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**MEETING DOCUMENT**

**From:** Commission  
**To:** Trade Policy Committee  
**Subject:** TTIP – Sanitary and Phytosanitary Issues – Draft SPS chapter

Delegations will find attached a note by the Commission services on the above-mentioned subject.

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EU-US TTIP Negotiations

27 June 2014

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EUROPEAN COMMISSION

Directorate-General for Trade

Brussels, 27 June 2014

**TRADE 41/2014**

**RESTREINT UE**

**NOTE FOR THE ATTENTION FO THE TRADE POLICY COMMITTEE**

**SUBJECT: TTIP – Sanitary and Phytosanitary Issues – Draft SPS chapter**

**ORIGIN:**        **DG SANCO – G7**  
Lorenzo TERZI  
Head of Unit, SANCO G7  
Tel. +32 229 68555  
[Lorenzo.Terzi@ec.europa.eu](mailto:Lorenzo.Terzi@ec.europa.eu)

**DG TRADE – D3**  
Ulrich WEIGL  
Deputy Head of Unit, TRADE D3  
+32 2 29 57232  
[Ulrich.Weigl@ec.europa.eu](mailto:Ulrich.Weigl@ec.europa.eu)

Damien LEVIE  
Head of Unit, TRADE E1  
+32 2 29 84402  
[Damien.Levie@ec.europa.eu](mailto:Damien.Levie@ec.europa.eu)

Catherine GUEGUEN  
Policy Co-ordinator, TRADE E1  
+32 2 29 59148  
[Catherine.Guegen@ec.europa.eu](mailto:Catherine.Guegen@ec.europa.eu)

**RESTREINT UE**

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

**OBJECTIVE:**    **For information and discussion**

**REMARKS:**     This chapter will be discussed at the next informal technical meeting on **3 July 2014** with TPC and SPS delegates. The main objectives of this draft SPS Chapter, which reflect the comments provided by Member States, industry and other associations during the preparatory phase, are:

- Respect of the Right to Regulate (c.f. Objectives and Article 8)
- The EU as one entity (Art 4)
- Systems Recognition under the Food Safety Modernization Act (Article 9, 11))
- Prominent coverage of Animal Welfare (c.f. Objectives and Article 11)
- Strong commitments on processes (Equivalence Art. 9, Regionalization Art. 10, reasonable verification procedures without cost Art. 12 and 14)
- A paradigm change on the plant health import regime of the US (Art 8 and 10)
- Transparency (Article 8 and 15)

Please note that the Annexes to this draft chapter will be provided at a later stage.

**RESTREINT UE**

CHAPTER [XX]

SANITARY AND PHYTOSANITARY MEASURES

Article 1

**Recognition and Termination of the Veterinary Agreement**

The Parties recognize the achievements that have been accomplished under the Agreement between the *European Community and the Government of the United States of America on sanitary measures to protect public and animal health in respect of trade in live animals and animal products* (the Veterinary Agreement) and confirm their intention to continue the work under the framework of this Agreement. [This Veterinary Agreement of 21 April 1998, as amended, is terminated from the date of entry into force of this Agreement. *[Exact wording and placement of this sentence to be decided by Legal Services]*]

Article 2

**Objectives**

**The objectives of this chapter are to:**

1. Facilitate trade between the Parties to the greatest extent possible while preserving each Party's right to protect animal or plant life or health in its territory and respecting each Party's regulatory systems, risk assessment, risk management and policy development processes;
2. Ensure that the Parties' sanitary and phytosanitary (SPS) measures do not create unjustified barriers to trade.
3. Further the implementation of the *WTO Agreement on the Application of Sanitary and Phytosanitary Measures* (WTO SPS Agreement);
4. Build upon and extend the scope of the Veterinary Agreement which is fully integrated in this chapter;
5. Improve communication and cooperation on sanitary and phytosanitary measures between the Parties;
6. Improve consistency, predictability and transparency of each Party's SPS measures;
7. Provide a framework for dialogue and cooperation with a view to enhancing the protection and welfare of animals and reaching a common understanding concerning animal welfare standards.

