CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



Agenda Item 4

CX/FICS 13/20/3 Add 1 November 2012

#### JOINT FAO/WHO FOOD STANDARDS PROGRAMME

#### CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

#### **Twentieth Session**

Chiang Mai (Thailand), 18 – 22 February 2013

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

(N06-2009)

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

(Comments from Members and Observers Argentina, Canada, Costa Rica, Honduras, Iran, Mauritius, Mexico, New Zealand, Norway, United States of America, Uruguay, FAO and INC)

#### **ARGENTINA**

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

Justification: A government structure is the same as institutions.

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

- provides leadership and coordination for the national food control system;
- develops, implements, <u>administers</u>, monitors, manages and reviews <u>the actions within its</u> <u>competency of</u> the national food control system;

*Justification: The competent authority administers the system. The additional text is for clarification.* 

- establishes and enforces science and risk based regulatory controls that encourage and promote positive food safety outcomes;
- supports and enables fair practices in the food trade;
- advances/fosters knowledge, science, research and education regarding food safety;
- engages with stakeholders to ensure transparency and to obtain views <u>regarding the established</u> <u>regulatory requirements</u> of interested parties; and

Justification: Clarify that the parties are giving their opinion of the regulatory requirements.

- establece y mantiene acuerdos con otros países, por ejemplo, por medio de programas de cooperación, acuerdos de equivalencia, etc.
- establishes and maintains arrangements with other countries e.g. cooperation programmes, equivalence agreements etc.

[Translator's note, Argentina deletes "por ejemplo" (e.g.), as it is superfluous being followed by "por medio de" (through) which is not present in the English text.]

27. Cuando haya más de una autoridad competente, se debería definir claramente sus funciones y responsabilidades y coordinar sus actividades en la mayor medida de lo posible para minimizar <del>lagunas</del> **vacios legales** y duplicaciones.

27. Where there is more than one competent authority their roles and responsibilities should be clearly defined and their activities coordinated to the greatest extent possible to minimise gaps and overlaps.

Justification: "lagunas" is not an appropriate term. [Translator's note: No change to the English]

28. El diseño y la aplicación implementación de un sistema nacional de control de los alimentos deberían regirse por un proceso lógico y transparente. Ello debería incluir la aplicación de un mecanismo sistemático para la evaluación y, de ser necesario, gestión de los riesgos en materia de inocuidad de los alimentos asociados a peligros existentes, nuevos y re emergentes.

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

Justification: Clarify that the control refers to risks.

[Translator's note: neither of these changes affects the English as these terms are already included.]

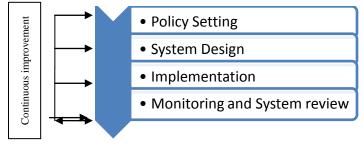
29. In developing **adopting** a national food control system the national competent authority, in consultation with stakeholders, should adopt the following processes, which will reflect the principles of a national food control system and are described in this document

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

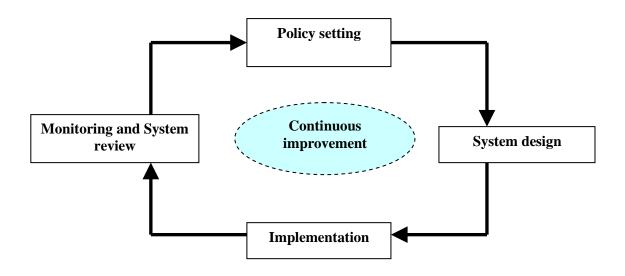
32. When establishing a national food control system countries should identify the main objectives to be addressed through the system for the short, medium and long term. The main objectives should be related to and assist in implementing the principles outlined in Section 3.

33. As a result of applying the guiding principles of Section 3 and the framework of Section 4 a national food control system should possess three main characteristics which, among other things, can be used in self-assessment or other evaluation to determine if the system is fully functional and effective:

- i)<u>Characteristic 1 Situational awareness</u> means that a national food control system avails itself of accurate and current information on the entire food chain as a whole and its various parts and participants
- ii) <u>Characteristic 2 Pro-activity</u> means that a national food control system is capable of identifying existing or emerging hazards in the environment before they materialise as risks in the food production/processing chain and at the early stages rather than in the end product. Early warning/rapid alert systems, traceability and contingency planning for managing and preparing for potential food safety incidents should be an inherent part of a pro-active control system.
- iii) <u>Characteristic 3 Continuous Improvement</u> means that a national food control system should possess the capability to learn through a process of review and reform utilising <u>control</u> mechanisms that check and evaluate whether the system is able to achieve its objectives
- NB: Paragraphs 30, 32 and 33 have been moved up because they are general topics.



**Proposed Possible Alternative Diagram** 



### SECTION 4.1 POLICY SETTING

31. En el establecimiento de normativas <u>constitutivas del SNCA</u> se debería <u>incluir considerar</u> la identificación y articulación clara de los resultados previstos; la relación entre el sistema nacional de control de los alimentos y las normas nacionales e internacionales <u>de referencia</u>; la identificación de los riesgos y <del>los</del> <u>otros</u> controles del sistema; las estructuras gubernamentales existentes <del>y previstas</del> y la necesidad de coordinación entre las autoridades responsables del control en las distintas etapas de la cadena alimentaria.

31. <u>NFCS p</u>Policy setting should include the identification and clear articulation of expected outcomes; how the national food control system relates to international and national standards; identification of risks and <u>other</u> system controls, existing or planned governmental structures and the need for coordination between authorities with control responsibilities in different parts of the food chain

[Translator's note: "...debería incluir considerar la identificación...", and ... "nacionales e internacionales de referencia" refer to the Spanish only and involve no change to the English.]

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

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

Justification: Make the text clearer. The last sentence repeats text already stated in the paragraph.

36. The legislation should provide the competent authority with the range of powers and mechanisms sufficient to manage and operate the national food control system. These authorities may include and are not limited to the following:

• establish standards or other <u>risk</u> management options to control food borne hazards such as diseasecausing organisms, contaminants, veterinary drug and pesticide residues;

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

- establish approaches to ensure the safety and safe use of food additives, and the appropriate use of pesticides, veterinary drugs;
- consider recognition of and/or harmonisation with Codex standards;
- perform audits, verification, inspections and investigations, gather evidence, collect and analyse samples and otherwise verify compliance with standards and requirements;
- [...]
- hacer respetar el cumplimiento de la ley y tomar medidas en casos de alimentos no aptos o de no conformidad, incluidas las investigaciones y la aplicación de sanciones y multas
- enforce legislation and take action in cases of unsafe or noncompliant food, including investigations and application of sanctions and penalties;

[Translator's note: No change in this bullet point to the English]

- coordinate ensure that unsafe or noncompliant food are withdrawn withdrawal from the market and its appropriate final disposal disposed of where appropriate; and
- prevent placing on the market unsafe or non-compliant product.

Justification: Clarification of RISK management. Intentional uses must be SAFE; the waste is relevant to the PROPER USE or APPROPRIATE USE. The competent authority must COORDINATE withdrawal which is the responsibility of the private sector.

37. Legislation may also include provisions, as appropriate, for the registration <u>and accreditation</u> of establishments, establishment approval, licensing or registration of traders, equipment design approval, penalties and <u>administrative and financial sanctions</u> in the event of non-compliance <del>and charging of fees, etc</del>.

Justification: Approval is interpreted as ACCREDITATION OF ESTABLISHMENTS. "Fees" are interpreted financial sanctions.

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

# **SECTION 4.2 SYSTEM DESIGN**

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

- 40. The design of a food control system should take into account the following elements:
  - existing or necessary regulatory and legislative framework (laws, <u>standards, etc.</u> regulations, <u>guidance</u>);

Justification: The regulatory or legislative framework is found in standards or laws. The regulations, guidance, etc. arise therefrom

• how the national food control system relates to international and <u>other</u> national standards <u>and</u> <u>harmonisation with reference to</u> international standards, including food import and export system requirements

Justification: The first part repeats the main premise of the paragraph. Combining them improves clarity.

- the recognition of other food control systems, including equivalence<sup>8</sup>;
- the level and method of oversight including of control programs from primary production through manufacturing to transportation and distribution;
- how issues and risks are managed;

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

• enforcement and compliance programs that manage the various priorities and risks;

*Justification: Merge the two sub-paragraphs to improve the interpretation.* 

- coordination and communication between authorities with control responsibilities in different parts of the food chain and with the public health authorities;
- the clear definition of clearly defined roles and responsibilities;
- <u>the need for access to adequate laboratory capacity and capability;</u>
- staff competence and training;
- the resources needed to meet the objectives of the national food control system, <u>its funding and</u> <u>appropriate provision their allocation and how the system is to be funded;</u>
- surveillance, investigation, emergency preparedness, and response to and investigation of foodborne and food related incidents;
- <u>the need for</u> assessment and evaluation;
- stakeholder engagement; and,
- international communication and harmonization;

General justification: the sub-paragraphs are worded to be consistent with the main premise of the paragraph. The text is clarified and rearranged.

41. Consideration should be given to the development and implementation of a standardised approach to risk management incorporating the *Working principles for risk analysis for food safety for application by governments*.

42. An appropriate system design should consider a range of factors including (but not limited to) **<u>each</u>** product risk, current scientific information, industry<u>-adapted</u> based controls and system review findings. It should also provide for flexibility in the application of control measures to reflect variations in these factors.

45. The national food control system should be fully documented, to ensure its transparency and <u>the solid</u> <del>consistent</del> application of control measures, including a description of its scope and operation, and a clear description of the roles and responsibilities of all parties.

46. National food control systems should be designed to ensure administrative procedures are in place for documentation of <u>In this respect, it is important to register</u> control programmes <u>operators</u> and their findings.

43. <u>The implementation</u> Development of an effective methods of data collection across the food chain is important for situational awareness, performance measurement and continuous review and system improvement. For instance, surveillance and monitoring programmes can be used to target priority risks.

44. The competent authority should utilise <u>this data</u> findings from laboratories to monitor trends in the food chain and assist in compliance and enforcement. Laboratory access and capacity should be commensurate with the need to address priority food risks.

NB: Paragraphs 43 and 44 have been moved down.

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

- the risk to human health posed by the food or food related product <u>in terms of food safety</u>;
- potential fraud or deception of consumers and other factors that may cause unfair practices in the food trade;
- information that may be available from a range of sources including academia, scientific institutions and industry data;

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

- statistical data on production, trade and consumption;
- results of previous controls including analytical results **and epidemiological data on foodborne disease**;

NB: The additional text is taken from the final sub-paragraph

- the effectiveness and reliability of <u>effective and reliable</u> controls including those of food business operators;
- knowledge of operators at various stages of the food chain; proper and improper <u>Typical and atypical</u> use of products, raw materials and by-products; Structure of production and supply chains; production technologies, processes and practices; relevant product tracing information;

#### • food safety hazards associated with different products;

Justification: Repetition of sub-paragraph 1.

#### • risk of unfair practices in the food trade associated with different products; and

Justification: Repetition of sub-paragraph 2.

• epidemiological data on foodborne disease.

