



EAST AFRICAN COMMUNITY

HARMONIZED SANITARY AND PHYTOSANITARY
MEASURES

VOLUME IV – FOOD SAFETY MEASURES

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LIST OF ACRONYMS

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| CA | Competent Authority |
| Codex | Codex Alimentarius Commission |
| EAC | East African Community |
| GAP | Good Agricultural Practices |
| GHP | Good Hygiene Practices |
| GMO | Genetically Modified Organisms |
| GMP | Good Manufacturing Practice |
| GPVD | Good Practice in the Use of Veterinary Drugs |
| HACCP | Hazard Analysis Critical Control Point |
| IPPC | International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended (FAO, 1990; revised ICPM, 2001) |
| MRL | Maximum Residual Levels |
| OIE | World Organisation for Animal Health |
| SPS | Sanitary and Phytosanitary Measure |
| WTO | World Trade Organization |

EAST AFRICAN COMMUNITY (EAC) HARMONIZED FOOD SAFETY MEASURES

PREAMBLE

The EAC recognizes the need for a comprehensive harmonized food safety measures to ensure a high level of consumer protection including restoration and maintenance of confidence in the safety and quality of both food and feed. EAC Partner States, Burundi, Kenya, Rwanda, Uganda and the United Republic of Tanzania have the desire to co-operate with one another in the area of health, social and cultural fields and, in particular, in the field of both human and animal medicines, and food and feed safety as detailed in the relevant provisions of Article 108 and Article 118 of the Treaty for the Establishment of the East African Community.

Similarly, the EAC recognizes the need for ensuring rational development of the agricultural sector and increased production to ensure food security and free trade in agricultural products within the Community and with other trading partners through adoption of harmonized food safety measures in pursuance of Articles 105 to 108 of the EAC Treaty for the Establishment of the East African Community and Article 38 (1) (c) of the Protocol on the Establishment of the East African Community Customs Union which are consistent with World Trade Organization Agreement on Application of Sanitary and Phytosanitary Measures (WTO-SPS Agreement), International Plant Protection Convention (IPPC), Codex Alimentarius Commission (CAC), World Organization for Animal Health (OIE), and other relevant agreements.

The provisions contained in this document shall be referred to as the *East African Community (EAC) Food Safety Measures*. They are part of 4 volumes of the Harmonized Sanitary and Phytosanitary Measures which include:

- Volume I: *Phytosanitary Measures;*
- Volume II: *Sanitary Measures for Mammals, Birds and Bees;*
- Volume III: *Sanitary Measures for Fish and Fishery Products;* and
- Volume IV: *Food Safety Measures*

These Food Safety Measures are being prepared to ensure a high level of consumer protection and restoration and maintenance of confidence in the safety and quality of food and feed produced, manufactured; traded; consumed in or exported from the EAC. Their use will be implemented through specific Standard Operating Procedures (SOPs) benchmarked on EAC standards, relevant food legislations of Partner States, Codex, OIE and IPPC standards.

1.0 OBJECTIVES

The specific objectives of these harmonized Food Safety Measures are to enhance trade on food and food products within the EAC and beyond through:

1.1 Establishing and maintaining confidence in the food safety measures implemented in EAC Partner States and among control agencies that manage measures to protect consumers from food-borne hazards in EAC Partner States and in potential third party markets;

1.2 Protecting consumers from risks arising from additives, contaminants, toxins or disease causing organisms in foods, beverages or feedstuffs, through the management of food safety hazards using a preventive approach;

1.3 Defining procedures for conformity assessment, establishing mutual recognition, and determining equivalence across the Partner States in order to improve intra-regional trade in foods, food supplements, beverages, animals, animal products, plants, plant products and other regulated food articles for the economic benefits of the citizens of the EAC region and to expand external trade;

1.4 Promoting harmonization of legislation at Partner State, regional (EAC) and international (Codex, OIE, IPPC) levels;

1.5 Promoting and facilitating the development of human resource capacities/skills and databases in all disciplines of food safety;

1.6 Establishing an East African Community Rapid Alert System for Food and Feed (EACRASSF) with regional and global operational linkages to ensure that only safe food is available to the public;

1.7 Strengthening the capacity to undertake formal risk analysis and enhancement of the EAC capacity for effective participation in international standards development;

1.8 Strengthening mechanisms for monitoring and evaluation of food safety practices along the food chain to prevent outbreaks of food borne diseases;

1.9 Strengthening national systems that will ensure traceability from farm to fork, also with reference to the EAC SPS Protocol and the EAC Protocol Establishing the EAC Commission for Medicines and Food Safety;

1.10 Establishing systems that mitigate emerging and re-emerging food safety challenges;

2.0 TERMS AND DEFINITIONS

For the purposes of these EAC Food Safety Measures, in addition to Terms and Definitions stated in the EAC SPS Protocol and in the EAC Protocol Establishing the EAC Commission for Medicines and Food Safety the following definitions/terminologies shall apply:

Audit - is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.

Certification - is the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that food or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.

Competent authority - the Partner State Governmental Authority of an having the responsibility and competence for ensuring for ensuring food safety management. This can be veterinary authority, plant health authority or food safety management authority as provided for in the food respective national legislation, taking into account the farm to table food continuum. Such authorities may also be the ones recognized under OIE, Codex and IPPC.

Cosmetic product - any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.

Designated Testing laboratory - public or private testing laboratory nominated by the government as the main testing laboratories representing the testing domain of a Partner State

Emerging disease - means a new infection resulting from the evolution or change of an existing pathogenic agent, a known infection spreading to a new geographic area or population, or a previously unrecognized pathogenic agent or disease diagnosed for the first time and which has a significant impact on animal or public health.

Equivalence of certification - is the capability of different inspection and certification systems to meet the same objectives.

Equivalence of sanitary measures - means the state wherein the sanitary measure(s) proposed by the exporting Partner State as an alternative to those of the importing Partner State, achieve(s) the same level of protection.

Designated Testing laboratory - public or private testing laboratory nominated by the government as the main testing laboratories representing the testing domain of a Partner State

Feed' (or 'feeding stuff') - any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

Feed business' - any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;

Feed business operator' - the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;

Final consumer' - the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

Food'(or 'foodstuff') - any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.

'Food' shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products;
- (e) cosmetics;
- (f) tobacco and tobacco products;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- (h) residues and contaminants.

Food business - any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;

Food business operator - the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;

Food hygiene - all conditions and measures necessary to ensure the safety and quality of food at all the stages of the food chain.

Food safety - assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food safety measures' - the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at EAC or Partner State level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food producing animals;

Food Safety Emergency: A situation whether accidental or intentional, that is identified, by a competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action.

