



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

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

(N06-2009)

(Comments at Step 3)

**(Argentina, Canada, Chile, Colombia, Costa Rica, Japan, Kenya, Mexico, New Zealand, Norway,
Philippines, South Africa, Uruguay, United States of America, IACFO, IIR, OIE)**

ARGENTINA

General Comments

Argentina is grateful for the possibility to make comments on this text and would like to congratulate Australia for the effort made to integrate in a single text the comments made by all participants in these negotiations.

Argentina considers that while the text has been improved considerably, additional clarity is still required as some aspects are still a little confused. The first part concerning the introduction, objectives and principles is well done and fluid, although we have a few comments about some paragraphs. The same cannot be said of the following sections.

Section 4 begins with an introduction that could perhaps be expanded with some of the elements of 4.1, and then deleting that paragraph because the system's characteristics in 4.1 could be included in the introduction to 4.

Similarly, there are repetitions with regard to the design and implementation of the system, when in reality the former should indicate the pillars of the system and tools that can be derived from them; and the latter should indicate how the design elements are applied and incorporated into the system. In order to establish each area clearly, we would work on a sort of logical framework indicating how each activity is to be considered, how it is to be designed and how it is to be implemented. In this way, it would be easier to introduce the paragraphs without repeating the content between the design and implementation.

While the document is still in its initial stages, it is important to bear in mind that as the national food control system is a whole, reference could usefully be made throughout the text to other relevant documents compiled by FICS, for example, those regarding Equivalence Agreements, the background to rejection and exchange of information, etc.

With regard to reference IOE documents, Argentina feels it would be convenient to mention which documents are relevant to the food safety control system and include a mention. If on the contrary, we are accepting that all IOE agreed texts are applicable to the national food control system, a far broader criteria than the one we used to include Codex documents.

Finally, and with regard to the previous point, Argentina would like to point out that while we are aware that the origin of this document was the need for some countries to have assistance to create or improve their control systems, we must not overlook that it is still a negotiation document and so we cannot accept the inclusion of texts that are not part of a negotiation process, irrespective of their value. For this reason,

Argentina considers that we should remove references to FAO documents that are not negotiation texts, but rather the result of work by the FAO and often written based on the opinion of external consultants.

Finally, we are concerned that certain adjectives such as those used in paragraph 35, **comprehensive scientific evaluation**", "**wide stakeholder participation**", depend on the capacity of the States, which is why we believe the document should focus on establishing the underlying issue; that is, scientific assessment and consultation with interested parties; the extent to which the countries perform these activities will depend on the capacity of their control system. This is the reason why we suggest such adjectives be avoided.

Specific Comments

Section 1: Introduction paragraph 2

...the document is consistent with other related Codex texts, **and should be read in conjunction with the Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates CAC/GL 38-2001, Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food CAC/GL 25-1997, Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations CACA/GL 19 -1995, Aad Code of Ethics for International Trade in Food. Including Concessional and Food Aid Transactions (CAC/RCP 20-1979).**

"...el presente documento ~~guarda coherencia~~ **es consistente** con otros textos del Codex, **y debe leerse conjuntamente con las** ~~los cuales deberían leerse las~~ **Directrices**

[Deleted text refers to changes in Spanish only.]

Grounds: Establish the provisions that are clearly the responsibility of the competent authorities and which require their consideration when designing a national food control system.

SECTION 2 OBJECTIVE OF A NATIONAL FOOD CONTROL SYSTEM

Paragraph 5. "...objective of a national food control system is to protect the health of consumers **with regard to food safety** and ensure fair practices in the food trade.

Grounds: We believe that it is necessary to define clearly the scope of the control system to which this document refers.

PRINCIPLE 1 PROTECTION OF CONSUMERS.

Paragraph 7. Argentina suggests deleting the second sentence: "National food control systems should be designed and maintained with the primary goal to protect the health of consumers. ~~In the event of a conflict, precedence should be given to protecting the health of consumers.~~

Grounds: This is of a very broad and dangerous principle to include in a text. Clearly, governments have the authority to implement all measures that they consider appropriate, and all WTO members must respect the principles of the Agreements, which is why we believe it is not appropriate to include such a broad authorisation in this text which could lead to unnecessary, unjustified and arbitrary practices.

PRINCIPLE 3 TRANSPARENCY

Paragraph 9. All aspects of a national food control system should be transparent and open to scrutiny by all interested parties, while respecting legal requirements to protect confidential information as appropriate. Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation and communication

Párrafo 9. Todos los aspectos del sistema nacional de control de los alimentos deberían ser transparentes y ~~podrían~~ **debería** ser objeto del escrutinio de todas las partes interesadas sin perjuicio del respeto a la legislación que gobierna la confidencialidad de la información, según corresponda. La transparencia se aplica a todos los participantes de la cadena alimentaria y puede lograrse mediante una documentación clara y una buena comunicación.

[Change to the Spanish only]

Grounds: Argentina considers that the verb "podría" does not contribute to transparency and leaves it up to the countries to consider the information available, whereas it is a central element to provide some type of information for the involvement of all interested stakeholders, for which reason we suggest using the verb "debería".

PRINCIPLE 4 ROLES AND RESPONSIBILITY

Grounds: Argentina suggests deleting roles from the title of this principle only refers to responsibilities.

Paragraph 14: Academics and scientific institutions may have a role in contributing to a national food control system, as they are a source of expertise to support/provide the scientific foundation for existing risks ~~risk based and of such a system.~~

Grounds: Clarification on the text's content. Argentina also suggests retaining the word "provide", as supposedly in some cases, scientific institutions will be performing scientific assessment of the risks and not the control authorities.

PRINCIPLE 6 INCORPORATION OF DECISIONS BASED ON RISK ANALYSIS ~~RISK BASED, SCIENCE BASED AND EVIDENCE BASED DECISION MAKING~~¹

Paragraph 16 Competent authorities should be making decisions within a national food control system based on risk analysis, taking into account the scientific information, evidence and/or risk analysis principles as appropriate (a footnote should be added regarding the Codex risk analysis principles for governments), **to the effects of establishing relevant regulatory controls.** To prevent or to react to food safety incidents a national food control systems should encompass the core elements of prevention, intervention and response.

Grounds: A Codex document of this scope cannot overlook the fact that measures must be based on risk analysis and in this context proof, science and scientific evidence are important as they are analysed and contextualised within the framework of a structured process. For this reason, decisions must be based on risk analysis. This analysis will subsequently reveal the value given to the result or new emerging scientific information in the future. In the same order of ideas, it is important to emphasise that even when the relevant authorities are unable to perform a complete risk analysis, they must base themselves on others, if they exist, and adapt to the local circumstances, or simply bear in mind the recommendations of international organisations, where they exist. For this reason, we say that decision making must be based on risk analysis. Finally, we suggest including the text of Principle 8, paragraph 18 on Preventive Measures in this Principle as these measures must also respond to a need arising from the examination of existing risks. Paragraph 16 would then be written as above.

PRINCIPLE 10 RECOGNITION OF SYSTEMS [EQUIVALENCE]²

Paragraph 20. Competent authorities should recognise that **two food control systems or their components** although designed and structured differently may ~~meet-be capable of meeting~~ the same objective.

Grounds: Argentina suggests clarifying that this refers to a comparison between two national systems or their components.

Argentina proposes adding two Principles:

PRINCIPLE OF HARMONISATION

When designing and applying a food control system, the competent authorities should take into account the relevant standards published by reference international organisations in order to facilitate trade.

PRINCIPLE OF COMPLIANCE WITH THE PLANNED OBJECTIVES:

The control systems must be completely effective in so far as they comply with meeting the established objectives and do not restrict trade more than is necessary to achieve the desired level of protection.

Grounds: To develop standard frameworks that take into account the obligations established in WTO agreements, it is necessary for these principles to be adopted by all the authorities with the regulatory responsibilities or activities on behalf of their own national government or provincial or municipal

¹ This text has been adapted from Principles for Food Import and Export Inspection and Certification CAC/GL 20/1995 para. 5.

² CAC/GI 34-1999 Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification, CAC/GL 53-2003 Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.

authorities; harmonisation with international standards will facilitate understanding; for this reason, it is important that this document take into consideration this principle.

With regard to including the principle of compliance and planned objectives, we believe it is important because the regulatory and control authorities when establishing measures or categorising risks must take into account non-discrimination and avoid arbitrariness that restricts trade.

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

Paragraph 22, “Also, while provincial or state laws may exist there should be a competent authority at the national level capable of ensuring ~~uniform~~ harmonious application”.

Grounds: With regards to the inclusion of the sentence suggested by New Zealand in this paragraph. While we are aware that this is the ideal situation, the same capacities or the same infrastructure is not always found across the entire national territory, which is why we suggest this change to the sentence so that it reads as above

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

- develops, implements, manages, monitors, ~~manages~~ and reviews the national food control system;
- establishes and enforces **food legislation to science and risk based regulatory controls** that encourage and promote positive food safety outcomes;
- advances/fosters knowledge, science, research and education regarding food safety for all stakeholders in the chain.

Grounds

- In the second bullet point, Argentina suggests changing the order between manages and monitors.
- In the third bullet point, the expression regulatory controls is not clear to us, in our view, the competent authority has a fundamental role to play in ensuring compliance with food legislation, irrespective of the form of system used to achieve it. Furthermore, we consider it is not necessary to repeat that these controls are based on science and risk, since this was already mentioned in paragraph 16.
- With regard to the fifth bullet point suggested by New Zealand, Argentina suggests clarifying that the educational function is horizontal and directed towards all stakeholders in the chain.

Paragraph 24. The design and operation of a national food control system should follow a logical, ~~and~~ transparent and documented process. This should include the consistent application of a systematic ~~framework~~ method for the evaluation [...]

- preliminary risk activities, including identification and characterisation of the risk and the categorisation and ranking or prioritisation of the risk to order ~~for~~ risk management ~~consideration~~;
- ~~... jerarquizar o~~ priorización ~~dar grado de prioridad a~~ del riesgo ...

[Also changes to the Spanish only in the same bullet point]

Grounds: This paragraph should have a reference to the document Working Principles for Risk Analysis for Food Safety for Application by Governments CAC/GL 62 – 2007.

In the second sentence of paragraph 24, Argentina suggests using the same vocabulary as in paragraph 31 of the document /GL 62- 2007, which is why we suggest replacing “framework” with “method”.

Paragraph 25. Regarding equivalence³ The competent authorities should recognise that two ~~Two~~ national food control systems or their components, although not the same and designed differently, may be able to deliver similar outcomes and this should be reflected in the national food control system

Párrafo 25 [... de control de los Alimentos, o sus componentes pueden tener ~~tienen~~ la capacidad de lograr ...]

³ CAC/GL 34-1999 Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems, CAC/GL 53-2003 Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.

[Also one change in the Spanish only: “**pueden tener**” instead of “~~tienen~~”]

Grounds: In the Framework and Design stage, the text in paragraph 25 is insufficient, and it should seek to clarify better that the system should rely on capacity and tools that enable it to examine other systems or their components in order to determine equivalence with systems other than its own.

This paragraph should also include a footnote that refers to the FICS documents on equivalence. It would also be relevant to examine jointly with the IOE whether it is necessary to make some reference to this organisation’s equivalence documents.

Paragraph 26: The national competent authorities should consider undertaking ~~arrangements~~ **commitments or memoranda of understanding** with other countries’ national competent authorities, including the establishment of equivalence agreements, in order to make efficient use of their own resources. [EU]

Grounds: It is not clear to what these agreements refer, but perhaps it would be relevant to refer to commitments or memoranda of understanding in order to be flexible but clear with regard to the commitments being made.

SECTION 4.1 SYSTEM CHARACTERISTICS

Paragraph 29: Argentina considers that this paragraph should be included in the general part of section 4, the remainder of the paragraph 4.1 should be deleted.

Grounds: The characteristics listed refer to the design of the control system, with regard to the pro-activity and continuous improvement characteristics; Argentina considers that the principles include all the components.

SECTION 4.2 SYSTEM DESIGN

It is difficult to visualise in this section which are the central components of the system and tools although this is the central question of the section. For this reason, we suggest clearly identifying the COMPONENTS or pillars of the system to ensure the effective implementation of the principles of a control system. In this respect, we feel that perhaps to improve understanding, it might be possible to begin by providing a diagram or a framework.

COMPONENTS

LEGISLATION: based on the risk and standards assessment

INFRASTRUCTURE: (laboratories, etc.)

HUMAN RESOURCES (including training)

MANAGEMENT CONTROL: to assess the systems effectiveness.

COMMUNICATION: between all interested stakeholders, communication of the risk, standards.

With regard to the paragraphs suggested by the EU in section 42, although we understand their intention, we believe that such a level of detail is excessive. However, we suggest retaining some of the concepts.

Paragraph 32. The design of an effective national food control system requires a continuous planning-monitoring review cycle, which is necessary to ensure that the system continues to deliver what is expected (~~principle 9 of this document~~). Successful implementation of the principles in section 3 requires that mechanisms to deliver according to those principles are built into the design of the system (rather than added as an afterthought). Effective implementation of all of the 10 principles depends on the combined effect of a number of components **developed in Sections 4.2 and 4.3**, including: ~~legislative foundation, allocation of resources, staff competence and training, laboratory network, verification of compliance, enforcement, surveillance, investigation, response, stakeholder engagement, international communication and harmonisation, assessment and evaluation.~~ [EU]

Grounds: In accordance with the comment above.

Paragraph 33. The design of a national food control system plays a key role in providing for the system characteristics outlined in section 4.1. Processing and analysing data collected through official controls is essential for situational awareness (29). ~~Data collection and analytical capability of the national food controls system determines the degree of pro-activity that the system will demonstrate (principle 8). Capability to~~

~~learn depends on the effectiveness and timeliness of the feed back from evaluation and review to the design or re-design processes. [EU]~~

Grounds: It is necessary to include the second part of this paragraph, as the topic is addressed in other parts of the document.

[Translators note: logically, this should read, "It is not necessary..."]

Paragraph 34, 2nd sentence. Control programmes **must establish general and specific objectives aligned on the national objectives and assessment in order to continually improve them. In this way, they** help to ensure that inspection actions relate to objectives, since the results of these programmes can be assessed against the objectives set for the national food control system (principle 9).

[Translators note: It is actually the third sentence.]

Grounds: Programmes must also meet with system's broader objectives.

Paragraph 35. As mentioned in the general comments, Argentina suggests deleting the adjectives from this paragraph, such as, *comprehensive* scientific evaluation, *wide* stakeholder participation.

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

Legislation:

Comment: Bearing in mind that legislation is the starting point of control system, its importance should be emphasised along with the other components of the system. And to give it greater relevance, it should be placed in point 4.2.1.

Paragraph 38: Legislation should provide clarity as to the roles and responsibilities of participants in the food chain, in particular that of central government, the competent authority (or of each competent authority where there is more than one) and any authorised providers (where these are used), ~~and~~ industry **and consumers**.

Grounds: In the first sentence of paragraph 38, we should also include consumers because legislation often considers them in different ways. This may be because the standards adopted take into account protection of their health, the information they must be given, all the rights to assist them, etc. Also, we wonder whether it would not be better to refer to operators in order not to have to detail whether referring to the industry, providers, marketers, etc.

Refocusing Paragraph 38. Argentina supports Australia's suggestion of referring to control programs as mentioned in CAC/GL 26-1997 rather than to inspection. Argentina also agrees that the chain should be considered in its totality.

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

Grounds: The frequency of controls and not of programmes

Paragraph 40. Control programme(s) should be based on **appropriate risk analysis and** clearly defined outcomes ~~and~~. In the absence of detailed scientific research, control programme(s) should be based on requirements developed from current knowledge and practice, **on the recommendations of reference international organisations or programmes implemented by third parties**. Every effort should be made to apply risk analysis based on internationally-accepted methodology, where available. [Aust/covers Brazil]

Grounds: It is possible that we are unable to perform complete risk analyses using international methods. In these cases, the competent authorities may take into consideration the method adopted by other parties to manage risk, or those suggested by international organisations, if they exist. Also, Argentina supports the suggestion by Australia and Brazil

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

Grounds: Argentina agrees with paragraph 41, but considers it should be moved to the section dealing with application.

Paragraph 42: Should be consistent with CAC/GL 26-1997 paragraphs 26-28.

National control programmes should be designed to account for factors such as:

- History of conformity of industry/operators; and
- Potential detection of fraudulent practices ~~fraud~~ or deception of consumers and unfair trade practices ~~other factors that may prevent fair trade practices~~

Grounds: In the introduction to paragraph 42 to distinguish the text from CAC/GL 26-1997, it would be appropriate to mention that this refers to national control programmes.

In the 5th bullet point, we should examine whether it is necessary to include any other link in the chain, which is why we suggest changing or adding the word “operators”. In the final bullet point, we suggest changing the wording to make the meaning clearer.

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

Grounds: Argentina suggests deleting the text between brackets, because these are not the only activities that may involve a control programme.

Paragraph 44. Where quality assurance systems are ~~used~~ **applied** by industry, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade. The competent authority should encourage the use of a Hazard Analysis Critical Control Point (HACCP) approach by industry. [Aust]

Assessment and Evaluation Argentina can accept both the proposal by Australia to include Assessment and Evaluation with Control (inspection), and the suggestion by the US to include a text referring to continuous improvement and to delete the section referring to Continuous Improvement, as we share the idea that it is not necessary to develop a separate section but rather to include the relevant idea and the components in each section.

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

Párrafo 47. La autoridad o autoridades competentes que implementan un sistema nacional de control de los alimentos deberían elaborar planes para emprender auto evaluaciones y exámenes de garantía de la calidad en forma periódica, diseñados para identificar ~~los puntos fuertes y débiles~~ **fortalezas y debilidades** de sus programas, o bien hacer evaluar su eficacia por terceros.

[Change to the Spanish only]

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

Medidas de Cumplimiento y Ejecución ~~medidas de cumplimiento~~ – Programas de cumplimiento y medidas de ejecución ~~cumplimiento~~ a fin de asegurar el cumplimiento de leyes y reglamentos.

[Change to the Spanish only]

Grounds: Argentina understands that enforcement measures are actions applied when compliance with the established requirements is not achieved.

48. **The competent authority must have the ability to take action when a product or process is found not to be in conformity.** **Specific** compliance and enforcement programmes **taking into account the operator’s past compliance record** should be designed to ~~provide for the ability for the competent authority to take action to ensure the situation is remedied where a product or process is found not to be in conformity.~~ The resulting actions should take into account any repeated non-conformity of the same product or process to

ensure that any action is proportionate to the degree of public health **safety** risk, potential fraud or deception of consumers. [Australia/also picks up some of the EU thoughts]

Grounds: The proposal aims to provide clearer content and makes an express reference to the operator or industry's past compliance record.

4.2.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING ETC.)

Argentina considers that laboratories and human resources are such fundamental pillars of a control system that to include them in a subtitle called resources undermines their importance. For this reason, Argentina suggests separating laboratories 4.2.2 and human resources and training 4.2.3. In this case, paragraphs 52 and 53 would be appropriate.

Paragraph 51: Argentina considers that the words “eficaz” and “cumpla con el objetivo” in this paragraph mean the same thing and therefore one of them should be deleted.

Paragraphs 56 and 57 regarding personnel training: Argentina agrees with both proposals, however, we have a preference for paragraph 57.

Paragraph 58, Argentina considers that this paragraph should be moved to the implementation section. In addition to this remark, we also suggest a change to the end of the first paragraph:

“Programmes and training manuals should be developed to ensure consistent application of requirements and uniform application of the national food control system **that takes into account the following:**”

The following addition should be made to the second bullet point • Job functions and qualifications **of the relevant employees** as appropriate.

Surveillance, Investigation, Response.

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

Párrafo 59. Al diseñar un sistema nacional de control de los alimentos se debería incorporar un sistema para vigilancia, investigación y respuesta que permita **documentar** ~~ción~~, **analizar** ~~el análisis~~, **la comunicare** ~~ción~~ y **hacer** el seguimiento de supuestos incidentes relacionados con los alimentos.

[Changes to the Spanish only]

Paragraph 60 a). Argentina would like clarification of the word “injury” in the context of this sentence and suggests changing the word ‘difuminar’ with the word ‘difundir’ in sub-paragraph b) [Change to Spanish only]

In paragraph 60 c) Argentina would like clarification as to whether it is capacity to “respond” or to “react”.

The 3rd bullet point of paragraph 60 c) refers to “Access to epidemiology support” and perhaps it would be important to include in the general part of the document what the sources of information are.

Paragraph 61, Mention should also be made of notification to the media by the SPS, TBT and WTO committees.

