



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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Agenda Item 4

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS**

Nineteenth Session

Cairns, Australia 17 – 21 October 2011

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

(N06-2009)

(At Step 3)

(prepared by a physical working group led by Australia with the assistance of Argentina, Brazil, Canada, Cape Verde, Chile, European Union, France, Germany, India, Italy, Japan, Lebanon, México, the Netherlands, New Zealand, Norway, Panama, South Africa, Switzerland, Thailand, United States of America, Uruguay, FAO, OIE, IACFO and INC)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 23 September 2011** to: Codex Australia, Australian Government Department of Agriculture Fisheries and Forestry GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272. 4389; E-mail: codex.contact@daff.gov.au - *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00153 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org - *preferably*).

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 the Annex to this document.

Please do not reproduce the document in track changes as this substantially increases the costs of translation and printing.

BACKGROUND

1. The 32nd Session of the Codex Alimentarius Commission approved new work on the proposed draft Principles and Guidelines for National Food Control Systems (N06-2009).
2. At its 18th Session the Committee considered the draft proposed Principles and Guidelines for National Food Control Systems developed by a working group led by Australia. The Committee noted that the document still required substantial work and that it would be necessary not only to consider the completeness of the framework but also to consider the document in the context of CCFICS and other relevant texts.
3. The following main comments were made: the document was needed to assist countries in using Codex texts; the document should establish a common understanding of national food control systems; the document should be a stand-alone document and draw from existing Codex texts and modified as necessary; the document should provide the broad framework and high level principles guiding countries in the development and enhancement of their national food control systems.
4. The Committee also took note that the FAO and WHO guidance documents, food control systems were referred to as the integration of a mandatory regulatory approach with preventive and educational strategies

that protect the whole food chain. The Representative recommended that information, education and communication be given due recognition, when describing the components of a food control system.

5. 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: characteristics/components; infrastructure; and system management.

6. The Committee was of the opinion that good progress had been made in improving the understanding of the scope and objective of the document, formulating a high-level statement, defining the structure of the document and agreeing on the high priority principles of a national food control system. In order to facilitate the further development of the document at its next session, the Committee agreed to establish a physical working group, chaired by Australia, open to all members and observers and working in English, French and Spanish and in accordance with the *Guidelines on physical working groups* to prepare revised proposed draft principles and guidelines. The working group should expand and elaborate around the guidance provided by the Committee as contained in the paragraphs above. The meeting of the working group was tentatively scheduled for the beginning of 2011.

7. The Committee agreed to return the proposed draft principles and guidelines to Step 2 for redrafting by a physical working group led by Australia, circulation for comments at Step 3 and further consideration at Step 4 at the next Session of CCFICS.

REPORT OF THE PHYSICAL WORKING GROUP

8. A physical working group chaired by Australia and co-hosted by Brazil met in Natal, Brazil from 1-3 March 2011. The working group was attended by 60 delegates from 22 member countries, 1 member organisation, FAO, one international governmental organisation and two non-governmental organisations; a full list of participants can be found at Appendix 2. The working group considered a revised document taking into account the previous discussions in the committee and comments submitted by members to Australia¹.

General Discussion and Introduction

9. The working group had a general discussion on the purpose of the document and noted that this should be a high level policy document which provides guidance to national governments on national food control systems development, implementation and ongoing review. The Chair noted that the document needed to stay current and that it would be a challenge for the working group to develop a text that remains current for the future. In order to facilitate the discussion the group broke into smaller groups to discuss the nature of the framework, the context of the document and identify any conceptual elements that may be missing from the working draft. The groups were reminded of the existence of FAO Guidance and the need to take into account the relevant international standards set out in the OIE Terrestrial Animal Health Code. The working group also noted the need to clarify what the problems are for countries as they develop a national food control system and would the document being developed assist those countries.

10. The working group had a general discussion on the key objectives of the document. The discussion highlighted the need to develop further the scope of the proposed draft and the need to spend more time on the key principles identified by the last session of CCFICS.

11. The working group made some additional changes to the key principles to make them more high level and added some explanatory text to provide clarity.

