

**CHAPTER [ ]**  
**SANITARY AND PHYTOSANITARY MEASURES**  
**CONSOLIDATED PROPOSALS**

# RESTREINT EU/EU RESTRICTED

## CHAPTER X

### SANITARY AND PHYTOSANITARY MEASURES

[*Note: Consistent with the recommendations of the US-EU High Level Working Group Report on Jobs and Growth, the Parties seek to establish an “SPS-plus” chapter that builds upon the key principles of the World Trade Organization (WTO) SPS Agreement, including with respect to science, while preserving each Party's ability to achieving its appropriate level of protection as it relates to human, animal or plant life or health.*]

#### [EU: 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 X.1: Scope [and Coverage]**

This Chapter [US: , unless otherwise specified,] applies to all SPS measures that may, directly or indirectly, affect trade between Parties.

[EU: This Chapter shall also apply to collaboration on animal welfare matters.]

#### **Article X.2 [EU: Rights and Obligations / ] Affirmation of the SPS Agreement**

The Parties affirm their rights and obligations [US: with respect to each other] under the [WTO] SPS Agreement.

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[EU: Nothing in this Chapter shall limit the rights or obligations of the Parties under the Agreement established by the World Trade Organization and its Annexes.

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

### **Article X.3: Competent Authorities [US: and Contact Points]**

[EU: 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.]

[US: Upon entry into force of this Agreement, each Party shall provide the other Party with the following information in writing:

(a) with respect to each of the Parties' competent authorities that have responsibility for developing, implementing, and enforcing SPS measures that may affect trade between the Parties;

(i) a description of each authority, including the authority's specific responsibilities, and

(ii) a point of contact within each authority; and

(b) the name and contact information for a representative of the Party with authority to accept correspondence or inquiries from the other Party regarding matters arising under this Chapter.

Each Party shall promptly transmit to the other Party any material changes to this information.]

### **Article X.4: Equivalence**

[EU: 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 measures achieve the importing Party's appropriate level of protection.]

[EU: 2. Equivalence may be recognized 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 bodies<sup>1</sup> recognized by the WTO SPS Agreement, as well as in the provisions of {Annex IV}, where applicable.]

[US: 1. Each Party recognizes that determining that SPS measures of the other Party achieve an equivalent level of sanitary or phytosanitary protection as its own SPS measures can facilitate trade

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<sup>1</sup> [EU: Internationally agreed guidelines include, but are not limited to Guidelines of Codex Alimentarius on the Judgment 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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between the Parties. Each Party shall permit such determinations of equivalence to be made with respect to a specific measure, on the basis of a product or category of products or on a system-wide basis.

2. Each Party, in determining whether an SPS measure of the other Party achieves the Party's appropriate level of protection, shall take into account the following, where relevant:

- (a) decisions of the WTO SPS Committee;
- (b) the work of the relevant international organizations; and
- (c) knowledge acquired through experience with the other Party's relevant competent authorities.

3. Each Party shall follow the process set forth in Annex X-A with respect to determinations of equivalence.]

**[EU:** 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.

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 recognizes that the measures of the exporting Party are equivalent to its own, and
- (b) The areas for which the importing Party recognizes that the fulfillment 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 recognized.]

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### [US: Article X.5: Science and Risk<sup>2</sup>

*Note: additional provisions aimed at improving the use of science in SPS decision-making to be considered.*

1. In undertaking a risk assessment appropriate to the circumstances, each Party shall ensure that it takes into account:

(a) relevant available scientific evidence, including quantitative or qualitative data and information; and

(b) relevant guidance from the WTO SOS Committee and international standards, guidelines, and recommendations concerning the risk at issue.

2. Prior to adopting an SPS regulation, each Party shall evaluate – in light of the results of any risk assessment that it undertook or relied upon in developing the SPS regulation – any alternatives to achieve the appropriate level of protection being considered by the Party or identified through timely submitted public comments, including where raised, the alternative of not adopting any regulation. Each Party shall conduct such evaluation with a view to ensuring compliance with the Party's obligation under 5.6 of the SPS Agreement.