4.2.2 COMMUNICATION (INCLUDES STAKEHOLDER ENGAGEMENT, EDUCATION AND INTERNATIONAL COMMUNICATION)

Paragraph 63. In order to promote consumer confidence in the safety and quality of their food, the competent authority should be clear and transparent in their communications relating to all aspects of the national food control system for which they are responsible, including the development, implementation and enforcement of the requirements. [modified EU proposal]

Grounds: Argentina understands the intention of paragraph 63 proposed by the EU, however we are not sure of the extent that this information should have, given that there is a whole series of provisions of a public nature, such as the distribution of competencies, functions, structure, requirements that products must meet, and many procedures, but other information is simply not published, which is why we would welcome clarification about the scope of the intention of this paragraph.

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

Párrafo 64. Es importante que los procedimientos de toma de decisiones sean transparentes y en caso de corresponder permitir que todas las partes interesadas en la cadena alimentaria contribuyan de manera eficaz, ~~de corresponder~~. [Propuesta de la UE modificada]

[Change to the Spanish only]

Paragraph 65, second and third sentences. Consumers should always be promptly, accurately and ~~fully~~ **concretely / specifically** informed about any disease outbreak, contaminated food incident, or food recall through an alert system using effective and practical communication methods. **For it to be effective, communication must be a two-way process so mechanisms need to be established by the competent authorities that take into account, where appropriate, consumers' opinions and concerns when justified.** ~~Communication must be a two-way process to ensure that authorities are aware of and take into account consumer concerns and perceptions, where appropriate.~~ [IACFO]

Education

Paragraph 66. Argentina believes that the reference to community relations programs is excessive in this text, since each country will use the communication, education and outreach programs within its capabilities.

Paragraph 67, Argentina supports the intention of this paragraph, however we consider that its wording needs to be improved. Additionally, paragraph 67 and 68 should refer to the relevant Codex documents regarding the exchange of information and rejection, and should also include notifications that are to be made to the SPS Committee and TBT in these cases.

Paragraph 72, Argentina agrees with the intention of this paragraph, however, perhaps it would be appropriate to refer to the procedures that both staff and operators need to follow when applying standards in force. "Guidance and instructions **regarding the procedures to follow** [...] should be provided"

Paragraph 73, Argentina considers that this paragraph requires greater clarity and that it should be read together with the paragraph regarding compliance programs and initiatives, although is not clear either, and about which we made comments earlier.

Paragraph 74 Continuous improvement. Argentina suggests changing the text and its position: **"Procedures need to be established for the collection of data, its assessment and establishing improvement objectives so that the programmes remain up-to-date and reflect the risk."**

Grounds: As it stands, it does not seem to bear any relation with section 4.2 and in fact it could be entered as 70b; changing the wording of the paragraph as above.

Paragraph 75, In Argentina's view, the provision of this paragraph corresponds to the design stage and has already been discussed. Perhaps in this stage, it should be mentioned that when the competent authorities establish control programs, they must identify or describe the tools that will apply to the control program.

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

Párrafo 88: Se deberían utilizar métodos analíticos **validados y reconocidos y validados internacionalmente**, siempre que estén disponibles, y cumplir con las Buenas prácticas de laboratorios. [UE]

[Changes to the Spanish only]

Paragraph 91. Having already indicated this in its general comments about the inclusion of FAO manuals, Argentina reiterates that they are not negotiated texts in Codex documents.

Paragraph 92, Argentina considers that control laboratory data is not scientific information and by itself is not sufficient to inform and support standards.

Training

As indicated, paragraph 58 should be included in this section, especially since it is more detailed in the paragraphs in this section.

Paragraphs 97 to 99, Argentina agrees with the proposals by Australia, United States and European Union.

Paragraph 102, Argentina considers that this statement proposed for IACFO does not correspond to the implementation stage.

Paragraph 103. Argentina considers that the intention of this paragraph is appropriate, however, there is no clear distinction between this paragraph and paragraph 66. Additionally, Argentina considers that it would be more important to include in Australia's proposal the nutritional information that must be provided for consumers to prevent non-transmissible diseases, but they need to learn to read food labels in order to avoid public health risks caused, among other factors, by their dietary decisions.

Section 4.4 Continuous improvement. Argentina fully supports the comments made by the United States, Australia and Canada regarding the recommendations to be included in each section where appropriate.

Paragraphs 107 to 109, Argentina supports the paragraphs proposed by Australia, however, we are not sure about their placement in the document.

Paragraph 110: "Food-related incidents are an opportunity ~~for to learn.~~ competent authorities **to use the information and facts arising from the incident to revise, if appropriate,** ~~should use these opportunities by way of carrying out "post mortems" and feeding the "lessons learned" back to the planning/design process.~~

Grounds: Argentina agrees with this paragraph, however, it does not feel the use of the word "learn" is appropriate, even if correct, and believes its use could be avoided. To this end, Argentina suggests the above changes to the paragraph.

CANADA

General Comments

Canada commends the pWG for the further elaboration of Section 3 – Principles of the document. We strongly support the principles as drafted as we believe they address key considerations for building/enhancing modern national food control systems.

In our view, a key consideration as CCFICS moves forward in further elaborating the document is the need to ensure that flexibility is maintained (as noted in Paragraph 1 of the document) to accommodate different national situations. We would invite CCFICS participants to keep this under consideration in further elaborating the document, so that the level of detail is kept to an appropriate level.

We believe this document should provide concise, practical guidance on the development, operation and improvement of national food control systems.

We generally support the structure of Section 4 - Framework for the design and operation of the national food control system. However, we note that further improvement is necessary to address gaps, avoid areas of duplication, and review/revise text that may be unnecessarily prescriptive. Canada has provided some suggestions under its specific comments.

Specific Comments

Section 4.1 System characteristics

Canada recognizes the importance of the main characteristics that a national food control system should have as described in Paragraphs 28 through 31, and which should be reflected in the Principles. We suggest, in recognition of their importance, that the Committee consider adding text to Principle 9 – Self assessment and Review Procedures. The proposed addition to Principle 9 (Paragraph 19) would be as follows:

19. The national food control system should possess the capacity to undergo continuous improvement and include mechanisms to evaluate its effectiveness. **It should also possess the three main following characteristics: situational awareness, pro-activity and capacity to learn.**

We would further suggest these paragraphs (28-31) could be moved or more appropriately integrated into sections further in the document. e.g. paragraphs 46 and 47, and Section 4.4. In our view, this would reduce redundancy.

Section 4.2 System Design

Paragraphs 32 through 37

As noted in our general comments, we support concise and practical guidance to the extent possible. In our view, Paragraphs 32 through 35 contain information that is more detailed than necessary for this purpose (e.g. how the principles and characteristics are interconnected). This Section – System Design should readily address the practical guidance relating to the key components to consider in system design, e.g. legislation, control programmes. We suggest the following condensed paragraphs could substitute for paragraphs 32 through 35:

32. When establishing a national food control system countries should identify the main objectives to be addressed and consider how to incorporate the principles in Section 3. Effective design gives consideration to a number of elements including: legislative foundation, allocation of resources, staff competence and training, laboratory network, verification of compliance, enforcement, surveillance, investigation, response, stakeholder engagement, international communication and harmonisation, assessment and evaluation.

33. Development of an effective method of data collection and analysis throughout the production chain is essential for situational awareness, performance measurement and continuous improvement.

Legislation – Paragraph 38

Canada believes that the establishment of a modern legislative framework is the essential foundation of a national food control system. Accordingly, this needs to be emphasized and additional clarity provided with respect to the elements of the legislation. We suggest the following text to replace paragraph 38:

38. Relevant and enforceable laws are the foundation of a national food control system. Legislation and regulations provide the essential legal framework for an effective food control infrastructure by codifying the overarching national objectives and any specific or lower objectives of the national food control system. Legislation also establishes the authorities needed for effective compliance and enforcement activities.

Comment: To reflect wording of principle 4 para 13

38 bis. Legislation and regulations should address the following:

- **Roles and responsibilities of participants in the food chain, in particular that of the central government, the competent authority, authorized providers and industry**
- **Provide the authority or basis for setting of standards and outcomes, and establishment of appropriate controls at all stages of the food chain, including manufacture, importation, processing, storage, transportation, distribution and trade**
- **Provide the authority for compliance and enforcement action where a product or process is found not be in conformity or where there is a risk to public health.**

Control Programmes – Paragraph 39

Canada supports the use of the term Control programmes. It would ensure coherence with the terminology used in CAC/GL 26- 1997. Although we recognize that the term Verification of compliance is a very fundamental component of a national food control system, the term Control programmes allows for recognition of the controls implemented by stakeholders along the food chain, and hence provide for their consideration in designing appropriate compliance activities.

Canada also feels that this section should specifically address the importance of developing clear policies, operational procedures and interpretive guidance in support of Principles 3 (Transparency), 4 (Roles and responsibilities to ensure participants are aware of expectations), 5 (Consistency and Impartiality through documented procedures) and 8 (Preventive Measures including related expectations and processes). We note that the Implementation section (paragraph 70) states that these will need to be adjusted to reflect changes, but this initial guidance is not provided in the Design section. Hence, we suggest the inclusion of the following text as Paragraph 40 (bis):

40 bis : Policies and operational procedures should be developed to ensure consistent and uniform application of the requirements of the of the national food control system and to provide interpretive guidance with respect to the legislation and regulations, preventive control requirements, methods of inspection and verification, and procedures for food recalls and investigations. The documents should form the basis for training for staff involved in compliance and enforcement activities.

Use of third party providers

We suggest the inclusion of additional text following Paragraph 44 so that, during the system design phase, consideration could be given to the use of third party providers, as appropriate. This addition would provide the flexibility necessary to accommodate different national situations. The proposed text is as follows:

44 bis : Where the national food control system includes the use of third party providers, the design should establish the objective criteria by which the competency of the providers can be assessed.

Section 4.4 Continuous Improvement

We support the retention of this section. We would also suggest that Paragraph 47 could be more appropriately placed as the first paragraph in Section 4.4, for coherence.

CHILE

General comments

For Chile, the topic is relevant and of interest to our country.

We consider that a set of principles and guidelines can help countries, especially those that are less developed, to establish or improve their national food control systems.

However, the current text does not seem to achieve this objective, as it does not contain in an ordered and clear manner the aspects that countries need to have to hand when establishing or improving their national food control systems. Given its current structure, the document is still a relatively preliminary text which will require much more work on its structure.

Nonetheless, Chile is of the opinion that the current text should be retained for Step 3.

COLOMBIA

Colombia congratulates Australia for the work done by the working group and submits the following comments and observations regarding the document CX/FICS 11/19/3 of July 2011.

PRINCIPLE 2 THE WHOLE FOOD CHAIN APPROACH

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

8. Un sistema nacional de control de los alimentos debería abarcar toda la cadena alimentaria - de la producción al consumo- es decir, los piensos, la producción primaria y la cosecha, **el procesamiento** ~~la elaboración~~, el almacenamiento, la distribución, el transporte, la venta, la importación y la exportación.

[Change to the Spanish only]

Grounds: Colombia requests that the word “elaboración” be replaced with “procesamiento” because the word used in the document relates to the last step in the chain when the consumer prepares the product for its final consumption.

PRINCIPLE 3 TRANSPARENCY

9. All aspects of a national food control system should be transparent and open to scrutiny by all interested parties, while respecting legal requirements to protect confidential information as appropriate. Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation and communication.

Comment: Colombia supports the proposal submitted by Mexico in that the wording of the principle be made sufficiently clear that it not allow for various interpretations.

PRINCIPLE 4 ROLES AND RESPONSIBILITY

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

Comment: Colombia requests that the relevance of including the “consumer” be discussed so that the principle is consistent with all the paragraphs.

PRINCIPLE 7 COOPERATION AND COORDINATION BETWEEN MULTIPLE COMPETENT AUTHORITIES

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

PRINCIPIO 7 COOPERACIÓN Y COORDINACIÓN ENTRE MÚLTIPLES AUTORIDADES COMPETENTES MÚLTIPLES

[Change to the Spanish only]

Comment: The word “múltiples” would be better placed to indicate that there are *multiple competent authorities*... Colombia considers that this change would make the title wording more consistent.

PRINCIPLE 10 RECOGNITION OF SYSTEMS [EQUIVALENCE]

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

Comment: Colombia considers that the approach to equivalence in our control systems requires greater discussion, given that food control systems include significant development in their ability to achieve the objectives.

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

21. El sistema nacional de control de los alimentos estará basado en la **estructura** ~~infraestructura~~ gubernamental o constitucional del país y sus instituciones (por eje. presencia o ausencia de gobiernos sub nacionales); y metas y objetivos nacionales.

[Change to the Spanish only]

Grounds: It is clearer to refer to government “estructura” [Translator’s note: “structure” rather than “infrastructure”].

22. Defining the roles and responsibilities of key participants in a national food control system is essential for ensuring the objectives are met efficiently and effectively and opportunities for duplication and gaps are minimised. For example, where different authorities in the same country have jurisdiction over different parts of the food chain, conflicting requirements must be avoided to prevent legal and commercial problems and obstacles to trade. Also, while provincial or state laws may exist there should be a competent authority at the national level capable of ensuring uniform application. [New Zealand]

22. Es esencial definir las funciones y responsabilidades de los principales participantes de un sistema nacional de control de los alimentos a fin de garantizar el cumplimiento eficaz y eficiente de los objetivos y minimizar la duplicación y **vacíos** ~~las lagunas~~. Por ejemplo: cuando en un mismo país haya distintas autoridades con jurisdicción sobre etapas diferentes de la cadena alimentaria, se deberían evitar los requisitos incompatibles a fin de prevenir problemas legales o comerciales y obstáculos al comercio. Asimismo, aunque hubiera leyes provinciales o estatales, la autoridad competente a nivel nacional debería tener la capacidad de asegurar una aplicación uniforme. [Nueva Zelanda]

[Change to the Spanish only]

24. The design and operation of a national food control system should follow a logical and transparent process. This should include the consistent application of a systematic framework for the evaluation and, ~~as necessary,~~ control of food safety risks associated with existing, new or re-emerging hazards. This food safety risk management framework should be based upon internationally agreed standards and guidelines and incorporate the following steps:

24. El diseño y la aplicación de un sistema nacional de control de los alimentos debería regirse por un proceso lógico y transparente. Ello debería incluir la aplicación coherente de un fundamento sistemático para la evaluación y, ~~de ser necesario,~~ el control de los riesgos en materia de inocuidad de los alimentos asociados a peligros existentes, nuevos y re emergentes. Dicho fundamento de gestión de riesgos en materia de inocuidad de los alimentos debería estar basado en normas y directrices acordadas en el ámbito a nivel internacional y debería incorporar las siguientes etapas:

Grounds: It is necessary to include control of safety risks in the application of the national food control system so that it does not become optional, ...

[And one change to the Spanish only]

Colombia suggests replacing “a nivel” by “en el ámbito”.

- identification, analysis and selection of possible risk management options;
- Identificación, análisis y selección de **posibles** opciones ~~posibles~~ de gestión de riesgos;

[Change to the Spanish only]

Grounds: The paragraph is more consistent with the wording “posibles opciones”.

29. Situational awareness means that a national food control system avails itself of accurate and current information on the entire food chain as a whole and its various parts and participants. [New Zealand] This information should include, but not be limited to:

- Through chain traceability;
- ~~Mediante la~~ **R**astreabilidad/rastreo a lo largo de la cadena;

[Change to the Spanish only]

Grounds: The word “mediante” does not refer to the information in the bullet point, so it is requested it be deleted.

30. Pro-activity means that a national food control system is capable of identifying existing or emerging hazards in the environment before they materialise as risks in the food production/processing chain and at the early stages rather than in the end product. Trends and changes in the production/processing methods should also be subject to monitoring to allow early detection of emerging risks. Early warning/rapid alert systems, traceability and contingency planning for managing and preparing for potential food safety incidents should be an inherent part of a pro-active control system. [EU/US leave in/Brazil Australia delete]

30. Pro actividad significa que un sistema nacional de control de los alimentos tiene la capacidad de identificar peligros existentes o emergentes en el medio ambiente antes de que se conviertan en riesgos para la cadena de producción/elaboración de alimentos, y abordarlos en sus etapas iniciales en lugar del producto final. Las tendencias y modificaciones a los métodos de producción/elaboración deberían ser objeto de control para permitir la detección temprana de riesgos emergentes. Un sistema de control proactivo debería **incluir** ~~comprender~~ como parte integral sistemas de prevención/alerta rápida, rastreabilidad y planes de contingencia a fin de gestionar y prepararse para posibles incidentes en materia de inocuidad alimentaria. [UE/EEUU retener el texto/Brasil, Australia, suprimirlo]

[Change to the Spanish only]

Comment: Colombia agrees with the EU/USA proposal to retain the paragraph but with the proposed replacement of the word “comprender” with “incluir” which we consider to be the correct word to indicate “inherent” in a proactive control system.

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

Comment: Colombia agrees with Australia's proposal to delete the paragraph as continuous improvement is included in paragraph 74.

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

33. El diseño de un sistema nacional de control de los alimentos juega un papel **importante** ~~importantísimo~~ ya que proporciona al sistema las características bosquejadas en la sección 4.1. [...]

[One change to the Spanish only]

Grounds: Colombia considers it is sufficient to indicate that the role is “importante” [Translator's note: translation of the English word “key”] and so requests that the “importantísimo” be deleted. Also, Colombia requests that “capability to learn” be replaced with “continuous improvement” in this paragraph and throughout the entire document.

34. When establishing a national food control system countries should identify the main objectives to be addressed through the system. The main objectives should be related to and assist in implementing the principles outlined in section 3. Control programmes help to ensure that inspection actions relate to objectives, since the results of these programmes can be assessed against the objectives set for the national food control system (principle 9). ~~More~~ specific operational objectives should be identified and aligned with the national objectives. Competent authorities should draw up control programmes based on precise objectives and appropriate risk analysis. [EU]

Grounds: The word “more” could be deleted from the paragraph without changing the meaning of the sentence.

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

Comment: For Colombia the scope of decision-making is not clear and so it requests the European Union to clarify this point for paragraph 35.

36. An appropriate system design should consider a range of factors ~~including (but not limited to)~~ **such as** product risk,...

Grounds: Colombia suggests replacing “including (but not limited to)” with “such as” as this improves the interpretation of the paragraph.

Legislation

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

38. La legislación debería proveer claridad con respecto a las funciones y responsabilidades de los participantes de la cadena alimenticia, en particular el gobierno central, la autoridad competente (o cada una de ellas en el caso de que hubiera más de una) y todo proveedor autorizado (en caso de utilizarse), y la industria. La legislación debería establecer los objetivos principales del sistema nacional de control de los alimentos y cualquier otro objetivo específico o secundario relativos a los participantes o sectores. Debería además proporcionar la autoridad o el fundamento para la formulación de normas y el establecimiento de controles adecuados a lo largo de todas las etapas de la cadena alimentaria, es decir, producción, **procesamiento manufactura**, importación, elaboración, almacenamiento, transporte, distribución y comercio.

[Change to the Spanish only]

Grounds: The word “procesamiento” [Translator’s note: used for the English “manufacture” here] is more appropriate for the paragraph text for which reason it is requested the word “manufactura” be deleted.

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

Programas de control Inspección Inspección [Australia]. El programa o programas de control deberían proporcionar un monitoreo continuo del sistema de control de los alimentos, **de la producción primaria al procesamiento a la manufactura** y transporte/distribución. [Uruguay propone suprimir transporte/distribución y sustituirlo con comercio minorista]

[And additional change to the Spanish only]

Grounds: Colombia suggests replacing “a la manufactura” with “de la producción primaria al procesamiento”, to improve the clarity.

[Translator’s note: Refer to paragraph 38 in which Colombia requested “procesamiento” be replaced with “manufactura” – no effect on the English]

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

- History of conformity of industry; and

Comment: Colombia requests clarification regarding the usefulness of history of industry and its focus.

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

Comment: Colombia considers that this paragraph should be deleted as its content is already included in paragraph 51.

Training

56. Training programmes should be designed to ensure that all inspectors, analysts, and other individuals carrying out technical/professional duties receive the training required to adequately perform their work assignments and to maintain their professional development. [Australia/Canada]

Comment: Colombia suggests deleting paragraph 56 because its content is already contained in paragraph 57.

61. Where appropriate, the national competent authority should utilize the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19/1995), the International Health Regulations (IHR), and the International Food Safety Authorities Network (INFOSAN), for national and international emergency notification and response. [Japan/Canada]

61. 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), y la Red internacional de autoridades de inocuidad de los alimentos para la notificación de emergencias y respuesta **a nivel** nacional e internacional (INFOSAN). [Japón/Canadá]

[Change to the Spanish only]

Grounds: Colombia considers that the words “a nivel” are unnecessary and do not change the meaning of the paragraph.

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

Comment: Colombia suggests deleting the word “processors” as they can be included in “producers”, and to include marketers who are part of the food chain and should be informed.

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

Grounds: The word “should” clarifies the notion of ‘allow’ in the text.

