



**REGULATIONS ON
THE APPLICATION OF SANITARY AND
PHYTOSANITARY MEASURES**

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Preamble

Recognising that most Member States have undertaken international commitments and obligations under the World Trade Organisation's (WTO's) Agreement on the Application of Sanitary and Phytosanitary measures (SPS Agreement), as well as under other international and regional agreements;

Recognising the crucial harmonising role of international standards, guidelines and codes of practice elaborated by international bodies, including the Codex Alimentarius Commission (Codex), the World Organisation for Animal Health (OIE) and the relevant international and regional organisations operating within the framework of the International Plant Protection Convention (IPPC) and any other organisation relevant to SPS matters;

Reaffirming the need to promote regional and international trade in food and agricultural commodities while at the same time protecting human, animal and plant life and health on the basis of regional and international standards, guidelines and recommendations developed by relevant regional and international organisations;

Reaffirming the commitment of the Member States to the adoption of measures necessary to achieve the overall objective of cooperation in the agricultural sector for the achievement of regional food security and rational agricultural production within the Common Market, in accordance with Article 130 of the Treaty;

Recalling their commitment to harmonise their policies and regulations relating to sanitary and phytosanitary measures without impeding the export of crops, plants, seeds, livestock, livestock products, fish and fish products, in accordance with Article 132 (d) of the Treaty;

Realising that the lack of harmonisation of SPS measures among Member States may act as a hindrance to trade in agricultural and food products;

Desiring therefore to elaborate rules for the harmonised application of sanitary and phytosanitary measures within the Common Market; and

ACTING in accordance with the provisions of the Treaty, the Council makes the following Regulations to govern the implementation of sanitary and phytosanitary matters in the Common Market:

1. Interpretation

- (1) Subject to sub-regulation 2, the definitions in Annex A of the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures shall have the same meaning in these Regulations, unless the context otherwise requires.
- (2) In these Regulations:

“**Committee**” means the Committee on Agriculture established under Article 15 of the Treaty;

“**Common Market**” means the Common Market for Eastern and Southern Africa established by Article 1 of the Treaty;

“**competent authority**” means a person, body or organisation designated by a Member State to be responsible for the enforcement of SPS measures relevant to a particular specialisation;

“**Council**” means the Council of Ministers of the Common Market established under Article 7 of the Treaty;

“**Court of Justice**” means the Court of Justice of the Common Market;

“**Farm-to-Table**” or “**Farm-to-Fork**” means the process which involves all steps in the conception, production, storage, handling, packaging, distribution and preparation of a food product;

“**Green Pass**” means the COMESA Green Pass established under Regulation 7;

“**Member State**” means a Member State of the Common Market;

“**National Green Pass Authority**” means the relevant national competent authority set up or designated by a Member State to issue a Green Pass for a particular commodity under Regulation 7;

“**regional accreditation body**” means a national SPS related institution designated as such by Council under Regulation 15;

“**risk**” means the probability and severity of an adverse effect or event occurring to human, animal and plant life or health or the environment following exposure, under defined conditions, to a risk source;

“**Secretariat**” means the Secretariat of the Common Market established by Article 7 of the Treaty;

“**Secretary-General**” means the Secretary-General of the Common Market referred to in Article 17 of the Treaty;

“**specialisation**” means any of the three sectors relevant to SPS matters, namely animal health, food safety or plant protection;

“**SPS**” means sanitary and phytosanitary;

“**SPS Related Institution**” means an institution with the appropriate legal mandate in a Member State to deal with animal diseases, plant pests and diseases and food safety matters;

“**SPS Unit**” means the unit set up under Regulation 21 (2);

“**Treaty**” means the Treaty establishing the Common Market.

