Background documents for the session on Standards and SPS at the WBI-CAREC Seminar on "Recent Developments in the Multilateral Trading System in the Agriculture Sector Vienna, 12-14 March 2012

The following documents are being made available to participants in the Seminar.

1: The role of SPS agencies

- **Document 1:** The WTO Agreement on the Application of Sanitary and Phytosanitary Measures
- **Document 2:** Summary of a WTO Member's rights and obligations under the Agreement

2: Risk-based approach to SPS management

- **Document 3:** A risk-based approach to SPS management

3: Management technique for SPS agencies

- **Document 4:** A compendium of SPS management issues
- **Document 5:** Competencies for top managers in SPS agencies
- **Document 6:** Outline of an SPS management development program

4: Market access strategy

- **Document 7:** An outline of a market access strategy based on WTO rights

5: Strategies for SPS capacity building

- **Document 8:** The concept of SPS capacity
- **Document 9:** A systematic approach to SPS capacity-building in a developing country

WBI
March 2012

Document 1:

WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)[1];

Hereby agree as follows:

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[1] In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

Article 1

General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.

2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.

3. The annexes are an integral part of this Agreement.

4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

Article 2

Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.

2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

Article 3

Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[2] Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

Article 4

Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the

[2] For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of

sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.[3]

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

Article 6

Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, *inter alia*, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or

[3] For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7

Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

Article 8

Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Article 9

Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, *inter alia*, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10

Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.

2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.

3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.

4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11

Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.

2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

Article 12

Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in

particular with respect to harmonization. The Committee shall reach its decisions by consensus.

2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.

3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.

4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.

6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.

7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, *inter alia*, to the experience gained in its implementation.

Article 13

Implementation

Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14

Final Provisions

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

ANNEX A

DEFINITIONS[4]

[4] For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

1. *Sanitary or phytosanitary measure* - Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

2. *Harmonization* - The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

3. *International standards, guidelines and recommendations*

(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

(b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

(c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and

(d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other

relevant international organizations open for membership to all Members, as identified by the Committee.

4. *Risk assessment* - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

5. *Appropriate level of sanitary or phytosanitary protection* - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

6. *Pest- or disease-free area* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area - whether within part of a country or in a geographic region which includes parts of or all of several countries -in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. *Area of low pest or disease prevalence* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

ANNEX B

TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations[5] which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.

2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into

[5] Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

(a) any sanitary or phytosanitary regulations adopted or proposed within its territory;

(b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;

(c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

(d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.

4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals[6] of the Member concerned.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

(a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

(b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the

[6] When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

(c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;

(d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

(a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);

(b) provides, upon request, copies of the regulation to other Members;

(c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

7. Notifications to the Secretariat shall be in English, French or Spanish.

8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.

9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:

(a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or

(b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

ANNEX C

CONTROL, INSPECTION AND APPROVAL PROCEDURES[7]

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

(a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;

(b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

(c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;

(d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;

(e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;

(f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or

[7] Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.

products originating in any other Member and should be no higher than the actual cost of the service;

(g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;

(h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and

(i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

Document 2:

A WTO Member's obligations under the SPS Agreement

Scope of the Agreement:

SPS measures are defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures. In practice, the Agreement applies to actions taken by the government of a WTO Member country to ensure the safety of food and to protect animal and plant health in that country, where such actions could adversely affect the trade of other Members of the WTO.

SPS measures can include laws, regulations, decrees by Ministers, standards[8], official requirements for inspection, certification, sampling, testing, and so forth.

Basic right:

A WTO Member has the right to take any measure that is necessary to protect human, animal or plant life or health provided that its measures are otherwise consistent with the provisions of the Agreement.

A Member can decide what level of protection against SPS risks it wants to maintain, but in making that decision it should take into account the objective of minimising negative effects on trade.

Basic obligations:

A Member's SPS measures cannot be more strict than is necessary to achieve sufficient protection of human, animal or plant life or health.

A Member's SPS measures must be based on scientific principles.

A Member's SPS measures cannot be maintained without sufficient scientific evidence, unless they are being implemented on a provisional basis while the necessary scientific evidence is being gathered and assessed.

A Member's SPS measures cannot favour domestically-produced goods by comparison with similar[9] imported goods (so-called "national treatment"); nor can they favour goods imported from one country by comparison with similar goods imported from another country.

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[8] Under the SPS Agreement a ***standard*** is a norm intended for mandatory application (such as a pesticide residue limit in food); under the TBT Agreement a standard is a norm that is intended for voluntary use by industry (such as a technical specification for recording video material on to a replayable disc).

[9] In this context, "similar" means taking into account the degree of sanitary or phytosanitary risk. associated with goods from different sources.