3. Each Party shall ensure that any risk assessment that it undertakes related to developing or reviewing an SPS regulation is under normal circumstances<sup>3</sup> made available on the Internet for public review and comment. Each Party shall ensure that any of its competent authorities responsible for undertaking a risk assessment take into account any relevant comments the Party receives during the period afforded for interested parties to provide public comment, including where appropriate by revising the risk assessment. Each Party shall also ensure that any of its competent authorities that are responsible for undertaking the risk assessment or that may use it in connection with developing or reviewing an SPS regulation, shall, upon request, discuss with the other Party in a timely manner any matters the other Party raises in its comments related to the risk assessment, including possible alternatives to achieve the Party's appropriate level of protection.

4. At the time a Party makes a risk assessment available for public comment, it shall include the following explanations:

(a) how the assessment is appropriate to the circumstances of the particular risk at issue and takes into account relevant scientific evidence, including quantitative or qualitative data and information;

(b) how, if at all, the assessment takes into account the relevant international standards, guidelines, and recommendations concerning the risks at issue; and

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2 [US: This Article shall not apply with respect to any SPS measure that conforms to international standards, guidelines, or recommendations.]

3 [US: {Note: Specific exceptional circumstances to be discussed}]

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(c) how the assessment takes into account any risk assessment techniques developed by the relevant international organizations.

5. When issuing or submitting any final administrative decision for an SPS regulation, the Party shall make publicly available on the Internet an explanation of:

(a) the relationship between the regulation and the scientific evidence and technical information, including any risk assessment and any other analyses or information the regulatory authority considered in preparing the regulation, as well as how the specific requirements set out in the regulation address the risks the regulation seeks to address;

(b) any alternative identified through public comments, including by a Party, as significantly less restrictive to trade; and

(i) whether any of those alternatives are significantly less restrictive to trade;

(ii) whether such alternatives were able to achieve the Party's appropriate level of protection or were technically or economically feasible; and

(iii) its reasons for selecting the measure set out in the final administrative decision.

6. Where a regulatory authority of a Party submits a proposal for an SPS measure for approval by a committee comprising national representatives and:

(a) the committee rejects or modifies the proposal; or

(b) the regulatory authority of a Party modifies the proposal in response to feedback, including any rejection, from the committee

each member of the committee or the regulatory authority of the Party, as the case might be, shall make publicly available an explanation of the basis for rejecting or modifying the proposal, including the extent to which it is supported by relevant scientific evidence and technical information and analysis, including any risk assessment.

7. Each Party that provisionally adopts an SPS measure pursuant to Article 5.7 of the SPS Agreement that affects trade between Parties shall, upon request, explain:

(a) to the extent possible, any alternatives significantly less restrictive to trade it considered and why it considered that any such alternatives do not achieve the Party's appropriate level of protection or are not technically or economically feasible;

(b) its view on any comments and information submitted by the other Party;

(c) the additional information it believes **[US: This Article shall not apply with respect to any SPS measure that conforms to international standards, guidelines, or recommendations necessary for a more objective assessment of risk and plans for obtaining such information; and**

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(d) under what circumstances, and if possible when, it will review whether to maintain or modify the measure.]

### **Article X.6: Adaption to Regional [US: Pest or Disease] Conditions**

#### **[EU: Animals, animal products and animal by-products]**

[EU: 1. The Parties recognize the principle of zoning which they agree to apply in their trade.]

[EU: 6. The Parties also recognize the concept of compartmentalization and agree to cooperate on this matter.]

[US: 1. Each Party recognizes that adaption of SPS measures to regional pest or disease conditions can facilitate trade. Each Party shall provide that such adaption may be made on the basis of an area or zone, place of production, or subpopulation. {not limited to animal products}]

[EU: 2. The importing Party shall recognize 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 X.18 {Emergency measures}, the importing Party shall recognize 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}.]

[US: 2. The competent authorities of each Party shall work together to establish the risk management measures that would apply to trade between the Parties in the event either Party has made any change with respect to disease or pest status of a demarcation in its territory. {not limited to animal products}

3. Each Party shall normally recognize the demarcations of the other Party located in the other Party's territory. {not limited to animal products}]

[EU: 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 [ ] {Audit and verification} and within 25 working days of receipt of the request for verification. The Parties shall endeavor 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 fulfills 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 to imports of live animals and animal products appropriate to the agreed status. The guarantees for specific diseases are specified in {Annex IV}.]

