Legend: [Text under consideration]

Article 1: Objectives

The objectives of this Chapter are:

1. to protect human, animal or plant life or health through the development, adoption and enforcement of sanitary and phytosanitary (hereinafter referred to as “SPS”) measures while minimizing negative effects of SPS measures on trade between the Parties;

2. to promote cooperation between the Parties on the implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures in Annex 1A to the WTO Agreement (hereinafter referred to as “SPS Agreement”); and

3. to provide a mean to improve communication and cooperation, and a framework for addressing issues related to the implementation of sanitary and phytosanitary measures, and achieve mutually acceptable solutions.

Article 2: Scope of Application

This Chapter shall apply to all SPS measures of the Parties under the SPS Agreement that may, directly or indirectly, affect trade between the Parties.

Article 3: Definitions

For the purposes of this Chapter:

1. The definitions set out in Annex A of the SPS Agreement shall apply.

2. The Parties may agree on other definitions for the application of this Chapter taking into consideration the glossaries and definitions developed by relevant international organisations, such as the CODEX Alimentarius Commission (hereinafter referred to as “Codex Alimentarius”), the International Office of Epizootics (hereinafter referred to as “OIE”) and the relevant international organizations operating within the framework of the International Plant Protection Convention (hereinafter referred to as “IPPC”). In the event of an inconsistency between definitions agreed by both Parties and the definitions
set out in the SPS Agreement, the definitions set out in the SPS Agreement shall prevail.

3. In addition, for the purpose of this Chapter,

   a) “import conditions” means any sanitary or phytosanitary measures that are required to be fulfilled for the import of products.
   b) "protected zone" for a specific regulated pest means an officially defined geographical part of the [territory][Area] of each Party in which that pest is not established in spite of favourable conditions and its presence in other parts of the [territory][Area] of the Party.

Article 4: Rights and Obligations

The Parties reaffirm their rights and obligations relating to SPS measures under the SPS Agreement.

Article 5: Competent Authorities and contact points

As of the date of entry into force, the Parties shall provide the other with a description of the competent authorities for the implementation of this Chapter and a contact point for communication on all matters arising under this Chapter.

The Parties shall inform each other of any significant changes in the structure, organization and division of competency of their competent authorities and ensure that the information on contact points is kept up to date.

Article 6: Risk Assessment

The Parties shall ensure that their SPS measures are based on risk assessment in accordance with relevant provisions, including Article 5, of the SPS Agreement.

Article 7: Import conditions, import procedures and trade facilitation

1. Import conditions shall be established by the importing Party in order to achieve the appropriate level of protection and shall be based on consultations between the Parties when necessary.

2. Without prejudice to the rights and obligations each Party has under the SPS Agreement,
the importing Party should apply import conditions for products to the total [territory][Area] of the exporting Party in a consistent manner if so requested by the exporting Party.

3. The provisions of the previous paragraphs shall not affect the import conditions existing between the Parties on the date of entry into force of this Agreement. The Parties shall give consideration to any request for a review of these import conditions.

4. The Parties shall ensure, with respect to any import procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, including that for approval and clearance process that:
   a) such procedures are simplified, expedited and completed without undue delay, in accordance with the SPS Agreement;
   b) such procedures are not applied in a manner which would constitute an arbitrary or unjustifiable discrimination against the other Party;
   c) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; and
   d) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs.

5. EU: More specifically, concerning approval procedure for food additives, food enzymes and food flavourings, on receipt of an application the Party shall acknowledge receipt of the application in writing to the applicant within 14 working days of receiving it shall as soon as possible request an opinion from a risk assessment body, where applicable. The risk assessment authority shall give its opinion within 9 months of receipt of valid application. Within 9 months of the risk assessment authority giving its opinion, the Party shall update the relevant legislation. Guidelines should be made available for describing the information required for the application.

Japan opposes to the EU proposal and proposes to delete the paragraph 5.

6. Taking into account applicable standards agreed under the International Plant Protection Convention (IPPC) the Parties undertake to maintain adequate information on their pest status (including surveillance, eradication and containment programmes and their results) in order to support the categorization of pests and to justify phytosanitary import conditions.

