ASEAN SECTORAL MUTUAL RECOGNITION ARRANGEMENT FOR INSPECTION AND CERTIFICATION SYSTEMS ON FOOD HYGIENE FOR PREPARED FOODSTUFF PRODUCTS

The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Republic of the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand, and the Socialist Republic of Viet Nam, Member States of the Association of Southeast Asian Nations ("ASEAN") (hereinafter collectively referred to as "Member States" or singularly as "Member State");

MINDFUL of the goals of establishing ASEAN as a single market and production base characterised by the free flow of goods, services, investment, skilled labour and freer flow of capital envisaged in the ASEAN Charter, the Declaration of the ASEAN Economic Community Blueprint signed by the ASEAN Leaders on 20 November 2007 in Singapore and the ASEAN Economic Community Blueprint 2025 adopted by the ASEAN Leaders on 22 November 2015 in Kuala Lumpur, Malaysia;

RECALLING that the ASEAN Trade in Goods Agreement ("ATIGA") signed on 26 February 2009 in Cha-am, Thailand has the objective of achieving free flow of goods in ASEAN as one of the principal means of establishing a single market and production base for the deeper economic integration of the region towards the realisation of the ASEAN Economic Community;

RECALLING the goals and objectives of the ASEAN Framework Agreement on Mutual Recognition Arrangement signed on 16 December 1998 in Hanoi, Viet Nam to provide a basis for developing and implementing mutual recognition arrangements in specified product sectors or what are known as sectoral mutual recognition arrangements;

RECOGNISING that mutual recognition arrangements for conformity assessment activities is an important means of eliminating technical barriers to trade as well as sanitary and phytosanitary measures which may, directly or indirectly, affect trade and enhance market access, and that such mutual recognition could be of particular interest to small and medium-sized businesses in ASEAN;

RECOGNISING further that mutual recognition arrangements will supplement and contribute positively to the harmonisation of standards, technical regulations, conformity assessment procedures and sanitary and phytosanitary measures in ASEAN;

MINDFUL of the different levels of infrastructure for standards and conformity assessment and economic development of Member States;

REITERATING Member States' commitments to the World Trade Organization Agreements on Technical Barriers to Trade ("TBT Agreement") as well as on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), as reaffirmed in ATIGA, which may, directly or indirectly affect trade;

NOTING that the TBT Agreement encourages Members to enter into negotiations for the conclusion of agreements for the mutual recognition of the results of each other's conformity assessment procedures, and the SPS Agreement encourages Members to accept the sanitary or phytosanitary measures of other Members as equivalent; and

DESIRING to establish a Sectoral Mutual Recognition Arrangement for Inspection and Certification Systems on Food Hygiene for Prepared Foodstuff Products (hereinafter referred to as "Sectoral MRA"), to facilitate the movement of prepared foodstuff products in ASEAN,

HAVE AGREED AS FOLLOWS:

ARTICLE 1
DEFINITIONS

For purposes of this Sectoral MRA, the following definitions shall apply:

a. **"ASEAN Food Safety Network ("AFSN")"** means a web-based platform operated on website for information exchanges and consultation among Member States;

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

c. **"certification system"** means official and officially recognised certification systems;

d. **"Competent Authority"** means the official government agency having jurisdiction;

e. **"conformity assessment"** means systematic examination to determine the extent to which a product, process or service fulfills specified requirements;

f. **"food"** means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs;

g. **"food hygiene"** means all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain;

h. **"inspection"** means 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;

i. **"inspection system"** means official and officially recognised inspection systems;

j. **"legislation"** means acts, regulations, requirements or procedures, issued by public authorities, related to foods and covering the protection of public health, the protection of consumers and conditions of fair trading;

k. **"official accreditation"** means the procedure by which a government agency having jurisdiction formally recognises the competence of an inspection and/or certification body to provide inspection and certification services;

l. **"official inspection systems" and "official certification systems"** means systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function, or both;

m. **"officially recognised inspection systems" and "officially recognised certification systems"** means systems which have been formally approved or recognised by a government agency having jurisdiction;

n. **"Party" or "Parties"** means a Member State that is, or Member States that are given approval to participate in this Sectoral MRA by the Joint Sectoral Committee;

o. **"prepared foodstuff"** means food that undergoes any action that substantially alters the initial products, including, but not limited to, heating, smoking, curing, maturing, drying, marinating, extraction or a combination of those processes; and

p. **"Regulatory Authority"** means an entity that exercises a legal right to control the import, use or sale of products within a Member State's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

ARTICLE 2
OBJECTIVE

The objective of this Sectoral MRA is to enable the mutual recognition of inspection and certification systems on food hygiene with regard to the production, import and export of prepared foodstuff products in order to facilitate trade in ASEAN and protect the health of consumers.

ARTICLE 3
GENERAL PROVISIONS

This Sectoral MRA sets out the arrangement under which Member States shall ensure that their inspection systems

and certification systems on food hygiene are consistent with the provisions of this Sectoral MRA and its Annexes.

ARTICLE 4
SCOPE AND COVERAGE

1. This Sectoral MRA shall apply to the prepared foodstuff products specified under HS Code 16-22.

2. The coverage of this Sectoral MRA shall apply to the mutual recognition of inspection and certification systems on food hygiene in ASEAN.

ARTICLE 5
MUTUAL RECOGNITION OBLIGATIONS

1. Parties shall ensure that their national food control systems are consistent with the provisions of Annex 1 of this Sectoral MRA.

2. Parties shall ensure that their production systems meet the general principles of food hygiene contained in Annex 2 of this Sectoral MRA.

3. Parties shall ensure that their inspection and certification systems are based on the principles contained in Annex 3 of this Sectoral MRA. The systems shall be implemented in accordance with Section 6 to 10 of Annex 4 of this Sectoral MRA.

4. Parties shall establish and maintain import control systems for prepared foodstuff products in a manner consistent with all the provisions of Annex 5 of this Sectoral MRA.

5. Member States shall recognise the results of inspection and certification systems for food hygiene of Parties in accordance with the provisions of this Sectoral MRA.

6. Where differences exist in product standards and requirements, the exporting Party shall comply with those standards and requirements of the importing Member States.

ARTICLE 6
TRANSPARENCY

1. Each Member State shall designate a contact point for exchange of information and shall notify the ASEAN Secretariat of its designated contact point. The ASEAN Secretariat shall establish and maintain the list of contact points for Member States in this Sectoral MRA.

2. Member States shall endeavour to exchange updated information on their regulatory systems in English, through publication on the AFSN's website, on the following:

    a. legislation, including the texts of all relevant legislation relating to the food control system for prepared foodstuff products;

    b. all existing technical regulations, sanitary and phytosanitary measures and standards for the prepared foodstuff sector in each Member State, including labelling requirements; and

    c. conformity assessment requirements for the import of prepared foodstuff products, including but not limited to certification, inspection, sampling and analysis required and import product registration requirements in each Member State.

3. Any changes to the information referred to in paragraph 2 and other measures affecting the implementation of this Sectoral MRA shall be promptly notified to the contact points in a timely manner in compliance with Annex B of the SPS Agreement. The notification should be made in advance within a reasonable period to permit the exporting Parties to make necessary changes in accordance with the new requirements and measures.

4. Member States shall provide immediate notification to the contact points and the ASEAN Secretariat of significant risks to public health related to product safety, manufacturing conditions, recalls, and other instances that involve significant hazard to health with regard to the prepared foodstuff products covered by this Sectoral MRA.

5. When the rejection of the prepared foodstuff products under the scope of this Sectoral MRA arises, the importing Member State shall immediately notify the exporting Party of the situation and information for the exporting Party to investigate the causes of the problem in accordance with Annex 6 of this Sectoral MRA.

ARTICLE 7
COMPETENT AUTHORITY

1. Member States shall identify their Competent Authority and notify the ASEAN Secretariat accordingly.

2. Member States having multiple Competent Authorities shall submit the names of all them and clearly define the assigned roles and responsibilities within the scope of this Sectoral MRA. Member States shall ensure that the competent authorities operate in a coordinated manner with no duplication and/or gaps.

3. The Competent Authority(ies) of a Party shall have the ability to enforce and take action based on adequate legislation in accordance with Section 6 of Annex 4 of this Sectoral MRA.

4. The Competent Authority(ies) of a Party shall ensure the integrity, impartiality and independence of inspection and certification systems to ensure that the inspection and certification programme complies with Annex 4 of this Sectoral MRA.

5. The Competent Authority(ies) of a Party may recognise officially accredited inspection or certification bodies located in ASEAN to provide services on behalf of official agencies. The Competent Authority(ies) of a Party shall ensure that officially accredited inspection or certification bodies are assessed against objective criteria and comply at least with Section 8 of Annex 4 of this Sectoral MRA , particularly in relation to the competence, independence and impartiality of personnel. The performance of officially accredited inspection or certification bodies shall be regularly assessed by the Competent Authority(ies) of a Party. Procedures should be initiated to correct deficiencies and, as appropriate, enable withdrawal of official accreditation.

ARTICLE 8
JOINT SECTORAL COMMITTEE ("JSC")

1. A JSC shall be established, and shall be responsible for the effective functioning of this Sectoral MRA. The JSC shall comprise official representatives designated by each Member State. Each Member State shall designate one representative and the representative may be accompanied by his/her delegates with the status of observers at meetings of the JSC.

2. The JSC shall be responsible for:

a. identifying the elements of inspection and certification systems on food hygiene of the prepared foodstuff products in accordance with Annex 3 and Annex 4 of this Sectoral MRA;

b. establishing the requirements, rules and procedures for the notification, evaluation, and approval of the inspection and certification systems of a Party;

c. evaluating and approving that the inspection and certification systems of a Party are consistent with the provisions of the Article 3, Article 5 and Article 7;

d. listing and withdrawing the approved scope of recognition of a Party;

e. considering any other matters and taking appropriate technical decisions relating to the effective functioning of this Sectoral MRA;

f. providing a forum for discussion of issues that may arise concerning the implementation of this Sectoral MRA; and

g. proposing amendment to this Sectoral MRA.

3. The JSC may establish technical and ad-hoc working groups, as required, for the purposes of this Sectoral MRA. The outcome of the technical and ad-hoc working groups shall be reported to the JSC.

4. The JSC shall establish its own rules of procedures and take its decisions by consensus.

5. The JSC shall meet to review the implementation of this Sectoral MRA, at least once a year, or as the need arises.

ARTICLE 9
IMPLEMENTATION

1. This Sectoral MRA is intended to be a multilateral arrangement in which all Member States are required to participate. However, taking into consideration paragraph 3 of Article 1 of the Framework Agreement on Enhancing ASEAN Economic Cooperation signed on 28 January 1992 in Singapore and paragraph 7 of Article 3 of the ASEAN Framework Agreement on Mutual Recognition Arrangements signed on 16 December 1998 in Hanoi, Viet Nam, a Member State which is not ready to fully implement this Sectoral MRA may withhold from participating in this Sectoral MRA subject to Article 13. The withholding period shall not exceed five years after the entry into force of this Sectoral MRA.

2. Any Member State that is ready to participate in this Sectoral MRA shall notify the JSC through the ASEAN Secretariat in writing of its intention to participate.

3. The notification for participation shall be followed by a submission of information and evidence of the Member State's compliance with the requirements of this Sectoral MRA to the JSC through the ASEAN Secretariat in a format as determined by the JSC. Upon receiving the submission of information and evidence, the JSC shall evaluate the inspection and certification systems of the Member State and undertake the decision on approval of participation as set out in its established rules and procedures.

4. The approval of participation of the Party in this Sectoral MRA shall be notified by the JSC through ASEAN Secretariat to the Party. The effective dates of implementation of the mutual recognition obligations of the Member States shall commence as soon as at least two Member States are approved to participate in this Sectoral MRA as Parties.

5. The ASEAN Secretariat will make available the list of Parties and scope of recognition that have been approved by the JSC.

ARTICLE 10
PRESERVATION OF REGULATORY AUTHORITY

1. Subject to the provisions of this Sectoral MRA, nothing in this Sectoral MRA shall be construed to:

   a. limit the authority of a Party to determine, through its legislative, regulatory and administrative measures, the level of protection it considers appropriate for the safety and protection of human, animal, or plant life or health,environment and consumers; and

   b. limit the authority of a Regulatory Authority of a Party to take all appropriate and immediate measures whenever it ascertains that a prepared foodstuff product may:

      i. compromise the health or safety of persons in its territory;

      ii. not meet the legislative, regulatory, or administrative provisions within the scope of this Sectoral MRA; or

      iii. fail to satisfy a requirement within the scope of this Sectoral MRA.

2. If the Regulatory Authority of a Party takes such measures pursuant to paragraph 1, it shall inform its counterpart Regulatory Authority in the affected Parties and other Member States of such measures taken and provide reasons thereof.

3. If such measures taken are import rejection, nothing will prevent the affected Party to conduct its investigation subject to paragraph 5 of Article 6.

ARTICLE 11
SETTLEMENT OF DISPUTES

1. Member States shall at all times endeavour to agree on the interpretation or implementation of this Sectoral MRA and shall make every attempt through communication, dialogue, consultation and cooperation to arrive at a mutually satisfactory resolution of any matter that might affect the implementation of this Sectoral MRA.

2. The ASEAN Protocol on Enhanced Dispute Settlement Mechanism, signed on 29 November 2004 in Vientiane, Lao PDR and amendments thereto, shall apply to disputes concerning the interpretation or implementation of any of the provisions of this Sectoral MRA.

ARTICLE 12
INSTITUTIONAL ARRANGEMENTS

1. The JSC shall monitor all aspects relating to the implementation of this Sectoral MRA.

2. The ASEAN Consultative Committee for Standards and Quality ("ACCSQ"), Prepared Foodstuff Product Working Group ("PFPWG") and the ASEAN Secretariat shall provide the support for coordinating and reviewing the implementation of this Sectoral MRA and assist the JSC in all matters relating thereto.

ARTICLE 13
COOPERATION AND TECHNICAL ASSISTANCE

1. Noting the different levels of development of the national food control systems and the Initiative for ASEAN Integration launched in 2000 by the ASEAN Leaders to narrow the development gap and to accelerate economic integration, Member States will seek to enhance cooperation and provision of technical assistance.

2. In order to facilitate effective implementation of this Sectoral MRA, each Member State will upon request, cooperate in technical assistance on mutually agreed terms and conditions, on building up and/or maintaining technical competence of inspection and certification systems for food hygiene of the prepared foodstuff products of other Member States. In particular, Member States shall consider cooperation and technical assistance towards:

    a. enhancing exchange of information, technical experts among the Member States; and

    b. providing training to other Member States for the purposes of enhancing the capacity for the inspection and certification system for food hygiene and other related activities of national food control systems.

ARTICLE 14
CONFIDENTIALITY

1. Member States shall maintain, to the extent permitted under their laws and regulations, the confidentiality of information exchanged under this Sectoral MRA.

2. Member States shall take all precautions reasonably necessary to protect information exchanged under this Sectoral MRA from unauthorised disclosure.

ARTICLE 15
RIGHTS AND OBLIGATIONS UNDER EXISTING INTERNATIONAL AGREEMENTS OR CONVENTIONS

This Sectoral MRA or any actions taken pursuant thereto shall not affect the rights and obligations of any Member State under any existing international agreements or conventions to which it is also a party.

ARTICLE 16
ANNEXES

The Annexes to this Sectoral MRA shall form an integral part of this Sectoral MRA.

ARTICLE 17
FINAL PROVISIONS

1. This Sectoral MRA may be reviewed by the Member States for the purpose of fulfilling the objective of this Sectoral MRA.

2. The provisions of this Sectoral MRA may only be amended by mutual written agreement of all the Member States.

3. Notwithstanding paragraph 2 of this Article, the Annexes to this Sectoral MRA may be amended subject to the endorsement of the PFPWG. Such amendments shall be administratively annexed to this Sectoral MRA

by the Depositary and form an integral part of this Sectoral MRA.

4. Any amendment shall not prejudice the rights and obligations of the Member States arising from or based on this Sectoral MRA before the entry into force of such amendment.

5. Member States shall undertake appropriate measures to fulfill the agreed obligations arising from this Sectoral MRA.

6. Member States shall make no reservations with respect to any of the provisions of this Sectoral MRA.

7. This Sectoral MRA shall enter into force on the date of its signature.

8. This Sectoral MRA shall be deposited with the Secretary General of ASEAN, who shall promptly furnish a certified copy thereof to each Member State.

IN WITNESS WHEREOF the undersigned, being duly authorised by their respective Governments, have signed this ASEAN Sectoral Mutual Recognition Arrangement for Inspection and Certification Systems on Food Hygiene for Prepared Foodstuff Products.

DONE at Singapore, ..., this Twenty Seventh day of April in Year Two Thousand and Eighteen, in a single copy in the English Language.

For Brunei Darussalam:

LIM JOCK SENG
Minister at the Prime Minister's Office
and Second Minister of Foreign Affairs and Trade

For the Kingdom of Cambodia:

PAN SORASAK
Minister of Commerce

For the Republic of Indonesia:

ENGGARTIASTO LUKITA
Minister of Trade

For the Lao People's Democratic Republic:

KHEMMANI PHOLSENA
Minister of Industry and Commerce

For Malaysia:

MUSTAPA MOHAMED
Minister of International Trade and Industry

For the Republic of the Union of Myanmar:

KYAW WIN
Union Minister for Planning and Finance

For the Republic of the Philippines:

RAMON M. LOPEZ
Secretary of Trade and Industry

For the Republic of Singapore:

LIM HNG KIANG
Minister for Trade and Industry (Trade)

For the Kingdom of Thailand:

APIRADI TANTRAPORN
Minister of Commerce

For the Socialist Republic of Viet Nam:

TRAN TUAN ANH
Minister of Industry and Trade

ANNEX 1

ASEAN Common Food Control Requirements

ASEAN PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS

(CAC/GL 82-2013 - PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS, MOD)

ASEAN PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS

FOREWORD

Effective national food control systems are essential for the protection of the health of consumers. Such systems are also critical in enabling countries to assure the safety and quality of their food. The first version of the current document was developed by the Prepared Foodstuff Product Working Group (PFPWG) and endorsed by ASEAN Consultative Committee for Standards and Quality (ACCSQ) in 2006. Recognizing that the ASEAN Trade in Goods Agreement that was concluded in 2009 requires Member States to be guided by international standards in implementing their Sanitary and Phytosanitary measures, and the requirement of the ASEAN Policy Guideline for Standard and Conformance to adopt international standards, a review of the first version of the "ASEAN Common Principles for Food Control" was undertaken by the PFWG. The PFPWG has decided to revise the document to align CAC/GL 82-2013 Principles and guidelines for national food control systems. This document revises and replaces the *ASEAN Common Principles for Food Control: 2006.*

The document is an adoption of CAC/GL 82-2013 Principles and guidelines for national food control systems published by the Codex Alimentarius Commission with the following modification:

Clause / Sub-clause	Modification
1. Introduction	Add: 1a. Definitions "Food" means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of 'food' but does not include cosmetics or tobacco or substances used only as drugs.