[US: 4. Each Party, in determining the pest or disease status respect to a particular demarcation

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located in the other Party, shall take into account the following where applicable:

- (a) decisions of the WTO SPS Committee;
- (b) the work of the relevant international organizations; and
- (c) knowledge acquired through experience with the exporting Party's relevant sanitary or phytosanitary authorities.

5. Each Party shall follow the procedures set forth in Annex X-B with respect to a request from the other Party to determine that a particular demarcation is free of a particular pest or disease.]

[US: *Note: Annex X-B will be tabled at a later date.*]

### [EU: Plants and plant products

7. Without prejudice to Article X.18 {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 Protocol 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 [ ] 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.]



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### **Article X.7: Transparency [US: of Sanitary and Phytosanitary Regulations]**

#### **[EU: 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

(any significant changes to the structure and organization of their competent authorities.

#### **Information exchange:**

2. The Parties will endeavor 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 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 another relevant international standard-setting body in accordance with the relevant rules, the requirements in paragraph 1 and 2 as they apply to that information are fulfilled.]

**[US: 1. During the time period described in paragraph 2, when a regulatory authority of a Party is developing an SPS regulation, it shall, under normal circumstances,<sup>4</sup> make publicly available on the Internet:**

(a) the text of the regulation it is developing;

(b) any risk assessment, as well as the scientific evidence and technical information and any other analyses and information the regulatory authority relied upon in support of the regulation and an explanation of how such evidence, information and analyses support the

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4 [US: Note: Specific exceptional circumstances to be discussed]

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regulation;

(c) an explanation of how the regulation, including its objectives, achieves those objectives, the rationale for the material features of the regulation, and any major alternatives being considered; and

(d) the name and contact information of an official who may be contacted for questions regarding the regulation.

2. Each Party shall make publicly available the information described in paragraph 1:

(a) after the relevant authority of the Party has developed a text for the regulation that contains sufficient detail so as to allow persons to evaluate how the regulation, if adopted, would affect their interests; and

(b) before the relevant authority of the Party that is developing the measure issues or submits any final administrative decision with respect to the regulation so that this authority may take into account timely received comments and, as appropriate, revise the regulation.

3. Where a regulatory authority of a Party is developing an SPS regulation and makes publicly available the information described in paragraph 1, the Party shall ensure that any person, regardless of domicile, has an opportunity, on no less favorable terms than any person of the Party, to submit comments on the regulation, including by providing written comments and other input with respect to the information described in paragraph 1, to the regulatory authority. The Party shall promptly make publicly available any comments it receives on the regulation, except to the extent necessary to protect confidential information or withhold personal identifying information or inappropriate content, in which case the Party shall ensure it makes publicly available a version that redacts such information or a summary of the comment that does not contain such information.

4. In determining the time period during which interested persons may submit comments on the regulation, each Party shall take into account the relevant decisions of the WTO SPS Committee.

5. Where a regulatory authority of a Party issues any final administrative decision for an SPS regulation, each Party shall also make publicly available:

(a) the text of the regulation;

(b) an explanation of the regulation, including its objectives, and how the regulation achieves those objectives, and the rationale for the material features of the regulation (to the extent different from the explanation provided in accordance with paragraph 1 (c));

(c) the regulatory authority's views on substantive issues raised in the comments; and

(d) an explanation of the nature and the reason for any significant revisions to the regulation since the Party made it available for public comment.

6. Each Party shall publish, in print or electronically, all final SPS regulations in a single official journal or website. Each Party shall publish in this single official journal or website the text of any

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SPS regulation it is developing and that it makes publicly available in accordance with paragraphs 1 and 2.]

### **[EU: Article X.8: Elimination of Redundant Control Measures**

1. The Parties recognize each other's competent authorities as responsible to ensure that establishment, 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 authorized and listed by the exporting Party without re-inspection, third party certification or any other additional guarantees.]

### **Article X.9 [EU: Audits and Verification] [US: Audit and Inspections]**

[EU: 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.

