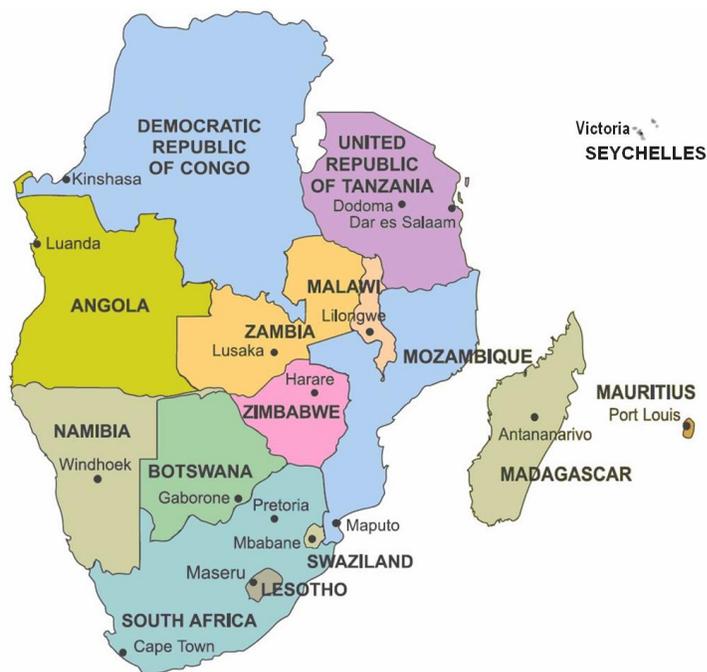




REGIONAL GUIDELINES FOR THE REGULATION OF FOOD SAFETY IN SADC MEMBER STATES

November 2011

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TERMS AND DEFINITIONS

For the purpose of these SADC Food safety management Regulations Guidelines, the following terms and terminologies, in addition to Terms and Definitions stated in the SADC SPS Annex to the Trade Protocol, shall apply.

'audit' - a systematic and functionally independent examination to determine whether activities and related results comply with planned food safety management objectives.

'certification' - the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods or food safety management 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 Governmental Authority having the responsibility and competence for ensuring food safety. This can be the veterinary authority, plant health authority or food safety authority as provided for in the food legislation, taking into account the farm to table food continuum. Such authorities may also be the ones recognized under OIE, Codex and IPPC.

'emerging disease' - 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' - the capability of different inspection and certification systems to meet the same objectives.

'equivalence of phytosanitary measures' - situation whereby an importing contracting party recognises alternative phytosanitary measures proposed by exporting contracting parties as equivalent when those measures are demonstrated to achieve the appropriate level of protection determined by the importing contracting party.

'equivalence of sanitary measures' - the state wherein the sanitary measure(s) proposed by the exporting country as an alternative to those of the importing country, achieve(s) the same level of protection.

'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 jurisdiction.

'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 after the point of potable), 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 ; and
- (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 safety management legislation are met within the food business under their jurisdiction

'food legislation' - the laws, regulations and administrative provisions governing food in general, and food safety management system in particular, whether at regional or member states level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food producing animals or animals for feeding food producing animals.

'food safety management 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 medicinal product' - the official recommended or authorized usage including withdrawal periods, approved by competent veterinary authority 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 country' - a country 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/or feedstuffs and covering the protection of public health, the protection of consumers and conditions of fair trading.

'maximum residue limit for veterinary medicinal products' - the maximum concentration of residue resulting from the use of a veterinary medicinal product (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.

'official accreditation' - the procedure by which a competent authority formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services.

'official certification systems' - are certification systems administered by the competent authority having jurisdiction empowered to perform a regulatory or enforcement function or both.

'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’ - 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 aquaculture, hunting, fishing and the harvesting of wild products.

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

‘residues of veterinary medicinal products’ – residues of the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary medicinal product 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’ - a process consisting of three interconnected components: 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. From the plant protection context, **‘risk assessment’** is defined as the evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country.

‘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, food and feed 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;

'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' - is 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 medicinal product' - 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 .

'withdrawal time and withholding time' - the period of time between the last administration of a medicinal product 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 this medicinal product.

PREFACE

The development of these guidelines has involved extensive consultations processes which included Member States and relevant stakeholders. These have been recommended for use by Member States in developing their specific regulations by Ministers responsible for Agriculture and Food Security.

The implementation of these regional guidelines will help to harmonise the regulations related to compliance of Sanitary and Phytosanitary (SPS) measures, including food safety, across the region. This will contribute to increased regional food security and trade opportunities.

I, therefore, urge all relevant stakeholders to embrace the implementation of these guidelines, in order to take full benefit of the greater trade in food and agricultural products in the region.

Tomaz Augusto Salomão
Executive Secretary
SADC Secretariat

1 INTRODUCTION

Sanitary and Phytosanitary measures as detailed under the World Trade Organization (WTO) Sanitary and Phytosanitary Measures Agreement (SPS) have become a major issue for global trade in agricultural and food products. The SPS measures relate to food safety management and animal and plant health. SPS measures are of concern in that they affect trade flows and the ability of developing countries to gain and or maintain access to markets for higher-value agricultural and food products, especially in industrialized countries. This concern is typically greatest for low-income countries that tend to have weak SPS management capacities that can thwart efforts towards export-led agricultural diversification and rural development.

The Southern African Development Community (SADC) 15 Member States (Angola, Botswana, Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe) are among the countries with agricultural sector, which is the base of their economies, constrained with the lack of access to international markets partly due to difficulties in complying with SPS measures.

The agricultural sector in the SADC Member States accounts for a large share of their gross domestic product (GDP), ranging from 2.7% in Botswana to about 56.3% in DRC and employing a large proportion of the labour force (14-85%). About 70% of the population of SADC depends on agriculture for food, income and employment. Agriculture is also the dominant source of exports in many of the countries, on average contributing about 13% to total export earnings and about 66% to the value of intra-regional trade. These countries, have as a result of inability to meet the SPS measures, seen a decrease in their agricultural export value of preferential market access offered by the EU or under the US Africa Growth Opportunities Act (AGOA).