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

Grounds: Colombia considers that the word “duly” is more appropriate in the context of the paragraph than the word “promptly”.

Education

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

Comment: For clarification, Colombia requests Australia to explain what it means by “community relations”.

International Communication

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

67. La autoridad competente debería contar con mecanismos destinados a actuar recíprocamente con la comunidad internacional con respecto a las normas internacionales de inocuidad de los alimentos ~~como así también~~ **debería ser así como** mecanismos para tomar medidas en casos de problemas de inocuidad de los alimentos que planteen inquietudes ~~a nivel~~ **internacionales**. [Japón].

[Change to the Spanish only]

Grounds: Colombia considers that the words “a nivel” are not necessary and so suggests that the word “internacional” be replaced with “internacionales”. Additionally, Colombia suggests replacing “como así también” with “debería ser así como” to clarify the paragraph.

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

Grounds: Colombia requests replacing “capacity to learn” with “continuous improvement” to ensure the same usage throughout the document.

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

Grounds: Colombia requests that the second reference to food business operators be deleted.

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

80. La evaluación de la eficacia del sistema nacional de control de los alimentos debería estar dirigida a las etapas más apropiadas de la cadena alimentaria, sobre la base de un análisis de riesgo realizado de conformidad con metodologías aceptadas ~~a nivel~~ internacionalmente. [Australia]

[Change to the Spanish only]

Grounds: Colombia considers it sufficient to mention that the methods are accepted internationally and so suggests deleting “a nivel”.

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

Comment: Colombia considers that the paragraph should be deleted because its content corresponds to the scope of the national accreditation body so it is not necessary for it to be included in the document.

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

90. Las autoridades competentes deberían asegurar que los laboratorios designados participen regularmente de pruebas de capacidad. Dichas pruebas pueden organizarse ~~a nivel~~ nacional **o internacionalmente**. El laboratorio nacional de referencia puede jugar un papel en la organización de dichas pruebas. [UE]

[Changes to the Spanish only]

Grounds: Colombia considers it is not necessary to include the words “a nivel” in the text, and suggests adding the words “o internacionalmente”. This change does not affect the meaning of the paragraph.

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

Comment: The content of paragraph 95 is already included in paragraph 56; which is why Colombia suggested it be deleted as it is also repeated in paragraph 57.

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

Comment: This paragraph 96 is already included in paragraph 58; Colombia therefore suggests unifying their content as required.

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

97. La autoridad o autoridades competentes deberían asegurar la eficacia del sistema de respuesta a los incidentes de inocuidad alimentaria ~~y~~, evaluarlo regularmente ~~establecer~~ y establecer una clara comunicación entre la autoridad competente, la industria y los consumidores. [Australia]

[Changes to the Spanish only]

Grounds: The word “establecer” is repeated in the paragraph. Also, the word “y” is not necessary in the text.

Stakeholder Engagement

100. In order to promote consumer confidence in the safety and quality of their food, the competent authority should be clear and transparent in their communications relating to all aspects of the national food control system for which they are responsible (from parking lot) [Canada]

Comment: The content of this paragraph 100 is the same as paragraph 63. Please revise.

Education

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

Comment: Colombia suggests unifying this paragraph with paragraph 66.

4.4 CONTINUOUS IMPROVEMENT

Comment: Colombia agrees with the United States' proposal not to include a specific section regarding continuous improvement.

COSTA RICA

Costa Rica is grateful for the opportunity to make the following **Specific observations:**

With regard to PRINCIPLE 10, Costa Rica considers that the wording should be as follows:

RECOGNITION OF THE EQUIVALENCE OF FOOD INSPECTION SYSTEMS.

Paragraph 20. Competent authorities should recognise that food control systems although designed and structured differently (**measures, standards, regulations, systems and procedures**) may be capable of meeting the same objective and should be provided for in the national food control system

Justification: Equivalence is one of the instruments for facilitating trade applied by countries in their relations with their trading partners. To determine equivalence, it is necessary to establish the objective of a regulation or procedure in order to assess compliance through its mutual acceptance in accordance with the various approaches by the sectors and products involved.

With regard to inspection programmes, Costa Rica supports the proposal by Australia regarding continuous monitoring and suggests the following wording:

Control Programmes ~~Inspection~~—~~Inspection~~ Control Programme(s) should provide ongoing monitoring of the food control system from production through manufacturing, **storage** to transportation/distribution.

Grounds: Storage is an important stage in the food chain which should not be omitted from food inspection programmes.

3. Costa Rica proposes including in paragraph 43. The control programme (inspections, audits, visits) should cover, **although not limited be to,** as appropriate:

And delete from the 4th bullet point the word “minorista” [Not present in English], to read as follows:

- Means of transport, distribution chain, and retail.
- **Medios de transporte, cadena de distribución y comercio minorista.**

Grounds: The food inspection programme should be as broad as possible and not be limited to the points listed; so, although in agreement with the situations presented, the list could be extended.

Paragraph 44. Where **food** quality and **safety** assurance systems are used by industry, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade. The competent authority should encourage the use of a Hazard Analysis Critical Control Point (HACCP) approach by industry. [Aust]

Plus one change to the Spanish only: **[...La autoridad competente debería fomentar el uso del Análisis de Riesgos Peligros y de los Puntos Críticos de Control (HACCP) por parte de la industria. [Australia]**

Grounds:

*Safety is a fundamental aspect for consumer health protection and so should not be omitted.

*The correct [Spanish] translation of HACCP is **“análisis de peligros y puntos críticos de control”**.

Paragraph 54. Costa Rica proposes the following wording:

The number and location of the laboratories, including the use of private laboratories, should be determined in relation to the objectives of the system and the volume of work. If more than one laboratory is required, consideration should be given to apportioning the analytical work to achieve the most effective coverage of

the food analyses to be performed and also to having a central reference laboratory equipped for sophisticated and reference analyses. In case the establishment of domestic laboratories is not a feasible option, either official or private laboratories in other countries **authorised by the exporting country's competent authority** may be considered. In such cases same quality criteria, monitoring and audit arrangements should be in place as for domestic laboratories.

Grounds: It is important that the laboratories be equivalent to the exporting country's official laboratories and that in turn the competent authorities authorise them through official recognition procedures and regulations. It is counter-productive for laboratories without recognition by the exporting countries' authorities to issue results of an official nature given that they would generate procedures that do not equate with the final results.

Paragraph 56. Training programmes should be designed to ensure that all inspectors, analysts, and other individuals carrying out technical/professional duties receive the training required to adequately perform their work assignments and to maintain their professional development. [Australia/Canada]

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

Comment: These two items state the same thing; Costa Rica supports the proposal by Australia/Canada

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

4.4 CONTINUOUS IMPROVEMENT

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

Comment: Costa Rica agrees.

JAPAN

General Comments

1. Framework of the proposed draft GL

Japan supports the framework of Sections of the proposed draft GL which consists of 4 Sections, namely "Introduction," "Objective of a National Food Control System," "Principles of a National Food Control System" and "Framework for the Design and Operation of the National Food Control System".

However we have the view that modifications are needed for Subsection level. For sub-section 4.1., Japan proposes the deletion of Subsection 4.1. Para 29 should be transferred in para 32-bis. Para 30 should be transferred to the explanatory text under Principle 8 and para 31 should be transferred in the subsection "Continuous improvement".

With regard to Subsection 4.4, "Continuous Improvement," Japan prefers this Subsection to be placed separately from other Subsections as currently proposed. This structure would be more useful for those countries which have already established National Food Control System but need to enhance their systems.

Japan proposes the integration of the Plan -Do-Check-Act (PDCA) cycle concept, which is effective in the system management area in Section 4. Please find our proposed new structure below.

Current structure	Our proposals
SECTION 4.1 SYSTEM CHARACTERISTICS	Section 4.1 System Design (Plan)
SECTION 4.2 SYSTEM DESIGN	Section 4.2 IMPLEMENTATION OF THE SYSTEM (Do)
SECTION 4.3 ELEMENTS TO CONSIDER IN IMPLEMENTATION OF THE SYSTEM	Section 4.3 System Check
Section 4.4 CONTINUOUS IMPROVEMENT	Section 4.4 CONTINUOUS IMPROVEMENT (Act)

Regarding the new Section 4.3. and 4.4, we think that we do not need to elaborate texts for each element.

2. The order of the Principles (Section 3)

We propose the new order below.

New No	Principles	Previous number
1	Protection and consumers	1
2	The whole food chain approach	2
3	Incorporation of risk based, science based and evidence based decision making	6
4	Preventive measures	8
5	Transparency	3
6	Roles and responsibility	4
7	Consistency and impartiality	5
8	Cooperation and coordination between multiple competent authorities	7
9	Self assessment and review procedures to ensure it maintains its fitness for purpose	9
10	Recognition of system [equivalence]	10

Rationale: Considering the importance of the principle “Incorporation of risk based, science based and evidence based decision making (currently Principle 6),” we believe that this principle should appear after “Consumer protection” and “Food chain approach”. It should be noted that risk analysis principles are fundamental concept in the framework of the Codex.

The concept of “Preventive measures “ is also important by the following reason:

In order to reduce the risk of unsafe food and consequently to assure the safety and suitability of food, it is critical to take preventive measures to controlling food safety hazards at an appropriate stage in the operation.(Reference: RECOMMENDED INTERNATIONAL CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE (CAC/RCP 1-1969, Rev. 4-2003).

3. To make it simple and user-friendly

As similar paragraphs or elements appear in different parts of this proposed draft GL, Japan proposes to delete or merge the similar paragraphs to avoid the duplication and make this GL simpler and more user-friendly. Also, as some paragraphs or elements better match the different parts of the GL, we propose to move some paragraphs or elements across section or subsection.

Please refer to the Specific Comments below for the more detailed comments on specific texts in the proposed draft GL.

Specific Comments

Please find the following specific comments of which proposed insertion is underlined and proposed deletion is ~~struck-out~~. Number of paras should be reordered in accordance with our proposal.

In addition, regarding small explanation attached to the small sections under Subsection 4.2 and/or 4.3 (e.g, Compliance and Enforcement –“compliance and enforcement programmes to enforce laws and regulations to

achieve compliance”), Japan proposes to attach explanation to small sections only in Subsection 4.2. in order to avoid this inconsistency and duplication,

SECTION 3 PRINCIPLES OF A NATIONAL FOOD CONTROL SYSTEM

para. 13.

13. The competent authorities have the responsibility to monitor compliance with and enforce legal requirements. They also have the responsibility to establish and maintain up-to-date and science based legal requirements **as appropriate**, to ensure the effective operation of the national food control system.

Rationale: The proposed draft GL covers wide range of stages in the food chain from production to sales and it’s difficult for each Member to establish and maintain up-to-date and science based legal requirements at all stages. Hence each Member should address this issue based on its own priority.

PRINCIPLE 8 PREVENTIVE MEASURES and Pro-activity

Para 18.

18 To prevent or to react to food safety incidents a national food control systems should encompass the core elements of prevention, intervention and response. A national food control system should be able to identify existing or emerging hazards in the environment before they materialise as risks in the food production/processing chain and at the early stages rather than in the end product. Trends and changes in the production/processing methods should also be subject to monitoring to allow early detection of emerging risks. Early warning/rapid alert systems, traceability and contingency planning for managing and preparing for potential food safety incidents should be an inherent part of a pro-active control system.

Rationale: To explain principle 8, transferred from the old para 30.

para. 20.

Principle 10 RECOGNITION OF SYSTEM [EQUIVORENCE]

Rationale: The issue related to equivalency is already adequately covered by GL-34 and GL-53..

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

para. 25. This paragraph should be deleted in order to avoid duplication with para. 1 and 20.

para.26. This paragraph should be deleted.

Rationale: This sentence deals with a specific issue, which is not relevant in the introduction part of the Section 4. Detailed guidance on the Establishment of equivalence should be refer to GL-34 and GL-53.

SECTION 4.1 SYSTEM CHARACTERISTICS

para. 28.

~~28. A national food control system should possess three main characteristics which can be used in self-assessment or other evaluation to determine if the system is fully functional and effective:~~

Rationale: We think this para should be transferred to the section 4.3 System Check (para.104 bis) with some modification .

para. 29.

~~29. Situational awareness means that a national food control system avails itself of accurate and current information on the entire food chain as a whole and its various parts and participants. [New Zealand] This information should include, but not be limited to:~~

- ~~• Statistical data on production, trade and consumption~~
- ~~• Knowledge of operators at various stages of the food chain;~~
- ~~• Typical and atypical use of products, raw materials and by products;~~
- ~~• Structure of production and supply chains;~~
- ~~• Production technologies, processes and practices;~~

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

Rationale: We think the situation awareness could be a part of “system design”, therefore this para should be transferred to the section System Design. (transferred to para 32 bis)

para. 30.

~~30. Pro active means that a national food control system is capable of identifying existing or emerging hazards in the environment before they materialise as risks in the food production/processing chain and at the early stages rather than in the end product. Trends and changes in the production/processing methods should also be subject to monitoring to allow early detection of emerging risks. Early warning/rapid alert systems, traceability and contingency planning for managing and preparing for potential food safety incidents should be an inherent part of a pro active control system. [EU/US leave in/Brazil Australia delete]~~

Rationale: To explain the principle 8, this sentence should be re-located under the principle 8 (para. 18.) as explanatory texts.

para. 31.

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

Rationale: We think this paragraph could be better fitted under the Capability to learn [Continuous Improvement] section, therefore this para should be transferred to the section 4.4 (para.105.) with modifications.

SECTION 4.1.2 SYSTEM DESIGN (Plan)

para. 32.

32. The design of an effective national food control system requires a P(plan)-D (Do)-C (Check)-A(Act) ~~continuous planning monitoring review~~ cycle, which is necessary to ensure that the system continues to deliver what is expected (principle 9 of this document). Successful implementation of the principles in section 3 requires that mechanisms to deliver according to those principles which are built into the design of the system (rather than added as an afterthought).

Effective implementation of all of the 10 principles depends on the combined effect of a number of components including: legislative foundation, allocation of resources, staff competence and training, laboratory network, verification of compliance, enforcement, surveillance, investigation, response, stakeholder engagement, international communication and harmonisation, assessment and evaluation. [EU]

Rationale: To introduce the PDCA cycle concept

32-Bis (old 29). Before initiating the system design, “Situational awareness” should be conducted. In this document, “Situational awareness” means that a national food control system avails itself of accurate and current information on the entire food chain as a whole and its various parts and participants. [New Zealand] This information should include, but not be limited to:

- Statistical data on production, trade and consumption
- Knowledge of operators at various stages of the food chain;
- Typical and atypical use of products, raw materials and by-products;
- Structure of production and supply chains;
- Production technologies, processes and practices;

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

Rationale: Situational awareness is the first step of the National Food Control System design.

para.33

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

Rationale: Wordings “ [t]he design of a national...in section 4.1.” should be deleted in accordance with the modifications on Subsection 4.1.

para. 36.

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

Rationale: More related to” design“ stage

Legislation

para. 38.

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

Rationale: More related to” design“ stage

Control Programmes

para.39.

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

Rationale: old para 75 describes an issue which should be addressed at the “design” stage, rather than the “implementation“stage.

para.43.

43-bis. The methods and techniques of a control programme should be designed to be appropriate to meet the objectives including, as appropriate:

- inspection of premise and processes for compliance with hygienic and other requirements of standards and regulations;
- evaluation of HACCP plan and its implementation
- sampling and analysis of food during harvest, processing, storage, transport, or sale to establish compliance, to contribute data for risk assessments and to identify offenders;;
- checks on hygiene, including personal hygiene and clothing;
- examination of written and other records;
- examination of the results of any verification systems operated by the establishment;

- audit of establishments by the national competent authority;
- national audit and verification of the control programme.

Rationale: These elements are listed in para 26 of the GL-26, so as the design stage of the control programme, the methods and techniques should be elaborated to meet the objectives of the national food control system.

Compliance and Enforcement

para.50.

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

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

Rationale: add the action to be taken in serious cases

4.12.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING ETC)

para.51. As para.94 partially provide similar aspect, we propose to combine paras.51 and some parts of 94.

51. The competent authorities and authorised providers should have, **or have access to**, adequate resources available, including personnel (**e.g. inspectors lab analysts, auditors**), funding, laboratories, equipment and other infrastructure to support an effective national food control system which meets the objective. **Qualified personnel should come from areas such as food science and technology, chemistry, biotechnology, microbiology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit and law.** [Australia also covers Mexico suggestions]

Rationale: To clarify the scientific background of the personnel involved.

para.53.

53-bis. Reliable transportation and communication systems should be designed between inspection programme staffs and laboratory personnel to transmit samples to laboratories without any adverse effects to the samples and analytical results (e.g. avoid delay between sampling and analysis).

Rationale: Good communication between inspection programme and lab personnel is important to get the reliable analytical results. Therefore the reliable transportation and communication systems should be designed between the two parties.

para.54.

54-bis. During the design process of laboratory analysis activities, considerations should be given to make sure the following activities to be carried out:

- Identifying contaminated foods/emergency food contamination events.
- Identifying the source of an outbreak of foodborne disease.
- Allowing regulators to bring enforcement action against adulterated and unsafe food.
- Confirming the safety of domestic food products as well as exports and imports.
- Allowing for dietary exposure assessments.
- Allowing consumer organizations and food processors to monitor and analyze the food quality at the user end.
- Assist in the regulatory decision making process and evaluate the effectiveness of risk management interventions.

Rationale: Laboratory activities should be designed in order to achieve important activities as listed.

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

Rationale: See second paragraph of preamble of specific comments

para.60. As the last sentence of para.99. describes “design” rather than “implementation,” the last sentence of para.99. should be moved to para.60. and placed as item c).

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

a) Surveillance and Investigation:

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

b) Review and Response:

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

c) Administrative procedures or contingency plans

(as appropriate) guidance on initiating coordination mechanisms when involvement of several competent authorities is required to resolve the incident

Rapid alert systems

⇒ **d) Documentation:**

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

Stakeholder Engagement and Communication

para.64.

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

Rationale: Old para 101 describes an issue to be addressed at the “design” stage, rather than the “implementation“ stage.,

International Communication

para.68.

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

Rationale: Since foods or ingredients may travel through the third countries before they reach direct trading partners, the design and operation of national food control system should be transparent not only to direct trading partners but to all countries concerned.

SECTION 4.2.3 ~~ELEMENTS TO CONSIDER IN IMPLEMENTATION OF THE SYSTEM~~ (DO)

para.70. Delete first sentence of para.70. in accordance with proposed modification on Subsection 4.1.

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

Legislation

para.71. This paragraph should be moved to new Section 4.1 after para.38.

para.74. This paragraph should be deleted in order to avoid duplication..

Control Programmes

para.75. This paragraph should be moved to new Section 4.1. after para.39.

paras. 78 to 81. These paragraphs should be moved to new Section 4.3.

para.83. This paragraph should be deleted in order to avoid duplication with para.20.

para.85. This paragraph should be deleted in order to avoid duplication with para.50. .

4.23.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING ETC)

para.92. This paragraph should be moved to new Section 4.1. after para.36.

para.94.

94. Competent Authorities should **maintain** ~~have, or have access to,~~ a sufficient number of qualified personnel as appropriate. [EU] Personnel should have access to adequate facilities, equipment and other resources to operate the national food control system. [Japan/Mexico]

Rationale: To make sure Competent Authorities should continuously maintain a sufficient number of qualified personnel during implementation stage.

Training

para.96. word “developed” should be deleted to avoid duplication with para.58.

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

para.98.

98. The competent authority(ies) should utilize information gained from the surveillance of foodborne illness as a risk management tool in the operation of their food control systems. Food recalls and adjustments to food production and processing operations , including emergency responses, may be based on information obtained from foodborne disease information **and food monitoring system.** [US]

Rationale: Food recalls could be initiated based on the food monitoring data.

98-bis. The competent authority(ies) should establish or strengthen early warning systems to allow rapid detection of contamination incidents to ensure prompt public alerts.

Rationale: This text is inserted from the FAO/WHO Guidelines for consumer organizations to promote National Food Safety System. page 6 .3rd para.

98-ter. The competent authority(ies) should promote dialogue and collaboration among human health, veterinary and food-related surveillance and investigations , with the view toward an integrated effort of foodborne risk reduction along the whole food-production chain in order to quickly indicate food safety problems and/or to identify the source of the problems.

Rationale: This concept is recommended by WHO World Health Assembly new resolution on food safety: Advancing food safety initiatives ([WHA63.3](#)).

para.99. the last sentence should be moved to para.60.

99. The competent authority should ensure that sufficient guidance, training and awareness programmes targeted at all relevant stakeholders are in place to facilitate effective notification of suspect cases of food

related illnesses or health hazards detected in the food chain. ~~Administrative procedures or contingency plans (as appropriate) should provide guidance on initiating coordination mechanisms when involvement of several competent authorities is required to resolve the incident. Rapid alert systems should be designed and implemented for this purpose.~~[EU]

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

Stakeholder Engagement (including consumers and food industry)

para.100.