3. For the purpose of paragraph 1, the importing Party shall endeavor 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 guidelines<sup>5</sup>.

5. Verification procedures may include, but are not limited to:

(a) an assessment of all or part of the exporting Party's total control program, including, where appropriate, reviews of the exporting Party's inspection and audit programs, 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.

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5 [EU: 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 Measure ISPM 20: Guidelines for a phytosanitary import regulatory system.]

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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 X.17 {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.]

[US: 1. Each Party shall conduct any audits of the other Party's competent authorities in accordance with Annex X-C.

*Note: Annex X-C will be tabled at a later date.*

2. Each Party recognizes that, in order to verify compliance with applicable SPS measures and any applicable requirements agreed upon by the Parties, a Party may inspect premises, laboratories, and other relevant facilities in the other Party's territory.]

*[US: Note: provisions to prevent the release of personal privacy and business confidential information, to be considered.]*

### **Article X.10: [EU: Export Certificates] [US: Certification]**

[EU: 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 the 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”.

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 X.15 {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

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shall cooperate in the implementation of electronic certification procedures in accordance with the provisions described in {Annex VIII}.]

**[US:** 1. Each Party shall endeavor to use means other than certification to demonstrate that imports from the other Party satisfy its appropriate level of protection or meet its applicable SPS requirements. To help ensure that any certification requirements, including any attestation or information requirements, are applied only to the extent necessary to protect human, animal, or plant life or health, each Party shall ensure that its certification forms:

(a) are prepared in a manner that avoids imposing unnecessary burdens on the other Party's regulatory and certification authorities, including duplicative attestations;

(b) are adapted to recognize the competent authorities of the other Party and facilitate their ability to make the requested certifications; and<sup>6</sup>

(c) take into account relevant decisions of the WTO SPS Committee, international standards, guidelines and recommendations, and determinations made by the Parties related to regional conditions and equivalence.

2. Each Party shall, on request, assist the other Party in determining the authenticity of specific certificates.

3. No later than {15} days after the date of entry into force of this Agreement, the Parties shall establish model certificates that take into account the circumstances of trade between the Parties. To the extent feasible, each Party shall base its certification requirements for imports from the other Party on these model certificates.]

### **[EU: Article X.11: Trade Facilitation/Conditions**

#### *Sanitary and phytosanitary import procedures*

1. Sanitary and phytosanitary procedures shall be established with the objective of minimizing negative trade effects and simplifying and expediting the approval and clearance process while ensuring the fulfillment 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 authorization process, including complete details about the mandatory administrative steps, expected timelines, and authorities in charge of receiving

<sup>6</sup> **[US:** For greater certainty, each Party recognizes that the other Party is entitled to designate the competent authorities that may make the requested certifications and that those authorities may, as appropriate, delegate their authority to other government entities.]

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

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, auditing 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 authorization 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.

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### Trade facilitation

11. Where it is necessary for the import 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 or regulated commodities shall be accepted on the basis of adequate guarantees by the exporting Party, without:

- (a) Preclearance programs. 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 intended to facilitate new trade. On a voluntary basis, the NPPO of the country of origin may request preclearance within the inspection activities carried out by the importing countries as a trade facilitation tool;
- (b) Import licenses or import permits;
- (c) Phytosanitary protocols or work plans prescribed by the importing Party.

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.]

### **[US: Article X.12: Regulatory Approvals for Products of Modern Agricultural Technology**

1. Where a Party requires a product of modern agricultural technology to be approved or authorized prior to its importation, use or sale in its territory, the Party shall allow any person to submit an application for approval at any time.

2. Where a Party requires a product of modern agricultural technology to be approved or authorized prior to its importation or sale in its territory, each Party shall make publicly available:

- (a) a description of the processes it applies to accept, consider, and decide applications for approval or authorization;
- (b) the competent authorities responsible for receiving and deciding applications for

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approval or authorization;

(c) the timelines for completion of any steps or procedures in the approval or authorization processes;

(d) any documentation, information, or actions it requires from applicants as part of its approval or authorization processes; and

under normal circumstances<sup>7</sup> each Party shall promptly make publicly available any risk assessment it conducts as part of an approval or authorization process for a product of modern agricultural technology.