Article 3

### **Rights and obligations**

The Parties reaffirm their rights and obligations with respect to each other under the WTO SPS Agreement.

#### Article 4

### **Application of SPS measures**

The Parties recognise each other as single entities for the purposes of this Chapter. Import conditions of one Party shall apply to the entire territory of the other Party without discrimination between Member States, Federal States, regions or entities. Each Party shall ensure that products which are in conformity with these conditions can be marketed or used across all the territory of each Party on the basis of a single authorisation, approval or certificate. The Parties shall avail themselves of the necessary resources to effectively implement this Chapter.

#### Article 5

### **Scope and coverage**

This Chapter applies to all SPS measures that may, directly or indirectly, affect trade between the Parties.

Additionally, this Chapter shall apply to collaboration on animal welfare matters.

Nothing in this Chapter shall limit the rights or obligations of the Parties under the Agreement establishing the World Trade Organisation and its Annexes.

#### Article 6

### **Definitions**

The WTO SPS Agreement means the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures.

The definitions in Annex A of the SPS Agreement apply, as well as those adopted by Codex Alimentarius (Codex), the World Organisation for Animal Health (OIE), and the International Plant Protection Convention (IPPC). In the event of an inconsistency between the definitions adopted by Codex, the OIE, the IPPC and the definitions set out in under the WTO SPS Agreement, the definitions set out in the WTO SPS Agreement shall prevail.

“Protected Zone” for a specified regulated harmful organism is an officially defined geographical area in the EU in which that organism is not established as demonstrated by annual surveys, in spite

**RESTREINT UE**

**RESTREINT UE**

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

of favourable conditions and its presence in other parts of the Union.

#### Article 7

### **Competent Authorities**

For the purpose of this Chapter, the competent authorities of each Party are those listed in [Annex 2]. The Parties shall inform each other of any change of these competent authorities.

## Article 8

### Trade facilitation/conditions

#### Procedures

1. The Parties shall ensure that all procedures established under this Chapter are undertaken and completed without undue delay and that they are not applied in a manner which would constitute an arbitrary or unjustifiable discrimination against the other Party.
2. Procedures shall be set with the objective to minimise negative trade effects and to simplify and expedite the clearance process while meeting the importing country requirements.
3. The Parties shall ensure that tolerances and maximum residue levels adopted through Codex Alimentarius are adopted by each party without undue delay and are applicable in their bilateral trade [*within 12 months*] after their adoption unless the importing party signals a reservation.

#### General import requirements

4. The importing Party shall make available information about the import authorisation process, including complete details about the mandatory administrative steps, requirements and conditions, expected timelines, and authorities in charge of receiving import applications and of processing them.
5. 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 import phytosanitary measures.
6. The Parties shall establish lists of regulated pests for commodities where a phytosanitary concern exists. The list shall contain:
  - a) the pests not known to occur within any part of its own territory;
  - b) the pests known to occur within any part of its own territory and under official control;
  - c) the pests known to occur within any part of its own territory, under official control and for which pest free areas are established.
7. For commodities where a phytosanitary concern exists, import requirements shall be restricted to measures ensuring the absence of regulated pests of the importing Party and shall be applicable to the total territory of the exporting Party.

**RESTREINT UE**

**RESTREINT UE**

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

#### Specific import requirements

8. Where it is necessary to establish specific import requirements and model certificates the importing Party shall take the necessary legislative and administrative steps to allow trade to take place on this basis without undue delay [*and normally within one year*]. In order to establish specific import requirements, the exporting Party shall, upon request of the importing Party:
  - a) provide all relevant information required by the importing Party; and
  - b) give reasonable access to the importing Party for inspection, testing, audit and other relevant procedures.
9. The importing party shall make available a list of commodities for which it is required to conduct a Pest Risk Analysis prior to the authorisation of imports.
10. A range of alternative risk mitigation or phytosanitary measures may be available to attain the appropriate level of protection of the importing party. If this is the case, upon request of the exporting Party, both parties shall establish a technical dialogue with a view to select the most practicable and least trade-restrictive solution.