Explanation: A Definition for "Food" has been included in order to establish a common interpretation of the scope of application of the principles and guidelines.

This document is one of the ASEAN Common Food Control Requirements (ACFCR)

July 2014

ASEAN COMMON PRINCIPLES AND GUIDELINES FOR FOOD CONTROL SYSTEMS

SECTION 1 INTRODUCTION

1. This document is intended to provide practical guidance to assist the national government, and their competent authority[1] in the design, development, operation, evaluation and improvement of the national food control system. It highlights the key principles and core elements of an efficient and effective food control system. It is not intended that the guidance results in "one system" being appropriate to all circumstances. Rather, various approaches may be used, as appropriate to the national circumstances, to achieve an effective national food control system.

2. While the focus of the Principles and Guidelines for National Food Control Systems is on the production, packing, storage, transport, handling and sale of foods within national borders, the document is consistent with and should be read in conjunction with relevant Codex texts. Codex texts of particular relevance include the *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995), the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification* (CAC/GL 26-1997), the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) and the *Guidelines for the Exchange of Information between countries on rejections of imported foods* (CAC/GL 25-1997). Reference to these texts relating to food import and export control is important since, while the national food control system is ultimately responsible for the safety of food offered within its border, in today's global market, much food is sourced from outside the country; hence, properly designed import and export control systems, as part of the overall national food control system, are essential.

3. In addition, the relevant chapters of the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code and Aquatic Animal Health Code are valuable resources for member governments and organizations. Documents and guidance material developed by FAO and WHO may also be useful resources[2].

4. A competent authority may apply these principles and guidelines, where appropriate, according to their particular situations.

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[1] Throughout the document "competent authority" refers to one or more competent authorities as appropriate

[2] http://www.fao.orf/food/food-safety-quality/publications-tools/food-safety-publications/en/

5. When developing a national food control system national governments and their competent authority should ensure that the objectives of the system are addressed as outlined in the principles below and should allow for flexibility and modification as required to ensure the objectives can be achieved.

6. **Definitions**

- "Food" means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of 'food' but does not include cosmetics or tobacco or substances used only as drugs.

SECTION 2 OBJECTIVE OF A NATIONAL FOOD CONTROL SYSTEM

6. The objective of a national food control system is to protect the health of consumers and ensure fair practices in the food trade.

SECTION 3 PRINCIPLES OF A NATIONAL FOOD CONTROL SYSTEM

7. A national food control system should be based on the following principles:

PRINCIPLE 1 PROTECTION OF CONSUMERS

8. National food control systems should be designed, implemented and maintained with the primary goal to protect consumers. In the event of a conflict with other interests, precedence should be given to protecting the health of consumers.

PRINCIPLE 2 THE WHOLE FOOD CHAIN APPROACH

9. The national food control system should cover the entire food chain from primary production to consumption.

PRINCIPLE 3 TRANSPARENCY

10. All aspects of a national food control system should be

transparent and open to scrutiny by all stakeholders, while respecting legal requirements to protect confidential information as appropriate. Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation and communication.

PRINCIPLE 4 ROLES AND RESPONSIBILITIES

11. All participants in a national food control system should have specific roles and responsibilities clearly defined.

12. Food business operators[3] have the primary role and responsibility for managing the food safety of their products and for complying with requirements relating to those aspects of food under their control.

13. The national government (and in some cases a competent authority) has the role and responsibility to establish and maintain up to date legal requirements. The competent authority has the responsibility to ensure the effective operation of the national food control system.

14. Consumers also have a role in managing food safety risks under their control and where relevant should be provided with information on how to achieve this.

15. Academics and scientific institutions have a role in contributing to a national food control system, as they are a source of expertise to support the risk based and scientific foundation of such a system.

PRINCIPLE 5 CONSISTENCY AND IMPARTIALITY

16. All aspects of a national food control system should be applied consistently and impartially. The competent authority and all participants acting in official functions should be free of improper or undue influence or conflict of interest.

PRINCIPLE 6 RISK BASED, SCIENCE BASED AND EVIDENCE BASED DECISION MAKING

17. A competent authority should make decisions within a national

[3] For the purpose of this document food business operator includes producers, processors, wholesalers, distributors, importers, exporters and retailers

food control system based on scientific information, evidence and/or risk analysis principles[4] as appropriate.

PRINCIPLE 7 COOPERATION AND COORDINATION BETWEEN MULTIPLE COMPETENT AUTHORITIES

18. The competent authorities within a national food control system should operate in a cooperative and coordinated manner, within clearly assigned roles and responsibilities, for the most effective use of resources in order to minimise duplication and/or gaps and to facilitate information exchange.

PRINCIPLE 8 PREVENTIVE MEASURES

19. To prevent and when necessary to respond to food safety incidents a national food control system should encompass the core elements of prevention, intervention and response.

PRINCIPLE 9 SELF ASSESSMENT AND REVIEW PROCEDURES

20. The national food control system should possess the capacity and capability to undergo continuous improvement and include mechanisms to evaluate whether the system is able to achieve its objective.

PRINCIPLE 10 RECOGNITION OF OTHER SYSTEMS (INCLUDING EQUIVALENCE)

21. Competent authorities should recognise that food control systems or their components although designed and structured differently may be capable of meeting the same objective. This recognition can apply at the national and international level. The concept of recognition of systems, including equivalence[5], should be provided for in the national food control system.

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[4] In accordance with members obligations under the World Trade Organisation Agreements, risk analysis frameworks adopted by national governments in the context of a national food control system should be consistent with the Codex *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007) and relevant risk analysis policies developed by the World Organisation for Animal Health (OIE).

[5] *Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems* (CAC/GL 34-1999) and *Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems* (CAC/GL 53-2003).

PRINCIPLE 11 LEGAL FOUNDATION

22. The government within each country should have in place fundamental legal structures to enable the establishment of food laws and competent authorities, so that they can develop, establish, implement, maintain and enforce a national food control system.

PRINCIPLE 12 HARMONISATION

23. When designing and applying a food control system, the competent authority should consider Codex standards, recommendations and guidelines whenever appropriate as elements of their national food control system to protect the health of consumers and ensure fair practices in the food trade. Standards, recommendations or guidelines from other international inter-governmental organisations whose membership is open to all countries may also be useful.

PRINCIPLE 13 RESOURCES

24. A national food control system should have sufficient resources to enable it to meet the system's objectives.

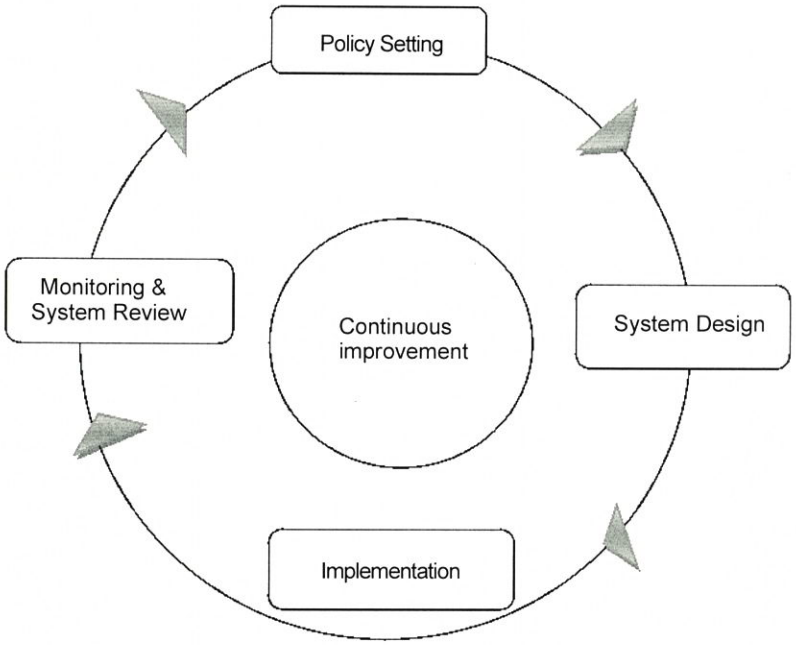
SECTION 4 FRAMEWORK FOR THE DESIGN AND OPERATION OF THE NATIONAL FOOD CONTROL SYSTEM

25. The national food control system of a country will be based on that country's particular governmental or constitutional arrangements and institutions, (e.g. presence or absence of sub national governments), national goals and objectives.

26. The competent authority has a pivotal role in the national food control system, in that the competent authority:

- Provides leadership and coordination for the national food control system;
- Designs, develops, operates, evaluates and improves the national food control system;
- Establishes, implements and enforces science and risk based regulatory requirements that encourage and promote positive food safety outcomes;
- Establishes, implements and enforces regulatory requirements supporting fair practices in the food trade;

- Establishes and maintains arrangements with supporting organizations such as officially recognised inspection, audit, certification and accreditation bodies, where appropriate;
- Advances and fosters knowledge, science, research and education regarding food safety;
- Engages with stakeholders to ensure transparency and to obtain their views; and



Framework for the development of a national food control system

27. Where appropriate, establishes and maintains arrangements with other countries e.g. cooperation programs, equivalence agreements etc.Where there is more than one competent authority their roles and responsibilities should be clearly defined and their activities coordinated to the greatest extent possible to minimise gaps and overlaps.

28. The design and implementation of a national food control system should follow a logical and transparent process. This should include the consistent application of a systematic framework for the identification, evaluation and, as necessary, control of food safety risks associated with existing, new or re-emerging hazards.

29. In developing a national food control system the competent authority, in consultation with stakeholders, should adopt the following

framework, which will reflect the principles of a national food control system and are described in Section 3 this document.

SECTION 4.1 POLICY SETTING

30. Policy setting is the process by which the goals and objectives for the national food control system are established by governments, along with the commitment to a course of action to achieve those goals and objectives. It should also include the identification and clear articulation of expected outcomes. Policy decisions guide subsequent actions, including the establishment of legislation and regulations.

31. Public policy decisions should take into account a broad range of factors and require a careful assessment of options. Governments should consider, among other things, stakeholder interests, how the food control system will relate to international and national standards, assessment of risks and/or benefits, effectiveness and efficiency of various controls and methods of oversight, existing and planned government structures, coordination among authorities along the food chain, technical and scientific information, the roles of government and food business operators, and best practices/models.

32. The competent authority should actively engage stakeholders, including food business operators and consumers, in the setting of policy.

33. National goals and priorities will ensure consumer protection by taking into account amongst other things, food production and consumption patterns, risk profile and consumer concerns in relation to food safety and fair practices in the food trade and also the preparedness and capability of the country.

34. When establishing a national food control system countries should identify the main objectives to be addressed through the system for the short, medium and long term. The main objectives should be aligned with and assist in implementing the principles outlined in Section 3. Consideration should be given to the development of a national food control strategy, which will aid clarification of the objectives to be addressed set priorities and support system design.

35. Once public policy goals and desired outcomes for the national food control system are established, they should be clearly articulated and described in order to effectively guide subsequent actions.

36. A national food control system should possess three main characteristics which, among other things, can be used in self-assessment or other evaluation to determine if the system is fully functional and effective:

i) **Characteristic 1** Situational awareness means that a national food control system avails itself of accurate and current information on the entire food chain.

ii) **Characteristic 2** Pro-activity means that a national food control system is capable of identifying existing or emerging hazards before they materialise as risks in the food production and/or processing chain and at the early stages rather than in the end product. Early warning and/or rapid alert systems, traceability and contingency planning for managing and preparing for potential food safety incidents should be an inherent part of a pro-active control system.

iii) **Characteristic 3** Continuous Improvement means that a national food control system should possess the capability to learn through a process of review and reform utilising mechanisms that check and evaluate whether the system is able to achieve its objectives.

37. Legislation[6] should clearly reflect the intended policy objective and be commensurate with the risks they are intended to mitigate. Legislation should, where appropriate take into account relevant scientific information and focus on prevention and outcomes and thereby allowing flexibility and innovation.

38. In order to reflect national policies and strategies legislation should, amongst other things:

- Frame the structure of the national food control system and its goals and objectives;
- Provide clarity on the roles and responsibilities of participants in the national food control system, i.e. the central government, the competent authority (or of each competent authority where there is more than one), third party[7] providers (where these are used), food business operators and other stakeholders as appropriate;
- Set out the overarching objectives of the national food control system and any specific or lower order objectives that relate to participants or sectors;
- Clearly define obligations for food business operators and other

[6] Legislation as defined in *Guidelines for Food Import Control Systems* (CAC/GL 47-2003)
[7] *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) paragraph 8

participants in the food chain to establish and monitor controls; and
- Clearly define obligations on food businesses to place only safe food on the market and apply fair practices in trade.

39. The legislation should provide the competent authority with the range of powers and mechanisms sufficient to manage
and operate the national food control system. These authorities may include and are not limited to the following:
- Establish standards or other management options to prevent and control food borne hazards such as disease-causing organisms, contaminants, veterinary drug and pesticide residues;
- Establish, monitor and enforce national standards;
- Recognise other competent authorities' standards at the appropriate stage(s) in the food chain;
- The establishment of cooperative arrangements with other government entities;
- Establish approaches to ensure the safety and safe use of inputs to the food chain, such as food additives, pesticides, veterinary drugs;
- Recognise and/or harmonize with Codex standards;
- Perform audits, verification, inspections and investigations, gather evidence, collect and analyze samples and otherwise verify compliance with standards and requirements;
- Consider official recognition of inspection, audit, certification and accreditation bodies;
- Enforce legislation and take proportionate, dissuasive and effective action in case of non-compliance with requirements including, as appropriate, investigations and application of sanctions and penalties;
- Ensure that risks associated with non-compliant foods are evaluated and the appropriate action taken; e.g. disposal, treated appropriately or redirected.
- Ensure the integrity, impartiality and independence of officially recognized inspection, audit, certification and accreditation;
- Enable traceability/product tracing; and

40. Ensure that unsafe food is prevented ffrom entering the market or is withdrawn and dealt with appropriately.Legislation may also include provisions, as appropriate, for the registration of establishments, establishment approval, licensing or registration of traders, equipment design approval, penalties in the event of non-compliance and charging of fees or levies.

41. The competent authority should, engage with stakeholders including the food business operators and consumers, in the development of new legislation, and when making regulatory changes. The competent authority should also disseminate the legislation.

SECTION 4.2 SYSTEM DESIGN

42. When designing a national food control system countries should ensure the main objectives as defined in the policy are addressed as well as how to incorporate the principles in Section 3.

43. The design of a food control system should take into account the following elements:

- Existing or necessary regulatory and legislative framework (laws, regulations, guidance);
- How the national food control system relates to international and national standards including food import and export system requirements;
- The recognition of other food control systems, including equivalence[8],
- The level and method of oversight including control programs from primary production through manufacturing to transportation and distribution;
- How issues and risks are managed;
- Enforcement and compliance programs;
- Coordination and communication between authorities with control responsibilities in different parts of the food chain and with the public health authorities;
- Clearly defined roles and responsibilities;
- Access to adequate laboratory capacity and capability;
- Staff competence and training;
- The resources needed to meet the objectives of the national food control system, their allocation and how the system is to be funded;
- Surveillance, investigation, emergency preparedness and response to food borne and food related incidents;
- Assessment and evaluation;
- Stakeholder engagement;
- International communication and harmonization; and
- Periodic review and continuous improvement.

44. Consideration should be given to the development and implementation of a standardised approach to risk management incorporating the *Working principles for risk analysis for food safety for application by governments* (CAC/GL 62-2007).

45. An appropriate system design should consider a range of factors including (but not limited to) product risk, current scientific information, industry based controls and system review findings. It should also

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[8] *Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems* (CAC/GL 53-2003)

provide for flexibility in the application of control measures to reflect variations in these factors.

46. Development of an effective method of data collection across the food chain is important for situational awareness, performance measurement and continuous review and system improvement. For instance, surveillance and monitoring programs can be used to target priority risks.

47. The competent authority should utilise findings from laboratories to monitor trends in the food chain and assist in compliance and enforcement. Laboratory access and capacity should be commensurate with the need to address priority food risks.

48. The national food control system should be fully documented and publicly available, to ensure its transparency and consistent application of control measures, including a description of its scope and operation, and a clear description of the roles and responsibilities of all parties.

49. National food control systems should be designed to ensure administrative procedures are in place for documentation of control programs and their findings.

50. Control programs[9] should be based on risk and designed to take into account a number of factors[10]
including but notlimited to:

- Food safety hazards associated with different products and the risk to human health posed by the food or food related products;
- Risk of unfair practices in the food trade associated with different products, such as potential fraud or deception of consumers;
- Information that may be available from a range of sources including government, academia, scientific institutions and industry data;
- Statistical data on production, trade and consumption;
- Results of previous controls including analytical results;
- The effectiveness and reliability of controls including those of food business operators;
- Knowledge of operators at various stages of the food chain typical and atypical use of products, raw materials and byproducts; structure of production and supply chains; production technologies, processes and practices; relevant product tracing information; and
- Epidemiological data on food borne disease.

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[9] Control program is the collective actions and activities in place to manage specific food safety hazards and assure the quality and safety of food and
fair practices in the food trade.

[10] Effective use of these factors provides for system characteristics 1 and 2 as described in paragraph 36.

51. In the absence of risk analysis data control programs should be based on technical and scientific data developed fromcurrent knowledge and practice.

52. Control programs should be applied at the point or points in the production or supply chain where hazards can be mosteffectively or efficiently controlled taking into account the available resources and capability. Control programs amongst other things may cover, as appropriate:

- Establishments, installations, equipment, personnel and material;
- Products, from raw material to the final products, including intermediate products;
- Preventative controls including Good Agricultural Practice GAP, Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and Hazard Analysis Critical Control Point (HACCP) principles;
- Means of distribution; and
- Human resources, infrastructure and confidentiality.

53. Control programs should be designed to include the following elements but not limited to:

- Inspection, verification and audit including on-site visits;
- Market surveillance;
- Sampling and analysis;
- Examination of written and other records;
- Documentation of observations and of findings; and
- Examination of the results of any verification systems operated by the establishment.

54. Where quality assurance systems are used by food business operators, the national food control system should takethem into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade. The competent authority should encourage, as appropriate, the use of Good Laboratory Practices (GLP)[11] GAP, GMP, GHP and HACCP approach in accordance with *General Principles of Food Hygiene* (CAC/RCP 1-1969).