3. Each Party shall endeavor to meet applicable timelines for all steps in its approval or authorization processes for products of modern agricultural technology. Where a Party does not meet the timeline for a step in an approval or authorization process, upon request of the other Party, the Party shall provide a timely notification to the other Party explaining why the timeline for that step was not met and identify and update the timeline for all remaining steps in the approval or authorization process.

4. Each Party shall avoid unnecessary duplication and burdens with respect to:

(a) any documentation, information, or actions required of applicants as part of its approval or authorization processes for products of modern agricultural technology; and

(b) any information the Party evaluates as part of the approval or authorization processes for products of modern agricultural technology.

5. Each Party shall promptly publish any changes to its required approval or authorization processes or related requirements for products of modern agricultural technology. Except in urgent circumstances, each Party shall endeavor to provide a transition period between publication of any material changes to its approval or authorization processes or related requirements for products or modern agricultural technology and their entry into force to allow interested persons to become familiar with and adapt to such changes, and endeavor to accommodate and avoid lengthening the approval or authorization process for applications that were submitted prior to publication of the changes. However, where the change reduces burdens on interested persons, entry into force should not be unnecessarily delayed.

6. Each Party shall maintain mechanisms or processes that provide an applicant seeking approval or authorization for a product of modern agricultural technology to timely obtain:

(a) information on the status of its application for approval or authorization;

(b) answers to questions regarding the approval or authorization processes and regulatory requirements for approval;

(c) notice that the Party requires clarification or additional information from the applicant;

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<sup>7</sup> [US: Note: Specific exceptional circumstances to be discussed]



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(d) opportunities to provide clarification with respect to its application or additional information in support of it during the review of the application; and

(e) opportunities to correct, or identify potential concerns regarding, information being considered or relied upon by the Party in considering and deciding on the application, including with respect to any risk or safety assessments conducted.

7. Each Party shall participate in the Global Low Level Presence Initiative to develop an approach or set of approaches to manage low-level presence in order to reduce unnecessary disruptions affecting trade.

8. The Parties hereby establish a Working Group on Trade in Products of Modern Agricultural Technologies (“Working Group”) to be co-chaired by representatives of each Party’s trade agency. Each Party shall designate officials from its competent authorities, including officials from authorities that conduct or evaluate risk assessments in connection with applications for approval of products of modern agricultural technology, to participate in the Working Group. The Working Group shall be a forum for the Parties to:

(a) discuss specific measures or issues related to modern agricultural technologies that may affect, directly or indirectly, trade between the Parties;

(b) discuss and resolve specific trade concerns arising from a measure of a Party affecting products of modern agricultural technology;

(c) facilitate the exchange of information, including on laws, regulations and policies of each Party, related to the trade of products of modern biotechnology; and

(d) consult on issues and positions related to international cooperative and standard-setting efforts related to modern agricultural technologies.

The Working Group shall provide an annual report to the Joint Committee concerning its activities as well as any progress it has made toward resolving trade concerns raised by a Party.】

### **Article X.13 Import Checks [EU: and Fees]**

[EU: {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

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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 case of pest interceptions, the notification should indicate the pest at the species level.]

**[US:** 3. When a Party prohibits or restricts the importation of a good of another Party on the basis of an adverse result of an import check, the Party shall provide a notification, where practicable by electronic means, about the adverse result to at least one of the following: the importer or its agent, the exporter, the manufacturer, or the exporting Party. When providing the notification, the Party shall:

(a) include in the notification

(i) the reason for the prohibition or restriction;

(ii) the legal basis or authorization for the action;

(iii) as appropriate, information on the disposition of the affected goods; and

(iv) information on the status of the goods; and

(b) provide the notification as soon as possible and normally not later than 10 days after the date it prohibits or restricts the importation of the goods unless the goods are seized by a customs authority of the Party.

4. Where a Party that has prohibited or restricted the importation of a good of another Party on the basis of an adverse result of an import check, it shall provide an opportunity for a review of the decision and consider any relevant information submitted to it to assist in the review.]

**[EU:** 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(12) 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.]