Scope

12. The working group had a general discussion on the need for a scope as there was some confusion with regards to the use of the terms scope and objective within the document. The working group agreed to develop an Introduction rather than a scope. The introduction notes that the document is intended to assist the national government, and their competent authority(ies) in the development, operation and improvement of national food control system. The introduction also notes that the document provides guidance while ensuring flexibility as any “one system” is not appropriate to all circumstances. Rather, various approaches

¹ Comments were received from Argentina, Brazil, Canada, European Union Member States, Japan, Mexico, New Zealand, Norway, Panama, Switzerland, United States of America, Uruguay, OIE and IACFO

may be used, as appropriate to the national circumstances, to achieve an effective national food control system

Principles for a National Food Control System

13. In further developing the section on Principles the working group further elaborated the principles developed and agreed to by the 18th Session of the Committee. Additional explanatory text for each Principle has been included for the Committee to consider at the 19th Session. The working group also agreed to delete the principle related to harmonization as it was considered this was more guidance than a principle and harmonisation was covered in the introduction. This principle was replaced with a new principle that covered the need for adequate resources to support a national food control system.

14. The working group also agreed that the Committee should further consider the order of the principles at its 19th Session, taking into consideration the structure of the document.

Guidelines – Framework for a National Food Control System

15. The working group had a lengthy discussion on the framework and content of the Section 4 Framework for the Design and Operation of the National Food Control System. The working group developed an introductory part to this section to:

- recognise that different systems can achieve the same outcomes (equivalence);
- define the roles and responsibilities of key participants in a national food control system;
- and that 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.

16. The working group further elaborated on the discussion from the 18th Session on the Section System Characteristics by developing further the concepts explored in relation to *situational awareness, pro-activity, and capability to learn*. The text was developed to identify the necessary characteristics covering the type of information that helps to build an effective system, the need for tools to assist with self-assessment or other evaluation to determine if a system is fully functional and effective and to ensure the system's ability to continuously improve.

17. The working group developed further text covering legislation, inspection (control programmes), assessment and evaluation, compliance and enforcement, resources including laboratories, staff, training and communication.

18. As the working group did not have sufficient time to develop all the text within **Section 4 Framework for the Design and Operation of the National Food Control System** further written comments were sought from members of the physical working group in order to fully develop the remainder of the document. Comments were received from Australia, Brazil, Canada, European Union, Japan, Mexico, New Zealand, Uruguay, United States of America, IACFO and INC. These comments were used to further develop the sections on System Design and Implementation.

Considerations and Conclusion

19. 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 principles, characteristics and components or other elements.

20. The Committee is invited to consider the attached proposed draft (Appendix 1) with a view towards its further progression in the Codex Step Procedure.

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 ~~striketrough 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.

Appendix 1

**PROPOSED DRAFT PRINCIPLES AND GUIDELINES
FOR NATIONAL FOOD CONTROL SYSTEMS
(at Step 3 of the Procedure)**

SECTION 1 INTRODUCTION

1. This document is intended to assist the national government, and their competent authority(ies) in the development, operation and improvement of national food control system. It highlights the key principles and elements that should be given due consideration. 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 other related Codex texts, in particular 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 Food and Agricultural Organisation (FAO) publications *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems* (FAO Food and Nutrition Paper 76), *Strengthening National Food Control Systems Guidelines to Assess Capacity Building Needs* and the relevant standards and guidelines developed by the World Organisation for Animal Health (OIE) are valuable resources for member governments and organizations.
4. The principles and guidelines set out in this document are consistent with and are drawn from existing Codex documents. Competent authorities may apply these principles and guidelines, where appropriate, according to their particular situations.

SECTION 2 OBJECTIVE OF A NATIONAL FOOD CONTROL SYSTEM

5. 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

6. To meet the objectives of a national food control system the following principles should apply:

PRINCIPLE 1 PROTECTION OF CONSUMERS

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

PRINCIPLE 2 THE WHOLE FOOD CHAIN APPROACH

8. The national food control system should cover the entire food chain from production to consumption, including feed, primary production and harvest, processing, storage, distribution, transport, retail, import and export.

