article 6.10.

2. The frequencies of physical import checks applied by each Party are set out in Appendix VII.B. A Party may amend these frequencies within its competences and in accordance with its internal legislation, as a result of progress made in accordance with Articles 6.7 and 6.8, or as a result of verifications, consultations or other measures provided for in this Chapter. The Sub-committee referred to in Article 6.15 shall by decision modify Appendix VII.B accordingly.

3. Inspection fees may only cover the costs incurred in by the competent authority for performing import checks. They shall be equitable in relation to fees charged for the inspection of similar domestic products.

4. The importing Party shall inform the exporting Party of any amendment, including the reasons for these amendments concerning the measures affecting import checks and inspection fees and of any significant changes in the administrative conduct for such checks.

5. For the commodities referred to in Article 6.8(4)(a), the Parties may agree to reduce reciprocally the frequency of physical import checks.

6. From a date to be determined by the Sub-committee referred to in Article 6.15, the



Parties may agree on the conditions to approve each other's controls, with a view to adapt the frequency of import checks or replace import checks. These conditions shall be included in Appendix VI by a decision of the Sub-committee referred to in Article 6.15. From that date, the Parties may reciprocally approve each other's controls for certain commodities and, consequently reduce or replace the import checks for these commodities.

## Article 6.12

### Information exchange

1. The Parties shall exchange information which is relevant for the implementation of this Chapter on a systematic basis, for developing standards, for providing assurance, for engendering mutual confidence and for demonstrating the efficacy of the programmes controlled. Where appropriate, this exchange of information may include exchanges of officials.

2. The Parties shall also exchange information on other relevant topics including:

- (a) significant events concerning commodities covered by this Chapter, including information exchange provided for in Articles 6.7 and 6.8;
- (b) the results of verification procedures provided for in Article 6.10;
- (c) the results of import checks provided for in Article 6.11 in the case of rejected or non-compliant consignments of animals and animal products;
- (d) scientific opinions, relevant to this Chapter and produced under the responsibility of a Party;
- (e) rapid alerts relevant to trade within the scope of this Chapter.

3. The Parties shall provide for the submission of scientific papers or data to the relevant scientific fora to substantiate any views or claims made in respect of a matter arising under this Chapter. Such information shall be evaluated by the relevant scientific fora in a timely manner, and the results of that examination shall be made available to both Parties.

4. When the information referred to in this Article has been made available by notification to the WTO in accordance with the relevant rules or when the above information has been made available on the official, publicly accessible and fee-free web-sites of the Parties, the information exchange shall be considered to have taken place.

In addition, for pests of known and immediate danger to the other Party, direct communication to the relevant Party shall be sent by mail or e-mail. The guidance provided by FAO International Standard for Phytosanitary Measures No 17 'Pest reporting' shall be followed.

5. The exchange of information referred to in this Article shall be made between the Parties through e-mail, fax or mail.

## Article 6.13

### Notification and consultation

1. Each Party shall notify the other Party in writing within two working days of any serious or significant public, animal or plant health risk, including any food control emergencies or situations where there is a clearly identified risk of serious health effects associated with the consumption of animal or plant products and in particular concerning:

(a) any measures affecting regionalisation decisions referred to in Article 6.6;

(b) the presence or evolution of any animal disease or pests listed in Appendix II.A. and II.B.;

(c) findings of epidemiological importance or important associated risks with respect to animal diseases and pests which are not in Appendix II.A. and II.B. or which are new animal diseases or pests; and

(d) any additional measures beyond the basic requirements of their respective measures taken to control or eradicate animal diseases or pests or protect public health and any changes in prophylactic policies, including vaccination policies.

2. (a) Notifications shall be made between the Parties.

(b) Written notification means notification by e-mail or mail. Notifications by e-mail shall only be sent between the Parties.

3. Where a Party has serious concerns regarding a risk to public, animal or plant health, consultations regarding the situation shall, on request, take place as soon as possible and, in any case, within 13 working days. Each Party shall endeavour in such situations to provide all the information necessary to avoid a disruption in trade, and to reach a mutually acceptable solution consistent with the protection of public, animal or plant health.

4. Upon request of a Party, consultations regarding animal welfare shall take place as soon as possible and, in any case, within 20 working days. Each Party shall endeavour, in such situations, to provide all the requested information.

5. Upon request of a Party, consultations referred to in paragraphs 3 and 4 shall be held by video or audio conference. The requesting Party shall ensure the preparation of the minutes of the consultation, which shall be formally approved by the Parties. For purposes of this approval, the provisions of Article 6.12(5) shall apply.