Recognition of the SPS management capacity constraints faced by SADC and other developing countries has served to highlight the role of technical assistance and other capacity-building support, both from bilateral donors and multilateral development agencies. While technical assistance has always been directed at overcoming acute compliance problems often in the context of actual or potential trade problems and disputes, increasing attention is being given to the need for a more strategic focus that enhances fundamental food safety management and animal and plant health management capacity and enables developing countries like SADC countries to be more 'proactive' in their responses to existing and evolving SPS measures in global trade.

2 FOOD SAFETY REGULATORY FRAMEWORKS AT NATIONAL AND SADC REGIONAL LEVEL

A needs assessment done in the SADC Region back in 2006 identified, among others, that food safety management control systems and food safety management policies are weak and poorly coordinated, particularly where a number of Government departments are involved.

More recently, a Stakeholder Regional Assembly on Food safety management - held under the auspicious of the Project in Gaborone, Botswana from 10 to 13 August 2009, SADC Member

States advocated for the development of relevant common guidelines for plant health, animal health and food safety management legislation/standards.

This paper presents a response from the Project of providing technical support to SADC Secretariat and Member States in Drafting of Regional Guidelines for Food Safety Management.

3 REGIONAL GUIDELINES FOR FOOD SAFETY MANAGEMENT

Food safety management is increasingly becoming a global challenge both by virtue of its public health impact as well as its economic and political implications. Food safety management is no longer considered solely as a domestic entity or the responsibility of a single government ministry. It involves relevant government agencies, industry, academia, researchers and consumer representatives as well as other stakeholders along the food production continuum.

Food safety regional guidelines provide a framework to assist the region and member states in the development and operation of regional and national food safety management systems. Such systems are intended to ensure that requirements for food, and the associated production systems, achieve or contribute to the achievement of the protection of the health of consumers and ensuring fair practices in the food trade.

Food safety framework shall have the recognition by the highest political level in the region or in the member states in the form a food safety management policy. Such food safety management policy shall provide direction to all stakeholders in establishing and implementing food safety management measures, through collaborative efforts to safeguard human health. The Policy shall also address food safety management throughout the food production continuum and require multi agency and multi disciplinary collaboration and cooperation involving relevant government agencies, food industries, consumers, the scientific community and others. The policy shall also clearly recommend for a science-based approach to food safety management and the application of the Hazard Analysis and Critical Control Point (HACCP) food safety management system to food production.

Essential elements of a food safety management policy will include food safety management infrastructure, food safety management legislation, inspection and enforcement services, food laboratory, ICT, scientific information gathering and analysis, product tracing, management of food safety management crisis, management systems for food safety management assurance, education on food safety management, safety of imported and exported foods, novel foods and technologies and participation in international food safety management fora.

All these elements, when effectively addressed and implemented at regional or member states level would then constitute an effective food safety management system.

The role of animal feed in the production of safe food is currently recognized worldwide and recent events have underlined its impacts on public health, food and feed trade and food security. Concerns prompted by the outbreak of bovine spongiform encephalopathy (BSE) in the United Kingdom, and other more common food problems associated with Salmonella, enterohaemorrhagic *Escherichia coli* and other micro-organisms, have encouraged food safety management regulators, health professionals and the feed industry to work closely in prevention

of these diseases. Food safety management policy shall therefore aim at ensuring the safety of food for human consumption through adherence to good animal feeding practice at the farm level and good manufacturing practices (GMPs) during the procurement, handling, storage, processing and distribution of animal feed and feed ingredients for food producing animals.

WHO has estimated that every year, there are about 4 billion cases of diarrhoea worldwide which result in deaths of about 2.2 million people. Given the use of water at various stages of the food production continuum, any food safety management policy shall advocate for measure to be taken to ensure safety of water for use in production of food and feed.

4 FOOD SAFETY LAW

A food safety law shall detail operational requirements for all the elements of the food safety management policy. That is, it will give concrete answers to questions in relation to the different stages/steps along the food production continuum of when, where, what, how and by whom. And as these questions are being addressed, close collaboration and cooperation among all stakeholders along the food production continuum, clearly defined jurisdiction and responsibilities, mechanism of cooperation and means of dealing with existing and emerging food safety management challenges will invariably be dealt with. Equally important would be the allocation and utilization of resources such as manpower and finance in a coordinated manner in order to achieve optimal results.

To ensure that the food safety management policy and food safety law are effectively implemented, there will be a need for establishment of coordinating body(ies) at the region and in member states. At the regional level, Article 14, 6(l), of the SPS Annex to the Protocol on Trade, requires the SADC Sanitary and Phytosanitary Coordinating Committee to establish Food Safety Expert Working Group¹, which will be responsible for all regional issues related to food safety management system. Again, under the same provision, there is requirement for establishment of Ad Hoc Technical Groups to discuss specific technical issues and to give scientific recommendations and actions on specific areas.

At the member state level however, there are different setups in terms of lead ministries insofar as coordination and implementation of food safety laws are concerned. Ideally, since improper food safety management will have effect on human health through direct consumption or as resulting from food imports, the ministry of health shall be the lead ministry.

It is also advised to establish a National Food safety management Committee, Council or Forum as a multi- sectoral forum to develop clear national food safety management policies and strategies for the continuous improvement of the food safety management system. It shall involve relevant government agencies, industry and consumer representatives as well as other stakeholders along the food production continuum.

This paper is an attempt to present a *Draft SADC Regional Guidelines for the Regulation of Food safety* for discussion in a SADC regional workshop and subsequent adoption by SADC Council of Ministers as *SADC Regional Guidelines for the Regulation of Food safety*. These guidelines when implemented at the regional and member states levels will contribute to the harmonisation

¹ Article 14, 6(l), of the SPS Annex to the Protocol on Trade, which requires the SADC Sanitary and Phytosanitary Coordinating Committee

of SPS measures in the SADC region such ensuring consumer health protection and promotion of smooth trade of agro-food products.