7. The Parties shall establish lists of regulated pests for commodities where a phytosanitary concern exists. The list shall contain as appropriate:
   a) the quarantine pests not known to occur within any part of its own [territory / Area];
   b) the quarantine pests known to occur within any part of its own [territory / Area]
but not widely distributed and under official control;
c) any other regulated pest for which phytosanitary measures may be taken.

For commodities for which a phytosanitary concern exists, import conditions shall be limited to measures ensuring the absence of regulated pests of the importing Party.

The importing Party shall make available its list of regulated commodities and the phytosanitary import requirements for all regulated commodities. This information shall include as appropriate the specific quarantine pests and additional declarations on phytosanitary certificates as prescribed by the importing Party.

8. Where it is necessary to establish import conditions to respond to a request by the exporting Party:
   a. the importing Party shall take all necessary steps to allow trade to take place without undue delay;
   b. the exporting Party shall:
      - provide all relevant information required by the importing Party; and
      - give reasonable access to the importing Party for audit and other relevant procedures.

9. Where a range of alternative sanitary or phytosanitary measures may be available to attain the appropriate level of protection of the importing Party, the Parties shall, upon request of the exporting Party, consider selecting more practicable and less trade-restrictive solution.

10. Where a certificate issued by the exporting Party is required for sanitary or phytosanitary objectives, the format of the certificate and its contents shall be agreed between the Parties, taking into account international standards, guidelines or recommendations of Codex Alimentarius, OIE or IPPC.

11. The Parties shall promote the implementation of electronic certification and other technologies to facilitate trade.

12. Verifications by officials of the importing Party in the [territory][Area] of the exporting Party should be to facilitate new trade and not be applied as a permanent measure. The importing Party shall accept replacing an existing verification measure by an alternative measure which verifies the compliance with the agreed requirements for phytosanitary measures by the exporting Party, if so requested by the exporting Party and subsequently agreed by the Parties without undue delay.

13. Consignments of regulated commodities shall be accepted on the basis of adequate assurances by the exporting Party, without specific import authorisations in the form of a licence or permit, except where official consent for import is necessary, based on the relevant
standards, guidelines and recommendations of IPPC.

14. Pest risk analysis shall begin as promptly as possible and conclude without undue delay.

15. Any fees imposed for the procedures on imported products from the exporting Party shall be equitable in relation to any fees charged on like domestic products and should be no higher than the actual cost of the service.

**Article 8: Audit**

1. In order to attain and maintain confidence in the effective implementation of this Chapter, the Parties shall assist each other to carry out audit of:
   a) all or parts of the exporting Party's inspection and certification system;
   b) the results of the controls carried out under the exporting Party's inspection and certification system; in accordance with the provisions of the SPS Agreement, taking into account the relevant international standards, guidelines and recommendations of the Codex Alimentarius, OIE or IPPC.

2. For the purposes of carrying out such audit, the importing Party may conduct audit by means of requests of information from the exporting Party or audit visits to the exporting Party.

3. An audit visit shall be carried out under the conditions discussed and agreed in advance by the exporting and the importing Parties.

4. The importing Party shall provide the exporting Party the opportunity to comment in writing on the findings of the audit. The importing Party shall take any such comment into account before it makes its conclusions and takes any action. The importing Party shall provide a report setting out its conclusions in writing to the exporting Party without undue delay.

5. The costs for audit shall be borne by the importing Party unless otherwise agreed between the Parties.

**Article 9: Procedure for Listing of Establishments or Facilities**

1. When required by the importing Party, the competent authorities of the exporting Party shall ensure that lists of establishments and facilities which comply with the importing Party's import conditions are drawn up, kept updated and communicated to the importing Party.
2. The importing Party may request the exporting Party to provide information which is necessary to consider the list referred to in paragraph 1. Except when additional information is required, the importing Party shall take the necessary measures to allow imports from these establishments and facilities without undue delay.

Without prejudice to provisions of Article 13 (Emergency Measures), such measures shall not include prior inspection except when such inspection is required by each Party's laws and regulations or agreed between the Parties. A Party shall notify the other Party of intentions to introduce new laws and regulations within the scope of this Article and allow the other Party to provide comments thereon.