PRINCIPLE 3 TRANSPARENCY

9. 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 RESPONSIBILITY

10. All participants in a national food control system have specific responsibilities.
11. Food business operators² have the primary responsibility for managing food safety and for complying with requirements relating to those aspects of food under their control.
12. 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.
13. The competent authorities have the responsibility to monitor compliance with and enforce legal requirements. They also have the responsibility to establish and maintain up-to-date and science based legal requirements, to ensure the effective operation of the national food control system.
14. Academics and scientific institutions may 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

15. 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

16. Competent authorities should be making decisions within a national food control system based on scientific information, evidence and/or risk analysis principles³ as appropriate.

PRINCIPLE 7 COOPERATION AND COORDINATION BETWEEN MULTIPLE COMPETENT AUTHORITIES

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

PRINCIPLE 8 PREVENTIVE MEASURES

18. 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 TO ENSURE IT MAINTAINS ITS FITNESS FOR PURPOSE

19. The national food control system should possess the capacity to undergo continuous improvement and include mechanisms to evaluate its effectiveness.

PRINCIPLE 10 RECOGNITION OF SYSTEMS [EQUIVALENCE]

20. Competent authorities should recognise that food control systems although designed and structured differently may be capable of meeting the same objective and should be provided for in the national food control system.

² For the purpose of this document food business operator includes producers, processors, wholesalers, distributors, importers, exporters and retailers

³ 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).

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

21. 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.

22. Defining the roles and responsibilities of key participants in a national food control system is essential for ensuring the objectives are met efficiently and effectively and opportunities for duplication and gaps are minimised. For example, 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. Also, while provincial or state laws may exist there should be a competent authority at the national level capable of ensuring uniform application. [New Zealand]

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

- provides leadership and coordination for the national food safety 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 trade in food; and
- advances/fosters knowledge, science, research and education regarding food safety. [New Zealand]

24. The design and operation 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. This food safety risk management framework should be based upon internationally agreed standards and guidelines and incorporate the following steps:

- preliminary risk activities, including identification and characterisation of the risk and ranking or prioritisation of the risk for risk management consideration;
- identification, analysis and selection of possible risk management options;
- implementation of the selected risk management option(s); and
- monitoring of the outcome or effectiveness of the implemented option(s) and review or revision as appropriate. [New Zealand]

25. Two national food control systems, although not the same and designed differently, may be able to deliver similar outcomes. [EU]

26. The national competent authorities should consider undertaking arrangements with other countries national competent authorities, including the establishment of equivalence agreements, in order to make efficient use of their own resources. [EU]

27. Thus every country may have a different national food control system that is designed, implemented and continuously improved, applying the above principles to achieve the objective.

SECTION 4.1 SYSTEM CHARACTERISTICS

Australia proposes incorporating this section into the body of section 4.
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28. A national food control system should possess three main characteristics which can be used in self-assessment or other evaluation to determine if the system is fully functional and effective:

29. 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. [New Zealand] This information should include, but not be limited to:

- Statistical data on production, trade and consumption;

- 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;
- Through chain traceability;
- Consumer practice on selection, storage and handling of products;
- Food safety hazards associated with different products; and
- Epidemiological data on foodborne disease.

30. 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. Trends and changes in the production/processing methods should also be subject to monitoring to allow early detection of emerging risks. 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. [EU/US leave in/Brazil Australia delete]

31. Capability to learn [Continuous Improvement] means that a national food control system has mechanisms in place to continuously update, review and analyse the above mentioned information. A national food control system should also have mechanisms to adapt to changes in the production/processing environment, and respond and intervene where/as required at the appropriate point in the food chain. [NZ leave with edits EU/US leave in/ Australia delete]