#### Justification: Transferred to sub-paragraph 5.

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

- 50. Control programs should be designed to include the following elements but not limited to:
  - inspection, verification and audit including on-site visits;
  - market surveillance;
  - sampling and analysis;
  - examination of written and other records;
  - documentation of observations and of findings; and
  - examination of the results of any verification systems operated by the establishment.
- 49. The  $\underline{A}$  control programme should cover <u>address</u>, as appropriate:
  - establishments, installations, equipment and material;
  - products, from raw material to the final products, including intermediate products;
  - Preventative controls including GAP, GMP, GHP and HACCP principles <u>in accordance with the</u> <u>Code of practice General Principles of Food Hygiene (CAC/RCP 1-1969);</u>
  - means of distribution; and
  - human resources, and government infrastructure and confidentiality.

*NB:* The order has been inverted with paragraph 50 for coherency. Confidentiality does not sit well there in relation to the text. The additional text in sub-paragraph 3 is taken from the text deleted in paragraph 51.

51. Where quality assurance systems are used by industry, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade. The competent authority should encourage the use of Good agricultural practice GAP, Good Manufacturing Practices (GMP)/Good Hygiene Practices (GHP) or Hazard Analysis Critical Control Point (HACCP) approach in accordance with *Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-1969).

Justification: Repetition of paragraph 49.

52. The system design should provide for the capability to evaluate the effectiveness of the national food control system. Verifying the effectiveness of the national food control system should be targeted at the most appropriate stages of the food chain, based on risk analysis conducted in accordance with internationally accepted methodology<sup>10</sup>

# *Justification: Deleted because it corresponds to implementation or control. The text is addressed in each of the specific sections.*

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

#### Justification: Refers to Control and inspection and comes at the end.

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

55. Compliance and Enforcement programmes and their compliance measures should be designed to:

- be proportionate to the degree of public health risk or potential fraud or deception of consumers;
- encourage acceptance of <u>separate</u> responsibility and <u>encourage</u> compliance by <u>all the</u> participants; and
- provide for a full range of responses from provision of information or education material, <u>and the</u> <u>establishment imposing</u> of corrective actions, setting of sanctions.
- take into account repeated non-conformity by food business operators.

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

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

- training and basic infrastructure *including laboratories*;
- suitably qualified personnel of relevant disciplinary backgrounds
- reliable transportation systems and equipment to perform inspection, audit and verification services and transmission of samples to laboratories; and
- information, communication and technology (ICT) systems;

58. The design of a national food control system should incorporate timely access to adequate information relating to the surveillance, investigation and response to food borne illness and food related incidents. Such information can identify the risks or issues **priorities** that need to should be addressed and also whether or not the controls or measures in place are effective.

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

60. The national food control system should <u>encourage the implementation of have</u> procedures covering the prompt removal of unsafe food<sup>11</sup> <u>and resolve the situation</u>. These procedures should ensure that

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

<sup>&</sup>lt;sup>11</sup> Codex *Principles for traceability/product tracing as a tool within a food inspection and certification system* CAC/GL 60-2006 and OIE Terrestrial Animal Health Code, Chapter 4.1.General principles on identification and traceability of live animals

products that are deemed to be unsafe should be recalled, appropriately dealt with to ensure consumer protection. Where distribution has occurred, appropriate consumer notification should be given.

#### [61]. National laws should include penalties for companies that fail to comply with recall requests.

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

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

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

### **SECTION 4.3 IMPLEMENTATION**

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

- priorities and time frames for implementation;
- deliverables;
- responsibilities for implementation;
- allocation of resources for personnel and infrastructure;
- training and the development of operation manuals; and
- stakeholder engagement.

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

- ensure all participants are fully aware of what is expected from them (Principle 4);
- ensure uniform application of legislation;

#### - objectives clearly communicated to them; and

Justification: Has nothing to do with the paragraph's text.

• <u>have access to</u> that they have the necessary resources (human, material and financial resources) available to carry out their tasks.

69. The competent authority should implement a range of food control activities, including inspections, audits, verification and surveillance to ensure that food business operators meet their responsibilities and are in compliance with requirements. Detailed procedures should be developed to articulate the key tasks and responsibilities of verification of compliance.

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

• increased intensity of audits/inspection and/or monitoring of products and/or processes; identified as being not in conformity and/or the undertakings concerned; and

• in the most serious or persistent cases, de-registration of the producer/processor or closure of the relevant establishment.

71. Programmes and training manuals should be developed and maintained to ensure consistent application of requirements <u>that include all the information needed for a NFCS and its management</u>. This material should include:

- an organizational chart of the official control system;
- roles of each level in the hierarchy (including other relevant jurisdictions; i.e. State, Provincial);
- job functions and qualifications as appropriate;
- operating procedures including methods of audit, verification, inspection and control, sampling, and testing;
- relevant legislation and requirements;
- processes and procedures relating to compliance and enforcement;
- arrangements for coordination with relevant ministries and stakeholders;
- relevant information about food contamination and food control;
- procedures for conducting food recalls and investigations;
- relevant information on staff training; and
- formal review process of the national food control system.

Justification: The bullet points are too prescriptive and not needed in this text. The general paragraph has been expanded accordingly.

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

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

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

Justification: This text is excessive.

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

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

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

# NB: Transferred from MONITORING AND SYSTEM REVIEW.

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

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

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

Justification: The deleted text is left as a NEW PARAGRAPH 61.

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

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

NB: Paragraphs 61, 62 and 63 have been transferred from SYSTEM DESIGN and the order rearranged accordingly.

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

- 79. As appropriate, <u>In this respect</u>, the competent authority should:
  - communicate food safety issues and concerns with (relevant competent authorities) trading partners;
  - participate in bilateral exchange with (relevant competent authorities) trading partners and international organisations related to food safety regulations and their enforcement; and
  - communicate and collaborate with international organisations in cases where food(s) implicated in incidents or outbreaks of foodborne illness may be circulating in international trade.

# SECTION 4.4 MONITORING AND SYSTEM REVIEW

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

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

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

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

opportunities to engage in continuous improvement by assessing an incident from first signal through response and incorporating lessons learned in the design and planning phase.

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

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

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

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

#### Justification: Repetition of paragraph 83.

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

### Justification: Moved to IMPLEMENTATION.

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

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

- effectiveness of control procedures;
- suitability in achieving objectives; whether the program has covered relevant stages in the production chain, taking into account risk factors; and
- consideration of emerging trends.

88. Any review and continual improvement of the national food control system should be communicated effectively and efficiently to ensure that clear exchange of information and engagement between all stakeholders in the national food control system occurs.

NB: The inversion of paragraphs 88 and 89 is intentional.

<sup>&</sup>lt;sup>13</sup> The OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) provides for independent evaluation of the performance of veterinary services. The OIE PVS tool could be used to evaluate the veterinary public health related elements of the national food control system.

<sup>&</sup>lt;sup>13</sup> La Herramienta de la OIE para la evaluación de las prestaciones de servicios veterinarios (Herramienta PVS de la OIE) proporciona una evaluación independiente del desempeño de los seervicios veterinarios. La Herramienta PVS de la OIE podría utilizarse para evaluar los elementos del sistema nacional de los alimentos relacionados a la salud pública veterinaria. [Translator's note: correction of a typo in Spanish]

# **CANADA**

Canada thanks Australia for circulating a revised proposed draft document, reflecting the discussions at the physical working group meeting in Grange, 9-12-July 2012.

We believe significant improvements were made to the document. In particular, we are of the view that the Proposed *Draft Principles and Guidelines for National Food Control Systems* has significantly improved in terms of logical flow and content, as well as reduced redundancy and duplicative text.

Generally, Canada continues to hold the view that this Codex text should provide high level guidance, which should inform/challenge countries in considering key elements/considerations in the design and/or enhancement of their systems. The text should be kept flexible enough so as to enable competent authorities to implement the appropriate options/activities that suit their national situation. In other words, we do not believe that "one model can suit all".

We consider that the purpose of the *Policy Setting* and *System Design* phases need to be better explained. Additionally, we believe that some parts of the document would benefit from additional editing in terms of clarity and structure. We have specific drafting suggestions in that regard.

#### **Section 4.1- Policy Setting**

The Policy Setting is clearly identified as an essential element of the process; however, the document does not, in our view, adequately explain what is to be achieved in this phase and does not articulate the necessary of stakeholder engagement in public policy discussions. Hence, we propose the inclusion of the following additional text:

(Should be immediately placed before Paragraph 30)

Policy setting is the process by which the goals and objectives for the national food control system are established by governments, along with the commitment to a course of action to reach those goals and objectives. Policy decisions guide subsequent actions, including the establishment of legislation and regulations.

<u>Public policy decisions should take into account a broad range of factors and require a careful</u> assessment of options. Governments should consider, among other things, public and stakeholder interests, international and national standards, assessment of risks/benefits, effectiveness and efficiency of various controls and methods of oversight, existing and planned government structures, coordination among authorities along the food chain, technical and scientific information, the roles of government and industry, and best practices/models.

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

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

Note: with the above additions, we believe that Paragraphs 31 and 32 could be deleted:

31. Policy setting should include the identification and clear articulation of expected outcomes; how the national food control system relates to international and national standards; identification of risks and system controls, existing or planned governmental structures and the need for coordination between authorities with control responsibilities in different parts of the food chain.

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

#### Section 4.2 - System Design

# Paragraph 39

We believe this paragraph should be augmented to explain the outcome of the design phase more clearly. We suggest the following wording addition at the end of the paragraph:

# System design is the determination of how a national food control system will achieve the goals and objectives contained in the policy. System design entails sufficient guidance and detail so as to allow for implementation by the competent authority and industry.

# Paragraph 45

We suggest this paragraph be moved to follow immediately Paragraph 39 and be reworded as follows:

para.45. <u>The system design</u> of the national food control system should be fully documented to ensure its transparency and the consistent application of control measures, including a description of its scope and operation, success indicators, and a clear description of the roles and responsibilities of all parties.

### Paragraphs 52 and 53

We believe that Paragraphs 52 and 53 could be removed from this section or addressed under Section 4.4 - *Monitoring and System Review*, also taking account of the proposed addition of "success indicators" to Paragraph 45.

# COSTA RICA

Costa Rica is grateful for the opportunity to make the following comments:

(i) General remarks:

It is suggested adding to the national food control systems, the terms "non-tariff obstacles or barriers to trade; and recognising international food control systems through bilateral or multilateral agreements between States".

(ii) Specific remarks

### Framework:

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

6. The objective of a national food control system is to protect the health of consumers and ensure fair practices in the food trade. **Costa Rica proposes adding** "that prevent technical obstacles to trade and also simplify procedures. The national food control system should not hinder the improved and growing trade of food products providing it is not detrimental to the protection of consumer health."

# II. "PRINCIPLE 11 LEGAL FOUNDATION

22. The government within each country needs to have in place fundamental legal structures to enable the establishment of food laws and competent authorities, so that they can develop, establish, implement, maintain and enforce a national food control system." Costa Rica proposes adding "and also to reach international agreements, mainly at the regional level, for the design, implementation and recognition of national food control systems, in order to harmonise the general standards needed to implement flexible systems that in addition to guaranteeing food safety also enable an appropriate free trade supply and demand dynamic".