3. The importing Party may conduct the audit in accordance with Article 8 of this Chapter.

4. The importing Party shall make these lists publicly available as appropriate.

Article 10: Adaptation to Regional conditions

Animals, animal products and animal by-products


2. When establishing or maintaining sanitary import conditions upon the request by the exporting Party, the importing Party shall recognise the zones or compartments established by the exporting Party as a basis for consideration towards the determination of allowing or maintaining the import.

3. The exporting Party shall identify its zones or compartments referred to in paragraph 2 and, if requested, provide a full explanation and supporting data based on the OIE Terrestrial Animal Health Code or the OIE Aquatic Animal Health Code, or in other ways as deemed appropriate by both Parties based on the knowledge acquired through experience of the exporting Party’s relevant sanitary authorities.

4. The Parties shall ensure that the procedures and provisions indicated in paragraphs 2 and 3 are carried out without undue delay.

5. The SPS Specialised-Committee will exchange information on or review a way to establish and maintain a mutual recognition of health status, unless otherwise agreed between the Parties, based on the OIE Terrestrial Animal Health Code and recommendations.

6. Each Party may establish zones or compartments referred to in paragraph 2 for diseases
not covered by the OIE Terrestrial Animal Health Code or the OIE Aquatic Animal Health Code and agree to apply such zones or compartments in the trade between the Parties.

**Plants and plant products**

7. The Parties 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 specified in the International Standards for Phytosanitary Measures developed under IPPC, as well as of protected zones which the Parties agree to apply in their trade.

8. When establishing or maintaining phytosanitary import conditions upon the request by the exporting Party, the importing Party shall recognise the pest free areas, pest free places of production, pest free production sites, areas of low pest prevalence and protected zones established by the exporting Party as a basis for consideration towards the determination of allowing or maintaining the import.

9. The exporting Party shall identify its pest free areas, pest free places of production, pest free production sites, areas of low pest prevalence or protected zones and, if requested, provide a full explanation and supporting data based on the relevant International Standards for Phytosanitary Measures or in other ways as deemed appropriate by both Parties based on the knowledge acquired through experience of the exporting Party’s relevant phytosanitary authorities.

10. In implementing provisions of paragraphs 7, 8 and 9 of this Article, technical consultations and audit may be carried out. Technical consultations shall take place in accordance with Article 12. The Audits shall be carried out in accordance with Article 8, taking into account the biology of the pest and the commodity concerned.

11. The Parties shall ensure that the procedures and provisions indicated in paragraphs 8, 9 and 10 are carried out without undue delay.

12. Whenever a quarantine pest is detected in a protected zone, the exporting Party shall immediately notify the importing party. In addition, it shall immediately suspend relevant export if so required by the importing Party. The resumption of its export can [Japan 18.01.2017: may] take place after the importing Party is satisfied with the assurance provided by the exporting Party.

**Article 11: Transparency and Exchange of Information**

1. The Parties shall, in accordance with Article 7 and Annexes B and C of the SPS
Agreement,

a) ensure transparency as regards:
- SPS measures, including import conditions;
- control, inspection and approval procedures, including complete details about the mandatory administrative steps, expected timelines, and authorities in charge of receiving import applications and of processing them;

b) enhance mutual understanding of each Party’s SPS measures and their application; and

c) upon reasonable request from the other Party and as soon as possible provide information on its SPS measures and their application, including:

i. import conditions that apply to the import of specific products;
ii. progress on the application for authorisation of specific products;
iii. the frequency of import checks carried out on products from the other party; and
iv. matters related to the development and application of its SPS measures, including the progress on new available scientific evidence, that affect, or may affect, trade between the Parties with a view to minimizing their negative trade effects.

2. When the information referred to in paragraphs 1(a) and (c) has been made available by notification of a Party under the SPS Agreement or when such information has been made available on an official, publicly accessible and fee free web-site of that Party, the information referred to in paragraphs 1(a) and (c) shall be considered to have been provided.

**Article 12: Technical Consultations**

1. Where a Party has significant concerns regarding human, animal, or plant life or health or measures proposed or implemented by the other Party, that Party can request technical consultations.

2. The other Party shall respond to such a request without undue delay and shall engage in the technical consultations to address these concerns.

3. Each Party shall endeavour to provide necessary information to avoid a disruption in trade and/or to reach a mutually acceptable solution.