These *Draft SADC Regional Guidelines for the Regulation of Food Safety* are organized in three parts, Part I defines the different terms and terminologies used in the body of the guidelines while Part II is the proposed Guidelines for Regional Food Safety Policy. Part III is the proposed Guidelines for Regional Food Safety Law.

In the drafting of these guidelines reference was made to Codex Guidelines CAC/GL (19, 20, 25, 26, 27, 33, 34, 40, 45, 46, 47, 53, 62, 63 and 71)² and CAC/RCP 54-2004³.

5 OVERVIEW OF FOOD SAFETY MANAGEMENT IN SADC

1. Food safety management policy guidelines provide a framework to assist national governments in the development and operation of a national food safety management system. Such systems are intended to ensure that requirements for food, and the associated production systems, achieve or contribute to the achievement of the protection of the health of consumers and ensuring fair practices in the food trade. National authorities may apply these guidelines, where appropriate, according to their particular situations.

2. Food safety management in SADC region is a responsibility shared among different government institutions in the 15 Member States (Angola, Botswana, Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe). Such shared responsibility is mandated under laws which have differences in relation to concepts, principles and procedures between Member States to the extent of possible impediment of free movement of food and creation of unequal conditions of competition thereby directly affecting the functioning of the internal market.

3. Different food legislations and uncoordinated food safety management responsibilities between the government food safety management institutions coupled with weak human and infrastructure resources have far reaching negative consequences on health and well-being of citizens of the region, and to their social and economic interests.

4. The region has also not realized the full advantage and potential of the agricultural sector due to failure to access international markets, partly due to difficulties in complying with the Sanitary

²CAC/GL 19-1995 rev. 1 2004 Guidelines for the Exchange of Information in Food Control Emergency Situations
CAC/GL 20-1995 Principles for Food Import and Export Certification and Inspection
CAC/GL 25-1997 Guidelines for the Exchange of Information between Countries on Rejections of Imported Foods
CAC/GL 26-1999 Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems
CAC/GL 27-1997 rev. 1 2006 Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods
CAC/GL 33-1999 Recommended Methods of Sampling for Pesticide Residues for the Determination of Compliance with MRLs
CAC/GL 34-1999 Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems
CAC/GL 40-1993 rev. 1 2003 Analysis of Pesticide Residues: Guidelines on Good Laboratory Practice in Pesticide Residue Analysis
CAC/GL 45-2003 rev. 1 2008 Guideline for the Conduct of Food safety management Assessment of Foods Derived from Recombinant-DNA Plants
CAC/GL 46-2003 Guidelines for Food Import Control Systems
CAC/GL 47-2003 rev. 1 2006 Guidelines for Food Import Control Systems
CAC/GL 53-2003 rev. 1 2008 Guidelines on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems
CAC/GL 63-2007 Working Principles for Risk Analysis for Food safety management for Application by Governments
CAC/GL 63-2007 rev. 1 2008 Principles and Guidelines for the Conduct of Microbiological Risk Management
CAC/GL 72-2009 Guidelines For The Design And Implementation Of National Regulatory Food safety management Assurance Programme Associated With The Use Of Veterinary Drugs In Food Producing Animals

³ Adopted 2004. Amendment 2008. CODE OF PRACTICE ON GOOD ANIMAL FEEDING CAC/RCP 54-2004

and Phytosanitary (SPS) measures as specified in World Trade Organization's (WTO) Agreement on SPS. It is for the same reason that the region is witnessing decreases in value of preferential market access offered by the EU or under the US Africa Growth Opportunities Act (AGOA) for certain agricultural products.

5. One of the reasons for the concerns pointed above is the lack of food safety management policy guidelines at both regional and individual member states' levels. In many of the member states, there is formulation and implementation of agricultural policies, which are essentially directed at higher production, which leads to increased yield per unit of area of land under cultivation with intention of making the countries food secure. There are no stand-alone food safety management policies, although some elements are embedded in some of the Agricultural Policies only insofar as they relate to increased crop cultivation and yield.

6. These regional food safety management policy guidelines are aimed at ensuring that the region takes maximum advantage of the great potential for effective collaboration among the Member States in coming up with sustainable food safety management policies and work to implement a regional plan to address the food safety management concerns of the region. These guidelines focus on principles of assuring food safety and quality through an integrated, multidisciplinary approach considering the whole of the food chain.

6 CONCEPT OF THE FOOD PRODUCTION CONTINUUM

7. Food safety management and quality are best assured by an integrated, multidisciplinary approach, considering the whole of the food chain from the primary production to the final consumer. Eliminating or controlling food hazards at source, i.e. a preventive approach, is more effective in reducing or eliminating the risk of unwanted health effects than relying on control of the final product, traditionally applied via a final 'quality check' approach. Approaches to food safety management have evolved in recent decades, from traditional controls, to more targeted food safety management systems based on good practices (Good Agricultural Practice, Good Hygienic Practice, Good Veterinary Practices, etc.), hazard analysis and critical control points (HACCP) risk-based approaches using food safety management risk analysis.

8. In order to take a sufficiently comprehensive and integrated approach to food safety management, there shall be a broad definition of food safety management legislation covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production.

9. Use has to be made of modernized legislative framework as the instrument for capacity building and for the protection of foods against biological, chemical and physical hazards and their associated risks.

New legislations would address key issues of food safety, animal and plant health required under the SPS Agreement and ensure compliance with international standards and guidelines such as published by the Codex Alimentarius Commission (Codex), the World Animal Health

Organization (OIE) and the International Plant Protection Convention (IPPC) or other international regulatory requirements as detailed in the International Health Regulations (IHR).