SECTION 4.2 SYSTEM DESIGN

EU proposal include 4 paras on general guidance on applying the principles

General guidance on applying the principles

32. The design of an effective national food control system requires a continuous planning-monitoring-review cycle, which is necessary to ensure that the system continues to deliver what is expected (principle 9 of this document). Successful implementation of the principles in section 3 requires that mechanisms to deliver according to those principles are built into the design of the system (rather than added as an after-thought). Effective implementation of all of the 10 principles depends on the combined effect of a number of components including: legislative foundation, allocation of resources, staff competence and training, laboratory network, verification of compliance, enforcement, surveillance, investigation, response, stakeholder engagement, international communication and harmonisation, assessment and evaluation. [EU]

33. The design of a national food control system plays a key role in providing for the system characteristics outlined in section 4.1. Processing and analysing data collected through official controls is essential for situational awareness (29). Data collection and analytical capability of the national food controls system determines the degree of pro-activity that the system will demonstrate (principle 8). Capability to learn depends on the effectiveness and timeliness of the feed-back from evaluation and review to the design or re-design processes. [EU]

34. When establishing a national food control system countries should identify the main objectives to be addressed through the system. The main objectives should be related to and assist in implementing the principles outlined in section 3. 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 national food control system (principle 9). More specific operational objectives should be identified and aligned with the national objectives. Competent authorities should draw up control programmes based on precise objectives and appropriate risk analysis. [EU]

35. Decision making should include comprehensive scientific evaluation (principle 6), wide stakeholder participation (principle 3), transparency of process (principle 3), consistent treatment of similar risks in different situations (principle 5), examinations of different options for risk management, and systematic,

documented decision-making (Principles 3 and 5). [EU]

36. An appropriate system design should consider a range of factors including (but not limited to) product risk, current scientific information, industry based controls, available resources, assessment, system review findings and cost effectiveness. It should also provide for flexibility in the application of control measures to reflect variations in these factors. [Australia]

37. In designing or redesigning a national food control system the government of a country along with the relevant competent authority(s) should take into consideration the guidance in the following sections. [New Zealand]

Legislation

38. Legislation should provide clarity as to the roles and responsibilities of participants in the food chain, in particular that of central government, the competent authority (or of each competent authority where there is more than one) and any authorised providers (where these are used), and industry. 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 or basis for the setting of standards and establishment of appropriate controls at all stages of the food chain, including production, manufacture, importation, processing, storage, transportation, distribution and trade.

Australia propose use of Control programmes as used in CAC/GL 26-1997, instead of Inspection programmes

EU suggested using Verification of compliance [and that this section fits after laboratories] – the language they have provided does not align with the concepts others have included under Control Programmes

Control Programmes ~~Inspection~~—~~Inspection~~—[Australia] Control Programme(s) should provide ongoing monitoring of the food control system from production through manufacturing to transportation/distribution. [Uruguay proposed to delete transportation/distribution and replace with retail]

39. When designing a control programme competent authority(s) should ensure that the objectives of the national food control system is addressed, but should allow for flexibility in the nature and frequency of control programmes, to ensure control measures are appropriate, and can be modified as required. [Australia]

40. Control programme(s) should be based on clearly defined outcomes and appropriate risk analysis. In the absence of detailed scientific research, control programme(s) 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. [Aust/covers Brazil]

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

42. Control programmes should be designed to account for factors such as:

- The risk to human health posed by the product or its packaging;
- The susceptibility of the target consumer group;
- The extent and nature of any further processing of the product;
- The effectiveness and reliability of own controls;
- History of conformity of industry; and
- Potential fraud or deception of consumers and other factors that may prevent fair trade practices.

43. The control programme (inspections, audits, visits) should cover, as appropriate:

- Establishments, installations, equipment and material
- Products, from raw material to the final products, including intermediate products.

- Process: evaluation and verification of GMP, HACCP.
- Means of transport, distribution chain, and retail.
- Human resources, capabilities, skills, expertise, confidentiality, etc.

44. 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 a Hazard Analysis Critical Control Point (HACCP) approach by industry. [Aust]

Assessment and Evaluation – As appropriate, assessment, audits, inspections or other tools to evaluate the effectiveness of the food control programme, including the recognition of trends.

