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FOOD AND AGRICULTURE  
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Agenda Item 5

CX/FICS 10/18/4  
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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION**  
**AND CERTIFICATION SYSTEMS**

**Eighteenth Session**

**Surfers Paradise, Australia 1 – 5 March 2010**

**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 Belize, Brazil, Canada, China, Denmark, Ethiopia, European Commission, France, Germany, Indonesia, Japan, Republic of Korea, Mexico, the Netherlands, New Zealand, Norway, Saint Lucia, South Africa, Spain, Switzerland, Thailand, United States of America, Zambia, FAO, OIE, and ICGMA)**

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 16 November 2009** 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](mailto: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](mailto: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.

## BACKGROUND

1. At its 15<sup>th</sup> Session and 16<sup>th</sup> Sessions of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) (2006 and 2007), the Committee considered Project Documents<sup>1</sup> and discussion papers prepared by Australia proposing the development of guidelines for national food inspection systems.

2. While there was general support for new work to develop guidelines for national food control systems, the Committee agreed that the discussion paper needed to be revised to further clarify the scope of the work and identify the gaps in existing CCFICS texts, and how to link these texts together, thereby providing a framework for national food control systems. With regard to whether CCFICS is the appropriate Committee to conduct this work, several delegations considered it necessary to better clarify the scope of the work as it may include aspects which could fall under the responsibility of other Committees.

<sup>1</sup> CRD 11 Proposal for New Work by Australia – 15CCFICS (2006)

3. The Committee agreed to establish an electronic Working Group, led by Australia, to prepare a comprehensive discussion paper that would include an outline of the principles and guidelines for a national food control system, for consideration at its next session.
4. At the 17<sup>th</sup> session of the Codex Committee on Food Import and Export Inspection and Certification Systems (2008), the Committee further considered the revised discussion paper<sup>2</sup> including the proposal for new work on the development of principles and guidelines for national food control systems that would complement existing Codex texts.
5. The Committee expressed general support for developing the document and considered that the CCFICS was the appropriate committee for this new work. It was noted that principles and guidelines for national food control systems were very useful for countries, in particular for those that were in the process of developing such systems; that it was necessary to evaluate the capacity of the national food control system to identify the specific needs; that the new work should promote the harmonisation and integration of the domestic (including import) and export food control system; and that the new work should consider the fundamental food safety principles, e.g. use of a risk based approach, coverage of the entire food chain, the primary responsibility of producers in ensuring the safety of their products.
6. The Committee revised the project document (Attachment 1 to CX/FICS 08/17/6): to specifically refer to the dual mandate of Codex (i.e. protecting the health of consumers and ensuring fair practices in the food trade); to include the fundamental food safety principles among the aspects to be considered by the new work; to add an assessment against the General Criterion for the Establishment of Work Priorities; to amend the assessment against the criteria on diversification of national legislation; to add references of relevant work undertaken by FAO and WHO; and to clarify that the proposed work addressing the development and implementation of food control systems could also lead to the revision of existing Codex texts.
7. The Committee agreed to forward the project document as amended to the 62<sup>nd</sup> session of the Executive Committee for critical review and to the 32<sup>nd</sup> Session of the Commission for approval as new work.
8. In order to facilitate the discussion at its 18<sup>th</sup> session it further agreed to establish a physical working group, chaired by Australia, and hosted by the United States of America, open to all Members and Observers and working in English, French and Spanish, to prepare proposed draft Principles and Guidelines for National Food Control Systems for circulation for comments at Step 3 and consideration at Step 4 at the next session of the CCFICS, subject to the approval of new work by the Commission. The Committee also agreed that there would be some preliminary electronic consultation among Codex members and observers (in English only) to facilitate the work.
9. The 31<sup>st</sup> Session of the Codex Alimentarius Commission approved the new work on the proposed draft Principles and Guidelines for National Food Control Systems (N06-2009).

## **REPORT OF THE PHYSICAL WORKING GROUP**

10. A physical working group chaired by Australia and hosted by the United States of America met in Miami, Florida, on 10 and 11 July 2009. The working group was attended by 59 delegates from 24 member countries, 1 UN agency, 1 member organisation, 1 international governmental organisation and 1 non-governmental organisation 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 of an electronic working group led by Australia<sup>3</sup>.