Good Practice in the Use of Veterinary Drugs (GPVD):- Is the official recommended or authorized usage including withdrawal periods, approved by competent authorities, of veterinary drugs under practical conditions.

Hazard - a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.

Importing Partner State - means a Partner State that is the final destination to which commodities are sent.

Inspection - is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.

Legislation - acts, regulations, requirements or procedures, issued by public authorities, related to foodstuffs and feedstuffs and covering the protection of public health, the protection of consumers and conditions of fair trading.

Maximum Residue Limit for Veterinary Drugs (MRLVD):- Is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or g/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food. It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects. When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available

Official accreditation- is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services.

Official inspection systems - are inspection systems administered by a competent authority empowered to perform a regulatory or enforcement function or both.

Officially recognized certification systems - are certification systems which have been formally approved or recognized by a competent authority having jurisdiction.

Officially recognized inspection systems - are inspection systems which have been formally approved or recognized by a competent authority having jurisdiction.

Phytosanitary measure” - any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of pests;

Placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;

Primary production’ - the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;

Proprietary medicinal product: any ready-prepared medicinal product placed on the market under a special name and in a special pack.

Requirements - are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.

Residues of Veterinary Drugs: - residues of the parent compounds and/or their metabolites in any edible portion of the animal product, and residues of associated impurities result from the use of the veterinary drug concerned.

Retail' - the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

Risk' - a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

Risk analysis - means the process composed of hazard identification, risk assessment, risk management and risk communication.

Risk assessment' - a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

Risk communication' - the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

Risk management' - the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

Stages of production, processing and distribution' - any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;

Tobacco products - means products for the purpose of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco

Traceability - the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;

Transparency - means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*. Conclusions shall be supported by an objective and logical discussion and the document shall be fully referenced.

Veterinary Authority - means the Partner State Governmental Authority comprising *veterinarians*, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and *welfare* measures, international veterinary certification and other standards and recommendations in the *Terrestrial Code* in the whole territory.

Veterinary Drug: - Any substance applied or administered to any food-producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic, or diagnostic purposes, or for modification of physiological functions or behaviour

Veterinary para-professional- means a person who, for the purposes of the *Terrestrial Code*, is authorised by the *veterinary statutory body* to carry out certain designated tasks (dependent upon the category of *veterinary para-professional*) in a territory, and delegated to them under the responsibility and direction of a *veterinarian*. The tasks for each category of *veterinary para-professional* shall be defined by the *veterinary statutory body* depending on qualifications and training, and according to need.

Veterinary Services - means the governmental and non-governmental organisations that implement animal health and *welfare* measures and other standards and recommendations in the *Terrestrial Code* in the territory. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, *veterinarians* or *veterinary paraprofessionals* are normally accredited or approved to deliver functions by the *Veterinary Authority*.

Veterinary statutory body - means an autonomous authority regulating *veterinarians* and *veterinary para-professionals*.

Withdrawal Time and Withholding Time: - This is the period of time between the last administration of a drug and the collection of edible tissue or products from a treated animal that ensures the contents of residues in food comply with the maximum residue limit for respective veterinary drug (MRLVD).

SECTION 1: GENERAL PRINCIPLES OF FOOD SAFETY MEASURES

1- GENERAL

1.1 An effective food safety management system is a necessity for every Partner State in order to protect its consumers (national and international) against foods that are contaminated, adulterated or in other ways injurious to health, or which are incorrectly packaged or labeled.

1.2 An EAC and thereafter a Partner State food safety measure shall address in an integrated approach, all elements related to regional and national production, import and export of food and feed products; and shall in particular, regulate the production, storage, transport and sale of foods and feeds within EAC and Partner State territorial borders.

1.3 EAC Food Safety Measures provide a framework for developing regional food trade regimes and to assist Partner States' governments in the development and operation of a national food safety measures.

1.4 These EAC Food Safety Measures also put in perspective the need to appreciate the roles played by different stake holders and professions at different stages of the food chain. They also spell out the roles to be played by the different competent authorities in the Partner states as the success of a food safety management system is closely linked to the collaboration of a wide range of multidisciplinary teams of experts.

1.5 Food and feed to be traded in EAC shall be entered through frontier posts designated and equipped by each Partner State so as to detect any condition in food or feed that may represent a health hazard.

The designated frontier posts shall be provided with equipment and facilities for isolating or destroying any food or feed unfit for human or animal use respectively. Currently, the designated frontier posts in EAC are:

Burundi

Designated frontier posts: Bujumbura International Airport, Bujumbura Port, Rumonge Port, Gatumba Port

Other Designated posts: Gasenyi, Upper Kanyaru, Ruhwa, Nyazalace harbour, Kobero and Lower Kanyaru

Kenya

Designated frontier ports: Mombasa Harbour, Moi International , Shimoni, Lokichoggio, Moyale, Mandera, Jomo Kenyatta International Airport and Eldoret International Airport.

Other designated posts: Lungalunga, Taveta, Oloitoktok, Namanga, Nyamutiru, Isebania, Kopanga, Muhuru Bay, Kisumu Pier, Usenge, Sio Port, Busia, Malaba, Luakhakha, Suam.

Rwanda:

Designated frontier posts: Kigali International Airport, Rusizi/Kamembe, Rusizi/Bugarama, Gisenyi/small barrier and Gisenyi/Corniche.

Other designated posts: Rusumo, Kagitumba, Gatuna, Kanyaru, Nemba and Cyanika.

Uganda:

Designated frontier posts: Entebbe International Airport, Bunagana, Ishasha River, Ntoronko, Vurra, Madi Opei, Lamuru, Mpondwe,

Other designated posts: Mirama Hills, Katuna, Cyanika, Kaya, Kikagati, Malaba, Busia, Luakhakha, Suam, Mutukula, Port Bell and Attiak.

United Republic of Tanzania:

Designated frontier posts: Julius Nyerere International Airport, Dar es Salaam Harbour, Tanga Harbour, Mtwara International Airport, Mtwara harbour, Kilimanjaro International Airport, Mwanza International Airport, Zanzibar International Airport and Zanzibar Harbour, Kigoma Harbour, Itungi and Tunduma.

Other designated posts: Sirari, Taveta, Namanga, Holili, Mbamba bay, Kasumulu, Rusumo, Kasesya, Kirando, Ikola, Bagamoyo and Pangani.

2 - SCOPE

2.1 These EAC food safety measures relate to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing. They also establish common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2.2 The requirements prescribed in Articles 3 to 7 shall form a general framework of a horizontal nature to be followed when Partner States decided to implement food safety measures.

2.3 Existing food safety laws and regulations in Partner states shall be adapted in order to comply with Articles 3 to 7. (Might wish to define timeframe)

2.4 Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in sub-sections 3 to 7.