[Australia has proposed including Assessment and Evaluation with Control (inspection)] [EU has proposed a section titled Assessment and Review] [US suggestions include language around continuous improvement that are supported by deletion of the Section on Continuous Improvement]

45. The system design should provide for the capability to evaluate the effectiveness of control programmes in the national food control system, including ongoing data collection. [Aus]

46. A national food control system should have mechanisms in place to continuously update, review and analyse the above mentioned information. A national food control system should also have mechanisms to adapt to changes in the production environment, and respond and intervene where/as required in the national food control system to ensure the protection of health of consumers and ensure of fair practices in trade. [Japan] [covers US proposal]

47. The competent authority(ies) implementing the national food control system should develop plans for periodic self-assessments and quality assurance reviews of the food control system that are designed to identify the strengths and weaknesses of their programme(s) or have their effectiveness evaluated by third parties. [Japan] [covers US proposal]

Compliance and Enforcement - Compliance and enforcement programmes to enforce laws and regulations to achieve compliance.

48. Compliance and enforcement programmes should be designed to provide for the ability for the competent authority to take action to ensure the situation is remedied where a product or process is found not to be in conformity. The resulting actions 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. [Australia/also picks up some of the EU thoughts]

49. Enforcement measures should be designed to be proportionate, dissuasive, and effective and to provide for a full range of actions which include the imposing of corrective actions, administrative sanctions and criminal sanctions. [EU]

50. Compliance and enforcement programmes may include the application of the following specific measures with regard to future production: [Australia]

- 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.

4.2.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING ETC)

51. The competent authorities and authorised providers should have adequate resources available, including personnel, funding, laboratories, equipment and other infrastructure to support an effective national food control system which meets the objective. [Australia also covers Mexico suggestions]

52. Feed and food control laboratories are an essential part of a national food control system. Analysis of food samples for physical, chemical and microbiological contamination is important to verify the safety and quality of food (including compositional characteristics, nutrition values, adulteration, presence of

contaminants, etc.) and to enable appropriate action to be taken to protect consumers whenever necessary. [EU]

53. The design of the national food control system should include laboratory support to ensure that capability is provided for food sample analysis, and, as appropriate, environmental and clinical samples. [Australia]

54. The number and location of the laboratories, including the use of private laboratories, should be determined in relation to the objectives of the system and the volume of work. If more than one laboratory is required, consideration should be given to apportioning the analytical work to achieve the most effective coverage of the food analyses to be performed and also to having a central reference laboratory equipped for sophisticated and reference analyses. In case the establishment of domestic laboratories is not a feasible option, either official or private laboratories in other countries may be considered. In such cases same quality criteria, monitoring and audit arrangements should be in place as for domestic laboratories. [EU /Japan]

Resources - Programme resources including the provision of adequate trained staff, facilities, equipment and funding.

55. In the design of a national food system, consideration should be given to the following to allow for the efficient and effective use of resources, while still ensuring the objective of the national food control system is met: [Australia]

- Clearly defined roles and responsibilities of all participants in a national food control system to ensure the system is delivered in a coordinated and consistent manner.
- The use of competent authorised providers and other available resources.
- Targeted controls to ensure the most efficient use of available resources.
- Undertaking arrangements with other countries' competent authorities, including the establishment of equivalence agreements [Australia]

Training

56. Training programmes should be designed to ensure that all inspectors, 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. [Australia/Canada]

57. The competent authority should have in place a training plan that ensures that all inspectors, analysts, and other individuals carrying out technical/professional duties receive the training required to adequately perform their work assignments to improve technical understanding and maintain professional development. The plan should include coursework as well as, when appropriate, joint inspections and/or field training and should provide for basic and advanced credentials. [Japan]

58. Programmes and training manuals should be developed to ensure consistent application of requirements and uniform application of the national food control system.