2. Objectives

The objectives of these Regulations are:

- (a) to set out principles and create mechanisms for cooperation in the implementation of SPS measures by Member States;
- (b) to ensure the protection of -
 - (i) human health and life from risks arising from additives in food and drink, contaminants in food and drink, toxins in food and drink, and plant or animal carried diseases;
 - (ii) animal health and life from risks arising from additives in feed and water, toxins in feed and water, pests, diseases and disease causing organisms;
 - (iii) plant health and life from risks arising from pests, diseases and disease causing organisms; and
 - (iv) the socio-economic structures and institutions of a Member State from risks arising from the entry, establishment and spread of pests and diseases;
- (c) to ensure that the application of SPS measures does not unnecessarily hinder trade in food and agricultural products in the Common Market.

3. General Obligations of Member States

- (1) Member States shall, in accordance with Article 5(2)(b) of the Treaty, take all appropriate measures, whether general or particular, to ensure the fulfilment of the obligations arising out of these Regulations or resulting from any action taken under these Regulations.
- (2) Member States shall, in accordance with Article 5(1) of the Treaty, facilitate the achievement of the objectives of the Common Market and shall abstain from taking any measure that could jeopardise the attainment of the objectives of these Regulations.
- (3) A Member State shall ensure that the provisions of its domestic laws and other measures relating to any SPS measures are in conformity with these Regulations.

4. Application of SPS Measures

- (1) Member States shall have the right to take SPS measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of these Regulations.

- (2) Subject to Regulation 5, a Member State shall ensure that any SPS measure:
 - (d) is applied only to the extent necessary to protect human, animal or plant life or health; and
 - (e) is based on scientific principles and is not maintained without sufficient scientific evidence.
- (3) A Member State shall avoid taking any arbitrary or unjustified measure which could result in discrimination or disguised restriction on regional or international trade.

5. Interim Measures

- (1) A Member State may, applying the precautionary principle and without waiting for the collection of sufficient scientific information to conclusively assess the existence or extent of risk to human, animal and plant life and health, take interim measures to avoid possible harm, provided that:
 - (a) the adopted SPS measures are based on available pertinent information, including from the relevant international organisations as well as from SPS measures applied by other Member States;
 - (b) such a Member State shall seek to obtain the additional information necessary for a more objective assessment of risk and review the SPS measures accordingly within a reasonable period of time; and
 - (c) such a Member State shall have given notice to the Secretary- General, in accordance with Article 50(1)(c) of the Treaty, of its intention to introduce such SPS measures.
- (2) The Committee shall periodically review measures taken under sub- regulation (1).

6. Specific Obligations on the Application of SPS Measures

- (1) Member States shall comply with Articles 3 to 8 of the WTO SPS Agreement, except as otherwise provided for in these Regulations.
- (2) Member States:
 - (a) undertake to harmonise SPS measures, including surveillance, emergency preparedness, traceability, control, inspection and approval procedures;
 - (b) shall ensure that any SPS measures taken with respect to products of novel technologies shall be based on scientific risk assessment;

- (c) shall ensure that in the entire process of risk analysis, no individual shall belong to both the risk assessment team and the risk management team;
- (d) shall take into account the different levels of development of other Member States and third parties when carrying out any risk assessment or risk management under paragraph (c);
- (e) shall forthwith communicate any notification, report or information made under Article 7 of the WTO SPS Agreement
- (f) to the Secretariat; and
- (g) shall have their SPS Related Institutions adopt international standards in respect of any procedures to check and ensure the fulfilment of SPS measures and, where appropriate, have them accredited by recognised international or regional accreditation bodies.

7. *Establishment of COMESA Green Pass*

- (1) There is hereby established a COMESA Green Pass, which shall be a commodity-specific SPS certification scheme and authority for movement of food and agricultural products within the Common Market, issued by a National Green Pass Authority.
- (2) Unless otherwise provided in these Regulations, a Green Pass issued by a National Green Pass Authority in one Member State shall be valid in another Member State.

