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CHAPTER 5

SANITARY AND PHYTOSANITARY MEASURES

ARTICLE 5.1

Objectives

The objectives of this Chapter are:

- (a) to reinforce the implementation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter referred to as "SPS Agreement") and international standards, guidelines and recommendations developed by relevant international organisations applicable to trade between the Parties;
- (b) to protect human, animal or plant life or health in the territory of each Party while facilitating trade between the Parties and to ensure that Sanitary and Phytosanitary (SPS) measures imposed by each Party do not create - unjustified barriers to trade;
- (c) to provide a means to strengthen communication, consultation, cooperation and resolution on SPS issues that may affect trade between the Parties and other agreed matters of interest to the Parties under this Chapter; and
- (d) to promote greater transparency and understanding on the application of each Party's SPS measures.

ARTICLE 5.2

Scope

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

ARTICLE 5.3

General Provisions

1. The Parties reaffirm their rights and obligations under the SPS Agreement.
2. Each Party commits to apply the principles of the SPS Agreement in the development, or application of any sanitary or phytosanitary measure with the intent to facilitate trade between the Parties while protecting human, animal or plant life or health in their respective territories.
3. SPS measures cannot be used so as to create unjustified barriers to trade.
4. The Parties shall ensure that procedures established under the scope of this Chapter are undertaken and completed without undue delay and that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination against the other Party.

ARTICLE 5.4

Definitions

1. For the purposes of this Chapter, the following definitions apply:
 - (a) the definitions in Annex A of the SPS Agreement;
 - (b) the relevant definitions adopted under the auspices of the Codex Alimentarius Commission (hereinafter referred to as "Codex");

- (c) the relevant definitions adopted under the auspices of the World Organisation for Animal Health (hereinafter referred to as "WOAH")
 - (d) the relevant definitions adopted under the auspices of the International Plant Protection Convention (hereinafter referred to as "IPPC");
 - (e) "competent authority" means an authority whose roles and functions are set out in Annex A, (Competent Authorities); and
 - (f) "emergency measure" means a sanitary or phytosanitary measure that is applied by a Party to products of the other Party to address an urgent problem of human, animal or plant life or health protection that arises or threatens to arise in the Party applying the measure.
2. In the event of any inconsistency between the definitions agreed by both Parties under this Chapter and the definitions set out in the SPS Agreement, the definitions set out in the SPS Agreement shall prevail.

ARTICLE 5.5

Competent authorities and contact points

1. As of the date of entry into force of this Agreement, the Parties shall provide each other a list of their respective competent authorities, and contact points for communication on all matters arising under this Chapter. The notification shall include the respective role, responsibilities, and contact information of these authorities.
2. The Parties shall inform each other, through their respective contact points, of any significant changes in the structure, organisation and division of competency of their competent authorities and ensure that the information on the contact points is kept up to date.

ARTICLE 5.6

Import conditions and process facilitation

1. Without prejudice to the rights and obligations of each Party under this Chapter, the import conditions¹ of the importing Party shall apply to the entire territory of the exporting Party.

2. Each Party shall:
 - (a) ensure that control, inspection, and approval procedures are undertaken and completed without undue delay.

 - (b) promptly communicate to the other Party any changes to import conditions and procedures; and

 - (c) except in duly justified circumstances related to its level of protection, provide a transition period between the publication of the changes to its control, inspection, and approval procedures and their application.

3. If the importing Party requires a product to be approved for import, it shall, on request of the exporting Party and without undue delay:
 - (a) inform the exporting Party of the anticipated processing period of the procedure;

 - (b) undertake and complete the examination of the documentation received from the exporting Party as part of its request and inform the exporting Party in a precise and complete manner of any deficiencies;

 - (c) inform the exporting Party of the status of the assessment of the request in a precise and complete manner, with any delay being explained, so that corrective action may be taken by the exporting Party, if necessary;

¹ For greater certainty, the term 'import conditions' means any sanitary or phytosanitary measures as set out in Annex A of the SPS Agreement that must be complied with for imports to achieve the appropriate level of protection of the importing Party. This does not preclude India from receiving and examining export requests from a Member State individually, in line with its laws and regulations and its obligations under international law.