**[US:** 1. Upon request, each Party shall provide the other Party with information on any import procedures and its basis for determining the nature and frequency of import checks, including the factors it considers in determining the risks associated with importations.

2. Upon request, each Party shall provide the other Party with information on the analytical methods, quality controls, sampling procedures, and facilities that the Party uses to test a good as part of an import check. Each Party shall ensure that any testing it conducts as part of an import

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check on goods of the other Party is done in accordance with appropriate, scientifically valid analytical methods, and in facilities operating under a quality assurance program that is consistent with international laboratory standards. Each Party shall maintain physical or electronic documentation regarding the identification, collection, sampling, transportation, and storage of test samples of goods of the other Party and the analytical methods used to test the samples.

5. Where a Party has determined a significant, sustained or recurring pattern of non-conformity with an SPS measure by another Party, it shall notify the other Party of the non-conformity.]

### **[EU: Article X.14: Application of SPS Measures**

Except as provided for in Article X.6 {Adaptation to regional conditions} each Party shall apply its sanitary or phytosanitary import conditions to the entire territory of the other Party. Where harmonized import conditions exist in one Party, these conditions shall apply to the entire territory of the exporting Party.

Without prejudice to Article X.6 {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 authorization, approval or certificate.]

### **Article X.15: [EU: Joint Management] Committee [US: on Sanitary and Phytosanitary Matters]**

**[EU: 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.]

**[US: 1.** The Parties hereby establish a Committee on Sanitary and Phytosanitary Matters (the “Committee”) comprising representatives of each Party. No later than {15}) days after the date of entry into force of this Agreement, the Parties shall establish the Committee’s terms of reference and identify through an exchange of letters the primary representative of each Party that shall serve as its co-chair on the Committee. Each Party shall ensure that its representatives on the Committee are the appropriate officials from its relevant trade agencies or ministries and competent authorities with responsibility for the development, implementation, and enforcement of SPS measures. The Committee shall meet at least once a year, unless the Parties decide otherwise.]

**[EU: 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;

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(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 organizations 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.

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 program 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 program 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.]

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**[US: 2.** The functions of the Committee shall include:

- (a) enhancing each Party's implementation of this Chapter and facilitating the exchange of information on each Party's progress in implementing this Chapter;
- (b) consulting on issues and positions related to the meetings and work of the WTO SPS Committee, the International Plant Protection Convention (hereinafter "IPPC"), World Animal Health Organization (hereinafter "OIE"), and the Codex Alimentarius Commission (hereinafter "Codex");
- (c) providing a forum for discussion of and reviewing progress on addressing specific trade concerns related to the application of SPS measures and other SPS matters with a view to reaching mutually acceptable solutions;
- (d) referring issues to technical working groups in support of work that the Committee considers to be a priority, establishing additional technical working groups, and eliminating technical working groups other than those established pursuant to Article X.13;
- (e) {approving any modifications to the Annexes of this Chapter}; and
- (f) reporting, at least annually, to the Joint Committee on its activities and progress on resolving specific trade concerns and other SPS matters, including those specific trade concerns for which a technical working group has developed an action plan.

3. A Party may request the Committee to refer a specific trade concern regarding an SPS measure or other SPS matter to a technical working group. If the Committee decides to refer the matter to a technical working group, it shall forward the request to the relevant technical working group and the requesting Party shall at that time provide the technical working group with technical information in support of its preferred approach for resolving the matter. Any decision to refer a matter to a technical working group shall take into account the resources of each Party and the need to balance the respective interest of each Party. The Committee may refer matters to a technical working group no more than once a year, except in cases of exceptional urgency.]

### **[US: Article X.16: Technical Working Groups**

1. Recognizing that the resolution of SPS matters is best achieved through bilateral cooperation and consultation informed by the applicable science and understanding of the relevant risks, the Parties hereby establish technical working groups to be co-chaired by representatives of each Party concerning the following subjects:

- (a) animal health;
- (b) plant health; and
- (c) food safety.

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The Parties may decide to designate existing bodies to serve as the relevant technical working group for purposes of this Article. No later than [15] days after the date of entry into force of this Agreement, the Parties shall establish the terms of reference or rules of procedure for each technical working group. The co-chairs of a technical working group may decide to establish subgroups that may include, as appropriate, experts that are not representatives of the technical working group to consider particular technical issues.