### **General Discussion and Introduction**

11. The working group had a general discussion on the purpose of the document and noted that this may be one of the most important texts developed by this Committee, due to its importance to both developed and developing countries and that as a starting point the working group should develop a document that provides the ideal framework as the core of a food control system. In order to do this the working group considered that the structure should outline a framework that would facilitate trade but at the same time achieve a

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<sup>2</sup> CX/FICS 08/17/6

<sup>3</sup> With the assistance of Brazil, Canada, Ethiopia, European Community, Japan, New Zealand, the Netherlands, South Africa, the United States of America and Zambia

country's appropriate level of protection. In doing this the working group also noted that it must not lose sight of some of the key principles that had already been developed by CCFICS in existing texts. In this regard, it was also noted that in the process of developing these principles and guidelines that the committee may identify a need to revise existing texts that had been developed prior to 2000 that were no longer in line with current worldwide practices.

12. 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 to identify the key principles that should apply to a national food control system. A general outline of the document including the introduction and scope, was developed which outlines the rationale or the need for an effective national food control system and recognises that a system should consist of integrated elements related to domestic production, import and export of food products and that the document should be read in conjunction with other Codex texts and those of other international organizations (FAO and OIE) where appropriate.

13. The working group then listed some key principles (protection of consumers, risk based, science based, international standards, fitness for purpose and transparency) which would be expanded further if time permitted.

### Scope

14. In developing the Scope section the working group considered that the principles and guidelines should provide a framework to assist national governments in verifying that such systems ensure that requirements for food and the associated production systems achieve or contribute to the achievement of the protection of the health of consumers and ensure fair practices in the food trade. In developing the Scope, the working group took into consideration that the document could apply to members that were setting up a new system or to members that were interested in updating older systems, therefore the document also recognises the ability of competent authorities to apply the principles and guidelines according to their particular situations.

### Principles for a National Food Control System

15. In developing the section on Principles the working group had a lengthy discussion drawing on existing texts such as the *Principles for Food Import and Export Inspection* (CAC/GL 20-1995) and the *Guidelines for Food Import Control* (CAC/GL 47-2003). This discussion identified four cross cutting themes (Principles) that should apply to national food control systems. The principles identified were as follows:

1. **Protection of consumers** – in the design of national food control systems, precedence should be given to protecting the health of consumers and ensuring fair practices in food trade.
2. The national food control system should be **risk based, science based and harmonised** to the greatest extent possible with international standards.
3. **Fitness for purpose** a food control system should be fit for purpose; it should be fully effective in achieving the objectives of the country's appropriate level of protection.
4. **Transparency** the principles and operations of national food control systems should be open to scrutiny, while protecting legitimate concerns to preserve confidentiality.

16. The working group in concluding its discussion on the draft principles contained in Appendix 1 noted that these principles are by no means complete and the Committee should consider the proposed text with a view to recommending additional explanatory text for each Principle. In particular with respect to Principle 2 the working group considered that it may be necessary to reference the *Codex Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007) as this document provides guidance to governments for risk assessment, risk management and risk communication, and this would also recognise that to the extent possible, the application of risk analysis should be established as an integral part of a national food safety system. With respect to Principle 3 Fitness for Purpose the explanatory text is in square brackets as the working group was not able to reach agreement on whether this should be considered a high level principle or if there was alternate language that could provide more clarity to this principle.

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

17. In developing the Guideline section the key questions considered by the working group were:

- What does the system apply to? (paragraphs 7 to 9 of the proposed draft principles and guidelines);

- What does the system achieve? (paragraphs 10 to 16 of the proposed draft principles and guidelines);
- What are the Characteristics of the system? (paragraphs 17 to 24 of the proposed draft principles and guidelines);

18. In considering what the system applies to the working group agreed that the system should apply to competent authorities and food businesses across the value chain from production to consumption whilst noting that consumers also share some responsibility for food safety. The working group also recognised that further text may be developed, taking into consideration existing Codex texts. For example the roles and responsibilities of the competent authority or authorities may be drawn from paragraphs 6 to 8 of CAC/GL 47-2003, whereas the roles and responsibilities of those involved in food businesses from production to consumption are identified in Section 2.1.2 of the Codex *Recommended International Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-1969).

19. In developing the section that deals with what the system achieves the working group considered that a key component of a national food control system is the ability of the competent authority to verify that the system meets its objectives, is implemented in a consistent manner, is integrated and coordinated, has appropriate notification and response procedures (both national and international) for food safety incidents, whilst also considering the costs of various interventions with respect to consumers, industry and governments.