4. Where the Parties have already established other mechanisms to address the concerns than those referred to in this Article, they shall utilize them to the maximum extent possible in order to avoid unnecessary duplication.
Article 13: Emergency Measures

1. If a Party adopts an emergency measure that is necessary for the protection of human, animal or plant life or health, the competent authority of the Party shall:
   a) immediately notify competent authorities of the other Party of such emergency measure;
   b) allow the other Party to make comments in writing;
   c) engage, if necessary, in technical consultations as referred to in Article 13;
   d) take the comments referred to in subparagraph (b) and results of technical consultations referred to in subparagraph (c) into account.

2. The importing Party shall consider information provided, in a timely manner, by the exporting Party when making decisions with respect to consignments that, at the time of adoption of emergency measures, are being transported between the Parties, in order to avoid unnecessary disruptions to trade.

3. The importing Party shall ensure that any emergency measure referred to in paragraph 1 is not maintained without scientific evidence. The importing Party shall review the measure with a view to minimizing its negative effect on trade by either repealing or replacing it by permanent measures.

Article 14: Equivalence

1. An importing Party shall accept an exporting Party’s SPS measures as equivalent, if the exporting Party objectively demonstrates to the importing Party that its measures achieve the importing Party’s appropriate level of SPS protection. For this purpose, reasonable access shall be given, upon request, to the importing Party for inspection, testing and other relevant procedures.

2. Each Party shall, upon request, enter into consultations with the aim of achieving bilateral arrangements related to (determination) of the equivalence of specified SPS measures.

3. In (determining) equivalence, the Parties shall take into account the relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations, in particular the “Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures” adopted by the Committee on SPS Measures of the WTO (G/SPS/19/Rev.2).

4. Where equivalence has been determined, the Parties may agree on alternative import conditions and simplified certificates, taking into account international standards, guidelines
or recommendations of Codex Alimentarius, OIE or IPPC.

Article 15: Specialised-Committee on SPS Measures

1. For the purposes of the effective implementation and operation of this Chapter, the Parties hereby establish a Specialised-Committee on SPS Measures (hereinafter referred to in this Article as “the Specialised-Committee”).

The Specialised-Committee shall be composed of representatives of the Parties who have a responsibility for SPS measures with relevant expertise.

2. The objectives of the Specialised-Committee are to:

   a) Enhance each Party's implementation of this Chapter;

   b) Consider Sanitary and Phytosanitary matters of mutual interest;

   c) Enhance communication and cooperation on Sanitary and Phytosanitary matters of mutual interest.

3. The Specialised-Committee:

   a) Shall provide a forum to improve the Parties' understanding of SPS issues that relate to the implementation of the SPS Agreement;

   b) Shall provide a forum to enhance mutual understanding of each Party's SPS measures and the regulatory processes that relate to those measures;

   c) Shall monitor, review and exchange information on the implementation and operation of this Chapter;

   d) Shall serve as a forum to address with a view to reaching mutually acceptable solutions, the concerns referred to in paragraph 1 of Article 12 provided that the Parties have first attempted to address them through the technical consultations pursuant to Article 12 and other topics agreed between the Parties;

   e) Shall determine the appropriate means, which may include ad hoc working groups, to undertake specific tasks related to the functions of the Specialised-Committee;

   f) May identify and consider technical cooperation projects between the Parties in

Limited

Japan-EU EPA Negotiator’s Use Only
Without prejudice
20 January 2017
relation to development, implementation, and application of SPS measures;

g) May consult on matters and positions for the meetings of the Committee on Sanitary and Phytosanitary measures established under Article 12 of the SPS Agreement, and meetings held under the auspices of the Codex Alimentarius, OIE and IPPC.

4. The Specialised-Committee shall establish its rules of procedures and may revise those procedures as needed.

5. The first meeting of the Specialised-Committee shall hold within one year of the date of entry into force of this Agreement and the Specialised-Committee normally meets once a year thereafter unless the Parties agree otherwise.

**Article 16: Non application of DS / Dispute Settlement**

[EU: No Party shall have recourse to dispute settlement under Chapter XX (Dispute Settlement) for a dispute that [JP delete: exclusively] alleges a violation of the provisions of the WTO SPS Agreement.]

[Japan: Chapter YY (Dispute Settlement) shall not apply to this Chapter.]