Use of international norms[10]**:**

Where relevant standards, guidelines and recommendations made by the Codex Alimentarius Commission, the World Organisation for Animal Health (OIE), and the organisations that operate within the framework of the International Plant Protection Convention are available, a Member must base its SPS measures on these international norms except where the international norms are not strict enough to achieve the appropriate level of protection or there is a scientific justification for not using the international norm.

A Member's measures that are based on international norms are consistent with the SPS Agreement.

Measures not based on international norms:

If there is no relevant international norm, or one is available but not strict enough to achieve a Member's appropriate level of protection, the SPS measure of a Member must be based on an appropriate risk assessment. The risk assessment must take into account risk assessment techniques developed by the relevant international organisations, which include Codex, OIE and IPPC.

When selecting the SPS measure that will reduce the assessed risk to an acceptably low level (that is, will achieve a Member's appropriate level of protection), a Member should maintain a consistent approach to risk management. A higher level of risk should not be accepted in one instance, by comparison with other situations, if the result would be discrimination against one of more trading partners or a disguised restriction on international trade.

There may be various methods by which SPS measures can reduce an assessed risk to an acceptably low level. A Member must choose the SPS measures that achieve its appropriate level of protection with the least negative effect on trade from other WTO Members.

Measures can be implemented without a prior risk assessment if there is not enough scientific information available. However a Member must take into account the information that is available when it establishes the provisional measure, and a Member must seek the information that is needed for a proper risk assessment and carry out that assessment within a reasonable period of time.

Equivalence:

Another WTO Member that wants to export a product to a Member can propose that SPS measures that are different from the ones specified by the importing country be used by the exporting Member to manage risk. The importing Member country must accept such a proposal if the other Member can show that the measures it proposes to

[10] ***International norms*** are the standards, recommendations and guidelines made by certain international standard-setting bodies.

use will be just as effective in managing risk as the measures specified by the importing country.

If a Member is making a claim of equivalence in respect of its exports, it must give the importing country reasonable access to the territory of the exporter for inspection, testing and other procedures necessary to verify the exporting country's claim.

Adaptation to regional circumstances:

When it is considering the risk associated with import of a particular product from another Member, a Member must take into account that the other country may be free of a pest or disease of concern to it, or that there are areas of the other country that are free of the pest or disease, or that a pest or disease may be present but only at low prevalence. Similarly a Member's assessment of risk and the SPS measures it applies should take into account the prevalence of pests and diseases within its own borders.

Control, inspection and approval procedures:

If a Member uses control, inspection and approval procedures to ensure that its SPS requirements are being met, these procedures must be reasonable, prompt, non-discriminatory, and transparent. Any fees imposed must be applied in a non-discriminatory way and must be no higher than the actual cost of the procedure. There should be a procedure to review complaints concerning the operation of control, inspection and approval procedures.

Transparency:

A Member must nominate and maintain a single enquiry point to answer the questions of other Members and provide relevant documents regarding SPS measures and related matters.

A Member must nominate and maintain a single national notification authority to implement specified notification procedures for its measures that are not based on a relevant international norm and which may have a significant affect on the trade of other Members. In particular, proposed new measures must be notified to other Members in advance, and their comments must be taken into account.

Provincial and local governments:

The national government of a Member is responsible to ensure that its provincial and local governments comply with the provisions of the SPS Agreement.

Other obligations:

A Member must participate fully (so far as its resources allow) in the work of the Codex Alimentarius Commission, the OIE and the IPPC standard-setting processes.

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Document 3:

Risk-based approach to SPS management

Risk-based measures and the SPS Agreement:

1. Developing countries that are Members of the WTO often indicate that they find the requirement in Article 5 of the SPS Agreement concerning risk assessment to be somewhat intimidating.[11] They say that they lack both the data and the expertise needed for proper risk analyses. (Even some developed countries find the risk assessment obligation to be onerous.) Accordingly developing countries often identify capacity-building in the field of risk assessment capability as a priority target for technical assistance. Donors are also inclined to direct resources towards strengthening risk analysis capacity in beneficiary countries because to do so supports implementation of WTO obligations and offers the hope that developed country exports will meet less arbitrary SPS requirements when seeking entry to developing countries.

2. However, it is not essential for a country to be able to perform detailed risk assessments to a standard that will withstand close scrutiny. Firstly, the SPS Agreement allows WTO Members to introduce and maintain SPS measures on a provisional basis pending risk assessment.[12] Second, measures that are not based on a risk assessment are unlikely to be challenged by another WTO Member unless they significantly restrict trade and appear to do so arbitrarily. In fact, most if not all WTO Members probably maintain a number of measures that do not have a basis in risk assessment, and they are likely to continue to do so indefinitely. Third, even a substantial investment in training or risk assessors over a long period will not necessarily result in a cadre of risk assessment staff ready and available to commence work on command. The work can be highly technical but it also requires well developed professional judgment. When staff *are* adequately trained, they may elect to move to other jobs. And in the event that a risk assessment is commissioned, the data needed to allow a risk assessment to be carried out are often not available.