### **Characteristics of the National Food Control System**

20. This section of the document outlines those characteristics that the working group considered essential to an effective national food control system. These characteristics include:

- i. Coordinated, cooperative management;
- ii. Adaptive and responsive;
- iii. Proactive and risk based;
- iv. Able to learn and capable of continuous improvement;
- v. Efficient and effective;
- vi. Transparent;
- vii. Independence as practical as possible;
- viii. Consistency of decision-making;
- ix. Uniform national implementation.

### **Components of the National Food Control System**

21. The components of the national food controls system are laid out in this section. The working group considered the key components of the national food control system to be those elements that support the functioning of the system such as ensuring clear roles and responsibilities for all parties, resources for implementation, training, laboratories, certification, competencies and the legislative framework.

### **How the System Functions (programs and controls)**

22. The final section developed by the working group contains the operational requirements for a national food control system. How the system is designed and developed, its operations and implementation and finally monitoring and evaluation which would support verification, maintenance and improvements.

### **Considerations and Conclusion**

23. The working group, due to time constraints was only able to develop an outline of the key contents of the proposed document. In the working group's view the proposed draft principles and guidelines contained in Appendix 1 still require additional work with respect to the format and layout. In developing the draft document further it will be necessary for members to not only consider the completeness of the framework provided but also consider the context of the text provided including existing CCFICS, Codex and relevant 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. It is envisaged that there is also a range of areas not addressed through existing Codex texts where elaboration will be required.

The intention of this document is not to duplicate existing text however in some instances this may be necessary to assist the readability of the document. In developing the proposed draft further the physical working group recognised that there may be a need to identify relevant Codex texts that provide additional information on roles and responsibilities of those involved in food production, including competent authorities.

#### **RECOMMENDATION**

24. The Committee is invited to review the framework in Appendix 1 and in doing so observe that the working group has included a range of text within the framework. Members are asked to consider that in progressing this document it will be necessary for members to not only consider the completeness of the framework provided but also the context of the text provided including existing CCFICS, Codex and relevant OIE texts. 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 and if possible identify other relevant Codex texts that may provide additional information.

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

26. The Committee at its 18<sup>th</sup> Session in March 2010 will consider the text in Appendix 1 at Step 3 together with comments at Step 4.

## 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.*

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

(N06-2009)

(At Step 3)

### INTRODUCTION

1. An effective national food control system is a necessity for every nation in order to protect its consumers (national and international) against foods that are contaminated, adulterated or in other ways injurious to health, or which are incorrectly packaged or labeled.
2. A national food control system consists of integrated elements related to domestic production, import and export of food products. 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.

### SCOPE

4. These principles and guidelines provide a framework to assist national governments in the development and operation of a national food control system. Such systems are intended to ensure that requirements for food, and the associated production systems, achieve or contribute to the achievement of the protection of the health of consumers and ensuring fair practices in the food trade.
5. 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.

### OBJECTIVE OF A NATIONAL FOOD CONTROL SYSTEM

6. The national food control system should be designed and maintained with the objective of protecting the health of consumers and ensuring fair practices in trade<sup>4</sup>.

### PRINCIPLES FOR A NATIONAL FOOD CONTROL SYSTEM

1. **Protection of consumers** – in the design of national food control systems, precedence should be given to protecting the health of consumers and ensuring fair practices in food trade<sup>5</sup>.
2. The national food control system should be **risk based, science based and harmonised** to the greatest extent possible with international standards.

(This should apply not only to product standards but also to the design of the national food control system; primary importance should be given to the use of international standards keeping in mind the resource implications of conducting risk analysis processes. The working group considered also that it may be useful to reference the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).)

3. **Fitness for purpose** – [inspection systems should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required<sup>6</sup>.]

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<sup>4</sup> This text has been adapted from CAC/GL 20-1995 Para 5 and 6.

<sup>5</sup> CAC/GL 47/2003 Guidelines for Food Import Control Systems

**4. Transparency** (Accountability and verifiable measures) - while respecting legitimate concerns to preserve confidentiality, the principles and operations of national food control systems should be open to scrutiny by consumers and their representative organisations, and other interested parties<sup>7</sup>.

## **GUIDELINES - FRAMEWORK FOR A NATIONAL FOOD CONTROL SYSTEM**

### **Higher level elements of a national food control system**

#### **What does the system apply to?**

[The working group envisaged that both the sub-points under the high level characteristics would be clear succinct statements and the detail will be in the Guideline section].