10. Provisions have to be made in food safety management legislations for competent authorities to use preventive and control measures to reduce the risks often associated with food contaminants or other hazards and which if not controlled, may give rise to food-borne diseases and illnesses. Such provisions might include:

- (a) the establishment of competent veterinary, food safety management and plant health authorities;
- (b) supporting administrative bodies or councils;
- (c) the appointment of key enforcers and with clearly defined administrative and regulatory functions;
- (d) restrictions of the importation and exportation of animals and/or plants and their-related products.
- e) strengthening capacities for Port Health Surveillance taking into consideration of the International Health Regulations

11. Within the context of food safety management it is appropriate to include requirements for feed, including its production and use where that feed is intended for food-producing animals. This is without prejudice to similar requirements which would have been applied so far and which will be applied in the future in feed legislation applicable to all animals, including pets.

12. Similarly, it is appropriate to include requirements for residues of veterinary drugs, pesticides and of other agricultural inputs in food safety management control programmes as determined by the importance of the various health risks that could be incurred by consumers of products derived from animal food products.

13. Water is ingested directly or indirectly like other foods, thereby contributing to the overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants as such, a food safety management system shall consider water safety and quality.

7 OBJECTIVES OF THE FOOD SAFETY MANAGEMENT POLICY GUIDELINES

14. The objectives of these regional policy guidelines are to:

- a) assure a high level of protection of human life and health in the pursuit of regional policies;
- b) assure the free movement of safe and wholesome food as an essential aspect of the regional market and to contribute significantly to their social and economic interests;
- c) ensure that national food safety management requirements do not differ significantly from Member State to Member State to the extent of impeding free movement of food within the region; and

- d) ensure that all the institutions in the Member States having mandates related to food safety management work together and collaborate with the private sector including producers, academia, research organizations and any other relevant stakeholders to ensure coordination and long-term sustainability of safety, quality and profitability of the food produced in the region.

8 ESSENTIAL ELEMENTS OF A FOOD SAFETY MANAGEMENT SYSTEM

15. A food safety management system shall be supported by the necessary legislative framework, controls, procedures, facilities, equipment, laboratories, transportation, information, communication, education, personnel and training.

16. A food safety management system shall avail itself of accurate and current information on food production systems which shall include, but not be limited to:

- a) statistical data on production, trade and consumption;
- b) knowledge of operators at various stages of the food chain;
- c) typical and atypical use of products, raw materials and by-products;
- d) structure of production and supply chains; and
- e) production technologies, processes and practices.

17. A food safety management system shall have mechanisms in place to continuously update, review and analyse the above mentioned information. Such system shall also have mechanisms to adapt to changes in the production environment, and respond and intervene where/as required in the food safety management system to ensure the protection of health of consumers and of fair practices in trade.

18. Food safety management system shall be able to detect and respond to emerging risks and identify trends and patterns based on data collected. This should consider risks arising from GMO products, as well as natural contaminants such as mycotoxins. To that end, a food safety management system shall have:

- a) monitoring and surveillance programs for disease and hazards, as appropriate;
- b) mechanisms to identify emerging risks, in particular, factors indicating increased risk of noncompliance due to commercial incentives;
- c) mechanisms to implement control actions proportionate to risks and targeted to cover high risk areas; and
- d) efficient use of resources by means of risk categorisation⁴ and adjusting the intensity and/or frequency of controls according to risk category in line with the guidelines issued by Codex Alimentarius.

19. The food safety management system shall possess the capacity to undergo continuous improvement. This requires:

- a) mechanisms to evaluate the effectiveness of the current system by means of self-assessments, internal and/or external audits;

⁴ CAC/GL 63-2007 Working Principles for Risk Analysis for Food safety management for Application by Governments

- b) mechanisms to design and implement effective corrective actions to address areas for improvement; and
- c) verification, maintenance and improvement/performance assessment (internal and external audits), import country findings, results of foreign assessments and domestic food safety management data.

20. Clearly defined and transparent legislation shall be developed which authorizes the establishment of the competent authority(ies) and food safety management requirements.

21. As appropriate, clearly defined and transparent legislation and operating procedures shall be developed which allow for the establishment of the competent authority(ies) and the processes and procedures required to verify the conformity of products against requirements.

22. Uniformity of operational procedures is particularly important. Programmes and training manuals shall be developed and implemented to ensure uniform application.

23. A food safety management system shall be developed and implemented to ensure uniform application by the competent authority(ies), including provisions for their effective collaboration.

9 INFRASTRUCTURE, PROGRAMS AND REQUIREMENTS FOR EFFECTIVE FOOD SAFETY MANAGEMENT SYSTEM

24. The competent authority(ies) involved at different levels of food safety management system must collaborate effectively and shall have clearly defined responsibilities and authorities, and ensure adequate resources and structures are available for the operation of an effective and efficient food safety management system.

25. Roles and responsibilities of the competent authority(ies) shall be well defined to avoid conflict of interests, multiple inspections, investigations and duplication of testing and to avoid gaps in the production to consumption continuum.

26. Food safety management systems shall meet a number of operational criteria so as to ensure their impartiality and effectiveness and in particular have, or have access to, a sufficient number of qualified and experienced personnel as appropriate in areas such as (but not limited to): food science and technology, nutrition (human and animal), environmental health, chemistry, biochemistry, microbiology, toxicology, veterinary science, human medicine, epidemiology, plant health, agronomic engineering, quality assurance, audit, IEC and law.

27. Personnel shall be capable and appropriately trained in the operation of food safety management systems. Staff shall have access to adequate resources (including facilities and equipment) to undertake necessary procedures and methodologies.

28. Appropriate and reliable transportation and communication systems are essential to ensure delivery of services and goods.

29. Food safety management systems shall utilize laboratories that are evaluated and/or accredited under officially recognized programs 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. Laboratories shall apply the principles of internationally accepted management techniques to ensure the reliability of analytical results.

30. The food industry is responsible for developing and managing systems to ensure that the food supplied complies with the requirements set by the competent authority(ies). The food business operator has primary responsibility for food safety.