#### **Trade facilitation**

11. For the import of commodities where establishment or facilities (including fields, orchards, nurseries, packing houses, etc) are required to be included on a list by the importing Party, the importing Party shall approve establishments or facilities which are situated on the territory of the exporting Party without prior inspection or individual establishments if:
  - a) the exporting Party has requested such an approval for a given establishment or facility, accompanied by the appropriate guarantees, and
  - b) the conditions and procedures set out in [Annex VI] are fulfilled.The importing Party shall make its lists publicly available.
12. Unless the Parties agree otherwise, consignments of regulated commodities shall normally be accepted on the basis of adequate guarantees by the exporting Party, without:
  - a) Pre-clearance
  - b) Import licenses or import permits;
  - c) Phytosanitary protocols or work plans prescribed by the importing party.
13. Each Party shall ensure that products – i.e. animals and animal products, plants and plant products, or other related good – exported to the other Party meet the appropriate level of protection of the importing Party. The responsibility for the implementation of adequate control protocols and inspections lies with the exporting party. The importing Party may require that the relevant competent authority of the exporting Party objectively demonstrate, to the satisfaction of the importing Party, that the import requirements are fulfilled.

#### Article 9

#### **Equivalence and systems recognition**

#### **RESTREINT UE**

## RESTREINT UE

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

1. The Parties recognise each other's competent authorities as responsible to ensure that eligible establishments and exported products meet the applicable sanitary or phytosanitary requirements of the importing Party. This implies that the importing party will deem to be acceptable such establishments as have been authorised and listed by the exporting party without a need for individual re-inspection or other additional guarantees.
2. The importing Party shall accept the SPS measures of the exporting Party as equivalent to its own if the exporting Party objectively demonstrates to the importing Party that its measure achieves the importing Party's appropriate level of protection. Equivalence may be recognised in relation to an individual measure and/or groups of measures and/or systems applicable to a sector or part of a sector. The equivalence determinations shall be applied to trade among the relevant Parties in animals and animal products, plants and plant products, or as appropriate to related goods.
3. For the determination, recognition and maintenance of equivalence the Parties shall follow the principles set out in the available guidance of international standard setting bodies, as well as in the provisions of [Annex IV], where applicable.
4. Once the importing Party has concluded a positive equivalence determination, the importing Party shall take the necessary legislative and/or administrative measures to implement it without undue delay [*and normally within 6 months*].
5. If necessary and objectively justified, the Parties may identify special conditions which, in combination with the exporting Party's measures will achieve the importing Party's appropriate level of protection.
6. [Annex V] sets out:
  - a) The areas for which the importing Party recognises that the measures of the exporting Party are equivalent to its own, and
  - b) The areas for which the importing Party recognises that the fulfilment of the specified special conditions, combined with the exporting Party's measures, achieve the importing Party's appropriate level of protection.
7. The Parties may agree on simplified sanitary or phytosanitary certificates for goods and products for which equivalence has been recognised.

### Article 10

#### **Adaptation to Regional conditions**

##### **Animals, animal products and animal by-products**

1. The Parties recognise the principle of zoning which they agree to apply in their trade.
2. The importing Party shall recognise for trade the health status of zones, as determined by the exporting Party, with respect to the animal and aquaculture diseases specified in [Annex II].

3. Without prejudice to [Article 16 Safeguard Measures] the importing Party shall recognise zoning decisions taken by the exporting Party in accordance with the criteria set out in Annex

#### **RESTREINT UE**

#### **RESTREINT UE**

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

III] as the basis for trade from a Party where an area is affected by one or more of the diseases listed in [Annex II].