- Operating procedures including methods of inspection and control, sampling, and testing;
- Job functions and qualifications as appropriate;
- Relevant legislation and requirements;
- Arrangements for coordination with key officials in relevant ministries and private sector organisations;
- Relevant information about food contamination and food control;
- Procedures for conducting food recalls and investigations; and
- Relevant information on staff training. [Japan]

Surveillance, Investigation, Response

59. The design of a national food control system should incorporate a system for surveillance, investigation and response which provides for documentation, analysis, communication and follow-up of alleged food-related incidents. [Japan/Australia/US]

60. The elements of such programmes should include the following. [Japan]

a) Surveillance and Investigation:

- Use epidemiological information supplied by local, regional and/or national authorities, as well as industry and the animal health sector, to detect incidents or outbreaks of food borne illness or injury.
- Investigate reports of illness, injury, and suspected outbreaks.

b) Review and Response:

- Correlate and analyze data.
- Conduct trace-back and trace-forward investigations of food implicated in an illness, injury, or outbreak.
- Disseminate public information.

c) Documentation:

- A written description of standard procedures regarding:
 - Response to illness, injury or outbreak.
 - Release of information to the public.
 - Access to epidemiology support that is available to the programme.
 - Follow-up/reporting.

61. 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), and the International Food Safety Authorities Network (INFOSAN), for national and international emergency notification and response. [Japan/Canada]

4.2.2 COMMUNICATION (INCLUDES STAKEHOLDER ENGAGEMENT, EDUCATION AND INTERNATIONAL COMMUNICATION) [Australia]

62. A national food control system design should promote transparency, including communication of the requirements, implementation and verification processes that are part of a national food control system. Consideration should be given to communication strategies with all stakeholders (private sector, producers, processors and consumers). [Canada]

Stakeholder Engagement and Communication

63. In order to promote consumer confidence in the safety and quality of their food, 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. [modified EU proposal]

64. It is important that decision-making processes are transparent, allow all stakeholders in the food chain to make effective contributions, where appropriate. [modified EU proposal]

65. Risk communication with the public and the food industry in emergency situations is an important component of the national food safety system. Consumers should always be promptly, accurately and fully informed about any disease outbreak, contaminated food incident, or food recall through an alert system using effective and practical communication methods. Communication must be a two-way process to ensure that authorities are aware of and take into account consumer concerns and perceptions, where appropriate. [IACFO]

Education

66. Consideration should be given to the development of industry and community relations programmes to provide outreach and education programmes and information exchange, amongst regulators, industry, consumers and academia. [Aus]

International Communication

67. The competent authority should have mechanisms in place to interact with the international community regarding international food safety standards as well as communication mechanisms to enact during food safety events of international concern. [Japan]

68. The design and operation of national food control system should be transparent to trading partners – this applies to both importing and exporting countries. System design should address the need for timely notification and communication of identified food risks both in imported as well as exported products. Timely information should be provided on existing requirements and proposed changes to requirements to trading partners. [EU]

SECTION 4.3 ELEMENTS TO CONSIDER IN IMPLEMENTATION OF THE SYSTEM*[EU proposal] General guidance on applying the principles*

69. Effective implementation of control programmes requires that all staff are fully aware of what is expected from them (Principle 4) and have objectives clearly communicated to them, have the necessary knowledge and skills to carry out their tasks and that they have the necessary resources (human, material and financial resources) available to carry out their tasks. Recruitment and training policies as well as documented procedures are necessary to maintain a high level of consistency (Principle 5). Effective cooperation and coordination (Principle 7) may require regular communications – or other coordinating mechanisms – between competent authorities in order to prevent emerging threats (Principle 8) and ensures full coverage of all relevant risks (Principle 6) without overlooking any essential stages in the feed and food chain (Principle 2).

70. Effective and timely implementation of new objectives, designs and plans provides for the visible part of the system characteristics outlined in section 4.1. Situational awareness can only be evident when operational procedures, training programmes and coordination mechanisms are promptly adjusted to reflect changes in the operational environment. Similarly, pro-activity and capability to learn depend on the effectiveness of the links between design/planning processes and implementation of controls.