3- RISK ANALYSIS

3.1 In order to achieve the objective of a high level of protection of human health and life, food safety measures shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

3.2 Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3.3 Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Scientific Committee referred to in sub-section 33, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in sub-section 4.1 are relevant, in order to achieve the general objectives of food safety measure established in Sub-section 3.

4 - PRECAUTIONARY PRINCIPLE

4.1 In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the EAC may be adopted, pending further scientific information for a more comprehensive risk assessment.

4.2 Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the EAC, regard being given to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

5- PROTECTION OF CONSUMERS' INTERESTS

5.1 Food safety measure shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

- (a) fraudulent or deceptive practices;
- (b) the adulteration of food; and
- (c) any other practices which may mislead the consumer.

SECTION 2: PRINCIPLES OF TRANSPARENCY

6 - PUBLIC CONSULTATION

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food safety measures, except where the urgency of the matter does not allow it.

7 - PUBLIC INFORMATION

Without prejudice to the applicable provisions of EAC and Partner States laws on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

SECTION 3: GENERAL OBLIGATIONS OF FOOD TRADE

8- FOOD AND FEED IMPORTED INTO THE EAC

8.1 Food and feed imported into the EAC for placing on the market within the EAC shall comply with the requirements set out in relevant EA standards or Partner States standards or food safety measures or conditions recognised by the EAC to be at least equivalent thereto or, where a specific agreement exists between the EAC and the exporting Partner State, with requirements contained therein.

8.2 Relevant EA standards shall be as listed in current EAC Standards Catalogue. In the absence of relevant EA Standard and Partner States standards or food safety measures, the relevant Codex Alimentarius standard shall be used.

8.3 Food and feed imported into the EAC for placing on the market within the EAC shall comply with the provisions prescribed in the Harmonized Sanitary and Phytosanitary Measures Volume I: *Phytosanitary Measures* for food and feed of plant origin, Volume II: *Sanitary Measures for Mammals, Birds and Bees* for food and feed of animal origin and Volume III: *Sanitary Measures for Fish and Fishery Products* for food and feed of aquatic origin.

8.4 In the absence of relevant provisions in the EAC Harmonized Sanitary and Phytosanitary Measures, food and feed imported into the EAC for placing on the market within the EAC shall comply with relevant provisions as prescribed by IPPC for food and feed of plant origin and by OIE for food and feed of animal origin shall be used.

9 - FOOD AND FEED EXPORTED FROM THE EAC

9.1 Food and feed exported or re-exported from the EAC for placing on the market of an importing Partner State shall comply with the requirements set out in relevant EAC standards or Partner States standards or food safety laws, unless otherwise requested by the authorities of the importing Partner State or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing Partner State.

9.2 In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the Partner State of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the EAC.

9.3 Where the provisions of a bilateral agreement concluded between the EAC or one of its Partner States and an importing Partner State are applicable, food and feed exported from the EAC or that Partner State to that the importing Partner State shall comply with the said provisions.

10 - FOOD AND FEED REJECTIONS

10.1 When the competent authorities in an importing Partner State reject a consignment of food or feed presented for importation they shall always provide information to the importer of the consignment giving the reasons for the rejection. Appropriate information shall also be provided to the exporter if the competent authorities receive such a request.

10.2 When the rejection of the consignment arises from:

- a) evidence of a serious food or feed safety or public health problem in the exporting Partner State; or
- b) evidence of serious misrepresentation or consumer fraud; or
- c) evidence of a serious failure in the food and feed safety management system in the exporting Partner State, the competent authorities in the importing Partner State shall notify the competent authorities in the exporting Partner State forthwith (by telecommunication or other similar rapid means of communication).

10.3 Where imported food or feed has been rejected on the basis of sampling and/or analysis in the importing Partner State, details shall be made available on request as to sampling and analytical methods and test results and the identity of the testing laboratory.

10.4 The following information shall be provided by the competent authorities in relation to rejections of imported food or feed as available and appropriate to the circumstances.

- a) Identification of the food or feed concerned
 - (i) Description and quantity of product
 - (ii) Type and size of package
 - (iii) Lot identification (number, production date, etc.)
 - (iv) Container number, bill of lading or similar transportation details

- (v) Other identification stamps, marks or numbers
- (vi) Certificate number
- (vii) Name and address of manufacturer, producer, seller and/or exporter, establishment number, as appropriate

b) Importation details

- (i) Port or other point of entry
- (ii) Name and address of importer
- (iii) Date presented for entry

c) Details of rejection decision

- (i) Whole/part of (specify) consignment rejected
- (ii) Name and address of food control authority making decision to reject
- (iii) Date of decision
- (iv) Name and address of food or feed competent authority which can provide more information on reason for rejection

d) Reason(s) for rejection

- (i) Biological/microbiological contamination
- (ii) Chemical contamination (pesticide or veterinary drug residues, heavy metals, etc.)
- (iii) Radionuclide contamination
- (iv) Incorrect or misleading labelling
- (v) Compositional defect
- (vi) Non-conformity with food additive requirements
- (vii) Organoleptic quality unacceptable
- (viii) Technical or physical defects (e.g., packaging damage)
- (ix) Incomplete or incorrect certification
- (x) Does not come from an approved Partner State, region or establishment
- (xi) Other reasons

e) Action taken

- (i) Food or feed destroyed
- (ii) Food or feed held pending reconditioning/rectification of deficiencies in documentation
- (iii) Food or feed held pending final judgement
- (iv) Place where food or feed is held
- (v) Import granted for use other than human consumption
- (vi) Re-export granted under certain conditions, e.g. to specified informed countries
- (vii) Importer notified
- (viii) Embassy/food or feed competent authorities of exporting Partner State notified
- (ix) Competent authorities in other likely destination countries notified
- (x) Other

10.5 Upon receipt of such a communication, the competent authorities in the exporting Partner State shall undertake the necessary investigation to determine the cause of any problem that had led to the rejection of the consignment. The competent authority in the exporting Partner State, if requested, shall provide the authorities in the importing Partner State with information on the outcome of the necessary investigation, if available. Bilateral discussions shall take place as necessary. In other circumstances, for example:

- a) where there is evidence of repeated failures of a correctable nature (e.g. labelling errors, mislaying of documents); or
- b) where there is evidence of systematic failures in handling, storage or transport subsequent to inspection/certification by the competent authorities in the exporting Partner States, the food control authorities in the importing Partner State shall also make appropriate notification to the food or feed competent authorities in the exporting Partner State, either periodically or upon request.

10.6 EAC Partner States shall in as far as possible minimise restrictions on the disclosure to other Partner States or other countries of information on rejected foods or feeds.