# **HONDURAS**

Honduras is grateful for the opportunity to submit comments regarding this document and congratulates the physical Working Group led by Australia for the effort made and work done to restructure this document to improve the reader's understanding, and provide assistance for the direction needed to design and operate a National Food Control System in our countries.

#### **Specific comments:**

# **PRINCIPLE 13 RESOURCES**

24. A national food control system should have sufficient (human, material and financial) resources to enable it to meet the system objectives

Justification: to be consistent with paragraph 68

29. Al elaborar un sistema nacional de control de los alimentos, la autoridad competente nacional, en consulta con las partes interesadas, debería adoptar las siguientes etapas, descriptas descritas en el presente documento, que reflejarán los principios de un sistema nacional de control de los alimentos.

### Justification: Spanish spelling.

29. Primer texto en el diagrama: Establecimiento de normativas políticas.

Justification: Better translation of the English text. Moreover, the context of the original document refers to the establishment of policies to achieve the objectives of a national food control system.

# SECCIÓN 4.1 ESTABLECIMIENTO DE NORMATIVAS POLÍTICAS

### SECTION 4.1 POLICY SETTING

30. Los objetivos y prioridades nacionales asegurarán la protección del consumidor, tomando en cuenta, entre otras cosas, los patrones de producción y consumo de alimentos, el perfil de riesgo y las exigencias del consumidor, y la preparación y capacidad del país.

Justification: Better wording of the paragraph in Spanish.

31. En el establecimiento de normativas **políticas** se debería incluir la identificación y articulación clara de los resultados previstos; la relación entre el sistema nacional de control de los alimentos y las normas nacionales e internacionales; la identificación de los riesgos y los controles del sistema; las estructuras gubernamentales existentes y previstas y la necesidad de coordinación entre las autoridades responsables del control en las distintas etapas de la cadena alimentaria.

Justification: Consistent with the change suggested for paragraph 29.

34. La legislación debería reflejar claramente el objetivo normativo previsto **previsto de la política** y guardar relación con los riesgos que propone mitigar. Debería, dentro de lo posible, hacer hincapié en la prevención y los resultados para permitir flexibilidad e innovación.

#### Justification: Consistent with the change suggested for paragraph 29.

36. La legislación debería conferir a la autoridad competente una serie de poderes y mecanismos suficientes para gestionar y operar el sistema nacional de control de los alimentos. Dichos poderes pueden incluir, pero estar no limitados a lo siguiente:

- establecer mecanismos para garantizar la inocuidad y el uso inocuo-seguro de aditivos alimentarios, plaguicidas y medicamentos veterinarios;
- hacer respetar el cumplimiento <u>cumplir</u> de la ley <u>las regulaciones</u> y tomar medidas en casos de alimentos no aptos o <u>no conformes</u> de no conformidad, incluidas las investigaciones y aplicación de sanciones y multas;

Justification: Better wording of the paragraph in Spanish.

37. La legislación puede incluir también en su caso, disposiciones relativas al registro de establecimientos, **aprobación** homologación de establecimientos, **autorización** a**probación** o registro de comerciantes, aprobación del diseño de los equipos, multas en caso de no conformidad y tarifas.

Justification: The word "aprobación" [approval] maintains the original concept of the paragraph as worded in English. The context refers to the approval of establishments and not to their certification.

# **SECTION 4.2 SYSTEM DESIGN**

39. Al diseñar un sistema nacional de control de los alimentos, los países deberían asegurar que se abordan los objetivos principales definidos en las normativas **políticas** y la manera de incorporar los principios de la Sección 3.

# Justification: Consistent with the change suggested for paragraph 29.

40. En el diseño de un sistema de control de los alimentos se deberían tomar en cuenta los elementos siguientes:

• (leyes, reglamentos, orientación, guías)

• La manera de gestionar imperativos situaciones de peligro y riesgos;

### Justification: Better translation of the terms used in English.

46. Los sistemas nacionales de control de alimentos deberían estar diseñados de manera <u>que se asegure</u> de asegurar que hay <u>se mantienen</u> procedimientos administrativos para documentar los programas de control y sus resultados.

Justification: Better wording of the text in Spanish.

• Productos, de desde la materia prima al producto final,

# Justification: Better wording of the text in Spanish.

53. Un sistema nacional de control de alimentos debería ser sujeto de mejora continua—ser sujeto a la **evaluación constante de los resultados obtenidos** para la mejora continua de manera de <u>v</u>reflejar cambios en el riesgo del producto, el ambiente productivo (incluida la tecnología), aumento del conocimiento científico, el nivel de confianza en la industria para garantizar que se logra el objetivo del SNC de manera eficiente y eficaz.

[Translator's note: No justification given. No change to the English.]

61. El gobierno nacional y los operadores de la industria alimentaria deberían coordinar sus esfuerzos con respecto a los sistemas de retiro y otros sistemas de recuperación del mercado. Cuando la autoridad competente solicita un retiro, los operadores deberían tener la obligación afirmativa de recuperar los productos retirados y destruirlos o desecharlos disponer de éstos adecuadamente. Las leyes nacionales deberían incluir sanciones para las empresas que no cumplen con los pedidos de retirada.

Justification: Better translation of the English. The disposal of products may include transformation activities to ensure product safety and declaration as safe for human consumption (e.g., cooking or relabelling).

[Translator's note: the deleted "desecharlos" means "to throw them out".]

66. De corresponder, la autoridad competente nacional debería utilizar los *Principios y Directrices para el intercambio de información en situaciones de emergencia relacionadas con la inocuidad de alimentos* (CAC/GL 19-1995), el Reglamento Sanitario Internacional (RSI), <u>los requerimientos de notificación de enfermedades de la OIE</u>, <u>las regulaciones de la CIPF</u> y la Red de Autoridades de Inocuidad Alimentaria (INFOSAN), para la notificación de emergencias y respuesta a nivel nacional e internacional. <del>(INFOSAN).</del>

Justification: Additions to the Spanish text to correspond to the English text, as the above added text did not appear in the Spanish version of the document.

68. Se debería elaborar orientación guías o lineamientos e instrucciones relativas al sistema nacional de control de los alimentos, los programas de control, incluidos los requisitos legislativos, para el personal de la autoridad competente y los operadores de la industria alimentaria para:

# [Translator's note: No justification provided. No change to the English.]

76. Las autoridades competentes deberían utilizar laboratorios que han sido evaluados <u>aprobados</u> y/o acreditados en el marco de programas reconocidos oficialmente para asegurar que se han establecido controles adecuados de calidad que garanticen resultados fiables de los ensayos. Se deberían utilizar métodos analíticos reconocidos y validados internacionalmente, siempre que estén disponibles, y cumplir con las Buenas

[Translator's note: No justification provided. No change to the English.]

77. Las autoridades competentes deberían asegurar que los laboratorios designados participan regularmente de pruebas de competencia <u>eficiencia o aptitud</u>. Dichas pruebas pueden organizarse nacional o internacionalmente y el laboratorio de referencia puede desempeñar un papel en la organización de los programas de pruebas de competencia <u>eficiencia o aptitud</u>.

[Translator's note: No justification provided. No change to the English.]

79. Según corresponda, la autoridad competente debería:

• dialogar <u>comunicar</u> y colaborar con las autoridades internacionales en los casos de alimentos implicados en incidentes o brotes de enfermedades de transmisión alimentaria circulantes en el comercio internacional.

As appropriate, the competent authority should:

[...]

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

[Translator's note: No justification provided. No change to the English.]

# <u>IRAN</u>

According to CX/FICS 13/20/3, paragraph 8 and agreement on the structure, "the document should contain the following sections: introduction, *scope*, objective ...", while in the Appendix I the "*scope*" section is missing.

Although the scope is implied in the introduction section, it is suggested to separate the scope from the introduction section. It can be either an independent section or added to section 2 as: "Scope and Objectives..."

### Section 4 – Framework for the design and operation ....

Since the figure under Paragraph 29 is intended to show the flow of process with a continual improvement within the framework, it is suggested to change the figure into circle shape (PDCA Circle) which will put emphasize on continual improvement.

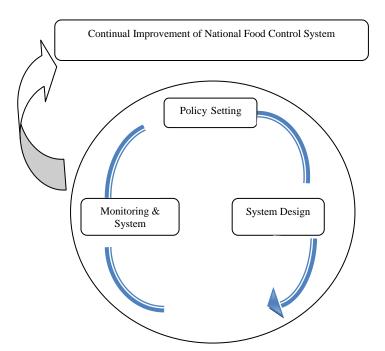


Figure 1 - Model of a process- based national food control system

Furthermore, referring to ISO 9000:2005, Clause 3- Terms and definitions, it is suggested to replace "continuous improvement" with "continual improvement" as defined in sub-clause 3.2.13 of the standard.

# MAURITIUS

# **General comments**

1. The FAO/WHO guidelines on "Strengthening National Food Control Systems and the FAO (2006) Document "strengthening national food control systems - guidelines to assess capacity building needs" are

very relevant for the subject being discussed. Have these been taken into consideration by the parties involved in the drafting of the proposed draft codex principles?

2. Spelling for the word "programme" not consistent in the text (program).

### **Specific comments**

3. Section 4, paragraph 26, last bullet point: Could the working group elaborate on the equivalence agreements as few equivalence agreements have been reached to date between trading partners, especially those from developing countries.

4. Section 4, paragraph 28, is it relevant to refer to the guidelines on food safety risk analysis prepared by Codex here?

5. Section 4.1, paragraph 33: is it relevant to include a list of possible indicators for self-assessment?

6. Section 4.1, paragraph 37, could we also include legislation pertaining to recall/emergency procedures, traceability, mandatory reporting of diseases

7. Section 4.2, paragraph 47, bullet point 7: capital lettering used in the middle of sentence. It seems that two bullet points have been merged.

8. Section 4.2, paragraph 65, it should be possible to evaluate the effectiveness of a programme

9. Section 4.3, paragraph 71, could we insert at fourth bullet point: "control, sampling, testing, certification and registration"

10. Section 4.3, paragraph 74, rewrite as "Industry should be encouraged to develop or access training and education programmes **and develop industry guides**"

11. Section 4.3, paragraph 76, to read as follows: "authorised or accredited under **ILAC and other** officially recognised programmes"

12. Section 4.4, paragraph 87, foot note, what will be the situation for issues pertaining to non-veterinary areas? Could we suggest other tools?

# **MEXICO**

Mexico congratulates the working group led by Australia for the considerable work on compiling the document and is also grateful for the opportunity to make the following comments on *CX/FICS 13/20/3*, "Annex I "Proposed Draft Principles and Guidelines for National Food Control Systems" (N06-2009).

# General Comments

Mexico has noted considerable progress in integrating and organising the document.

#### Specific Comments

(Linguistic comments unless otherwise stated)

# SECTION 1 INTRODUCTION

**Para. 2.**- *It is suggested using the plural form:* "...el documento es coherente con otros texto<u>s</u> afines del Codex y debería leerse conjuntamente..."

