Sanitary and Phytosanitary (SPS) Annex VIII to the SADC Protocol on Trade

Approved by the SADC Committee of Ministers of Trade on 17 July, 2014, Gaborone, Botswana
ANNEX VIII

CONCERNING SANITARY AND PHYTOSANITARY MEASURES
(Human, Animal and Plant Life or Health)

PREAMBLE

The SADC Member States,

*Emphasising* the importance of human, animal and plant life or health in the SADC region and specifically their importance in relation to trade;

*Desiring* the protection of human, animal and plant life or health including protection of the environment through the employment of environmentally safe and sustainable farm production and agro-industrial methods;

*Recognising* the importance of establishing and maintaining confidence in the sanitary and phytosanitary measures of SADC Member States among agencies that apply measures to protect human or animal or plant life or health, businesses, and consumers in SADC Member States and in existing and potential third party markets;

*Recognising* the urgency of mutual recognition of the equivalence of sanitary or phytosanitary measures across the Member States in order to improve regional trade in foods, beverages, animals, animal products, plants, plant products and other regulated articles for the economic benefits of the citizens of the SADC region and to expand external trade;

*Recalling* the provision in Article 16 of the SADC Protocol on Trade which requires Member States to base their sanitary or phytosanitary measures on international standards, guidelines and recommendations and that they work towards mutual recognition of the equivalence of specific sanitary and phytosanitary measures, in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures;

*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;

HEREBY AGREE as follows:
ARTICLE 1
Terms and Definitions

For the purposes of this Annex, the following definitions shall apply:

1. “Appropriate level of sanitary or phytosanitary protection” or “Acceptable level of risk” - The level of protection deemed appropriate by the Member State establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

2. “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.

3. “Codex Alimentarius Commission (Codex)” - See “International Standards” in this list of definitions.

4. “Food Safety” - Assurance that food will not cause harm to the consumer when it is prepared and eaten according to its intended use.

5. “Harmonisation” - The establishment, recognition and application of common sanitary and phytosanitary measures by different Member States.


8. “International standards, guidelines, and recommendations”
   a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission (Codex) 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 OIE;
c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the IPPC in cooperation with regional organizations operating within the framework of the IPPC; 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 Member States, as identified by the WTO SPS Committee.

9. *(Pest)* Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

10. *(Disease)* means the clinical and/or pathological manifestation of infection, which means the entry and development or multiplication of an infectious agent in the body of humans or animals (based on the 2011 OIE Terrestrial Animal Health Code, but entirely applicable to aquatic animal diseases).

11. *(Pesticide)* Any substance, mixture of substances or any biological agent intended for preventing, destroying or controlling any pest; to act as growth regulator, defoliants, desiccant, thinning agent on crops; or to prevent the fall of buds, flowers and fruits from crops.

12. *(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. Such an identified area may surround, be surrounded, 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.

13. *(Phytosanitary measure)* See *(Sanitary or phytosanitary measure)* in this list of definitions.

14. *(Plant Genetic Resources)* Plants or collection of plants bearing certain desirable traits and used as starting material for breeding or seed multiplication programs.

15. *(Regulated Article)* Any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved.

16. *(Risk assessment)* The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member State 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.

17. “Sanitary or phytosanitary measure” Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member State 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 State 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 State 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 State 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.


**ARTICLE 2**

**Objectives**

1. The objectives of this Annex are:

   a) to facilitate the protection of human, animal or plant life or health in the territory of the Member States;

   b) to enhance the Member States’ implementation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures;

   c) to enhance technical capacity to implement and monitor SPS measures including promoting greater use of international standards and other matters concerning SPS;
d) to provide a regional forum for addressing sanitary and phytosanitary matters; and

e) to provide a regional forum for resolving trade related sanitary or phytosanitary issues.

ARTICLE 3
Scope and Coverage

1. This annex applies to all sanitary and phytosanitary measures of a Member State that may, directly or indirectly, affect trade between the Member States.