In some countries information about the results obtained in public food or feed control is freely available; whereas in others legal constraints may prevent or restrict the dissemination to third parties of information on, for example, import rejections. In some cases information cannot be exchanged before a certain time has elapsed.

11 - HARMONIZED EAC AND INTERNATIONAL FOOD AND FEED SAFETY AND QUALITY STANDARDS

11.1 Without prejudice to their rights and obligations, the EAC and the Partner States shall:

- (a) endeavour to development EAC harmonized technical standards for foods and feeds;
- (b) endeavour to approximate their individual countries' food laws and standards to EAC harmonized technical foods and feeds standards;
- (c) contribute to the development of international technical standards for foods and feeds and sanitary and phytosanitary standards;
- (b) promote the coordination of work on foods and feeds standards undertaken by international governmental and nongovernmental organisations;
- (c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific foods and feeds-related measures; and
- (e) promote consistency between international technical foods and feeds standards and their foods and feeds laws while ensuring that the high level of protection adopted in the EAC is not reduced.

SECTION 4: GENERAL REQUIREMENTS OF FOOD SAFETY LAW

12 - FOOD SAFETY REQUIREMENTS

12.1 Food shall not be placed on the market if it is unsafe.

12.2 Food shall be deemed to be unsafe if it is considered to be:

- (a) injurious to health; and
- (b) unfit for human consumption.

12.3 In determining whether any food is unsafe, regard shall be given:

- (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
- (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

12.4 In determining whether any food is injurious to health, regard shall be given to :

- (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
- (b) the probable cumulative toxic effects; and
- (c) the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

12.5 In determining whether any food is unfit for human consumption, regard shall be given to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

12.6 Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

12.7 Food that complies with specific EAC (or Partner States) provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific EAC (or Partner States) provisions are concerned.

12.8 Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

12.9 Where there are no specific EAC provisions, food shall be deemed to be safe when it conforms to the specific provisions governing food safety of the Partner State in whose territory the food is marketed.

13 - FEED SAFETY REQUIREMENTS

13.1 Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.

13.2 Feed shall be deemed to be unsafe for its intended use if it is considered to:

- (a) have an adverse effect on human or animal health; and
- (b) make the food derived from food-producing animals unsafe for human consumption.

13.3 Where the feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.

13.4 Feed that complies with specific EAC (or Partner States) provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific EAC (or Partner States) provisions are concerned.

13.5 Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

13.6 Where there are no specific EAC provisions, feed shall be deemed to be safe when it conforms to the specific provisions governing feed safety of the Partner State in whose territory the feed is marketed.

14 - PRESENTATION

Without prejudice to more specific provisions of food or feed safety measures, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

15 - RESPONSIBILITIES

15.1 Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food or feed safety measures which are relevant to their activities and shall verify that such requirements are met.

15.2 Partner States shall enforce food safety measures, and monitor and verify that the relevant requirements of food safety measures are fulfilled by food and feed business operators at all

stages of production, processing and distribution. For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Partner States shall also lay down the rules on actions and penalties applicable to infringements of food and feed safety measures. The actions taken and penalties provided for shall be effective, proportionate and dissuasive.

16 - RESPONSIBILITIES FOR FOOD SAFETY: FOOD BUSINESS OPERATORS

16.1 If a food business operator considers or has reason to believe that a food which it has produced, processed, manufactured, imported, or distributed is not in compliance with the food safety requirements, shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

16.2 A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

16.3 A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with Partner State law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

16.4 Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

17 - RESPONSIBILITIES FOR FEED SAFETY: FEED BUSINESS OPERATORS

17.1 If a feed business operator considers or has reason to believe that feed which it has produced, processed, manufactured, imported or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of sub-section 13.3, where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise.

The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

17.2 A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

17.3 A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with Partner State law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

17.4 Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.

18 - TRACEABILITY

18.1 The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

18.2 Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

18.3 Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

18.4 Food or feed which is placed on the market or is likely to be placed on the market in the EAC shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

19 - Liability

The provisions of this article shall be without prejudice to EAC requirement on the approximation of the laws, regulations and administrative provisions of the Partner States concerning liability for defective products.

20 - FOOD EMERGENCIES AND RAPID ALERT SYSTEM

20.1 Where a competent authority in a Partner State, as either importing and/or exporting Partner State, becomes aware of a food safety emergency situation, communication of the information and risks surrounding the emergency situation must be undertaken. Principles for exchange of information shall include:

- a) clear and complete description of the nature and extent of the food emergency, where possible, by the relevant competent authority;
- b) Partner State detecting a food safety emergency situation, whether it is an importing or an exporting Partner State, informing all known affected and potentially affected countries without delay;
- c) Exchange of information between official contact points designated by the competent authorities in the Partner States.
- d) Sharing all relevant information by the competent authority detecting a food safety emergency to enable all affected and potentially affected countries to make informed risk management and/or risk communication decisions.
- e) Clear, relevant, factual and timely information provided to all relevant stakeholders to the extent possible by competent authorities;
- f) Transparent and continuous flow of information during all phases of the food emergency situation to enable continuous evaluation and development of the emergency response.

20.2 Competent authorities shall exchange with all known affected and potentially affected countries the following information, as relevant upon identification of a food safety emergency.

- a. The nature of the food safety emergency including the hazards and risks identified, the methodology used and any assumptions made.
- b. Detailed identification of the food or foods concerned including product markings, certificate information.
- c. Affected and potentially affected populations group(s).
- d. Shipping and related information, e.g. the name and contact information for the exporter, importer, consignee and shippers.
- e. Action taken to reduce or eliminate the hazard.
- f. Full details of the designated official contact point and the relevant competent authority.

20.3 Action taken by exporting or importing Partner State in case of food emergencies shall also include:

- a) measures to identify and prevent the sale and export of the food;
- b) measures to recall food from markets including whether these recalls are voluntary or mandatory;

- c) measures to prevent further occurrences;
- d) measures to reduce the risk by appropriate physical treatment;
- e) methods of diagnosis and treatment of affected persons;
- f) measures taken regarding final disposition (e.g. destruction of the food).

20.4 A system for rapid alert on food emergencies shall be developed by the Scientific Committee (sub-section 33.1) covering foods and feeds and managed by the EAC Secretariat in coordination with relevant Competent Authorities and other food safety management institutions in the Partner States.

20.5 The Scientific Committee shall provide its scientific and technical assistance in the form of advice in the event of a food crisis to EAC and to Partner States.

SECTION 5: INSPECTION AND CERTIFICATION

21 - INSPECTION AND CERTIFICATION SYSTEMS

21.1 Inspection and certification systems for ensuring food and feed safety shall be designed and operated on the basis of objective risk assessment appropriate to the circumstances and based on current available scientific evidence.