31. The competent authority(ies) retains the fundamental responsibility to verify and provide assurances as to the conformity of food and the associated production with prescribed requirements. The competent authority(ies) retains the fundamental responsibility to ensure the effective operation of the food safety management system and shall be free of improper or undue influence when implementing this responsibility.

10 LEGISLATIVE FRAMEWORK

32. Clearly defined and transparent food safety management legislation shall be developed to afford appropriate level of health protection and to apply in a non-discriminatory manner whether food or feed is traded in-country, on the regional market or internationally. Such legislation shall also provide for the establishment of the competent authority(ies) and food safety management requirements.

33. The competent authority(ies) shall be responsible for developing the legislation that applies to all parts of the food chain and for verifying that industry operates acceptable systems that ensure compliance with the relevant requirements, and when required, taking appropriate enforcement action.

34. It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food safety management legislation, its scientific basis and the structures and independence of the institutions protecting health and other interests.

35. Food safety management legislation shall provide for measures aimed at guaranteeing that safe food is placed on the market and at ensuring that systems exist to identify and respond to food safety management problems in order to ensure the proper functioning of the regional market and to protect human health. Similar issues relating to feed safety shall be addressed.

36. In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety management.

37. Aspects shall be considered of the production, manufacture, transport, storage and distribution of feed given to food-producing animals, including the production of animals which

may be used as feed on aquaculture farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.

11 DESIGN AND DEVELOPMENT OF A FOOD SAFETY MANAGEMENT SYSTEM

38. The design and operation of a food safety management system shall be based on risk and fully documented, including a description of its scope and operation, responsibilities and actions for staff, in order that all parties involved know what is expected of them. Documented procedures assist in ensuring that the controls are carried out consistently and uniformly.

39. Documentation of a food safety management system shall include but not be limited to:

- a) an organizational chart of the official control system;
- b) roles of each level in the hierarchy (including other relevant jurisdictions i.e., State, Provincial);
- c) job functions/descriptions as appropriate;
- d) operating procedures including methods of sampling, control and testing;
- e) relevant legislation and requirements;
- f) important contacts;
- g) relevant information about food contamination;
- h) procedures for conducting food recalls and investigations; and
- i) relevant information on staff training.

40. Requirements, including food regulations, standards and codes of practice shall be based on sound science, developed using risk analysis principles and to the extent possible, be consistent with international standards where such requirements achieve the appropriate level of protection established by the competent authority(ies).

12 RISK ANALYSIS

41. Food safety management measures developed to govern food and feed safety shall generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. Recourse to a risk analysis prior to the adoption of such measures shall facilitate the avoidance of unjustified barriers to the free movement of foodstuffs and feedstuffs.

42. Where a food safety management measure developed is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis — risk assessment, risk management, and risk communication — provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health. Risk assessments shall be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data to ensure confidence in the scientific basis.

43. In some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision could be based, and that other factors relevant to the matter under

consideration shall legitimately be taken into account including technological, societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

13 PRECAUTIONARY PRINCIPLE

44. The precautionary principle may be invoked to ensure health protection in the region. In order to ensure that it does not give rise to barriers to the free movement of food or feed, it is necessary to apply the principle in accordance with the provisions of the SPS/WTO Agreement.

45. In such specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure health protection and allow the free movement of food and feed.

14 ETHICAL FOOD TRADING

46. Food safety management and the protection of consumer's interests is of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. It is necessary to ensure that consumer confidence and the confidence of trading partners is secured through the open and transparent development of a food safety management system and through competent authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.

47. The safety and confidence of consumers within and outside the region are of paramount importance. As the region develops into a global trader in food and feed and, in this context, it would enter into international trade agreements, contributes to the development of international standards which underpin food legislation. It would support the principles of free trade in safe feed and safe wholesome food in a non-discriminatory manner, following fair and ethical trading practices.

48. It is necessary to ensure that food and feed exported or re-exported from the region comply with food safety management legislations based on HACCP principles or the requirements set up by the importing country. In other circumstances, food and feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.

49. It is necessary to establish the general principles upon which food and feed may be traded and the objectives and principles for the contribution of the region to developing international standards and trade agreements.

50. Some Member States have adopted horizontal legislation on food safety management imposing, in particular, a general obligation on economic operators to market only food that is safe. However, these Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other

Member States, barriers to trade in foods are liable to arise. Similarly such barriers may arise to trade in feed.

It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the trade within the region in such products functions effectively.

15 TRACEABILITY

51. Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety management problems.

52. It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.

53. A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it shall have primary legal responsibility for ensuring food safety, in line with HACCP principles. Although this principle exists in some Member States and areas of food legislation, in other areas this is either not explicit or else responsibility is assumed by the competent authorities of the Member State through the control activities they carry out. Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.

54. A food business operator shall make its food safety management system, including its traceability system, available to the competent authority for inspection at all times. The competent authority shall have the power to take legally acceptable action on any food business operator who contravenes food safety regulations. This may include forfeiture and appropriate disposal of food found unfit for human consumption.

16 INSPECTION AND CERTIFICATION SYSTEMS

54. Food inspection and certification systems shall be developed and used wherever appropriate to ensure that foods, and their production systems, meet requirements in order to protect consumers against food-borne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate product description. Inspection and certification systems shall be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required.

55. Food import rejections caused by failure to comply with importing country requirements and cover all types of foods shall be communicated in a structured information exchange system.

56. A framework for the development of import and export inspection and certification systems shall be put in place to assist Member States in the application of requirements and the determination of equivalency. This will protect consumers and facilitate trade in foodstuffs and help build and maintain the necessary confidence in the inspection and certification system of an exporting country so as to facilitate fair trade, taking account of the expectations of consumers for an appropriate level of protection. Similar requirements shall apply to feed and feed business operators.

17 SCIENTIFIC AND TECHNICAL CAPACITY

57. The scientific and technical basis of the legislations in the region relating to the safety of food and feed shall contribute to the achievement of a high level of health protection within the region. The region shall have access to expert, independent and efficient scientific and technical support.