100. In order to promote ~~consumer~~ confidence of stakeholders in the safety and quality of their food, the competent authority should **maintain transparent communications with them** ~~be clear and transparent in their communications~~ relating to **implementation** ~~all aspects~~ of the national food control system for which they are responsible (from parking lot) [Canada]

Rationale: to clarify the para deals with ongoing communication during the implementation stage.

para.101. This paragraph should be moved to new Section 4.1 after para.64.

para.102.

102-bis. On-going training in specific skills, such as communication, and technical capacity building for inspectors, laboratory personnel, scientists, consumer organizations, and the food industry should be designed to ensure that existing inspection programs are prepared to handle emerging hazards and to integrate new technologies to reduce hazards.

Rationale: WHO/FAO Guidelines for Consumer Organizations to Promote National Food Safety Systems, page 13, Last para modified

102-ter. In order to deliver information, education and advice to stakeholders across the food chain, the following activities should be established:

- Provision of balanced factual information to consumers
- Information packages and educational programmes for officials and workers in the food industry
- Train the trainer programmes,
- Provision of reference literature to extension workers in agriculture and health sectors.

Rationale: FAO Food and Nutrition Paper 76, page 9, (e) 1st para, modified

International Communication

para.104.

104. As appropriate, the competent authority should:

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

Rationale: 1st and 2nd bullet: as same rationale provided in para.68, the 3rd bullet: to provide practical examples of the international communication programme.

4.3 System Check (evaluating the results)

104-bis (old 28 and 106). A national food control system should possess capabilities of self-assessment or other evaluation to determine if the system is fully functional and effective. The Competent authority(ies) should analyze the effects of the national food control systems by comparing the data/information gained through the implementation of the national food control system to the baseline data to determine whether the

national food control systems were achieved the intended target. The examples of the activities performed are:

- Comparison of the results and data gained through the implementation of the national food control system against the measurable pre-determined targets. Data and information source could include (but not limited to), control programme data, non-compliances, food safety incidents, scientific research, history of conformance, external and self-reviews of the system, changes to product risk or the production environment.
- Documentation of lessons learned, knowledge gained, and any surprising results that emerged.
- Determination of the potential causes of a problem in the system
- Selection of the most probable underlying cause or causes
- Development of plan(s) to eliminate the root cause or reduce the effects to an acceptable level.

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

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

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

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

Rationale: These paragraphs are related to system check.

4.4 CONTINUOUS IMPROVEMENT (ACT)

105 (old 31). A national food control system should have mechanisms in place to continuously improve the system design reflecting the results of the evaluation . A national food control system should also have mechanisms to adapt to changes in the production/processing environment, and respond and intervene where/as required at the appropriate point in the food chain. [NZ leave with edits EU/US leave in/ Australia delete]

105-bis (old 105). A national food control system should be continuously improved to reflect changes in product risk, the production environment (including technology), increased scientific knowledge, and level of confidence in industry, to ensure the objective of the national food control system is met in an efficient and effective manner. [Australia] These changes may also require amendments to legislation; changes to control programmes and/or laboratory practices.

Rationale: These paragraphs are related to continuous improvement.

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

Rationale: transferred to the section 4.3 Check (new 104-bis) with modifications.

KENYA

Kenya would like to extend its appreciation and thanks to the working group led by Australia for the good work to come up with the documents to be commented on now.

SECTION 1 INTRODUCTION

1. This document is intended to assist ~~the~~ national governments, and their competent authority(ies) in the development, operation and improvement of national food control system.

Rationale: This is to make flow.

2. While the focus of the *Principles and Guidelines for National Food Control Systems* is on the production, **processing**, storage, ~~transport~~ **distribution** and sale of foods within national borders,----

Rationale: We propose to add the word 'processing and distribution' to cover the whole food chain

PRINCIPLE 2 THE WHOLE FOOD CHAIN APPROACH

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

Rationale: The deleted statement is already covered so it is a repetition.

PRINCIPLE 3 TRANSPARENCY

9. ...Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation, **consultation** and communication.

Rationale: Kenya feels that there is need to consult regionally and internationally to come up with effective system and for transparency purposes.

PRINCIPLE 4 ROLES AND RESPONSIBILITY

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

PRINCIPLE 8 PREVENTIVE AND INTERVENTION MEASURES

18. To prevent or to react to food safety incidents a national food control systems should encompass the core elements of prevention, intervention and response.

PRINCIPLE 9 SELF ASSESSMENT AND REVIEW PROCEDURES TO ENSURE IT MAINTAINS ITS FITNESS FOR PURPOSE

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

PRINCIPLE 11: ADEQUATE MEANS AND RESOURCES

National food control systems should have sufficient resources, including facilities, personnel and funding to carry out their responsibilities.

Rationale: Add principle 11

PRINCIPLE 12: EXTERNAL ASSESSMENT AND REVIEW PROCEDURES TO ENSURE IT MAINTAINS ITS FITNESS FOR PURPOSE

The national food control system should be open to third party assessment to ensure competence.

Rationale: Add principle 12

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

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

Rationale: We propose to delete paragraph 25 because it is a repetition of section 27

26. The national competent authorities should consider undertaking arrangements with other countries national competent authorities, including the establishment of equivalence agreements, in order to make efficient use of their own resources. [EU] **‘The two guidelines to be used are CAC/GL 53-2003 guidelines on the judgement of equivalence on sanitary measures associated with CCFICS and SPS Agreement and CAC/GL 34 :1999 guidelines for development of equivalence agreement regarding food CCFICS’**

Rationale: We propose to add the titles of the two codex standards in the text since referencing to these standards are crucial.

SECTION 4.1 SYSTEM CHARACTERISTICS

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

Rationale: Kenya recommends this to be a stand-alone section (4.1) and add the word ‘third party’

29. Situational awareness ~~means~~ that a national food control-.....

30. Pro-activity ~~means~~ that a national food control system is capable of identifying existing or emerging hazards in the environment before they materialise as risks in the.....

31. ~~Capability to learn~~ [Continuous Improvement] ~~means~~ that a national food control system has mechanisms in place to.....

SECTION 4.2 SYSTEM DESIGN

General guidance on applying the principles

34. When establishing a national food control system countries should identify the **specific operational** ~~main~~ objectives to be addressed through the system. ~~These main~~ objectives should be related to and assist in implementing the principles outlined in section 3. ~~Control programmes help to ensure that inspection actions relate to objectives, since the results of these programmes can be assessed against the objectives set for the national food control system (principle 9). More specific operational objectives should be identified and aligned with the national objectives. Competent authorities should draw up control programmes based on precise objectives and appropriate risk analysis. [EU]~~

Rationale: We replaced the word ‘main’ with ‘specific operation’ since all the operations are specific and the main ones were not mentioned in the text.

Legislation

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

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

Rationale: Inspection is part of control programme

39. When designing a control programme competent authority(**ies**) should ensure that the objectives of the national food control system is addressed,

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

- Establishments, installations, equipment and material
- Products, from raw material to the final products, including intermediate products.
- Process: **Monitoring**, evaluation and verification of GMP, HACCP.

- Means of ~~transport, distribution chain, and retail.~~
- Human resources **and** ~~confidentiality capabilities, skills, expertise, etc.~~

Rationale: Transport and retail are part of the distribution chain.

4.2.1 RESOURCES (INCLUDES LABORATORIES, STAFF PERSONNEL, TRAINING ETC)

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

Laboratories

52. Feed and food control laboratories are an essential part of a national food control system. Analysis of food samples for physical, chemical and ~~microbiological~~ contamination is important.....

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

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

55. Bis. PERSONNEL

Personnel

55-bis. National food control systems should have or have access to sufficient number of qualified personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, veterinary science, human medicine, epidemiology, parasitology, agronomic engineering, quality assurance, audit and food law.

Training

58. Programmes and training manuals should be developed to ensure consistent application of requirements and uniform application of the national food control system. **The elements of the program include:**

FUNDING

58 bis. The design and operation of a food control system should have a provision for adequate funding by the government.

EQUIPMENT

58 bis, bis. The National food control systems should ensure the appropriate equipment is available and well maintained.

SECTION 4.3 ELEMENTS TO CONSIDER IN IMPLEMENTATION OF THE SYSTEM

[EU proposal] General guidance on applying the principles

69.without overlooking any essential stages in the feed and food chain (Principle 2). **National food control systems should have sufficient resources, including facilities, personnel and funding to carry out their responsibilities'. The national food control system should be open to third party assessment to ensure competence' respectively.**

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

4.4 CONTINUOUS IMPROVEMENT

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

MEXICO

General comments

Mexico recognises the significant work done by the working group led by Australia and is grateful for the opportunity to make the following comments regarding CX/FICS 11/19/3 “Proposed Draft Principles and Guidelines for National Food Control Systems”

Mexico emphasises that significant progress has been made in compiling the document, however, given that the chapters (Legislation, Inspection Programmes, Assessment and Evaluation, Compliance Programmes and Measures, etc.) in Sections 4.2. System Design and 4.3 Implementation are repeated and that in general there are no substantial differences between the texts regarding the System Design and the System Implementation defining any clear distinction between the two sections, it is considered that the chapters in these two sections could be combined into a single section 4.2. “System Design and Implementation”. The consolidation of these sections would lessen the possibility for confusion while retaining the relevant components of each of the chapters.

Additionally, Mexico suggests several changes to the wording of the document in Spanish to maintain consistency with the English text. We have only included the texts that would change sections or for which linguistic or wording changes are made.

Specific comments

SECTION 1 INTRODUCTION

2. Si bien los *Principios y directrices para los sistemas nacionales de control de los alimentos* hacen hincapié en la producción, el almacenamiento, el transporte y la venta de alimentos en el mercado nacional, el presente documento guarda coherencia **y debería leerse conjuntamente** con otros textos del Codex, ~~los cuales deberían leerse~~, en particular...

2. While the focus of the *Principles and Guidelines for National Food Control Systems* is on the production, storage, transport and sale of foods within national borders, the document is consistent with and should be read in conjunction with other related Codex texts, in particular...

Rationale: Spanish wording.

SECTION 3 PRINCIPLES OF A NATIONAL FOOD CONTROL SYSTEM

PRINCIPLE 3 TRANSPARENCY

9. Todos los aspectos del sistema nacional de control de los alimentos deberían ser transparentes y ~~podrían ser objeto de~~ **abierto** al escrutinio de todas las partes interesadas sin perjuicio del respeto a los **requerimientos legales** ~~la legislación que~~ **protege** ~~gobierna~~ la confidencialidad de la información, según corresponda. La transparencia se aplica a todos los participantes de la cadena alimentaria y puede lograrse mediante una documentación clara y una buena comunicación.

All aspects of a national food control system should be transparent and open to scrutiny by all interested parties, while respecting legal requirements to protect confidential information as appropriate. Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation and communication.

Rationale: Spanish wording.

PRINCIPLE 4 ROLES AND RESPONSIBILITY

12. También incumbe a los consumidores gestionar los riesgos de inocuidad de los alimentos bajo su control, **y donde sea relevante** ~~deberían, además,~~ recibir información sobre la manera de lograrlo.

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

Rationale: Spanish wording.

13. Incumbe a las autoridades... Asimismo, tienen la responsabilidad de establecer y mantener **actualizados** los requisitos legales ~~actualizados~~, basados en la ciencia, para asegurar el **efectivo** ~~buen~~ funcionamiento del sistema nacional de control de los alimentos.

13. The competent authorities have the responsibility to monitor compliance with and enforce legal requirements. They also have the responsibility to establish and maintain up-to-date and science based legal requirements, to ensure the effective operation of the national food control system.

Rationale: Spanish wording.

14. Las instituciones académicas... ya que constituyen una fuente de conocimientos que respaldan el fundamento científico y **basado en riesgo** ~~en base al~~ riesgo de dichos sistemas.

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

Rationale: Spanish wording.

PRINCIPLE 5 CONSISTENCY AND IMPARTIALITY

15. Todos los aspectos del sistema... y todos los participantes que cumplan funciones oficiales deben desempeñar sus obligaciones libres de toda interferencia impropia o **indebida** ~~excesiva~~ o conflicto de interés.

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

Rationale: Spanish wording.

PRINCIPIO 6 INCORPORACIÓN DE TOMA DE DECISIONES BASADAS EN EL RIESGO, LA CIENCIA Y LAS EVIDENCIAS PRUEBAS

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

Rationale: Spanish wording.

16. Las decisiones que tomen las autoridades competentes con respecto a un sistema nacional de control de los alimentos deberían estar basadas en información científica, **evidencias** ~~pruebas~~ y/o principios de análisis de riesgos³, según corresponda.

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

Rationale: Spanish wording.

PRINCIPIO 7 COOPERACIÓN Y COORDINACIÓN ENTRE MÚLTIPLES AUTORIDADES COMPETENTES MÚLTIPLES

17. Las autoridades competentes... evitar la duplicación/**vacíos** ~~de información~~ y facilitar el intercambio de información.

PRINCIPLE 7 COOPERATION AND COORDINATION BETWEEN MULTIPLE COMPETENT AUTHORITIES

17. The competent authorities [...] in order to avoid duplication/gaps and to facilitate information exchange.

Rationale: Spanish wording.

PRINCIPIO 10 RECONOCIMIENTO DE LOS SISTEMAS [EQUIVALENCIA]

20. Las autoridades competentes... y estructuras diferentes y ello debe **considerarse** ~~contemplarse~~ en el sistema nacional de control de los alimentos.

PRINCIPLE 10 RECOGNITION OF SYSTEMS [EQUIVALENCE]

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

Rationale: Spanish wording.

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

21. El sistema nacional de control de los alimentos estará basado en la ~~infra~~estructura gubernamental o constitucional del país y sus instituciones (por eje. presencia o ausencia de gobiernos sub nacionales); yen sus metas y objetivos nacionales.

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

Rationale: Spanish wording.

22. Es esencial definir las funciones... y minimizar la duplicación y vacíos ~~las lagunas~~. Por ejemplo: cuando en un mismo país haya distintas autoridades con jurisdicción...

22. Defining the roles and responsibilities [...] and gaps are minimised. For example, where different authorities in the same country have jurisdiction...

Rationale: Spanish wording.

23. La autoridad competente tiene un papel fundamental en el sistema nacional de control de los alimentos. A saber:

- establece, implementa, verifica, administra ~~gestiona~~ y examina el sistema nacional de control de los alimentos;
- avanza/estimula ~~promueve/fomenta~~ el conocimiento, la ciencia, la investigación y la educación en materia de inocuidad de los alimentos. [Nueva Zelandia]

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

[...]

- develops, implements, monitors, manages and reviews the national food control system;

[...]

- advances/fosters knowledge, science, research and education regarding food safety. [New Zealand]

Rationale: Spanish wording.

24. El diseño y la aplicación de un sistema... Ello debería incluir la aplicación coherente de un mecanismo ~~fundamento~~ sistemático para la evaluación y, de ser necesario, el control de los riesgos en materia de inocuidad de los alimentos asociados a peligros existentes, nuevos y re-emergentes. Dichos mecanismos ~~fundamentos~~ de gestión de riesgos... y debería incorporar las siguientes etapas:

- actividades preliminares de evaluación (no citado en inglés) riesgo, incluida la identificación y caracterización del riesgo, y la jerarquización ~~o dar grado de priorización~~ del riesgo a fin de considerar la gestión del riesgo;

• actividades de comunicación de riesgos con todas las partes interesadas.

24. The design and operation of a national food control system should follow a logical and transparent process. This should include the consistent application of a systematic framework for the evaluation and, as necessary, control of food safety risks associated with existing, new or re-emerging hazards. This food safety risk management framework should be based upon internationally agreed standards and guidelines and incorporate the following steps:

- preliminary risk activities, including identification and characterisation of the risk and ranking or prioritisation of the risk for risk management consideration;

[...]

- **risk communication activities involving all interested parties**

Rationale: Spanish wording and proposed new bullet point.

27. Por lo tanto, cada país puede tener un sistemas diferentes de control de los alimentos, diseñados, implementados y sujetos a mejora continua, y aplicando los principios mencionados anteriormente para lograr el objetivo.

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

Rationale: Spanish wording.

SECTION 4.1 SYSTEM CHARACTERISTICS

Australia proposes incorporating this section into the body of section 4.

28. Un sistema nacional de control de los alimentos debería tener tres características principales que pueden ser utilizadas en autoevaluaciones u otros tipos de evaluaciones destinadas a determinar su pleno funcionamiento y su eficacia: **conciencia situacional, pro-actividad y capacidad de aprendizaje (y convertir 29, 30 y 31 en a, b y c, o en viñetas)**

~~29-a)~~ Conciencia ~~ión~~ situacional significa que un sistema nacional de control de los alimentos dispone de ~~comprende~~ información precisa y actualizada sobre toda la cadena alimentaria, sus componentes y participantes. [Nueva Zelanda]. Esta información debería incluir, aunque no restringirse, a lo siguiente:

- ~~Mediante~~ **Rastreabilidad/rastreo (not in the English version)** a lo largo de la cadena;

~~30-b)~~ Pro actividad significa... antes de que se conviertan en riesgos para la cadena de producción/elaboración de alimentos, y **abordarlos (not in the English version)** en sus etapas iniciales...

~~31-c)~~ Capacidad para aprendizaje ~~y~~ {mejora continua} significa...

28. A national food control system should possess three main characteristics which can be used in self-assessment or other evaluation to determine if the system is fully functional and effective: **situational awareness, pro-activity and capacity to learn (and change 29, 30 and 31 into a, b and c or bullet points)**

~~29-a)~~ Situational awareness means that a national food control system avails itself of accurate and current information on the entire food chain as a whole and its various parts and participants. [New Zealand] This information should include, but not be limited to:

- Through chain traceability; **[Spanish claims not in the English version, but it is]**

~~30-b)~~ Pro-activity means that [...] before they materialise as risks in the food production/processing chain and **deal with them** at the early stages...

~~31-c)~~ Capability to learn [Continuous Improvement] means ...

Rationale: Spanish wording and contextualisation of the three characteristics in paragraph 28 in which they are already quoted.

The Spanish version includes text that does not appear in the English version. It is suggested the two versions be harmonised. Additional new text.

SECTION 4.2 SYSTEM DESIGN AND IMPLEMENTATION

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

General guidance on applying the principles

Rationale: structure that improved comprehension and avoid chapters and repeated text. Referred to in the general comments.

32. El diseño de un efectivo sistema nacional de control de los alimentos exige in ciclo continuo de planeación-control-revisión, necesario para garantizar que el sistema sigue suministrando lo esperado (principio 9 del presente documento). La implementación efectiva de los principios de la sección 3 exige que los mecanismos se incorporen al ~~diseño del sistema~~ **de acuerdo a esos principios, dentro del diseño del sistema** (y no **como** un agregado ~~de~~ último momento) ~~de acuerdo a los principios~~. La efectiva implementación de los diez principios depende del efecto conjunto de una serie de componentes. A saber: Fundamento legislativo, distribución de recursos, competencia y capacitación del personal, red de laboratorios, verificación de cumplimiento, ~~vigilar~~ **medidas de cumplimiento**, vigilancia, investigación **y respuesta en incidentes relacionados con inocuidad alimentaria**, compromiso de las partes interesadas, comunicación internacional y armonización, verificación y evaluación **del sistema**. [UE]

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

Rationale: Spanish wording. Alignment of the actions of surveillance, investigation, and response in accordance with the corresponding chapter. New text.

33. El diseño de un sistema nacional de control de los alimentos juega un papel ~~clave~~ **importantísimo** ~~y a~~ **que** ~~al~~ proporcionar al sistema las características bosquejadas en la sección 4.1. El procesamiento y análisis de datos recabados mediante controles oficiales es esencial para la conciencia ~~de~~ **situación** (29). La recopilación de datos y la capacidad analítica del sistema nacional de control de los alimentos determina el grado de proactividad que demostrará el sistema (principio 8). La capacidad de aprender depende de la ~~eficacia y prontitud del resultado~~ **efectividad y oportunidad de la retroalimentación** de las evaluaciones y exámenes ~~a utilizarse en los procedimientos~~ **del proceso** de diseño o ~~de re-~~ **diseño** ~~ulterior~~. [UE]

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

Rationale: Spanish wording.

35. Decision-making...

Comment: Requires clarification with regard to the scope of decision-making: For the system design? For the implementation of the inspection programmes? For the implementation of compliance programmes? For the implementation of compliance measures? Depending on the scope, the text needs to be aligned and placed in the corresponding chapter.

36. Un diseño adecuado del sistema debería considerar una serie de factores incluidos s pero no limitados s al riesgo planteado por el producto...

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

Rationale: Spanish wording.