Legislation

71. The national food control system should be fully documented⁴, including a description of its scope and operation, responsibilities and actions for staff, in order that all parties involved are aware of their responsibilities. [Mexico]

72. Guidance and instructions for the interpretation of legal requirements concerning food business operators should be provided to both control staff and food business operators to ensure uniform application of legislation. For example, approval of food producing establishments is typically an activity where legal requirements are not always self-explanatory and therefore require practical implementation guidance to be effective and uniform.

73. Another example is the application of enforcement measures which requires careful judgement and depends on the specific circumstances. Guidance is necessary to ensure uniform application of enforcement measures in a wide range of varying situations.

⁴ Detailed guidance on documenting a national food control system can be found in the Food and Agricultural Organisation (FAO) publications *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems* (FAO food and nutrition paper 76), *Strengthening National Food Control Systems Guidelines to Assess Capacity Building Needs*

Continuous Improvement [Australia]

74. A national food control system should be continuously improved, for example in response to modifications to the system design, control programme data, non-compliances, food safety incidents, scientific research, history of conformance, external and self-reviews of the system. [Australia]

Control Programmes

75. Competent authority(s) should ensure that control programmes are consistent with national legislation (including regulations, guidelines, policies and procedures). [Australia]

76. The competent authority should take measures to ensure that the control system is operated in a consistent and effective manner, avoiding arbitrary and unjustified distinctions in its application. [Mexico]

77. Implementation of any control programme should be risk based and targeted at the most appropriate stages and operations. Implementation of a control programme should not compromise the quality or safety of foods, particularly in the case of perishable products. [Australia]

Assessment and Evaluation – As appropriate, assessment, audits, inspections or other tools to evaluate the effectiveness of the food control programme, including the recognition of trends.

Secretariat Note; Assessment and Evaluation – there seemed to be a general view that these activities were or could be included in either Compliance or Enforcement or in Continuous Improvement it may also only be relevant to the Design section. The Committee should have a further discussion on this particular area.

78. The effectiveness and appropriateness of the national food control system should be regularly assessed against the objective of the system, as well as against legislative and other regulatory requirements. Criteria for assessment should be established, clearly defined and documented. [Australia]

79. Self-assessment audits of the national food control system should be carried out periodically, the results of the self assessment should be taken into account in further development of the national food control system. [Australia]

80. Assessment of the efficacy of the national food control system should be targeted at the most appropriate stages in the food chain, based on risk analysis conducted in accordance with internationally accepted methodology [Australia]

81. The performance of officially accredited bodies should be regularly assessed by the competent authority. Procedures should be initiated to correct deficiencies and, as appropriate, enable withdrawal of official accreditation. [Canada/Mexico/Brazil]

Compliance and Enforcement - Compliance and enforcement programmes to enforce laws and regulations to achieve compliance

82. Competent authority(s) should ensure that compliance and enforcement programmes are implemented consistently to ensure the objective is maintained. [Australia]

83. In verifying compliance with requirements, competent authorities should acknowledge that different means can be used to achieve same objectives – unless the means have been explicitly prescribed in legislation. [EU]

84. 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.

85. The specific measures applied with regard to future production 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.

86. The competent authority should provide the operator concerned, or a representative, with written notification of its decision concerning the action to be taken and the reason for the decision. Information on right of appeal against such decisions and on the applicable procedure and timeframe should also be provided.

4.3.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING ETC)

87. The laboratories should have adequate facilities for physical, microbiological and chemical analyses. In addition to simple routine analysis, the laboratories can be equipped with more sophisticated instruments, apparatus and library facilities as required. It is not only the type of equipment that determines the accuracy and reliability of analytical results but also the qualification and skill of the analyst and the reliability of the method used. [EU]

88. Competent authorities 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. Internationally recognized and validated analytical methods should be used wherever available and Good Laboratory Practices should be adhered to. [EU]

89. Laboratories should maintain the necessary analytical expertise, facilities, and equipment to carry out the tests required by the competent authority. If third party laboratories are used, the competent authority maintains a written agreement or contract with the laboratories covering the services to be provided including quality assurance and accreditation programmes. [US]

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

91. The effective linkages should be established between laboratories in food control agencies and those in the public health system to utilize information on foodborne diseases for developing risk based food control policies. (FAO Food and Nutrition Paper 76, page 8 last para modified) [Japan]

92. The scientific information produced by food control laboratories may be used to inform and support policy and decision making processes related to food safety and quality, for instance to design surveillance and monitoring programmes that target priority hazards or to investigate adulteration, misleading information, fraud, consumer complaints, disease outbreaks, etc. and other emerging food safety and quality issues. [EU]

Resources - Programme resources including the provision of adequate staff, facilities, equipment and funding.