58. The scientific and technical issues in relation to food and feed safety are becoming increasingly important and complex. The establishment of ad-hoc Technical Groups under the SADC Food Safety Expert Working Group, (FSEWG) shall provide the necessary scientific and technical support needed for ensuring the safety of food and feed produced and traded in and from the region.

59. Pursuant to the general principles of food law, the ad-hoc Technical Groups shall take on the role of an independent scientific point of reference in risk assessment and in so doing shall assist in ensuring the smooth functioning of the regional market. They may be called upon to give opinions on contentious scientific issues, thereby enabling the SADC institutions and Member States to take informed risk management decisions necessary to ensure food and feed safety whilst helping avoid the fragmentation of the regional market through the adoption of unjustified or unnecessary obstacles to the free movement of food and feed.

The Terms of Reference for the ad-hoc Technical Groups form an Annex to the FSEWG Terms of Reference.

18 FOOD EMERGENCIES AND RAPID ALERT SYSTEM

60. When a food safety management emergency arises, in order to minimize potential adverse public health effects, it is essential to communicate the nature and extent of the food safety management problem to all relevant parties as expeditiously as possible. This must be done in a manner that avoids unwarranted action against other foods from the same or other Member States or trade partners, which are not involved in the emergency situation. The global nature of food trade requires that this communication occur between nations at the appropriate government level.

61. Food safety management incidents experienced worldwide have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed shall be subject to common measures in the event of a serious risk to human health, animal health or the environment. Such a comprehensive approach to emergency

food safety management measures shall allow effective action to be taken and avoid artificial disparities in the treatment of a serious risk in relation to food or feed.

62. Food crises have also shown the benefits of having in place properly adapted rapid procedures for food crisis management. These organisational procedures shall make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information. The ad-hoc Technical Groups shall provide its scientific and technical assistance in the form of advice in the event of a food crisis.

63. A system for rapid alert shall be developed by the Ad-hoc Technical Groups covering foods and feeds and managed by the Food Safety Expert Working Group in coordination with relevant food safety management institutions in the Member States.

19 REGISTRATION AND APPROVAL OF VETERINARY PRODUCTS, PLANT PROTECTION PRODUCTS AND FOOD AND FEED PRESERVATION PRODUCTS

64. Controlling the levels of pesticides and veterinary drugs residues and residues of other agricultural inputs in foods and feeds to amounts that may not pose a health risk shall be done in an integrated approach involving the key players along the food chain from primary production, transportation, storage to final point of use. The Ad-hoc Technical Groups shall, from the food safety management context and in order to avoid duplication of efforts, develop guidelines for approval and registration of veterinary medicinal products, plant protection products and food preservation products.

65. Besides requirements for Good Agricultural Practice, Good Veterinary Practice and Good Hygienic Practices, the guidelines to be developed by the Ad-hoc Technical Groups shall focus on more targeted food safety management systems based on hazard analysis and critical control points (HACCP) to risk-based approaches using food safety risk analysis taking into account withdrawal and withholding times and maximum residue limits of the parent compounds and/or their metabolites in any edible portion of the food or feed product including residues of associated impurities of the veterinary or pesticide compound concerned.

66. Guidelines developed by the Ad-hoc Technical Groups shall address, but be not limited to, prescription of the format and content of a registration dossier, number of samples, labelling and product information, package requirements and studies and data considered minimum for demonstrating the quality, safety and efficacy of veterinary medicinal products, plant protection products and food preservation products.

67. Compliance to these regional guidelines in the submission of applications will facilitate transparent, uniform and speedy processing and evaluation of the applications and hence market authorization. This will enable applicants for registration of their products to market them on time and make it available to the consumers while observing protection of human health, animal health and plant health and protection of the environment.

20 GUIDELINES FOR SADC GENERAL FOOD SAFETY LAW

Article 1 - General

An effective food safety management system is a necessity for every Member State in order to protect consumers against foods that are contaminated, adulterated or in other ways injurious to health, or which are incorrectly packaged or labelled.

A national food safety law shall address in an integrated approach, all elements related to national production, import and export of food and feed products; and shall in particular, regulate the production, storage, transport, handling and sale of foods and feeds within territorial borders.

Food safety law guidelines provide a framework for developing regional food trade regimes and to assist Member States in the development and operation of a national food safety management law and regulations.

These guidelines also put in perspective the need to appreciate the roles played by different professions at different stages of the food chain. The guidelines also try to spell out the roles to be played by the different competent authorities in Member 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.

Article 2 - Scope

1. These guidelines for a food safety law relates to all stages of the food production continuum, including feed produced for, or fed to food-producing animals and address all the elements in the Guidelines for Regional Food safety management Policy. 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. The requirements prescribed in Articles 3 to 8 shall form a general framework of a horizontal nature to be followed when member states decided to take measures

3. Existing food safety laws and regulations in Member States shall be adapted in order to comply with Articles 3 to 8.

4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 3 to 8.

SECTION 1: GENERAL PRINCIPLES OF FOOD SAFETY LAW

Article 3 - General objectives

1. Food safety law shall pursue one or more of the general objectives of a appropriate level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

2. Food safety law shall aim to achieve the free movement in the Region of food and feed manufactured or marketed according to the general principles and requirements in this law.

3. Where regional or international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food safety law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food safety law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the region.

Article 4 - Risk analysis

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

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

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the ad hoc Technical Groups, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 3(1) are relevant, in order to achieve the general objectives of food safety management law established in Article 3.

Article 5 - Precautionary principle

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 region may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the appropriate level of health protection chosen in the region, 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.

Article 6 - Protection of consumers' interests

1. Food safety law 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

Article 7 - Public consultation

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food safety law.

Article 8 - Public information

Without prejudice to the applicable provisions of national 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 AND FEED TRADE

Article 9 - Food and feed imported into the SADC Region

Food and feed imported into the Region for placing on the market within the Region shall comply with the relevant requirements of this food safety law or conditions recognised by the Region to be at least equivalent thereto or, where a specific agreement exists between the Region and the exporting country, with requirements contained therein.