Risk-based SPS management:

3. On the other hand, SPS agencies in developing countries must extract maximum value from the very limited resources available to them by ensuring that resources are allocated to reduce aggregate risk as much as possible. Therefore the highest priority (not necessarily the most resources) must go to addressing the highest risks. So, for example, certain imported foods - perhaps uncooked meat and seafood -

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[11] Article 5.1 says that measures that are not based on an international standard, guideline or recommendation must be based on a risk assessment appropriate to the circumstances.

[12] Article 5.7 says that where necessary scientific information is not available to allow a risk assessment to be carried out, measures may be applied provisionally on the basis of available evidence; but the necessary information must be sought and an appropriate risk assessment must be carried out within a reasonable period of time.

will present higher risks than imported biscuits and therefore should receive more intensive inspection and testing. But domestically produced meat, and even fresh fruit and vegetables, may present higher risks to human health than any imported products.

4. These considerations suggest that in the short to medium term government support and technical assistance for developing risk assessment capability should be directed more at establishing a robust capacity for evaluating everyday risks and facilitating resource allocation decisions rather than equipping agencies to perform sophisticated import risk analyses of the kind carried out by developed countries.

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Document 4:

A compendium of SPS management issues

- **Structuring SPS regulatory agencies**
  - optimizing administrative arrangements to achieve SPS objectives
  - centralization versus regionalization
  - effective cooperation with related agencies

- **Regulatory strategies**
  - command-and-control regulation
  - regulatory partnership and co-regulation
  - use of quality assurance systems, HACCP, etc
  - the appropriate level of protection

- **Management development**
  - modelling executive leadership in a regulatory organisation
  - coaching, mentoring and other management development techniques
  - measuring management performance
  - staff feedback mechanisms
  - business concepts and regulatory agencies of government
  - integrating science and operational management

- **Business planning**
  - strategic planning
  - annual and triennial business planning
  - needs assessment and estimation of resource requirements
  - prioritization
  - performance indicators, milestones and reporting obligations
  - optimizing international technical assistance

- **Business risk management**
  - biosecurity risks and business risks
  - identifying and evaluating business risks
  - strategies and techniques for control of business risks
  - biosecurity/food safety breakdowns and crisis management
  - management information systems

- **Financial management**
  - cost recovery policy
  - mechanisms for cost recovery
  - financial reporting systems

- **Performance measurement and evaluation**
  - biosecurity/food safety system testing by trial emergency exercises
  - the role of external evaluation
  - evaluation of individual staff members' performance

- **Human resource development**
  - recruitment and promotion protocols
  - defining, building, and retaining technical skills
  - relevant training tools and resources
  - individual development plans
  - staff consultation and industrial relations
  - remuneration principles

- **Integrity**
  - code of ethics for agency staff
  - incentive structures
  - internal audit and investigation
  - building a reputation for integrity

- **Compliance and enforcement**
  - investigation protocols
  - ensuring the integrity of compliance staff
  - penalty and incentive structures

- **Legal framework**
  - principles of the legal framework (clarity of purpose, comprehensiveness, minimization of overlap between agencies, primary versus subordinate legislation, etc)
  - optimising trade-offs (e.g. administrative flexibility versus risks of inconsistency, uncertainty and scope for corruption)

- **Communications**
  - communications policy
  - media skills development
  - media management in emergency situations
  - identifying stakeholders and their role
  - mechanisms for communicating with stakeholders

- **Record keeping and management**
  - policy on record-keeping

- **Information technology applications**
  - recording border interceptions, and other specialised applications
  - electronic certification of SPS requirements (export and import)

- **Government relations**
  - informing and advising ministers on SPS issues
  - elucidating government policy directions

- **International relations**
  - meeting WTO obligations
  - participation in WTO SPS activities

- dealing with counterpart agencies of trading partner countries
- participation in international standard-setting organisations
- bilateral liaison and negotiation on SPS issues

- **Technical perspectives on management of SPS organisations**
  - animal health perspective
  - plant health perspective
  - food safety perspective

- **Export enhancement strategies**
  - development of technical market access strategy
  - stakeholder input

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Document 5

Competencies for top managers of SPS agencies

1. Some of the tasks of managers of SPS agencies are indistinguishable from those of managers in other areas of government; some are characteristic of regulatory organisations; and some are specific to organisations that are responsible for biosecurity and food safety. Top managers need not be technical experts, but they do need to be able to understand major technical issues and to make appropriate decisions on matters involving technical considerations. It is also characteristic of SPS agencies that the normal course of program implementation is intermittently interrupted by crises of one kind or another: an incursion of a new pest or disease with the potential to cause significant damage to crops or livestock; rejection of an export consignment on arrival in an importing country by reason of contamination with a chemical residue or the presence of a quarantine pest; an outbreak of life-threatening food-borne disease; and so forth. Competent, preferably experienced, and well-prepared management is a crucial element in the successful handling of such incidents, the cost of which may otherwise be extreme.