7. The national food control system applies to competent authorities and food business across the value chain from production to consumption. [The committee may like to consider GL 47 -2003 paragraphs 6, 7 and 8 which defines the responsibilities of competent authorities for import control systems and could be drawn on to expand this section]

8. All those involved in food businesses from production to consumption, including growers, processors, regulators, transporters, distributors, retailers, [academics and scientific institutions – *maybe a separate bullet point*] have the primary responsibility for complying with requirements and ensuring safe food on those aspects of food which are under their control.

Alternate 8. Taken from the *Recommended International Codex of Practice General Principles for Food Hygiene* (CAC/RCP 1-1969, Rev 4 (2003) – Preamble – *Everyone including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to ensure that food is safe and suitable for consumption.*

9. Complementing food business responsibility, consumers (national and international) must also manage food safety risks.

#### **What does a national food control system achieve?**

10. National food control policies should address the central issues of protecting consumers' health and ensuring fair practices in the food trade.

11. In developing or amending the elements of a national food control system, consideration should be given to the costs and effect of various interventions with respect to consumers, industry and governments.

12. National food control systems should be developed and implemented to ensure consistent delivery by the competent authority(ies).

*[Alternative wording for 13: The requirements of national food control systems should be implemented and enforced in a uniform and consistent manner by the competent authority(ies)]*

13. Verification of the national food control system may involve the competent authority or other recognized bodies at any relevant point in the food chain.

14. The competent authority(ies) involved in the national food control system should have clearly defined responsibilities. Where different authorities in the same country have jurisdiction over different parts of the food chain, multiple inspections or duplication of testing is to be avoided.

*[The working group noted that the high level principle will include many of the same concepts such as integration and coordination that will be elaborated in more detail in the following sections.]*

15. Communication of the requirements, implementation and verification of a National Food Control System should be clear and transparent to allow for the development of consumer confidence. This communication should include:

- Following the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* CAC/GL 19/1995, International Health Regulations (IHR), INFOSAN for national and international emergency notification and response.

<sup>6</sup> Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) paragraph 6.

<sup>7</sup> Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) paragraph 13.

- Communication strategies with all stakeholders (private sector, producers, processors and consumers)
- Food safety education and information to consumers

16. A National Food Control System should be developed to ensure food security in the context of both access to food and food safety.

#### **Characteristics of the national food control system**

17. A national food control system must be supported by the necessary legislative framework, controls, procedures, facilities, equipment, laboratories, transportation, communications, personnel and training.

18. A national food control system should avail itself of accurate and current information on food production systems. 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; and
- Production technologies, processes and practices.

19. 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.

20. The national food control system should be able to detect and respond to emerging risks and identify trends and patterns based on data collected. To that end, a national food safety system should have:

- Monitoring and surveillance programs for disease and hazards, as appropriate;
- Mechanisms to identify emerging risks, in particular, factors indicating increased risk of non-compliance due to commercial incentives;
- Mechanisms to implement control actions proportionate to risks and targeted to cover high risk areas; and
- Efficient use of resources by means of risk categorisation and adjusting the intensity and/or frequency of controls according to risk category.

21. The national food control system should possess the capacity to undergo continuous improvement. This requires:

- Mechanisms to evaluate the effectiveness of the current system by means of self-assessments, internal and/or external audits; and
- Mechanisms to design and implement effective corrective actions to address areas for improvement.
- Verification, maintenance and improvement/performance assessment (self and third party audits), import country findings, results of foreign assessments and domestic food safety data.

22. Clearly defined and transparent legislation should be developed which authorizes the establishment of the competent authority and food safety requirements.

23. As appropriate, clearly defined and transparent legislation and operating procedures should be developed which allows for the establishment of the competent authority(ies) and the processes and procedures required to verify the conformity of products against requirements. Uniformity of operational procedures is particularly important. Programmes and training manuals should be developed and implemented to ensure uniform application<sup>8</sup>.

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<sup>8</sup> Guidelines for Food Import Control Systems CAC/GL 47-2003 paragraph 14

24. A national food control system should be developed and implemented to ensure uniform application by the competent authority(ies).

### **Components of the systems**

#### **Infrastructure, programs and requirements**

25. The competent authority(ies) involved in the national food control system should have clearly defined responsibilities and ensure adequate resources and structures are available for the operation of an effective and efficient national food control system.

26. Roles and responsibilities should be well defined to avoid multiple inspections, investigations and duplication of testing and to avoid gaps in the production to consumption continuum.

