



## Agenda Item 4

CX/FICS 13/20/3  
August 2012JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION  
AND CERTIFICATION SYSTEMS

Twentieth Session

Chiang Mai (Thailand), 18 – 22 February 2013

DRAFT AND PROPOSED DRAFT PRINCIPLES AND GUIDELINES  
FOR NATIONAL FOOD CONTROL SYSTEMS

(N06-2009)

## Section 1-3 at Step 6 and Section 4 at Step 3

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the draft and proposed draft Principles and Guidelines for National Food Control Systems (*see* Appendix I) are invited to do so **no later than 15 November 2012** to: Codex Australia, Australian Government Department of Agriculture Fisheries and Forestry GPO Box 858, Canberra ACT, 2601 (E-mail: [codex.contact@daff.gov.au](mailto:codex.contact@daff.gov.au)), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00153 Rome, Italy (E-mail: [codex@fao.org](mailto:codex@fao.org)).

**Format for submitting comments:** In order to facilitate the compilation of comments and prepare more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in Annex 1 to this document.

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## CURRENT STATUS

## (a) Sections 1 to 3

1. The 35<sup>th</sup> Session of the Commission adopted the proposed draft Sections 1 to 3 of the Principles and Guidelines for National Food Control Systems, as proposed by the CCFICS, and invited delegations to resubmit the comments at Step 6 in order to be considered by the next Session of CCFICS.

## (b) Section 4

2. Section 4 was elaborated by a physical Working Group, which met in Grange (Ireland) from 9 to 12 July 2012.

## REQUEST FOR COMMENTS

3. In order to facilitate the discussion of the 20<sup>th</sup> CCFICS, Sections 1 to 3, as adopted by the 35<sup>th</sup> CAC, and Section 4 of the Principles and Guidelines for National Food Control Systems, have been compiled together in Appendix I to this document.

4. Governments and international organizations in Observer status with the Codex Alimentarius Commission are invited to submit comments, as directed above, on the document as presented in Appendix I.

## BACKGROUND

5. At its 19<sup>th</sup> Session the Committee considered the draft proposed Principles and Guidelines for National Food Control Systems, developed by a working group led by Australia.

6. The Committee noted that this work had been undertaken to address the need to provide, in a single document, coherent guidance to governments on how to establish and operate national food control systems. The Committee further noted that both developing and industrialised countries would benefit from such guidance because it would enhance their capacity to respond to the challenges related to national food control.

7. The Committee agreed that the document needed a clearer introduction and that the core components of a national food control system needed to be better described. It was mentioned that the document still contained some gaps concerning policy and regulations and also a number of repetitions. The structure and logical flow of the document, in particular of Section 4, should be improved to make it more user-friendly. It was also mentioned that the document should emphasise the need for a good coordination between food safety and animal health authorities.

8. After a general discussion on the structure the Committee agreed that the document should contain the following sections: introduction; scope; objective of a national food control system; principles of a national food control system; framework for the design and operation of a national food control system – guidance for competent authorities including sub-sections on: policy setting; system design; implementation and monitoring and system review.

9. The Committee acknowledged progress made on the development of the proposed draft Guidelines and principles. The Committee agreed that the Introduction and Sections 1 to 3 only needed some editorial improvements and possibly some re-ordering of the Principles and could be advanced in the Step procedure.

10. The Committee noted that good progress had been made on developing the structure of Section 4 and its introductory paragraphs, which logically linked to the sub-sections. The Committee had also identified the proper location of paragraphs and areas for improvements<sup>1</sup>.

11. In view of this progress, the Committee agreed that the proposed draft Principles and guidelines could be finalised at its next session.

12. The Committee agreed to forward the Sections 1 to 3 to the 35<sup>th</sup> Session of the Commission for adoption at Step 5 and to return Section 4 to Step 2 for revision by a pWG, circulation for comments at Step 3 and further consideration at its 20<sup>th</sup> Session.

13. The Committee agreed to establish a physical Working Group (WG), chaired by Australia and hosted by the European Union, open to all Codex Members and Observers and working in English, French and Spanish, to prepare a revised Section 4. The pWG should further elaborate the section based on CRD 12 and the written comments submitted (CX/FICS 11/19/3 Add.1; CX/FICS 11/19/3 Add.2; CRD 4; and CRD 8). A draft paper would be made available to the WG participants prior to the meeting. The meeting of the pWG was tentatively scheduled to be held in Grange (Ireland) in the second quarter of 2012.