2. The top management cadre of a government agency that has SPS responsibilities may be defined as the chief executive officer, his/her deputies and the heads of functional divisions. The competencies needed for their positions are generally those of senior managers in any substantial public sector organisation, but there are differences of emphasis that reflect the special circumstances of the SPS control function. Examples include:

* Top managers should be able to design and implement resource allocation and financial management systems based on their own analysis of business risks and of SPS risks.
* Top managers should be capable of organising, motivating and managing teams of technical specialists in the relevant disciplines (e.g. veterinarians, plant pathologists, entomologists, epidemiologists) to achieve agency objectives.
* Top managers should be capable of exercising judgment on technical and administrative issues, including under the pressure of emergency situations such as the incursion of an exotic pest or disease or a food safety breakdown, making appropriate policy decisions and initiating consequential actions.
* Top managers should have communication skills commensurate with their responsibilities to interact on a day-to-day basis with Ministers, staff, stakeholders, counterparts in other organisations and in other countries, media, etc., as well as to effectively handle communication strategies and actions in SPS crisis situations.
* Top managers should be capable of designing and implementing merit-based and performance-based systems of recruitment, promotion and remuneration within their organisations, to the extent allowed by whole-of-government rules and guidelines.

* Top managers must model personal integrity and ethical behaviour appropriate to a regulatory environment; ensure that agency staff are aware of their obligations to conform with professional standards and ethical requirements; and institute systems to detect and deter illegal or improper actions by staff.

3. There are many different approaches that may be followed to develop these and other competencies in top managers, including formal in-service training courses, peer seminars on management topics, individual coaching, mentoring, definition and monitoring of personal performance and improvement goals, team building workshops, assessment by superiors and subordinates, study assignments in counterpart agencies, job rotations and so on. Other initiatives may include the establishment of selection criteria and procedures relevant to recruiting or promoting staff who are best fitted to be SPS managers.

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Document 6:

Outline of an SPS management development program

Background:

1. For both governments and the private sector, systems for the development and/or implementation of technical regulations and sanitary and phytosanitary measures are typically of fundamental importance to the successful operation of the responsible institutions and business enterprises. At the same time the management of these systems often presents complex, multi-dimensional challenges. Skilled and effective managers working with appropriate management tools to organise and direct resources to efficiently achieve defined goals are vital components of national SPS capacity. Managers must identify goals and objectives, assess risks carefully, design programmes to achieve the required outcomes, gather and utilize personnel and financial resources, monitor progress, communicate with stakeholders and make improvements progressively. Preparation for and management of emergency situations requires management abilities of a very high order.

2. Managers in the SPS field must be able to work effectively in a technical environment that at the same time involves international trade (and therefore also international political) considerations. A cooperative relationship with counterparts in trading-partner countries, and especially countries with whom there are common borders, is essential. As regulators, public sector managers must establish and maintain appropriate working relationships with private sector enterprises and their representative organizations.

3. Despite the crucial nature of the management component of national SPS capacity, there is very little history of this topic being directly addressed in capacity-building initiatives. Countries rarely if ever ask for technical assistance in this area, and for donors, the design and successful implementation of management strengthening initiatives may seem more complex and diffuse than support for, say, the construction and equipping of laboratories and training technical staff that are the most common components of SPS technical assistance projects.

4. The development of a cadre of effective managers in the institutions responsible for the administration of SPS regimes depends upon a number of elements, including:

- an understanding at the most senior levels of government of the crucial role of managers in developing and operating effective SPS institutions
- availability of suitably qualified candidates, whether already in management positions or ready for recruitment
    - generally candidates will have relevant technical qualifications, or demonstrated ability to understand technical issues
- provision of targeted (on the job?) training in management skills and the use of management tools

- opportunity for candidate managers to progressively gain relevant experience and develop sound judgment
- selection of appropriately trained and experienced managers to fill positions that will fully utilise their expertise
- allowing people in management positions to manage (ie, delegation of authority).

5. Suboptimal management may occur for innumerable reasons. Significant impediments to development of good management may include:

- recent or current instability in the organisation of public administration caused by civil disturbance, frequent change of government, etc.
- confusion of roles between managers and ministers (failure to allow managers to manage)
- lack of scrutiny and evaluation of management performance
- lack of accountability for poor management performance
- failure to appoint and reward managers on the basis of merit and performance
- lack of resources for necessary training
- lack of conventional management tools adapted to SPS needs
- barriers to inter-agency cooperation
- diversion of management attention to exploiting opportunities for corruption.