93. Implementation of the national food control system requires that the competent authority (s) or delegate have access to appropriate resources including human, financial and other required support (e.g., access to inspectors, analytical capacity, vehicles, and other equipment) [Canada]

94. Competent Authorities 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. [EU] Personnel should have access to adequate facilities, equipment and other resources to operate the national food control system. [Japan/Mexico]

Training

95. The competent authority should implement a training programme(s) that ensures that all inspectors, analysts, and other individuals carrying out technical/professional duties receive the training required to adequately perform their work assignments to improve technical understanding and maintain professional development. [US]

96. Programmes and training manuals should be developed, implemented and maintained to ensure consistent application of requirements

Surveillance, Investigation, Response - Capability to provide for surveillance, investigation, response, documentation, analysis, and follow-up of food-related illnesses and injuries.

97. Competent authority(s) should ensure that the response system in regards to food safety incidents, is effective, with clear communication between competent authority(s), industry and consumers, and is regularly assessed. [Australia]

98. 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. [US]

99. 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. [EU]

4.3.2 COMMUNICATION (INCLUDES STAKEHOLDER ENGAGEMENT, EDUCATION AND INTERNATIONAL COMMUNICATION) [Australia]

Stakeholder Engagement

100. In order to promote consumer confidence in the safety and quality of their food, 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 (from parking lot) [Canada]

101. The competent authority should, as part of the regulatory process, engage with stakeholders including the food industry and consumers, in the development of new laws and regulations, and when making significant changes to their operating practices that will affect them. [US]

102. Communication among food safety, agriculture and other relevant authorities, consumers and consumer organizations, and the food business operators should be a continuous function of a national food control system. [IAFCO]

Education

103. 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. [Aus]

International Communication

104. As appropriate, the competent authority should:

- Communicate food safety issues and concerns with trading partners.
- Participate in bilateral exchange with trading partners related to food safety regulations and their enforcement.
- Communicate and collaborate with international authorities in cases where food(s) implicated in incidents or outbreaks of foodborne illness may be circulating in international trade. [US]

4.4 CONTINUOUS IMPROVEMENT

Note: The United States does not believe a specific section devoted to this aspect of food control systems is necessary. This characteristic (continuous improvement) should be included as a characteristic if Section 4.1 above is retained and any specific provisions can be placed in the appropriate sections relating to implementation. Where specific occurred in this section we have moved it (or equivalent wording) into the body of the text above.

Note: suggest that continuous improvement be applied to all elements – rather than applying the concept to each element. [Canada/Australia]

Self assessment and review procedures to ensure fitness for purpose (meeting programme design and legislation) [Canada]

105. A national food control system should 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. [Australia] These changes may also require amendments to legislation; changes to control programmes and/or laboratory practices.

106. Recommendations for continuous improvement may be drawn from a wide range of available information, including (but not limited to), control programme data, non-compliances, food safety incidents, scientific research, history of conformance, external and self-reviews of the system, changes to product risk or the production environment. [Australia]

107. When considering and incorporating recommendations into the system design and implementation, competent authority(s) should consider cost-benefits, effectiveness and efficiency. [Australia]

108. When continuously improving the national food control system, competent authority(s) may incorporate recommendations at the level of system design or implementation as appropriate. [Australia]

109. 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. [Australia]

110. Food-related incidents are an opportunity to learn. Competent authorities should use these opportunities by way of carrying out "post-mortems" and feeding the "lessons-learned" back to the planning/design process. 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. [EU]

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