4. The exporting Party shall, if requested by the importing Party, provide full explanation and supporting data for the determinations and decisions covered by this Article and may request technical consultations in accordance with [Article 15(4)]. [*The importing Party shall assess the additional information within 15 working days following receipt. Any verification the importing party may request shall be carried out in accordance with [Article 12 verification] and within 25 working days following receipt of the request for verification.*] The Parties shall endeavor to avoid unnecessary disruption to trade.
5. Where a Party considers that it has a special status with respect to a specific disease other than those in [Annex II] and which fulfils the criteria laid down in the OIE Terrestrial Code Chapter 1.2, it may request recognition of this status. The importing Party may also request additional guarantees in respect of imports of live animals and animal products appropriate to the agreed status. The guarantees for specific diseases are specified in [Annex IV].
6. The Parties also recognise the concept of compartmentalization and agree to cooperate on this matter.

#### **Plants and plant products**

7. Without prejudice to [Article 16 safeguard measures], each Party shall recognize for trade the phytosanitary status of the exporting Party as determined by the exporting Party in accordance with the following provisions:
  - a) The Parties recognize 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 relevant FAO/IPPC International Standards for Phytosanitary Measures (ISPM), and of Protected Zones according to Council Directive 2000/29/EC, which they agree to apply in their trade.
  - b) 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, areas of low pest prevalence, as well as protected zones established by the exporting Party.
  - c) The exporting Party shall identify Pest Free Areas, Pest Free Places of Production, Pest Free Production Sites, Protected Zones or areas of low pest prevalence to the other Party and, upon request, provide a full explanation and supporting data as provided for in the relevant ISPMs or otherwise deemed appropriate. Unless the importing Party



raises an objection and requests consultations [*within 90 days*], the regionalization decision so notified shall be understood as accepted.

- d) Consultations referred to in subparagraph (c) shall take place in accordance with [Article 15(4) Technical Consultations]. The importing Party shall assess additional information requested [*within 90 days*] after receipt. Any verification the importing party may request shall be carried out in accordance with [Article 12 verification] [*and within 12 months*] following receipt of the request for verification, taking into account the biology of the pest and the crop concerned.

Article 11  
**Animal welfare**

**RESTREINT UE**

**RESTREINT UE**

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

1. The Parties recognise that animals are sentient beings. They undertake to respect trade conditions for live animals and animal products that are aimed to protect their welfare.
2. The Parties undertake to exchange information, expertise and experiences in the field of animal welfare with the aim to align regulatory standards related to breeding, holding, handling, transportation and slaughter of farm animals.
3. The Parties will strengthen their research collaboration in the area of animal welfare to develop adequate and science-based animal welfare standards related to animal breeding and the treatment of animals on the farm, during transport and at slaughter.
4. In accordance with [Article 19] The Parties undertake to collaborate in international fora with the aim to promote the further development of good animal welfare practices and their implementation.
5. The Committee described in [Article 18] may appoint a working group to implement this provision.

Article 12  
**Audit and Verification**

1. In order to maintain confidence in the effective implementation of the provisions of this Chapter, each Party has the right to carry out an audit or verification, or both, of all or part of the other Party's control system. Systems-based audits rely on the examination of a sample of system procedures, documents or records and, where required, a selection of sites.
2. The nature and frequency of audits and verifications shall be determined by the importing party taking into account the inherent risks of the commodity, 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.
3. For the purpose of paragraph 1 the importing Party shall endeavour to rely on audits and verification undertaken by the competent authority of the exporting Party.