"... the document is consistent with and should be read in conjunction with relevant Codex texts."

# SECTION 3 PRINCIPLES OF A NATIONAL FOOD CONTROL SYSTEM

# PRINCIPLE 5 CONSISTENCY AND IMPARTIALITY

**Para.-** 16.- *It is suggested using the plural form*: "...La autoridad competente y todos los participantes que cumplan funciones oficiales deberían desempeñar sus obligaciones libre<u>s</u> de toda interferencia..."

"The competent authority and all participants acting in official functions should be free of improper or undue influence..."

# PRINCIPLE 6 INCORPORATION OF RISK BASED, SCIENCE BASED AND EVIDENCE BASED DECISION MAKING

**Para.-** 17.- The following change is suggested: "...should be making decisions within a national food control system based on scientific information, evidence proof and/or risk analysis principles as appropriate."

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

Para.- 29.- The following change is suggested: Al elaborar En el desarrollo de un sistema nacional..."

"In developing a national food control..."

In the diagram, it is suggested changing the word "normativa" to "políticas".

**SECTION 4.1** The following change *is suggested*: **"ESTABLECIMIENTO DE NORMATIVAS** <u>POLÍTICAS"</u> "POLICY SETTING"

It is suggested making the same change in

Para. 31- "En el establecimiento de normativas..." to "En el establecimiento de la política..."

Para. 34- "La legislación debería reflejar claramente el objetivo normativo previsto" to "... el objetivo <u>de la</u> política..."

Para. 39- "los objetivos principales definidos en las normativas..." to "principales definidos en la política..."

Para. 36, 5th bullet point.- The following change is suggested: • "hacer respetar el cumplimiento de <u>cumplir</u> la ley y tomar medidas…"

"• enforce legislation and take action..."

Para. 37.- It is suggested changing: "La legislación puede incluir también, en su caso, disposiciones relativas al registro de establecimientos, homologación <u>aprobación</u> de establecimientos, autorización o registro de comerciantes, aprobación del diseño de los equipos, <del>multas <u>sanciones</u> en caso de no conformidad, y tarifas."</del>

"Legislation may also include provisions, as appropriate, for the registration of establishments, establishment approval, licensing or registration of traders, equipment design approval, penalties in the event of non-compliance and charging of fees etc."

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

Para. 40, 1st bullet point.- It is suggested changing orientación to "lineamientos"

Para. 40, 5th bullet point.- It is suggested changing imperativos to "asuntos"

Para. 40, 11th bullet point.- The following change is suggested "the <u>financial, material and human</u> resources needed to meet the objectives...

Justification: To detail the resources referred to

Para. 40, 12<sup>th</sup> bullet point.- The following changes are suggested: "la vigilancia, investigación, preparación para las emergencias y respuesta a los incidentes las enfermedades transmitid<u>os</u>as por los alimentos  $\Theta$  <u>y los incidentes</u> relacionados con los mismos;"

"surveillance, investigation, emergency preparedness and response to foodborne and food related incidents"

**b** The following change is suggested: "Un diseño adecuado del sistema debería considerar una serie de factores incluidos (sin limitarse a<del>l</del>) **el** riesgo planteado por el producto..."

"An appropriate system design should consider a range of factors including (but not limited to) product risk..."

Para. 43.- The following change is suggested: "La elaboración de un método efectivo para la recolección de datos a través de la cadena alimentaria es esencial para el conocimiento de la situación, <del>las medidas de rendimiento <u>la</u> <u>medición del desempeño</u> y la mejora continua…"</del>

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

Para. 47, 1st bullet point.- The following changes are suggested: "el riesgo para la salud humana planteado por el alimento o por el producto relacionado con el alimento o el envase;"

"...the risk to human health posed by the food or food related product"

Para. 49, 2nd bullet point.- The following change is suggested: "productos, de<u>sde la</u> materia prima al producto final..."

"products, from raw material to the final products..."

Para. 49, 3rd bullet point.- The following change is suggested: "controles preventivos, incluidos GAP-<u>BPA</u>, BPF, BPH..."

"Preventative controls including GAP, GMP, GHP ... "

Para. 56.- The following change is suggested: "The competent authority(s) should be resourced sufficiently and transparently, **and, if applicable, to be able to count on mechanisms for the participation of third party suppliers,** to enable the national food control programs to achieve its objectives without compromising the programs integrity and independence."

Justification: Third-party organisations should be included as a possibility for optimising resources.

Para. 57.- It is suggested changing the word atribuirse to "asignarse"

### **SECTION 4.3 IMPLEMENTATION**

Para. 70.- It is suggested changing the word proceso by "procedimiento" (2 instances)

Para. 70, bullet point 1.- It is suggested changing the word procedimientos to "procesos"

Para. 79, 1st bullet point.- The following change is suggested: "communicate food safety issues and concerns with (relevant competent authorities), trading partners, **food industry operators and consumers**."

Justification: To take into consideration communication with food industry operators and consumers.

# SECTION 4 MONITORING AND SYSTEM REVIEW

Para. 80.- The following change is suggested: "La eficacia y competencia del sistema nacional de control de los alimentos debería evaluarse regularmente en función de los objetivos del sistema y la eficacia de los programas de control, así <u>como</u>-también en función de los requisitos…"

"The effectiveness and appropriateness of the national food control system should be regularly assessed against the objective of the system, effectiveness of control programmes, as well as against legislative and other regulatory requirements..."

# NEW ZEALAND

New Zealand would like to thank the Australian secretariat for the work they have undertaken in preparing this draft of the Draft and Proposed Draft Principles and Guidelines for National Food Control Systems for consideration at CCFICS 20.

New Zealand reaffirms its support for this guideline as an important document to help countries identify and implement the key principles and elements that make up a robust and effective national food control system.

In reference to section 4 of this document New Zealand has the following general comments:

New Zealand is pleased with the overall result of the pWG work in July 2012. New Zealand supports the advancement of this document to step 5/8 following a full review of the document at the upcoming session. Most of the specific comments below are editorial or stylistic in nature but there are some suggestions on matters of substance that New Zealand would like the committee to consider.

New Zealand prefers to see the document remain as addressing the matters covered in section 4 in a general, relatively high level manner with detailed requirements of a national food control system only mentioned by way of example, if at all.

New Zealand has the following specific comments:

Singular (+ plural) references to the competent authority in the document vary in style, in some places it is written "competent authority(ies)" in other places it is written "competent authority(s)". The document uses both "programme" and "program", there needs to be consistent use of only one version of the word.

13. The national governments (and in some cases <u>the</u> competent authorit<u>yies</u>) have the role and responsibility to establish and maintain up to date science based legal requirements. <u>and t</u><u>T</u>he competent authority <u>also</u> has the responsibility to ensure the effective operation of the national food control system, including the delivery of verification and enforcement activities either themselves or by other parties.

Rationale: made singular for consistency – particularly with P 11. It is important to capture the delivery of these activities within the principles – is an essential component of effective operation of a national food control system.

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

#### Rationale: correction

17. Competent authorities should be makeing-decisions within a national food control system based on scientific information, evidence and/or risk analysis principles as appropriate

#### Rationale: editorial correction

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

# Rationale: to assist flow and clarity. Also 'effective use of resources' is not just to minimise gaps and duplication but is an objective in its own right

20. The national food control system should possess the capacity to undergo continuous improvement and include mechanisms to evaluate whether the system is able to achieve its objective( $\underline{s}$ ).

Rational: a national food control system may have more than one objective.

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

#### Rationale: to maintain consistency of language.

23. When designing and applying a <u>national</u> food control system, the competent authority should consider Codex standards, recommendations and guidelines (or those of other international inter-governmental organizations whose membership is open to all countries) whenever appropriate as elements of their national food control system to facilitate trade and consumer confidence. <u>Standards or guidelines from other international inter-governmental organizations whose membership is open to all countries may also be useful.</u>

Rationale: "national" for completeness. Other edits are for ease of readability. We also need to be careful that this document doesn't imply that the standards or guidelines produced by ALL intergovernmental organisations (even those open to all countries) are at an equal level or relevance to those of Codex.

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

Rationale: A national food control system, may or may not have more than one objective – maintains consistency throughout the principles.

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

• ...

• advances/ and fosters knowledge, science, research and education regarding food safety;

#### Rationale: improves clarity

27. Where there is more than one competent authority their roles and responsibilities should be clearly defined and their activities coordinated to the greatest extent possible to minimise gaps and overlaps

Rationale: this is a duplication of what is covered in Principal 7 and is also covered in para 31.

32. ... Consideration should be given to the development of a national food control strategy which will aid clarification of the objectives to be addressed, set priorities and support system design.

Rationale: a multi-objective strategy should identify priorities to ensure the most important objectives are addressed first; and to help with planning the work and allocation of resources.

33. As a result of applying the guiding principles of Section 3 and the framework of described in this Section 4-a national food control system should possess three main characteristics which, among other things, can be used in self-assessment or other evaluation to determine if the system is fully functional and effective:

i) <u>Characteristic 1 Situational awareness</u> means that a national food control system avails itself of accurate and current information on the entire food chain as a whole *[NZ comment: text does not need both 'entire' and 'as a whole'. One should be deleted]* and its various parts and participants

ii) <u>Characteristic 2 Pro-activity</u> 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 <u>and</u> /processing chain; and at the early stages rather than in the end product. Early warning/rapid alert systems, traceability and contingency planning for managing and preparing for potential food safety incidents should be an inherent part of <u>can assist in making</u> a pro-active control system <u>pro-active.</u>

# Rationale: Editorial changes. The components listed under pro-activity should not be presented as mandatory. This is a guidance document, stating them as being beneficial to pro-activity is sufficient.

34. Legislation should clearly reflect the intended policy objective <u>(s)</u> and be commensurate with the risks they are intended to mitigate. Legislation it should <u>also</u>, where possible, focus on prevention and outcomes to allow for flexibility and innovation.

# *Rationale:* For consistency – a national food control system may have more than one objective. Readability and grammar.

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

Rationale: grammar, improve clarity and flow. Deleted sentence should be moved to paragraph 36.

36. The legislation should provide the competent authority with the range of powers and mechanisms sufficient to manage and operate the national food control system. These authorities <u>or powers</u> may include and are not limited to the following:

• establishing standards or other management options to control food borne hazards and requiring food business operators and other participants to establish and monitor appropriate controls at all stages of the food chain, including production, manufacture, importation, processing, storage, transportation, distribution and tradesuch as disease causing organisms, contaminants, veterinary drug and pesticide residues;

- establish approaches to ensure the safety and safe use of **<u>inputs to the food chain, such as</u>** food additives, pesticides, veterinary drugs;
- consider recognition of and/or harmonisation with Codex standards; [NZ Suggestion this bullet may be better as a footnote to the first bullet. It does not really stand alone and is a direct reference to Principle 12]
- performing audits, verification, inspections and investigations, gathering evidence, collecting and analyzeing samples and otherwise verifingy compliance with standards and requirements;

- enforceing legislation and take action in cases of unsafe or noncompliant food, including <u>undertaking</u> investigations and <u>the</u> application of sanctions and penalties;
- ensure the integrity, impartiality and independence of officially recognized inspection systems;
- ensure that unsafe or noncompliant food are is prevented from entering the market or are withdrawn from the market and dealt with appropriately disposed of where appropriate; and
- prevent placing on the market unsafe or non-compliant product.