4. The importing party shall provide the exporting party with the risk assessment it conducted as part of approval procedure within a reasonable period of time.
5. On request, the importing party shall, without undue delay, provide the exporting Party with an explanation of the relationship between the SPS measure and international standards, guidelines and recommendations and, if a measure is not based on an international standard, with the information, including scientific evidence, on which the SPS measure is based and an explanation of the reasons for such measure.
6. Information requirements are limited to what is necessary for appropriate control, inspection and approval procedures.
7. In case of export request from a Member State for a product which has previously been approved for import from one or more other Member States, India shall expedite the assessment of such request.
8. With respect to plants and plant products, each Party shall limit its import requirements to measures ensuring the absence of regulated pests², in accordance with the applicable standards agreed under the IPPC.

ARTICLE 5.7

Certification

1. Where a Party requires an official certificate for the importation of a product, these shall be based on the principles laid down in the international standards of the Codex Alimentarius, the IPPC and WOA. H.
2. The importing Party shall not put in place any additional administrative measure that duplicates the requirements of the official certificate.

² For India, 'Regulated Pest' shall mean 'Quarantine Pest'.

3. Each Party shall ensure that its certification, including any attestations are prepared in a manner that avoids imposing an unnecessary burden on trade.
4. An importing Party shall promptly provide to the other Party, on request, information on the certificates required for a specific product.
5. The Parties shall encourage the implementation of electronic certification and other technologies to facilitate trade.
6. Each Party shall accept either paper certificates or electronic certificates as far as they offer equivalent certification, and relevant security and guarantees.

ARTICLE 5.8

Audits

1. For the purpose of attaining and maintaining the confidence in the exporting Party's compliance with the SPS requirements of the importing Party, the relevant competent authority of the importing Party may conduct an audit of all or part of the control system of the competent authority of the other Party, taking into account the relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations of the Codex Alimentarius, WOH and IPPC.
2. The audit referred to in paragraph 1 shall:
 - (a) focus on the control system of the competent authority of the exporting Party rather than on specific establishments of the exporting Party;
 - (b) evaluate the effectiveness of the control system of the competent authority of the exporting Party; and

- (c) follow a systems-based approach which relies on the examination of a sample of system procedures, relevant documents or records and, if required, on-site inspections of establishments of the exporting Party.
3. The importing Party shall determine the nature and frequency of audits and decide to carry out an audit, taking into account the inherent risks of the product concerned, 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.
 4. The importing Party shall share a pre-audit questionnaire with the exporting Party, prior to notifying the decision for conducting an audit. The exporting Party shall be granted at least six months to respond to the said pre-audit questionnaire.
 5. Once the importing Party decides to carry out an audit of the exporting Party, it shall notify its decision, including the scope of audit and its calendar, to the exporting Party at least 60 days before the planned starting date of the audit unless the Parties agree otherwise or in case of emergency. Any modification of the starting date or the calendar of the audit shall be agreed by the Parties.
 6. The importing Party shall bear its own costs associated with audits.
 7. The exporting Party shall give reasonable access to the importing Party for conducting an audit.
 8. The importing Party shall set forth its findings, preliminary conclusions and, if applicable, its recommendations from the audit in writing in a draft audit report.
 9. The importing Party shall provide the draft audit report to the exporting Party within 30 working days after the date of conclusion of the audit, unless otherwise agreed between the Parties. However, where a significant public, animal or plant health risk has been identified during the audit, the importing Party shall inform the exporting Party as quickly as possible and in any case within 10 working days after the date of conclusion of the audit.
 10. The exporting Party shall inform the importing Party of comments and if required any corrective action planned or taken, based on the findings, conclusions and, if applicable, the

recommendations in the draft audit report, within 35 working days after the date of receipt of the draft report, unless otherwise agreed between the Parties. However, where a significant public, animal or plant health risk has been identified during the audit, the exporting Party shall inform the importing Party as quickly as possible and in any case within 10 working days after the date of receipt of the draft report.