## **REPORT OF THE PHYSICAL WORKING GROUP<sup>2</sup>**

14. A physical working group chaired by Australia and co-hosted by the European Union met in Grange, Ireland from 9-12 July 2012. The working group was attended by 51 delegates from 23 member countries, 1 member organisation, FAO, one international governmental organisation and three non-governmental organisations; a full list of participants can be found in Annex 2. The working group considered a revised document, prepared by Australia, taking into account the previous discussions in the committee and comments submitted by members to the 19<sup>th</sup> Session of CCFICS<sup>3</sup>.

### **General Discussion and Introduction**

15. The Chairperson noted that Sections 1 through 3 including the Principles had been adopted at Step 5 by the 35<sup>th</sup> Session of the Commission and that the principles had been worked on substantially over a number of years. He reminded participants that the working group was tasked with working on Section 4 Framework for the design and operation of a national food control system. In undertaking its work the working group should consider that a number of detailed projects (information technology, regulatory oversight, standards,

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<sup>1</sup> Based on CRD 12 and the written comments submitted (CX/FICS 11/19/3 Add.1; CX/FICS 11/19/3 Add.2; CRD 4; and CRD 8)

<sup>2</sup> Led by Australia with the assistance of Argentina, Brazil, Canada, Colombia, Croatia, Czech Republic, European Union, Finland, France, Germany, India, Ireland, Italy, Japan, the Netherlands, New Zealand, Norway, Poland, South Africa, Sweden, Thailand, United Kingdom, United States of America, FAO, OIE, IACFO, INC and SSAFE

<sup>3</sup> Based on CRD 12 and the written comments submitted (CX/FICS 11/19/3 Add.1; CX/FICS 11/19/3 Add.2; CRD 4; and CRD 8)

laboratories etc.) would flow logically out of the design elements leading to a range of questions with regards to the types of legislative powers and resources that would be needed to successfully implement a national food control system.

16. The working group had a general discussion of different countries experiences in re-designing their national food control systems and agreed to start with a detailed discussion on the system design section followed by implementation and monitoring and system review and to return to the policy section at the end to ensure that the relevant policy elements were covered.

17. While the Introduction and Principles were not part of the discussion the working group agreed to move text from the Design section to the Introduction as it was felt it provided additional clarity to the introduction. The new text is in Paragraph 5 “When developing a national food control system national governments and their competent authority(s) 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.”

## **Guidelines – Framework for a National Food Control System**

### **Policy Setting**

18. In considering the policy setting section the working group considered the changes it had made to the sections on systems design, implementation and monitoring and systems review. The working group reordered and reworded the paragraphs relating to legislation to provide further guidance with regards to how the legislation supports the structure of a national food control system, the types of legislative powers that should be considered, the need for provisions for enforcement to support charging of fees or taking action against non-compliant food businesses. The working group also highlighted the importance of communication and engagement with stakeholders during the policy setting process.

### **System Design**

19. The working group made substantial changes to the draft provided to the working group by re-ordering the content, adding additional bullet points to reflect the elements that should be taken into account during the design phase (Appendix II, paragraph 40), these elements reflect the principles in Section 3. The working group re-ordered text from the implementation section to reflect the factors that should be considered in designing control programmes (risk posed to human health, potential fraud or deception of consumers, statistical data on production, trade and consumption data, effectiveness and reliability of controls, food safety hazards with different products and epidemiological data on foodborne disease.

20. The working group included text to ensure that the design of the system incorporated the ability to evaluate and verify the effectiveness of national food control system so that it could be continuously improved and to ensure that compliance and enforcement programmes were designed to provide for the ability of the competent authority to take corrective actions. The working group considered that compliance and enforcement programmes should be proportionate to the degree of public health risk, encourage acceptance of responsibility and compliance by all participants and take into account repeated non-conformity by food business operators.