Rationale: To improve clarity and flow. Bullet 1 - examples are too narrow and limiting, inserted text moved from para 35. Bullet 2 - this bullet was too narrow – the list should not have the appearance of being exhaustive. Bullet 5 - to remove duplication as is covered in a subsequent bullet. Bullet 7 - the points about unsafe and noncompliant food should be in one place. "Disposed of" could imply that non-compliant food must always be destroyed, which is not always the case. Bullet 8 – remove duplication.

37. Legislation may also include provisions, as appropriate, for the registration <u>or approval</u>, of establishment approval, licensing or registration of traders, equipment design approval, penalties in the event of non-compliance and <u>the</u> charging of fees <u>or levies</u> etc.

Rationale: improve flow, "etc" is superfluous in this context. Non-compliance is already covered in para 36.

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

### Rationale: grammar.

44. The competent authority should utilise  $f\underline{F}$  indings from laboratories <u>can also contribute</u> to <u>the</u> monitor<u>ing of</u> trends in the food chain and assist in compliance and enforcement. Laboratory access and capacity should be commensurate with the need to address priority food risks.

*Rationale: findings from laboratories are one of the data sources that can be used – the previous wording implies that it is the only or primary tool and gives laboratories a prominence that may not be warranted in all cases.* 

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

*Rationale: availability is an important component of ensuring transparency – there is not much point in documenting if such documents are not readily available to all interested parties.* 

47. Control programmes should be based on risk and designed to take into account a number of factors [NZ comment on footnote 6: "Paragraph 33 provides additional guidance on the main characteristics of a national food control system" COMMENT: this footnote does not seem relevant as this is about control programmes and para 33 is about the national food control system. If this footnote is retained then it needs to be elaborated on to make it clear as to why the content of para 33 is relevant to control programmes. A better reference may be the FAO publication 'Strengthening National Food Control Systems'.] including but not limited to:

- the risk to human health posed by the food or food related product ;
- <u>the potential for</u> fraud or deception of consumers and other factors that may cause unfair practices in the food trade;
- ...
- knowledge of operators at various stages of the food chain: <u>Ttypical and atypical use of products</u>, raw materials and by-products; <u>Ss</u>tructure of production and supply chains; production technologies, processes and practices; relevant product tracing information;
- food safety hazards associated with different products; and
- risk of unfair practices in the food trade associated with different products; and

Rationale: improve grammar. Deleted bullet – already covered in second bullet.

49. The e<u>C</u>ontrol programmes should cover, as appropriate: <u>be applied at the point or points in the</u> <u>production or supply chain where hazards can be most effectively or efficiently controlled; taking into</u> <u>account the available resources and capability.</u>

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

*Rationale: this list is too prescriptive and should be replaced with the text above which is broader and more enabling and highlights the key point – which is that hazards must be controlled* 

<u>49bis. The competent authority should encourage the use of Good agricultural practice GAP, Good Manufacturing Practices (GMP)/Good Hygiene Practices (GHP) or Hazard Analysis Critical Control Point (HACCP) approach in accordance with *Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-1969).</u>

Rationale: this is an important point and has been moved up from para 51.

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

- inspection, verification and audit including on-site visits;
- market surveillance;
- sampling and analysis;
- examination of written and other records;
- documentation of observations and of findings; and
- examination of the results of any verification systems operated by the establishment.
- the range of activities or products within the scope of the national food control system;
- the risks posed by the products or activities
- the available interventions or controls to address the risks
- <u>mechanisms or procedures to check that the interventions or controls are implemented and effective</u>
- mechanisms or procedures to address or resolve any adverse findings.

Rationale: this list is too detailed and prescriptive. It needs to be more inclusive and able to be applied to all aspects. This guidance should focus on the outcome we want to achieve not on the procedures that might be needed

51. Where quality assurance systems are used by industry, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade. The competent authority should encourage the use of Good agricultural practice GAP, Good Manufacturing Practices (GMP)/Good Hygiene Practices (GHP) or Hazard Analysis Critical Control Point (HACCP) approach in accordance with *Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-1969).

#### Deleted text moved to its own paragraph given as 49bis in these comments

54. Compliance and enforcement programmes should be designed to provide the ability for the competent authority to take corrective action to ensure the situation is remedied where the participants are not meeting their obligations or a product or process is found not to be in conformity. 55. Compliance and Enforcement p Programmes should be designed to:

• be proportionate to the degree of public health risk or potential fraud or deception of consumers;

- encourage acceptance of responsibility and compliance by all participants; and
- provide for a full range of responses from provision of information or education material, imposing of corrective actions, setting of sanctions.
- take into account repeated non-conformity by food business operators.

Rationale: these bullets should be listed under para 54. This improves the flow and removes the duplicate words at the beginning of the para.

56. The competent authority(s) and any other parties undertaking compliance and enforcement <u>activities</u> should be resourced sufficiently and transparently to enable the national food control programs to achieve its objectives without compromising the program's integrity and independence.

*Rationale: Grammar. It is important that all the regulatory actors are sufficiently resourced – the CA may be only one of the players in this respect.* 

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

- training and basic infrastructure;
- suitably qualified personnel of relevant disciplinary backgrounds
- reliable transportation systems and equipment to perform inspection, audit and verification services and transmission of samples to laboratories; and
- information, communication and technology (ICT) systems;

Rationale: this list is not necessarily complete - it also assumes that every country is starting at the same point which is not the case - the key point is already made by stating that resources should be prioritised to protect public health.

59bis. Where appropriate, the national competent authority should utilize the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19/1995), the International Health Regulations (IHR), OIE disease notification requirements, IPPC regulations and the International Food Safety Authorities Network (INFOSAN), for national and international emergency notification and response.

Rational: moved from para 66 to 59 bis. This is a better place for this para - it improves the flow of the information provided.

60. The national food control system should have procedures covering the prompt <u>identification and</u> removal of unsafe food. These procedures should ensure that products that are deemed to be unsafe should be recalled, and appropriately dealt with to ensure consumer protection. <u>The competent authority should</u> ensure appropriate consumer notification is carried out when distribution has occurred., appropriate consumer notification should be given.

Rationale: Grammar and readability. Identification of affected product is a key component.

Footnote 8 in Para 60: <u>Guidance that may assist in developing such procedures includes</u> Codex *Principles for traceability/product tracing as a tool within a food inspection and certification system* CAC/GL 60-2006 and OIE Terrestrial Animal Health Code, Chapter 4.1.General principles on identification and traceability of live animals.

*Rationale:* This footnote needs an introduction to clearly identify the connection to the sentence in the main document – otherwise it appears to imply that traceability and animal identification are the only available tools

61. Recall systems and other market withdrawal systems should be a coordinated effort between the national government competent authority(s) and food business operators and be effective and enforceable. If the competent authority requests a recall, operators should have an affirmative duty to recover recalled products and to destroy or dispose of them properly. National laws should include penalties for companies that fail to

#### comply with recall requests.

Rationale: It is the competent authority (or their agent) that is the most likely body to be involved in recalls etc. Also it is important to emphasise that recall or withdrawal systems must be effective and enforceable. The inclusion of these words also supports the removal of the remainder of this para which is overly detailed and prescriptive. The points are already covered in the preceding paras and enforcement is covered in para 54-55

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

#### Rationale: change in placement of identified groups of interest improves readability.

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

#### Rational: to improve clarity and flow.

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

#### Moved to para 59bis

67. Following the design or modification of the national food control system the competent authority should prepare a<u>n</u>-roadmap of implementation <u>plan, including and</u> the sequence of rollout of <u>for</u> different elements of <u>designthe system to be established or introduced</u> in keeping with their preparedness and capability <u>of</u> <u>the relevant participants</u>. This will require engagement and analysis by a variety of experts, disciplines and all stakeholders. *[NZ COMMENT: New Footnote: "Additional guidance on developing an implemention* <u>plan can be found in FAO publication Strengthening National Food Control Systems</u>"/ The competent authority's roadmap may include;

- priorities and time frames for implementation;
- deliverables;
- responsibilities for implementation;
- allocation of resources for personnel and infrastructure;

Rationale: to improve the clarity and flow to the sentence and to remove colloquial language that may not translate well. This list is prescriptive but does not provide any actual guidance. Specific guidance has been developed by FAO and this could be referenced as a footnote.

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

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

#### Rationale: consistency in the presentation of the items in the list, grammar.

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

in compliance with requirements. Detailed  $p\underline{P}$  rocedures should be developed to articulate the key tasks and responsibilities of verification of compliance and the consequences of non-compliance, including repeated non-compliance.

Rationale: these additional words are the key point being made in para 70. Para 70 is at a level of detail that is not necessary or appropriate for this document.

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

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

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

- an organizational chart of the official control system;
- roles of each level in the hierarchy (including other relevant jurisdictions; i.e. State, Provincial);
- job functions and qualifications as appropriate;
- operating procedures including methods of audit, verification, inspection and control, sampling, and testing;
- relevant legislation and requirements;
- processes and procedures relating to compliance and enforcement;
- arrangements for coordination with relevant ministries and stakeholders;
- relevant information about food contamination and food control;
- procedures for conducting food recalls and investigations;
- relevant information on staff training; and
- formal review process of the national food control system.

Rationale: this list is too detailed and prescriptive.

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

#### *Rationale: This added text is the key element from para* 71 – *all the rest was excess detail.*

75. Where the competent authorities intend to use third12 party providers to implement controls, before being authorised the third party provider should be assessed against objective criteria. The <u>competent</u> <u>authority should regularly assess the</u> ongoing performance of officially authorised bodies <del>should be regularly assessed</del> by the competent authority. <u>The competent authority should initiate</u> procedures <del>should be initiated</del> to correct deficiencies and, as appropriate, enable withdrawal of official authorisation.

# Rationale: readability. The $3^{rd}$ sentence did not explicitly identify who should initiate the identified procedures.

76. Competent authorities should <u>ensure sampling is appropriate to the circumstances and purpose of</u> <u>the test</u>, utilize laboratories <u>with the necessary competency to ensure</u> that are authorised or accredited under officially recognized programmes to ensure that adequate quality controls are in place to provide for the reliability of test results and the purpose for which the results are being used, and correctly interpret the reported results.

[NZ suggestion: New Footnote: "Guidance on laboratory competency is available in CAC/GL 27 & CAC/GL 28. ISO/IEC Guide 17025 may also be useful."]

Internationally recognized and validated analytical methods should be used wherever available and Good Laboratory Practices should be adhered to.

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

Rationale: To focus on what is needed for reliable test of food rather than the competency of laboratories which is provided elsewhere and can be included in the new footnote proposed.