11. The importing Party shall provide the final audit report to the exporting Party within 30 working days after the date of receipt of the exporting Party's comments and information on corrective actions, if applicable on the draft audit report.

12. Any measures taken by the importing Party on the basis of audits shall be proportionate to the risks identified while taking into account any additional information that may be provided by the exporting Party and shall not be more trade restrictive than necessary to achieve the importing Party's appropriate level of protection. Nothing in this paragraph prevents a Party from taking an emergency measure consistent with Article 13 (Emergency Measures).

13. Each Party shall ensure, in accordance with their respective laws and regulations, that procedures are in place to prevent the disclosure of confidential information that is acquired during the audit process.

ARTICLE 5.9

Procedure for registration or publication of list of establishments

1. For the purpose of this Article, the exporting Party shall ensure that the establishments and products it approved for export meet the applicable sanitary requirements of the importing Party.

2. If the importing Party maintains a list of establishments of the exporting Party for import of a specific product, the procedure for registration or publication of lists shall be based on an evaluation of the official control system of the relevant competent authority of the exporting Party, and the following shall apply:

- (a) The competent authority of the exporting Party shall approve the establishment of the exporting Party which intend to export the specific product to the importing Party;
 - (b) The exporting Party shall share with the importing Party the list of establishments approved pursuant to (a);
 - (c) On receipt of the list of approved establishments from the exporting Party, the importing Party shall register or publish on its official website, the list of these establishments; and
 - (d) Once an establishment of the exporting Party has been registered or published pursuant to subparagraph (c), the importing Party shall allow imports of the specific product without prior inspection of that establishment within 40 days after the date of receipt of the list of the approved establishments pursuant to subparagraph c).
3. The importing Party shall make publicly available the said list of establishments.
 4. In the event of serious or repeated non-compliance of consignments from an approved establishment, the importing Party may conduct intensified official controls on the consignments of such establishment and shall promptly notify the exporting Party of the specific instances of non-compliance or identified health risks, and request the exporting Party to conduct the necessary investigations.
 5. The exporting Party shall send to the importing Party a report on the outcome of the investigation and share, without delay, the action plan including the proposed corrective measures to effectively remedy the identified issues. The corrective measures may include the temporary withdrawal of the relevant establishment from the list of approved establishments by the competent authority of the exporting Party.
 6. The exporting Party, on undertaking the corrective measures mentioned in paragraph 5, shall communicate these and the results of such action plan to the importing Party. Upon receipt of such communication, the importing Party shall promptly evaluate the corrective measures taken. If it concludes that the corrective measures taken effectively remedy the identified issues and that the results of its intensified official controls are satisfactory, it shall promptly terminate these controls for such establishment.

ARTICLE 5.10

Transparency and exchange of information

1. The Parties shall, through their respective contact points referred to in Article 5 (Competent Authorities and Contact Points), ensure transparency as regards SPS measures, including any amendment or modification, applicable to trade, as set out in Article 7 and Annex B of the WTO SPS Agreement, *mutatis mutandis*.
2. A Party shall promptly inform the other Party of :
 - (a) any significant finding of epidemiological importance or change to a plant pest or animal disease status, such as the presence and evolution of a pest or disease relevant for trade between the Parties; or
 - (b) any significant food safety issue relevant for trade between the Parties;
3. On request of a Party, the other Party shall communicate:
 - (a) the import conditions that apply for the import of specific products without undue delay after the receipt of the request; and
 - (b) the progress of the import approval procedure of specific products without undue delay after the receipt of the request.
 - (c) any other information related to SPS measures under this Chapter that may affect trade between the Parties
4. Each Party shall make publicly available up-to-date information on:
 - (a) all its sanitary and phytosanitary laws and regulations that are adopted.