69. Effective implementation of control programmes requires that all staff are fully aware of what is expected from them (Principle 4) and have objectives clearly communicated to them, have the necessary knowledge and skills to carry out their tasks and that they have the necessary resources (human, material and financial resources) available to carry out their tasks. Recruitment and training policies as well as documented procedures are necessary to maintain a high level of consistency (Principle 5). Effective

cooperation and coordination (Principle 7) may require regular communications – or other coordinating mechanisms – between competent authorities in order to prevent emerging threats (Principle 8) and ensures full coverage of all relevant risks (Principle 6) without overlooking any essential stages in the feed and food chain (Principle 2).

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

37. Al diseñar o **re**-diseñar un sistema...

37. In designing or redesigning...

Rationale: Spanish wording.

Legislation

38. La legislación debería proveer... la autoridad competente (o cada una de ellas en el caso de que hubiera más de una) y todo proveedor **de tercera parte oficialmente reconocido** ~~autorizado~~ (en caso de utilizarse), y la industria...

38. Legislation should provide [...] the competent authority (or of each competent authority where there is more than one) and any **third party providers as officially recognised bodies** ~~authorised~~ providers (where these are used), and industry...

Rationale: Use of terminology in accordance with para. 8 de CAC/GL 47-2003.

72. Se debería proporcionar orientación e instrucciones para interpretar los requisitos legislativos relativos a los operadores de la industria alimentaria a todo el personal de control y los operadores de la industria de manera de garantizar una aplicación uniforme de la legislación. Por ejemplo: ~~no siempre son obvios los requisitos legislativos referentes a la autorización de los establecimientos de producción de alimentos, es~~ **típicamente una actividad donde los requerimientos legales no siempre explican por sí mismos** ~~aunque sea una actividad típica~~ y, por lo tanto, requieren una orientación de tipo práctico para que la aplicación de la legislación sea eficaz y uniforme.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

Programas de control~~Inspección~~~~Inspección~~ [Australia].

n.-El programa o programas de control deberían proporcionar un monitoreo continuo del sistema de control de los alimentos, de la producción a la manufactura, ~~y~~ transporte/ distribución **y comercio mayorista y minorista** [Uruguay propone suprimir transporte/distribución y sustituirlo con comercio minorista]

Control Programmes ~~Inspection~~~~Inspection~~ [Australia]

n.-Control Programme(s) should provide ongoing monitoring of the food control system from production through manufacturing to transportation/distribution **and large and small retail** . [Uruguay proposed to delete transportation/distribution and replace with retail].

Rationale: Mexico prefers the use of “Control Programmes”, a concept widely used in CAC/GL 26-1997 and which includes inspection activities. Leave the title and the descriptive text but as a separate paragraph. Also Spanish wording.

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

Rationale: Flexibility with regard to the frequency and nature should be placed alongside the control program tools.

42. Al establecer los programas de control se deberían considerar otros factores. A saber:

- La eficacia y la fiabilidad de ~~sus propios~~ **los auto**controles;

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

[...]

- The effectiveness and reliability of own controls

Rationale: Spanish wording.

43. The control programme (inspections, audits, visits **and samplings**) should cover...

Rationale: Include samplings as they are applicable to the second sub-paragraph (products)

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

Verificación y evaluación del sistema ~~(cómo título)~~ Según corresponda, evaluaciones, auditorías, inspecciones u otros instrumentos para evaluar la eficacia del programa de control de los alimentos.

Assessment and evaluation of the system – (as a title) ~~As appropriate, assessment, audits, inspections or other tools to evaluate the effectiveness of the food control programme, including the recognition of trends.~~

Rationale: As the assessment and evaluation refer to the system, and not to the activities of assessing the economic operators' establishments, quoted in other chapters (Control Programmes, Compliance Measures and Programmes). As a consequence, Mexico prefers the proposed title.

45. The system design should provide for the capability to evaluate **through visits, audits, inspections or other instruments**, the effectiveness of control programmes in the national food control system, including ongoing data collection. [Aus]

Rationale: Improve the structure by adding the text “Assessment and evaluation of the system” as a title and the additional text by joining it together in para. 45.

46. A national food control system should have mechanisms in place to continuously update, review and analyse the ~~above-mentioned~~ information **mentioned in paragraphs 42/43 (?)**...

Rationale: State to which information the paragraph refers (para. 42/43?)

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

Programas de Cumplimiento y medidas de cumplimiento – (como título)

n.- El diseño de un sistema nacional de control de alimentos debería considerar programas de cumplimiento y medidas de cumplimiento a fin de asegurar el cumplimiento **la observancia** de leyes y reglamentos.

Compliance and enforcement programmes and measures (as a title)

n.- The design of a national food control system should consider compliance programmes and measures to enforce **observance of** laws and regulations ~~to achieve compliance~~

Rationale: Improve the structure by adding the text “Compliance Programmes and Measures” as the title and the additional text placed in a new paragraph. Changes to the Spanish wording.

Enforcement measures should be designed to be proportionate, dissuasive, and effective and to provide for a full range of actions which include the imposing of corrective actions, administrative sanctions and criminal sanctions. [EU]], **without interrupting trade more than is necessary to guarantee the protection of consumers' health and avoid fraud or deceit.**

Rationale: Include text that expands on the idea that the compliance measures must not be excessive.

50. Los programas de cumplimiento...

- Aumento de la intensidad de auditorías/inspecciones y/o seguimiento de productos y/o procedimientos identificados como no conformes y/o ~~las garantías~~ **los compromisos de corrección** correspondientes; y
- En los casos más graves o reincidentes, la anulación del **registro** ~~la registraci3n~~ del productor/elaborador o el cierre del establecimiento pertinente.

50. Compliance and enforcement programmes [...]

- 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.

Rationale: Spanish wording.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments. It is considered that the direction of the most appropriate stages in the chain refer to the assessment of compliance with the requirements by establishments, and not the system, which explains the suggested inclusion of this chapter (Compliance programs and measures)

86. La autoridad competente debería cursar al operador en cuestión, o a un representante, una notificación por escrito acerca de la decisión tomada respecto de las medidas que se han de aplicar y el motivo para ello. Se deberá proveer además información sobre el derecho de apelación, el procedimiento pertinente y el plazo previsto de tiempo.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording.

Surveillance, Investigation, Response **to incidents related to food safety**

Rationale: We do not consider that the chapter should be included under the title of "Resources".

Given that the actions refer to incidents related to food safety in accordance with the paragraphs included in this chapter.

59. Al diseñar un sistema nacional de control de los alimentos se debería incorporar un sistema para vigilancia, investigación y respuesta que permita la documentación, el análisis, la comunicación y el seguimiento de ~~supuestos~~ incidentes **presuntamente** relacionados con los alimentos. [Japón/Australia/EE.UU.]

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

Rationale: Spanish wording.

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

a) Surveillance and Investigation:

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

b) Review and Response:

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

c) Documentation:

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

o Follow-up/reporting.

61. Where appropriate, the national competent authority should utilize the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19/1995), the International Health Regulations (IHR), and the International Food Safety Authorities Network (INFOSAN), for national and international emergency notification and response. [Japan/Canada]

97. La autoridad o autoridades competentes deberían asegurar la eficacia del sistema de respuesta a los incidentes de inocuidad alimentaria, y evaluarlo regularmente ~~establecer~~ establecer una clara comunicación entre la autoridad competente, la industria y los consumidores. [Australia]

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording.

98. La autoridad o autoridades competentes deberían utilizar la información procedente de la vigilancia de enfermedades de transmisión alimentaria como un instrumento para la gestión del riesgo en el funcionamiento de sus sistemas de control de los alimentos. ~~La información obtenida sobre las enfermedades de transmisión alimentaria puede formar las bases para~~ El retiro de los alimentos y los ajustes efectuados a las operaciones de producción y elaboración de alimentos, incluidas las respuestas a emergencias alimentarias, **pueden basarse en la información obtenida sobre las enfermedades de transmisión alimentaria.** [EE.UU.]

98. The competent authority(ies) should utilize information gained from the surveillance of foodborne illness as a risk management tool in the operation of their food control systems. Food recalls and adjustments to food production and processing operations, including emergency responses, may be based on information obtained from foodborne disease information. [US]

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording.

99. La autoridad competente debería asegurar que todas las partes interesadas tienen a su alcance suficientes programas de orientación, capacitación y concientización ~~educación~~ para facilitar la notificación de posibles casos de enfermedades de transmisión alimentaria o peligros planteados para la salud y detectados en la cadena alimentaria. Los procedimientos administrativos o los planes de contingencia (según corresponda) deberían proporcionar orientación acerca de cómo iniciar los mecanismos de coordinación cuando se requiera la participación de varias autoridades competentes para resolver el problema. Los sistemas de alerta rápida deberían diseñarse e implementarse para dicho propósito. [UE]

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording.

4.2.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING, ETC.)

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

Rationale: Use of terminology in accordance with para. 8 de CAC/GL 47-2003.

55. Cuando se establece un sistema nacional de control de los alimentos se deberían considerar los temas siguientes para que haya una utilización efectiva y eficaz de los recursos y se garantice el cumplimiento del objetivo del sistema: [Australia]

- Funciones y responsabilidades claramente definidas para todos los participantes del sistema nacional de control de los alimentos de manera de asegurar que el sistema se completa de forma coordinada y coherente.
- La utilización de proveedores de tercera parte oficialmente reconocidos y competentes y otros recursos disponibles.
- Controles previstos para asegurar un uso eficaz de los recursos disponibles.
- Establecimiento de acuerdos con las autoridades competentes de otros países, incluido el establecimiento de acuerdos de equivalencia [Australia].

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

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

94. Competent Authorities should have, or have access to, a sufficient number of qualified personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit and law. [EU] Personnel should have access to adequate facilities, equipment and other resources to operate the national food control system. [Japan/Mexico]

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

Laboratories

Rationale: It is considered appropriate to include a title ahead of the texts referring to laboratories.

52. Feed and food control laboratories are an essential part of a national food control system. Analysis of food samples for physical, chemical and microbiological contamination is important to verify the safety and quality of food (including compositional characteristics, nutrition values, adulteration, presence of CX/FICS 11/19/3 11 contaminants, etc.) and **the analysis of environmental and clinical samples** to enable appropriate action to be taken to protect consumers whenever necessary. [EU]

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

Rationale: Improve the structure by merging paragraphs 52 and 53.

87. Los laboratorios deberían contar con instalaciones adecuadas para los análisis físicos, microbiológicos y químicos. Además de efectuar análisis simples de rutina, los laboratorios pueden estar equipados con instrumentos sofisticados, aparatos y biblioteca, según corresponda. La exactitud y la ~~fiabilidad~~ confiabilidad de los resultados analíticos no sólo dependen del tipo de equipo utilizado sino también de las calificaciones y capacidad del analista y la ~~fiabilidad~~ confiabilidad del método utilizado. [UE]

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording

88. Las autoridades competentes deberían utilizar laboratorios que han sido evaluados y/o acreditados en el marco de programas reconocidos oficialmente para asegurar que se han establecido controles adecuados de calidad que garanticen resultados ~~fidedignos~~ confiables de los ensayos. Se deberían utilizar métodos analíticos reconocidos y validados internacionalmente, siempre que estén disponibles, y cumplir con las Buenas prácticas de laboratorios. [UE]

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording

89. Los laboratorios deberían mantener ~~los conocimientos~~ la experiencia analítica ~~o necesarios~~, las instalaciones y los equipos necesarios para efectuar las pruebas exigidas por la autoridad competente. De utilizar laboratorios de terceras partes, la autoridad competente debería tener un acuerdo por escrito o contrato con los laboratorios que prestan sus servicios así como también programas de garantía de la calidad y acreditación. [EE.UU.]

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording

90. Las autoridades competentes deberían asegurar que los laboratorios designados participan regularmente de pruebas de competencia ~~o capacidad~~. Dichas pruebas pueden organizarse a nivel nacional o internacional. El laboratorio nacional de referencia puede jugar un papel en la organización de dichas pruebas. [UE]

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

92. Se puede utilizar la información científica ~~preparada~~ generada por los laboratorios de control de los alimentos para fundamentar y respaldar las normativas y los procedimientos de toma de decisiones relativos a la inocuidad y calidad de los alimentos; por ejemplo: para elaborar programas de vigilancia y monitoreo dirigidos a peligros prioritarios o para investigar adulteraciones, información engañosa, fraude, quejas del consumidor, brotes de enfermedades, etc. y otros temas emergentes en materia de inocuidad y calidad de los alimentos. [UE]

92. The scientific information produced by food control laboratories may be used to inform and support policy and decision making processes related to food safety and quality, for instance to design surveillance and monitoring programmes that target priority hazards or to investigate adulteration, misleading

information, fraud, consumer complaints, disease outbreaks, etc. and other emerging food safety and quality issues. [EU]

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording

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

~~55. In the design of a national food system~~

Rationale: Integration of the Design and Implementation sections in accordance with the general comments. This argument is repeated in all the texts so it is proposed moving it to the proposed section “Design and Implementation”.

Training

~~56. Training programmes should be designed to ensure that all inspectors, analysts, and other individuals carrying out technical/professional duties receive the training required to adequately perform their work assignments and to maintain their professional development. [Australia/Canada]~~

Rationale: Repeated in 57.

57. La autoridad competente debería establecer un programa de capacitación de manera de asegurar que todos los inspectores, analistas u otro personal a cargo de funciones técnicas/profesionales reciben la capacitación necesaria para desempeñar sus funciones adecuadamente y ~~actualizar~~ **mantener** su desarrollo profesional. El programa debería incluir cursos **así** como ~~así también~~ inspecciones conjuntas y/o capacitación de campo, de corresponder, y proporcionar credenciales a nivel básico y superior. [Japón]

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

Rationale: Spanish wording.

58. Deberían elaborarse y utilizarse programas y manuales de capacitación para garantizar una aplicación coherente de los requisitos y una aplicación uniforme del sistema nacional de control de los alimentos, **los cuales deberían considerar, entre otros:**

58. Programmes and training manuals should be developed to ensure consistent application of requirements and uniform application of the national food control system that should be considered, among others:

Rationale: A link is missing between paragraph 58 and the subsequent bullet points.

~~Surveillance, Investigation, Response~~

~~Paragraphs 59 to 61 are moved before the section on Resources (after para. 50)~~

~~Grounds for the change: Integration of the Design and Implementation sections in accordance with the general comments.~~

~~59. The design...~~

~~60. The elements of such programmes...~~

~~a) Surveillance and Investigation...~~

~~b) Review and Response...~~

~~c) Documentation...~~

~~61. Where appropriate, the national competent authority...~~

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

Stakeholder Engagement and communication

101. La autoridad competente debería, en el contexto del procedimiento reglamentario, fomentar la participación de las partes interesadas, incluidos la industria alimentaria y los consumidores, en la formulación de nuevas leyes y reglamentos, y en los casos en que la autoridad efectúa modificaciones significativas de ~~envergadura~~ las prácticas operativas que puedan afectar a las partes interesadas. [EE.UU.]

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments and Spanish wording.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

Education

66. Se debería considerar establecer programas de relaciones con animación social para la industria y la comunidad...

66. Consideration should be given to the development of industry and community relations programmes...

Rationale: Spanish wording.

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

International communication

104. As appropriate, the competent authority should:

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

SECTION 4.3 ELEMENTS TO CONSIDER IN IMPLEMENTATION OF THE SYSTEM

[EU proposal] General guidance on applying the principles

Paragraphs 69 to 73 move to the suggested section: “Design and Implementation”

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

~~69. Effective implementation of control programmes ...~~

~~70. Effective and timely implementation of new objectives...~~

Legislation

~~71. The national food control system...~~

~~72. Guidance and instructions for the interpretation of...~~

~~73. Another example is the application of enforcement measures ...~~

Continuous Improvement [Australia]

~~74. A national food control system...~~

Rationale: Transfer to the “Continuous Improvement” section

Control Programmes

Paragraphs 75 to 77 are transferred to the suggested section “Design and Implementation”.

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

~~75. Competent authority(s)...~~

~~76. The competent authority should take measures...~~

~~77. Implementation of any control programme...~~

Assessment and Evaluation

Paragraphs 78 and 79 are transferred to the suggested section “Design and Implementation”.

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

~~78. The effectiveness and appropriateness...~~

~~79. Self-assessment audits...~~

~~80. Assessment of the efficacy of the national food control system...~~

Rationale: It is suggested changing and transferring to the Compliance and Enforcement section.

Compliance and Enforcement

Paragraphs 81 to 83 are transferred to the suggested section “Design and Implementation”.

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

~~81. The performance of officially accredited bodies...~~

~~82. Competent authority(s) should...~~

~~83. In verifying compliance with requirements~~

~~84. Where a product or process is found~~

Rationale: (Repeated in 48).

~~85. The specific measures~~

Rationale: (Repeated in 50).

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

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

4.3.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING ETC)

Paragraphs 87 to 94 are transferred to the suggested section “Design and Implementation”.

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

~~87. The laboratories should have...~~

~~88. Competent authorities should...~~

~~89. Laboratories should maintain...~~

~~90. Competent authorities should ensure...~~

~~91. The effective linkages should be established...~~

~~92. The scientific information produced by food control laboratories...~~

~~93. Implementation of the national food control system...~~

~~94. Competent Authorities should...~~

Training

95. The competent authority should implement

Rationale: Repeated in 57.

~~96. Programmes and training manuals should...~~

Rationale: Repeated in 58.

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

Paragraphs 97 to 99 are transferred to the suggested section “Design and Implementation”.

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

~~97. Competent authority(s) should...~~

~~98. The competent authority(ies) should...~~

~~99. The competent authority should...~~

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

~~Stakeholder Engagement~~

~~100. In order to promote consumer confidence...~~

Rationale: Repeated in 63.

~~101. The competent authority should...~~

~~102. Communication among food safety...~~

Paragraphs 101 and 102 are transferred to the suggested section “Design and Implementation”.

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

Education

~~103. Where appropriate, the competent authority(ies) should provide access to educational information on food safety risks and mitigation steps which may be taken to reduce these risks. [Aus]~~

Paragraph 103 is transferred to the suggested section “Design and Implementation”.

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

International Communication

~~104. As appropriate, the competent authority should...~~

Paragraph 104 is transferred to the suggested section “Design and Implementation”.

Rationale: Integration of the Design and Implementation sections in accordance with the general comments.

4.4 CONTINUOUS IMPROVEMENT

Mexico considers that this section is appropriate providing it includes compliances with the system that do not necessarily derive from assessment and evaluation exercises.

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

Rationale: It is considered that this paragraph corresponds to the Continuous Improvement chapter.

~~105. A national food control system should be continuously improved to~~ The process of continuous improvement should reflect changes in product risk...

Rationale: Match the text to paragraph 74.

107. Al considerar e incorporar las recomendaciones al diseño e implementación del programa, la autoridad o autoridades competentes deberían considerar ~~los~~ el costos beneficio, la eficacia y la eficiencia. [Australia]

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

Rationale: Spanish wording.

110. Los incidentes planteados por los alimentos constituyen una oportunidad para aprender. Las autoridades competentes deberían utilizar dichas oportunidades para efectuar un análisis posterior(~~postmortem~~) al incidente y utilizar las lecciones aprendidas ~~lo aprendido~~ en la etapa de planeamiento/diseño...

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

Rationale: Spanish wording.

NEW ZEALAND

General comments

New Zealand supports this work and believes that once completed it will provide valuable advice for member governments.

The Working Group made good progress in developing the current draft. New Zealand participated at the meeting in Natal and would like to thank both Brazil and Australia for hosting the meeting and the excellent way in which it was run.

New Zealand believes that the early parts of the paper (section 1, 2 and 3) are now in good shape and require no more than an editorial tidy. Section 4 however is still in need of significant revision. This section is to provide the guidance for member governments to give effect to the principles presented in section 3.

At this point there is too much prescription, detail and repetition. There is also a mixing of higher level concepts and recommended approaches on 'what' needs to be considered with 'how' to do things. New Zealand suggests that section 4 should present higher level guidance and that the current 'how to' detail should be removed. We recall previous discussion on this work and the resources already available to member governments and organisations. These are specifically referenced in paragraph 3 – ie the FAO publications and those of OIE.

We do not believe that our Codex document should be paraphrasing what already exists in these other documents. Rather the guidance we provide in Section 4 should provide the link between the principles we have identified and the detail in the FAO and OIE documents and other relevant Codex texts. Currently there is considerable repetition between the 'design' and 'implementation' parts of section 4. In several instances we suggest that the text is actually in the wrong section.

We suggest that as the Committee considers the draft text the question should be asked – is this design or implementation?

Specific comment

New Zealand offers the following specific comments and suggestions for consideration by CCFICS 19.