81bis. Control programmes should be subject to ongoing monitoring to ensure that its objectives are being achieved at all stages of the food chain, including production, manufacture, importation, processing, storage, transportation, distribution and trade. The assessment of control programs should cover issues such as:

- <u>effectiveness of control procedures;</u>
- <u>suitability in achieving objectives; whether the program has covered relevant stages in the production chain, taking into account risk factors; and</u>
- consideration of emerging trends.

Rationale: This is a better place for para 89 and improves the flow of the information.

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

Rationale: grammar and improve clarity. It was not clear what planning phase this related to. We would suggest that it should relate to the design or redesign of control programmes and not to the design of a national food control system.

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

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

This whole para should be deleted. Rational: it interrupts the flow of the section and is pitched at a level of detail that is not appropriate for this guidance document. Further this level of detail is not supported by any discussion of surveillance systems in the rest of the document and we do not consider that it would be appropriate to add text to do this.

Surveillance systems are referred to in a general sense in para 86 – which is appropriate – removing para 84 does not diminish the role such systems can play while retaining it adds little to this paper.

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

- effectiveness of control procedures;
- suitability in achieving objectives; whether the program has covered relevant stages in the production chain, taking into account risk factors; and

#### - consideration of emerging trends.

Text moved and inserted as 81bis. NZ believes para 88 is an appropriate ending for this part of the document.

New Zealand looks forward to a robust consideration of the entire document at the upcoming CCFICs meeting.

### **NORWAY**

We appreciate this opportunity to comment upon section 1 - 3 at step 6 and section 4 at step 3.

#### (I) General Comments

The structure of the document is getting better, and as the text is narrowed down it is also easier to comment upon the flow and the content of the document. We also appreciate this opportunity to comment upon the principles, as a holistic approach on the document is easier now as we have worked more on the text in section 4.

Although a lot of work has been put into drafting and redrafting this document, there still is a need to further narrow down the text to be clearer and more to the point.

Sections 1 - 3 are the core body of the document. Section 4 builds up underneath and aims at giving a more practical guidance to what might be useful for understanding and interpreting the principles. By removing repetition of the principles in section 4, and also avoiding saying the same in different wordings; we will avoid confusion on what the document is actually saying.

Further, having followed the development of this document, we still think that there is a need to clarify what national food control systems encompass. The introduction of the document should be clear on the fact that there is a prerequisite that food legislation is provided for (in line with principle 11) and consequently that the objective of a national food control system is to ensure compliance with the food legislation in order to achieve safe food and fair practices in the food trade. We will come back to this, when commenting upon paragraphs 34 - 38.

To better explain what this guidance document aims at, we would have preferred in the introduction a short paragraph explaining what a national food control system shall achieve.

We would like to suggest that we use *may* throughout the document. The reason for this is that this is a guideline and the wording should reflect the status of this as a guideline. Also with reference to Section 1 paragraph 1 flexibility should be allowed.

#### **(II) SPECIFIC COMMENTS**

#### **SECTION 1**

#### Paragraph 4 and 5

We would like to suggest deleting the paragraphs 4 and 5.

4. Competent authorities may apply these principles and guidelines, where appropriate, according to their particular situations.

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

Reason: They are repeating, in different words, the same substance as is captured in the last sentence in paragraph 1: "Rather, various approaches may be used, as appropriate to the national circumstances, to achieve an effective national food control system." We would like the document to be clear and to the point, not to have duplicating text, saying the same thing again and again in different words. In paragraph 4 it is also unclear which principles it is referred to in "these" principles.

#### **SECTION 2**

Paragraph 6

The objective of a <u>national food control system</u> should be clearly stated. It should be better explained early in the document what this guidance aims at. We would like to put forward some wording to better reflect the objective of <u>control systems</u>:

6. The objective of a national food control system **is to verify that food business operators comply with requirements given in the food legislation** protect the health of consumers and ensure fair practices in the food trade.

Reason: As it was stated, it states the main objectives of the legislation, and it is our opinion that we should focus on what is the objective of the nfcs what the nfcs should aim at.

This will sort out one of the problems with understanding this document. A national food control system is based on the fact that legislation is given to achieve protection of the health of consumers and to ensure fair practices in the food trade, and that power is given to the competent authority to enforce this legislation.

# **SECTION 3**

The principles are important and they need to be clear, since much of the information in the document builds up under these principles.

We suggest reorganizing the principles as follows: 11, 2, 4, 6, 3, 5, 7, 8, 9, 13, 12 and 10.

Reason: This will provide a logical flow.

# Principle 1

We would like to suggest deleting principle 1 as it repeats the objective and thus creates confusion instead of clarity.

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

# Principle 4 Roles and Responsibilities

# Paragraph 13

Amend paragraph 13 by deleting science based.

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

Reason: There are other legitimate factors, also recognized in Codex (such as economics, labeling, quality and fair trade) that must be taken into account in the national legislation.

# Paragraph 13bis

A competent authority has a pivotal role in the national food control system; this should be reflected in principle 4 (in fact the competent authority is mentioned barely in parentheses). We would therefore like to suggest inserting a new Paragraph 13bis to clarify the pivotal role of the competent authority:

# <u>13bis. A competent authority has a pivotal role in that it provides leadership and coordination for the national food control system.</u>

Reason: for clarity on the importance of the competent authorities role, and to cover the first bullet point of paragraph 26, which should be deleted (see below).

# Paragraph 14

The introduction states in the first sentence that "all participants should have roles and etc. clearly defined". It continues in paragraph 14 describing the role of *consumers* in a national food control system. If the meaning is that consumers are a part of the national food control system, we would like to draw your attention to the wording **of principle 3**, stating that all <u>aspects</u> of a national food control system should be transparent and open to scrutiny... It continues with transparency in regard documentation etc. It cannot be CCFICS' intention to suggest that consumers, when operating in their own homes, should be open to scrutiny?

We would therefore suggest deleting consumers from "all participants" by deleting paragraph 14:

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

Reason: Consumers have a responsibility for safe food, but not within the control system. Codex standards are key tools to secure consumers safe and wholesome food, however how the consumers handle the food in their private homes is not covered by national legislation nor by Codex Standards. The national food control system cannot oblige consumers to ensure documentation and transparency of activities in their own homes.

### Principle 5 Consistency and impartiality

It seems contradictory to both say that **all aspects** of a control system should be applied consistently and impartially, and continues that **all participants** should be free of improper or undue influence. A better wording would be to delete all aspects, and just say NFCS should be applied etc. and further, delete all before participants in the last sentence.

16. All aspects of a 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.

Reason: To avoid the misunderstanding that consumers, stakeholders (the industry) academia etc. can be without conflict of interest.

### **SECTION 4 FRAMEWORK**

**Paragraphs 26 - 28** are repeating some of the principles, which should not be necessary. These paragraphs also add to the confusion of the logical sequence of this document:

**Paragraph 26** is repeating parts of what is already said in principles 3, 4, 5, 6, 9 and 10. We wonder if it is adding anything new to the understanding of the principles, and whether some of the principles could be amended for better understanding the intention of the principles, for example principle 4, roles and responsibilities. Bullet point one could be included in paragraph 13bis (see above).

The rest of the bullet points could be deleted, and if necessary included in their respective principles.

We would like to suggest deleting paragraph 26 for the above mentioned reasons.

**Paragraph 27** is repeating principle 7, and parts of it could be included under principle 4 (in connection with our suggested new paragraph 13 bis. (*more than one competent authority etc....*). We would like to suggest deleting paragraph 27 for the above mentioned reasons.

Paragraph 28 is merely repeating principles 3, 5 and 9 and could be deleted.

#### We would like to suggest deleting paragraph 28 for the above mentioned reason.

# SECTION 4.1 POLICY SETTING

We would suggest a general reference to the fact that policy setting is based upon fulfilling the principles and then keep the first sentence of paragraph 31, keep paragraph 33 and delete 30, parts of 31 and 32.

# New paragraph: <u>Policy setting is based upon the principles under section 3 and should include the</u> identification and clear articulation of expected outcomes.

Reason: We consider this section not adding anything to better understanding and clarification on national food control systems. This section could therefore be shortened. We understand that policy setting is founded upon the principles and therefore it does not need to repeat the principles. Paragraph 32 is very confusing if we look at the current wording of section 2 objective of the national food control system together with the second sentence of 32.

**Paragraph 34 - 38** is dealing with regulatory framework. Consideration should be given to whether these paragraphs could be deleted or amended to better reflect control systems.

These comments are linked to the fact that this document gives guidelines for food control systems and paragraph 34 - 38 speaks about what the legislation should reflect, frame, include and provide for. To avoid

misunderstanding these paragraphs should be deleted or amended and the document should focus on what the food control system should encompass. We will come back to this at the meeting.

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

**Paragraph 40** needs more work. It is intended to list <u>elements</u> to fulfil the principles, and it is therefore our understanding that <u>elements</u> should be the focus i.e. (words used in the documents which reflects elements):

- official control programmes,
- contingency plans and
- systems for recall, response, evaluation etc. which are mentioned later in the document.

As the bullet points stands now, they are on very different levels and not all of them are on elements. Some of them are also repeating the principles, this should not be necessary.

### **SECTION 4.3 IMPLEMENTATION**

These sections are too detailed. They have a lot of repetition of text and is not very clear. Some of the paragraphs are too detailed. We will come back with detailed comments at the meeting.

# **UNITED STATES OF AMERICA**

The following is the United States response to the request for comments on the *Proposed Draft Principles* and Guidelines for National Food Control Systems, CX/FICS 13/20/3.

The United States appreciates the efforts of the physical Working Group to further develop the *Proposed Draft Principles and Guidelines for National Food Control Systems*. Very good progress has been made in revising the text. We believe the document is well advanced and contains the essential information that national governments need to design and implement an effective national food control system.

There remain a few situations in which some reordering of text might be helpful for logic flow; these are indicated in our specific comments. Additionally there is a need for a final editorial review to improve the grammar in certain instances and to ensure the consistency of certain terms; for example, "food safety system" and "food control system" often appear to be used interchangeably.

Our specific comments on the document are provided below.

#### **Section 1 Introduction**

Paragraph 1: Revise the first sentence to read: "This document is intended to provide practical guidance to assist the **a** national government and their-its competent authority (ies) in the development... national food control system.

Rationale: grammatical change to indicate the guidance is to a national government.

Paragraph 2: Insert the following sentence at the end of the paragraph:

Reference to these texts relating to food import and export control is important since, while the national food control system is ultimately responsible for the safety of food offered within its border, in today's global market, much food is sourced from outside the country; hence, properly designed import and export control systems, as part of the overall national food control system, are essential.

Rationale: provides rationale for including reference to Codex texts relating to food import and export control; additionally, calls attention to the relationship that exists between a national food control system and its import/export control component, and why the import/export control component is important.

Paragraph 4: Delete "where appropriate." The sentence would read: "Competent authorities may apply these principles and guidelines, where appropriate, according to their particular situations.

*Rationale:* "where appropriate" and "according to their particular situations" refer to the same situation and hence "where appropriate" is redundant

# Section 3 Principles Of A National Food Control System

Paragraph 8 In the second sentence delete "In the event of a conflict,". The sentence would read: "In the event of a conflict p-Precedence should be given to protecting the health of consumers."