21. The working group considered a range of text to cover the need for respond to food safety emergencies; the need for coordination between national governments and food business operators in food recall situations and the need for procedures to ensure prompt removal of unsafe food and agreed to cross reference this text to the Codex *Principles for traceability/product tracing as a tool within a food inspection and certification system* (CAC/GL 60-2006).

22. The working group reduced the text in relation to transparency and communication but considered the guidance in the document was broad enough to cover what might be considered during system design in order to implement effective communication tools to ensure ongoing communication among all parties, transparency and education of stakeholders.

### **Implementation**

23. The working group developed an introductory part to this section to identify the need for preparation of a roadmap or plan to assist with the rollout of the different elements of design. This section also takes note of the need to keep in mind the preparedness and capability of the particular country during the development of the roadmap to assist in the development of priorities and timelines for implementation, allocation of

resources, development of training and operational manuals and that this phase will also require the involvement of a variety of experts, disciplines and stakeholders.

24. The implementation section identifies the need for competent authorities and food business operators to consider the development of training programmes and manuals, a range of food control activities (inspections, audits, verification and surveillance), the use of accredited laboratories and/or third party providers and some additional considerations in relation to communication.

### **Monitoring and System Review**

25. The section on monitoring and system review highlights the need to ensure regularly assess the effectiveness of control programmes as well as against the objectives of the system, legislative and other regulatory requirements. The criteria for assessment should be clearly defined and documented and may also include cost benefits and efficiency.

26. The working group considered that a national food control system should be regularly reviewed to contribute to the systems improvement, in response to for example, control programme 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. The working group considered that reviews may take place at the level of the system or program design or implementation as appropriate.

27. The section also provides guidance on the types of information that can be utilised to support reviews of the national food control system such as information from food related non-compliances/incidents (both food safety and fraud), links between the symptomatic foodborne illness surveillance system and the food monitoring system, data on foodborne contamination, effectiveness of control programmes including results of evaluations.

### **Considerations and Conclusion**

28. The proposed draft principles and guidelines contained in Appendix 1 are presented for further consideration by the Committee. In considering the draft document further members should consider the completeness of the framework provided taking into consideration existing CCFICS, Codex and relevant FAO and OIE texts. The intent of this document is to provide an overarching framework for the development of national food control systems enabling relevant Codex texts to be referenced within it. The intention of this document is not to duplicate existing texts however in some instances this may be necessary to assist the readability of the document. Members are requested to review the text with a view to determining whether gaps exist with respect to Section 4 Framework for the Design and Operation of the National Food Control System.

## PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS

(N06-2009)

### SECTION 1 INTRODUCTION (at Step 6)

1. This document is intended to provide practical guidance to assist the national government, and their competent authority(ies) in the 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, storage, transport 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) and the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003).
3. In addition, the relevant chapters of the World Organisation for Animal Health (OIE) terrestrial animal health and aquatic animal health codes are valuable resources for member governments and organizations. Other documents and guidance material developed by FAO and WHO may also be useful resources.
4. Competent authorities may apply these principles and guidelines, where appropriate, according to their particular situations.
5. When developing a national food control system national governments and their competent authority(s) 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.

### SECTION 2 OBJECTIVE OF A NATIONAL FOOD CONTROL SYSTEM (at Step 6)

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 (at Step 6)

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 and maintained with the primary goal to protect consumers. In the event of a conflict, 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 interested parties, 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<sup>4</sup> 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 governments (and in some cases competent authorities) have the role and responsibility to establish and maintain up to date science based legal requirements and 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 in 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 INCORPORATION OF RISK BASED, SCIENCE BASED AND EVIDENCE BASED DECISION MAKING**

17. Competent authorities should be making decisions within a national food control system based on scientific information, evidence and/or risk analysis principles<sup>5</sup> 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/gaps and to facilitate information exchange.

#### **PRINCIPLE 8 PREVENTIVE MEASURES**

19. To prevent or to react to food safety incidents a national food control systems 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 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<sup>6</sup>, should be provided for in the national food control system.

#### **PRINCIPLE 11 LEGAL FOUNDATION**

22. The government within each country needs to 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 (or those of other international inter-governmental organizations

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<sup>4</sup> For the purpose of this document food business operator includes producers, processors, wholesalers, distributors, importers, exporters and retailers

<sup>5</sup> 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).