8. *Objectives of Green Pass*

The objectives of the Green Pass are:

- (a) to facilitate movement and trade in food and agricultural commodities;
- (b) to protect:
 - (v) human health and life from risks arising from additives in food and drink, contaminants in food and drink, toxins in food and drink, and plant or animal carried diseases;
 - (vi) animal health and life from risks arising from additives in feed and water, toxins in feed and water, pests, diseases and disease causing organisms;
 - (vii) plant health and life from risks arising from pests, diseases and disease causing organisms; and
 - (viii) the socio-economic structures and institutions of a Member State from risks arising from the entry, establishment and spread of pests and diseases.

9. National Green Pass Authority

- (1) Member State may set up under domestic laws or designate a National Green Pass Authority for certification in accordance with Regulation 11.
- (2) Where a Member State sets up or designates a National Green Pass Authority, it shall notify the Secretary-General officially, in writing, of the setting up or designation of such an institution, not more than a month after it has been officially set up or designated by the Member State.

10. Functions and Powers of National Green Pass Authority

A Member State shall ensure that a National Green Pass Authority shall have functions and powers to:

- (a) receive and consider applications for Green Passes;
- (b) register enterprises eligible to be issued with a Green Pass;
- (c) monitor and evaluate enterprises registered under paragraph (b);
- (d) assist enterprises in meeting eligibility criteria for Green Pass;
- (e) establish and maintain a register, comprising of such information as the Authority may decide, subject to confidentiality rules, of eligible enterprises; and
- (f) collaborate and coordinate with the Regional SPS Unit at the Secretariat, with regard to the issuance of the Green Pass.

11. Certification of National Green Pass Authority

- (1) The Committee shall certify a national institution as a Green Pass Authority for purposes of these Regulations, where it is satisfied that the institution:
 - (a) complies with the requirements of these Regulations;
 - (b) has adequate resources to carry out its functions under these Regulations;
 - (c) has an effective monitoring and surveillance system;
 - (d) has an effective emergency preparedness system; and
 - (e) has an effective traceability system.
- (2) Where a Member State applies for authority to issue a Green Pass for a particular commodity or group of commodities but fails to meet the requirements stipulated for the commodity or group of commodities, the

Secretariat may assist the Member State to formulate a programme of interventions and source funds to address the specific deficiencies observed.

- (3) The Committee shall consider an application for certification after having received a request on the issue from the SPS Unit.

12. Registration of Enterprise

- (1) An enterprise may be registered under Regulation 10(b) where it satisfies the SPS requirements as required for the commodity in question in the specific Council regulations, directives and codes of practice issued in accordance with Regulation 18.
- (2) Where an enterprise, which has applied for registration under sub-regulation (1), fails to meet the requirements stipulated for the commodity or group of commodities, the National Green Pass Authority may assist the enterprise to formulate a programme of interventions and source funds to address the specific deficiencies arising or observed.
- (3) Where an enterprise registered under sub-regulation (1) subsequently fails to meet the requirements stipulated for the commodity or group of commodities, the National Green Pass Authority may suspend the registration of such an enterprise until the specific deficiencies are remedied.

13. Suspension of Importation under a Green Pass

- (1) Where a Member State has valid grounds to believe that a Green Pass has not been issued in accordance with these Regulations, it may;
 - (a) prevent the importation of the commodity subject matter of the Green Pass; and
 - (b) request for additional information from the exporting Member State.
- (2) Any action taken under sub-regulation (1) shall be forthwith notified to the Secretariat.
- (3) The Secretariat shall inquire and report on the matter to the Member States involved within four weeks.

14. Mutual Recognition Agreements

Member States are individually or collectively encouraged to sign mutual recognition agreements with any country or group of countries outside the Common Market for the recognition of the Green Pass as authority of entry of commodities into that country's or group of countries' market.