Rationale: Since the health of consumers is the primary goal, there should never be a conflict. The existing language weakens the goal.

Paragraph 11 Revise the paragraph to read: "All participants in a national food control system should have specific **and clearly defined** roles and responsibilities <del>clearly defined</del>.

#### Rationale: Improved grammar.

Paragraph 13 Insert "provide oversight and" into the sentence; it would read: "The national government.....and the competent authority has the responsibility to **provide oversight and** to ensure the effective operation of the national food control systems."

Rationale: Includes the concept of providing oversight into the guidance.

Paragraph 14 Delete "where relevant"; the sentence would read: "Consumers also have a role…risks under their control and where relevant should be provided with information on how to achieve this.

Rationale: Consumers always have a role in managing food safety risks and should always be provided with information on how to achieve this.

Paragraph 18 Revise as follows: "The competent authorities within a national food control system should operate in a cooperative and coordinated manner, within clearly assigned roles and responsibilities **in order to achieve** for the most effective use of resources, in order to minimize duplication/gaps, and to-facilitate information exchange."

### Rationale: improved grammar and clarity.

Paragraph 23 Insert "to enhance" before "consumer. " The sentence would read: "When designing... of their national food control system to facilitate trade and **to enhance** consumer confidence.

Rationale: The objective is not to facilitate consumer confidence but to enhance it.

#### Section 4 Framework for the Design And Operation of the National Food Control System

Paragraph 29 Insert a title for the continuous program diagram. A suggested title is: "Processes for Continuous Improvement of a National Food Control System".

Rationale: To provide a title to the diagram.

Paragraph 30 Add an "s" to "profiles" and replace "demands" with "expectations". The sentence would read: "National goals and priorities…risk profiles and consumer **expectations** <del>demands</del> and also the preparedness and capability of the country.

Rationale: Better word choice; "demands" is too harsh a word.

Paragraph 34 Revise the paragraph to read: "Legislation should clearly reflect the intended policy objective and be commensurate with the risks they are intended to mitigate. It should where possible focus on prevention and outcomes to allow for flexibility and innovation."

Rationale: The paragraph as drafted contains two sentences that are not separated.

Paragraph 34 Footnote "legislation" with the Codex definition. The footnote would read: "Legislation includes acts, regulations, requirements or procedures, issued by public authorities, related to foods and covering the protection of public health, the protection of consumers, and conditions of fair trading."(from: CAC/GL 47-2003).

Paragraph 35 Divide the first sentence into two separate sentences as follows: "Legislation should frame the structure of the national control system **and** provide clarity as to the roles and responsibilities of participants in the national food control system. **In** particular, **legislation should provide for the** that of central government, the competent authority (or of each competent authorityies where there is more than one) and any third party providers (where these are used), and food business operators."

Rationale: the sentence as drafted is awkward and hard to understand. Separation into two sentences improves the clarity of the text.

Paragraphs 47, 48, 49 and 50 Consider moving these paragraphs to follow 43.

### Rationale: For better logic flow of the document.

Paragraph 47 third bullet: Insert "government" into the list of information sources. The revised bullet would read: "information that may be available from a range of sources including academia, scientific institutions, **government**, and industry data."

Rationale: In many instances, government is a provider of information for food safety control programs.

Paragraph 51 Revise the title of the food hygiene document to read: "*Recommended International Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969).

### Rationale: Title correction.

Paragraph 55 revise third bullet to read: "provide for a full range of responses from provision of information or education material, imposing of corrective actions, **to the** setting of sanctions."

#### Rationale: Grammatical correction.

Paragraph 57 Revise the paragraph to read: "While providing for the safety of food, the design and implementation of a national food control system should be on a scale appropriate to the resources available, while allowing for appropriate expansion. Resources should be prioritized to maximize protection of public health. In this regard, resource allocations made in the context of a national food control system may, dependent on the above, be directed to the following: attributed to"

Rationale: While the design and implementation of a national food control system should be properly scaled with respect to resources, it needs to first take into account the need to provide for food safety. Changes to the latter part of the paragraph are editorial for improved clarity.

Additionally, add a new bullet to read: "adequate facilities including laboratories"

Rationale: adequate physical facilities and, in particular, laboratories, are important to the operation of a national food control system and should be included in any priority allocation of resources. The placement of the bullet is not critical but could be after the current second bullet.

Paragraph 65 Revise the second sentence to read: "The education materials developed should have adequate language **for** to the intended audience."

# Rationale: Grammar

Section 4.3 Consider the use of subheadings to highlight sub-sections; for example, "Training" before paragraph 71, "Use of Third Parties" before Paragraph 74, and "Laboratories" before paragraph 76.

Rationale: Improved clarity of the document.

Paragraph 68: The United States would inquire why there is a reference to a Principle in this paragraph when no other such references are made in the document.

Paragraph 75 Revise the first sentence to read: "Where the competent authorities... should be assessed against objective criteria **to ensure their competency.**"

Rationale: to provide the rationale for assessing third party providers.

Insert new Paragraph 79-bis to read:

In order to promote confidence, the competent authority should have in place a program for engagement with stakeholders including the food industry, consumers, and other interested parties. Such a program should include: public meetings, education and outreach events, and dissemination of information through electronic or other means.

Rationale: Apart from a short reference to stakeholder engagement in paragraph 67 there is little additional guidance on this area. The addition provides important additional guidance on this subject.

Paragraph 88 Rewrite to read as follows:

"Any review and continual improvement of the national food control system should be communicated effectively and efficiently to **all stakeholders of the food control system.** ensure that clear exchange of information and engagement between all stakeholders in the national food control system occurs.

Rationale: More concise means of expressing thought.

Insert new Paragraph 89-bis to read:

"The use of qualified third-parties may be appropriate, particularly with respect to audit and review functions, to achieve monitoring and system review objectives.

Rationale: to provide guidance on the appropriate use of third parties.

#### **URUGUAY**

Uruguay is grateful for the work by the physical Working Group that met in Grange (Ireland) on compiling the present Proposed Draft.

#### **Specific Comments**

Above all, we have noted several words in Spanish that are not entirely appropriate.

As a consequence of which we have listed the following comments below:

35. La legislación debería formular la estructura del darle el marco al sistema nacional de los alimentos,...

Legislation should frame the structure of the national food control system...

[Translator's note: no change to the English.]

37. La legislación puede incluir también, en su caso, disposiciones relativas al registro de establecimientos, homologación habilitación de establecimientos, autorización o registro de comerciantes, aprobación del diseño de los equipos, multas en caso de no conformidad, y tarifas, <u>etc.</u>.

Legislation may also include provisions, as appropriate, for the registration of establishments, establishment approval, licensing or registration of traders, equipment design approval, penalties in the event of non-compliance and charging of fees etc.

[Translator's note: no change to the English.]

40. En el diseño de un sistema de control de los alimentos se deberían tomar en cuenta los elementos siguientes:

- el fundamento reglamentario y el marco el marco regulatorio y legislativo existentes o necesarios (leyes, reglamentos, orientación guías), etc.;
- la manera de gestionar imperativos y como son gestionados los eventos y los riesgos;
- los recursos necesarios para alcanzar los objetivos del sistema nacional de control de los alimentos, su distribución <u>asignación</u> y la manera de financiar el sistema;

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

- existing or necessary regulatory and legislative framework (laws, regulations, guidance) etc.;
- how issues and risks are managed;
- the resources needed to meet the objectives of the national food control system, their allocation and how the system is to be funded;

#### [Translator's note: no change to the English.]

43. La elaboración de un método efectivo para la recolección de datos a través de la cadena alimentaria es esencial para el conocimiento de la situación, las medidas de rendimiento y la mejora continua. Por ejemplo, se pueden utilizar programas de vigilancia y monitoreo dirigidos a <del>peligros</del> <u>riesgos</u> prioritarios.

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

#### [Translator's note: no change to the English.]

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

• the risk to human health posed by the food or food related product products in contact with the food;

61. El gobierno nacional y los operadores de la industria alimentaria deberían coordinar sus esfuerzos con respecto a los sistemas de retiro y otros sistemas de recuperación del mercado. Cuando la autoridad competente solicita un retiro, los operadores deberían tener la obligación afirmativa de recuperar los productos retirados y destruirlos o desecharlos adecuadamente. Las leyes nacionales deberían incluir sanciones para las empresas que no cumplen con <del>los pedidos de retirada</del> <u>las solicitudes de retiro de mercado</u>.

Recall systems and other market withdrawal systems should be a coordinated effort between the national government and food business operators. If the competent authority requests a recall, operators should have an affirmative duty to recover recalled products and to destroy or dispose of them properly. National laws should include penalties for companies that fail to comply with recall requests.

### [Translator's note: no change to the English.]

62. A fin de fomentar la confianza del consumidor en materia de inocuidad de los alimentos y garantizar prácticas leales en el comercio de alimentos, la autoridad competente debería establecer una comunicación clara y transparente referente a todos los aspectos del sistema nacional de control de los alimentos, del cual es responsable, incluidos el establecimiento <u>desarrollo</u>, la implementación y el cumplimiento de los requisitos.

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

#### [Translator's note: no change to the English.]

63. <u>La comunicación entre</u> <u>Una función continua de</u> la autoridad competentes <u>de la salud pública</u> (inocuidad alimentaria), agricultura y otras autoridades pertinentes, consumidores y organizaciones <u>de consumidores, y operadores de la industria alimentaria debería ser una función contínua de la(s)</u> <u>autoridad(des) competente(s)</u> responsables de un sistema nacional de control de los alimentos. es la comunicación entre las autoridades de salud pública (inocuidad alimentaria), de agricultura y otras autoridades pertinentes, los consumidores y las organizaciones de consumidores, y los operadores de la industria alimentaria.

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

#### [Translator's note: no change to the English.]

66. De corresponder, la autoridad competente nacional debería utilizar los *Principios y Directrices para el intercambio de información en situaciones de emergencia relacionadas con la inocuidad de los alimentos* (CAC/GL 19-1995), el Reglamento Sanitario Internacional (RSI), <u>requisitos de notificación de enfermedades de la OIE</u> y la Red internacional de autoridades de inocuidad de los alimentos para la notificación de emergencias y respuesta a nivel nacional e internacional (INFOSAN).

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

#### [Translator's note: no change to the English.]

68. Se debería<u>n</u> elaborar orientación e instrucciones <u>guías e instructivos</u> relativ<u>ao</u>s al sistema nacional de control de los alimentos, los programas de control, incluidos los requisitos legislativos, para el personal de la autoridad competente y los operadores de la industria alimentaria para:...

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

[Translator's note: no change to the English.]

70. ....

- aumento de la intensidad de auditorías/inspecciones y/o monitoreo de productos y/o procedimientos procesos identificados como no conformes y/o las garantías correspondientes; y
- 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

### [Translator's note: no change to the English.]

76. Las autoridades competentes deberían utilizar laboratorios que han sido evaluados <u>autorizados</u> y/o acreditados en el marco de programas reconocidos oficialmente para asegurar que se han establecido controles adecuados de calidad que garanticen resultados fiables de los ensayos. Se deberían utilizar métodos analíticos reconocidos y validados internacionalmente, siempre que estén disponibles, y cumplir con las Buenas prácticas de laboratorios.