4. Audits and verification shall be conducted in accordance with [Annex VII] and in line with Codex Guidance document for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1997).
5. Verification procedures may include, but are not limited to:
  - a) An assessment of all or part of the exporting Party's total control programme, including, where appropriate, reviews of the exporting Party's inspection and audit programmes, and
  - b) On-site checks and inspections of a selection of sites within the scope of the audit.
6. For the Union, the European Commission will carry out the verification procedures provided for in paragraph 1. The US agencies identified in [Annex I] shall facilitate the performance of these verification procedures by the Commission.
7. The US agencies identified in Annex I will carry out the verification procedures provided for in paragraph 1 for the US. The Union shall facilitate the performance of these verification procedures by those agencies.
8. Any measures 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

**RESTREINT UE**

**RESTREINT UE**

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

accordance with [Article 15(4)]. The Parties shall consider any information provided through such consultations.

9. Either Party may publish the results and conclusions of its verification procedures.
10. Each Party shall bear its own costs associated with the audit or verification.

#### Article 13

#### **Export certification**

1. Where official certificates are required, these should be defined in line with the principles laid down in the international standards of Codex Alimentarius, IPPC and OIE.
2. In respect of certification of plants, plant products and regulated articles, the competent authorities shall apply the principles laid down in the FAO International Standards for Phytosanitary Measures No 7 "Export Certification System" and No 12 "Guidelines for Phytosanitary Certificates."
3. When an official health certificate is required for the importation of a consignment of live animals or animal products and if the importing Party has accepted the measures of the exporting Party as equivalent to its own, the Parties shall use simplified model health attestations prescribed in [Annex VIII], unless the Parties jointly decide otherwise. The Parties may also define model attestations for other products if they so jointly decide in accordance with [Article 18 Joint Management Committee].

4. The exchange of original certificates or other original documents may occur by paper based systems or by secure methods of electronic data transmission that offer equivalent certification guarantees. The Parties shall cooperate in the implementation of electronic certification procedures in accordance with the provisions described in [Annex VIII].

Article 14  
**Import checks/fees**

1. [Annex IX] sets out principles and guidelines for import checks and fees, including the frequency rate for import checks.
2. In the event that import checks reveal non-compliance with the relevant import requirements, the action taken by the importing Party shall be based on an assessment of the risk involved, and shall ensure that such measures are not more trade-restrictive than required to achieve the Party's appropriate level of sanitary or phytosanitary protection.
3. The importer of a non-compliant consignment, or its representative, shall be notified of the reasons for non-compliance, and be provided the opportunity to contribute relevant information to assist the importing Party in taking a final decision. In parallel, the importing Party shall inform the certifying Competent Authority in case of rejection of a consignment that is accompanied by an official certificate. In the case of pest interceptions, the notification should indicate the pest at the species level.
4. Upon request, in the case of an interception of regulated pests, the exporting Party shall provide information about monitoring and possible mitigation measures undertaken.
5. Any fees imposed for the procedures on imported products from the exporting Party shall not be higher than the actual cost of the service.

**RESTREINT UE**

**RESTREINT UE**

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

Article 15  
**Transparency**

**Notification:**

1. Each Party shall notify the other Party without undue delay of
  - a) Significant changes in pest/disease status, such as the presence and evolution of diseases in [Annex II Process of Recognition of Regional Conditions];
  - b) Changes in their respective sanitary or phytosanitary measures;
  - c) Findings of epidemiological importance with respect to animal diseases, which are not in Annex II; or which are new diseases;
  - d) Significant food safety issues relating to products traded between the Parties; and
  - e) Any significant changes to the structure, organization of their competent authorities.

**Information exchange:**

2. The Parties will endeavour to exchange information on other relevant issues including:
  - a) On request, the results of a Party's official controls and a report concerning the results of the controls carried out;
  - b) The results of import checks provided for in [Article 9 Import Checks] in case of rejected or non-compliant consignments of products;
  - c) On request, risk analyses and scientific opinions, relevant to this Chapter and produced under the responsibility of the Party.
3. Unless otherwise decided by the Committee referred in [Article 18], when the information referred to in paragraph 1 has been made available via notification to the WTO or relevant international standard setting body in accordance with the relevant rules, the requirements in paragraphs 1 as they apply to that information are fulfilled.