21.2 Partner states shall ensure that they avoid arbitrary or unjustifiable distinctions in the level of risk deemed to be appropriate in different circumstances so as to avoid discrimination or a disguised restriction on trade.

21.3 Partner states shall apply consistent and transparent risk analysis to facilitate intra-regional, inter-regional and international food trade by increasing confidence in the food and feed safety and in the inspection systems by trading partners.

Partner states shall also enable inspection resources to be targeted effectively on hazards to public health arising at any stage of the food production and distribution chain.

21.4 Inspection and certification systems shall efficiently perform their task taking regard to costs to consumers and to the costs in money and time to the affected food or feed industry and government consulting with interested bodies as appropriate.

22 - EQUIVALENCE

22.1 Partner States shall recognise that different inspection/certification systems may be capable of meeting the same objective, and are therefore equivalent. The obligation to demonstrate equivalence rests with the exporting Partner State.

22.2 The voluntary utilization of quality assurance systems by food or feed businesses shall also be encouraged in order to achieve greater confidence in the safety and quality of products obtained. If safety and/or quality assurance tools are used by food or feed businesses, the official inspection and certification systems shall take them into account while retaining the fundamental responsibility of an official inspection and certification of ensuring conformity of foodstuffs or feedstuffs to requirements.

22.3 The recognition of equivalence of inspection and certification systems shall be facilitated where it can be objectively demonstrated that there is an appropriate system for inspection and certification of food or feed by the exporting Partner State.

22.4 For the determination of equivalence, Partner States governments shall recognize that:

- a) inspection and certification systems are organized for the risk involved, considering that the same food or feed commodities produced in different countries may present different hazards; and,
- b) control methodologies can be different but achieve equivalent results. For example, environmental sampling and the strict application of good agricultural practices, with limited end product testing for verification purposes, may produce a result equivalent to extensive end product testing for the control of agriculture chemical residues in raw products.

22.5 Controls on safety and quality of imported foods or feeds and domestically produced foods or feeds shall be designed to achieve the same level of protection.

The importing Partner State shall avoid unnecessary repetition of controls where these have been already validly carried out by the exporting Partner State. In these cases a level of control equivalent to domestic controls shall have been achieved at the stages prior to import.

22.6 The exporting Partner State shall provide access to enable the inspection and certification systems to be examined and evaluated, on request of the competent authorities of the importing Partner State.

22.7 Evaluations of inspection and certification systems carried out by the competent authorities of an importing Partner State shall take into account internal programme evaluations already carried out by the competent authority or evaluations performed by independent third-party bodies recognized by the competent authority in the exporting Partner State.

22.8 Evaluations of inspection and certification systems by an importing Partner State for purposes of establishing equivalence shall take account of all relevant information held by the competent authority of the exporting Partner State.

22.9 The application of equivalence principles may be in the form of agreements or letters of understanding established between Partner States either for inspection and/or certification of production areas, sectors or parts of sectors.

22.10 Equivalence may also be established through the administration of a comprehensive EAC agreement (regulations) which would cover inspection and certification of all food and feed commodity forms traded intra- and or inter-regionally.

22.11 Agreements on the recognition of equivalence of inspection and certification systems may include provisions concerning:

- a) the legislative framework, control programmes and administrative procedures;

- b) contact points in inspection and certification services;
- c) demonstration by the exporting Partner State of the effectiveness and adequacy of its enforcement and control programmes, including hard and soft laboratory infrastructure;
- d) where relevant, lists of products or establishments subject to certification or approval, accredited facilities and accredited bodies;
- e) mechanisms supporting continued recognition of equivalence, e.g., exchange of information on hazards and monitoring and surveillance.

22.12 Agreements shall include mechanisms to provide for periodic review and updating and include procedural mechanisms for resolving differences arising within the framework of the agreement.

23 - TRANSPARENCY

23.1 While respecting legitimate concerns to preserve confidentiality, the principles and operations of food or feed, inspection and certification systems shall be open to scrutiny by consumers and their representative organizations, and other interested parties.

23.2 Importing Partner States shall provide information on existing food or feed inspection and certification systems requirements and proposed changes to requirements shall be published and, except in the case of serious and immediate danger, an adequate time period permitted for comment.

23.3 The views of exporting Partner States shall be taken into account in taking a final decision. A reasonable period shall be allowed before a new requirement takes effect in order to permit exporting Partner States to make necessary changes to their food or feed inspection and certification systems.

23.4 Importing Partner States shall make available to the exporting Partner States, upon request, timely advice as to the basis of the decision they have taken regarding the compliance of foods with their relevant requirements.

23.5 Upon request by the competent authorities of the importing Partner States, the exporting Partner States shall provide access to view and assess the actual working of their relevant inspection and certification systems.

24 - CONTROL AND INSPECTION PROCEDURES

Importing Partner States shall complete without undue delay any procedures necessary to assess compliance with requirements. Information requirements and any fees imposed by importing Partner States shall be limited to what is reasonable and necessary.

25 - CERTIFICATION VALIDITY

Partner States that certify exports of food or feed and those importing Partner States which rely on export certificates shall take measures to assure the validity of certification. Validation

measures by exporting Partner States may include achieving confidence that official or officially recognised inspections systems have verified that the product or process referred to in the certificate conforms to requirements. Measures by importing Partner States may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate

26 - ELECTRONIC CERTIFICATION

26.1 Certification may be provided by electronic documentation sent directly from the exporting Partner State to the importing Partner State. Such system will also provide an interface with the commercial organisation marketing the commodity for provision of information to the certifying authority. The certifying authority must have access to all information such as laboratory results and animal identification data.

26.2 Electronic certificates may be in a different format but shall carry the same information as conventional paper certificates.

26.3 The certifying authority must have in place systems for the security of electronic certificates against access by unauthorised persons or organisations. The certifying authority must be officially responsible for the secure use of his/her electronic signature.

27 - INSPECTION AND CERTIFICATION SYSTEM INFRASTRUCTURE

27.1 Partner States shall identify the main objectives to be addressed through import and export inspection and certification systems.

27.2 Partner States shall have in place the legislative framework, controls, procedures, facilities, equipment, laboratories, transportation, communications, personnel and training to support the objectives of the inspection and certification systems.

27.3 Where different authorities in the same Partner State have jurisdiction over different parts of the food chain, conflicting requirements must be avoided to prevent legal and commercial problems and obstacles to trade. For example, while provincial or state laws may exist there shall be a competent authority at the national level capable of ensuring uniform application.

However, an importing Partner State competent authority may recognize a sub-national competent authority for purposes of inspection or certification where this arrangement is acceptable to the Partner State authorities concerned.