## Article 6.14

### Safeguard clause

1. Should the exporting Party take domestic measures to control any cause likely to constitute a serious hazard to human, animal and plant health, the exporting Party, without

prejudice to the provisions of paragraph 2, shall take equivalent measures to prevent introduction of the hazard into the territory of the importing Party.

2. The importing Party may, on serious public, animal or plant health grounds, take provisional transitional measures necessary for the protection of public, animal or plant health. For consignments in transport between the Parties, the importing Party shall consider the most suitable and proportional solution in order to avoid unnecessary disruptions to trade.

3. The Party taking the measures shall notify the other Party thereof within one working day of the decision to implement them. Upon request of either Party, and in accordance with the provisions of Article 6.13(3), the Parties shall hold consultations regarding the situation within 13 working days of the notification. The Parties shall take due account of any information provided through such consultations and shall endeavour to avoid unnecessary disruption to trade, taking into account, where applicable, the outcome of the provisions of Article 6.13(3).

#### Article 6.15

##### Sub-committee on Sanitary and Phytosanitary Measures

1. The Parties establish a Sub-committee on Sanitary and Phytosanitary Measures. This Sub-committee shall be composed for representatives of the European Union and Chile with responsibilities on Sanitary and Phytosanitary matters.

2. The Sub-Committee will:

(a) monitor the implementation of this Chapter and its Appendix and consider any matter relating to this Chapter, and examine all matters which may arise in relation to its implementation;

(b) make recommendations for modifications to this Chapter and its Appendix notably in the light of progress made under the consultations and procedures provided for under this Chapter.

3. The Sub-committee will agree on the actions to put in place in pursuing the objective of this Chapter with objectives and milestones for these actions. The Sub-committee will evaluate the results of the implementation of the actions agreed.

4. The Sub-committee will agree to establish technical working groups, when appropriate, consisting of expert-level representatives of the Parties, which shall identify and address technical and scientific issues arising from the application of this Chapter.

5. The Sub-committee may recommend to the Trade Council the adoption of specific working procedures for this Sub-committee in view of the specificity of the SPS matters.

## Article 6.16

### Working cooperation in multilateral fora

1. The Parties shall promote working 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 Sub-committee established in Article 6.15 shall be the forum to exchange information and cooperate in the field of matters covered by paragraph 1.

## Article 6.17

### Cooperation on Food Safety, animal health and plant protection science

1. The Parties should endeavor to facilitate the scientific cooperation between the responsible bodies of the Parties for the scientific evaluation in the food safety, animal health and plant protection fields.
2. The Parties could create a Technical Working Group on the scientific cooperation established in paragraph 1 consisting of expert level representatives of the scientific bodies appointed by each Party.
3. The SPS Sub-committee established under Article 6.15 shall define the mandate, scope and work programme of this technical working group.
4. The working group would exchange information, inter alia, on:
  - a. Scientific and technical information
  - b. Data collection.
5. The Parties shall ensure that the work carried out by this technical working group will not endanger the independency of their respective national or regional agencies.
6. The Parties shall also ensure that the experts they have designated do not have conflict of interests under their respective domestic law and legislation.

## Article 6.18

### Territorial application<sup>2</sup>

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<sup>2</sup> This provision should remain in this chapter without prejudice to the horizontal provisions of the agreement. In any case, it should take into account the territories defined in the EU SPS legislation.

Chile NOTE: Do not understand the links between the definition of territory and the EU SPS legislation, therefore we suggest the following wording for better understanding:

1. This Chapter shall apply, on the one hand, as regards animals and animal products, plants and plant products and other goods to the territories of Member States of the Union and, on the other hand to the territory of the Republic of Chile.

For the Union

The territories of Member States of the Union as laid down in Annex I to Regulation (EU) 2017/625 and as regards plants, plant products and other goods in Article 1 of Regulation (EU) 2016/2031).

For Chile

As provided for in Article XXX of the Association Agreement.

2. The Parties understand that as regards the territory of the European Union, its specificity shall be taken into account recognizing the EU as a single entity.

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<sup>2</sup> This provision should remain in this chapter without prejudice to the horizontal provisions of the agreement. In any case, the definition of territory of the agreement should be taken into account.

EU NOTE: As stated in the current Agreement, the EU territory for SPS matters is established in the relevant legislation for animals and products of animal origin in one side and for plants, plant products and other goods in another side. We suggest the following drafting:

<sup>2</sup> This provision should remain in this chapter without prejudice to the horizontal provisions of the agreement. In any case, the definition of the EU territory should take into account the territories defined in the EU SPS legislation.