55. The system design should provide for the capability to evaluate the effectiveness of the national food control system.Verifying the effectiveness of the national food control system should be targeted at the most appropriate stages of the food chain, based on risk analysis conducted in accordance with internationally accepted methodology[12].

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[11] Guidance on laboratory competency is available in the *Guidelines for the assessment of the competence of testing laboratories involved in the import and export of food* (CAC/GL 27-1997) and *International harmonised protocol for the proficiency testing of (chemical) analytic laboratories* (CAC/GL 28- 1997) may be useful.

[12] *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007)

56. A national food control system should be subject to regular review of results obtained so that it can be continuouslyimproved to reflect changes in product risk, the production environment (including technology), increased scientific knowledge, and level of confidence in industry, to ensure the objective of the national food control system is met in an efficient and effective manner.

57. Compliance and enforcement programs should be designed to provide the ability for the competent authority to take corrective action to ensure the situation is remedied where the food business operators are not meeting their obligations or a product or process is found not to be in conformity. Programs should be designed to:

- Be proportionate to the degree of public health risk or potential fraud or deception of consumers;
- Encourage acceptance of responsibility and compliance by all participants; and
- Provide for a full range of responses from provision of information or education material, imposing of corrective actions, setting of sanctions.
- Take into account repeated non-conformity by food business operators.

58. The competent authority and any officially recognised bodies undertaking compliance and enforcement activities on behalf of the competent authority should be resourced sufficiently and transparently to enable the national food control programs to achieve its objectives without compromising the programs integrity and independence. Third party providers may be approved and/or authorised to implement the national food control system and the competent authority must have capacity to supervise and control third party providers.

59. The design and implementation of a national food control system should be on a scale appropriate to the resourcesavailable, while allowing for appropriate expansion. Resources should be prioritized to maximise protection of public health. Resource allocations made in the context of a national food control system may, dependant on the above be attributed to:

- Training and basic infrastructure;
- Suitably qualified personnel of relevant disciplinary backgrounds
- Reliable transportation systems and equipment to perform inspection, audit and verification services and transmission of samples to laboratories; and
- Information, communication and technology (ICT) systems;

60. The design of a national food control system should incorporate timely access to adequate information relating to thesurveillance,

investigation and response to food borne illness and food related incidents. Such information can identify the risks or issues that need to be addressed and also whether or not the controls or measures in place are effective.

61. In order to respond to food safety emergencies, consideration should be given to the establishment of a national foodsafety emergency plan with establishment of a coordination arrangement with links to public health authorities, law enforcement agencies, food recall systems, risk assessment specialists, food business operators, and others. Traceability/product tracing systems[13] provides for the timely identification of the sources for emergencies and allowing effective recall of affected products.

62. The national food control system should have procedures covering the prompt removal of unsafe food[14]. Setting upthese procedures is the primary responsibility of food business operators and they should ensure that products that are deemed to be unsafe should be recalled, appropriately dealt with to ensure consumer protection. The competent authority should ensure appropriate consumer notification is carried out when distribution has occurred.

63. Recall systems and other market withdrawal systems should be a coordinated effort between the competent authorityand food business operators and be effective and enforceable. If the competent authority requires or requests a recall, operators should have an affirmative duty to give effect to established procedures to recover recalled products and to destroy or dispose of them properly. National laws should include penalties or sanctions for companies that fail to comply with recall requests.

64. In order to promote consumer confidence in food safety and ensure fair practices in the food trade, the competentauthority should be clear and transparent in their communications relating to all aspects of the national food control system for which they are responsible, including the development, implementation and enforcement of the requirements.

65. Communication among public health (food safety), agriculture and other relevant authorities, consumers and consumerorganizations, and food business operators should be an ongoing function of a competent authority with responsibility for a national food control system.

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[13] *Principles for Traceability/product tracing as a tool within a food inspection and certification system* (CAC/GL 60-2006)

[14] *Principles for traceability/product tracing as a tool within a food inspection and certification system* (CAC/GL 60-2006) and OIE Terrestrial Animal Health Code, Chapter 4.1.General principles on identification and traceability of live animals

67. Consideration should be given to the development of communication programs to provide outreach and educationprograms and information exchange on food safety risks and mitigation steps which may be taken to reduce these risks, amongst regulators, food business operators, consumers and academia.

68. When developing an educational program the relevant authorities should clearly identify the target audience, the priority content and the strategies to be implemented. The educational materials developed should use language suitable for the intended audience. Basic elements of food safety educational activities should be widely disseminated, preferably using mass communication.

69. Where appropriate, the competent authority should utilize the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995), the International Health Regulations (IHR), OIE disease notification requirements, IPPC regulations and the International Food Safety Authorities Network (INFOSAN), for national and international emergency notification and response.

SECTION 4.3 IMPLEMENTATION

70. Following the design or modification of the national food control system the competent authority should prepare an implementation plan including the sequence for different elements of design suitable with their preparedness and capability. This will require engagement and analysis by a variety of experts, disciplines and all stakeholders. The competent authority's plan may include;

- Priorities and time frames for implementation;
- Deliverables;
- Responsibilities for implementation;
- Allocation of resources for personnel and infrastructure;
- Training and operation manuals; and
- Stakeholder engagement.

71. Guidance and instructions relating to the national food control system, control programs and compliance and enforcement, including legal requirements should be developed for competent authority staff and food business operators to ensure;

- That all participants are fully aware of the objectives of the system and what is expected from them;
- Uniform application of legislation; and
- That they have the necessary resources (human, material and financial resources) available to carry out their tasks.

72. Programs and training manuals should be developed and maintained to ensure consistent application of requirements. This material should include as appropriate and not limited to:

- An organizational chart of the official control system;
- Roles of each level in the hierarchy (including other relevant jurisdictions; i.e. State, Provincial);
- Job functions and qualifications as appropriate;
- Operating procedures including methods of audit, verification, inspection and control, sampling plans, and testing;
- Relevant legislation and requirements;
- Processes and procedures relating to compliance and enforcement;
- Arrangements for coordination with relevant competent authorities and stakeholders;
- Relevant information about food contamination and food control;
- Procedures for dealing with food safety emergencies and conducting food recalls and investigations;
- Relevant information on staff training; and
- Formal review process of the national food control system.

73. National food control systems should be supported by training programs designed to ensure that all appointed officers (e.g. inspectors or verifiers), analysts, and other individuals carrying out technical and/or professional duties receive the training required to adequately perform their work assignments and to maintain their professional competence and ensure consistent application of requirements.

74. The competent authority should ensure that sufficient guidance, training and awareness programs targeted at all relevant stakeholders are in place to facilitate effective notification of suspect cases of food related illnesses or health hazards detected in the food chain. Administrative procedures or contingency plans (as appropriate) should provide guidance on initiating coordination mechanisms when involvement of several competent authorities is required to resolve the incident. Rapid alert systems and response should be designed and implemented for this purpose.

75. Food business operators should also be encouraged to develop or access training and education programs relevant to their activities and responsibilities. Such programs can include formal education and/or academic studies, industry training organisation courses or individual business staff training

76. Where a competent authority intends to use third party[15]

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[15] *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) paragraph 8

providers to implement controls, before being authorised the third party provider should be assessed against objective criteria to ensure their competency. The ongoing performance of officially authorised bodies should be regularly assessed by the competent authority. The competent authority should initiate procedures to correct deficiencies and, as appropriate, enable withdrawal of official authorisation.

77. Competent authorities should utilize laboratories that are authorised or accredited under officially recognized programs to ensure that adequate quality controls are in place to provide for the reliability of test results. Internationally recognized and validated analytical methods should be used wherever available and Good Laboratory Practices should be adhered to.

78. Competent authorities should ensure that authorised or accredited laboratories[16] participate in regular proficiency testing. Such testing may be organised nationally or internationally and reference laboratory may have a role in organising proficiency testing programs.

79. Where appropriate, the competent authority should provide access to educational information on food safety risks and mitigation steps, which may be taken to reduce these risks.

80. As appropriate, the competent authority should:

- Communicate food safety issues and concerns with (relevant competent authorities) trading partners;
- Participate in bilateral exchange with (relevant competent authorities) trading partners and international organisations related to food safety regulations and their enforcement;
- Communicate and collaborate with international organisations, such as FAO and WHO through International Food Safety Authorities Network (INFOSAN), WHO in accordance with the International Health Regulations (2005) and OIE as appropriate, in cases where food(s) implicated in incidents or outbreaks of food borne illness may be circulating in international trade and.
- Have in place a process for engagement with stakeholders including food business operators, consumers and other interested parties.

81. The competent authority should implement a range of food control activities, including inspections, audits, verification and surveillance to ensure that food business operators meet their responsibilities and are in compliance with requirements. Detailed

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[16] Guidance on laboratory competency is available in the *Guidelines for the assessment of the competence of testing laboratories involved in the import and export of food* (CAC/GL 27-1997) and the *International harmonised protocol for the proficiency testing of (chemical) analytic laboratories* (CAC/GL 28- 1997) may be useful.

procedures should be developed to articulate the key tasks and responsibilities of verification of compliance and the consequences of non-compliance, including repeated non-compliance.

82. Where a product or process is found not to be in conformity, the competent authority should take action to ensure that the operator remedies the situation. The resulting measures should take into account any repeated non-conformity of the same product or process to ensure that any action is proportionate: to the degree of public health risk, potential fraud or deception of consumers. As an example to illustrate this point the specific measures that may be applied in continuous cases of nonconformity may include:

- Increased intensity of audits and/ or inspection and/or monitoring of products and/or processes; identified as being not in conformity and/or the undertakings concerned; and
- In the most serious or persistent cases, de-registration of the producer and/or processor or closure of the relevant establishment.

SECTION 4.4 MONITORING AND SYSTEM REVIEW

83. The effectiveness and appropriateness of the national food control system should be regularly assessed against the objective of the system, effectiveness of control programs, as well as against legislative and other regulatory requirements. Criteria for assessment should be established, clearly defined and documented, and may also include cost benefits and efficiency.

84. Control programs should be subject to ongoing monitoring to ensure that its objectives are being achieved at all stages of the food chain, including production, manufacture, importation, processing, storage, transportation, distribution and trade. The assessment of control programs should cover issues such as:

- Effectiveness of control procedures;
- Suitability in achieving objectives;
- Whether the program has covered relevant stages in the production chain, taking into account risk factors; and
- Consideration of emerging trends.

85. A national food control system should be regularly reviewed to contribute to the systems improvement, in response to for example, control program data, non-compliances, food safety incidents, scientific research, and history of conformance, external and self-reviews of the system and changes to product risk or the production environment. Such reviews may take place at the level of system or program design or implementation as appropriate.

86. The review of food-related non-compliances and/or incidents is an opportunity to learn which can be used as a feedback loop for the planning process by the competent authority. A competent authority should use these opportunities to engage in continuous improvement by assessing an incident from first signal through response and incorporating lessons learned in the design and planning phase.

87. Competent authorities should ensure that the response system in regards to food safety and related events is effective, with clear communication between competent authorities, food business operators and consumers. These systems should be periodically tested to ensure that the communication and response systems work effectively.

88. Competent authorities and/or national governments should periodically review their surveillance systems with respect to their capacity to recognize emergencies rapidly. Elements of review include:

- Links between the symptomatic food borne illness surveillance system and the food monitoring system;
- Data on the symptoms and effects of chronic exposure to food borne contamination;
- Systems to allow rapid detection of contamination incidents to ensure prompt public alerts; and
- Links with the veterinary public health sector.

89. Particular attention should be paid to early warning mechanisms, coordination between competent authorities, communication to stakeholders and the use and effectiveness of contingency planning. Corrective action should be taken as appropriate.

90. A competent authority should utilize information gained from the surveillance of food borne illness as a risk management tool in the operation of their food control systems. Food recalls and adjustments to food production and processing operations, including emergency responses, may be based on information obtained from food borne disease information and food monitoring systems. Food borne illness and outbreak information should be used to inform the risk analysis activities of competent authorities.

91. The results of the evaluations[17], including the results of self-assessment and audits should also be taken into account in further

[17] For example, the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) provides for independent evaluation of the performance of veterinary services. The OIE PVS tool could be used to evaluate the veterinary public health related elements of the national food control system.

improvement of the system, and corrective actions should be taken into account as appropriate.

92. Any review and continuous improvement of the national food control system should be communicated effectively and efficiently to ensure that clear exchange of information and engagement between all stakeholders in the national food control system occurs. Following any review, all related documentation, procedures and guidance should be reviewed and updated if necessary to reflect any changes.

93. Competent authorities should consider the results of monitoring and review processes and take preventive or corrective action or improve the system as appropriate.

ANNEX 2

ASEAN Common Food Control Requirements

ASEAN GENERAL PRINCIPLES OF FOOD HYGIENE

(CAC/RCP 1-1969, Rev.4-2003, GENERAL PRINCIPLES OF FOOD HYGIENE, MOD)

ANNEX 2

ASEAN GENERAL PRINCIPLES OF FOOD HYGIENE

FOREWORD

ASEAN Common Principles and Requirements for Food Hygiene (ACPRFH) is aimed to guide ASEAN food operators and/or food producers to comply with the food hygiene provisions in food production from farm to table. The first ACPRFH was developed by the Prepared Foodstuff Product Working Group (PFPWG) and endorsed by ASEAN Consultative Committee for Standards and Quality (ACCSQ) in 2006. Recognizing the ASEAN Trade in Goods Agreement that was concluded in 2009 requires Member States to be guided by international standards in implementing their Sanitary and Phytosanitary measures, and the requirement of the ASEAN Policy Guideline for Standard and Conformance to adopt international standards, a review of the first version of the "Common Principles and Requirements for Food Hygiene" was undertaken by the PFWG, The PFPWG, has decided to revise the document based on Codex General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4 - 2003). This document revises and replaces the ASEAN Common Principles and Requirements for Food Hygiene:2006

The document is an adoption of the Codex General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4 - 2003) with the following modification:

Clause / Sub-clause	Modification
5.8 on Recall Procedures	Add: **The need for informing competent authorities** in the last sentence of the first paragraph of the clause.

Explanation: The addition has been made in order to enhance the transparency and the effectiveness of the recall procedures.

This document is one of the ASEAN Common Food Control Requirements (ACFCR).

July 2014

ANNEX 2

ASEAN GENERAL PRINCIPLES OF FOOD HYGIENE

INTRODUCTION

People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

International food trade, and foreign travel, are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major change in many countries over the last two decades and new food production, preparation and distribution techniques have developed to reflect this. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

These General Principles lay a firm foundation for ensuring food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria. The document follows the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage. It recommends a HACCP-based approach wherever possible to enhance food safety as described in *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application* (Annex).

The controls described in this General Principles document are internationally recognized as essential to ensure the safety and suitability of food for consumption. The General Principles are commended to Governments, industry (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike.

SECTION I - OBJECTIVES

1.1 THE CODEX GENERAL PRINCIPLES OF FOOD HYGIENE:

- identify the *essential* principles of food hygiene applicable *throughout the food chain* (including primary production through to the final consumer), to achieve the goal of ensuring that food is safe and suitable for human consumption;
- recommend a HACCP-based approach as a means to enhance food safety;
- indicate *how* to implement those principles; and
- provide a *guidance* for specific codes which may be needed for - sectors of the food chain; processes; or commodities; to amplify the hygiene requirements specific to those areas.

SECTION II - SCOPE, USE AND DEFINITION

2.1 SCOPE

2.1.1 The food chain

This document follows the food chain from primary production to the final consumer, setting out the necessary hygiene conditions for producing food which is safe and suitable for consumption. The document provides a base-line structure for other, more specific, codes applicable to particular sectors. Such specific codes and guidelines should be read in conjunction with this document and *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application* (Annex).

2.1.2 Roles of Governments, industry, and consumers

Governments can consider the contents of this document and decide how best they should encourage the implementation of these general principles to:

- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population;
- provide assurance that food is suitable for human consumption;
- maintain confidence in internationally traded food; and
- provide health education programmes which effectively communicate the principles of food hygiene to industry and consumers.

Industry should apply the hygienic practices set out in this document to:

- provide food which is safe and suitable for consumption;
- ensure that consumers have clear and easily-understood information, by way of labelling and other appropriate means, to enable them to protect their food from contamination and growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and
- maintain confidence in internationally traded food.

Consumers should recognize their role by following relevant instructions and applying appropriate food hygiene measures.

2.2 USE

Each section in this document states both the objectives to be achieved and the rationale behind those objectives in terms of the safety and suitability of food.

Section III covers primary production and associated procedures. Although hygiene practices may differ considerably for the various food commodities and specific codes should be applied where appropriate, some general guidance is given in this section. Sections IV to X set down the general hygiene principles which apply throughout the food chain to the point of sale. Section IX also covers consumer information, recognizing the important role played by consumers in maintaining the safety and suitability of food.

There will inevitably be situations where some of the specific requirements contained in this document are not applicable. The fundamental question in every case is "what is necessary and appropriate on the grounds of the safety and suitability of food for consumption?"

The text indicates where such questions are likely to arise by using the phrases "where necessary" and "where appropriate". In practice, this means that, although the requirement is generally appropriate and reasonable, there will nevertheless be some situations where it is neither necessary nor appropriate on the grounds of food safety and suitability. In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach. This approach allows the requirements in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of activities and varying

degrees of risk involved in producing food. Additional guidance is available in specific food codes.

2.3 DEFINITIONS

For the purpose of this Code, the following expressions have the meaning stated:

Cleaning - the removal of soil, food residue, dirt, grease or other objectionable matter.

Contaminant - any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

Contamination - the introduction or occurrence of a contaminant in food or food environment.

Disinfection - the reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

Establishment - any building or area in which food is handled and the surroundings under the control of the same management.

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

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

HACCP - a system which identifies, evaluates, and controls hazards which are significant for food safety.

Food handler - any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements

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

Food suitability - assurance that food is acceptable for human consumption according to its intended use.

Primary production - those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

SECTION III - PRIMARY PRODUCTION

OBJECTIVES:

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

- avoiding the use of areas where the environment poses a threat to the safety of food;
- controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety;
- adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

RATIONALE:

To reduce the likelihood of introducing a hazard which may adversely affect the safety of food, or its suitability for consumption, at later stages of the food chain.

3.1 ENVIRONMENTAL HYGIENE

Potential sources of contamination from the environment should be considered. In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular, this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimize that probability. The HACCP-based approach may assist in the taking of such measures see *Hazard Analysis and Critical Control (HACCP) Point System and Guidelines for its Application* (Annex).

Producers should as far as practicable implement measures to:

- control contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product; and
- protect food sources from faecal and other contamination.

In particular, care should be taken to manage wastes, and store harmful substances appropriately. On-farm programmes which achieve specific food safety goals are becoming an important part of primary production and should be encouraged.