Legislative framework

27.4 For the purposes of this section, the effectiveness of controls related to foodstuffs or feedstuffs in Partner States depends on the quality and completeness of the legislation for foods or feeds safety. Legislation shall provide authority to carry out controls at all stages of production, manufacture, importation, processing, storage, transportation, distribution and trade.

27.5 Without prejudice to **Article 11**, food and feed safety legislation may also include provisions as appropriate for the registration of establishments or listing of certified processing

plants, establishment approval, licensing or registration of traders, equipment design approval, penalties in the event of non-compliance, coding requirements and charging of fees.

27.6 The competent authority in the exporting or importing Partner State shall have the ability to enforce and take action based on adequate legislation. It shall take all necessary steps to insure the integrity, impartiality and independence of official inspection systems and officially recognized inspection systems and to ensure that the inspection programme contained in national legislation is delivered to a prescribed standard.

Control programmes and operations

27.7 Control programmes help to ensure that inspection actions relate to objectives, since the results of these programmes can be assessed against the objectives set for the inspection and certification system. Inspection services shall draw up control programmes based on precise objectives and appropriate risk analysis. In the absence of detailed scientific research, control programmes shall be based on requirements developed from current knowledge and practice.

27.8 Every effort shall be made to apply risk analysis based on EAC or internationally-accepted methodology, where available. In particular, Partner States shall require or encourage the use of a HACCP approach by food or feed establishments. Official inspectors shall be trained in the assessment of the application of HACCP principles.

27.9 Where programmes include the drawing and analysis of samples, adequate sampling and appropriately validated analytical methods shall be established and used to ensure that the results are representative and reliable in relation to the specific objectives.

27.10 The elements of a control programme shall include, as appropriate:

- a) inspection/auditing;
- b) sampling and analysis;
- c) checks on hygiene, including personal cleanliness and clothing;
- d) examination of written and other records;
- e) examination of the results of any verification systems operated by the establishment;
- f) audit of establishments by the Partner State competent authority;
- g) national audit and verification of the control programme.

27.11 Administrative procedures shall be in place to ensure that controls by the inspection system are carried out:

- a) regularly in proportion to risk;
- b) where non-compliance is suspected;
- c) in a co-ordinated manner between different authorities, if several exist.

27.12 Controls shall cover, as appropriate:

- a) establishments, installations, means of transport, equipment and material;
- b) raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs and feedstuffs;
- c) semi-finished and finished products;
- d) materials and objects intended to come into contact with foodstuffs and feedstuffs;
- c) cleaning and maintenance products and processes, and pesticides;

- d) processes used for the manufacture or processing of foodstuffs and feedstuffs;
- e) the application and integrity of health, grading and certification marks;
- d) preservation methods;
- f) labelling integrity and claims.

27.13 The elements of the control programme shall be formally documented including methods and techniques.

Decision criteria and action

27.14 The controls programme shall be targeted at the most appropriate stages and operations, depending on the specific objectives. Control procedures shall not compromise the safety or quality of foods or feeds, particularly in the case of perishable products.

27.15 The frequency and intensity of controls by inspection systems shall be designed so as to take account of risk and the reliability of controls already carried out by those handling the products including producers, manufacturers, importers, exporters, and distributors.

27.16 Physical checks applying to import shall be based on risks associated with the importation. Partner States shall avoid systematic physical checks on imports except in justified cases such as products associated with a high level of risk; a suspicion of non-conformity for a particular product; or a history of non-conformity for the product, processor, importer or Partner State.

27.17 When physical checks are to be undertaken, sampling plans for imported products shall take into account the level of risk, the presentation and type of commodity to be sampled, the reliability of controls of the exporting Partner State and of those responsible for handling the product in the importing Partner State.

27.18 Where an imported product is found not to be in conformity, the resulting measures shall take into account the following criteria to ensure that any action is proportionate to the degree of public health risk, potential fraud or deception of consumers:

- a) repeated non-conformity in the same product or in the same category of products;
- b) history of non-conformity of those responsible for handling the products;
- c) reliability of checks made by the Partner State of origin.

27.19 The specific measures applied may be cumulative if necessary and may include:

In respect of the product not in conformity —

- a) requirement for the importer to restore conformity (e.g. where problems relate to labelling for consumer information and have no effect on inspection or health);
- b) rejection of consignments or lots, in whole or in part;
- c) in the case of potentially serious health risk, destruction of the product;

In respect of future imports —

- a) control programmes implemented by the importer or exporter to ensure problems do not reoccur;

- b) increased intensity of checks on categories of products identified as being not in conformity and/or the undertakings concerned;
- c) request for information and cooperation on the product or the category of products found not to be in conformity by the competent authorities in the Partner State of origin;
- d) on-site visits;
- e) in the most serious or persistent cases, imports from establishments or Partner States may be suspended.

27.20 Where possible, and upon request, the importer or their representative shall be given access by the relevant food control authority of the importing Partner State to a rejected or detained consignment and in the latter case, the opportunity to contribute any relevant information to assist the control authorities of the importing Partner State to make their final decision.

27.21 Where product is rejected, the following information shall be provided by the rejecting Partner State as available and appropriate to the circumstances:

Identification of the food or feed concerned

- a) Description and quantity of product
- b) Type and size of package
- c) Lot identification (number, production date, etc.)
- d) Container number, bill of lading or similar transportation details
- e) Other identification stamps, marks or numbers
- f) Certificate number
- g) Name and address of manufacturer, producer, seller and/or exporter, establishment number, as appropriate

Importation details

- a) Port or other point of entry
- b) Name and address of importer
- c) Date presented for entry

Details of rejection decision

- a) Whole/part of (specify) consignment rejected
- b) Name and address of food or feed competent authority making decision to reject
- c) Date of decision
- d) Name and address of food or feed competent authority (ies) which can provide more information on reason for rejection

Reason(s) for rejection

- a) Biological/microbiological contamination
- b) Chemical contamination (pesticide or veterinary drug residues, heavy metals, etc.)
- c) Radionuclide contamination
- d) Incorrect or misleading labelling
- e) Compositional defect

- f) Non-conformity with food additive requirements
- g) Organoleptic quality unacceptable
- h) Technical or physical defects (e.g., packaging damage)
- i) Incomplete or incorrect certification
- j) Does not come from an approved Partner State, region or establishment
- k) Other reasons

27.22. Where imported food has been rejected on the basis of sampling and/or analysis in the importing Partner State, details shall be made available on request as to sampling and analytical methods and test results and the identity of the testing laboratory.