Goals of an SPS management initiative:

6. The main goals of an initiative, supported by government and donors, on management of SPS matters would include:

- identification of key tools and skills applicable to management of the SPS regime
- enhancement of the knowledge and skills of SPS managers
- identification of regionally-based initiatives for information-sharing, emergency management, resource-sharing and mutually-reinforcing alignment of programme activities
- building mutual confidence in the capabilities and effectiveness of counterpart managers and agencies in A Member
- sharing experience in SPS management in areas such as strategic planning, risk assessment, governance, anti-corruption initiatives, cooperation with the private sector, co-regulation, cost-sharing and cost recovery, etc.

Outline:

7. For the purposes of this report, the working title of the hypothetical project is the Initiative on SPS Management (ISM).

8. The programme would be conducted in a series of phases over a three year span. Initial phases would be more about scoping and planning and later phases would be more about skill and knowledge acquisition.

- The programme would be targeted at a relatively small number of participants (up to 20 individuals, say) at the level of agency head/deputy agency head/discipline leader[13]. The number of actual participants might be increased with progression from the initial to the later phases.
- The primary modality in each phase would be for expert facilitators to draw contributions on specific topics from the participants. These contributions would then be processed collectively in a workshop or seminar setting. The contributions by individuals would be prepared in advance of each workshop, and would require quality approval before attendance is finalized.
- There would also be a component at each workshop comprising topic presentations by the experts, for example on approaches to performance measurement in regulatory agencies, or models for obtaining productive input from stakeholders. Typically a presentation by experts on a topic at one workshop would lead to individual inter-sessional tasks for participants before the subsequent workshop.
- There would be a strong orientation towards the identification and development of common approaches to management issues.
- Specific management topics, as adapted to the management of the SPS regulatory regime, could include:
  - agency governance
  - programme structure
  - management by objective
  - performance measurement
  - merit-based recruitment and promotion
  - human resource planning
  - business risk analysis and management
  - accountability and reporting
  - stakeholder liaison
  - financial planning, service pricing and cost recovery
  - ethics and integrity
- There would be a component in each programme dealing in detail with the relevant provisions of the SPS agreement and other multilateral aspects. Examination of the WTO Agreement would consider not only the issues surrounding compliance with obligations but also the use of WTO rights under the agreement to improve market access for exports.
- Incentives to participants to engage fully and energetically in the successive phases could be provided in the third year by the prospect of study tours or short-term attachments with like agencies in developed

[13] "Discipline leader" would for example include, in the case of SPS, the chief veterinary officer or plant protection officer and, in the case of TBT, the head of the standards agency or national director of technical laboratories.

countries for selected individuals, subject to a high standard of performance in the workshops, and achievement of milestones.

- Workshops would include site visits where directly relevant to the curriculum.

Expected outcomes:

9. Consistent with the goals outlined in para. 31 above, the ISM programme should:

- significantly enhance participants' understanding of the management task inherent in the SPS area of technical regulation;
- equip participants with a good working knowledge of relevant, contemporary management tools and techniques;
- enable participants to formulate viable, competent management plans for their organisations that would utilize these tools and techniques;
- strengthen mutual knowledge and trust between counterpart managers and organisations;
- develop outlines for cooperative initiatives between the relevant government agencies;
- through study tours, establish relationships with the SPS authorities of other countries, with key individuals in major trading partner countries, and with counterparts in developed countries that could be the basis of further mentoring.

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Document 7:

Outline of a market access strategy based on WTO rights

1. The implicit right of every WTO Member is to have its fellow Members meet their obligations under the covered agreements. In the case of SPS and TBT matters, a Member can evaluate the technical barriers faced by its products in export markets against the rules set out in the relevant agreements, and then decide upon the most appropriate strategy for forcing the removal or reduction of barriers that are apparently arbitrary or unjustifiable. For countries that export many products to many markets, there are likely to be many such barriers, and they should be addressed in order of priority. Therefore it is desirable to develop a coherent strategy for progressively reducing barriers and enhancing what can be termed "technical market access". A national Technical Market Access Strategy is a means of using available scientific and diplomatic resources as effectively as possible to enhance export trade. The actions available to a WTO Member to seek reduction of technical barriers to trade range from private bilateral consultations to ventilating specific trade problems in either the SPS or TBT Committee or formal (expensive and protracted) WTO dispute settlement proceedings.

- Private voluntary standards

2. Many developing countries have recently begun to express concern about the costs and the increased difficulty of access to developed country markets for their agricultural produce associated with the imposition of strict conditions by purchasers, in particular very large supermarket chains in the importing countries. These conditions may deal with production methods as well as actual product attributes, and may cover not only food safety (traditionally the function of government authorities in importing countries) but also food quality, animal feedstuffs, animal welfare, environmental protection, labour practices and occupational health and safety. Even in relation to food safety, where regulatory authorities in the importing countries could be expected to insist that official requirements are fully adequate to protect consumers' health, standards imposed by buyers may be yet more stringent. For their part, private interests in the importing countries assert that their private voluntary standards (PVS) are necessary to ensure compliance with official requirements, to complement or reinforce official import controls, to respond to consumer concerns, and (most important of all) to protect the value of private brands and retailers' reputations.