2. Any technical working groups established shall, with respect to the subject matter of the working group:

(a) consider specific SPS measures or sets of measures that are likely to affect, directly or indirectly, trade;

(b) engage, at the earliest appropriate point, in scientific and technical exchange and cooperation regarding SPS matters that may, directly or indirectly, affect the trade;

(c) provide a forum to facilitate consideration, discussion, and reviews of specific risk assessments and possible risk mitigation and management options;

(d) seek to resolve specific trade concerns; and

(e) provide a regular opportunity for each Party's representatives to update the technical working group on the progress the Party has made on addressing and resolving specific trade concerns.

3. Each technical working group established under this Chapter shall annually develop a work program taking into account the resource constraints of each Party and the need to balance each Party's respective interests.

4. The work program shall include action plans to address, with a view to resolving, specific trade concerns regarding SPS measures or other SPS matters. *[Additional provisions on action plans to be considered.]*

5. Each technical working group shall provide the Committee with a report, at least annually, regarding the progress of its current work programs, including timelines for future actions where appropriate.]

### **Article X.17: [EU: Technical Consultation]**

[EU: 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 endeavor 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 videoconference.]

### **[US: Cooperative Technical Consultations to Resolve SPS Trade Concerns]**

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**[US:** 1. Each Party may request cooperative technical consultations to discuss any SPS measure of the other Party that it considers might adversely affect trade. The request shall be made in writing and identify:

- (a) the measure at issue;
- (b) the provisions of this Chapter or the SPS Agreement to which the concerns relate; and
- (c) the reasons for the request, including a description of the requesting Party's concerns regarding the measure.

2. A Party shall deliver its request to the representative of the other Party identified in Article X.3(b) and, where the measure is under discussion by a technical working group or the working group on modern agricultural technologies, to the chairs of the relevant working group.

*Additional provisions on the role of technical working groups to be considered.*

3. In the event the measure identified in the request is not under discussion in a working group or no consensus exists in the working group that further work by it could address the concerns in the request, the Party to which the request is made shall, unless the Parties decide otherwise, reply to the request in writing within {15} days of the date it receives the request whether it is willing to discuss the concerns identified in the request. If the Party to whom the request is made is willing to discuss the concerns in the request, it shall meet with the other Party, in person or via video or teleconference, to discuss the matters identified in the request no later than {60} days after the date it receives the request. If the Party requesting cooperative technical consultations believes that the matter is urgent, it may request that any discussions take place within a shorter time frame. In such cases, the Party to whom the request is made shall give positive consideration to the request.

4. Prior to the meeting of the Parties provided for in paragraph 3 or within {15} days thereafter, either Party may request an expert to serve as a facilitator to resolve the concerns identified in the request for cooperative technical consultations. The other Party shall respond to the request within {7} days of the date it receives it. If the Parties agree to use a facilitator, the Parties shall try to agree on an individual to serve as facilitator.

5. If the Parties are unable to agree on an individual to serve as the facilitator within {7} days:

- (a) each Party shall nominate an individual who is not a national of any Party to serve as the facilitator; and
- (b) the Party requesting cooperative technical consultations shall select by lot an individual to serve as the facilitator, unless the Parties decide otherwise.

The Party to which the request has been made shall have the right to be present for the selection.

6. A facilitator shall be deemed to be appointed on the date the Parties receive written notification

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from the individual that he or she agrees to serve as the facilitator and confirms the he or she agrees to abide by the requirements set out in paragraph 7. The Parties shall meet with the facilitator, in person or by electronic means, within {30} days of the date the facilitator is appointed.

7. Any individual appointed to serve as a facilitator shall:

- (a) be independent of, and not be affiliated with or take instructions from, any Party;
- (b) not have a financial interest in the matter;
- (c) abide by terms and conditions that may be determined by the Parties;
- (d) not comment on the consistency of the measure at issue with respect to this Agreement or the SPS Agreement, during the course of his or her duties or afterwards;
- (e) agree to keep confidential, except between the Parties, any of the following received in the course of the facilitator's duties:
  - (i) any technical or scientific information submitted by a Party;
  - (ii) any statements by a Party regarding its position on the matter before the facilitator; and
  - (iii) the substance of any discussions between the Parties; and
- (f) not serve as an arbitrator or expert in any dispute concerning the matter.