3.3 HANDLING, STORAGE AND TRANSPORT

Procedures should be in place to:

- sort food and food ingredients to segregate material which is evidently unfit for human consumption;
- dispose of any rejected material in a hygienic manner; and
- protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

Care should be taken to prevent, so far as reasonably practicable, deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Appropriate facilities and procedures should be in place to ensure that:

- any necessary cleaning and maintenance is carried out effectively; and
- an appropriate degree of personal hygiene is maintained.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

OBJECTIVES:

Depending on the nature of the operations, and the risks associated with them, premises, equipment and facilities should be located, designed and constructed to ensure that:

- contamination is minimized;
- design and layout permit appropriate maintenance, cleaning and disinfections and minimize air-borne contamination;
- surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable, and easy to maintain and clean;
- where appropriate, suitable facilities are available for temperature, humidity and other controls; and
- there is effective protection against pest access and harbourage.

RATIONALE:

Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled.

4.1 LOCATION

4.1.1 Establishments

Potential sources of contamination need to be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food. Establishments should not be located anywhere where, after considering such protective measures, it is clear that there will remain a threat to food safety or suitability. In particular, establishments should normally be located away from:

- environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;
- areas subject to flooding unless sufficient safeguards are provided;
- areas prone to infestations of pests;
- areas where wastes, either solid or liquid, cannot be removed effectively.

4.1.2 Equipment

Equipment should be located so that it:

- permits adequate maintenance and cleaning;
- functions in accordance with its intended use; and
- facilitates good hygiene practices, including monitoring.

4.2 PREMISES AND ROOMS

4.2.1 Design and layout

Where appropriate, the internal design and layout of food establishments should permit good food hygiene practices, including protection against cross-contamination between and during operations by foodstuffs.

4.2.2 Internal structures and fittings

Structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected. In particular the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use;
- walls and partitions should have a smooth surface up to a height appropriate to the operation;
- floors should be constructed to allow adequate drainage and cleaning;
- ceilings and overhead fixtures should be constructed and finished to minimize the build up of dirt and condensation, and the shedding of particles;
- windows should be easy to clean, be constructed to minimize the build up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed;
- doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect;
- working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

4.2.3 Temporary/mobile premises and vending machines

Premises and structures covered here include market stalls, mobile sales and street vending vehicles, temporary premises in

which food is handled such as tents and marquees.

Such premises and structures should be sited, designed and constructed to avoid, as far as reasonably practicable, contaminating food and harbouring pests.

In applying these specific conditions and requirements, any food hygiene hazards associated with such facilities should be adequately controlled to ensure the safety and suitability of food.

4.3 EQUIPMENT

4.3.1 General

Equipment and containers (other than once-only use containers and packaging) coming into contact with food, should be designed and constructed to ensure that, where necessary, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food. Equipment and containers should be made of materials with no toxic effect in intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and, for example, to facilitate inspection for pests.

4.3.2 Food control and monitoring equipment

In addition to the general requirements in paragraph 4.3.1, equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment should also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of food. These requirements are intended to ensure that:

- harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled;
- where appropriate, critical limits established in HACCP-based plans can be monitored; and
- temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

4.3.3 Containers for waste and inedible substances

Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Containers used to hold dangerous substances should be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

4.4 FACILITIES

4.4.1 Water supply

An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food.

Potable water should be as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.

4.4.2 Drainage and waste disposal

Adequate drainage and waste disposal systems and facilities should be provided. They should be designed and constructed so that the risk of contaminating food or the potable water supply is avoided.

4.4.3 Cleaning

Adequate facilities, suitably designated, should be provided for cleaning food, utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where appropriate.

4.4.4 Personnel hygiene facilities and toilets

Personnel hygiene facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Where appropriate, facilities should include:

- adequate means of hygienically washing and drying hands, including wash basins and a supply of hot and cold (or suitably temperature controlled) water;

- lavatories of appropriate hygienic design; and
- adequate changing facilities for personnel.

Such facilities should be suitably located and designated.

4.4.5 Temperature control

Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

4.4.6 Air quality and ventilation

Adequate means of natural or mechanical ventilation should be provided, in particular to:

- minimize air-borne contamination of food, for example, from aerosols and condensation droplets;
- control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity, where necessary, to ensure the safety and suitability of food.

Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, they can be adequately maintained and cleaned.

4.4.7 Lighting

Adequate natural or artificial lighting should be provided to enable the undertaking to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting colour is misleading. The intensity should be adequate to the nature of the operation. Lighting fixtures should, where appropriate, be protected to ensure that food is not contaminated by breakages.

4.4.8 Storage

Where necessary, adequate facilities for the storage of food, ingredients and non-food chemicals (e.g. cleaning materials, lubricants, fuels) should be provided. Where appropriate, food storage facilities should be designed and constructed to:

- permit adequate maintenance and cleaning;
- avoid pest access and harbourage;
- enable food to be effectively protected from contamination during

storage; and
- where necessary, provide an environment which minimizes the deterioration of food (e.g. by temperature and humidity control).

The type of storage facilities required will depend on the nature of the food. Where necessary, separate, secure storage facilities for cleaning materials and hazardous substances should be provided.

SECTION V - CONTROL OF OPERATION

OBJECTIVE:

To produce food which is safe and suitable for human consumption by:

- formulating design requirements with respect to raw materials, composition, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items; and
- designing, implementing, monitoring and reviewing effective control systems.

RATIONALE:

To reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards.

5.1 CONTROL OF FOOD HAZARDS

Food business operators should control food hazards through the use of systems such as HACCP. They should:
- **identify** any steps in their operations which are critical to the safety of food;
- **implement** effective control procedures at those steps;
- **monitor** control procedures to ensure their continuing effectiveness; and
- **review** control procedures periodically, and whenever the operations change.

These systems should be applied throughout the food chain to control food hygiene throughout the shelf-life of the product through proper product and process design.

Control procedures may be simple, such as checking stock rotation calibrating equipment, or correctly loading refrigerated display units. In some cases a system based on expert advice, and involving documentation, may be appropriate. A model of such a food safety system is described in *Hazard Analysis and Critical Control (HACCP) System and Guidelines for its Application* (Annex).

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

Inadequate food temperature control is one of the most common causes of foodborne illness or food spoilage. Such controls include time and temperature of cooking, cooling, processing and storage. Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety and suitability of food. Temperature control systems should take into account:

- the nature of the food, e.g. its water activity, pH, and likely initial level and types of micro- organisms;
- the intended shelf-life of the product;
- the method of packaging and processing; and
- how the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

Such systems should also specify tolerable limits for time and temperature variations. Temperature recording devices should be checked at regular intervals and tested for accuracy.

5.2.2 Specific process steps

Other steps which contribute to food hygiene may include, for example:

- chilling
- thermal processing
- irradiation
- drying
- chemical preservation
- vacuum or modified atmospheric packaging

5.2.3 Microbiological and other specifications

Management systems described in paragraph 5.1 offer an effective way of ensuring the safety and suitability of food. Where microbiological, chemical or physical specifications are used in any food control system, such specifications should be based on sound

scientific principles and state, where appropriate, monitoring procedures, analytical methods and action limits.

5.2.4 Microbiological cross-contamination

Pathogens can be transferred from one food to another, either by direct contact or by food handlers, contact surfaces or the air. Raw, unprocessed food should be effectively separated, either physically or by time, from ready-to-eat foods, with effective intermediate cleaning and where appropriate disinfection.
Access to processing areas may need to be restricted or controlled. Where risks are particularly high, access to processing areas should be only via a changing facility. Personnel may need to be required to put on clean protective clothing including footwear and wash their hands before entering.
Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food, particularly meat and poultry, has been handled or processed.

5.2.5 Physical and chemical contamination

Systems should be in place to prevent contamination of foods by foreign bodies such as glass or metal shards from machinery, dust, harmful fumes and unwanted chemicals. In manufacturing and processing, suitable detection or screening devices should be used where necessary.

5.3 INCOMING MATERIAL REQUIREMENTS

No raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing. Where appropriate, specifications for raw materials should be identified and applied.
Raw materials or ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests should be made to establish fitness for use. Only sound, suitable raw materials or ingredients should be used.
Stocks of raw materials and ingredients should be subject to effective stock rotation.

5.4 PACKAGING

Packaging design and materials should provide adequate protection

for products to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases where used must be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Where appropriate, reusable packaging should be suitably durable, easy to clean and, where necessary, disinfect.

5.5 WATER

5.5.1 In contact with food

Only potable water, should be used in food handling and processing, with the following exceptions:

- for steam production, fire control and other similar purposes not connected with food; and
- in certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water).

Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored. Recirculated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

5.5.2 As an ingredient

Potable water should be used wherever necessary to avoid food contamination.

5.5.3 Ice and steam

Ice should be made from water that complies with section 4.4.1. Ice and steam should be produced, handled and stored to protect them from contamination.

Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

5.6 MANAGEMENT AND SUPERVISION

The type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers and supervisors should have enough knowledge

of food hygiene principles and practices to be able to judge potential risks, take appropriate preventive and corrective action, and ensure that effective monitoring and supervision takes place.

5.7 DOCUMENTATION AND RECORDS

Where necessary, appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.

5.8 RECALL PROCEDURES

Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market. Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions, and which may present a similar hazard to public health, should be evaluated for safety and may need to be withdrawn. The need for informing competent authorities and warning the public should be considered.

Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

OBJECTIVE:

To establish effective systems to:

- ensure adequate and appropriate maintenance and cleaning;
- control pests;
- manage waste; and
- monitor effectiveness of maintenance and sanitation procedures.

RATIONALE:

To facilitate the continuing effective control of food hazards, pests, and other agents likely to contaminate food.

6.1 MAINTENANCE AND CLEANING

6.1.1 General

Establishments and equipment should be kept in an appropriate state of repair and condition to:

- facilitate all sanitation procedures;
- function as intended, particularly at critical steps (see paragraph 5.1);
- prevent contamination of food, e.g. from metal shards, flaking plaster, debris and chemicals.

Cleaning should remove food residues and dirt which may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the food business. Disinfection may be necessary after cleaning.

Cleaning chemicals should be handled and used carefully and in accordance with manufacturers' instructions and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.

6.1.2 Cleaning procedures and methods

Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids.

Cleaning procedures will involve, where appropriate:

- removing gross debris from surfaces;
- applying a detergent solution to loosen soil and bacterial film and hold them in solution or suspension;
- rinsing with water which complies with section 4, to remove loosened soil and residues of detergent;
- dry cleaning or other appropriate methods for removing and collecting residues and debris; and
- where necessary, disinfection with subsequent rinsing unless the manufacturers' instructions indicate on scientific basis that rinsing is not required.

6.2 CLEANING PROGRAMMES

Cleaning and disinfection programmes should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of cleaning equipment.

Cleaning and disinfection programmes should be continually and effectively monitored for their suitability and effectiveness and where necessary, documented.

Where written cleaning programmes are used, they should specify:

- areas, items of equipment and utensils to be cleaned;
- responsibility for particular tasks;
- method and frequency of cleaning; and
- monitoring arrangements.

Where appropriate, programmes should be drawn up in consultation with relevant specialist expert advisors.

6.3 PEST CONTROL SYSTEMS

6.3.1 General

Pests pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices should be employed to avoid creating an environment conducive to pests. Good sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

6.3.2 Preventing access

Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

6.3.3 Harbourage and infestation

The availability of food and water encourages pest harbourage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean.

Where appropriate, refuse should be stored in covered, pest-proof containers.

6.3.4 Monitoring and detection

Establishments and surrounding areas should be regularly examined for evidence of infestation.

6.3.5 Eradication

Pest infestations should be dealt with immediately and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food.

6.4 WASTE MANAGEMENT

Suitable provision must be made for the removal and storage of waste. Waste must not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business. Waste stores must be kept appropriately clean.

6.5 MONITORING EFFECTIVENESS

Sanitation systems should be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or, where appropriate, microbiological sampling of environment and food contact surfaces and regularly reviewed and adapted to reflect changed circumstances.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

OBJECTIVES:

To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by:

- maintaining an appropriate degree of personal cleanliness;
- behaving and operating in an appropriate manner.

RATIONALE:

People who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers.

7.1 HEALTH STATUS

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, should not be allowed to enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.
Medical examination of a food handler should be carried out if clinically or epidemiologically indicated.

7.2 ILLNESS AND INJURIES

Conditions which should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered, include:

- jaundice;
- diarrhoea;
- vomiting;
- fever;
- sore throat with fever;
- visibly infected skin lesions (boils, cuts, etc.);
- discharges from the ear, eye or nose.

7.3 PERSONAL CLEANLINESS

Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

Personnel should always wash their hands when personal cleanliness may affect food safety, for example:

- at the start of food handling activities;
- immediately after using the toilet; and
- after handling raw food or any contaminated material, where

this could result in contamination of other food items; they should avoid handling ready-to-eat food, where appropriate.

7.4 PERSONAL BEHAVIOUR

People engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example:

- smoking;
- spitting;
- chewing or eating;
- sneezing or coughing over unprotected food.

Personal effects such as jewellery, watches, pins or other items should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

7.5 VISITORS

Visitors to food manufacturing, processing or handling areas should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

SECTION VIII - TRANSPORTATION

OBJECTIVES:

Measures should be taken where necessary to:

- protect food from potential sources of contamination;
- protect food from damage likely to render the food unsuitable for consumption; and
- provide an environment which effectively controls the growth of pathogenic or spoilage micro-organisms and the production of toxins in food.

RATIONALE:

Food may become contaminated, or may not reach its destination in a suitable condition for consumption, unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain.

8.1 GENERAL

Food must be adequately protected during transport. The type of conveyances or containers required depends on the nature of the food and the conditions under which it has to be transported.

8.2 REQUIREMENTS

Where necessary, conveyances and bulk containers should be designed and constructed so that they:

- do not contaminate foods or packaging;
- can be effectively cleaned and, where necessary, disinfected;
- permit effective separation of different foods or foods from non-food items where necessary during transport;
- provide effective protection from contamination, including dust and fumes;
- can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to
    - render it unsuitable for consumption; and
    - allow any necessary temperature, humidity and other conditions to be checked.

8.3 USE AND MAINTENANCE

Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection should take place between loads.

Where appropriate, particularly in bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES:

Products should bear appropriate information to ensure that:

- adequate and accessible information is available to the next person in the food chain to enable them to handle, store,

process, prepare and display the product safely and correctly;

- the lot or batch can be easily identified and recalled if necessary. Consumers should have enough knowledge of food hygiene to enable them to:
  - understand the importance of product information;
  - make informed choices appropriate to the individual; and
  - prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using it correctly.

Information for industry or trade users should be clearly distinguishable from consumer information, particularly on food labels.

RATIONALE:

Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or products becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain.

9.1 LOT IDENTIFICATION

Lot identification is essential in product recall and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev. 1(1991)) applies.

9.2 PRODUCT INFORMATION

All food products should be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly.

9.3 LABELLING

Prepackaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store

and use the product safely. Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev. (1991)) applies.

9.4 CONSUMER EDUCATION

Health education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product information and to follow any instructions accompanying products, and make informed choices. In particular consumers should be informed of the relationship between time/temperature control and foodborne illness.

SECTION X - TRAINING

OBJECTIVE:

Those engaged in food operations who come directly or indirectly into contact with food should be trained, and/or instructed in food hygiene to a level appropriate to the operations they are to perform.

RATIONALE:

Training is fundamentally important to any food hygiene system. Inadequate hygiene training, and/or instruction and supervision of *all* people involved in food related activities pose a potential threat to the safety of food and its suitability for consumption.

10.1 AWARENESS AND RESPONSIBILITIES

Food hygiene training is fundamentally important. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

10.2 TRAINING PROGRAMMES

Factors to take into account in assessing the level of training required include:

- the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms;
- the manner in which the food is handled and packed, including the probability of contamination;
- the extent and nature of processing or further preparation before final consumption;
- the conditions under which the food will be stored; and
- the expected length of time before consumption.

10.3 INSTRUCTION AND SUPERVISION

Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively.
Managers and supervisors of food processes should have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

10.4 REFRESHER TRAINING

Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

ANNEX 2

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION Annex to CAC/RCP 1-1969 (Rev. 4 - 2003)

PREAMBLE

The first section of this document sets out the principles of the Hazard Analysis and Critical Control Point (HACCP) system adopted by the Codex Alimentarius Commission. The second section provides general guidance for the application of the system while recognizing that the details of application may vary depending on the circumstances of the food operation.

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering, according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems.

While the application of HACCP to food safety was considered here, the concept can be applied to other aspects of food quality.

DEFINITIONS

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

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

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.
Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

PRINCIPLES OF THE HACCP SYSTEM

The HACCP system consists of the following seven principles:
PRINCIPLE 1: Conduct a hazard analysis.
PRINCIPLE 2: Determine the Critical Control Points (CCPs).
PRINCIPLE 3 : Establish critical limit(s).
PRINCIPLE 4: Establish a system to monitor control of the CCP.
PRINCIPLE 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
PRINCIPLE 6: Establish procedures for verification to confirm that the HACCP system is working effectively.
PRINCIPLE 7: Establish documentation concerning all procedures and records appropriate to these principles and their application.

INTRODUCTION

Prior to application of HACCP to any sector of the food chain, that sector should have in place prerequisite programs such as good hygienic practices according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety requirements. These prerequisite programs to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system.

For all types of food business, management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills.

During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at Critical Control Points (CCPs). Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found. HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

The application of the HACCP principles should be the responsibility of each individual businesses. However, it is recognised by governments and businesses that there may be obstacles that hinder the effective application of the HACCP principles by individual business. This is particularly relevant in small and/or less developed businesses. While it is recognized that when applying HACCP, flexibility appropriate to the business is important, all seven principles must be applied in the HACCP system. This flexibility should take into account the nature and size of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints.

Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing the HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration. More detailed information on the obstacles in implementing HACCP, particularly in reference to SLDBs, and recommendations in resolving these obstacles, can be found in "Obstacles to the Application of HACCP, Particularly in Small and Less Developed Businesses, and Approaches to Overcome Them" (document in preparation by FAO/WHO).

The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate.

APPLICATION

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

1. Assemble HACCP team

The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources, such as, trade and industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement HACCP in-house. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

2. Describe product

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including Aw, pH, etc), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc), packaging, durability and storage conditions and method of distribution. Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP plan.

3. Identify intended use

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

4. Construct flow diagram

The flow diagram should be constructed by the HACCP team (see also paragraph 1 above). The flow diagram should cover all steps in the operation for a specific product. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

5. On-site confirmation of flow diagram

Steps must be taken to confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards

(SEE PRINCIPLE 1)
The HACCP team (see "assemble HACCP team" above) should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption.

