

This document contains the consolidated text resulting from the 30th round of negotiations (6-10 November 2017) on sanitary and phytosanitary measures in the Trade Part of the EU-Mercosur Association Agreement. This is without prejudice to the final outcome of negotiations. Both sides reserve the right to make subsequent modifications to their proposals.

For the purposes of the negotiation of this chapter, the term “Parties” should be understood, on the side of Mercosur, as each of the individual Mercosur Signatory Member State and on the EU side, the Party should be understood as the EU. In case commitments are undertaken by Mercosur, Mercosur will be expressly mentioned. This is without prejudice to the horizontal discussion on the definition of the Parties. The text will be revised in light of the outcome of the discussion of the Institutional group.

Chapter XX
Sanitary and phytosanitary measures

07 NOV 2017

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 international fora.

ARTICLE 2
SCOPE

1.

1. This Chapter shall apply to all SPS measures¹, 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.

**[MCS: ARTICLE XX
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 under the auspices of the Codex Alimentarius Commission (the "Codex");
 - (c) the definitions adopted under the auspices of the World Organisation for Animal Health (the "OIE");
 - (d) the definitions adopted under the auspices of the International Plant Protection Convention (the "IPPC");
 - (e) protected zone (...);
- and
- (f) a competent authority of a Party means an authority listed in accordance with Article 4.

¹ Negotiator note: There is a common understanding that this Chapter applies to all SPS measures but only to SPS measures. Such matters concerning the relation between the Parties will be governed only by this Chapter.

2. Further to paragraph 1, the definitions under the SPS Agreement prevail to the extent that there is an inconsistency between the definitions adopted under the auspices of the Codex, the OIE, the IPPC and the definitions under the SPS Agreement.]

ARTICLE 3 RIGHTS AND OBLIGATIONS

The Parties reaffirm their rights and obligations under the SPS Agreement [MCS: which are hereby made an integral part of this Agreement, except otherwise provided].

EU: the Parties reaffirm their rights and obligations relating to SPS measures under the SPS Agreement. Nothing in this chapter shall affect their rights and obligations that each Party has under the SPS Agreement.

[MCS: ARTICLE 3bis PRIVATE STANDARDS

1. The Parties undertake to exert every precaution to avoid that the commitments under this Chapter are undermined by the application of private standards related to sanitary and phytosanitary issues generated by no-governmental organizations.

2. The Parties reaffirm their commitment to the Article 13 of the SPS Agreement and agree to address specific trade concerns arising from the implementation of private standards in the Joint Management Committee established under this Chapter, if requested by one of the Parties.

Alternative proposal 19.08.17

The Parties shall ensure that the commitments under this Chapter are not undermined by the use within their territories of standards developed and applied by private entities that conflict with SPS measures in force. In light of governmental authority related to public safety, health, consumer protection, the Parties shall ensure that products marketed under those standards in their territories do not conflict with SPS regulation in force, misguide the consumer, distort market competition or generate unnecessary barriers to trade.]²

**ARTICLE 4
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

² Negotiator note: EU considers that private standards belong to the private scope and that neither the European Commission nor the authorities of EU Member States can intervene in this regard. Therefore the EU considers that the issue should be excluded from the Agreement.

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 10 (Transparency and exchange of information), inform each other of any change of these competent authorities.

ARTICLE 5 GENERAL OBLIGATIONS

1. Products exported from a Party shall meet the applicable SPS requirements of the importing Party.
2. [EU alternative proposal (05.09.17): The SPS requirements of the importing Party shall be the same for [MCS: the zones or areas of the exporting Party that have the same sanitary or phytosanitary status in accordance with obligations established in Article 9] [EU: the entire territory of the exporting Party without prejudice of Article 9

(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 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.

[EU: 7. 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.]³

[MCS: The deadlines agreed in this Chapter shall not be subject to Chapter XX ("Dispute Settlement") in the first six years after the entry into force of this Agreement.]

ARTICLE 6

TRADE FACILITATION MEASURES

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

³ Negotiator Note: Parties agreed to evaluate points 7 and 8 of Article 5 in the light of horizontal chapters.

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—referred to in Annex I.
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 Party⁴ for 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

⁴ Pending on the identification of the competent authorities in accordance with Article 4.

that the establishments meet the sanitary requirements of the importing Party.

5. The importing Party shall authorise the imports from the proposed establishments as follows:

a) In the case of establishments of products of animal origin for human consumption, the importing Party shall approve the imports from the proposed establishments within [MCS: XX] [EU: 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 [MCS: XX] [EU: 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 [MCS: XX] [EU: 40] working days after the receipt of the additional information.

b) In the case of establishments of animal by-products and animal products not intended for human consumption the importing Party shall approve the imports from the proposed establishments within XX 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 XX deadline the importing Party shall inform the exporting Party and establish a new deadline for the approval that shall in no case exceed additional XX 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 13 (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.