Article 10 - Food and feed exported from the SADC Region

1. Food and feed exported or re-exported from the Region for placing on the market of an importing country shall comply with the relevant requirements of this food safety law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

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 country 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 Region.

2. Where the provisions of a bilateral agreement concluded between the Region or one of its Member States and another Region or an importing country are applicable, food and feed exported from the Region or that Member State to that the importing country shall comply with the said provisions.

Article 11 - Food and feed rejections

1. When the competent authorities in an importing country 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.
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 country;
 - b) evidence of serious misrepresentation or fraud;
 - c) evidence of a serious failure in the food and feed safety management system in the exporting country, the competent authorities in the importing country shall notify the competent authorities in the exporting country forthwith (by telecommunication or other similar rapid means of communication).
3. Where imported food or feed has been rejected on the basis of sampling and/or analysis in the importing country, details shall be made available on request as to sampling and analytical methods and test results and the identity of the testing laboratory.
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
 - Description and quantity of product
 - Type and size of package
 - Lot identification (number, production date, etc.)
 - Container number, bill of lading or similar transportation details
 - Other identification stamps, marks or numbers
 - Certificate number
 - Name and address of manufacturer, producer, seller and/or exporter, establishment number, as appropriate
 - b) Importation details
 - Port or other point of entry
 - Name and address of importer
 - Date presented for entry
 - c) Details of rejection decision
 - Whole/part of (specify) consignment rejected
 - Name and address of competent authority making decision to reject
 - Date of decision
 - Name and address of food or feed competent authority which can provide more information on reason for rejection

d) Reason(s) for rejection

- Biological/microbiological contamination
- Chemical contamination (pesticide or veterinary drug residues, heavy metals, etc.)
- Radionuclide contamination
- Incorrect or misleading labelling
- Compositional defect
- Non-conformity with food additive requirements
- Organoleptic quality unacceptable
- Technical or physical defects (e.g., packaging damage)
- Incomplete or incorrect certification
- Does not come from an approved country, region or establishment
- Other reasons

e) Action taken

- Food or feed destroyed
- Food or feed held pending reconditioning/rectification of deficiencies in documentation
- Food or feed held pending final judgement
- Place where food or feed is held
- Import granted for use other than human consumption
- Re-export granted under certain conditions, e.g. to specified informed countries
- Importer notified
- Embassy/food or feed competent authorities of exporting country notified
- Competent authorities in other likely destination countries notified
- Other

5. Upon receipt of such a communication, the competent authorities in the exporting country 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 country, if requested, shall provide the authorities in the importing country with information on the outcome of the necessary investigation, if available. Bilateral discussions shall take place as necessary. The competent authorities in the importing country shall also make appropriate notification to the competent authorities in the exporting country, either periodically or upon request, in other circumstances such as:

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 countries;

6. Countries shall in as far as possible minimise restrictions on the disclosure to 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 other countries 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.

Article 12 - International standards

Without prejudice to their rights and obligations, the SADC Secretariat and the Member States shall:

- (a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;
- (b) promote the coordination of work on food and feed 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 food and feed-related measures;
- (d) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Region is not reduced.
- (e) adopt international technical standards for food and feed sanitary and phytosanitary measures.

SECTION 4: GENERAL REQUIREMENTS OF FOOD SAFETY LAW

Article 13 - Food safety requirements

1. Food shall not be placed on the market or distributed (i.e. as food aid) if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
 - (a) injurious to health;
 - (b) unfit for human consumption.
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.
4. In determining whether any food is injurious to health, regard shall be given to:
 - (a) not only 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;

(c) the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

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.

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.

7. Food that complies with the specific provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific provisions are concerned.

8. Conformity of a food with the 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.

9. Where there are no specific national provisions in the food safety law of the Member State in whose territory the food is marketed, food shall be deemed to be safe when it conforms to the regional specific provisions.

Article 14 - Feed safety requirements

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

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;

(b) make the food derived from food-producing animals unsafe for human consumption.

3. Where a 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.

4. Feed that complies with the specific provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific provisions are concerned.

5. Conformity of a feed with the 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.

6. Where there are no specific national provisions in the national law governing feed safety of the Member State in whose territory the feed is marketed, feed shall be deemed to be safe when it conforms to the regional specific provisions.

Article 15 - Presentation

Without prejudice to more specific provisions of food safety management law, 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.

Article 16 - Responsibilities

1. Food and feed business operators along the food chain continuum, within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food safety law which are relevant to their activities and shall verify that such requirements are met.

2. Member States through their competent authorities shall enforce food safety law, and monitor and verify that the relevant requirements of food safety law 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 and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed safety laws. The measures and penalties provided for shall be effective, proportionate and dissuasive.

Article 17 - Responsibilities for food safety: food business operators

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, it 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 an appropriate level of health protection.

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.

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 national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

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.

Article 18 - Responsibilities for feed: feed business operators

1. If a feed business operator considers or has reason to believe that a 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 Article 14(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.

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.

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 national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

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.

Article 19 - Traceability

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.

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.

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.

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

Article 20 - Liability

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

Article 21 - Food emergencies

1. Where the competent authorities in either the importing and/or exporting countries become 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) Its nature and extent, where possible, be clearly and completely described by the relevant competent authorities.

b) The exchange of information shall be between official contact points designated by the competent authorities.

c) A country detecting a food safety emergency situation, whether it is an importing or an exporting country, shall inform all known affected and potentially affected countries without delay.

d) All relevant information shall be shared by competent authorities detecting a food safety emergency to enable all affected and potentially affected countries to make informed risk management and/or risk communication decisions.

e) Competent authorities shall also provide clear, relevant, factual and timely information to relevant stakeholders to the extent possible.

f) Information flow shall be transparent and continue during all phases of the food emergency situation to enable continuous evaluation and development of the emergency response.