The remuneration and expenses paid to the facilitator shall be borne equally by the Parties, unless the Parties decide otherwise.

8. Each Party shall ensure that representatives from the relevant trade and competent authorities participate in any meetings held pursuant to this Article. Where the Parties choose to meet in person, the meeting shall take place in the territory of the Party to which the request has been made, unless the Parties decide otherwise.

9. All communications related to cooperative technical discussions sought or carried out pursuant to this Article shall be kept confidential, unless the Parties decide otherwise, and shall be without prejudice to the rights and obligations under this Agreement or the WTO Agreement.

10. Each Party shall seek to resolve any concerns with respect to an SPS measure of the other Party through cooperative technical consultations pursuant to this Article prior to initiating dispute settlement proceedings under this Agreement.

11. Either Party may terminate cooperative technical consultations by notifying the other Party in writing. Such notification may be provided at any time, provided that more than {45} days have elapsed, or such other period of time as the Parties may decide, since the data on which the Party receiving a request for cooperative technical consultations replied that it is willing to enter into such consultations.]



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### **[EU: Article X.18: 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 is taken and, on request, technical consultations regarding the situation shall be held in accordance with Article 17 {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 avoiding unnecessary trade disruption.]

### **[EU: Article X.19: Animal Welfare**

1. The Parties recognize 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 farms, during transport and at slaughter.
4. In accordance with Article X.20 {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 X.15 [Joint Management Committee] may appoint a working group to implement this provision.]

### **[EU: Article X.20: Collaboration in International Flora**

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

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### [EU: Article X.21: Recognition and Termination of the Veterinary Agreements

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 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*.}

### Article X.22: Definitions

For purpose of this Chapter [EU: ,] [US: :]

[EU: “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 favorable conditions and its presence in other parts of the Union;

The “SPS Agreement” means the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures.

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

[US: **appropriate level of protection** shall have the same meaning ascribed to the term 'appropriate level of sanitary and phytosanitary protection' in the WTO SPS Agreement:

**area** shall have the meaning ascribed to that term by the OIE when used in relation to animal health, and shall have the meaning ascribed to that term by the IPPC when used in relation to plant health;

**competent authority** means the authorities in each Party responsible for measures and matters referred to in this Chapter.

**demarcation** means an area or zone, place of production, or subpopulation that maintains a distinct status with respect to a pest or disease prevalence and may be identified on a geographical basis using natural, artificial, or legal boundaries or on the basis of management and biosecurity practices employed at particular establishments or places of production;

**final administrative decision, regulation, and regulatory authority** shall have the same meaning ascribed to those terms in Chapter X (Regulatory Coherence, Transparency and Other Good

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Regulatory Practices);

**import check** means any inspections, examinations, sampling, review of documentation, texts or procedures, including laboratory, organoleptic, and identity, conducted at the border by an importing Party or its representative to determine if the consignment complies with the SPS requirements of the importing Party;

**international standards, guidelines and recommendations** shall have the same meaning ascribed to those terms in the WTO SPS Agreement;

**low-level presence** means the inadvertent low-level presence in a shipment of plants or plant products of rDNA plant material that is authorized for use in at least one country, but not in the importing country;

**modern agricultural technology** means [to be defined];

**place of production** shall have the meaning ascribed to that term by the IPPC;

**relevant international organization** means:

- (a) with respect to food safety, the Codex Alimentarius Commission;
- (b) with respect to animal health and zoonoses, the World Animal Health Organization; and
- (c) with respect to plant health, the Secretariat of the International Plant Protection Convention; and

**risk assessment** shall have the same meaning ascribed to the term in the WTO SPS Agreement;

**SPS measure** shall have the same meaning ascribed to the term sanitary and phytosanitary measure in the WTO SPS Agreement;

**zone, establishment, and subpopulation** shall have the meaning ascribed to those terms by the OIE.]