9. The list included in Annex I is provisional; it will be amended by means of a decision of the Subcommittee, established in Article 19.

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 possible, 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*, [EU: among other criteria.] [MCS: Additional criteria for simplifying controls may be agreed by the Parties.]
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 11 (Notifications), the results of the import checks as soon as possible and normally within [EU: 3] [MCS: XX] working days from the date of the rejection.

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

[EU:

C – Simplification of approval procedures⁵:

1. Products shall not be subject to more than a single physical import check.

The competent authorities of the EU on one side and MERCOSUR on the other side, as defined in Article 4 (Competent authorities), shall ensure that, at entry into force of this Agreement, the provisions of this Chapter are applied to products included in Annex III (List of products subjected to regional trade conditions) in such a way that each product is subjected to an uniform import approval process for the entire territory.

2. The import approval referred to in point 1 shall:

a) be based on one single questionnaire;

⁵ MCS Negotiator note: the discussion of point C will be carried out in light of the outcome of the discussions of the rest of the Chapter.
EU Negotiator note: there is no reason to postpone the discussion; it should be done as all the other Articles.

- b) consist in one single certificate, and
- c) include the list of approved establishments, if applicable.

3. The list included in Annex III is provisional; it will be amended by means of a decision of the Subcommittee, established in Article 19.]

[MCS: 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, the MERCOSUR will make its best efforts for the harmonization of import requirements and certificates. The EU, on its side, will ensure that all requests related to exports of EU Member States to MERCOSUR countries will be channelled by the Commission.]

ARTICLE 7 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 8 (Equivalence).

ARTICLE 8 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 19, 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 9

RECOGNITION OF ANIMAL HEALTH AND 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 and areas of low pest and disease prevalence, whether for the first time or after an outbreak of an animal disease [or a re-introduction of 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.

A. Animals, animal products products of animal origin and animal by-products⁶:

1. The procedure for the recognition of the disease-free zones or compartments referred to in point 2 is established in Annex II (procedure for recognition of zones and compartments and pest status). The Subcommittee established in Article 19 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. When determining such zones or compartments the importing Party shall, in principle, base its determination on the information provided by the exporting Party including the determination made by the exporting Party.
4. The importing Party shall assess the information requested (including any additional information) within [EU: 90] [MCS: XX working] days after its receipt. Any verification the importing party may request shall be carried out in accordance with Article 13 (Verification of the official control system) and within **XX days** following receipt of the

⁶ EU Negotiator note: This provision should not enter into force before April 2021.

request for verification, unless otherwise decided by the Parties.

The importing Party will expedite the procedure established in paragraph 4, 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. After finalisation of the procedure established in Annex II (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.

6. 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 12 (Consultations).

B. Plants and plant products:

1. Each Party shall establish a list of regulated pests and regulated products where a [technically justified] phytosanitary concern exists, [MCS: according to the Pest Risk Analysis (PRA)]. 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.⁷

[EU: In the case of plants officially defined by the importing party as representing a high phytosanitary risk for its territory, import can only be allowed after establishment of import requirements based on a specific risk analysis].

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 Annex II 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, [EU: and of Protected Zones⁸ which they agree to apply in their trade].

7 Previous point 6, moved as proposed by EU on April 28th

8 EU negotiator note: protected zones are pest free areas under EU control in the EU territory. They are recognised by Regulation (EU) No 2031/2016. This concept is not applied out of the EU territory and it is not an import requirement. [MCS: Final Note: For the purposes of this Chapter and for the recognition of Protected Zones, the same conditions as for Pest-Free Areas shall apply].

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, [EU: as well as Protected Zones established by the exporting Party].

4. The exporting Party shall communicate Pest Free Areas, Pest Free Places of Production, Pest Free Production Sites, [EU: 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 [EU: 90] [MCS: XX] 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 [EU: 90] [MCS: XX] days after receipt. Any verification the importing party may request shall be carried out in accordance with Article 13 (Verification of the official control system) and within XX days following receipt of the request for verification unless otherwise agreed between the Parties, 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 19 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 10 TRANSPARENCY AND EXCHANGE OF INFORMATION

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

- i) SPS administrative import procedures required to accept, proceed and conclude the approval of a product;
- ii) The requirements that apply for the import of specific products, including as appropriate the model of certificate;
- iii) Information on the pest status, including surveillance, eradication and containment programs and their results in order to support such pests status and import phytosanitary measures;
- iv) The state of play of the procedure for import approval of specific products;

[EU: v) Any **The** scientific information on which the SPS measure is based and an explanation of the reasons for such SPS measure **[including its relationship with the international standards, guidelines and recommendations].]**

[EU: vi) Any additional information that **[a the Party adopting a provisional measure may have obtained with a view to conduct a more objective assessment of risk.]**

[MCS: vi) In cases where relevant scientific evidence is insufficient, a Party adopting a provisional measure shall provide the available pertinent information in which the measure is based, and the additional information necessary for a more objective assessment of the risk.]