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.
3. Action taken by exporting or importing country in case of food emergencies shall 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 problems;
 - 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).

SECTION 5: INSPECTION AND CERTIFICATION⁵

Article 22 - Inspection and certification systems

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.
2. Member 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.
3. Member States shall apply consistent and transparent risk analysis to facilitate international trade by increasing confidence in the food and feed safety and in the inspection systems by

⁵ (CAC GL 20, 26, 27)

trading partners. It will also enable inspection resources to be targeted effectively on hazards to public health arising at any stage of the food production and distribution chain.

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.

Article 23 - Equivalence

1. Member 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 country.

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 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.

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 country.

4. For the determination of equivalence, governments shall recognize that:

a) inspection and certification systems shall be 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.

5. Controls on imported food or feed and domestically produced foods or feeds shall be designed to achieve the same level of protection. The importing country shall avoid the unnecessary repetition of controls where these have been already validly carried out by the exporting country. In these cases a level of control equivalent to domestic controls shall have been achieved at the stages prior to import.

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

7. Evaluations of inspection and certification systems carried out by the competent authorities of an importing country 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 country.

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

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

10. Equivalence may also be established through the administration of a comprehensive agreement which would cover inspection and certification of all food and feed commodity forms traded between two or more countries.

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 country of the effectiveness and adequacy of its enforcement and control programmes, including laboratories;
- 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.

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.

Article 24 - Transparency

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.

2. Importing countries 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.

3. The views of exporting countries 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 countries to make necessary changes to their food or feed inspection and certification systems.

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

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

Article 25 - Control and inspection procedures

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

Article 26 - Certification validity

1. Countries that certify exports of food or feed and those importing countries which rely on export certificates shall take measures to assure the validity of certification. Validation measures by exporting countries 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 countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate.

Article 27 - Electronic certification

1. Certification may be provided by electronic documentation sent directly from the exporting country to the importing country. Such system also normally provides 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.

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

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.

4. Alternative systems for management of certificates shall be in place in case of failure of electronic certificate management.

Article 28 - Inspection and Certification System Infrastructure

1. Countries shall identify the main objectives to be addressed through inspection and certification systems.
2. Countries 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.
3. Where different authorities in the same country 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 country competent authority may recognize a sub-national competent authority for purposes of inspection or certification where this arrangement is acceptable to the national authorities concerned.

Legislative framework

4. For the purposes of this section, the effectiveness of controls related to foodstuffs or feedstuffs depends on the quality and completeness of 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.
5. 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.
6. The competent authority in the exporting or importing country shall have the ability to enforce and take action based on adequate legislation. It shall take all necessary steps to ensure 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

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. Every effort shall be made to apply risk analysis based on internationally accepted methodology, where available. In particular, countries 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.

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

9. 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 national competent authority;
- g) national audit and verification of the control programme.

10. 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.

11. 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;
- e) 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) preserving methods;
- f) labelling integrity and claims.

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

Decision criteria and action

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

14. 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.

15. Physical checks applying to import shall be based on risks associated with the importation. Countries 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 country.

16. 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 country and of those responsible for handling the product in the importing country.

17. 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 country of origin.

18. 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 country of origin;
- d) on-site visits;
- e) in the most serious or persistent cases, imports from establishments or countries may be suspended.

19. Where possible, and upon request, the importer or their representative shall be given access by the relevant food control authority of the importing country 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 country to make their final decision.

20. Where product is rejected, the following information shall be provided by the rejecting country 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 country, region or establishment
- k) Other reasons

21. Where imported food has been rejected on the basis of sampling and/or analysis in the importing country, 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 reconditioning/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 countries
- g) Importer notified
- h) Embassy/food control authorities of exporting country notified
- i) Authorities in other likely destination countries notified
- j) Other

Article 29 - Facilities, equipment, transportation and communications

1. Inspection staff shall have access to adequate facilities and equipment to undertake inspection procedures and methodologies.
2. Appropriate and 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.
3. Communications 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

4. Inspection services shall utilize laboratories that are evaluated and/or accredited 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.
5. Inspection systems' laboratories shall apply the principles of internationally accepted quality assurance techniques to ensure the reliability of analytical results.

Personnel

6. Official inspection services shall have, or have access to, a sufficient number of qualified personnel as appropriate in areas such as (but not limited to): food science and technology, nutrition (human and animal), environmental health, chemistry, biochemistry, microbiology, toxicology, veterinary science, human medicine, epidemiology, plant health, agronomic engineering, quality assurance, audit, IEC and law.
7. Personnel shall be capable and appropriately trained in the operation of food 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

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

11. Certification shall provide assurance of the conformity of a product or batch of products, or that a food 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.

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.

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

14. Countries may officially accredit inspection or certification bodies to provide services on behalf of competent authority(ies).

15. To be officially accredited, an inspection or certification body must be assessed against objective criteria and must comply at least with the standards set out in these guidelines, particularly in relation to the competence, independence and impartiality of personnel.

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.

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.

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.

19. The inspection services of a country 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.

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

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

22. Exporting countries 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.

Article 30 - Assessment of the competence of testing laboratories involved in the import and export control of food or feed safety

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

2. Test laboratories shall adopt 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 Guide 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 methods of analysis 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.

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 Guide 58: “Calibration and testing laboratory accreditation systems - General requirements for operation and recognition”.

Article 31 - Maximum Residue Limits (MRLs) for pesticides

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

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 or birds.

Article 32 - Methods of Sampling for the Determination of Pesticide Residues for Compliance with Codex Maximum Residue Limits (MRLs) for pesticides

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.

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.

Article 33 - Registering Pesticides

1. Pesticides must be registered or exempted by Competent Authorities before they may be sold or distributed in the Region. Once registered, a pesticide shall not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labelling. Competent Authorities shall initiate registration pesticides by considering the ingredients of the pesticide; 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 they will not have adverse effects on humans, the environment and non-target species.

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

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

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