Regional Accreditation Bodies

- (1) The Council may designate such number of national SPS related institutions as regional accreditation bodies as may be required for the purpose of these Regulations.
- (2) A regional accreditation body shall, in its field of accreditation:
 - (a) carry out audit, inspection and accreditation of any recognised national SPS related institution or a process;
 - (b) assist recognised national SPS related institutions in establishing quality assurance and management systems;
 - (c) assist the Secretariat in establishing national certification bodies in Member States, with the aim of establishing common certification criteria, for the Green Pass;
 - (d) establish a peer review mechanism for ensuring compliance with agreed standards; and
 - (e) conduct relevant training to ensure effective operations.
- (3) A regional accreditation body shall itself be accredited in accordance with the relevant international standards.
- (4) Council shall determine the relevant international standards..

15. Regional SPS Reference Laboratories

- (1) The Committee may select such number of national SPS related laboratories as may be necessary, in accordance with such criteria and modalities as the Council shall determine, as SPS regional reference laboratories, for the effective implementation of SPS measures in the Common Market.
- (2) The functions of the regional reference laboratories shall be:
 - (a) to monitor compliance with regional disease and pest requirements by countries as well as producer/processor enterprises, and oversee the appropriate certification process;
 - (b) to process selected samples of commodities for the purpose of maintaining a databank of disease causing agents and pests relevant to international trade;
 - (c) to validate and standardise diagnostic procedures and reagents on behalf of satellite and national laboratories;
 - (d) to gather technical information with regards to SPS matters and make it available to Member States and other interested parties;

- (e) to provide credible scientific basis for resolution of disputes between the importing and/or exporting parties;
- (f) to assist Member States in carrying out risk analysis;
- (g) to train personnel from the national laboratories of Member States;
- (h) to establish and implement inter-laboratory comparison schemes;
- (i) to designate, supervise and coordinate the work of Regional SPS Related Satellite Laboratories; and
- (j) to serve as centres of excellence for SPS technical matters.

16. Regional Satellite Laboratories

- (1) Council may designate such number of national SPS related laboratories as may be necessary, as regional SPS satellite laboratories specialised in a specific area of competence, in accordance with such criteria and modalities as the Council may determine.
- (2) The functions of the regional SPS satellite laboratories shall be:
 - (a) to process selected samples of commodities for the purpose of maintaining a databank of disease causing agents and pests relevant to international trade in a specific area of competence;
 - (b) to gather technical information with regard to SPS matters and make it available to Member States and other interested parties in a specific area of competence;
 - (c) to assist Member States in carrying out risk analysis in a specific area of competence;
 - (d) to train personnel from the national laboratories of Member States in a specific area of competence; and
 - (e) to establish and implement inter-laboratory comparison schemes in a specific area of competence.

17. Powers of Council

Council may make such regulations, issue such directives and develop such codes of practice as may be required to:

- (a) implement and enforce a Green Pass for a particular commodity or group of commodities;
- (b) ensure the effective operation of regional reference laboratories, regional satellite laboratories and national SPS related laboratories.

18. Mutual Support and Cooperation

- (1) Member States shall cooperate in:
 - (a) the harmonisation of national legislation in relation to SPS measures;
 - (b) the development of codes of practice, guidelines and procedures on SPS measures, including procedures for monitoring, surveillance, emergency preparedness, traceability, control, inspection approval, laboratory testing and management, certification and accreditation;
 - (c) the establishment of appropriate coordinating mechanisms amongst recognised national SPS institutions;
 - (d) areas of processing technologies, diagnosis, research and infrastructure, including the establishment and upgrading of national regulatory bodies or national or regional SPS related facilities;
 - (e) training and capacity building at the national and regional levels;
 - (f) the establishment and implementation of the necessary mechanisms for monitoring and surveillance, emergency preparedness and traceability of human food-borne illness and zoonoses, as well as, animal and plant pests and diseases;
 - (g) the establishment of an early warning system to enhance national and regional emergency response capacity; and
 - (h) matters of bio-safety as provided for under the relevant international conventions and protocols.
- (2) Member States shall cooperate in collectively accessing technical assistance to promote compliance with SPS measures and shall identify areas of common interest with a view to prioritising them for such support.
- (3) Where a Member State requires specific assistance, other Member States shall consider cooperating with such a Member State in rendering or sourcing the assistance.
- (4) Nothing in this Article shall prevent individual Member States from taking the initiative to access technical assistance under the provisions of the WTO SPS Agreement.