2. The Parties shall make publically available up to date information of its:

i) SPS import requirements for all products.

[EU: ii) SPS administrative approval import procedures **(step-by-step including a comprehensive description of the administrative steps, expected timelines, and authorities in charge of receiving import applications and of processing them) required to accept, proceed and conclude the approval of a product, including relevant programs, reports, records, other documentation or actions to be provided or undertaken by the exporting Party].**

iii) List of regulated pests.

3. The Parties shall inform each other of:

i) Any change in the sanitary and phytosanitary status that may affect trade between the Parties.

ii) Matters related to the development and application of SPS measures that may affect trade between the Parties.

iii) 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 11
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 10 (Transparency and exchange of information), within [EU: two] [MCS: XX] 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 Article 10.5.

ARTICLE 12 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 [EU: 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 11, 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. [MCS: At the request of the exporting Party, the importing Party [Parties] shall provide all the information necessary to avoid trade disruptions or to avoid limiting

trade. This information will include that indicated in article 10.1 [scientific justification that supports the measure or proposed measure, including a proper explanation of its relationship with the international standards, guidelines and recommendations.]

[EU: In the consultation established in paragraph 1 and 2, each Party shall endeavour to provide all the information necessary to avoid trade disruptions or to avoid limiting trade. This information will include that indicated in article 10.1.]

3. Consultations may be held for a reasonable period of time to review and suggest any procedure to resolve the difficulties.

4. 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.

5. If the Parties do not reach a satisfactory solution after the consultation, the case may be submitted to the Subcommittee established in Article 19 that may meet in special session]⁹.

ARTICLE 13

VERIFICATION OF THE OFFICIAL CONTROL SYSTEM

⁹ Negotiator note: Pending of the definition in the institutional group of the agreement.

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.

MCS: The nature and frequency of audits and verifications shall be determined by the importing Party taking into account the inherent risks 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.

2. The verification visits shall be 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. [MCS: Except as otherwise provided in the national legislation of one of the Parties and/or with the agreement of the Parties,] 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 [EU: 20] working days after the end of the visit. The Party receiving the verification may comment on the draft report within [EU: 25] 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 [XX] working days after the receipt of the comments on the draft report.

MCS: any measure taken as a consequence of audits and verifications shall be proportionate to risks identified. If so requested, technical consultations regarding the situation shall be held in accordance with Article XX (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 14¹⁰

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 [EU: 24 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

10 Negotiator note: review the place of the Article within the text.

the requested information is available.

6. Upon request of either Party and in accordance with the provisions of Article 12 (Consultations), the Parties shall hold consultations regarding the situation within [EU: 15 working days] of the notification. The Parties may consider options for the facilitation of the implementation or the replacement of the measures.

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 19 shall be the forum to exchange information and cooperate in the field of matters covered by paragraph 1.

ARTICLE 18
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 19.

ARTICLE 19¹¹
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

¹¹ Negotiator note: to be reviewed to include reference to Dialogue Proposal

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 10 (Transparency and exchange of information).
 - d. Promote the collaboration on international 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 Annexes.
3. The Subcommittee shall be comprised of representatives of the Parties with responsibility for SPS, [EU: animal welfare and antimicrobial resistance matters].
 4. The Subcommittee may establish ad hoc working groups.

**[MCS: ARTICLE 20
SPECIAL AND DIFFERENTIAL TREATMENT**

1. When the Parties of MERCOSUR identify significant difficulties with regard to SPS measures proposed or adopted by the European Union or its Member States, on request in this regard, the Parties shall hold discussions to reach agreement with respect to:
- i) cooperation and technical assistance;
 - ii) gradual implementation, and/or
 - iii) a period of 12 months for compliance with the measures.)]

ANNEX I

ESTABLISHMENTS TO BE APPROVED FOR THE IMPORT OF ANIMAL PRODUCTS, PRODUCTS OF ANIMAL ORIGIN AND ANIMAL BY-PRODUCTS FOLLOWING THE PROCEDURE OF ARTICLE 6.A

Procedure established in Article 6.A shall initially be limited to the approval of the

following categories of establishments:

- Establishments for fresh meat of domestic species;
- Establishments for fresh meat of wild and farmed game;
- Establishments for poultry and lagomorphs;
- Establishments for meat products of all species;
- Establishments for meat preparations and minced meat of all species;
- Establishments for casings, treated stomach, bladders and intestines;
- Establishments for milk, dairy products, colostrum and colostrum based products for human consumption;
- Establishments for eggs and egg products;
- Establishments, freezer and factory vessels for fishery products for human consumption including bivalve molluscs and crustaceans;

- Production areas and expedition centres for bivalve molluscs;
- Establishments for frog's legs, snails, gelatine and collagen, raw materials for gelatine and collagen, honey, royal jelly, apiculture products, highly refined products (e.g. chondroitin, hyaluronic acid, rennet, etc.);
- Any other category of establishments decided by the Parties.
- Establishments for animal by-products.