(b) the animal disease status or plant quarantine pest list in its territory.

5. With respect to plants and plant products, each Party shall make publicly available an updated list of regulated pests³ for which a phytosanitary concern exists, in accordance with the applicable standards agreed under the IPPC.

6. When the information referred to in this Article has been made available by notification to the WTO in accordance with the relevant rules when the above information has been made available on the official and publicly accessible websites of the Parties, the information exchange shall be considered to have taken place.

ARTICLE 5.11

Adaptation to regional conditions

1. The Parties recognise the concepts of regional conditions, including pest- or disease-free areas and areas of low pest or disease prevalence, zoning and compartmentalisation as set out in Article 6 of the SPS Agreement and WOAHA respectively, and that the adaptation of SPS measures to regional conditions is an important means of facilitating trade, while protecting human, animal or plant life or health. In developing SPS measures that are adapted to regional conditions, the Parties shall take into account the relevant decisions of the WTO SPS Committee, the official animal health status recognized by the WOAHA, and international standards, guidelines and recommendations developed by the relevant international organisations.

2. On receiving a request from the exporting Party for determination of its regional conditions, the importing Party shall inform the exporting Party whether it has sufficient information it needs to start the assessment, while providing an opportunity to the exporting Party to provide required information. The information shared by the exporting Party shall be in accordance with paragraph 3 of Article 6 of the SPS Agreement. Once the importing Party determines that the information provided is sufficient, it shall initiate an assessment without undue delay from such determination.

³ For India, 'Regulated Pest' shall mean 'Quarantine Pest'.

3. The importing Party shall assess the information received from the exporting Party within a reasonable period of time after the date of receipt of the information. Any audit the importing Party may request shall be carried out in accordance with Article 8 (Audits) and be initiated within 90 days after the date of receipt of the information, unless otherwise agreed between the Parties.
4. The importing Party shall base its own determination of the plant pest or animal disease status of the exporting Party on the evidence provided by the exporting Party in accordance with applicable international standards, guidelines and recommendations. The importing Party shall take into account any relevant information and previous experience with the authorities of the exporting Party.
5. If the importing Party decides not to recognise the regional conditions of the exporting Party, it shall provide the exporting Party with the rationale for its determination and, to the extent practicable, indicate the required conditions for which the process under this article may be reinitiated within a reasonable period of time from the receipt of such information. Upon request, the importing Party shall hold consultations with the exporting Party, within a reasonable period of time from receipt of the request.
6. If there are circumstances that result in the importing Party modifying or revoking a decision recognising the regional conditions of the exporting Party, the Parties shall cooperate to assess whether the determination can be reinstated.

Article 5.12

Technical consultations

1. If a Party has significant concerns regarding human, animal, or plant life or health, with respect to an SPS measure proposed or implemented by the other Party, it may request technical consultations with the other Party, through the contact points established under this chapter.
2. The requested Party shall respond to such a request within 30 days after the date of delivery of the request.

3. During technical consultations, each Party shall make every effort to provide the necessary information to address these concerns, and to reach a mutually acceptable solution that effectively manages any sanitary or phytosanitary risk and avoids a disruption in trade.
4. Where the Parties have already established other mechanisms than those referred to in this Article to address the concerns, they shall make use of them to the extent possible in order to avoid unnecessary duplication.
5. Each Party shall seek to resolve any concerns with respect to sanitary and phytosanitary measures of the other Party referred to in paragraph 1 through technical consultations pursuant to this Article prior to initiating dispute settlement proceedings under this Agreement.
6. Each Party may terminate technical consultations by notifying the other Party in writing at any time no less than 180 days after the date of receipt of the response by the other Party referred to in paragraph 2, or any other time period as agreed by the Parties.

