

*This **TEXTUAL PROPOSAL** is the European Union's initial proposal for legal text on "Sanitary and Phytosanitary Measures (SPS)" in TTIP. It was tabled for discussion with the US in the negotiating round of 29 September-3 October 2015 and made public on 7 January 2015. The actual text in the final agreement will be a result of negotiations between the EU and US.*

TEXTUAL PROPOSAL

SANITARY AND PHYTOSANITARY MEASURES (SPS)

Article 1

Scope and coverage

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

This Chapter shall also apply to collaboration on animal welfare matters.

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 human, animal or plant life and 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 unnecessary 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 under the WTO SPS Agreement.

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

The Parties shall avail themselves of the necessary resources to effectively implement this Chapter.

Article 4 **Definitions**

For the purpose of this Chapter,

“Protected Zone” for a specified regulated organism of phytosanitary concern means an officially defined geographical area in the EU in which that organism is not established as demonstrated by annual surveys, in spite of favourable conditions and its presence in other parts of the Union;

The “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 of 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, or the OIE, the IPPC and the definitions set out in the WTO SPS Agreement, the definitions set out in the WTO SPS Agreement shall prevail.

Article 5 **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 6 **Application of SPS measures**

Except as provided for in Article 10[Adaptation to regional conditions] each Party shall apply its sanitary or phytosanitary import conditions to the entire territory of the other Party. Where harmonised import conditions exist in one Party, these conditions shall apply to the entire territory of the exporting Party.

Without prejudice to Article 10 [Adaptation to regional conditions] each Party shall ensure that products which are in conformity with these import conditions can be placed on the market and used in its entire territory on the basis of a single authorisation, approval or certificate.

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Article 7
Trade facilitation/conditions

Sanitary and phytosanitary import procedures

1. Sanitary and phytosanitary procedures shall be established with the objective to minimise negative trade effects and to simplify and expedite the approval and clearance process while ensuring the fulfilment of the importing Party's requirements.
2. The Parties shall ensure that all sanitary and phytosanitary procedures affecting trade between the parties 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.

General sanitary and phytosanitary import requirements

3. The importing Party shall make available information about sanitary and phytosanitary import requirements and conditions and about the import authorisation process, including complete details about the mandatory administrative steps, expected timelines, and authorities in charge of receiving import applications and of processing them.
4. In accordance with 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 import phytosanitary measures.
5. 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.
6. For commodities for which a phytosanitary concern exists, import requirements shall be limited to measures ensuring the absence of regulated pests of the importing Party. Such import requirements shall be applicable to the entire territory of the exporting Party.

Specific sanitary and phytosanitary import requirements

7. The Parties shall ensure that tolerances and maximum residue levels adopted by the Codex Alimentarius Commission after the entry into force of this Agreement will be applied by each Party without undue delay unless the importing Party had signalled a reservation in the Codex Alimentarius Commission. Such tolerances and maximum residue levels, shall apply between the Parties within 12 months after their adoption.

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8. Where it is necessary to establish specific import requirements, such as model certificates, the importing Party shall take the necessary legislative and administrative steps to allow trade to take place 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. Pest risk analyses shall be carried out as promptly as possible and normally within one year of a request being made.
10. 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, establish a technical dialogue with a view to selecting the most practicable and least trade-restrictive solution.

Trade facilitation

11. Where it is necessary for the importation of a product that an establishment or facility be included on a list by the importing Party, the importing Party shall approve such establishments or facilities which are situated on the territory of the exporting Party within [one month] and without prior inspection of individual establishments or facilities 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. Without prejudice to existing arrangements at the time of entry into force of this Agreement and unless the Parties agree otherwise, consignments of regulated commodities shall be accepted on the basis of adequate guarantees by the exporting Party, without:
 - a) Pre-clearance programmes. Control activities at the country of origin performed by the NPPO of the country of destination should not be applied as a permanent import measure and only foreseen to facilitate **new** trade. On a voluntary basis, the NPPO of the country of origin may request pre-clearance within the inspection activities carried out by the importing countries as a trade facilitation tool;
 - b) Import licences or import permits;
 - c) Phytosanitary protocols or work plans prescribed by the importing party.

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13. Each Party shall ensure that products exported to the other Party meet the appropriate level of protection of the importing Party. The responsibility for the implementation of adequate control measures 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 8

Elimination of redundant control measures

1. The Parties recognise each other's competent authorities as responsible to ensure that establishments, facilities and products eligible for exports meet the applicable sanitary or phytosanitary requirements of the importing Party.
2. The importing Party shall accept establishments or facilities that were authorised and listed by the exporting Party without re-inspection, third party certification or any other, additional guarantees.

Article 9

Equivalence

1. The importing Party shall accept sanitary and phytosanitary 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.
2. 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. For the determination, recognition and maintenance of equivalence the Parties shall follow the principles set out in the available guidance of international standard setting bodies¹ recognised by the WTO SPS Agreement, as well as in the provisions of [Annex IV], where applicable.
3. The final determination whether a sanitary measure maintained by an exporting Party achieves the importing Party's appropriate level of sanitary protection rests solely with the importing Party acting in accordance with its administrative and legislative framework.
4. Where 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 six months.