**Technical Consultation:**

4. Where a Party has significant concerns regarding food safety, plant health, or animal health, or regarding a measure proposed or implemented by the other Party, that Party can request technical consultations. The other Party should respond to such a request without undue delay [*and normally within 15 days*]. Each Party shall endeavour to provide all the information necessary to avoid a disruption to trade and to reach a mutually acceptable solution. Consultations may be held by audio or video conference.

**RESTREINT UE**

**RESTREINT UE**

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

Article 16

**Safeguard and emergency measures**

1. The importing Party may, on serious grounds, take emergency measures necessary for the protection of consumer safety or animal or plant health.
2. Emergency measures concerning the other party shall be notified to that Party [within 24 hours] without undue delay after the decision to implement them and, on request, technical consultations regarding the situation shall be held in accordance with [Article 15(4)]. The Parties shall consider the information provided through such consultations.
3. The importing Party shall:
  - a) 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, and
  - b) Revise or repeal, without undue delay, the emergency measures or replace them by permanent measures with a view to avoid unnecessary disruptions to trade.

4. 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.

#### Article 18

#### **Joint Management Committee**

1. The Parties hereby establish a Joint Management Committee (JMC) for SPS Measures, hereafter called the Committee, comprising regulatory and trade representatives of each Party who have responsibility for SPS measures.
2. The functions of the Committee include:
  - a) To monitor the implementation of this Chapter and to consider any matter relating to this Chapter, and to examine all matters which may arise in relation to its implementation;
  - b) To provide direction for the identification, prioritization, management and resolution of issues;
  - c) To address any requests by the Parties for the modification of import checks;
  - d) To review the Annexes to this Agreement;
  - e) To provide a regular forum for exchanging information relating to each Party's regulatory system, including the scientific basis;
  - f) To prepare and maintain a document detailing the state of discussions between the Parties on their work on recognition of the equivalence of specific SPS measures.
3. In addition, the Committee should, *inter alia*:

#### **RESTREINT UE**

#### **RESTREINT UE**

EU-US TTIP Negotiations

27 June 2014  
Without prejudice

- a) Identify opportunities for greater bilateral engagement, including enhanced relationships, which may include exchanges of officials;
  - b) Discuss at an early stage, changes to, or proposed changes to, measures being considered;
  - c) Facilitate improved understanding between Parties related to the implementation of the WTO SPS Agreement, promoting cooperation between Parties on SPS issues under discussion in multilateral fora, including the WTO SPS Committee and international standard-setting bodies, as appropriate;
  - d) Identify and discuss, at an early stage, initiatives that have an SPS component and would benefit from cooperation.
4. The Committee may establish working groups consisting of expert-level representatives of the Parties, to address specific SPS issues.
5. A Party may refer any SPS issue to the Committee. The Committee should consider any matter referred to it as expeditiously as possible.

6. [In the event that the Committee is unable to resolve an issue expeditiously, the Committee shall, upon request of a Party, report promptly to the [TTIP Oversight Body]. Pending outcome of institutional chapter]
7. Unless the Parties otherwise agree, the Committee shall meet and establish its work programme no later than six months following the entry into force of this Agreement, and its rules of procedure no later than one year after the entry into force of this Agreement.
8. Following its initial meeting, the Committee shall meet as required, normally on an annual basis. If agreed by the Parties, a meeting of the Committee may be held by videoconference or teleconference. The Committee may also address issues out of session by correspondence.
9. The Committee shall report annually on its activities and work programme to the [TTIP Oversight Body]. ***Pending outcome of institutional chapter.***
10. Upon entry into force of this Agreement, each Party shall designate and inform the other Party of a Contact Point to coordinate the Committee's agenda and to facilitate communications on SPS matters.

#### Article 19

#### **Collaboration in international fora (multilateral and bilateral)**

The Parties will collaborate in the international setting standard bodies (OIE, *Codex alimentarius*, IPPC, etc.), with a view to reaching mutually satisfactory outcomes.

#### **RESTREINT UE**