Article 5.13

Emergency Measures

1. If a Party adopts an emergency measure that is necessary for the protection of human, animal or plant life or health, it shall:
 - (a) promptly notify the other Party of such measure; and
 - (b) allow the other Party to make comments in writing.
2. If a Party has a concern regarding an emergency measure adopted by the other Party, it may request technical consultations pursuant to Article 12 (Technical Consultations) with the other Party. The Party that adopts the emergency measure shall take into consideration any information provided by the other Party during technical consultations.

3. If a consignment is being transported between the Parties at the time of the adoption of the emergency measure, the importing Party adopting the emergency measure shall consider any information that has been provided by the exporting Party, when it makes its decision with respect to that consignment. The importing Party shall consider the most suitable and proportionate solution to avoid unnecessary disruptions to trade.

4. If a Party adopts an emergency SPS measure, it shall commence a science-based review of the measure within a reasonable period of time. The Party shall then review the need for the emergency SPS measure as required, and if it remains in place provide, on request, the justification for maintaining the emergency SPS measure. If the exporting Party considers, on the basis of scientific evidence, that an emergency measure is being maintained by the importing Party without justification, in that case, it may provide that evidence to the other Party and request the other Party to review the measure or engage in technical consultations under Article 12 (Technical Consultations).

5. Without prejudice to emergency measures, the importing Party shall not stop the importation of a good of the other Party solely for the reason that the importing Party is undertaking a review of an existing SPS measure, if the importing Party permitted importation of the good of the other Party at the time of the initiation of the review.

Article 5.14

Equivalence

1. The Parties shall strengthen cooperation on equivalence in accordance with Article 4 of the SPS Agreement while taking into account relevant decisions of the WTO SPS Committee and international standards, guidelines and recommendations, in accordance with Annex A of the SPS Agreement, *mutatis mutandis*.

2. A Party shall, upon request from the other party, enter into bilateral consultations with the aim of achieving the recognition of an individual measure, group of measures, or measures on a systems-wide basis as equivalent.

3. The Party shall, within a reasonable period of time after receipt of request from other party, initiate the consultation process of determination of equivalence and shall finalise such determination taking into account any knowledge and past experience it has in trading with the other Party.
4. The importing Party shall conclude its assessment within a reasonable period of time from the date of request and shall notify the determination of equivalence, including non-recognition of the measure as equivalent, to the exporting Party, within a reasonable period of time of conclusion of the assessment and in writing. To this effect, the importing Party shall implement the determination of equivalence within 60 days from the conclusion of assessment.
5. The consideration by the importing Party of a request from the exporting Party for recognition of the equivalence of its measures with regard to a specific product or group of products shall not be in itself a reason to disrupt or suspend ongoing trade from the exporting Party of the product or group of products in question. When an equivalence determination is made, it shall be formally recorded and applied to the trade between the Parties.
6. If a Party proposes to modify, amend, repeal or remove an SPS measure which are the subject of an equivalence arrangement between the Parties, it shall, notify the other Party and indicate its likely effect on recognition of equivalence within 30 days from such modification, amendment, repeal or removal. Following such notification, the importing Party shall continue to apply its determination of equivalence unless its appropriate level of protection is not met.
7. Compliance of a product or a group of products with SPS measures that have been accepted as equivalent to SPS measures of the other Party shall not remove the need for that product or a group of products to comply with any other relevant mandatory requirements.
8. The final determination of equivalence, and any subsequent withdrawal or suspension of equivalence, remains with the importing Party, acting in accordance with its administrative and legislative framework, taking into account international guidelines, standards, and recommendations.