<sup>6</sup> *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).

whose membership is open to all countries) whenever appropriate as elements of their national food control system to facilitate trade and consumer confidence.

### PRINCIPLE 13 RESOURCES

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

## SECTION 4 FRAMEWORK FOR THE DESIGN AND OPERATION OF THE NATIONAL FOOD CONTROL SYSTEM (at Step 3)

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.

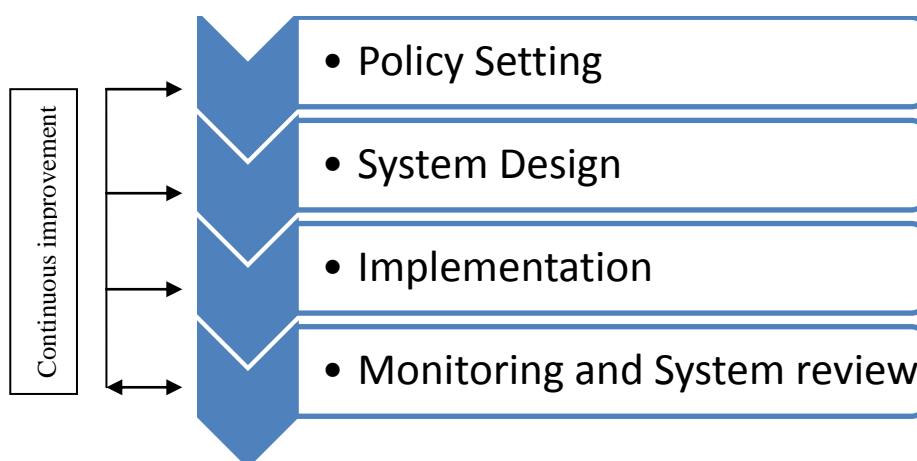
26. The competent authority has a pivotal role in the national food control system, in that it:

- provides leadership and coordination for the national food control system;
- develops, implements, monitors, manages and reviews the national food control system;
- establishes and enforces science and risk based regulatory controls that encourage and promote positive food safety outcomes;
- supports and enables fair practices in the food trade;
- advances/fosters knowledge, science, research and education regarding food safety;
- engages with stakeholders to ensure transparency and to obtain views of interested parties; and
- establishes and maintains arrangements with other countries e.g. cooperation programmes, equivalence agreements etc.

27. 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 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 national competent authority, in consultation with stakeholders, should adopt the following processes, which will reflect the principles of a national food control system and are described in this document.



### SECTION 4.1 POLICY SETTING

30. National goals and priorities will ensure consumer protection by taking into account amongst other things, food production and consumption patterns, risk profile and consumer demands and also the preparedness and capability of the country.

31. Policy setting should include the identification and clear articulation of expected outcomes; how the

national food control system relates to international and national standards; identification of risks and system controls, existing or planned governmental structures and the need for coordination between authorities with control responsibilities in different parts of the food chain.

32. 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 related to 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 and support system design.

33. As a result of applying the guiding principles of Section 3 and the framework of Section 4 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 as a whole and its various parts and participants
- ii) **Characteristic 2 Pro-activity** means that a national food control system is capable of identifying existing or emerging hazards in the environment before they materialise as risks in the food production/processing chain and at the early stages rather than in the end product. Early warning/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.

34. Legislation should clearly reflect the intended policy objective and be commensurate with the risks they are intended to mitigate it should where possible focus on prevention and outcomes to allow for flexibility and innovation.

35. Legislation should frame the structure of the national food control system, provide clarity as to the roles and responsibilities of participants in the national food control system, in particular that of central government, the competent authority (or of each competent authorities where there is more than one) and any third party<sup>7</sup> providers (where these are used), and food business operators. Legislation should set out the overarching objectives of the national food control system and any specific or lower objectives that relate to participants or sectors. It should provide the authority for competent authorities to set/recognise standards and require food business operators and other participants to establish and monitor appropriate controls at all stages of the food chain, including production, manufacture, importation, processing, storage, transportation, distribution and trade. Legislation should clearly define obligations on food businesses to produce safe food.