19. Special Treatment

- (1) With a view to ensuring that all Member States are able to comply with the provisions of these Regulations, Council shall take such steps as are appropriate, including longer time frames for compliance, to ensure that the special needs of a Member State are addressed taking into account the principle of variable geometry.

- (2) Nothing in these Regulations shall prevent two or more Member States from complying with these Regulations within a shorter time than may be set by the Council.

20. Administration

- (1) The Committee shall:
- (a) be responsible for the comprehensive implementation of these Regulations;
 - (b) monitor and keep under constant review any programme developed and implemented under these Regulations;
 - (c) with the approval of Council, set up such sub committees as may be appropriate for the attainment of the objectives of these Regulations;
 - (d) have a supervisory role over any regional body or institution created for the purpose of implementing these Regulations; and
 - (e) determine the duties and responsibilities of each subcommittee and where appropriate establish the rules of procedure governing such sub committees.

- (2) There shall be established an SPS Unit within the Secretariat which shall:

- (a) facilitate the formulation of programs under these Regulations;
- (b) provide appropriate technical guidance to Member States on SPS matters;
- (c) facilitate capacity building in SPS matters at both National and Regional levels;
- (d) facilitate the collection and dissemination of technical information on SPS matters to the Member States;
- (e) advise the Committee on any request for certification as a National Green Pass Authority;
- (f) coordinate all regional programmes and institutions related to SPS matters;
- (g) coordinate and support the work of regional reference and satellite laboratories; and
- (h) perform any other such functions as the Committee may direct.

21. Public and Private Sector Consultations

Member States are encouraged to set up such national bodies or institutions as may be appropriate to facilitate the implementation and administration of these Regulations, including providing such forum as will allow consultation between the public and the private sector on SPS issues.

22. Establishment of Database

The Secretariat shall establish and maintain a database of experts in SPS matters who may be called upon to assist the Secretary-General, the Committee, Member States and the Court of Justice in the implementation of these Regulations.

23. Dispute Settlement

- (1) Any dispute arising under these Regulations shall be resolved in accordance with the provisions of this Regulation.
- (2) A Member State may request consultations with another Member State in relation to any dispute arising from the implementation of these Regulations.
- (3) A Member State shall accord due consideration to a request made under sub-regulation (2) and shall afford adequate opportunity for consultation regarding any representation made by the Member State making the request.
- (4) The Secretary-General may, at the request of any Member State that is party to a dispute, use his good office to facilitate the resolution of any dispute under these regulations.
- (5) Where a dispute has not been resolved within a period of sixty days of the request referred to in sub regulation (2), the aggrieved Member State may refer the dispute to the Committee for resolution.
- (6) Where a Member State is not satisfied with the decision of the Committee on the dispute, the Member State may refer the dispute to the Court of Justice for arbitration under Article 28 of the Treaty provided that the parties to the dispute so agree.
- (7) Nothing in –sub-regulation (6) shall be construed as ousting the jurisdiction of the Court of Justice under Article 23 of the Treaty.
- (8) The Secretary General, the Committee or the Court of Justice may, where appropriate, seek advice from experts on scientific or technical issues arising from any dispute.

24. Collaboration with International SPS Related Organisations and Institutions

The Common Market may enter into cooperation arrangements in SPS related matters with any organisation or institution dealing with SPS matters.

25. Amendments

These regulations may be amended in accordance with such procedures as may be adopted by Council.

26. *Entry into Force*

These Regulations shall come into force on the date of their publication in the Official Gazette of the Common Market.