The HACCP team (see "assemble HACCP team") should next conduct a hazard analysis to identify for the HACCP plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents; and,
- conditions leading to the above.

Consideration should be given to what control measures, if any exist, can be applied to each hazard.
More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

7. Determine Critical Control Points

(SEE PRINCIPLE 2)
There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP

system can be facilitated by the application of a decision tree (e.g., Diagram 2), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or proc process should be modified at that step, or at any earlier or later stage, to include a control measure.

8. Establish critical limits for each CCP

(SEE PRINCIPLE 3)
Critical limits must be specified and validated for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, Aw, available chlorine, and sensory parameters such as visual appearance and texture.

Where HACCP guidance developed by experts has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration. These critical limits should be measurable.

9. Establish a monitoring system for each CCP

(SEE PRINCIPLE 4)
Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to

microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product.

All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

10. Establish corrective actions

(SEE PRINCIPLE 5)
Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.
The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

11. Establish verification procedures

(SEE PRINCIPLE 6)
Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

Examples of verification activities include:
- Review of the HACCP system and plan and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control.

Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP system.

12. Establish Documentation and Record Keeping

(SEE PRINCIPLE 7)
Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature

and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business.

Documentation examples are:
Hazard analysis;
CCP determination;
CAC/RCP 1-1969, Rev. 4-2003 - Annex Page 28
Critical limit determination.
Record examples are:
• CCP monitoring activities;
• Deviations and associated corrective actions;
• Verification procedures performed;
• Modifications to the HACCP plan;

An example of a HACCP worksheet for the development of a HACCP plan is attached as Diagram 3.

A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

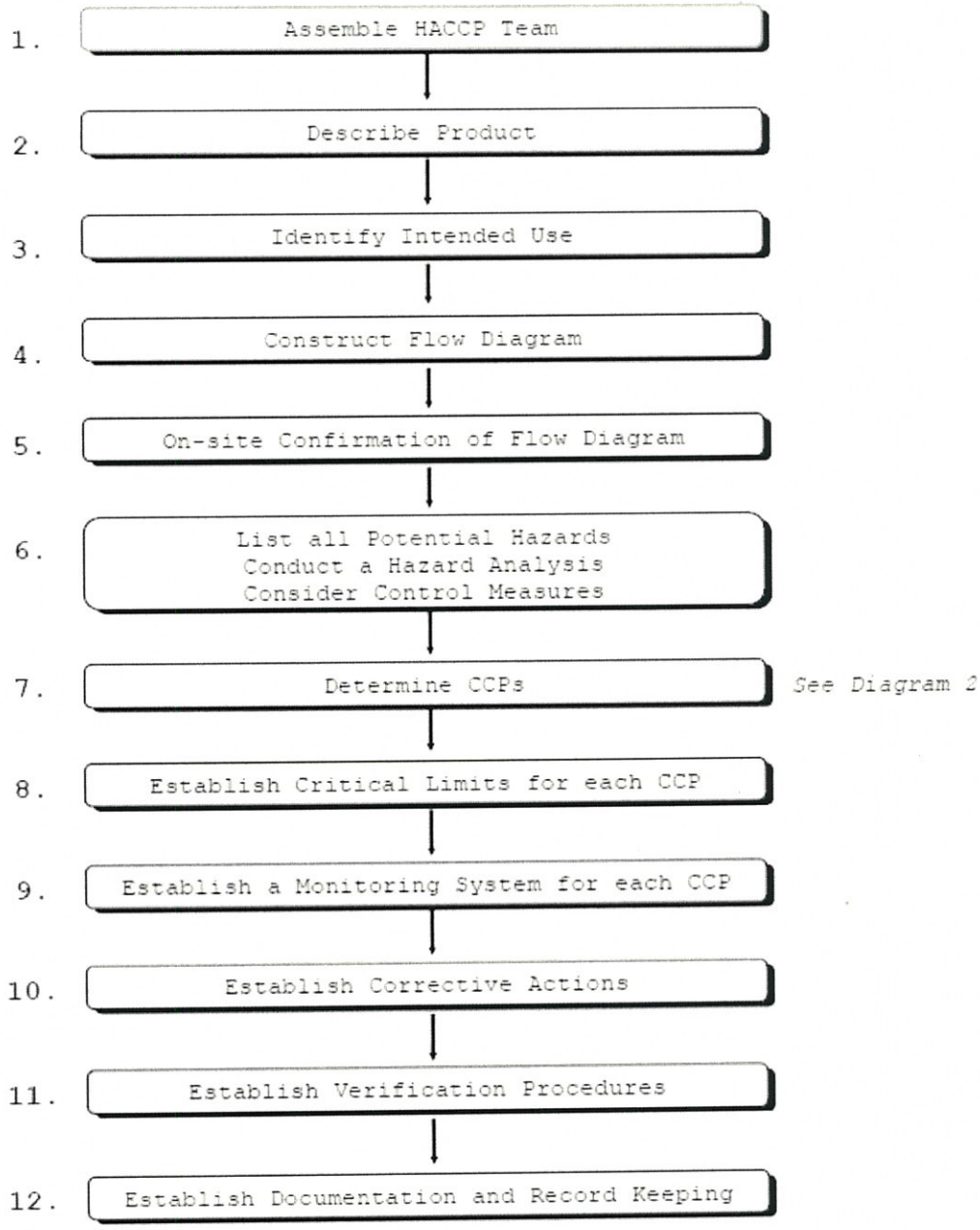
TRAINING

Training of personnel in industry, government and academia in HACCP principles and applications and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.
Cooperation between primary producer, industry, trade groups, consumer organisations, and responsible authorities is of vital important. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

ANNEX 2

DIAGRAM 1

LOGIC SEQUENCE FOR APPLICATION OF HACCP

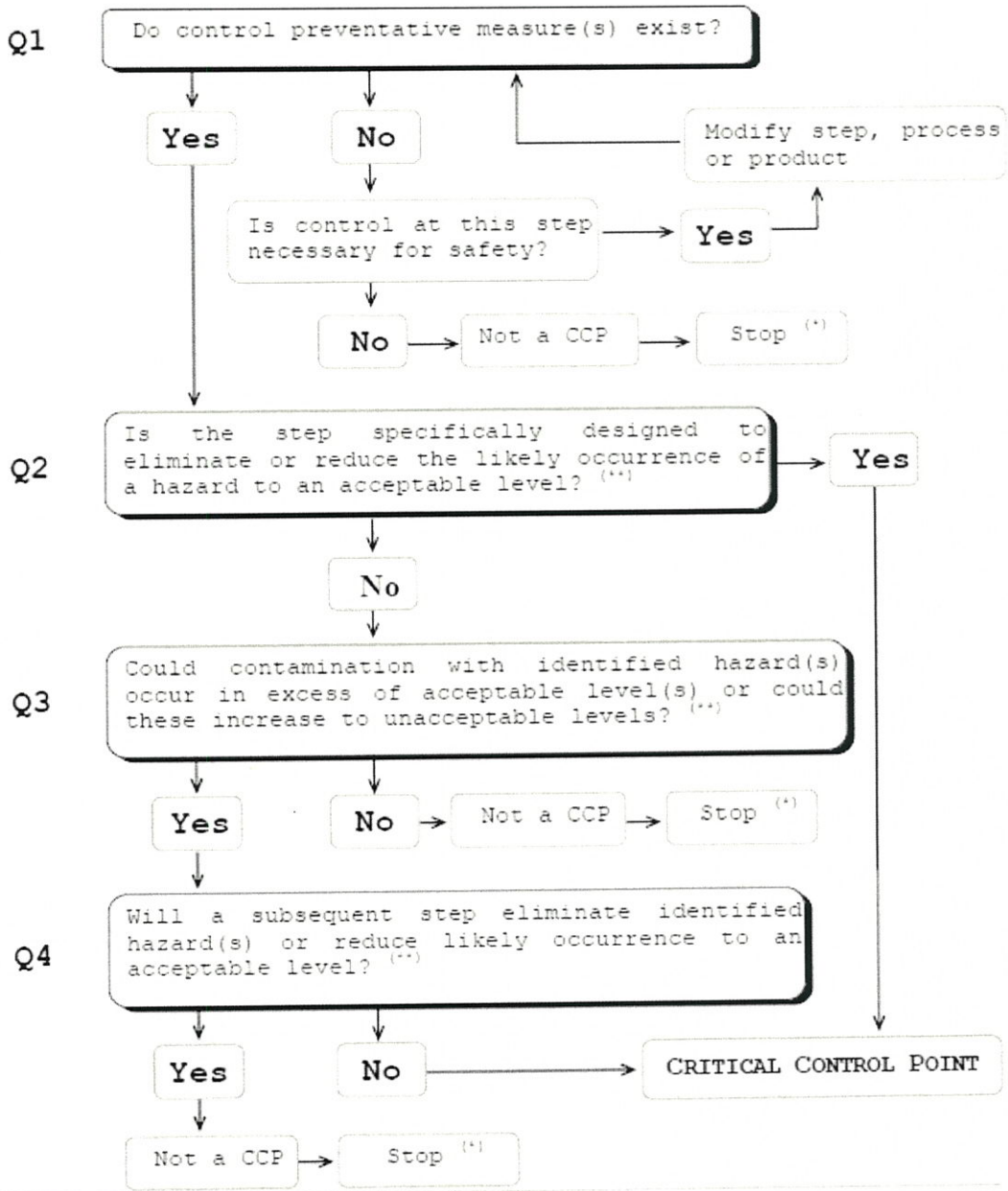


ANNEX 2

DIAGRAM 2

EXAMPLE OF DECISION TREE TO IDENTIFY CCPs

(answer questions in sequence)



(*) Proceed to the next identified hazard in the described process.

(**) Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan.

ANNEX 2

DIAGRAM 3

EXAMPLE OF A HACCP WORKSHEET

1. Describe Product

2. Diagram Process Flow

3.

LIST							
Step	Hazard(s)	Control Measure(s)	CCPs	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

4. Verification

ASEAN Common Food Control Requirements

ASEAN PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION (CAC/GL 20-1995-PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION, MOD)

ASEAN PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION

FOREWORD

The Prepared Foodstuff Product Working Group (PFPWG) under the ASEAN Consultative Committee for Standards and Quality (ACCSQ has been assigned the task of removing or reducing technical barriers to trade in the prepared food sector. The PFPWG has undertaken to harmonise the requirements for export and import inspection and certification systems for food systems towards this objective. Recognizing that the ASEAN Trade in Goods Agreement that was concluded in 2009 requires Member States to be guided by international standards in implementing their Sanitary and Phytosanitary measures, and the requirement of the ASEAN Policy Guideline for Standard and Conformance to adopt international standards, the PFWG has been guided by the Codex standard "CAC/GL 20-1995-PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION 5th edition" as the "ASEAN Principles for Food Import and Export Inspection and Certification".

The document is an adoption of the Principles for Food Import and Export Inspection and Certification (CAC/GL-20 1995 5th edition) published by the Codex Alimentarius Commission with the following modification:

Section/para	Modification
2. Definitions	Additional Definition **Competent Authority (ies)** means the official government agency having jurisdiction.
3., para 17	Explanatory Note added: Explanatory Note: The special and differential treatment refers to the provisions of Article 10 of the WTO/SPS Agreement.

Explanation: The term "competent authority "is utilised in several instances in the document. A definition for "Competent Authority (ies)" has been included in order to establish a common interpretation and ensure consistency with other ASEAN Documents.

The addition of the note on the "special and differential treatment" is to avoid any ambiguity in the interpretation of the principle.

This document is one of the ASEAN Common Food Control Requirements (ACFCR).

July 2014

ASEAN PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION

SECTION 1 – INTRODUCTION

1. Official and officially recognized inspection and certification systems are fundamentally important and very widely used means of food control; the following principles apply to such systems. The confidence of consumers in the quality (including safety) of their food supply depends in part on their perception as to the effectiveness of food control measures. A substantial part of the worldwide trade in food, for example in meat and meat products, depends upon the use of inspection and certification systems. However, inspection and certification requirements may significantly impede international trade in foodstuffs. Consequently it is desirable that the design and application of these systems should reflect appropriate principles.
2. Inspection of food may occur at any stage in the production and distribution process. For some foods, inspection oversight of harvesting, processing, storage, transport, and other handling of product may be the most appropriate means of ensuring food safety. According to the methods of preservation used, it may be necessary to maintain inspection oversight on a continuous basis up to the time of retail sale. Inspection systems may be focused on the foodstuffs themselves, on the procedures and facilities employed in the production and distribution chain, on the substance and materials which can be incorporated into or contaminate foodstuffs.
3. Inspection should be carried out at the most appropriate stages (e.g. control of refrigeration at every stage of the cold chain). For some requirements, e.g. those pertaining to product description, it may be possible to limit inspection to the distribution process and prior to final sale.
4. In both design and use, food inspection and certification systems should be governed by a number of principles which will ensure an optimal outcome consistent with consumer protection and facilitation of trade.

SECTION 2 – DEFINITIONS

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

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

Competent Authority (ies) means the official government agency having jurisdiction.

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.

Official inspection systems and official certification systems are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.

Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.

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

Risk assessment is the evaluation of the likelihood and severity of adverse effects on public health arising, for example, from the presence in foodstuffs of additives, contaminants, residues, toxins or disease-causing organisms.

SECTION 3 – PRINCIPLES

5. Food inspection and certification systems should be used wherever appropriate to ensure that foods, and their production systems, meet requirements in order to protect consumers against foodborne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate product description.

Fitness for purpose

6. Inspection and certification systems should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required.

Risk assessment

7. Inspection systems to ensure food safety should be designed and operated on the basis of objective risk assessment appropriate to the circumstances. Preferably the risk assessment methodology employed should be consistent with internationally accepted approaches. Risk assessment should be based on current available scientific evidence.

8. Inspection systems should be applied to particular commodities and processing methods in proportion to the assessed risks. In undertaking a risk assessment or in applying the principles of equivalence, importing countries should give due consideration to statements by exporting countries on a national or area basis of freedom from food-related disease.

Non-discrimination

9. Countries should 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.

Efficiency

10. Inspection and certification systems should have adequate means to perform their task. In the choice of inspection and certification systems, there should be regard to costs to consumers and to the costs in money and time to the affected food industry and government consulting with interested bodies as appropriate. Such systems should be no more restrictive of trade than is necessary in order to achieve the required level of protection.

Harmonization

11. Member countries should use Codex standards, recommendations and guidelines (or those of other international organizations whose membership is open to all countries) whenever appropriate as elements of their inspection and certification systems. Countries should participate actively in the work of the Codex Alimentarius Commission

and other relevant international bodies to promote and facilitate the development, adoption and review of Codex norms.

Equivalence

12. Countries should 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.

Transparency

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

14. Importing countries should provide information on existing requirements and proposed changes to requirements should be published and, except in the case of serious and immediate danger, an adequate time period permitted for comment. The views of exporting countries, and particularly those received from developing countries, should be taken into account in taking a final decision. A reasonable period should be allowed before a new requirement takes effect in order to permit exporting countries, and in particular developing countries, to make necessary changes to methods of production and control measures.

15. Importing countries should 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.

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

Special and differential treatment

17. In the design and application of food inspection and certification systems, importing countries should take into account of the capabilities of developing countries to provide the necessary safeguards.

Explanatory Note: The special and differential treatment refers to the provisions of Article 10 of the WTO/SPS Agreement.

Control and inspection procedures

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

Certification validity

19. Countries that certify exports of food and those importing countries which rely on export certificates should 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 with 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.

ASEAN Common Food Control Requirements

ASEAN GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

(CAC/GL 26-1997 - GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS, MOD)

ASEAN GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

FOREWORD

The Prepared Foodstuff Product Working Group (PFPWG) under the ASEAN Consultative Committee for Standards and Quality (ACCSQ has been assigned the task of removing or reducing technical barriers to trade in the prepared food sector. The PFPWG has undertaken to harmonise the requirements for export and import inspection and certification systems for food systems towards this objective. The PFPWG has thus undertaken to establish harmonised guidelines for the export-import inspection and certification systems for use by the competent authorities in all ASEAN Member States. Recognizing that the ASEAN Trade in Goods Agreement that was concluded in 2009 requires Member States to be guided by international standards in implementing their Sanitary and Phytosanitary measures, and the requirement of the ASEAN Policy Guideline for Standard and Conformance to adopt international standards, the PFWG has been guided by the Codex standard "CAC/GL 26-1997 GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS" as the "ASEAN Principles for Food Import and Export Inspection and Certification".

The document is an adoption of the CAC/GL 26-1997: Guidelines for the Design Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification, 5th Edition Revision 2010) published by the Codex Alimentarius Commission with the following modification:

Section/para	Modification
2. Definitions	Additional Definition **Competent Authority (ies)** means the official government agency having jurisdiction.

Explanation: The term "competent authority "is utilised in several instances in the document. A definition for "Competent Authority (ies)" has been included in order to establish a common interpretation and ensure consistency with other ASEAN Documents.

This document is one of the ASEAN Common Food Control Requirements (ACFCR).

July 2014

ASEAN GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

SECTION 1 – OBJECTIVES

1. These guidelines provide a framework for the development of import and export inspection and certification systems consistent with the *Principles for Food Import and Export Inspection and Certification*[1]. They are intended to assist countries[2] in the application of requirements and the determination of equivalency, thereby protecting consumers and facilitating trade in foodstuffs[3].

2. The document deals with the recognition of equivalence of inspection and/or certification systems and not with standards related to specific food products or their components (e.g., food hygiene, additives and contaminants, labelling and quality requirements).

3. Application by governments of the guidelines presented in this document should help build and maintain the necessary confidence in the inspection and certification system of an exporting country and facilitate fair trade, taking account of the expectations of consumers for an appropriate level of protection.

SECTION 2 – DEFINITIONS

Audit is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives[4].

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

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[1] CAC/GL 20-1995

[2] For the purpose of these guidelines, "countries" includes regional economic integration organizations to which a group of countries have transferred competences as regards food import and export inspection and certification systems and/or the negotiation of equivalency agreements with other countries

[3] The Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) includes that in the design and application of food inspection and certification systems, importing countries should take into account the capabilities of developing countries to provide the necessary safeguards (Paragraph 18).

[4] Consistent with the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995).

Competent Authority (ies) means the official government agency having jurisdiction.

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

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.

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

Official inspection systems and official certification systems are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.4

Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction[4].

Requirements are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading[4]

Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication[5]

Risk assessment is a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization.[5]

Risk management is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.[5]

Risk communication is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.[5]

[5] Codex Alimentarius Procedural Manual

SECTION 3 – RISK ANALYSIS

4. Consistent and transparent application of risk analysis will facilitate international trade by increasing confidence in the food safety and in the inspection systems of 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.