36. 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 control food borne hazards such as disease-causing organisms, contaminants, veterinary drug and pesticide residues;
- establish approaches to ensure the safety and safe use of food additives, pesticides, veterinary drugs;
- consider recognition of and/or harmonisation with Codex standards;
- perform audits, verification, inspections and investigations, gather evidence, collect and analyze samples and otherwise verify compliance with standards and requirements;
- enforce legislation and take action in cases of unsafe or noncompliant food, including investigations and application of sanctions and penalties;
- ensure the integrity, impartiality and independence of officially recognized inspection systems;
- ensure that unsafe or noncompliant food are withdrawn from the market and disposed of where

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<sup>7</sup> *Guidelines for Food Import Control Systems CAC/GL 47-2003 paragraph 8*



appropriate; and

- prevent placing on the market unsafe or non-compliant product.

37. 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 etc.

38. 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.

#### **SECTION 4.2 SYSTEM DESIGN**

39. 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.

40. 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<sup>8</sup>;
- 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 foodborne and food related incidents;
- assessment and evaluation;
- stakeholder engagement; and,
- international communication and harmonization;

41. 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.

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

43. 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 programmes can be used to target priority risks.

44. 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

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<sup>8</sup> *Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems* CAC/GL53-2003

need to address priority food risks.

45. The national food control system should be fully documented, 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.

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

47. Control programmes should be based on risk and designed to take into account a number of factors<sup>9</sup> including but not limited to:

- the risk to human health posed by the food or food related product ;
- potential fraud or deception of consumers and other factors that may cause unfair practices in the food trade;
- information that may be available from a range of sources including 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 by-products; Structure of production and supply chains; production technologies, processes and practices; relevant product tracing information;
- food safety hazards associated with different products;
- risk of unfair practices in the food trade associated with different products; and
- epidemiological data on foodborne disease.

48. In the absence of risk analysis data control programmes should be based on technical and scientific data developed from current knowledge and practice.

49. The control programme should cover, as appropriate:

- establishments, installations, equipment and material;
- products, from raw material to the final products, including intermediate products;
- Preventative controls including GAP, GMP, GHP and HACCP principles;
- means of distribution; and
- human resources, infrastructure and confidentiality.

50. 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.

51. Where quality assurance systems are used by industry, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade. The competent authority should encourage the use of Good agricultural practice GAP, Good Manufacturing Practices (GMP)/Good Hygiene Practices (GHP) or Hazard Analysis Critical Control Point (HACCP) approach in accordance with *Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-

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<sup>9</sup> Paragraph 33 provides additional guidance on the main characteristics of a national food control system

1969).

52. 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<sup>10</sup>.

53. A national food control system should be subject to regular review of results obtained so that it can be continuously improved 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.

54. Compliance and enforcement programmes should be designed to provide the ability for the competent authority to take corrective action to ensure the situation is remedied where the participants are not meeting their obligations or a product or process is found not to be in conformity.

55. Compliance and Enforcement programmes 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.

56. The competent authority(s) should be resourced sufficiently and transparently to enable the national food control programs to achieve its objectives without compromising the programs integrity and independence.

57. The design and implementation of a national food control system should be on a scale appropriate to the resources available, 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;

58. The design of a national food control system should incorporate timely access to adequate information relating to the surveillance, 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.

59. In order to respond to food safety emergencies, consideration should be given to the establishment of a national food safety emergency plan with establishment of a coordination arrangement with links to public health authorities, law enforcement and intelligence agencies, food recall systems, risk assessment specialists, the food industry, and others.

60. The national food control system should have procedures covering the prompt removal of unsafe food<sup>11</sup>. These procedures should ensure that products that are deemed to be unsafe should be recalled, appropriately dealt with to ensure consumer protection. Where distribution has occurred, appropriate consumer notification should be given.

61. Recall systems and other market withdrawal systems should be a coordinated effort between the national government and food business operators. If the competent authority requests a recall, operators should have an affirmative duty to recover recalled products and to destroy or dispose of them properly.

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<sup>10</sup> *Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)*

<sup>11</sup> *Codex 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*

National laws should include penalties for companies that fail to comply with recall requests.

62. In order to promote consumer confidence in food safety and ensure fair practices in the food trade, the competent authority 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.

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

64. Consideration should be given to the development of communication programmes to provide outreach and education programmes and information exchange on food safety risks and mitigation steps which may be taken to reduce these risks, amongst regulators, industry, consumers and academia.