27. National food control systems should meet a number of operational criteria so as to ensure their impartiality and effectiveness and in particular have, or have access to, a sufficient number of qualified and experienced personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, toxicology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit and law. Personnel should be capable and appropriately trained<sup>9</sup> in the operation of national food control systems. Staff should have access to adequate facilities and equipment to undertake necessary procedures and methodologies. National food control systems should also possess adequate facilities and equipment to enable personnel to carry out their duties properly.

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

29. National food control systems should utilize laboratories that are evaluated and/or accredited under officially recognized programs to ensure that adequate quality controls are in place to provide for the reliability of test results. Validated analytical methods should be used wherever available. Laboratories should apply the principles of internationally accepted management techniques to ensure the reliability of analytical results<sup>10</sup>.

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

31. The competent authority retains the fundamental responsibility to verify and provide assurances as to the conformity of food and the associated production with requirements.

32. The competent authority retains the fundamental responsibility to ensure the effective operation of the national food control system and should be free of improper or undue influence when implementing this responsibility.

*[Many of the points below have corresponding texts in existing Codex documents – The committee will need to identify these references]*

33. Effort should be made to improve capacity of regulatory authorities, particularly those of developing countries. Capacity building for developing countries either through bilateral arrangements or with assistance of international organizations should be directed toward implementation of these principles and guidelines.

#### **Legislative framework**

34. Clearly defined and transparent legislation should be developed which authorizes the establishment of the competent authority and food safety requirements.

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

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<sup>9</sup> Guidelines for food Import Control Systems CAC/ GL 47-2003 paragraphs 41 – 43

<sup>10</sup> Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems. CAC/GL 26-1997 paragraphs 41 – 42

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

37. Requirements, including food regulations, standards and codes of practice should be based on sound science, developed using risk analysis principles<sup>11</sup> and to the extent possible, be consistent with international standards where such requirements achieve the appropriate level of protection established by the competent authority.

38. The General Principles of Food Hygiene (including, as relevant, Hazard Analysis Critical Control Point (HACCP)) developed by the Codex Committee on Food Hygiene<sup>12</sup> and Good Manufacturing Practices should be utilized by food businesses and recognized by competent authority(ies) as a fundamental tool for improving the safety of food.

39. National food control systems should be designed and operated on the basis of risk analysis principles that are consistent with internationally accepted approaches for example the *Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL63-2007)* and include, as appropriate to the circumstances, comprehensive scientific evaluation, wide stakeholder participation, transparency of process, consistent treatment of similar risks in different situations and systematic decision-making.

40. Verification 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<sup>13</sup>. The frequency and intensity of controls should be designed so as to take account of risk and the effectiveness of controls already carried out by those handling the products including producers, manufacturers, transporter, distributors, and point of sale operators.

41. The nature and frequency of audit/inspection of food production systems should be based on the risk to human health and safety presented by the product, its origin and the history of conformance to requirements and other relevant information, including potential for fraud. Control should be designed to account for factors such as:

- The risk to human health posed by the product or its packaging;
- The history and likelihood of non-compliance with requirements;
- The susceptibility of the target consumer group;
- The extent and nature of any further processing of the product;
- History of conformity of producers, processors, manufacturers, transporters and distributors; and
- Potential fraud or deception of consumers and other factors that may prevent fair trade practices.

42. The voluntary utilization of quality assurance systems by food businesses should be encouraged in order to achieve greater confidence in the quality of products. The General Principles of Food Hygiene (including, as relevant, HACCP principles) developed by the Codex Committee on Food Hygiene<sup>1</sup> should be utilized by food businesses and recognized by competent authority(ies) as a fundamental tool for improving the safety of food.

43. Where quality assurance systems are used by food businesses, 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.

44. Member countries should use Codex standards and related texts whenever appropriate.

*[Comment: The committee may wish to consider where this point is required as it is an overarching principle of Codex]*

45. National food control system requirements should be developed based on science and be no more

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<sup>11</sup> FAO–WHO Food Safety Risk Analysis: A guide for national food safety authorities (FAO Food and Nutrition Paper 87)

<sup>12</sup> CAC/RCP 1-1969, rev. 4-2003: Recommended International Code of Practice; General Principles of Food Hygiene

<sup>13</sup> FAO–WHO Food Safety Risk Analysis: A guide for national food safety authorities (FAO Food and Nutrition Paper 87)

restrictive than is necessary in order to achieve the country's appropriate level of protection.