- [EU: Genetic material].

ANNEX II
PROCEDURE FOR RECOGNITION OF ZONES, COMPARTMENTS AND PEST STATUS

1. In accordance with the provisions of Article 11 (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 [EU: or a protected zone], shall notify its measures to the importing Party.

2. Within [EU 20] [MCS: 30]¹² working days following the receipt of the notification

12 Negotiator note: coherence between deadlines must be checked

referred to in paragraph 1, the importing Party may raise an explicit objection or request additional information, consultation or verification. The consultations shall take place according to Article 12 (Consultations) and the verifications according to Article 13 (Verification of the official control system). The importing Party shall assess the additional information within [EU: 25] [MCS: 30] working days following its receipt.

3. 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.

4. Notification shall include explanation and supporting data setting out in particular:

4.1. In the case of animal health:

- the nature of the disease and the history of its occurrence in its territory;
- 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;
- the period over which the surveillance was carried out;
- where applicable, the period during which vaccination against the disease was prohibited and the geographical area concerned by the prohibition;
- the measures to verify the absence of the disease.

4.2. In the case of plant health:

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

[EU:

- Pests not known to occur within any part of its own territory.
- Pests known to occur within any part of its own territory and under official control;
- 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 (including movement and import requirements for host plants).]

[MCS:

- Quarantine Pests: Pests **of potential economic importance** not known to occur within any part of its own territory.
- Quarantine Pests: Pests **of potential economic importance present but not widely distributed in** its own territory and under official control;
- Non-quarantine Pest]

4.2.2. Any change to the list established in point 4.2.1 of [MCS: regulated] pests shall be [MCS: based on pest risk analysis or relevant scientific information and] communicated to the other Party in accordance with Article 10 (Transparency and exchange of information).

<p>[EU: ANNEX III LIST OF PRODUCTS SUBJECTED TO REGIONAL TRADE FACILITATION MEASURES ACCORDING TO ARTICLE 6 (Trade facilitation measures)]</p>

[MCS: COOPERATION

The Parties agree that cooperation and exchange of information on the following issues mentioned below are of mutual interest.

1- Animal Welfare

- exchange technical and scientific information, expertise and experiences to deal with animal welfare issues, and standards related issues;
- discuss specific topics on animal welfare that could have impact on mutual trade;
- collaboration in the area of animal welfare to develop adequate and science-based animal welfare standards related, based on the Terrestrial and Aquatic Animal Health Codes of the World Organization for Animal Health (OIE);
- collaborate in international fora to promote the further development of good animal welfare practices and their implementation.

2- Biotechnology

- exchange information on policies, legislation, guidelines, good practices, and projects, of genetically modified organisms (GMOs) and new breeding techniques;
- discuss specific topics on biotechnology that could have impact on mutual trade;

- exchange information to avoid asynchronous authorisations of genetically modified products;
- evaluate the economic and trade outlook of authorisations of genetically modified products;
- exchange information to evaluate cases of low level presence of GMOs -in shipments- that are non-authorized in the importing Party but authorized in the exporting Party.

3- Antimicrobial Resistance (AMR)

- exchange information in guidelines, standards, recommendations and actions developed in relevant international organizations, initiatives and national plans;
- exchange information regarding the implementation of agreed international action plans on anti-microbial resistance.

4- Food Safety (Maximum Residue Limits for Agricultural Pesticides, Veterinary Medicinal Products and Additives for Food and Feed)

- exchange information on policies, legislation, guidelines, good agricultural practices, and projects, notably those aimed at improving the process of authorisation and their uses and limits;

- exchange information in national positions in the framework of the *Codex Alimentarius*;
- facilitate scientific cooperation, dialogue and exchange of information in particular regarding risk assessment and processes for authorizing pesticides, veterinary medicinal products and additives, and for establishing their respective limits;
- exchange information regarding the process for the authorisation and renewal of pesticides, veterinary medicinal products and additives,
- exchange information on the regulatory agendas of the official bodies responsible for the risk assessments and reasoned opinions that will ground new regulations on limits and their revisions and renewals.
- to foster cooperation between the official bodies responsible for the risk assessments and reasoned opinions in order to avoid that lack of information lead to the adoption of measures more restrictive than necessary.]