3. In reaction to the trend towards increasingly strict and comprehensive private voluntary standards over the past decade, developing countries have turned to the World Trade Organisation to explore whether relief may be available under the provisions of the relevant covered agreements, in particular the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the Agreement on Technical Barriers to Trade (the TBT Agreement). Representatives of very large supermarket chains acknowledge that there is a business risk associated

with the negative reaction of developing countries to their private voluntary standards.

4. Ideally, a Technical Market Access Strategy of the kind described in para.1 above would be designed so that it took the issues arising from the spread of private voluntary standards into account.

Document 8:

The concept of SPS capacity

1. ***"SPS capacity"*** ("SPS infrastructure" has a similar meaning) can be understood to mean all of the laws, systems, programmes, activities and associated resources that are organized and used by government agencies to ensure food safety and preserve animal and plant health by means of SPS measures. The SPS capacity of a country can be defined as its ability to maintain and enhance human, animal and plant life and health by identifying, evaluating and controlling pest and disease risks and ensuring the safety of the food supply by means of sanitary and phytosanitary measures.

2. The main components of SPS capacity include:

- national policies, goals, strategies and plans for food safety and biosecurity;
- legislation
  - both primary legislation like food laws and laws concerning animal and plant health, and subordinate legislation like regulations made under these laws, ministerial orders and directives, and so forth
- institutions
  - the government agencies that have mandates to deal with SPS matters, their organisational structure, their management, and the mechanisms for inter-agency coordination
- standards
  - food standards and related requirements to ensure food safety, and requirements that are applied by government concerning animal and plant health
- risk analysis
  - the ability to identify and evaluate sanitary/phytosanitary risks by applying appropriate methodology to objective data
- programmes
  - written plans, operating procedures, identified goals, objectives, milestones and performance measures, intended to achieve SPS-related outcomes
- trained staff
  - staff with appropriate qualifications and experience to design, implement and manage SPS programmes
  - staff development programmes
- systems and methods for inspection and certification, such as:
  - auditing of Hazard Analysis and Critical Control Point (HACCP) systems used by industry to meet official requirements

- food testing equipment
- animal/plant field testing equipment
- vehicles

- monitoring and surveillance
  - food safety monitoring, by means such as reporting by physicians and hospitals of cases of food-borne disease;
  - active and passive animal and plant health surveillance

- laboratory capacity
  - buildings, equipment and consumables (test kits, laboratory reagents, filter papers, etc.)
  - trained personnel
  - national/international accreditation

- quarantine facilities/treatment
  - border facilities e.g. to hold animals
  - analytical capacity at entry points
  - plant quarantine station
  - fumigation facility

- auditing and compliance
  - regular programme auditing
  - investigation of breaches of official requirements
  - support for legal action against non-compliance
  - measures to ensure honesty and integrity among staff members

- research capability
  - capacity to conduct research in support of programme activities and programme re-design

- funding mechanisms
  - budget provisions
  - cost recovery through fee-for-service

- stakeholder consultation mechanism
  - identification of interested parties, e.g. in the private sector
  - consultation via circulation of information for comment, committee meetings, etc

- engagement with relevant international organizations
  - enquiry and notification points established, as required by the SPS Agreement
  - participation in the international standard-setting organisations

- information systems
  - mechanisms and facilities for gathering, processing and storing information needed for risk analysis, programme improvement, and as the basis of reports to the Minister(s), government and private sector stakeholders

- awareness building.

3.Other elements could be added, but the above provides a broad outline.

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Document 9:

A systematic approach to SPS capacity-building in a developing country

Developing a national action plan:

1. The optimal approach to matching demand for and supply of technical assistance and budgetary resources for SPS capacity-building is the preparation of a national program comprised of prioritised individual projects. Key steps in the process for the formulation of a national plan include:

- understanding and recognition of the essential relationship between SPS (biosecurity and food safety) capacity and national economic, social and environmental goals;
- clear identification of the roles and responsibilities of relevant Ministers and agencies of government, and of coordination mechanisms needed both to liaise with the donor community and to deal with internal issues that may arise;
- recognition of the interest and role of the private sector in SPS capacity-building, including the strengthening of biosecurity and food safety capability of individual enterprises;
- identification at the national level of broad strategies and priorities in relation to biosecurity and food safety;
- using available methodologies and expert advice, detailed needs assessment for capacity-building of SPS systems in each of the areas of animal health, plant health and food safety, having regard to both external threats and export[14] possibilities, and to the needs of both the public and private sectors;
- identification of priority initiatives for funding by government from its own resources and by donors, taking into account complementarities, sequencing, sustainability and risks of non-performance;
- compilation of a national action plan for SPS capacity-building in both the public and private sectors, including contingent relationships between donor-funded projects and local initiatives, and between earlier and later projects;
- design of individual projects to achieve increments in capacity, with associated milestones and performance measures;
- consideration of the action plan, either individually or (for preference) collectively, by donors who enter into commitments to provide resources for implementation over an appropriate time period and with full transparency;
- the government and the private sector make complementary commitments;

[14] Exports may include services such as in-bound international tourism, which is influenced by, inter alia, a country's reputation for safe food, its environmental amenity, and other factors that depend in part on SPS capacity.