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

### [Translator's note: no change to the English.]

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

79. Según corresponda, la autoridad competente debería:

• establecer comunicación con los interlocutores comerciales (autoridades competentes pertinentes) acerca de temas e inquietudes en materia de inocuidad de los alimentos. <u>Comunicar a las</u> <u>autoridades competentes pertinentes de los socios comerciales los asuntos y cuestiones de</u> <u>inocuidad alimentaria.</u>

As appropriate, the competent authority should:

• communicate food safety issues and concerns with ( <u>the</u> relevant competent authorities) <u>of</u> trading partners.

# [Translator's note: Spanish reworded completely and consequent minor change to the English as indicated.]

81. Un sistema nacional de control de los alimentos debería examinarse regularmente a fin de contribuir a <u>la</u> mejora continua del sistema, por ejemplo, en respuesta a los datos del programa de control, no conformidad, incidentes en materia de inocuidad de los alimentos, investigación científica, historial de conformidad y evaluaciones externas e internas del sistema y modificaciones al riesgo planteado por el producto o el ambiente de producción. Dichos exámenes pueden llevarse a cabo a nivel de sistema, diseño del programa o implementación, según corresponda.

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

[Translator's note: no change to the English.]

# FAO

1) The proposed draft "Principles and guidelines for national food control systems" are currently stating principles and proposing outcomes to be reached by national food control systems. To be more explicit for

member countries we would suggest that it gives more explicit consideration to <u>key elements and functions</u> of a national food control system and the outcomes related to these elements and functions. This could possibly be addressed through a better and clearer structure of section "4.2 system design", where subtitles could clearly indicate the functions of each component of the system and the expected outcomes. This section is currently quite heavy and structuring it into components would help the reader keeping the flow and remembering these important functions.

2) FAO would also like to suggest the CCFICS to address some current and specific weaknesses in the text:

- the risk assessment functions are not well evidenced, although it would represent the basis for a science based food control system. In doing so, we should also consider highlighting the importance of functional separation between risk assessment and management activities at national level.
- section 2 states the objectives of a food control system, but doesn't make reference to the concept of appropriate level of protection (ALOP). The policy setting considerations should reflect the necessary articulation between the concept of ALOP and the science based safety regulations and standards (for example along the lines of the approach taken by the CCFH, where performance objectives, the derived performance criteria and the national regulations are linked to the initial ALOP).
- while the enforcement activities pertaining to a national food control system are quite well developed, the prevention dimensions are not very explicit.

3) While it is right that this text should not give excessive details on how to reach these outcomes, this being left to each member country depending on its needs, resources and overall situation, it is nevertheless useful to point out to complementary work done by FAO and WHO in this regard, which is providing that type of information. While it is clear that this is no way binding, this would certainly help addressing that gap. This could be referred in footnotes, introduced by a statement like "for more information countries may refer to the following publications: …". Specific references could be included;

- in paragraph 3 : reference shall be made to 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 "Food safety risk analysis: a guide for National food safety authorities" (FAO food and Nutrition Paper 87)
- paragraph 48: This paragraph refers to situations when there is absence of risk analysis data. The
  wording of the paragraph should be more consistent to the guidance developed by leading
  international experts working under the auspices of FAO and WHO. Explicit reference should be
  made to the "FAO/WHO guide for application of risk analysis principles and procedures during food
  safety emergencies".

FAO has started the development of a food control system assessment tool. This tool will take into account the guidance provided in this draft proposed principle and guidelines. An initial review of all relevant existing tools has been performed as well as available literature on food control system assessments as a basis for developing the conceptual outline for the food control system assessment tool. A technical meeting of stakeholders and potential collaborators will be held in January/February 2013.

4) FAO would like to ask two questions to the CCFICS members:

- The document refers to food control systems. However, food safety is heavily impacted by feed safety. Should we consider including the term feed in relevant sections, to avoid it being overlooked from a regulatory point of view in a food control system, like in Paragraph 5, "The objective of a national food control system is to protect the health of consumers and ensure fair practices in the food <u>and feed</u> trade."?
- the current text makes many references to recall systems. However, these will only be operational if traceability tools are in place whatever these would be in practice. Mention of traceability tools are in paragraph 33 and footnote for cross reference in paragraph 60. Shouldn't we consider being a bit more explicit about these linkages?

5) Terminology issues:

Given the wide audience and subsequent translation needs, it would appear useful to thoroughly review the terminology used throughout the document.

For example, "control" is being used with different meaning through the document, to "qualify" the system, as a synonym for "management" and including in some cases for "compliance verification" and "inspection".

The term "Government" is also use to refer to either the executive branch of it and in some other instances to the executive, legislative and judicial authorities. In addition, the understanding of "Government" may differ among countries.

The term "legislation" sometimes refers to the law, regulatory requirements and standards, and sometimes only for the law. In para. 40 "guidance" seem also considered mandatory and part of the legislation.

Reference to "emerging issues" cohabits with reference to "new or re-emerging" issues for the same concept.

The document also recognizes that there may be multiple competent authorities (para 18 and 28). Further down in the text it sometimes refer to "the National Competent Authority", "the Competent Authority" or "Competent Authorities" which can be confusing.

### Specific comments

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

Rationale: it may be useful to better spell out what is at stake here in terms of consumer protection, that could also encompass many other areas.

Paragraph 13 The national governments (and in some cases competent authorities) have the role and responsibility to establish and maintain up to date science <u>and evidence</u> based legal requirements and the competent authority has the responsibility to ensure the effective operation of the national food control system.

Rationale: all regulatory texts pertaining to food control, and the overarching food law, may contain provisions that while being legitimate, are not science based.

PRINCIPLE 8 PREVENTIVE MEASURES PREVENTION AND PREPAREDNESS FOR RESPONSE

Paragraph 19 To prevent <u>and timely and effectively respond</u> or to react to food safety incidents, a national food control systems should encompass the core elements of <u>surveillance and event identification, early</u> warning and response planning for rapid intervention prevention, intervention and response.

*Rationale: better coherence between the title and the content of the paragraph (prevention and response) ; and spell out the notion of preparedness which was missing.* 

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

- (...)
- develops, implements, monitors, manages, **enforces** and reviews the national food control system;
- (...)
- Establishes, implements and enforces regulatory requirements supporting and enabling supports and enables fair practices in the food trade;
- (...)
- Establishes and maintains arrangements with other countries e.g. cooperation programmes, <u>recognition or</u> equivalence agreements etc.

Paragraph 28. The design and implementation of a national food control system should follow a logical and transparent process. This should include **hazard identification and surveillance and** 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.

Rationale: to apply the risk analysis framework to existing, new or re-emerging hazards, this presupposes that they are identified and that surveillance is implemented.

# Paragraph 33, ii: Characteristic 2 Pro-activity Prevention

Rationale: more specific from a technical point of view

Paragraph 36: The legislation should provide the competent authority with the range of powers ad mechanisms sufficient to manage and operate the national food control system <u>such as enacting regulatory</u> <u>requirements</u>. (...)

- establish standards or other <u>risk</u> management options to control food borne hazards such as diseasecausing organisms, naturally occurring contaminants, and pesticide residues;
- establish approaches to ensure the safety and safe use of food additives, pesticide residues, veterinary drugs, **packaging and materials in contact with food**.
- enforce legislation <u>and regulatory requirements</u> and take action in case of unsafe or non compliant food, including investigations, <u>prosecutions</u> and application of sanctions and penalties, <u>including</u> <u>suspend or cancel food business operator registration</u>
- ;
- ensure the integrity, impartiality and independence of officially recognized inspection systems, <u>and</u> <u>consistent inspection procedures;</u>
- (...)

# <u>Establish a food recall system</u>

Paragraph 40: The design of a food control system should take into account the following elements:

- (...)
- How issues are addressed and risks are managed
- enforcement and compliance programs and enforcement tools;
- coordination and communication between authorities with control responsibilities in different parts of the food chain and with the public health and veterinary authorities;
- (...)
- surveillance, investigation, <u>early warning and early action</u>, emergency preparedness, <u>emergency</u> and <u>response planning and timely</u> response to foodborne <u>diseases outbreaks</u> and food related incidents;
- (...)

Paragraph 44: the competent authority should utilize findings from the laboratories <u>and other surveillance</u> <u>systems to generate and collect data necessary to perform risk assessments, design inspection,</u> <u>compliance verification and enforcement programmes, as well as target inspection compliance and</u> <u>enforcement resources, including the design, capacity and workplan of laboratories</u> to monitor trends in the food chain and assist in compliance and enforcement. (...)

Rationale: more technically specific wording

Section 4.3 Implementation of the system

Paragraph 68: third bullet "objectives clearly communicated to them" is unclear.

Paragraph 70: a bullet on prosecution should be added.

Paragraph 75: Where the competent authorities intends to use third party providers to implement controls, before being authorized the third party provider should be assessed against objective criteria. <u>Third party</u> providers should be independent. The ongoing performance (...) official authorization. <u>The legal</u> responsibility of the competent authority delegating the implementation of the controls and of the third party provider implementing them should defined.

Paragraph 79: 3<sup>rd</sup> bullet:

• Communicate and collaborate with international organizations, <u>such as FAO /WHO through</u> <u>INFOSAN, WHO in accordance with the IHR (2005) and OIE as applicable,</u> in cases where foods(s) implicated in incidents or outbreaks of foodborne illness may be circulating in international trade.

Paragraph 84,

1<sup>st</sup> bullet: replace by: "<u>links between syndromic public health surveillance systems, foodborne outbreaks</u> surveillance systems, food monitoring and surveillance systems, animal diseases surveillance systems and food borne zoonoses in particular, ecosystem health surveillance systems including environment and wildlife".

3<sup>rd</sup> bullet: systems to allow rapid detection of contamination incidents to ensure prompt **public** alerts

Delete last bullet

*Rationale:* 1<sup>st</sup> *bullet more specific;* 3<sup>rd</sup> *bullet: not contamination incidents do necessitate public alert.* 

Paragraph 89, last bullet: consideration of emerging trends risks

Rationale: there is currently no universal understanding of what an "emerging food safety trend" is and how to analyse them.

### **INTERNATIONAL NUT AND DRIED FRUIT COUNCIL (INC)**

(ii) Specific Comments

Section 4.1 Policy Setting

Paragraph 36 – In the seventh bullet point, delete the words "disposed of where appropriate" and replace them with "treated or diverted to appropriate channels." So the seventh bullet point would read "Ensure that unsafe or noncompliant food are withdrawn from the market and <del>disposed of where appropriate</del> **treated or diverted to appropriate channels;** and".

Rationale: the term "disposed of" can be narrowly interpreted to mean that non-compliant food should be destroyed. In many cases, treatment options are available for non-compliant food or mislabeled product can be relabeled and brought into compliance.