ARTICLE 4
General Provisions

1. The appendices are an integral part of this Annex and the SADC Protocol on Trade.

2. Nothing in this Annex shall affect the rights of Member States under Article 17 of the SADC Protocol on Trade, Standards and Technical Regulations on Trade, or under the WTO Agreement on Technical Barriers to Trade and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

ARTICLE 5
Basic Rights and Obligations

1. Member States affirm their existing rights and obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

2. Nothing in this Annex shall prevent a Member State from adopting or maintaining, in accordance with its international rights and obligations any measure necessary to achieve its appropriate level of sanitary or phytosanitary protection.

ARTICLE 6
Harmonisation

1. The Member States shall, where appropriate, work towards harmonization of their respective mandatory requirements taking into account relevant international standards, guidelines or recommendations, in accordance with their international rights and obligations.
2. Member States, within the limits of their resources, shall make every effort to participate in relevant international organizations and, whenever possible, if mandated, present a common SADC position in these organizations in an effort to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to sanitary and phytosanitary measures.

ARTICLE 7
Equivalence

1. Member States shall to the extent practicable, without compromising their appropriate level of sanitary or phytosanitary protection and in accordance with guidelines developed by the WTO SPS Committee and the relevant international standard setting bodies, enter into consultations aimed at achieving bilateral or regional agreements on the recognition of equivalence of their respective sanitary or phytosanitary measures.

2. An importing Member State:

   (a) shall accept a sanitary or phytosanitary measure adopted or maintained by an exporting Member State as equivalent to its own where the exporting Member State, in cooperation with the importing Member State, provides to the importing Member State scientific evidence or other information, in accordance with risk assessment methodologies agreed on by the Members, to demonstrate objectively, that the exporting Member State’s measures achieve the importing Member State’s appropriate level of protection;

   (b) may, refuse to accept a sanitary or phytosanitary measure adopted or maintained by an exporting Member State as equivalent to its own where it has scientific basis to determine that the exporting Member State’s measures does not achieve the importing Member State’s appropriate level of protection; and

   (c) shall provide to the exporting Member State, on request, its reasons in writing for a determination made under subparagraph (b).

ARTICLE 8
Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Member States shall in accordance with their international rights and obligations ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances of the risks to human, animal and plant life or health.
2. In conducting a risk assessment and in determining the sanitary or phytosanitary measure to be applied to achieve the appropriate level of protection, each Member State shall take into account:

   a) relevant scientific evidence;
   
   b) relevant risk assessment techniques and methodologies developed by international organisations;
   
   c) relevant processes and production methods;
   
   d) relevant inspection, sampling and testing methods;
   
   e) the prevalence of relevant diseases or pests, including the existence of pest-free or disease-free areas or areas of low pest or disease prevalence;
   
   f) relevant ecological and other environmental conditions;
   
   g) relevant treatments, such as quarantines;
   
   h) relevant economic factors such as the potential damage in terms of loss of production or sales in the event of 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.

3. Notwithstanding the provisions of paragraphs 1 and 2 of this Article, where a Member State conducting a risk assessment determines that available relevant scientific evidence or other information is insufficient to complete the assessment, it may adopt a provisional sanitary or phytosanitary measure on the basis of available relevant information, including from international standardizing organizations and from sanitary or phytosanitary measures of other Member States. In such circumstances Member States 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.

4. Where an exporting Member State is able to achieve the importing Member State's appropriate level of protection through the phased application of a sanitary or phytosanitary measure, the importing Member State may, at the request of another Member State and in accordance with the provisions of this Annex, allow for such a phased application, or grant specified exceptions for limited periods from the measure, taking into account the requesting Member State's export interests.
ARTICLE 9
Adaptation to Regional Conditions, Including Pest or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Member States shall in accordance with their international rights and obligations 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.

2. Member States shall in assessing the sanitary or phytosanitary characteristics of a region, take into account, inter alia:
   a) the level of prevalence of specific diseases or pests;
   b) the existence of eradication or control programmes; and
   c) appropriate criteria or guidelines which may be developed by the relevant international organizations or by the SADC Sanitary and Phytosanitary Coordinating Committee.