- regular progress reporting by all parties;
- regular review and up-dating of the action plan to take account of progress made and new developments.

2. The central feature of this presentation of good practice is the compilation and implementation of a ***national action plan for SPS capacity-building***. It is not implied that this plan should incorporate every initiative that increases SPS capacity; there will be, for example, other initiatives that are taken ad hoc in response to immediate needs. But the plan should be sufficiently comprehensive to serve as the main framework for bringing coherence and focus to capacity-building. The plan should also be flexible in response to unanticipated events, such as changes in national political priorities, or an uncoordinated intervention by a donor.

3. Various criticisms might be offered concerning this schema for good practice in SPS capacity-building. One is that it presents an idealised solution that is unconstrained by the realities of poor governance, the limitations of needs assessment methodologies, and the inflexibilities imposed by budget cycles and conflicting priorities in donor countries. These are indeed major concerns, as are a range of other factors. Plainly any model for rational provision of support for capacity-building must be adapted to the circumstances in which it is to be employed. The level of corruption in government and the weakness of the private sector, for example, should influence capacity planning just as the existence of common borders with other countries is an important consideration in designing biosecurity strategies.

4. In the field of SPS capacity-building, the history of technical assistance seems to indicate that a piecemeal approach has typically been followed much more often than a systematic one, as might be expected where there are multiple donors each with their own agenda and where beneficiaries are inclined to put forward requests that are more likely to receive funding support and/or that accord more with narrow institutional (or even private) interests.

5. The action planning approach should have at least these advantages over a piecemeal approach to capacity-building:

- The comprehensive reviewing of all capacity gaps should ensure that all of the most important things that need to be done are brought forward for consideration, rather than only those projects that are nominated by the beneficiary government or that catch the eye of a donor.
- The same comprehensive needs assessment allows SPS capacity to be correctly viewed as the combination of elements working together as systems, so that technical complementarities are taken into account.
- Action planning is driven by demand, in the form of risk reduction or support for export activities, so that there should be less potential for investment in “white elephants” - grandiose or unnecessary projects that are unrelated to priority needs.
- Providing an action plan as a framework within which donors can cooperate should reduce the probability of overlapping or duplicative effort.

- An SPS capacity-building action plan can give this area of policy a higher profile in domestic budget discussions and when donors are allocating available funds, and its coherence should reinforce donors' confidence that proposals for use of their funds have been well thought out.
- Development of an action plan can help to highlight the need for clarification and reform of SPS-related institutional and legislative arrangements within the beneficiary country.
- The comprehensive approach complements actions to prepare for accession to the WTO and to implement post-accession commitments in the SPS field.

Coordinating development of the plan:

6. A national action plan can only be developed as the joint endeavour of donors, relevant national authorities and (desirably) representatives of the private sector. If food safety, plant health and animal health issues are all to be covered, a significant number of organisations need to be involved. Lead agencies and donors would have to be designated, and an appropriate consultative and deliberative framework set up to prepare detailed documentation for consideration and approval at the political level in the beneficiary country. Not merely political endorsement but strong political commitment will be required in order to drive the plan into implementation.

Regional approaches:

7. Some SPS programs, and their associated needs for capacity-building, can only work effectively on a regional basis. Bringing Foot and Mouth Disease or HPAI under control in any country in Central Asia, for example, will be difficult if not impossible if neighbouring countries do not also have the diseases under control. When countries in a region agree that a regional control program should be pursued, this priority should be reflected in national action plans for SPS capacity-building if and when they are drawn up.

Cost:

8. The cost of developing a national action plan for SPS capacity-building might be in the vicinity of $150,000. Costs will vary for many reasons, including the availability of local expertise in SPS issues, the existence of relevant prior studies and useful databases, the comprehensiveness of the needs assessment that is carried out, and the extent of consultation with stakeholders. Possibly the cost might be as low as $100,000 or as high as $200,000.