¹ Internationally agreed guidelines include, but are not limited to Guidelines of Codex Alimentarius on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems CAC/GL 53-2003; International Standard for Phytosanitary Measures ISPM 24 Guidelines for the determination and recognition of equivalence of phytosanitary measures.

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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 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 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 [Emergency measures] the importing Party shall recognise zoning decisions taken by the exporting Party in accordance with the criteria set out in [Annex III] 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 [Technical consultation]. The importing Party shall assess the information within 15 working days following receipt. Any verification the importing party may request shall be carried out in accordance with Article 11 [Audit and verification] and within 25 working days following receipt of the request for verification. The Parties shall endeavour to avoid unnecessary disruption to trade.
5. Where a Party considers that a specific region 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].

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6. The Parties also recognise the concept of compartmentalisation and agree to cooperate on this matter.

Plants and plant products

7. Without prejudice to Article 16 [Emergency measures] each Party shall recognize 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 [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 11 Audit and 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

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. Audits shall follow a systems based approach which relies 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 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.

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3. For the purpose of paragraph 1, the importing Party shall endeavour to rely on audits and verifications undertaken by the competent authority of the exporting Party.
4. Audits and verifications shall be conducted in accordance with [Annex VII] and in line with internationally agreed Guidelines².
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 European 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 European 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 accordance with [Article 15 Technical Consultation]. 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 12 **Export certificates**

1. When a party requires an export certificate for the importation of a product, this shall be based on the principles laid down in the international standards of the Codex Alimentarius, the IPPC and the OIE.
2. In respect of certification of plants, plant products and regulated commodities, 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".

² Internationally agreed guidelines include, but are not limited to Codex Guidance document for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1997); International Standards for Phytosanitary Measures ISPM 20: Guidelines for a phytosanitary import regulatory system.

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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. Original certificates or other original documents may either be transmitted by mail 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 13

Import checks and 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 necessary to achieve the Party's appropriate level of sanitary or phytosanitary protection.
3. The importer of a non-compliant consignment, or its representative, and, on demand the competent authorities of the exporting Party shall be notified of the reason for non-compliance, and be provided the opportunity to contribute relevant information to assist the importing Party in taking a final decision.
4. Where the consignment is accompanied by a certificate, the importing Party shall inform the competent authority of the exporting Party in case of a rejection and provide all appropriate information, including detailed laboratory results and methods,. In the case of pest interceptions, the notification should indicate the pest at the species level.
5. Upon request, in the case of an interception of regulated pests, the exporting Party shall provide information about monitoring and possible mitigation measures undertaken.
6. Any fees imposed for the procedures on imported products from the exporting Party shall not be higher than the actual cost of the service.
7. Inspections carried out in accordance with [Article 7(130 Preclearance)] shall only be conducted in exceptional cases and with the understanding that they are temporary measures to build confidence. Fees and other costs of such inspections shall be borne by the importing party.

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Article 14 **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 and organisation 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 13 [Import checks and fees] 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 a Party.
3. Unless otherwise decided by the Committee referred to in Article 18 [Joint management committee], when the information referred to in paragraph 1 or 2 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 and 2 as they apply to that information are fulfilled.

Article 15 **Technical consultation**

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 relevant information necessary to avoid unnecessary disruption to trade and to reach a mutually acceptable solution. Consultations may be held by audio- or video conference.

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Article 16

Emergency measures

1. The importing Party may, on serious grounds, provisionally take emergency measures necessary for the protection of human, animal or plant health.
2. Emergency measures shall be notified to the other Party within 24 hours after the decision to implement them and, on request, technical consultations regarding the situation shall be held in accordance with Article 15 [Technical consultation]. The Parties shall consider the information provided through such consultations.
3. The importing Party shall:
 - a) Consider information provided, 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;
 - b) Consider the most suitable and proportionate solution for consignments in transport between the Parties, in order to avoid unnecessary disruptions to trade and
 - c) Revise or repeal, without undue delay, the emergency measures or replace them by permanent measures with a view to avoid unnecessary trade disruption.

Article 17

Animal welfare

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 [Collaboration in international fora (multilateral and bilateral)] 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 Joint management committee] may appoint a working group to implement this provision.

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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 may, *inter alia*:
 - 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. When additional expertise is needed, participants from non-governmental organisations may be included, with the agreement of the parties.
5. A Party may refer any SPS issue to the Committee. The Committee should consider any matter referred to it as expeditiously as possible.

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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 standard setting bodies (OIE, *Codex alimentarius*, IPPC, etc.), with a view to reaching mutually satisfactory outcomes.

Article 20

Recognition and termination of the Veterinary Agreement

The Parties recognise 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 this 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*]