5. The principles of Hazard Analysis Critical Control Point (HACCP) developed by the Codex Committee on Food Hygiene[6] provide a systematic basis for the identification and control of hazards so as to ensure the safety of food. The use of a HACCP approach by food businesses should be recognized by governments as a fundamental tool for improving the safety of foodstuffs.

SECTION 4 – QUALITY ASSURANCE

6. The voluntary utilization of quality assurance by food businesses should 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 businesses, the official inspection and certification systems should take them into account in particular through the adaptation of their control methodologies.

7. Governments do, however, retain the fundamental responsibility to ensure by official inspection and certification[7] the conformity of foodstuffs to requirements.

8. The degree to which industry effectively utilizes quality assurance procedures can influence the methods and procedures by which government services verify that requirements have been met, where official authorities consider such procedures to be relevant to their requirements.

SECTION 5 – EQUIVALENCE

9. The recognition of equivalence of inspection and certification should be facilitated where it can be objectively demonstrated that there is an appropriate system for inspection and certification of food by the exporting country in accordance with these guidelines.

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[6] Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Annex to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

[7] For the purpose of these guidelines, "inspection and certification" means "inspection and/or certification".

10. For the determination of equivalence, governments should recognize that:

- inspection and certification systems should be organized for the risk involved, considering that the same food commodities produced in different countries may present different hazards; and,
- 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.

11. Controls on imported food and domestically produced foods should be designed to achieve the same level of protection. The importing country should 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 should have been achieved at the stages prior to import.

12. The exporting country should provide access to enable the inspection and certification systems to be examined and evaluated, on request of the food control authorities of the importing country. Evaluations of inspection and certification systems carried out by the authorities of an importing country should 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.

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

Equivalency agreements

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

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

- the legislative framework, control programmes and administrative procedures;
- contact points in inspection and certification services;
- demonstration by the exporting country of the effectiveness and adequacy of its enforcement and control programmes, including laboratories;
- where relevant, lists of products or establishments subject to certification or approval, accredited facilities and accredited bodies;
- mechanisms supporting continued recognition of equivalence, e.g., exchange of information on hazards and monitoring and surveillance.

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

SECTION 6 – INSPECTION AND CERTIFICATION SYSTEM INFRASTRUCTURE

17. Countries should identify the main objectives to be addressed through import and export inspection and certification systems.

18. Countries should 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 programme.

19. 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 should be a competent authority at the national level capable of ensuring uniform application. However, an importing country 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

20. For the purposes of this section, legislation includes acts, regulations, requirements or procedures, issued by public authorities,

related to foodstuffs and covering the protection of public health, the protection of consumers and conditions of fair trading.

21. The effectiveness of controls related to foodstuffs depends on the quality and completeness of legislation for foods. Legislation should provide authority to carry out controls at all stages of production, manufacture, importation, processing, storage, transportation, distribution and trade.

22. 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.

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

Control programmes and operations

24. 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 should draw up control programmes based on precise objectives and appropriate risk analysis. In the absence of detailed scientific research, control programmes should be based on requirements developed from current knowledge and practice. Every effort should be made to apply risk analysis based on internationally-accepted methodology, where available.

25. In particular, countries should require or encourage the use of a HACCP approach by food establishments. Official inspectors should be trained in the assessment of the application of HACCP principles. Where programmes include the drawing and analysis of samples, adequate sampling and appropriately validated analytical methods should be established to ensure that the results are representative and reliable in relation to the specific objectives.

26. The elements of a control programme should include, as appropriate:
- inspection;

- sampling and analysis;
- checks on hygiene, including personal cleanliness and clothing;
- examination of written and other records;
- examination of the results of any verification systems operated by the establishment;
- audit of establishments by the national competent authority;
- national audit and verification of the control programme.

27. Administrative procedures should be in place to ensure that controls by the inspection system are carried out:

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

28. Controls should cover, as appropriate:

- establishments, installations, means of transport, equipment and material;
- raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs;
- semi-finished and finished products;
- materials and objects intended to come into contact with foodstuffs;
- cleaning and maintenance products and processes, and pesticides;
- processes used for the manufacture or processing of foodstuffs;
- the application and integrity of health, grading and certification marks;
- preserving methods;
- labelling integrity and claims.

29. The elements of the control programme should be formally documented including methods and techniques.

Decision criteria and action

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

31. The frequency and intensity of controls by inspection systems should 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.

32. Physical checks applying to import should be based on risks associated with the importation. Countries should 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.

33. When physical checks are to be undertaken, sampling plans for imported products should 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.

34. Where an imported product is found not to be in conformity, the resulting measures should 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:

- repeated non-conformity in the same product or in the same category of products;
- history of non-conformity of those responsible for handling the products;
- reliability of checks made by the country of origin.

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

In respect of the product not in conformity

- 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);
- rejection of consignments or lots, in whole or in part;
- in the case of potentially serious health risk, destruction of the product;
- In respect of future imports
- control programmes implemented by the importer or exporter to ensure problems do not re-occur;
- increased intensity of checks on categories of products identified as being not in conformity and/or the undertakings concerned;
- request for information and cooperation on the product or the category of products found not to be in conformity by the responsible authorities in the country of origin (increased checks at origin including controls as indicated in paragraphs 27-28);

- on-site visits;
- in the most serious or persistent cases, imports from establishments or
  countries may be suspended.

36. Where possible, and upon request, the importer or their representative should 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.

37. Where product is rejected, information should be exchanged in accordance with the Codex Guidelines for the Exchange of Information between Countries on Rejections of Imported Food[8].

Facilities, equipment, transportation and communications

38. Inspection staff should have access to adequate facilities and equipment to undertake inspection procedures and methodologies.

39. 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.

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

Laboratories

41. Inspection services should 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 should be used wherever available.

[8] CAC/GL 25-1997

42. Inspection systems' laboratories should apply the principles of internationally accepted quality assurance techniques to ensure the reliability of analytical results[9].

Personnel

43. Official inspection services should have, or have access to, a sufficient number of qualified personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit and law. Personnel should be capable and appropriately trained in the operation of food inspection and control systems. They should have a status which ensures their impartiality and have no direct commercial interest in the products or establishments being inspected or certified.

SECTION 7 – CERTIFICATION SYSTEMS

44. An effective certification system depends on the existence of an effective inspection system as described above in Section 6.

45. Demand for certification should be justified by risk to health or risk of fraud or deception. Alternatives to certification should 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. 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.

46. Certification should 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:

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

[9] Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods (CAC/GL 27-1997

47. Competent authorities should take all necessary steps to ensure the integrity, impartiality and independence of official certification systems and officially-recognized certification systems. They should 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.

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

- should not certify matters without their personal knowledge or which cannot be ascertained by them;
- should 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 should be in possession of that document;
- should have no direct commercial interest in the products being certified.

SECTION 8 – OFFICIAL ACCREDITATION

49. Countries may officially accredit inspection or certification bodies to provide services on behalf of official agencies.

50. 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.

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

SECTION 9 – ASSESSMENT AND VERIFICATION OF INSPECTION AND CERTIFICATION SYSTEMS

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

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

54. 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.

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

56. Exporting countries should 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.

57. Guidelines on procedures for conducting an assessment and verification of the systems of an exporting country by an importing country are in the Annex.

SECTION 10 – TRANSPARENCY

58. Consistent with the principles on transparency contained in the Principles for Food Import and Export Inspection and Certification, 1 and in order to promote consumer confidence in the safety and quality of their food, governments should ensure that the operations of their inspection and certification systems are as transparent as possible, while respecting any legitimate constraints of professional and commercial confidentiality and avoiding the creation of new barriers to trade by giving a misleading impression of the quality or safety of imported products in comparison with domestic products.

ANNEX

PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF ASSESSMENTS OF FOREIGN OFFICIAL INSPECTION AND CERTIFICATION SYSTEMS

SECTION 1 – INTRODUCTION

1. An importing country may determine that it is necessary to assess an exporting country's official inspection and certification systems[10]. This annex is not intended to mandate the use of such assessments but to provide guidance that should be taken into account where they are used.

2. These assessment activities should concentrate primarily on evaluating the effectiveness of the official inspection and certification systems rather than on specific commodities or establishments in order to determine the ability of the exporting country's competent authority(s) to have and maintain control and deliver the required assurances to the importing country. A number of tools are available for the conduct of an assessment of an exporting country's official inspection and certification system these include, but are not limited to, audits, inspections and visits. The level of experience, knowledge and confidence[11]11 the importing country has in the exporting country's official inspection and certification system is important in determining the appropriate tool to undertake the assessment, including whether a visit to the country is required.

3. This annex is to be read in conjunction with section 9 - Assessment and verification of inspection and certification systems of Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997). In addition, the relevant sections of the OIE Performance of Veterinary Service Tool for Evaluation of Veterinary Services, Chapter 3.2 of the OIE Terrestrial Animal Health Code should be considered where appropriate

[10] Official inspection and certification systems refers to both 'Official inspection systems and official certification systems' and 'Officially recognized inspection systems and Officially recognized certification systems' as defined in the parent document.

[11] Experience, knowledge and confidence in an exporting country's food inspection and certification system by an importing country includes the history of food trade between two countries and the history of compliance of foods with the importing country's requirements, particularly the food products involved. Further examples that may inform the importing country's experience, knowledge and confidence are listed in paragraph 10 points (a) to (n) in CAC/GL 53-2003.

SECTION 2 – SCOPE

4. This annex provides guidance for use by competent authorities of both importing and exporting countries to ensure an effective, efficient, transparent[12]12, and consistent approach when using audits or inspections for assessment of an exporting country's official inspection and certification system(s), or component thereof. This annex should also apply to any other visit or request for information that may be part of an assessment which has the ability to impact on the exporting country.

SECTION 3 – OPENING MEETING

5. The overarching principle of this annex is that the competent authority of an importing country may conduct an assessment of an exporting country's official inspection and certification system with the agreement of the exporting country. In conducting assessments of an exporting country's official inspection and certification systems, the following additional principles apply.

Principles A to C apply to the conduct of the competent authorities of the importing and exporting countries throughout the assessment process

A. Assessments should be outcome focused, transparent, evidence-based and conducted in a cooperative, ethical and professional manner respecting confidential information, where appropriate.

B. The importing and exporting countries should have an agreed process to address any issues that may arise throughout the assessment process.

C. The importing and exporting countries should agree on an appropriate tool for the conduct of the assessment prior to its commencement based on the agreed scope and objectives. In most cases the preferred assessment approach would consider the official inspection and certification system as a whole or part.
Principles for the assessment process are provided in Principles D to G

D. The assessment process should be planned, systematic, transparent, consistent, fully documented and well communicated.

E. The plan incorporating rationale, objective, scope, assessment tools and, requirements against which the exporting country's official inspection and certification system is assessed should be clearly

[12] CAC/GL 20 1995, paragraphs 13-16, and CAC/GL 26-1997, paragraph 58.

identified by the importing country, notified to and agreed by the exporting country's competent authority(s), within a reasonable period of time prior to the commencement of the assessment.
Principles F and G cover assessment reporting

F. Agreed corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.

G. The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.

SECTION 4 – CONDUCT OF ASSESSMENT

Principle A

Assessments should be outcome focused, transparent, evidence-based and conducted in a cooperative, ethical and professional manner, respecting confidential information where appropriate.

6. The importing country's competent authority should be able to demonstrate that its assessment findings, conclusions and recommendations are primarily focused on whether the required outcomes are likely to be achieved by the system and that they are supported by objective evidence or data which can be verified as accurate and reliable.

7. Where there are multiple competent authorities in an importing country, these authorities should coordinate their assessments in order to avoid any duplication of effort on the part of the exporting country.

8. The exporting country's competent authority or authorities should cooperate, coordinate and assist in the performance of the assessment so that the assessment objectives are achieved.

9. Throughout the course of the assessment, all issues arising should be dealt with in a cooperative, ethical and professional manner by the competent authorities.

10. The importing country's competent authority should ensure the impartiality of their auditors, inspectors or auditing organization. The assessors should have the appropriate qualifications, experience and training both in the relevant area of technical expertise and in audit techniques.

11. In conducting an assessment importing countries should ensure that confidential information is protected. For countries with specific laws relating to confidentiality, an agreement between the two parties should be reached as to how the laws will be adhered to, in order to proceed.

12. The anticipated costs for undertaking the assessment should be understood by both competent authorities in advance of undertaking the assessment.

13. The costs incurred in undertaking an assessment, including all travel costs, costs of technical experts and auditors or inspectors, and costs of support staff should normally be borne by the competent authority of the importing country except as may otherwise be agreed.

14. The costs incurred by the competent authority of the exporting country, in supporting the assessment, for support staff and technical experts in the exporting country should normally be borne by the competent authority of the exporting country except as may otherwise be agreed.

Principle B

The importing and exporting countries should have an agreed process to address any issues that may arise throughout the assessment process.

15. Prior to the commencement of the assessment the key elements of a process to address issues that may arise throughout an assessment should be agreed. Where they are available, the competent authorities of the importing and exporting countries should use existing processes to resolve issues arising from the assessment to the extent possible. The competent authorities of the importing and exporting country should aim to resolve any issues which may arise in the course of the assessment in an open, transparent and cooperative manner. If any issues remain outstanding they should be indicated in the assessment report with appropriate justification.

Principle C

The importing and exporting countries should agree on an appropriate tool for the conduct of the assessment prior to its commencement based on the agreed scope and objectives. In most cases the preferred assessment approach would consider the official inspection and certification system as a whole or a part.

16. The most efficient and effective tool that can assess the effectiveness of the exporting country's official inspection and certification system including the exporting country's competent authority(s) ability to have and maintain control and deliver the required assurances to the importing country should be selected.

17. In selecting the assessment tool, it is important to consider the reason the assessment is being undertaken. Assessments can, for example, be part of a risk analysis prior to commencement of trade, can assess the official inspection and certification system, or controls for a particular component e.g. commodity (e.g. dairy, fish or meat) or controls for a particular element (e.g. chemical residues) or specific exporting establishments.

18. The importing country's experience, knowledge and confidence[13]13 in an exporting country's official inspection and certification systems, should be considered in selecting an assessment tool.

19. In general, the preferred assessment tools would be audits of all or part of an exporting country's official inspection and certification system including the ability of the competent authority. Inspections can also be an appropriate assessment tool. Where competent authorities use other terms to describe assessment activities, e.g. visits, information exchanges, such activities should also be subject to these guidelines.

Audit Tools

20. The audit tool, often described as 'systems based audit' should focus on assessing whether the implementation of the official inspection and certification system or components thereof in operation in the exporting country is capable of meeting its objectives.

21. Systems-based audits rely on the examination of a sample of system procedures, documents or records and, where required, a selection of sites within the scope of the system under audit, as opposed to examining all procedures.

22. A system-based approach focuses on the control system(s) and recognizes that any compliances/non-compliances found must be viewed in the context of the over-all system.

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[13] Paragraphs 9-14 of the Appendix to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003) provides additional guidance relating to what constitutes experience, knowledge and confidence and expands on information presented in paragraph 10-12 of that Guideline

23. In conducting a systems-based audit, the audit may involve examination of the elements as contained in Section 6, Inspection and Certification System Infrastructure or other elements as appropriate.

Inspection Tool

24. The inspection tool may be used in some instances to confirm the effectiveness of controls by the competent authority(s) in the exporting country.

25. Inspections may involve the examination of:

a) how establishments meet requirements, including review of specific activities and product specifications, observation and review of establishment operations and appropriate operating records;
b) establishment's personnel capabilities, when specified in requirements;
c) inspectors' capability, if specified in requirements.

SECTION 5 – ASSESSMENT PROCESS

Principles D to G cover the assessment process.

Principle D

The assessment process should be planned, systematic, transparent, consistent, fully documented and well communicated.

26. The transparency and consistency of the assessment process may be facilitated by good documentation and communication. Documents supporting findings, conclusions and recommendations should be standardised as much as possible in order to make the performance of the assessment and the presentation of its outcome uniform, transparent and reliable.

27. In order to prepare and carry out an assessment, ongoing and transparent communication is required. Consultation should occur between the competent authorities of the importing and exporting countries at all points in the process, from developing the assessment plan through to final reporting and resolution of any issues arising during the assessment. To ensure ongoing and transparent communication the competent authorities of the importing and exporting country should

designate responsible contact persons or contact points for assessments.

28. Processes and protocols for addressing assessment findings and recommendations should be documented and agreed prior to the assessment.

Principle E
The plan incorporating the rationale, objective, scope, assessment tools and requirements against which the exporting country's official inspection and certification system is assessed, should be clearly identified by the importing country, notified to and agreed by the exporting country's competent authority(s), within a reasonable period of time prior to the commencement of the assessment.

29. When establishing the rationale, objective, scope, frequency of assessment and assessment tools, the importing country's competent authority should take into account the established level of experience, knowledge and confidence together with the history of previous assessments, the period since the last assessment and any other relevant factors.

30. A systematic evaluation procedure for undertaking the assessment should be used based on a predetermined and structured program consistent with the purpose of the assessment.

Notification

31. The following information should be exchanged during the initial request and prior to commencing an assessment of a country's official inspection and certification system:

a) The rationale or need to conduct an assessment may arise from a number of reasons including, an importing country's legal obligations or the need to understand the respective roles of the competent authorities in both importing and exporting countries or the need to verify the capability of an exporting country's system or food production/processing facilities to meet requirements.
b) The objective of the assessment, for example is; to verify the effective application/implementation of specific measures or technical requirements of the exporting country's inspection and certification system; to verify compliance with measures of the importing country that the exporting country is implementing; to assess compliance with equivalency agreements or other types of mutual acceptance of systems, conduct an investigation of

outbreaks of foodborne diseases related to imported/exported food and to follow up corrective action resulting from previous assessments or of situations derived from food safety issues. The risk assessment component of an exporting country's food control system may be audited where it is necessary to support a risk management approach.

c) The scope of the assessment, that is, whether the assessment is to cover a whole system or its sub-components, measures, technical requirements, or products should be defined.
d) The assessment tool intended to be used including the requirements against which the official inspection and certification system of the exporting country will be assessed should be identified. 32. In all cases, the competent authority of the importing country should provide the competent authority of the exporting country with sufficient notice of the intended assessment, in order to enable it to make the necessary arrangements such as logistics and information gathering. If the rationale for the assessment is a critical public health issue the advance notice should reflect the urgency related to the public health risk.