Principle 4 – paras 10-14 The order of these paragraphs should be amended. We suggest that para 13 which deals with the competent authority should be placed before those referring to industry and consumers. The sentences within para 13 should also reordered. The relevant paragraphs would then read as follows:

PRINCIPLE 4 ROLES AND RESPONSIBILITY

10. All participants in a national food control system have specific responsibilities.

1143. The competent authorities have the responsibility to ensure the effective operation of the national food control system and to establish and maintain up-to-date and science based legal requirements. They also have the responsibility monitor compliance with and enforce legal

requirements

1241. Food business operators¹ have the primary responsibility for managing food safety and for complying with requirements relating to those aspects of food under their control.

1342. Consumers also have a role in managing food safety risks under their control and where relevant should be provided with information ~~in~~ **on** how to achieve this.

~~13. The competent authorities have the responsibility to monitor compliance with and enforce legal requirements. They also have the responsibility to establish and maintain up-to-date and science-based legal requirements, to ensure the effective operation of the national food control system.~~

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

Rationale: This order of paragraphs provides a logical cascade from higher level roles and responsibilities to those at the lower level. Similarly the reorder of the sentences within para 13 provides a logical flow from the general and overarching to the more specific.

Principle 10 para 20 The title of this principle should read ‘Recognition of Other Countries Systems’. Add the words ‘of other countries’ after ‘food control systems’ and the words ‘from its own’ before ‘may be capable’. The amended text would read:

PRINCIPLE 10 RECOGNITION OF OTHER COUNTRIES SYSTEMS [EQUIVALENCE]

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

Rationale: The suggested title change is made because ‘equivalence’ has often taken on a particular meaning that implies a particular approach to how this is measured or assessed. The additional words in the text are suggested for clarity and completeness.

Para 22, second sentence Replace ‘commercial problems’ with ‘implementation problems’. The amended sentence would read:

For example, where different authorities in the same country have jurisdiction over different parts of the food chain, conflicting requirements must be avoided to prevent legal and ~~commercial~~ **implementation** problems and obstacles to trade.

Rationale: ‘Commercial problems’ is covered by ‘trade’, implementation is the point at which conflict occurs and should therefore be captured, it is also different from ‘legal’.

Para 23 bullet list Amend third bullet to reflect Codex language. Insert new bullet to cover point currently in paragraph 26. The amended text would read:

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

- provides leadership and coordination for the national food safety control system;
 - develops, implements, monitors, manages and reviews the national food control system;
 - establishes and enforces science and risk based regulatory controls that encourage and promote positive food safety outcomes;
 - supports and enables fair **practices in the food** trade ~~in food~~; and
 - **establishes and maintains arrangements with other countries, eg co-operation programmes, equivalence agreements, etc;**
- advances/fosters knowledge, science, research and education regarding food safety.

Rationale: The amended wording in the third bullet is to reflect Codex language. The new bullet reflect the current paragraph 26 which it is proposed should be deleted. This role of the competent authority sits better in this list of functions.

Sub section heading – System Design: General guidance on applying principles – should be inserted above paragraph 24.

Rationale: this is a more logical place to commence this subsection given the other amendments being suggested. Further Paragraph 24 is the start of the general advice.

Paras 25, 26 and 27 These paragraphs should be deleted.

Rationale: Paragraph 25 and 27 are a restatement of Principle 10. Paragraph 26 is now covered by the additional bullet in paragraph 23.

Section 4.1 New Zealand supports the Australian comment that this section would be better incorporated into the body of the section. At this time we do not have any specific suggestion as to how this can be achieved

Para 32 Last sentence Replace ‘laboratory network’ with ‘access to laboratory services’. Insert ‘clear and transparent documentation’. The amended sentence would read:

32. Effective implementation of all of the 10 principles depends on the combined effect of a number of components including: legislative foundation, allocation of resources, staff competence and training, access to laboratory services ~~network~~, verification of compliance, enforcement, surveillance, investigation, response, clear and transparent documentation, stakeholder engagement, international communication and harmonisation, assessment and evaluation.

Rationale: It is not necessary for a country to have a laboratory ‘network’, rather that they should have ‘access to laboratory services’ that may be in the country or may be in another. Clear and transparent documentation is a critical aspect and should be included in this overarching list

Para 33 This paragraph will need to be revised if the decision is made to incorporate the current section 4.1 into the body.

Para 34 This paragraph should be amended as follows:

34. When establishing a national food control system countries should identify the main objectives to be addressed through the system for the short medium and long term. The main objectives should be related to and assist in implementing the principles outlined in section 3. ~~Control programmes help to ensure that inspection actions relate to objectives, since the results of these programmes can be assessed against the objectives set for the national food control system (principle 9).~~ More specific operational programmes should be designed to achieve the identified and aligned with the national short medium and long term objectives. Competent authorities should draw up control programmes based on precise objectives and appropriate risk analysis.

Rationale: Additional words suggested for clarity and to ensure a logical flow of advice from the higher level to the detail level. The deleted sentence implies control programme as the only source of information that objectives are being meet.

Para 35 This paragraph should be deleted.

Rationale: The Paragraph is repeating points that are already covered in the preceding paragraphs and is essentially paraphrasing the principles to which it is referring.

Sub-heading – Control Programmes New Zealand supports the Australian suggestion that ‘control’ replace ‘inspection’ in the subheading and should be the term used in the text. The sentence following the subheading should be amended to include ‘trade’. New Zealand does not support the suggestion from Uruguay that ‘transport /distribution’ be deleted and replaced with retail. This sentence would be included in the numbered text as follows:

38 (biz)Control Programme(s) should provide ongoing monitoring of the food control system from production through manufacturing to transportation/distribution and trade.

Rationale: The term inspection is older language and is often interpreted to mean a particular approach – despite the CCFICS definition of the term. Transport/distribution is a key part of the food chain and should not be exclude, the term ‘trade’ is broader and therefore able to capture all aspects including retail sale.

Para 39 The paragraph should be amended as follows:

39. When designing a control programme competent authority(s) should ensure that the **design provides the capacity to assess if the objectives of the national food control system are being achieved.** ~~is addressed, but~~ **The design** should allow for flexibility in the nature and frequency of control programmes, to ensure control measures are appropriate, and can be modified as required. **The design should also provide for appropriate documentation.**

Rationale: The suggested changes are to improve clarity and completeness as to what the design needs to achieve, it also captures the content of paragraph 45 (in support of the comment by Australia that guidance on assessment and evaluation should be incorporated into this sub-section).

Para 41 This paragraph should be deleted. *Rationale:* *The point being made is now covered in the redrafted paragraph 39.*

Para 43 The bullet points should be deleted and replaced with the following:

43. The control programme(s) (~~inspections, audits, visits~~) should **be designed to** cover, as appropriate:

- **the rang of activities or products covered by the national food control system;**
- **the risks posed by the products or activities**
- **the available controls or interventions to address the risk**
- **mechanises or procedures to check that the controls or interventions are implemented and effective**
- **mechanises or procedures to address or resolve any adverse findings.**

Rationale: The previous text was too detailed. The guidelines should be general. There are other documents that provide this level of detail, the Codex guidelines does not need to repeat or paraphrase these.

Para 43 (biz) Current paragraph 46 should be moved to follow paragraph 43 and amended to improve clarity and flow. The amended paragraph would read:

43 (biz) 46 A national food control system should have mechanisms in place to ~~continuously~~ update, review and analyse the **system as a whole and any of its component parts or programmes, such mechanisms can include periodic self-assessments, quality assurance reviews or evaluation by a third party** ~~above mentioned information.~~ A national food control system should also have mechanisms to adapt to changes in **product risk,** the production environment (**including technology,** **or increased scientific knowledge, noting that these changes may also require amendments to legislation; changes to control programmes and/or other aspect of the national control system.** ~~and~~ **The system should also be designed to allow the competent authority to** respond and intervene where/as required in the national food control system to ensure the protection of health of consumers and ~~ensure of~~ fair practices in **the food** trade.

Rationale: This position improves the flow of the guidance and achieves the suggestion from Australia that the text related to assessment and evaluation is incorporated into the main section. The additional text incorporates the concepts in current paragraph 47 and from paragraph 105 relating to continuous improvement.

Paras 45, 46, 47 These paragraphs can be deleted. *Rationale:* *The matters covered have now been captured in previous paragraphs.*

Sub-heading – Compliance and Enforcement If the sub-heading is retained the text immediately following should be deleted. *Rationale:* *This sentence is not necessary.*

Paras 48, 49, 50 The order of these paragraphs would be changed and the text should refer to both compliance and enforcement. While detail and duplication should be removed some additional text in the reformed paragraphs 48 and 49 means that paragraph 50 is not needed and can be deleted. The subsection would read as follows:

48 49. Compliance and Enforcement programmes ~~measures~~ should be designed to be:

- proportionate **to the degree of public health risk or potential fraud or deception of consumers;**
- ~~dissuasive~~ **encourage acceptance of responsibility and compliance by all participants;**

- and ~~effective and to~~ provide for a full range of **responses** actions which include **from provision of information or education material**, the imposing of corrective actions, **setting** administrative sanctions (**e.g. increased intensity or frequency of audits/inspection**) and/or ~~criminal~~ **legal** sanctions (**e.g. removal of licence or registration, closure, or prosecution**).

~~49~~ 48. Compliance and enforcement programmes should be designed to provide for 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. ~~The resulting actions should take into account any repeated non-conformity of the same product or process to ensure that any action is proportionate to the degree of public health risk, potential fraud or deception of consumers.~~

Para 50 and bullets – delete all.

Rationale: This is a more logical order of the paragraphs and provides clarity as to what compliance and enforcement programmes are intended to achieve. It provides for a flow of guidance starting with higher level concepts and allows for repetition to be removed.

4.2.1 Resources (includes laboratories, staff, training etc) This entire subsection (paragraphs 52 to 61) contains far too much detail and a significant amount of information relating to implementation rather than design. It should essentially be rewritten. The reordered and amended paragraphs would be:

Para 51 – delete. *Rational: this paragraph is about implementation not design.*

Para 52 – delete. *Rational: this is not the right place to start a section of resources and places an emphasis on laboratories that is not in proportion to the paper it then goes into too much detail.*

New Para 52 (biz) – current paragraph 55 should be moved to be the opening paragraph.

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

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

Rationale: This is a more logical opening paragraph

Para 53 Additional words relating to 'access' and that the laboratory support needs to be 'appropriate to the products and activities covered by the national food control system'. The amended paragraph would read as:

53. The design of the national food control system should include **access (either in country or by arrangement with another country) to adequate** laboratory support to ensure that capability **appropriate to the products and activities covered by the national food control system** is provided for food sample analysis, and, as appropriate, environmental and clinical samples.

Rationale: It is not necessary for every country to have a comprehensive and sophisticated laboratory system, what is important is that the competent authority should have access to adequate laboratory services for their national food control system.

Para 54 – delete. *Rational: this paragraph is too detailed and is not necessary as the points being made are already made in other paragraphs or in other Codex or other international texts.*

Para 55 – moved to before paragraph 53. *Rational: This is a more logical opening paragraph for this subsection.*

56. **National food control systems should be supported by** Training programmes ~~should be~~ 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.

Rationale: to improve the flow and ensure completeness. It is not necessary to detail the various aspects that are necessary. Information on this is available in other international texts and should not be paraphrased here.

56 (biz) 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

Rationale: Industry also has responsibility to ensure that staff are adequately trained. Similarly academic also have a role. In the current text neither of these are acknowledged.

57. deleted. *Rational: this is too detailed and unnecessary.*

58. deleted. *Rational: this is too detailed and unnecessary. Guidance on these points is already provided in Codex or other international texts.*

59. **Information on food borne illness or alleged food-related incidents can provide information vital to the design and operation of a national food control system. Such information can identify the risks or issues that need to be addressed and also whether or not the controls or measures in place are effective.** The design of a national food control system should **therefore** incorporate **access to information relating to the** a system for surveillance, investigation and response to **food borne illness and** ~~which provides for documentation, analysis, communication and follow up of~~ alleged food-related incidents.

59 (biz) Where some or all of these activities are not the responsibility of the national food control system competent authority, systems and mechanism should be in place to ensure the national food control system competent authority has adequate and timely access to the relevant information to allow it to fulfil its responsibilities.

Rationale: For completeness and to provide context. The additional text at the beginning of paragraph 59 bring the concepts expressed in paragraph 92 forward as they relate more to design than implementation. It is also important to be clear that it is not necessary for all aspects of surveillance, investigation and response to be under the control of the competent authority responsible for the national food control system. Rather what is important is that the competent authority has adequate and timely access to the relevant information. How member government set up their government agencies is for each to decide. As previously worded the text assumed a structure that it not necessarily reflective of all countries.

60 and all bullet points – delete. *Rational: this is too detailed and unnecessary.*

61 – move to the Implementation section. Include a reference to CAC/GL 19/1995 in Communication. *Rational: this paragraph is not in the relevant sub-section and should be moved.*

4.2.2 Communication This sub-section should also be significantly rewritten. Current paragraph 61 should be included as should paragraph 101. Current paragraph 63 should be moved to the Implementation section. The sub-headings are also not necessary as they are covered in the title of the sub-section. The sub-section would read:

4.2.2 COMMUNICATION (INCLUDES STAKEHOLDER ENGAGEMENT, EDUCATION AND INTERNATIONAL COMMUNICATION)

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

Stakeholder Engagement and Communication

63. Deleted. *Rational: move to Implementation*

64 It is important that decision-making processes are **designed to be** transparent, **allowing** all stakeholders in the food chain to make effective contributions, where appropriate.

Rationale: for clarity that this guidance relates to design

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

Rationale: this paragraph relates to design rather than implementation

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

Rationale: to clarify that this guidance relates to the design of the system

Education

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

International Communication

67. The competent authority should have mechanisms in place to **communicate** ~~interact~~ with the international community regarding international food safety **best practice and** standards as well as communication mechanisms to enact during food safety events of international concern. (Footnote reference to CAC/GL 19/1995)

Rationale: for completeness.

SECTION 4.3 ELEMENTS TO CONSIDER IN IMPLEMENTATION OF THE SYSTEM

New Zealand suggest that this section needs to be completely re-written. There is a considerable level of detail that does not seem appropriate and is likely covered either in other Codex texts or in the guidance that has already been developed by FAO. It is our suggestion that this section of the draft guideline could be significantly shorter.

Para 70 This paragraph may need to be reworked depending on how section 4.1 is dealt with.

New Paras – Paragraphs 106 and 106 should be in this introductory section.

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

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

Para 72 this paragraph should be shortened and the language more general, as follows:

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

Rationale: it is not necessary that additional guidance and instruction be provided. The main responsibility rest with business to ensure they are complying and a ‘command and control’ approach should not be the first option to ensure this. It is also confusing to include ‘guidance’ under Legislation.

Para 73 delete or substantially rewrite. If the paragraph is retained it needs to refer to consistent interpretation in similar circumstances. *Rational: this paragraph is confusing if there are a wide range of variable then uniform application is not possible.*

Assessment and Evaluation Paragraphs 78 to 81 New Zealand suggests that these paragraphs be combined and included under Continuous Improvement (current paragraph 74). The amended paragraphs would read:

Continuous Improvement

73(biz) 78. The effectiveness and appropriateness of the national food control system should be regularly assessed against the objective of the system, as well as against legislative and other regulatory requirements. **Such assessments should be targeted at the most appropriate stages in the food chain, based on risk analysis conducted in accordance with internationally accepted methodology** Criteria for assessment should be established, clearly defined and documented

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

74(biz) 81. The performance of officially accredited bodies should be regularly assessed by the competent authority. Procedures should be initiated to correct deficiencies and, as appropriate, enable withdrawal of official accreditation.

Paras 79 & 80 – Delete. Rational covered in a general manner by the new paragraphs under Continuous Improvement

Paragraphs 84 & 85 – Delete. Rational: these are too detailed and are repeating or paraphrasing information and guidance provided in other international text, particularly that provided by the FAO.

4.3.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING ETC)

Paras 87 to 92. All these paragraphs **except** paragraph 88 should be deleted. Rational: There is too much detail and some text repeats or paraphrases information and guidance provided in other international text, particularly that provided by the FAO. Paragraph 92 relates more to design than implementation and the concepts have been captured in the amended paragraph 59.

Paras 93 & 94 These paragraphs should be combined to remove duplication and some of the detail. A combined paragraph could read:

93. **Effective i** Implementation of the national food control system requires that the competent authority (s) or delegate have access to appropriate human, financial and other required support resources including human, financial and other required support (e.g., access to inspectors, analytical capacity, vehicles, and other equipment). ~~94. The Competent Authority~~ **(s)** should have, or have access to, a sufficient number of qualified personnel as appropriate **for the scope of the national food control system**. ~~in areas such as: food science and technology, chemistry, biochemistry, microbiology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit and law. [EU] Personnel should have access to adequate facilities, equipment and other resources to operate the national food control system.~~

Rationale: it is not necessary to give so much detail, which is adequately provided in other documents.

Para 99 Delete.

Rationale: this is too detailed and it may also not be the responsibility of the National Food Control System competent authority, Coxed guidance should not assume that all members structure their government agency responsibilities in the same way.

4.3.2 COMMUNICATION

The guidance provided in paragraphs 61 and 63 is better placed in this section and should be moved and combined with the current text. The amended text would read:

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

Rationale: additional text from paragraph 63.

101. Moved to Design section as new paragraph 64(biz).

102. Communication among food safety, agriculture and other relevant authorities, consumers and consumer organisation, and the food business operators should be **an ongoing** ~~continuous~~ function of a national food control system.

102(biz) 61. Where appropriate, the national competent authority should utilize the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19/1995) and the International Health Regulations (IHR), and the International Food Safety Authorities Network (INFOSAN), for national and international emergency notification and response.

Rationale: reference to these Codex and international text is more closely related to implementation than design.

4.4 CONTINUOUS IMPROVEMENT

New Zealand agrees that a specific section on continuous improvement is not necessary as these points should be included in the body of the text. Suggestions have been made as to where some of these paragraphs could be located. Paragraph 105 relates to the design section and paragraphs 106 and 107 should be in the introductory section of implementation.

The remaining paragraphs should be deleted. Paragraphs 108 and 109 are essentially already covered, while paragraph 110 is going into detail that is not necessary.

NORWAY

General comments

Good progress has been made on this document, and we would like to thank Australia for all their work on incoming comments. Section 4 is, in our opinion, still too unorganized to give a good understandable framework. Repeating the different elements under the subsections was suggested in Natal, however it does not read well.

We would like to suggest that the information in section 4 could be sorted under headlines reflecting the principles in section 3 as has been done in previous CCFICs texts. This gives the reader the opportunity to link the information on design and operation given in section 4 to the high level principles in section 3. In this way we may also capture if there are gaps in the list of principles.

When looking into section 3 and 4 we find that there is a need for a principle stating the importance of having in place a legal structure to enable establishment of a food control system. The document should therefore clearly establish and highlight the importance of each country having in place a legal substantial framework to enable the establishment of food laws and national authorities. We therefore suggest including a high level principle on this: **The government within each country needs to have in place fundamental legal structure to enable the establishment of food laws and national authorities, so that they can develop, establish, implement and enforce a national food control system.**

Rationale: Having a legal framework is fundamental for the development of a national food control system; consequently this should be included as a high level principle.

Specific comments

Section 1 Introduction

Para 1 First sentence: *This document provides.....*

Insert **implementation** between development and operation.

This document provides principles and guidelines to assist the competent authority(s) of national governments in the development, **implementation**, operation and improvement of a national food control system.

Rationale: Implementation is crucial after development and for further operation of a system, and therefore should be mentioned in the introduction. This is followed up and in line with the text in paragraph 32, which talks about effective implementation.

Section 3 Principles of a National Food Control System

Principle 2 The whole food chain approach

Insert a footnote and replace consumption with distribution:

The national food control system should cover the entire food chain from production (**footnote**) to consumption, **distribution** including feed, primary production and harvest..... footnote which reads: **Production could be interpreted in such a broad manner as to cover food producing animals, fertilizers, pesticides, veterinary drugs and any input of plant or animal origin, etc.**

Rationale: Insert a footnote for consistency. This will be in line with CAC/GL 60-2006, paragraph 12 footnote 8. This broad approach also reflects the reality for many existing national food control systems and forms a broad approach regarding food safety.

Further, being clearer on the systems responsibility in regard the final point; In CAC/GL 60-2006 we have the term distribution, this could also be clarified with a footnote, since using the term consumption goes too far. It is our understanding that 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 Codex Standards.

Insert a new principle **Principle 11** as mentioned above: **The government within each country needs to have in place fundamental legal structure to enable the establishment of food laws and national authorities, so that they can develop, establish, implement and enforce a national food control system.**

Principle 4 Roles and responsibilities

Move paragraph 12 after paragraph 14. And we would like to underline again, that within a national food control system it is our opinion that the consumers do not have a role. They have a responsibility for safe food, but not within this system. And also, 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 Codex Standards.