3. In determining whether an area is a pest-free or disease-free area or an area of low pest or disease prevalence Member States shall inter alia, base their determination on factors such as geography, ecosystems, epidemiological surveillance and the effectiveness of sanitary or phytosanitary controls in that area.

4. Exporting Member States 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 State that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, each exporting Member State shall provide reasonable access to its territory to the importing Member State for inspection, testing and other relevant procedures.

5. Member States may, in accordance with this Annex:
   a) adopt, maintain or apply a different risk assessment procedure for a pest-free or disease-free area than for an area of low pest or disease prevalence; or
   b) make a different final determination for the disposition of a product produced in a pest-free or disease-free area than for a product produced in an area of
low pest or disease prevalence, taking into account any relevant conditions, including those relating to transportation and handling.

6. Member States shall, in adopting, maintaining or applying sanitary or phytosanitary measures relating to the introduction, establishment or spread of an animal disease or plant pest, accord a product produced in a pest-free or disease-free area in the territory of another Member State no less favorable treatment than it accords a product produced in a pest-free or disease-free area, in another country, that poses the same level of risk.

7. Member States shall where appropriate adopt and use equivalent risk assessment guidelines developed by CAC, OIE and IPPC to evaluate relevant conditions and controls in the pest-free or disease-free area and in the area surrounding that area and take into account any relevant conditions, including those relating to transportation and handling.

8. An importing Member State may upon request, pursue an agreement with an exporting Member State, on specific requirements the fulfillment of which allows a product produced in an area of low pest or disease prevalence in the territory of an exporting Member State to be imported into the territory of the importing Member State.

**ARTICLE 10**

Transparency

1. Member States shall provide all required notifications and information in accordance with Appendix A to this Annex and WTO transparency guidelines.

2. Member States shall, in notifying the World Trade Organization copy the same notification to the SADC Secretariat.

**ARTICLE 11**

Control, Inspection and Approval Procedures

1. Each Member State shall, upon the request of any other Member State, following the procedures set down from time to time by the relevant international organisations (Appendix B), give consideration with a view to accepting the relevant control, inspection and approval procedures of another Member State, provided it is satisfied that these achieve the same outcomes as its own regulatory requirements.

2. Each Member State shall upon request and in accordance with its international obligations and applicable laws, regulations and policies, review its inspection, testing, certification and other relevant import and export approval systems or procedures to ensure these are reasonable and necessary, so as to further facilitate access of traded products to its territory.
3. Member States shall where appropriate adopt guidelines set out in SADC Seed Import/Export Procedures Manual as the relevant import and export approval systems for seed.

4. Member States shall where appropriate adapt the guidelines set out in SADC Seed Import/Export Procedures Manual as the relevant import and export approval systems for all other commodities subject to sanitary or phytosanitary measures.

5. Member States shall cooperate on a product trace back system for the notification of non-compliance of imported consignments for commodities subject to sanitary or phytosanitary measures drawing on the guidelines of relevant international organizations where available.

**ARTICLE 12**

**Technical Assistance**

1. Where substantial investment is required in order for an exporting Member State to fulfil the sanitary or phytosanitary requirements of the importing Member State, the latter shall consider providing such technical assistance that will permit the exporting Member State to maintain and expand its market access opportunities for the product involved.

2. The SADC Secretariat shall in consultation with the SADC Sanitary and Phytosanitary Coordinating Committee facilitate resource mobilisation for technical assistance to enhance Member States capacity to implement and monitor sanitary and phytosanitary measures including promoting greater use of international standards.

**ARTICLE 13**

**Dispute Settlement**

The rules and procedures of Article 32 of the SADC Protocol on Trade shall apply to the settlement of disputes between Member States concerning their rights and obligations under this Annex.

**ARTICLE 14**

**Administration**

1. Member States hereby establish a SADC Sanitary and Phytosanitary Coordinating Committee comprising of two representatives of each National Committee on Sanitary and Phytosanitary Measures.
2. Not later than 60 days after the adoption of this Annex, each Member State will establish a National Committee on Sanitary and Phytosanitary Measures and appoint two representatives on the SADC Sanitary and Phytosanitary Coordinating Committee.