33. In the case of a request for assessment from an exporting country, the importing country should respond in a timely manner providing a commitment to conduct the assessment[14].14

Assessment Preparation

34. A plan for undertaking the assessments, including the assessment tool, timeframes and exchange of required information should be prepared and communicated to the exporting country's competent authority within a reasonable period of time. The plan should include the following:

a) objective and scope of the assessment including whether it is a stand-alone assessment or related to another assessment (e.g. follow-up of previous assessment) or series of assessments;
b) items/ elements to be reviewed/ undertaken which may include records and assessment checklists;
c) the anticipated timeframe within which the assessment will be conducted and reported;
d) criteria against which the assessment of the exporting country's official inspection and certification system will be carried out;
e) a contact person for the assessment team who can negotiate the details of the assessment plan and if required, assessment team

[14] CAC/GL 20-1995 para 18.

members including foreign auditors/inspectors, the lead auditor/inspector, technical experts and translators;

f) the language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.
g) an indication of the type or where possible/relevant the identity of locations to be visited (e.g. offices, laboratories or other facilities) and the timing and responsibility for the notification to the sites where necessary (although this task may be completed at the assessment opening/entry meeting);
h) the dates for the conduct of the assessment, the dates of the opening and closing meeting and the anticipated date for reporting the observations of the assessment;
i) travel schedules and other logistics, as necessary for an assessment visit; and
j) provisions to protect confidential information.

35. While efforts should be made to adhere to the assessment plan it should be designed to be flexible in order to permit changes in emphasis based on information gathered prior to, or during the assessment. Proposed significant amendment(s) to the assessment plan should only be made in extenuating circumstances and should be communicated by the proposing competent authority to the other competent authority as soon as possible.

36. As part of the assessment plan, the competent authorities of both countries should reach agreement on how the results of the evaluation will be conveyed to the exporting country, such as findings, non-compliance and recommendations.

37. Advanced agreement should be reached on the language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.

38. To the extent possible documentary information required for planning, conducting and completing the assessment should be requested and provided in advance of the assessment, utilizing electronic means wherever possible.

a) The assessment preparation request should be focused and related to the stated scope and objectives.
b) If this is a follow-up assessment, then the exporting country should only need to provide any information that has changed since the previous assessment or that has not been requested during a previous assessment.
c) In case the purpose of an information-request is not clear to the exporting country and it has some issues related to the requested

information, it may seek clarification from the importing country as to the purpose and use of such information.

d) When an on-site visit is the assessment tool proposed a review of documents describing the system including legislative support should be conducted prior to commencement of the assessment visit. This is to allow the most efficient and effective use of time spent on-site i.e. to reduce the burden of assessments on the competent authorities of both countries.

39. In some cases the assessment may be suspended or concluded prior to an on-site visit depending on the nature of information provided by the competent authority of the exporting country and in which case the reason should be communicated clearly to the competent authority of the exporting country by the competent authority of the importing country. The competent authority of the exporting country should have the opportunity to clarify the information provided should they consider this necessary.

40. Agreement should be reached in advance concerning the use of information sharing from assessments and the parties with whom information can be shared.

Assessment Logistics

41. When an assessment includes an on-site visit the competent authority of the exporting country should have primary responsibility for the logistical aspects of the assessment including advising on internal travel and accommodation arrangements. It is the responsibility of the competent authority of the exporting country to communicate with the responsible parties of the site(s) to b e assessed.

Assessment Opening / Entry Meeting

42. In the case of an assessment involving a visit an opening or entry meeting should be held.

a) The meeting should be held at a place designated by the competent authority of the exporting country.

b) The meeting should review all aspects of the assessment plan including any final adjustments and is intended to provide an overview of the official inspection and certification system of the exporting country and to confirm the parameters and logistics of the assessment.

c) Agreement should be reached on the methods to ensure continuous liaison and communications between the parties during the assessment.

Assessment Closing / Exit Meeting

43. In the case of an assessment involving a visit a closing or exit meeting should be held.

a) The meeting should be held at a place designated by the competent authority of the exporting country.
b) The assessment team should summarize main findings and preliminary conclusions. Any non-conformities should be identified and outline the objective evidence to support the conclusions. Correction of non-conformities should be left to the competent authority of the exporting country and verified by the competent authority of the importing country including a follow-up assessment if required.
c) This meeting provides an opportunity for the competent authority of the exporting country to raise questions or seek clarification of the findings and observations provided at the meeting.

SECTION 6 – ASSESSMENT REPORTING

Principles F and G cover assessment reporting.

Principle F

Agreed corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.
Principle G
The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.

44. A collaborative approach to report preparation and a process for distribution and presentation should be agreed in advance.

45. The assessed party should have the opportunity to review the draft report in an agreed timeframe, provide comments and correct factual errors before its finalization. The final report should incorporate, or be accompanied by, the comments provided by the competent authority of the exporting country.

46. The report of assessment should provide a balanced picture of the findings and include conclusions and recommendations that accurately reflect those findings. It should: a) describe the objective, scope, and outcome;

a) b) describe the criteria and assessment process;
b) include assessment findings with supporting evidence for each conclusion, along with any details of significance discussed during the closing meeting;
c) be made available as agreed to between the importing and exporting country's competent authorities, including and addressing the comments made by the competent authority of the exporting country to enhance the
d) accuracy of the report;
e) take into account the timeframe for the finalisation of the report and response procedures agreed upon between importing and exporting countries' competent authorities;
f) include how corrective actions will be communicated and agreed to, including how follow-up verification will be completed;
g) include any checklists of elements evaluated, where required to support the findings;
h) include a summary of the assessment outcome;
i) include outstanding matters and issues arising during the assessment in the report if there is no agreement on the conclusions and the corresponding corrective actions;
j) include uncertainties and/or any obstacles encountered that could affect the reliability of the assessment conclusion; and
k) indicate any areas not covered in the assessment process, though within the scope, and the reasons for such deviation from the agreed scope.

47. The timeframe and protocol for any follow-up verification should be clearly stated.
Verification of corrective actions may include:

a) review of assurances provided by the competent authority of the exporting country;
b) review of documentation provided by the competent authority of the exporting country; or
c) review of stated corrective action in a subsequent assessment.

48. Confidential information must be respected in the preparation and subsequent distribution of the assessment report.

49. Once an assessment report has been finalised the competent authorities of the importing and exporting countries should discuss and if possible agree if and how any or all of the report will be published respecting confidentiality of information where appropriate.

ASEAN Common Food Control Requirements

ASEAN GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS

(CAC/GL 47-2003 GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS, MOD)

ASEAN GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS

FOREWORD

The Prepared Foodstuff Product Working Group (PFPWG) under the ASEAN Consultative Committee for Standards and Quality (ACCSQ has been assigned the task of removing or reducing technical barriers to trade in the prepared food sector. The PFPWG has undertaken to harmonise the requirements import control systems for food systems towards this objective. The PFPWG has thus undertaken to establish harmonised guidelines for import control systems for use by the competent authorities in all ASEAN Member States. Recognizing that the ASEAN Trade in Goods Agreement that was concluded in 2009 requires Member States to be guided by international standards in implementing their Sanitary and Phytosanitary measures, and the requirement of the ASEAN Policy Guideline for Standard and Conformance to adopt international standards, the PFWG has been guided by the Codex standard "CAC/GL 47-2003 GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS" as the "ASEAN GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS".

The document is an adoption of the CAC/GL 47-2003 GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (Adopted 2003 Revision 2006) published by the Codex Alimentarius Commission with the following modification:

Section/para	Modification
2. Definitions	Additional Definition **Competent Authority (ies)** means the official government agency having jurisdiction.

Explanation: The term "competent authority "is utilised in several instances in the document. A definition for "Competent Authority (ies)" has been included in order to establish a common interpretation and ensure consistency with other ASEAN Documents.

This document is one of the ASEAN Common Food Control Requirements (ACFCR).

July 2014

ASEAN GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS

SECTION 1 – SCOPE

1. This document provides a framework for the development and operation of an import control system to protect consumers and facilitate fair practices in food trade while ensuring unjustified technical barriers to trade are not introduced. The Guideline is consistent with the Codex Principles for Food Import and Export Inspection and Certification[1]1 and provides specific information about imported food control that is an adjunct to the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems[2].

SECTION 2 – DEFINITIONS[3]

Appropriate Level of Protection (ALOP) is the level of protection deemed appropriate by the country establishing a sanitary measure to protect human life or health within its territory. (This concept may otherwise be referred to as the "acceptable level of risk".)

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

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

Competent Authority (ies) means the official government agency having jurisdiction.

Inspection is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and

[1] Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995)
[2] Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997).
[3] Definitions drawn from the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) are marked with *. Definitions drawn from Codex Alimentarius Commission, Procedural Manual are marked with**

finished product testing, in order to verify that they conform to requirements.

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

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

Official inspection systems and official certification systems are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.

Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.

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

Risk assessment A scientifically based process consisting of the following steps (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation.

Risk analysis A process consisting of three components: risk assessment, risk management and risk communication.

SECTION 3 – GENERAL CHARACTERISTICS OF FOOD IMPORT CONTROL SYSTEMS

2. Food import control systems should have the following main characteristics:

- requirements for imported food that are consistent with requirements for
- domestic foods;
- clearly defined responsibilities for the competent authority or authorities;
- clearly defined and transparent legislation and operating procedures;
- precedence to the protection of consumers;

- provision of the importing country for recognition of the food control system applied by an exporting country's competent authority;
- uniform nationwide implementation;
- implementation that ensures the levels of protection achieved are consistent with those for domestic food.

Requirements for imported food that are consistent with requirements for domestic foods

3. Requirements are commonly expressed as end-point standards with specific limits and complementary sampling regimes. These requirements may consist of standards, provisions for sampling, process controls, conditions of production, transport, storage, or a combination of these.

4. The extent and stringency of requirements applied in specific circumstances should be proportionate to risk, noting that risk may vary from one source to another because of factors such as specific and/or similar situations in the region of origin, technology employed, compliance history, etc. and/or examination of relevant attributes of a sample of products at import.

5. As far as possible, requirements should be applied equally to domestically produced and imported food. Where domestic requirements include process controls such as good manufacturing practices, compliance may be determined or equivalence confirmed by auditing the relevant inspection and certification systems and, as appropriate, the facilities and procedures in the exporting country[4]

Clearly defined responsibilities of competent authority or authorities

6. The competent authority(ies) involved in any of the imported food inspection functions at the point or points of entry, during storage and distribution and/or at point of sale, should have clearly defined responsibilities and authority. Multiple inspection and duplicative testing for the same analyte(s) on the same consignment should be avoided to the extent possible.

7. Some countries, for example those that are part of a regional economic grouping, may rely on import controls implemented by another country. In such cases, the functions, responsibilities, and

[4] Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997), para. 54.

operating procedures undertaken by the country which conducts the imported food control should be clearly defined and accessible to authorities in the country or countries of final destination with the aim of delivering an efficient and transparent import control system.

8. Where the competent authorities of an importing country use third party providers as officially recognised inspection bodies and/or officially recognized certification bodies to implement controls, such arrangements should be conducted in the manner discussed in CAC/GL 26-1997, Section 8, Official Accreditation. The functions that can be conducted by such providers may include:

- sampling of target consignments;
- analysis of samples;
- compliance evaluation of relevant parts or all of a quality assurance system that may be operated by importers in order to comply with official requirements.

Clearly defined and transparent legislation and operating procedures

9. The object of legislation is to provide the basis and the authority for operating a food import control system. The legal framework allows for the establishment of the competent authority(ies) and the processes and procedures required to verify the conformity of imported products against requirements.

10. Legislation should provide the competent authority with the ability to:

- appoint authorised officers;
- require prior notification of the importation of a consignment of a foodstuff;
- require documentation;
- inspect, including the authority to enter premises within the importing country, physically examine the food and its packaging; collect samples and initiate analytical testing; inspection of documentation provided by an exporting country authority, exporter or importer; and verification of product identity against documentary attestations;
- apply risk-based sampling plans, taking into consideration the compliance history of the particular food, the validity of accompanying certification, and other relevant information;
- charge fees for the inspection of consignments and sample analysis;
- recognize accredited or accredit laboratories;

- accept; reject; detain; destroy; order to destroy; order reconditioning, processing, or re-export; return to country of export; designate as non-food use;
- recall consignments following importation;
- retain control over consignments in transit during intra-national transport or during storage prior to import clearance; and,
- implement administrative and/or judicial measures when the specific requirements are not satisfied.

11. In addition, the legislation may make provisions for:
- licensing or registration of importers;
- recognition of verification systems used by importers;
- an appeal mechanism against official actions;
- assessing the control system of the exporting country; and
- certification and/or inspection arrangements with competent authorities of exporting countries.

Precedence to the protection of consumers

12. In the design and operation of food import control systems, precedence should be given to protecting the health of consumers and ensuring fair practices in food trade over economic or other trade considerations.

Provision of the importing country for recognition of the food control system applied by an exporting country's competent authority

13. Food import control systems should include provisions for recognition as appropriate of the food control system applied by an exporting country's competent authority. Importing countries can recognise the food safety controls of an exporting country in a number of ways that facilitate the entry of goods, including the use of memoranda of understanding, mutual recognition agreements and equivalence agreements and unilateral recognition. Such recognition should, as appropriate, include controls applied during the production, manufacture, importation, processing, storage, and transportation of the food products, and verification of the export food control system applied.

Uniform nation-wide implementation

14. Uniformity of operational procedures is particularly important. Programmes and training manuals should be developed and

implemented to assure uniform application at all points of entry and by all inspection staff.

Implementation that ensures the levels of protection achieved are consistent with those for domestic food

15. As an importing country has no direct jurisdiction over process controls applied to food manufactured in another country, there may be a variation in approach to the compliance monitoring of domestic and imported food. Such differences in approach are justifiable provided they are necessary to ensure that the level of protection achieved is consistent with that of domestically produced food.

SECTION 4 – IMPLEMENTATION OF THE CONTROL SYSTEM

16. Operational procedures should be developed and implemented to minimize undue delay at the point or points of entry without jeopardizing effectiveness of controls to meet requirements. Implementation should take into account the factors listed in this section and the possibility of recognizing guarantees at origin that includes implementation of controls in the exporting countries.

Point of control

17. Control of imported food by the importing country can be conducted at one or more points including the points of:

- origin, where agreed upon with the exporting country;
- entry to the country of destination;
- further processing;
- transport and distribution;
- storage; and,
- sale, (retail or wholesale).

18. The importing country can recognize controls implemented by the exporting country. The application of controls by the exporting country, during production, manufacture and subsequent transit should be encouraged, with the aim of identifying and correcting problems when and where they occur, and preferably before costly recalls of food already in distribution are required.

19. Pre-shipment clearance is a possible mechanism for ensuring compliance with requirements of, for example, valuable bulk packed products that if opened and sampled upon entry, would be seriously

compromised, or for products that require rapid clearance to maintain safety and quality.

20. If the inspection system encompasses pre-shipment clearance then the authority to conduct the clearance should be determined and procedures defined. The importing country's competent authority may choose to conduct pre-shipment clearance from an exporting country's official certification system or from officially recognised third party certification bodies working to defined criteria. The pre-shipment clearance should be based on the results of the documentary check on the consignments.

Information about food to be imported[5]

21. The efficacy of the control system in applying efficient targeted control measures depends upon information about consignments entering the jurisdiction. Details of consignments that may be obtained include:

- date and point of entry;
- mode of transport;
- comprehensive description of the commodity (including for example product description, amount, means of preservation, country of origin and/or of dispatch, identifying marks such as lot identifier or seal identification numbers etc);
- exporter's and importer's name and address;
- manufacturer and/or producer, including establishment registration number;
- destination; and,
- other information.

Frequency of inspection and testing of imported food

22. The nature and frequency of inspection, sampling and testing of imported foods should be based on the risk to human health and safety presented by the product, its origin and the history of conformance to requirements and other relevant information. Control should be designed to account for factors such as:

- the risk to human health posed by the product or its packaging;
- the likelihood of non-compliance with requirements;
- the target consumer group;
- the extent and nature of any further processing of the product;

[5] Generic Official Certificate Formats and the Production and Issuance of Certificates (CAC/GL 38-2001)

- food inspection and certification system in the exporting country and existence of any equivalence, mutual recognition agreements or other trade agreements; and,
- history of conformity of producers, processors, manufacturers, exporters, importers and distributors.

23. Physical checks of imported product, preferably using statistically based sampling plans, should represent valid methods for the verification of compliance with requirements by the product as established by the importing country, or in the case of importing a product for the purposes of re-exportation, verification should be made on the requirements of the country of final destination and said requirements should be specified in the certificate of re-exportation. Inspection procedures should be developed to include defined sampling frequencies or inspection intensities, including for re-exported product.

24. Sampling frequency of products supplied from a source for which there is no or known poor compliance history may be set at a higher rate than for products with a good compliance history provided this is shown through transparent and objective criteria. The sampling process enables a compliance history to be created. Similarly, food from suppliers or imported by parties with a known poor compliance history should be sampled at higher intensity. In these cases, every consignment may need to be physically inspected, until a defined number of consecutive consignments meets requirements. Alternatively the inspection procedures can be developed to automatically detain product from suppliers with a known poor compliance history and the importer may be required to prove the fitness of each consignment through use of a laboratory (including official laboratory) recognized, accredited and/or listed by the competent authority until a satisfactory compliance rate is achieved.

Sampling and analysis

25. The inspection system should be based on Codex sampling plans for the particular commodity/contaminant combination where available. In the absence of Codex sampling plans, reference should be made to internationally accepted or scientifically based sampling plans.

26. Internationally validated standard methods of analysis or methods validated through international protocols should be used where available. Analysis should be conducted in official or officially accredited laboratories.

Decisions

27. Decision criteria (without prejudice to the application of customs procedures) should be developed that determine whether consignments are given:

- acceptance;
- entry if cleared upon inspection or verification of conformance;
- release of non-conforming product after re-conditioning and/or corrective measures have been taken;
- rejection notice, with redirecting product for uses other than human consumption;
- rejection notice, with re-exportation option or return to country of export option at exporter expense;
- rejection notice with destruction order.

28. Results of inspection and, if required, laboratory analysis, should be carefully interpreted in making decisions relating to acceptance or rejection of a consignment. The inspection system should include decision-making rules for situations where results are borderline, or sampling indicates that only some lots within the consignment comply with requirements. Procedures may include further testing and examination of previous compliance history.

29. The system should include formal means to communicate decisions regarding clearance and status of consignments[6]. There should be an appeal mechanism and/or opportunity for review of official decisions on consignments[7]. When food is rejected because it fails to meet national standards of the importing country but conforms to international standards, the option of withdrawing the rejected consignment should be considered.

Dealing with emergency situations

30. The responsible authority should have procedures that can respond appropriately to emergency situations. This will include holding suspect product upon arrival and recall procedures for suspect product already cleared and, if relevant, rapid notification of the problem to international bodies and possible measures to take.