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

66. Where appropriate, the national 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

67. Following the design or modification of the national food control system the competent authority should prepare a roadmap of implementation and the sequence of rollout of different elements of design in keeping with their preparedness and capability. This will require engagement and analysis by a variety of experts, disciplines and all stakeholders. The competent authority's roadmap 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.

68. Guidance and instructions relating to the national food control system, control programmes, including legal requirements should be developed for competent authority staff and food business operators to;

- ensure all participants are fully aware of what is expected from them (Principle 4);
- ensure uniform application of legislation;
- objectives clearly communicated to them; and
- that they have the necessary resources (human, material and financial resources) available to carry out their tasks.

69. 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 procedures should be developed to articulate the key tasks and responsibilities of verification of compliance.

70. 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 non-conformity may include:

- increased intensity of audits/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/processor or closure of the relevant establishment.

71. Programmes and training manuals should be developed and maintained to ensure consistent application of requirements. This material should include:

- 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, and testing;
- relevant legislation and requirements;
- processes and procedures relating to compliance and enforcement;
- arrangements for coordination with relevant ministries and stakeholders;
- relevant information about food contamination and food control;
- procedures for conducting food recalls and investigations;
- relevant information on staff training; and
- formal review process of the national food control system.

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

73. The competent authority should ensure that sufficient guidance, training and awareness programmes 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 should be designed and implemented for this purpose.

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

75. Where the competent authorities intend to use third<sup>12</sup> party providers to implement controls, before being authorised the third party provider should be assessed against objective criteria. The ongoing performance of officially authorised bodies should be regularly assessed by the competent authority. Procedures should be initiated to correct deficiencies and, as appropriate, enable withdrawal of official authorisation.

76. Competent authorities should utilize laboratories that are authorised or accredited under officially recognized programmes 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.

77. Competent authorities should ensure that designated laboratories participate in regular proficiency testing. Such testing may be organised nationally or internationally and reference laboratory may have a role in organising proficiency testing programmes.

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

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<sup>12</sup> *Guidelines for Food Import Control Systems* CAC/GL 47-2003 paragraph 8

79. 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; and
- communicate and collaborate with international organisations in cases where food(s) implicated in incidents or outbreaks of foodborne illness may be circulating in international trade.

#### **SECTION 4.4 MONITORING AND SYSTEM REVIEW**

80. The effectiveness and appropriateness of the national food control system should be regularly assessed against the objective of the system, effectiveness of control programmes, 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.

81. A national food control system should be regularly reviewed to contribute to the systems improvement, in response to for example, control programme 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.

82. The review of food-related non-compliances/incidents is an opportunity to learn which can be used as a feedback loop for the planning process by the competent authority. Competent authorities 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.

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

84. 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 foodborne illness surveillance system and the food monitoring system;
- data on the symptoms and effects of chronic exposure to foodborne contamination;
- systems to allow rapid detection of contamination incidents to ensure prompt public alerts; and
- links with the veterinary public health sector.

85. 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.

86. The competent authority(ies) should utilize information gained from the surveillance of foodborne 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 foodborne disease information and food monitoring systems. Foodborne illness and outbreak information should be used to inform the risk analysis activities of competent authorities.

87. The results of the evaluations<sup>13</sup>, including the results of self-assessment and audits should also be taken into account in further improvement of the system, and corrective actions should be taken into account as appropriate.

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<sup>13</sup> 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.

88. Any review and continual 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.

89. Control programmes 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.

## GENERAL GUIDANCE FOR THE PROVISIONS OF COMMENTS

In order to facilitate the compilation of comments and prepare more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strike through font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.

Example of how comments should be prepared

### SECTION 2 OBJECTIVE

Paragraph 4 - At the end of the last sentence add the words "and can be applied as relevant to any inspections of establishments or other facilities that may occur as part of an audit." So the last sentence would read "This annex applies equally to assessments carried out onsite or by documentary review alone **and can be applied as relevant to any inspections of establishments or other facilities that may occur as part of an audit**".

*Rationale: To remove duplication of concepts – standardized and consistent. Efficiency is an outcome of following these guidelines and should be included here. To clarify the use of inspection as an associated tool not the prime focus.*



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