Action taken

- a) Food destroyed
- b) Food held pending re-conditioning/rectification of deficiencies in documentation
- c) Food held pending final judgement
- d) Place where food is held
- e) Import granted for use other than human consumption
- f) Re-export granted under certain conditions, e.g. to specified informed Partner States or other trading countries
- g) Importer notified
- h) Embassy/food control authorities of exporting Partner State or other trading country notified
- i) Authorities in other likely destination Partner States or other trading countries notified
- j) Other

28 - FACILITIES, EQUIPMENT, TRANSPORTATION AND COMMUNICATIONS

28.1 Inspection staff shall have access to adequate facilities and equipment to undertake inspection procedures and methodologies.

28.2 Reliable transportation and communication systems are essential to ensure delivery of inspection and certification services when and where they are needed and for the transmission of samples to laboratories.

28.3 Communication facilities shall be provided to ensure adequate compliance action and to address potential recalls. Consideration shall be given to developing electronic information exchange systems, in particular to facilitate trade, protect consumer health, and to combat fraud.

Laboratories

28.4 Inspection services shall utilize designated laboratories under officially recognized programmes to ensure that adequate quality controls are in place to provide for the reliability of test results. Validated analytical methods shall be used wherever available.

28.5 Inspection systems' laboratories comply with *EAC Regulation for Designating Testing Laboratories* and shall, in particular be encouraged to apply the principles of internationally

accepted laboratory quality assurance techniques including compliance to ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories* to ensure the reliability of analytical results.

Personnel

28.6 Official inspection services shall have, or have access to, a sufficient number of qualified personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit and law.

28.7 Personnel shall be capable and appropriately trained in the operation of food safety inspection and control systems. They shall have a status which ensures their impartiality and have no direct commercial interest in the products or establishments being inspected or certified.

Certification Systems

28.8 An effective certification system depends on the existence of an effective inspection system and demand for certification shall be justified by risk to health or risk of fraud or deception.

28.9 Alternatives to certification shall be considered wherever possible, in particular where the inspection system and requirements of an exporting Partner State are assessed as being equivalent to those of the importing Partner State.

28.10 Bilateral or multilateral agreements, such as mutual recognition agreements or pre-certification agreements, may provide for dispensing with certification and/or the issuance of certificates which were previously required in certain cases.

28.11 Certification shall provide assurance of the conformity of a product or batch of products, or that a food safety inspection system conforms to specified requirements, and will be based, as appropriate, on:

- a) regular checks by the inspection service;
- b) analytical results;
- c) evaluation of quality assurance procedures linked to compliance with specified requirements;
- d) any inspections specifically required for the issuance of a certificate.

28.12 Competent authorities shall take all necessary steps to ensure the integrity, impartiality and independence of official certification systems and officially-recognized certification systems. They shall ensure that personnel empowered to validate certificates are appropriately trained and fully aware, if necessary from notes of guidance, of the significance of the contents of each certificate which they complete.

28.13 Certification procedures shall include procedures to ensure the authenticity and validity of certificates at all the relevant stages and to prevent fraudulent certification. In particular, personnel:

- a) shall not certify matters without their personal knowledge or which cannot be ascertained by them;

- b) shall not sign blank or incomplete certificates, or certificates for products which have not been produced under appropriate control programmes. Where a certificate is signed on the basis of another supporting document, the person signing the certificate shall be in possession of that document;
- c) shall have no direct commercial interest in the products being certified.

Official accreditation

28.14 Partner States may officially accredit inspection or certification bodies to provide services on behalf of competent authority (ies).

28.15 To be officially accredited, an inspection or certification body must be assessed against objective criteria like ISO 17020 - ***General Criteria for the Operation of Various Types of Bodies Performing Inspection*** and must comply at least with the standards set out in these guidelines, particularly in relation to the competence, independence and impartiality of personnel.

28.16 The performance of officially accredited inspection or certification bodies shall be regularly assessed by the competent authority. Procedures shall be initiated to correct deficiencies and, as appropriate, enable withdrawal of official accreditation.

28.17 A national system shall be subject to audit separate from routine inspection. Inspection and certification services shall be encouraged to carry out self-evaluation or have their effectiveness evaluated by third parties.

28.18 Self-assessment or third-party audits shall be carried out periodically at various levels of the inspection and certification system, using internationally-recognized assessment and verification procedures.

28.19 The inspection services of a Partner State may undertake self-assessment for such purposes as assuring the adequacy of consumer protection and other matters of national interest, improving internal efficiency or facilitating exports.

28.20 A prospective importing Partner State may undertake a review with the agreement of the exporting Partner State of the inspection and certification systems of an exporting Partner State as part of its risk analysis process, with a view to determining requirements for imports from that Partner State. Periodic assessment reviews may be appropriate following the commencement of trade.

28.21 For the purpose of assisting an exporting Partner State to demonstrate that its inspection or certification systems are equivalent, the importing Partner State shall make readily available adequate information on its system and its performance.

28.22 Exporting Partner States shall be able to demonstrate adequate resources, functional capabilities and legislative support in addition to effective administration, independence in the exercise of their official function and, where relevant, performance history.

29 - ASSESSMENT OF THE COMPETENCE OF TESTING LABORATORIES INVOLVED IN THE IMPORT AND EXPORT CONTROL OF FOOD AND FEED SAFETY AND QUALITY

29.1 Test laboratories involved in the import and export control of foods and feeds shall have a framework for implementation of quality assurance measures to demonstrate competence in the application of requirements for trade in foodstuffs and feedstuffs in order to protect the consumers' health and to facilitate fair trade.

29.2 Test laboratories shall comply with *EAC Regulation for Designating Testing Laboratories* and shall, in particular be encouraged to apply the principles of internationally accepted laboratory quality assurance techniques including adoption of the following quality criteria when involved in the import and export control of foods or feeds:

- a) Compliance with the general criteria for testing laboratories laid down in ISO/IEC 17025 *General requirements for the competence of calibration and testing laboratories*;
- b) Participation in appropriate proficiency testing schemes for food analysis which conform to the requirements laid down in *The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories* (Pure & Appl. Chem. 78 (2006) 145-196);
- c) Whenever available, use harmonized EAC methods of analysis or methods which have been validated according to the principles laid down by the Codex Alimentarius Commission; and
- d) Use internal quality control procedures, such as those described in the *Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories* (Pure & Appl. Chem. 67 (1995) 649-666).

29.3 The bodies assessing the laboratories referred to above shall comply with the general criteria for laboratory accreditation, such as those laid down in the ISO/IEC 58: *Calibration and testing laboratory accreditation systems - General requirements for operation and recognition*.

30 - MAXIMUM RESIDUE LIMITS (MRLs) FOR PESTICIDES AND VETERINARY DRUGS

30.1 Maximum Residue Limits (MRLs) for pesticides and veterinary drugs shall be based on Good Agricultural and Animal Husbandry Practice data and foods derived from commodities that comply with the determined MRLs are intended to be toxicologically acceptable.