31. If the food control authorities in importing countries detect problems during import control of foodstuffs which they consider to be so serious

[6] Paragraph 4 of the Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997) should be consulted in this regard.
[7] Paragraph 6 of the Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997) should be consulted in this regard.

as to indicate a food control emergency situation, they should inform the exporting country promptly by telecommunication[8].

Recognition of export controls

32. Consistent with paragraph 13 of these guidelines, the importing country should establish mechanisms to accept control systems in an exporting country where these systems achieve the same level of protection required by the importing country. In this regard, the importing country should:

- develop procedures to conduct assessment of the exporting country systems consistent with the Annex of the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997);
- take into account the scope of the arrangement, for example, whether it covers all foods or is restricted to certain commodities or certain manufacturers;
- develop clearance procedures that achieve its appropriate level of protection if arrangements developed with an exporting country are limited in scope;
- provide recognition of export controls through, for example, exemption from routine import inspection;
- conduct verification procedures for example, occasional random sampling
- and analysis of products upon arrival. (Section 5 and Annex of CAC/GL 26-1997 deal with the provision and verification of systems that provide certification for food in trade);
- recognize that arrangements need not rely on the presentation of certificates or documentation with individual consignments, when such an approach is acceptable to both parties.

33. The competent authority of the importing country may, develop certification agreements with exporting country official certification bodies or officially recognized certification bodies, with the aim of ensuring requirements are met. Such agreements may be of particular value where, for example, there is limited access to specific facilities such as laboratories and consignment tracking systems[9].

[8] Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995).

[9] Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999).

Information exchange

34. Food import control systems involve information exchange between competent authorities of exporting and importing countries. The information may include:

- requirements of food control systems;
- "hard copy" certificates attesting to conformity with requirements of the particular consignment;
- electronic data or certificates where accepted by the parties involved;
- details about rejected food consignment, such as destruction, re-exportation, processing, re-conditioning or redirection of consignment for uses other than human consumption;
- list of establishments or facilities that conform to importing country requirements.

35. Any changes to import protocols, including specifications, which may significantly affect trade, should be promptly communicated to trading partners, allowing a reasonable interval[10] between the publication of regulations and their application.

Other considerations

36. The competent authority may consider developing alternative arrangements in lieu of routine inspection. This may include agreements where the competent authority assesses the controls that importers implement over suppliers and the procedures that are in place to verify compliance of suppliers. Alternative arrangements may include some sampling of product as an audit, rather than routine inspection.

37. The competent authority may consider developing a system where registration of importers is mandatory. Advantages include the ability to provide the importers and exporters with information about their responsibilities and mechanisms to ensure imported food complies with requirements.

38. If a product registration system exists or is implemented, a clear rationale for such product registration (e.g. specific and documented food safety concerns) should exist. Such product REGISTRATIONS SHOULD TREAT IMPORTED AND DOMESTIC PRODUCT IN THE SAME OR EQUIVALENT MANNER.

[10] WTO Decision WT/MIN (01)17

Documenting the system

39. A food import control system should be fully documented, including a description of its scope and operation, responsibilities and actions for staff, in order that all parties involved know precisely what is expected of them.

40. Documentation of a food import control system should include:
- an organizational chart of the official inspection system, including geographical location and the roles of each level in the hierarchy;
- job functions as appropriate;
- operating procedures including methods of sampling, inspection and testing;
- relevant legislation and requirements that should be met by imported food;
- important contacts;
- relevant information about food contamination and food inspection; and,
- relevant information on staff training.

Trained inspectorate

41. It is fundamental to have adequate, reliable, well-trained and organised inspection staff, with supporting infrastructure, to deliver the food import control system. Training, communication, and supervisory elements should be organised to provide consistent implementation of requirements by the inspectorate throughout the food import control system.

42. Where third parties are officially recognised by the competent authority of the importing country to perform specified inspection work, the qualifications of the inspection staff should be at least the same as inspection staff of the competent authority who may carry out similar tasks.

43. The competent authority of the importing country responsible for conducting assessment of food control systems of exporting countries should engage personnel with appropriate qualifications, experience and training required of personnel assessing domestic food controls.

System verification

44. Verification should be carried out on the basis of Section 9 of the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) and the food import control system should be independently assessed on a regular basis.

SECTION 5 – FURTHER INFORMATION

45. The Food and Agriculture Organization of the United Nations Manual of Food Quality Control. Imported Food Inspection (Food and Nutrition Paper 14/15, 1993) and World Health Organization/Western Pacific Regional Center for the Promotion of Environmental Planning and Applied Science (PEPAS): Manual for the Inspection of Imported Food (1992) contribute valuable information for those engaged in the design and re-design of food import control systems.

APPENDIX
PRINCIPLES AND GUIDELINES FOR IMPORTED FOOD INSPECTION BASED ON RISK[11]

SECTION 1 – INTRODUCTION

1. This Annex elaborates on paragraphs 22–26 of the main text (CAC/GL 47-2003).

2. The implementation of an imported food inspection programme based on risk provides a more effective means for addressing the food safety risks that are associated with imported food[12], ensuring compliance of imported foods with importing countries' food safety requirements and allows greater attention to be given to foods that present a higher level of risk to human health.

3. This document should be read in conjunction with all relevant Codex guidelines.

SECTION 2 – OBJECTIVE

4. This annex is intended to provide competent authorities with information to assist them with the design and implementation of inspection programmes for imported food, based on the food safety risks.

SECTION 3 – PRINCIPLES

5. The following principles apply to the development and implementation of an imported food inspection programme based on risk.

- In determining the level of risk assigned to an imported food an importing country should consider the assessed food safety risk to human health the food presents or is likely to present based on available scientific information in relation to the consumption of the food.
- Requirements for an imported food inspection programme based on risk should be developed using a risk analysis approach, and should not be applied arbitrarily or in a

[11] A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. Definition of Risk Analysis Terms Related to Food Safety, Codex Alimentarius Procedural Manual

[12] Imported food in this annex also includes food ingredients. Inspection may also cover feeding stuffs for food producing animals where appropriate.

discriminatory manner, and should not result in unjustified barriers to trade or unnecessary delays.

- The nature[13] and frequency of inspection of a specific imported food should be proportionate to the level of risk attributed to it and take into account, all relevant factors[14].
- Sampling plans[15] and methods of analysis should, be based on Codex standards, guidelines, and recommendations. In the absence of Codex sampling plans, reference should be made to internationally accepted or scientifically based sampling plans when practically feasible[16].
- Information regarding a country's imported food inspection programme based on risk should be transparent, easily accessible, and up to date.

SECTION 4 – DESIGNING AN IMPORTED FOOD INSPECTION PROGRAMME BASED ON RISK

6. The competent authority should use relevant information to assess the level of risk associated with the imported food. This information could include, inter alia:

- The scientific determination of the food safety risk to the extent possible[17]1
- The adequacy of processing controls in place in the exporting country as evidenced by its laws, regulations, and other policies; its infrastructure; and its ability to effectively enforce food safety requirements, as may be verified by audits and on-site visits by the competent authority of the importing country[18]18.
- The compliance history of the food generally, irrespective of the source of the food.
- The compliance history of the food with respect to the source of the food including, where available, the compliance history of:
  - the exporting country or region/area within an exporting country;
  - the producer and manufacturer;
  - the exporter;

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[13] Examples of the nature of inspection could include documentation check, visual examination, sampling and testing

[14] Examples of relevant factors where appropriate are included in paragraph 22 of CAC/GL 47-2003

[15] Principles for the Establishment or Selection of Codex Sampling Procedures, Codex Alimentarius Procedural Manual

[16] Statistical validation of sampling requirements should always be the aim but may not be practical where the consignment is not homogenous.

[17] Risk assessments, foodborne illness outbreak and epidemiological findings/history, contaminant and/or residue information can be key components of this information

[18] Laboratory sampling programmes and results may provide this type of information. Audits are another way of gaining information..

  - the shipper; and
  - the importer.
- Reports from officially recognized inspection and/or certification bodies.

7. The level of risk assigned to a food should be reviewed periodically or when new information that may affect the food safety risk associated with the food becomes known in order to maintain the proportionality between the nature and frequency of inspection and the risk assessed.

8. The competent food safety authority may establish levels of inspection based on the above factors in order to determine the nature and frequency of inspections at the border/point of control of a given food from a given country, producer/manufacturer, exporter, shipper, and importer. The nature and frequency of inspection may then be adjusted according to the demonstrated compliance to food safety requirements. The nature and frequency of inspection should be fully documented.

9. The importing country should adjust the nature and frequency of inspection of the imported food based on information from competent authorities in the exporting country regarding the exported foods. This information may include:

- certificates;
- equivalence determinations;
- memoranda of understanding;
- mutual recognition agreements; or
- other appropriate means acceptable between countries.

10. The importing country may also adapt/alter the nature and frequency of inspection of the imported food based on an assessment by the importing country's competent authority of controls its importers exercise over their suppliers.

11. Exporting countries can provide information on the control systems in place in their country and, as appropriate, may provide assurance to the importing country that a particular food complies with the food safety requirements of the importing country.

12. Audits by the importing country may, where appropriate, verify an exporting country's inspection controls, and the information gained from these audits could be used as part of the review of the level of risk assigned to the food from that country.

13. When an importing country does not have prior knowledge of an exporting country's processing controls or of the food itself, that is those items listed in paragraph 6, a compliance history is lacking or such information cannot be readily obtained, an importing country may, until there is such knowledge, initially establish inspections of a more comprehensive nature and of a higher frequency than that which it might assign to the food when such information is available.

14. Sustained conformance with the importing country's requirements, as demonstrated, for example, by audit results and results of border/point of control checks, provides an opportunity for importing countries to adjust the nature and frequency of inspection at the border/point of control, in proportion to the level of compliance verified.

15. Foodborne illness outbreaks; epidemiological findings; results of audits conducted in the exporting country; the detection of non-compliances with food safety requirements at the point of import and detection of pathogens, contaminants and harmful residues in imported food; and the results of border/point of control checks, may lead an importing country to adjust the nature and frequency of inspection, or in extreme cases, to suspend the trade in that food until it is confirmed that corrective measures have been introduced and are being implemented effectively[19]. An importing country may work with an exporting country to prevent the occurrence of further outbreaks.

16. The level of adjustment/modification of the nature and frequency of inspection applied to a food should be proportional to the changes in the level of assessed risk for the food in question.

SECTION 5 – DEVELOPING REQUIREMENTS AND PROCEDURES

17. Competent authorities should take into account Codex standards, recommendations, and guidelines, in developing requirements for border/point of control checks of imported food and make use, when available, of:

- Relevant information from risk assessments conducted according to internationally recognized protocols for the biological, chemical, and physical hazards associated with the type of food.
- Internationally accepted or scientifically based sampling plans, to the extent possible.

[19] In such cases, the importing country will ensure that corrective measures put in place by the exporting country are evaluated in a reasonable interval.

- Appropriate inspection procedures, appropriate sampling techniques, and
- official or officially accredited laboratories using validated analytical methods.

18. The nature of inspection may consist of a range of procedures to ensure that imported foods meet the importing country's food safety requirements. When defining these procedures to verify compliance with safety requirements, the proportionality of these measures with the level of risk of the food or group of foods should be considered. These procedures may include for example:

- checking the documentation and/or the general condition of the shipment;
- checking documentation plus periodic food sampling (e.g., 1 in 20 or 1 in 40 shipments) to confirm the accuracy of the documentation;
- sensory examination;
- random or targeted sampling and testing of, or within, shipments according to a sampling plan; or
- lot-by-lot inspection, sampling, and testing, which, in general, should be reserved for those foods that present, or have the potential to present, the highest food safety risk.

SECTION 6 – IMPLEMENTING THE IMPORT INSPECTION PROGRAMME BASED ON RISK

19. Competent authorities with responsibility for imported food inspection programs based on risk should ensure that relevant policies and procedures are implemented in a transparent, coordinated, and consistent manner. Personnel should be appropriately trained to enable such coordination, and information should be shared among competent authorities.

20. A failure of food shipments to meet importing country food safety requirements might, besides other actions, trigger a change in the manner in which risk is managed by the importing country for the food concerned. The response could include food being held pending final judgment combined with enhanced sampling and testing from the establishment involved. These actions may also be applied to other exporting establishments from the same country producing similar foods where there is evidence of a systemic problem. The suspension of the importation of a food by an importing country should be reserved only for those situations involving a serious food safety risk that has not been managed by other means. Procedures should provide for appeal.

21. When the results of border/point of control checks indicate failure of a shipment to meet the requirements of the importing country, competent authorities of the importing countries should consider action as described in the Codex Guidelines for the Exchange of Information Between Countries on Rejection of Imported Food (CAC/GL 25-1997) or in the Codex Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995).
22. Competent authorities of the importing country should ensure adequate laboratory competency, capability and capacity is available to conduct the testing of imported food.

ASEAN Common Food Control Requirements

GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOODFOOD IMPORT CONTROL SYSTEMS

(CAC/GL 25-1997 GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD)

GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD

CAC/GL 25-1997[1]

SECTION 1 – PREAMBLE

1. The following guidelines provide the basis for structured information exchange on import rejections. The most important information elements to be considered in such guidelines are shown in the Annex and each category is discussed in more detail below. The guidelines are intended to cover all types of food.

2. These guidelines deal only with import rejections caused by failure to comply with importing country requirements. Information exchange in food control emergency situations is dealt with in the Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995).

3. The use of these Guidelines for the Exchange of Information on Rejections of Imported Food is intended to assist countries to conform with the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995), in particular the transparency provisions contained in paragraph 14 of the Principles.

SECTION 2 – GENERAL CONSIDERATIONS

4. When the food control authorities in an importing country reject a consignment of food presented for importation they should always provide information to the importer of the consignment giving the reasons for the rejection. Appropriate information should also be provided to the exporter if the control authorities receive such a request.

5. When the rejection of the consignment arises from:

- evidence of a serious food safety or public health problem in the exporting country; or
- evidence of serious misrepresentation or consumer fraud; or
- evidence of a serious failure in the inspection or control system in the exporting country.

[1] Governments and organizations interested in receiving a List of Contacts for Food Import Control and Information Exchange in Food Control Emergency Situations should contact the Codex Contact Point for Australia, Australian Quarantine and Inspection Service, GPO Box 858, Canberra, ACT, 2601, AUSTRALIA. Telefax: 61-6-272-3103.

The food control authorities in the importing country should notify the food control authorities in the exporting country forthwith (by telecommunication or other similar rapid means of communication) supplying the details set out in the Annex to these Guidelines.

6. Upon receipt of such a communication, the food control authorities in the exporting country should undertake the necessary investigation to determine the cause of any problem that has led to the rejection of the consignment. The food control authority in the exporting country, if requested, should provide the authorities in the importing country with information on the outcome of the necessary investigation, if available. Bilateral discussions should take place as necessary.

7. In other circumstances, for example:

- where there is evidence of repeated failures of a correctable nature (e.g. labelling errors, mislaying of documents); or
- where there is evidence of systematic failures in handling, storage or transport subsequent to inspection/certification by the authorities in the exporting countries.

The food control authorities in the importing country should also make appropriate notification to the food control authorities in the exporting country, either periodically or upon request.

8. It is also open to an importing country to supply information on rejections to an exporting country even when this is not specified in these guidelines.

9. In some countries information about the results obtained in public food control is freely available, whereas in others legal constraints may prevent or restrict the dissemination to third parties of information on, for example, import rejections. In some cases information cannot be exchanged before a certain time has elapsed. So far as possible countries should minimise restrictions on the disclosure to other countries of information on rejected foods.

10. To enable FAO and WHO to assist exporting countries in their efforts to meet the requirements of importing countries, information on rejections of imported food should be made available to FAO and WHO on request.

SECTION 3 – DETAILED INFORMATION

Identification of the food concerned

11. A certain amount of basic information is required in order to be able to identify the consignment or lot of food that has been refused entry when presented for importation.

The most important information in this respect is a description of the nature and quantity of the food, any lot identification or other identification stamps, marks or numbers and the name and address of the exporter and/or food producer or manufacturer. Information about importers or sellers is also useful. Where a lot has been certified, the certificate number can provide an important method of identification.

Importation details

12. Information about importation or presentation for importation is necessary. The most important elements here are: place and date of entry, and the identity and contact details of the importer.

Rejection decision

13. It is important to obtain information about the decision to refuse importation, especially the name of the food control authority which made the decision, when the decision was made and whether the whole or only part of the consignment was refused entry.

Reasons for rejection

14. The reason(s) why a consignment of food has been refused entry should be clearly stated and reference should be made to the regulations or standards which have been contravened.

15. Foods may be rejected because they are found to be unacceptable when subjected to an organoleptic examination or because they have technical/physical defects, e.g. leaking cans, broken seals and damaged boxes. In circumstances where physical examination has led to rejection, a clear description of the criteria used should be provided.

16. When the level of a contaminant in a food has been found to be above the maximum permitted level, the contaminant should be specified, together with the level found and the maximum permitted level. In the case of biological contamination or contamination by biological toxins, where no maximum level has been fixed, the identity of the organism or toxin concerned should be given as specifically as possible, and as appropriate, the level of contamination found. Similarly, contraventions of regulations on food additive or compositional standards should be specified. Some countries accept certain foods (e.g. fresh meat) only from specifically approved establishments in the exporting country. If such foods are refused entry because evidence that they come from such an establishment is lacking or incomplete, this should be stated.

17. Where consignments of imported food are rejected on the basis of analysis performed in the importing country, the importing country authority should make

available upon request details of the sampling and analytical methods employed and the results obtained.

Action taken

18. Information should be supplied about the action taken following the rejection or retention of a consignment of food. This should include information about the fate of the consignment, such as whether it was destroyed or detained for reconditioning.

19. If the rejected food is re-exported, the conditions attached to such re-export should be stated. For example, some countries permit re-export only to the country of origin or to countries which have stated in advance that they are prepared to accept the consignment knowing that it has been refused entry elsewhere.

20. In addition to the exchange of information between the food control authorities of exporting and importing countries it may also be valuable to inform the embassy or other representative body of the exporting country of the situation so that the country concerned can take action to rectify the deficiencies found and thus avoid rejection of future shipments.

ANNEX

STANDARD FORMAT FOR EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD

The following information should be provided by countries in relation to rejections of imported food as available and appropriate to the circumstances.

Identification of the food concerned

- Description and quantity of product
- Type and size of package
- Lot identification (number, production date, etc.)
- Container number, bill of loading 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

Importation details

- Port or other point of entry
- Name and address of importer
- Date presented for entry

Details of rejection decision

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

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

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

Action taken

- Food destroyed
- Food held pending reconditioning/rectification of deficiencies in documentation
- Food held pending final judgement
- Place where food 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 control authorities of exporting country notified
- Authorities in other likely destination countries notified
- Other