Capacity-building without a plan:

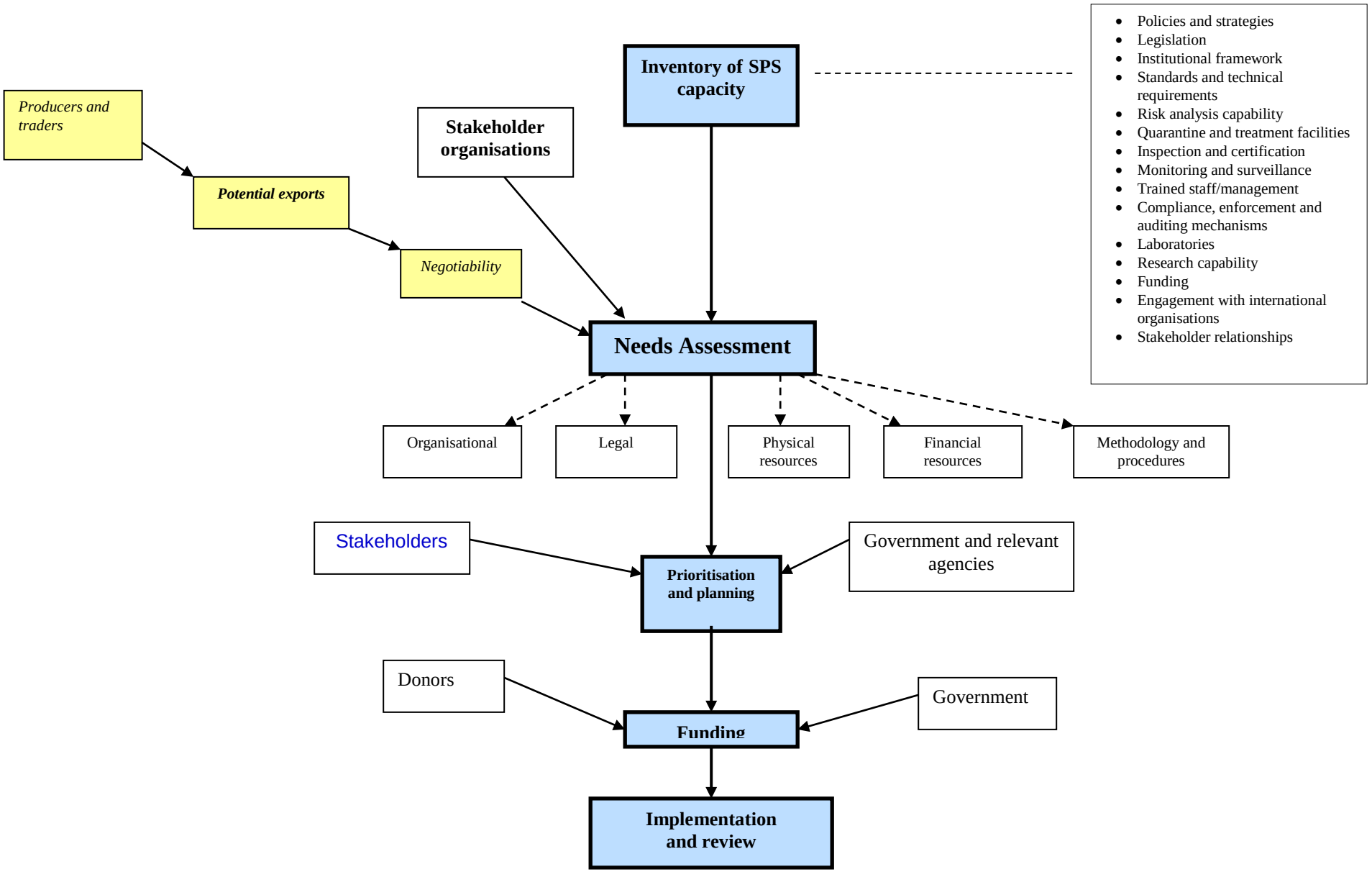
9. Where a comprehensive action plan is not available, matters must proceed piecemeal as they have done in the past. Absent a comprehensive plan, how can donors and the government improve the *quality* (relevance, cost-effectiveness,

sustainability, etc.) of the programs and projects that they agree should be implemented in the SPS field?

10. One approach might be to promote more careful analysis before projects are proposed for funding. On the evidence of past SPS capacity-building initiatives in many countries, there are some obvious targets: bids for support for laboratory development, and risk analysis training, typically need more incisive scrutiny than they apparently receive. SPS control is achieved by *systems*: that is, not by laboratory capacity *per se* but by laboratory analysis as a component of a risk-based monitoring and surveillance program delivered by trained inspectors operating under relevant legislation and detailed administrative instructions.

11. Another initiative might be to increase the availability of on-demand SPS expertise to assist in, inter alia, project selection and design. Such a proposal would respond to the very evident need for continuity of availability of expert advice, to deal with matters ranging from the trivial ("where can I find a standard for mineral water that we might adopt?") to the complex ("would it be possible for us to export chicken meat to the European Community, and if so what steps should we take?")

SPS Capacity-building for Developing Countries



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