PHILIPPINES

Specific Comments

Paragraph 12

Delete the word 'where' between 'and' and 'relevant' and insert the word 'information' after 'relevant'. The revised text to read as:

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

Rationale: The current wordings of the paragraph is of the undertone that providing information to consumers are arbitrary and will be done only where relevant or on a case to case basis. Instead, we believe that consumers should be provided as much information as possible so as they can effectively manage food safety risks

Paragraph 13

1st sentence: interchange the phrases “monitor compliance” and “enforce legal requirements”. Insert the phrase “to these legal requirements, including monitoring of officially recognized inspection bodies in which part of the national food control system was delegated to”

2nd sentence: Insert the phrase “and to work towards equivalence determination with other countries on part or parts of the national food control system”

New sentence: Insert the sentence to read as: The competent authorities should also encourage involvement of the public in policy making processes related to food safety and quality.

The new text to read as:

“The competent authorities have the responsibility to ~~monitor compliance with and enforce legal requirements~~ **enforce legal requirements and monitor compliance with these requirements, including monitoring of officially recognized inspection bodies.** They also have the responsibility to establish and maintain up-to-date and science based legal requirements, to ensure the effective operation of the national food control system, **and to work towards equivalence determination with other countries on part or parts of the national food control system. The competent authorities should also encourage involvement of the public in policy making processes related to food safety and quality.**

Rationale:

1st sentence – Chronological order such that there should be enforcement of legal requirements first before compliance to these requirements can be monitored. Moreover, the competent authorities will have to make sure that the officially recognized inspection bodies (accredited) should be monitored for their compliance with the legal requirements. To these officially recognized inspection bodies, a part of the national food control system is being deputized.

2nd sentence – The insertion in the 2nd sentence is to take into account texts in the subsequent sections of the draft guidelines and principles such that equivalence determination has been mentioned and discussed.

New sentence: This is to highlight the important role of the public consultation in coming up with policies, especially new ones.

Paragraph 15

The phrase ‘improper or undue’ is very vague. What qualifies improper influence? Undue influence? We believe that to maintain impartiality, any influence for that matter should be avoided. Thus, we would like to recommend the deletion of the phrase. The new text to read as:

“All aspects.... The competent authority and all participants acting in official functions should be free of ~~improper or undue~~ influence or conflict of interest.

Paragraph 20

Insert the phrase “and as such should endeavour to work towards equivalence determination with other countries”

“Competent authorities should recognize that food control systems although designed and structured differently may be capable of meeting the same objective, **and such should endeavor to work towards equivalence determination with other countries**, and should be provided for in the national food control system

Rationale: Countries, whenever possible, should attempt to achieve equivalence with other countries’ food control system to ensure freer trade of goods.

Paragraph 22

We support the text as proposed by New Zealand. There are countries having multiple competent authorities over a specific commodity. In such cases, there has to be a delineation of responsibilities among these authorities so as to avoid confusion both to the public and industry stakeholders. Moreover, the safety of food supply is ensured.

Paragraph 23

Add another text after the 3rd bullet. The text to read as:

“protects and promotes public health through food safety

Rationale: To give emphasis on the health component of the whole food control system

Paragraph 23

Insert another bullet with the following text: “ensure public and private sectors participation in the development of policies on food safety and quality”

“ensure public and private sectors participation in the development of policies on food safety and quality”

Paragraph 30 and 31

Retain these paragraphs

Paragraph 38

1st sentence: replace the phrase ‘any authorized providers’ with ‘officially recognized’. The text to be read as:

“Legislation should provide clarity as the roles and responsibilities... and any ~~authorized providers~~ **officially recognized bodies** (where these are used), and industry.

Rationale: This text is being used throughout CCFICS documents.

Paragraph 43, 2nd bullet

Add the phrase ‘local and imported’ after the word ‘products’. The text to read as:

“Products, from raw material to the final products, including intermediate products, **local and imported**”

Paragraph 43, additional bullet

Insert another bullet mentioning the ability of the control programme to monitor accreditation of officially recognized inspection bodies, etc.

“Policy and mechanisms for recognition / accreditation of inspection bodies”

Rationale: The above additional bullet is to serve ensure that there is a component in the control programme that ensures compliance of officially recognized inspection bodies to a set of legal requirements/ procedure

Paragraph 48

Revise the text as below to provide clarity to the statement:

“Compliance and enforcement....or process ~~is found not to be in conformity~~ **found not to be in conformity with the set of standards**. The resulting actions should take into account any repeated non-conformity....”

Paragraph 50

Add 3rd bullet to include:

“recall and destruction of non-compliant or non conforming products

Rationale: This process is included as part of enforcement program

Paragraph 54

Replace the phrase ‘private laboratories’ with ‘recognized or accredited laboratories’.

“The number and location of the laboratories, including the use of ~~private~~ **recognized or accredited private** laboratories, should be...”

Rationale: In most cases, government accredits private laboratories.

Paragraph 54, additional sentence

Insert another sentence after the last sentence which will be read as:

“In cases, where the laboratory of the national competent authority is unable to meet the timelines for the submission of results of analyses, accreditation of private laboratories should be considered.

Rationale: The accreditation of private laboratories ensures uniformity of procedure thereby giving reliable results.

Paragraph 85, 2nd bullet

Insert the phrase ‘and recall of all non-compliant products’

“In the most serious or persistent cases, de-registration of the producer/processor or closure of the relevant establishment **and recall and destruction of all non-compliant or products with non-conformities**”

Rationale: This is part of enforcement to recall and destroy the non-compliant

4.4 Continuous Improvement

We believe that this section should not be made as a separate one since all elements of a national food control system should be continuously improved. Thus, this should be integrated in each section.

SOUTH AFRICA**SECTION 1 INTRODUCTION**

1. This document is intended to assist the national government, and their competent authority(ies) in the development, operation and improvement ~~of a~~ national food control system.

SECTION 2 OBJECTIVE OF A NATIONAL FOOD CONTROL SYSTEM

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

PRINCIPLE 2 THE WHOLE FOOD CHAIN APPROACH

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

Rationale: The examples given in relation to feed as one of the critical linkages in the food chain is confusing granted the fact that feed is one of the inputs into primary production. South Africa proposes that the principle be revised by deleting examples of constituent points in the entire food chain.

PRINCIPLE 8: PREVENTIVE AND CORRECTIVE MEASURES

Rationale: the title of Principle 8 should be revised to emphasize the point that is captured in the principle itself which states, "...react to food safety" and even "... intervention". Basically a national food control system can only react or intervene in the instances where one corrects food safety incident that has already occurred.

PRINCIPLE 10 RECOGNITION OF SYSTEMS [EQUIVALENCE]

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

Rationale: It may be difficult to arrive at or determine equivalence of a National Food Control system of a country compared to a situation where elements of a national food control systems are recognized individually for equivalency within a National food control systems. Reference with respect to equivalence determination and judgment should be in relation to CAC/GL 34-1999 and CAC/GL 53-2003.

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

21. The national food control system of a country will be based on that country's particular governmental or constitutional ~~arrangement~~ and institutional **arrangements.....**

22. Defining the roles and responsibilities of key participants in a national food control system is essential for ensuring the objectives are met efficiently and effectively and opportunities for duplication and gaps are minimised. For example, where different authorities in the same country have jurisdiction over different parts of the food chain, conflicting requirements must be avoided to prevent legal and commercial problems and obstacles to trade. ~~Also while provincial or state law may exist~~ There should be a competent authority(ies) at the national level capable of ensuring uniform application **of laws**. [New Zealand]

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

- ~~▪ provides leadership and coordination for the national food control system;~~
- ~~▪ develops, implements, monitors, manages and reviews the national food control system;~~
- ~~▪ establishes and enforces science and risk based regulatory controls that encourage and promote positive food safety outcomes;~~
- ~~▪ supports and enables faire trade in food; and~~
- ~~▪ Advances/fosters knowledge, science, research and education regarding food safety. [new zealand]~~

Rationale: The proposal in its current form is instructive and does not take into account the differences that exist between countries in terms of the existence of more than one competent authority.

24. The design and operation of a national food control system should follow a logical and transparent process. This should include the consistent application of a systematic framework for the evaluation and, as necessary, control of food safety risks associated with existing, new or re-emerging hazards. This food safety risk management framework should be based upon **Codex Alimentarius standards** and guidelines. ~~internationally agreed standards and guidelines and incorporate the following steps:~~

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

Rationale: The only relevant internationally agreed standards and guidelines can safely be drawn from Codex Alimentarius. It therefore be ideally accepted that even the steps will be found in the Codex standards and guidelines hence the proposal to delete the above steps.

25. Although the design and operation of the National food control system may differ from country to country, it may be possible to deliver similar outcomes. Countries may use or apply the CAC/GL 34-1999 and CAC/GL 53-2003 to determine and judge sanitary measures of a national food control systems for purposes of equivalence.

Rationale: Paragraph 25, 26 and 27 has been well captured under the CAC/GL 34-1999 and CAC/GL 53-2003 and therefore the draft on principles and guidelines for national food control systems

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

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

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

URUGUAY

Uruguay is grateful for the work done by Australia which is chairing the present group and all the other members of the group for the compilation of the present Proposed Draft.

General Comments

In the abovementioned Proposed Draft, we noted that a lot of the concepts developed in various paragraphs are repeated in Section 4, so we suggest improving the paragraph order.

Uruguay points out that the Proposed Draft should include the principles and objectives referred to in the National Food Control Systems, without indicating the strategies to be followed in implementing them.

Uruguay proposes following the outline of the FAO Document 76 “Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems”.

Uruguay suggests harmonising the number of competent authorities as in some paragraphs it is written as a plural and in others as a singular. Uruguay proposes using the plural form.

Taking into account the results of Meeting 18 of the Codex Committee on Food Import and Export Inspection and Certification Systems, Uruguay suggests updating and adapting the terms used in English to be translated into the Spanish.

Specific Comments

PRINCIPLE 5 CONSISTENCY AND IMPARTIALITY

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

15. Todos los aspectos del sistema nacional de control de los alimentos deberían aplicarse de manera coherente e imparcial. La autoridad competente y todos los participantes que cumplan funciones oficiales ~~deben~~ **deberían** desempeñar sus obligaciones libre de toda interferencia impropia o excesiva o conflicto de interés **intereses**.

[Translator's note: Changes to the Spanish only.]

Justification: For the first change, as these are Guidelines, the verb should be in the conditional tense; the second change is a syntactical suggestion.

PRINCIPLE 9 SELF ASSESSMENT AND REVIEW PROCEDURES TO ENSURE IT MAINTAINS ITS FITNESS FOR PURPOSE

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

Justification: This phrase adds nothing to the meaning.

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

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

- provides leadership and coordination for the national food safety control system **within the scope of its jurisdiction**;
- develops, implements, monitors, manages and reviews the national food control system;
- establishes and enforces science and risk based regulatory controls that encourage and promote positive food safety outcomes;
- supports and enables fair trade in food; and
- advances/fosters knowledge, science, research and education regarding food safety. [New Zealand]
- ~~apoya y facilita el comercio equitativo de los alimento~~ **alimentos**; y

[Translator's note: Change to the Spanish only]

Justification: As there may be more than one competent authority, the leadership applies to the scope of each.

24. The design and operation of a national food control system should follow a logical and transparent **Risk analysis** process **based on internationally agreed standards and guidelines**. ~~This should include the consistent application of a systematic framework for the evaluation and, as necessary, control of food safety risks associated with existing, new or re-emerging hazards. This food safety risk management framework should be based upon internationally agreed standards and guidelines and incorporate the following steps:~~

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

Justification: Risk analysis includes the risk assessment, management and control mentioned in the paragraph.

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

Justification: The proposed wording is consistent with the Principle of Equivalence.

SECTION 4.1 SYSTEM CHARACTERISTICS

29. **Knowledge of the situation** ~~Situational awareness~~ means that a national food control system avails itself of accurate and current information on the entire food chain as a whole and its various parts and participants. [New Zealand] This information should include, but not be limited to:

- Statistical data on production, trade and consumption;
- Knowledge of operators at various stages of the food chain;
- Typical and atypical use of products, raw materials and by-products;
- Structure of production and supply chains;
- Production technologies, processes and practices;
- Through chain traceability;
- Consumer practice on selection, storage and handling of products;
- Food safety hazards associated with different products; and
- Epidemiological data on foodborne disease.
- **Mediante Datos que surgen de** la rastreabilidad/rastreo a lo largo de la cadena;
- **Práctica Prácticas** de los consumidores con respecto a la selección, almacenamiento y manipulación de los productos;

[Translator's note: Changes to the Spanish only]

Justification: The translation of the concept is better expressed as “knowledge of the situation”. The second and third changes are suggested for syntactical reasons.

~~30. Pro activity means that a national food control system is capable of identifying existing or emerging hazards in the environment before they materialise as risks in the food production/processing chain and at the early stages rather than in the end product. Trends and changes in the production/processing methods should also be subject to monitoring to allow early detection of emerging risks. Early warning/rapid alert systems, traceability and contingency planning for managing and preparing for potential food safety incidents should be an inherent part of a pro-active control system. [EU/US leave in/Brazil Australia delete]~~

Justification: Uruguay agrees with Brazil and Australia's proposal to delete the paragraph because the ideas are already contained in paragraphs 16 and 24.

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

Justification: The idea is discussed in Principle 9, paragraph 19.

SECTION 4.2 SYSTEM DESIGN

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

General guidance on applying the principles

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

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

~~34. When establishing a national food control system countries should identify the main objectives to be addressed through the system. The main objectives should be related to and assist in implementing the principles outlined in section 3. Control programmes help to ensure that inspection actions relate to objectives, since the results of these programmes can be assessed against the objectives set for the national food control system (principle 9). More specific operational objectives should be identified and aligned with the national objectives. Competent authorities should draw up control programmes based on precise objectives and appropriate risk analysis. [EU]~~

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

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

Justification: Uruguay proposes deleting paragraphs 32 to 36 because they deal with strategies to be followed which it considers are the jurisdiction of each country.

Legislation

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

38. La legislación debería proveer claridad con respecto a las funciones y responsabilidades de los participantes de la cadena ~~alimenticia~~ **alimentaria**, en particular el gobierno central, la autoridad competente (o cada una de ellas en el caso de que hubiera más de una) y todo proveedor autorizado (en caso de utilizarse), y la industria. La legislación debería establecer los objetivos principales del sistema nacional de control de los alimentos y cualquier otro objetivo específico o secundario relativos a los participantes o sectores. Debería además ~~proporcionar la autoridad o el~~ **proveer la autoridad y las bases** para la formulación de normas y el establecimiento de controles adecuados a lo largo de todas las etapas de la cadena alimentaria, es decir, producción, manufactura, importación, elaboración, almacenamiento, transporte, distribución y comercio.

[Translator's note: Changes also to the Spanish only]

Justification: The proposed changes are of two types: the first is because this wording in Spanish corresponds better to the English expression; the second involves changing “or” to “and” because both faculties are required to formulate standards and establish controls.

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

Justification: Uruguay proposes that this concept covers the entire chain

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

41. Los sistemas nacionales de control de los alimentos deberían estar diseñados de manera de asegurar que hay procedimientos administrativos para documentar los programas de control y ~~sus resultados~~ la información recabada. [Australia]

[Translator's note: Change to the Spanish only]

Justification: Uruguay considers that all the information should be documented and not just the results. This would make the text consistent with paragraph 29.

[Translator's note: the words Uruguay suggests deleting from the Spanish do not appear in the English version.]

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

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

42. Al establecer los programas de control se deberían considerar otros factores-, ~~A saber~~ **tales como:**

- El riesgo para la salud humana planteado por el producto o el envase;
- La susceptibilidad del grupo objetivo de consumidores;
- El alcance y la naturaleza de cualquier otra elaboración ulterior del producto;
- La eficacia y la fiabilidad de sus propios controles;
- ~~El~~ **H**istorial de conformidad de la industria; y
- ~~La~~ **P**osibilidad de fraude o engaño de los consumidores y otros factores que puedan impedir las prácticas leales de comercio.

[Changes to the Spanish only]

Justification: Uruguay considers that this is not a complete list but rather a series of points given as examples.

[Translator's note: the Spanish "A saber" could imply that the list is complete. "Tales como" equates to the English "such as".]

44. Where quality assurance systems are used by industry, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade. The competent authority should encourage the use of a Hazard Analysis Critical Control Point (HACCP) approach by industry. [Aust]

44. Cuando la industria ~~alimenticia~~ **alimentaria** usa sistemas de garantía de la calidad, se deberían tomar en cuenta en el sistema nacional de control de los alimentos siempre que estén relacionados con la protección de la salud de los consumidores y garanticen prácticas leales en el comercio de los alimentos. La autoridad competente debería fomentar el uso del Análisis de ~~Riesgos~~ **Peligros** y de los Puntos Críticos de Control (HACCP) por parte de la industria. [Australia]

[Changes to the Spanish only]

Justification: The HACCP uses the term "peligros" and not "riesgos" [in Spanish]

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

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

Justification: The above paragraphs refer to the strategies to be implemented which are the jurisdiction of the countries.

48. Compliance and enforcement programmes should be designed to provide for the ability for the competent authority to take action to ensure the situation is remedied where a product or process is found not to be in conformity. The resulting actions should take into account any repeated non-conformity of the same product or process to ensure that any action is proportionate to the degree of public health risk, potential fraud or deception of consumers. [Australia/also picks up some of the EU thoughts]

48. Se deberían establecer programas ~~de cumplimiento~~ y medidas de cumplimiento para que la autoridad competente tenga la capacidad de tomar medidas para remediar la situación en caso de que un producto o proceso no cumpla los requisitos. Al tomar medidas se debería tener en cuenta si es que se trata de una no conformidad reincidente del mismo producto o de un procedimiento, a fin de asegurar que toda medida es sea proporcional al grado de riesgo para la salud pública, ~~de posible fraude~~ fraude potencial o engaño del consumidor. [Australia/también incluye algunos puntos presentados por la UE]

[Translator's note: Changes to the Spanish only]

Justification: Uruguay suggests the proposed changes to improve the translation and syntax.

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

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

50. Los programas de cumplimiento y las medidas de cumplimiento podrían incluir la aplicación de las siguientes medidas específicas con respecto a la futura producción: [Australia]

- Aumento de la intensidad de auditorías/inspecciones y/o seguimiento de productos y/o procedimientos identificados como no conformes y/o las garantías correspondientes; y
- En los casos más graves o reincidentes, la anulación ~~de la registración~~ del registro del productor/elaborador o el cierre del establecimiento pertinente.

[Translator's note: Changes to the Spanish only]

Justification: suggestions for the translation.

4.2.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING ETC.)

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

Justification: Suggested wording and syntax.

52. ~~Feed and food control laboratories are an essential part of a national food control system. Analysis of food samples for physical, chemical and microbiological contamination is important to verify the safety and quality of food (including compositional characteristics, nutrition values, adulteration, presence of contaminants, etc.) and to enable appropriate action to be taken to protect consumers whenever necessary.~~ [EU]

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

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

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

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

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

Justification: Uruguay suggests deleting these paragraphs because they duplicate ideas and define the strategies to be followed.

Training

~~57. The competent authority should have in place a training plan that ensures that all inspectors, analysts, and other individuals carrying out technical/professional duties receive the training required to adequately perform their work assignments to improve technical understanding and maintain professional development.~~

~~The plan should include coursework as well as, when appropriate, joint inspections and/or field training and should provide for basic and advanced credentials. [Japan]~~

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

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

Justification: Uruguay suggests deleting these paragraphs because they duplicate ideas and define the strategies to be followed.

Surveillance, Investigation, Response

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

~~59. **El diseño de** Al diseñar un sistema nacional de control de los alimentos se debería incorporar un sistema para vigilancia, investigación y respuesta que permita **provea** la documentación, el análisis, la comunicación y el seguimiento de supuestos incidentes relacionados con los alimentos. [Japón/Australia/EE.UU.]~~

[Translator's note: Changes to the Spanish only]

Justification: Uruguay suggests making the proposed changes to improve the translation and syntax.

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

~~a) Surveillance and Investigation:~~

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

~~b) Review and Response:~~

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

~~e) Documentation:~~

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

Justification: Uruguay suggests deleting this paragraph because it repeats ideas presented in paragraph 21 of Risk Analysis.

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

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

62. El sistema nacional de control de los alimentos debería fomentar la transparencia, **incluyendo** la comunicación de los requisitos, y los procedimientos de implementación y verificación que forman parte **del sistema** ~~de un sistema nacional de control de los alimentos~~. Se deberían considerar estrategias de comunicación con todas las partes interesadas (sector privado, productores, elaboradores y consumidores). [Canadá]

[Translator's note: Changes to the Spanish only]

Justification: Align the Spanish wording on the English version.