30.2 MRL for a plant, egg or dairy product shall take into account the maximum level expected to occur in a composite sample, which has been derived from multiple units of the treated product and which is intended to represent the average residue level in a lot. A MRL set for meat and poultry shall also take into account the maximum level expected to occur in the tissues of individual treated animals (including fish) or birds.

31 - METHODS OF SAMPLING FOR THE DETERMINATION OF PESTICIDE AND VETERINARY DRUGS RESIDUES FOR COMPLIANCE WITH CODEX MAXIMUM RESIDUE LIMITS (MRLs)

31.1 Standardized and validated sampling procedures are necessary for enabling representative samples to be obtained from a lot, for analysis to determine compliance with acceptable Maximum Residue Limits (MRLs) for pesticides and veterinary drugs.

31.2 MRLs for meat and poultry shall apply to a bulk sample derived from a single primary sample, whereas MRLs for plant products, eggs and dairy products shall apply to a composite bulk sample derived from 1-10 primary samples.

32 - REGISTERING PESTICIDES AND VETERINARY DRUGS

32.1 Pesticides and veterinary drugs must be registered or exempted by Competent Authorities before they may be sold or distributed in EAC. Once registered, a pesticide and veterinary drugs shall not legally be used unless the use is consistent with the approved directions for use on the pesticide's or veterinary drugs label or labelling.

32.2 Competent Authorities shall initiate registration of pesticide by considering among others, the active ingredient(s); the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. Pesticide shall be evaluated to ensure that it will not have adverse effects on humans, animals, the environment and non-target species.

32.3 Competent Authorities shall initiate registration of veterinary drugs by considering the evaluation of the safety of the active ingredient; the pharmacokinetics of the final formulation, Safety of target animal (including fish) and the presence of residues (active ingredient/metabolite) in meat, offal, eggs, milk, and/or honey.

32.4 Manufacturers shall sell in the EAC pesticides and veterinary drugs which have been thoroughly evaluated by the Competent Authority to ensure that they meet EAC safety standards to protect human health and the environment. Competent Authority shall grants a "registration" or license that permits a pesticide's or veterinary drugs distribution, sale, and use only after the company meets the scientific and regulatory requirements.

32.5 Potential registrants must generate scientific data necessary to address the identity, composition, potential adverse effects, and environmental fate of each pesticide or veterinary drug. The data will allow the Competent Authority to evaluate whether a pesticide or veterinary drug has the potential to cause harmful effects on certain non-target organisms and endangered species including contamination of surface or ground water

32.6 The Competent Authorities shall develop test guidelines to be followed by the pesticide or veterinary drug registrant in conducting tests for generating the scientific data.

SECTION 6: EAC FOOD SAFETY SCIENTIFIC COMMITTEE (FSSC)

33 - MISSION OF THE SCIENTIFIC COMMITTEE

33.1 EAC Food Safety Scientific Committee (FSSC) is hereby established under the EAC SPS Protocol and the EAC Protocol Establishing the EAC Commission for Medicines and Food Safety; in short ‘the Scientific Committee’.

33.2 The Scientific Committee shall provide scientific advice and scientific and technical support for the EACs sanitary and phytosanitary measures and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks.

33.3 The Scientific Committee shall contribute to a high level of protection of human life and health, and in this respect take account of animal health, plant health and the environment, in the context of the operation of the EAC Common Market.

33.4 The Scientific Committee shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.

33.5 The mission of the Scientific Committee shall also include the provision of:

- (a) scientific opinions on other matters relating to animal and plant health as they relate to food safety management; and
- (b) scientific opinions on products other than food and feed relating to genetically modified organisms

33.6 The Scientific Committee shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of EAC measures in the fields falling within its mission.

33.7 The Scientific Committee shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it. It shall act in close cooperation with the competent bodies in the Partner States carrying out similar tasks to these of the Scientific Committee.

33.8 The Scientific Committee and competent bodies in the Partner States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.

34 - COMPOSITION OF THE SCIENTIFIC COMMITTEE

34.1 The Scientific Committee shall be composed of representatives from the Competent Authorities in the Partner States which undertake tasks similar to those of the Scientific Committee, on the basis of one representative designated by each Partner State. Representatives may be represented by alternates, appointed at the same time.

34.2 The Scientific Committee shall elect a chairperson and a vice-chairperson during its first meeting. Holding of these positions shall be for a term of three years and rotation among Partner States.

34.3 Experts can, as deemed necessary, be invited by the Scientific Committee in their individual capacities to offer their expertise on relevant issues in any meeting.

35 - FUNCTIONS OF THE SCIENTIFIC COMMITTEE

35.1 The functions of the Scientific Committee shall be the following:

- (a) to provide the EAC institutions and the Partner States with the best possible scientific opinions in all cases provided for by Partner State measures and on any question related to food and feed safety;
- (b) to promote and coordinate the development of uniform risk assessment methodologies for food and feed safety;
- (c) to provide scientific and technical interpretation and consideration of risk assessment opinions from EAC trade partners;
- (d) to identify and commission scientific studies necessary for ensuring safety of foods and feeds in the EAC;
- (e) to establish Ad-hoc Scientific Sub-committees when and as deemed necessary;
- (f) to search for, collect, collate, analyse and summarise scientific and technical data in the fields of food and feed safety;
- (g) to undertake action to identify and characterise emerging and re-emerging food and feed safety risks;
- (h) to establish a system of networks of organisations in the EAC operating in the fields of food and feed safety and be responsible for their operation;
- (i) to provide scientific and technical assistance when requested, to Partner States with a view to improving cooperation between the EAC, international organisations and trading partners in the fields of food and feed safety;
- (j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields of food and feed safety;

36 - MEETINGS AND WORKING PROCEDURES OF THE SCIENTIFIC COMMITTEE

The Scientific Committee shall define the frequency of holding meetings and also its working procedures in its first meeting.

37 - Establishment of Ad Hoc Scientific Sub-committees

37.1 Ad Hoc Scientific Sub-committees will be formed to discuss and to give scientific recommendations on specific food or feed safety concerns. The members of these Ad Hoc Scientific Sub-committees will be chosen from the EAC by the Scientific Committee according to their scientific knowledge and experience on the issues to be addressed.

37.2 The Scientific Committee will appoint a Chairperson; define the Terms of Reference, the timeframe and reporting requirements for the Ad Hoc Scientific Sub-committees

38 - Budgeting and funding of the Scientific Committee

8.1 Budgeting and funding for the Scientific Committee shall be by the EAC Secretariat through normal EAC budgeting.