Committee on Sanitary and Phytosanitary Measures

1. The SPS Committee shall include official representatives of the competent authorities of the Parties. All decisions made by the SPS Committee shall be by mutual agreement.
2. The SPS Committee shall meet in person within one year of the entry into force of this Agreement. It shall meet at least annually thereafter or as mutually determined by the Parties. It shall establish its rules of procedures at its first meeting. It shall meet in person, via teleconference, video-conference, or through other means as mutually agreed by the Parties.
3. The SPS Committee may establish ad-hoc working groups consisting of expert-level representatives of the competent authorities of the Parties which shall identify and address SPS issues arising from this Chapter.
4. The SPS Committee may address any matter related to this Chapter, including facilitating communication and strengthening cooperation between the Parties., It shall particularly have the following responsibilities and functions:
 - (a) monitoring the implementation of this Chapter;
 - (b) providing a forum to exchange information, expertise and experiences on each Party's SPS measures;
 - (c) providing a forum for the identification, prioritisation, discussion, and resolution of sanitary and phytosanitary issues
 - (d) agreeing on a written record of the discussions between the Parties on their work and decisions made by it, within a reasonable period of time.
5. The SPS Committee shall report, as needed, on its activities to the Trade Committee.

Import checks

1. The importing Party shall have the right to carry out import checks based on the SPS risks associated with imports. These checks shall be carried out without undue delay, with minimising trade disrupting effects and in a non-discriminatory manner. The Parties shall ensure that their control, inspection and approval procedures are conducted in accordance with Annex C of the SPS Agreement.
2. A Party shall make available to the other Party, to the extent possible, on request, information on the frequency of its import checks and the factors that it considers relevant for determining the SPS risks associated with imports.
3. In carrying out SPS import checks, where sampling takes place, the importing Party shall ensure that plants and plant products, animal products and other goods and their packaging are sampled in a representative manner.
4. If import checks reveal non-compliance with the relevant import conditions, the following shall apply:
 - (a) the action taken by the importing Party shall be based on an assessment of the risk involved and not be more trade-restrictive than required to achieve the importing Party's appropriate level of protection;
 - (b) the importing Party shall notify the importer or its authorised representative or the exporter's authorised representative, located in the territory of the importing Party, of the non-compliance, including the reason for the non-compliance, and shall, subject to its domestic laws and regulations, provide them with an opportunity for a review of the decision;
 - (c) the importing Party shall give the importer or its authorised representative or the exporter's authorised representative, located in the territory of the importing Party, during the review, an opportunity to provide relevant information to assist it in taking a final decision, consider that information, and take the final decision within a reasonable period of time;

- (d) the importing Party shall provide the importer or its authorised representative or the exporter's authorised representative, located in the territory of the importing Party, with the opportunity to seek a second expert opinion, including which may include secondary testing of consignments. The outcome of such second expert opinion, including secondary testing shall be considered by the importing Party in making a final determination on the acceptance or rejection of consignments, provided that this consideration shall not affect the obligation of competent authorities of the importing Party to take prompt action to eliminate or contain the risks to human, animal and plant health;
- (e) unless there is an identified risk, the importing Party shall, in accordance with its domestic administrative and legislative framework, provide the opportunity for the operator or its authorized representative to take back the consignment, where reasonably practicable; and
- (f) nothing in this Article prevents an importing Party from disposing of a consignment which is found to present risks to human, animal or plant life or health, that can, if urgent action is not taken, cause damage to human, animal or plant life or health in the importing Party's territory.

COMPETENT AUTHORITIES

SECTION 1

Competent authorities of the European Union

1. Official controls are shared between the European Commission (hereinafter referred as "Commission") and the authorities of the Member States. In this respect, the following applies:
 - (a) for exports to India, the Member States are responsible for the control of the production circumstances and requirements, including audits and issuing health certificates in relation to the adopted SPS measures and requirements;
 - (b) for imports from India, the Member States are responsible for the control of compliance of the imports with the European Union's import conditions; and
 - (c) the Commission is responsible for the overall coordination, inspection or audits of control systems and the necessary measures, including legislative action to ensure uniform application of standards and requirements of Chapter XX (Sanitary and Phytosanitary Measures).

SECTION 2

Competent authorities of India

1. Those authorities recognised by the Government of India, as responsible for developing and administering the SPS measures.