3. The National Committee on Sanitary and Phytosanitary Measures shall include the WTO SPS National Notification Authority and Enquiry Point(s).

4. The SADC Sanitary and Phytosanitary Coordinating Committee shall promote transparency in the area of sanitary and phytosanitary measures, including overseeing the implementation of the transparency provisions.

5. The SADC Sanitary and Phytosanitary Coordinating Committee will act as a consultative forum for promoting the objectives of this Annex and for strengthening cooperation between the regulatory agencies having responsibility for sanitary and phytosanitary measures.

6. The SADC Sanitary and Phytosanitary Coordinating Committee will report to the SADC Trade Negotiating Forum and shall have the following specific functions:

   a) To act as a forum for regional liaison with corresponding organisations for consultations and exchange of technical information relating to sanitary or phytosanitary issues;

   b) To raise awareness on SPS matters to private and public sectors in the region;

   c) To facilitate capacity building in the region for sanitary and phytosanitary matters through cooperation and collaboration with relevant organisations;

   d) To establish Technical Committees and ad hoc Working Groups as necessary on specific issues related to sanitary or phytosanitary Measures;

   e) To identify regional needs/ challenges and facilitate the development and implementation of programmes to address them;

   f) To promote the greater participation by the private sector/industry in SADC sanitary and phytosanitary related activities;

   g) To review progress and monitor the implementation of this Annex and the WTO SPS Agreements, and provide recommendations to the Committee of Ministers;

7. The SADC Sanitary and Phytosanitary Coordinating Committee shall meet as often as required, and shall reach all its decision by consensus.
ARTICLE 15
Implementation

Member States shall be fully responsible under this Annex for the implementation of all obligations set forth herein. Member States shall in particular formulate and take available measures to enforce positive mechanisms to support the implementation of the provisions of this Annex.

ARTICLE 16
Regulations

The Committee of Ministers responsible for Trade, in the Member States shall adopt regulations to facilitate the implementation of this Annex, in consultation with other relevant Ministers (Agriculture/Fisheries and Health).
APPENDIX A
Transparency of Sanitary and Phytosanitary Regulations

Publications of regulations

1. Member States shall ensure that all sanitary and phytosanitary regulations are published promptly in such a manner as to enable interested Member States to become acquainted with them.

2. Except in urgent circumstances, Member States shall normally allow a period of not less than six months between the publication of a sanitary or phytosanitary regulation and its entry into force to allow time for producers in exporting Member States, to adapt their products and methods of production to the requirements of the importing Member State. The entry into force of measures which contribute to the liberalisation of trade should not be unnecessarily delayed.

Enquiry points

3. Each Member State shall ensure that a WTO SPS Enquiry Point exists, which is responsible for the provision of answers to all questions from interested Member States 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 State, 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 Annex, and the texts of such agreements and arrangements.

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

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

b) notify other Member States, through the WTO Secretariat, of the products to be covered by the regulation together with a brief indication of the 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 of other Member States 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 Member States 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 State, that Member State may omit such steps enumerated in paragraph 5 of this Appendix as it finds necessary, provided that the Member State:

a) immediately notifies other Member States, through the WTO 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 Member States;

c) allows other Member States 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 WTO Secretariat shall be in the languages of the WTO.

8. Each Member State's National Committee on Sanitary and Phytosanitary Measures, in cooperation with its WTO SPS National Notification Authority and Enquiry Point(s), shall be responsible for the implementation at the national level of the provisions concerning notification procedures according to this Appendix.
General reservations

9. Nothing in this Annex shall be construed as requiring Member States to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.
APPENDIX B
Control, Inspection and Approval Procedures

1. Member States 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 transits 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 applicant 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 levels 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 products originating in any other Member State and should not be higher than the actual cost of the service;

g) the same criteria should be used in the setting up 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 State operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants to 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 State 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 State 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 Annex shall prevent Member States from carrying out reasonable inspection within their own territories.