46. The requirements for imported and exported food should be consistent with the requirements for domestic food to the extent possible. These requirements may consist of standards, provisions for sampling, process controls, conditions of production, transport, storage, or a combination of these.

*[Comment: The committee may wish to consider that there will be situations where requirements for exported foods, which are being sent to countries with different requirements and ALOP, will not be the same as domestic requirements]*

*[Alternative wording para 47: National food control systems should be designated and operated such that domestic (including import) and export food control system are harmonized and integrated to the fullest extent possible]*

## **How the system functions (programs, controls)**

### **Design and Development**

47. The design and operation of national food control systems should be based on risk.

48. The national food control system should be fully documented, including a description of its scope and operation, responsibilities and actions for staff, in order that all parties involved know what is expected of them. Documented procedures assist in ensuring that the controls are carried out consistently and uniformly. Documentation of a national food control system 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 as appropriate;
- Operating procedures including methods of sampling, control and testing;
- Relevant legislation and requirements;
- Important contacts;
- Relevant information about food contamination and food control;
- Procedures for conducting food recalls and investigations; and
- Relevant information on staff training.

49. Requirements, including food regulations, standards and codes of practice should be based on sound science, developed using risk analysis principles<sup>14</sup> and to the extent possible, be consistent with international standards where such requirements achieve the appropriate level of protection established by the competent authority.

### **Operations/implementation**

50. The responsibilities of the competent authority may include, but not be restricted, to:

- Approval of processors or other operators, e.g. license or registration;
- Appointing authorized officers;
- Recognizing accredited or accredit laboratories in accordance with internationally recognized standards;
- Auditing or inspection of food and food production methods which may include but is not restricted to, as appropriate and necessary:
  - direct monitoring of premises and processes for compliance with hygienic, safety and other requirements. This may include sampling during processing, storage, transport, or sale; and/or

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<sup>14</sup> FAO-WHO Food Safety Risk Analysis: A guide for national food safety authorities (FAO Food and Nutrition Paper 87)

- verification of the food industry's systems via audits to determine compliance with relevant requirements;
- Verification may be used to ensure that programs and HACCP plans are being implemented as documented and are effective on a continuous basis;
- Identifying food which doesn't meet the requirements; or food which is otherwise deceptively sold to the consumer; and taking the necessary remedial action;
- Providing for tracing of food products<sup>15</sup> and for the recall of unsafe products;
- Implementing administrative and/or judicial measures when specific requirements are not satisfied; and
- Certification with the recognition that food businesses meet national requirements through their registration listing through to attestations to other parties in this regard<sup>16</sup>

51. A number of these responsibilities should provide proactive prevention of breaches of a national food control system.

52. Where a product or process is found not to be in conformity, the competent authority shall 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.

53. 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 or closure of the producing establishment.

54. The competent authority shall 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.

55. Where the competent authorities use third<sup>17</sup> party providers as officially accredited bodies to implement controls, to be officially accredited, the body should be assessed against objective criteria.

### **Verification/maintenance and Improvement**

56. Verification 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<sup>18</sup>. The frequency and intensity of controls should be designed so as to take account of risk and the effectiveness of controls already carried out by those handling the products including producers, manufacturers, transports, distributors, and point of sale operators.

57. The national food control system should possess the capacity to undergo continuous improvement. This requires:

- Mechanisms to evaluate the effectiveness of the current system by means of self-assessments, internal and/or external audits; and
- Mechanisms to design and implement effective corrective actions to address areas for improvement.

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<sup>15</sup> Principles for Traceability/Product tracing as a tool within a food inspection and certification system CAC/GL 60-2006

<sup>16</sup> Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems CAC/GL 26-1997 paragraph 22 *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates CAC/GL 38-2001*

<sup>17</sup> Guidelines for Food Import Control Systems CAC/GL 47-2003 paragraph 8

<sup>18</sup> FAO-WHO Food Safety Risk Analysis: A guide for national food safety authorities (FAO Food and Nutrition Paper 87)

58. 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.

59. The competent authority(ies) implementing the national food control system should carry out self-evaluation or have their effectiveness evaluated by third parties.

60. Self-assessment or third-party audits should be carried out periodically at various levels of the national food control system, using internationally-recognized procedures. The national food control services of a country may undertake self-assessment for such purposes as assuring the adequacy of consumer protection and other matters of national interest or improving internal efficiency.

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