Stakeholder Engagement and Communication

63. In order to promote consumer confidence in the safety and quality of their food, the competent authority should be clear and transparent in their communications relating to all aspects of the national food control system ~~for which they are responsible, including the development, implementation and enforcement of the requirements.~~ [modified EU proposal]

Justification: The deleted text adds nothing to the idea of the paragraph.

Education

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

66. Se debería considerar establecer programas de ~~animación~~ **educación** social para la industria y la comunidad a fin de proporcionar actividades de extensión y educación e intercambio de información entre los reguladores, la industria, los consumidores y el sector académico. [Australia]

[Translator's note: Change to the Spanish only]

Justification: The sense of the word “educación” is closer to the proposed idea.

International Communication

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

Justification: Uruguay proposes deleting the paragraph because the exchange of information is discussed in paragraph 61.

SECTION 4.3 ELEMENTS TO CONSIDER IN IMPLEMENTATION OF THE SYSTEM

[EU proposal] General guidance on applying the principles

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

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

Justification: Uruguay proposes deleting paragraphs 69 and 70 because they define strategies to be followed which are the authority of each country.

Legislation

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

Justification: Uruguay suggests moving paragraph 71 to the end of paragraph 38.

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

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

Justification: Uruguay proposes deleting paragraphs 72 and 73 as they refer to strategies to be followed which are the jurisdiction of each country.

Continuous improvement [Australia]

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

Justification: Uruguay suggests moving paragraph 74 to the end of paragraph 45.

Control Programmes

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

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

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

Justification: Uruguay proposes deleting paragraphs 75 to 77 as they do not provide any new ideas.

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

Justification: Uruguay suggests using paragraph 78 to expand paragraph 45.

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

Justification: Uruguay suggests moving paragraph 79 to the end of paragraph 45.

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

Justification: Uruguay suggests moving paragraph 80 to the end of paragraph 24.

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

Justification: Uruguay proposes adding “if it(they) exist” since officially accredited authorities do not exist in all countries.

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

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

Justification: Paragraphs 82 and 83 should be used to expand paragraphs 48 to 50. Uruguay proposes deleting the phrase struck through as the means are the jurisdiction of each country.

~~84. Where a product or process is found not to be in conformity, the competent authority should take action to ensure that the operator remedies the situation. The resulting measures should take into account any repeated non-conformity of the same product or process to ensure that any action is proportionate to the degree of public health risk, potential fraud or deception of consumers.~~

Justification: Paragraph 84 should be used to expand paragraph 48.

~~85. The specific measures applied with regard to future production may include:~~

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

Justification: Uruguay proposes deleting the paragraph because the idea is already included in paragraph 50.

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

[Translator's note: text not struck through in Uruguay's Spanish text.]

Justification: Uruguay considers it appropriate to delete the paragraph because it indicates a strategy to be followed.

4.3.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING ETC.)

~~88.~~ Competent authorities should utilize laboratories that are evaluated and/or accredited under officially recognized programmes to ensure that adequate quality controls are in place to provide for the reliability of test results. Internationally recognized and validated analytical methods should be used wherever available and Good Laboratory Practices should be adhered to. [EU]

Justification: Uruguay considers that this paragraph should be placed after paragraph 51.

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

Justification: Uruguay considers that this paragraph should be placed after paragraph 51. Additionally, Uruguay proposes deleting "and accreditation" because the quality guarantee programme may or may not include accreditation.

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

Justification: Uruguay considers that this paragraph should be placed after paragraph 51.

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

Justification: Uruguay considers that this paragraph should be placed after paragraph 51. Additionally, Uruguay proposes deleting the last phrase because it does not add any information to the idea and moreover reference laboratories may be either national or foreign.

[Translator's note: Presumably, this second part of the justification refers to paragraph 90 rather than 91.]

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

Justification: Uruguay proposes deleting the paragraph because it defines the strategy to be followed for using the information.

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

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

~~94.~~ Competent Authorities should have, or have access to, a sufficient number of qualified personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit and law. [EU] Personnel should have access to adequate facilities, equipment and other resources to operate the national food control system. [Japan/Mexico]

Justification: Uruguay believes it would be appropriate to move paragraphs 93 and 94 to the end of paragraph 51.

Training

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

Justification: Uruguay believes it would be appropriate to move paragraphs 95 to the end of 56 to replace paragraph 57.

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

Justification: Uruguay considers the paragraph should be deleted because it defines a procedure.

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

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

~~98.~~ The competent authority(ies) should utilize information gained from the surveillance of foodborne illness as a risk management tool in the operation of their food control systems. Food recalls and adjustments to food production and processing operations, including emergency responses, may be based on information obtained from foodborne disease information. [US]

Justification: Uruguay believes it would be appropriate to move paragraphs 97 and 98 to the end of paragraph 59.

~~99. The competent authority should ensure that sufficient guidance, training and awareness programmes targeted at all relevant stakeholders are in place to facilitate effective notification of suspect cases of food related illnesses or health hazards detected in the food chain. Administrative procedures or contingency plans (as appropriate) should provide guidance on initiating coordination mechanisms when involvement of several competent authorities is required to resolve the incident. Rapid alert systems should be designed and implemented for this purpose. [EU]~~

Justification: Uruguay considers this paragraph should be deleted because the ideas are already contained in paragraph 61.

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

Stakeholder Engagement

~~100. In order to promote consumer confidence in the safety and quality of their food, the competent authority should be clear and transparent in their communications relating to all aspects of the national food control system for which they are responsible (from parking lot) [Canada]~~

Justification: Uruguay believes it would be appropriate to delete the paragraph because it is repeated in paragraph 63.

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

Justification: Uruguay considers this paragraph should be moved to the end of paragraph 65.

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

Justification: Uruguay believes it would be appropriate to delete the paragraph because the ideas are included in paragraph 65.

Education

~~103. Where appropriate, the competent authority(ies) should provide access to educational information on food safety risks and mitigation steps which may be taken to reduce these risks. [Aus]~~

Justification: Uruguay considers it important to transfer this paragraph to the end of paragraph 66.

International Communication

~~104. As appropriate, the competent authority should:~~

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

Justification: Uruguay proposes deleting the paragraph because the ideas are expressed in paragraph 67.

4.4 CONTINUOUS IMPROVEMENT

~~Note: The United States does not believe a specific section devoted to this aspect of food control systems is necessary. This characteristic (continuous improvement) should be included as a characteristic if Section 4.1 above is retained and any specific provisions can be placed in the appropriate sections relating to implementation. Where specific occurred in this section we have moved it (or equivalent wording) into the body of the text above. Note: suggest that continuous improvement be applied to all elements — rather than applying the concept to each element. [Canada/Australia]~~

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

~~105. A national food control system should be continuously improved to reflect changes in product risk, the production environment (including technology), increased scientific knowledge, and level of confidence in industry, to ensure the objective of the national food control system is met in an efficient and effective manner. [Australia] These changes may also require amendments to legislation; changes to control programmes and/or laboratory practices.~~

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

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

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

~~109. Any review and continual improvement of the national food control system should be communicated effectively and efficiently to ensure that clear exchange of information and engagement between all stakeholders in the national food control system occurs. [Australia]~~

~~110. Food-related incidents are an opportunity to learn. Competent authorities should use these opportunities by way of carrying out "post-mortems" and feeding the "lessons learned" back to the planning/design process. Particular attention should be paid to early warning mechanisms, coordination between competent authorities, communication to stakeholders and the use and effectiveness of contingency planning. Corrective action should be taken as appropriate. [EU]~~

Justification: Uruguay agrees with the proposal by the United States which considers that it is not necessary to include a specific section relating to this aspect of food control.

UNITED STATES OF AMERICA

General Comments

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*. We believe the document is well developed and contains much of the essential information that national governments need to design and implement an effective national food control system. In our specific comments below we have suggested the addition of certain guidance to augment the current text. We are also suggesting some minor movement of text and reformatting for clarity and logic flow.

We note that, because the construct of the document employs sections on design and on implementation with both sections containing similar subsections, there is some redundancy in the text. The Committee should consider whether it wishes to retain the current construct or whether it wishes to reorganize the document using the various components of a food control system as the main headings and incorporating both design and implementation elements under the various components. The United States prefers the latter approach but recognizes that both approaches can provide the needed guidance.

Specific Comments

SECTION 1 INTRODUCTION

Paragraph 1 – First sentence: insert “its” before “national” so the sentence reads: “This document...and improvements of its national food control system.

Rationale: clarifying editorial change.

Paragraph 4- First sentence: insert commas after “with” and after “from” so the sentence reads: “The principles...are consistent with, and are drawn from, existing Codex documents.”

Rationale: editorial change.

SECTION 3 PRINCIPLES

Paragraph 8 (Principle 2). Modify to delete the list of prescriptive elements that represent the entire food chain from production to consumption so that the sentence reads: “The national food control system should cover the entire food chain from production to consumption.”

Rationale: Use of the phrase “entire food chain from production to consumption” is sufficient without listing the steps in the process, which may not be all inclusive.

Paragraph 9 (Principle 3). Modify the first sentence to read: “All aspects...protect confidential and proprietary information as appropriate.”

Rationale: additional clarity as to the handling of information that should be protected.

Paragraph 10 (Principle 4). Modify the sentence to read: “All participants in a national food control system have specific responsibilities and should be actively engaged to ensure that the objectives of a national food control system are achieved.”

Rationale: As drafted, the paragraphs under the principle are written as statements and are not written to provide an actual principle. Rewording is needed to provide an actual principle under “roles and responsibilities.”

Paragraph 13 (Principle 4). Modify the first sentence to read: “The competent authorities have the responsibility to design and implement an effective food control system including activities to monitor compliance with and enforce legal requirements.”

Rationale: It is helpful to expand the statement on responsibilities since monitoring and compliance are only a portion of the overall responsibility of competent authorities.

Paragraph 14 (Principle 4). Delete “may” in the sentence so it reads: “Academics and scientific institutions ~~may~~ have a role...system.”

Rationale: Academics and scientific institutions have a clear role to play and this should be clearly stated.

Principle 10. Delete “equivalence” from the title so it reads “Recognition of Systems ~~{Equivalence}~~”

Rationale: Equivalence is only one form of recognition. This principle needs to be broadened because recognition is not limited only to equivalence.

Add a new Principle 11 which would read as follows:

PRINCIPLE 11 ADEQUATE MEANS AND RESOURCES

National Food Control systems should have sufficient resources including facilities, personnel, and funding to carry out their responsibilities.

Rationale: Resources are a critical aspect of implementing a national food control system and this aspect should be included as a principle.

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

Paragraph 23. Add a new bullet at the end of the bulleted sequence as follows.

- **Engages with stakeholders to ensure transparency and to obtain views of interested parties.**

Rationale: This is an important additional role of a competent authority that is not included in the list.

Paragraph 25. Delete paragraph.

Rationale: repetitive to the current paragraph 27.

Paragraph 26. Redraft the paragraph to read: “The national competent authorities should consider undertaking arrangements with other countries’ national competent authorities, **which could include undertaking equivalence determinations or other means of systems recognition** ~~including the establishment of equivalence agreements~~ in order to make efficient use of their own resources.

Rationale: The forms of recognition need to be broadened to include systems recognition more broadly rather than just equivalence.

Paragraph 27. Insert “**same**” at the end of the sentence between “the” and “objective,” so that it will read: Thus every country may have a different national food control system that is designed, implemented and continuously improved, applying the above principles to achieve the **same** objective.

Rationale: clarification

Text block under the Section 4.1 Heading. The United States believes this section is sufficiently different and should be kept as a separate section.

Paragraph 28. Insert the three main characteristics into the paragraph to read:

A national food control system should possess three main characteristics, **including situational awareness, pro-activity, and continuous improvement,** which can be used in self-assessment or other evaluation to determine if the system is fully functional and effective.

Rationale: clarification

Paragraph 29. Modify the bulleted list as follows:

Second bullet: rewrite as “Knowledge of operators at various stages of the food chain **including their standard business and industry practices.**”

Rationale: additional clarity on information to be known.

Sixth bullet- rewrite as “**Findings arising from** ~~T~~through chain traceability”.

Rationale: The focus should be on the findings of traceability, as opposed to the process itself.”

Seventh bullet- Delete “selection” so the bullet would read: “Consumer practice on ~~selection~~, storage and handling of products;”

Rationale: Consumer selection itself is not a component of importance with respect to the operation of a national food control system.

Add a new 9th bullet: **The potential for the intentional contamination of food.**

Rationale: It is important to include the potential for intentional contamination of food as an item to be cognizant of.

Paragraph 30. Modify the first sentence to read: “Pro-activity means...rather than in the end product, **that is, preventing problems before they arise.**”

Rationale: Adding clarifying language to help ensure understanding of the text.

Paragraph 31. Modify the first sentence to read: “Capability to learn **and continuous improvement** [~~Continuous improvement~~] means a national food control system has a mechanism in place to continuously update, review, and analyze the above mentioned information, **and that all elements of a national food control system are assessed on a regular basis to ensure that they are operating properly and that they reflect the current state of science, knowledge, and best practices.**”

Rationale: The United States can accept inclusion of continuous improvement as a component of this element rather than having it as a stand alone element as we originally suggested. Additional text strengthens and clarifies the concept of the continuous improvement.

Section 4.2, System Design: Add a new first paragraph (31 bis) as follows:

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

- **Regulatory foundation and legislative framework (laws, regulations, guidances);**
- **Inspectional programs from production through manufacturing to transportation and distribution;**
- **Compliance and enforcement programs;**
- **Adequate laboratory capacity and capability;**
- **Staff competence and training;**
- **Provision for sufficient resources and their allocation;**
- **Surveillance, investigation and response to foodborne incidents;**
- **Assessment and evaluation;**
- **Stakeholder engagement; and,**
- **International communication and harmonization;**

Rationale: Provides a clarifying introductory paragraph to the section clearly identifying the elements that should be included in a national food control system.

Paragraph 32. Redraft the last sentence to read: “Effective implementation of all of the 10 principles depends on the combined effect **of the elements identified above.** ~~of a number of components including: legislative foundation, allocation of resources; staff competence and training, laboratory network, verification of compliance, enforcement, surveillance, investigation, response, stakeholder engagement, international communication and harmonization, assessment and evaluation.~~”

Rationale: The deleted items are now called-out in the new paragraph above and can be deleted from this paragraph.

Paragraph 36. Redraft the first sentence to read: “An appropriate system design...assessment system review **and associated** findings and cost effectiveness.”

Rationale: editorial change for clarity.

Legislation: Add two new paragraphs at the beginning of this section, as follows:

37 bis. National food control systems should be authorized through appropriate and adequate legislation and implemented through appropriate laws, regulations, guidelines, policies, and procedures.

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

Rationale: Provides additional guidance relating to legislation and relocates text for clarification and logic flow.

Paragraph 38. In the first sentence, insert the word “the” as follows: Legislation should provide clarity...chain, in particular that of **the** central government, ... and industry.”

Rationale: editorial change.

Also in Paragraph 38. Delete the last sentence: “~~It should provide the authority or basis for the setting of standards and establishment of appropriate controls at all stages of the food chain, including production, manufacture, importation, processing, storage, transportation, distribution and trade.~~”

Rationale: Sentence moved up for clarification and logic flow to become part of the new paragraph (37 bis bis).

Add two new paragraphs, 38 bis and 38 bis bis to follow paragraph 38.

38. bis The legislation should provide the national competent authority with the authority to:

- **establish standards or other management options to control food borne hazards such as disease-causing organisms, naturally occurring contaminants, and pesticide residues;**
- **establish approaches to ensure the safety and safe use of food additives, pesticide residues, veterinary drugs.**
- **perform inspections and investigations, gather evidence, collect and analyze samples and otherwise verify compliance with standards and requirements;**
- **enforce and take action based on adequate legislation, including investigations prosecutions;**
- **ensure the integrity, impartiality and independence of officially recognized inspection systems;**
- **ensure that the inspection program contained in national legislation is delivered to a prescribed standard; and**
- **Recall unsafe products.**

38 bis bis. Legislation may also include provisions, as appropriate, for the registration of establishments or listing of certified processing plants, establishment approval, licensing or registration of traders, equipment design approval, certain process approvals (e.g., for low acid canned foods), penalties in the event of non-compliance, coding requirements and charging of fees. Legislation may also provide for the investigation of food borne illness and the development of epidemiological and foodborne disease prevention information.

Rationale: Provides additional guidance with respect to legislation.

Paragraph 43-Edit third bullet to read as follows:

- ~~Process: evaluation~~ Evaluation and verification of **process, such as** GMP, HACCP.

Rationale: Clarification

Add a new paragraph to follow paragraph 43:

43. bis. Inspectional programs should be designed to include the following elements:

- **on-site inspection;**
- **sampling and analysis;**
- **checks on hygiene, including personal hygiene and clothing;**
- **examination of written and other records; and,**
- **examination of the results of any verification systems operated by the establishment.**

Rationale: Provides additional guidance on control programs, particularly as related to inspections.

Section on “Assessment and Evaluation: Retain this section but move this section down to follow the section on “Training.” Take the explanatory phrase accompanying the heading and convert it into a new first paragraph for the section, as follows:

44 bis. As appropriate, assessment, audits, inspections or other tools to evaluate the effectiveness of the food control programme, including the recognition of trends should be a part of the food control system.

Rationale: For logic flow, the section is better placed further down the document. The phrase accompanying the heading is useful guidance, but should be formatted clearly as a sentence and appears to be best placed as new first paragraph to this section.

Paragraph 45. Add a new second sentence, as follows:

Verifying the efficacy 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. (with an accompanying footnote that reads: “Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007).

Rationale: Provides additional guidance regarding assessment and evaluation.

Section heading on “Compliance and Enforcement.” Remove the accompanying phrase and incorporate into the first sentence of paragraph 48 as follows:

48. Compliance and enforcement programmes should be designed **to ensure that compliance is achieved with food laws and regulations and** to provide for the ability...conformity.

Rationale: For consistency; section headings should be consistent and without accompanying phrases. The phrase is helpful guidance and can be incorporated into paragraph 48.

Add a new paragraph 48 bis as follows.

48 bis. Compliance and enforcement programs should be designed to include the following elements.

- **Written enforcement strategies**
- **Tracks critical and chronic violators**
- **Uses a risk-based system to determine when a directed investigation follow-up, or re-inspection is needed**
- **Establishes a timeline for progressive actions**
- **Includes internal scientific and legal reviews to ensure appropriateness and integrity of compliance actions**
- **Has a system to communicate verbal and written policy and guidance to managerial and non-managerial staff**
- **Includes specific program elements for specific food safety systems such as HACCP, good manufacturing practices and good agricultural practices.**

Rationale: Provides additional guidance regarding compliance and enforcement.

Add a new paragraph 50 bis:

50 bis. Where the competent authorities use third⁴ party providers to implement controls, the third party provider should be assessed against objective criteria and officially accredited by the competent authority. The performance of the third party provider should be monitored by the competent authority.

Accompanying footnote: Guidelines for Food Import Control Systems CAC/GL 47-2003 paragraph 8

Rationale: Provides additional guidance on compliance and enforcement.

Delete 4.21. Heading- ~~4.2.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING, ETC)~~

Rationale: Laboratories, resources, training, and surveillance-investigation-response should be individual sections and not combined under “resources” as they have an importance that is generally the same as other sections of this part of the document.

Move paragraph 51 down in the text under “Resources” (see paragraph 54 bis below) and create a heading “Laboratories” before paragraph 52, as follows:

~~51. The equipment and authorized providers should have adequate resources available, including personnel, funding, laboratories, equipment and other infrastructure to support an effective national food control system which meets the objective.~~

Laboratories

~~52. Feed and Food control laboratories...~~ whenever necessary.

Rationale: Paragraph 51 is better placed under resources (see paragraph 54 bis below). Create a section heading for laboratories. Delete reference to feed given the focus on national food control systems.

Delete phrase after “Resources” section heading: ~~Resources- Programme resources including the provision of adequate trained staff, facilities, equipment and funding.~~

Rationale: Heading content contained in new paragraph 54 bis.

Add a new paragraph 54 bis, as follows:

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

Rationale: Paragraph moved down in text from just under Section 4.2.1

Add three new paragraphs, 55 bis, 55 bis bis, and 55 bis bis bis, as follows:

55. bis National food control systems should have, or have access to, a sufficient number of qualified personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit, and law.

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

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

Rationale: Provides additional guidance on resources.

Paragraphs 56 and 57. Redraft as indicated.

Paragraph 56. Training programmes should be designed...work assignments to **improve their technical understanding**, and to maintain their professional development.

Paragraph 57. The competent authority should have in place a training plans **for employees that ensure their competency and professional development**. ~~That all inspectors, analysts, and other individuals carrying out technical/professional duties receive the training required to adequately perform their work assignments to improve technical understanding and maintain professional development.~~ The plan should include...for basic and advanced credentials.

Rationale: removes redundancies between the two paragraphs.

Paragraph 58. At end of the first sentence, add a new introductory phrase for the list of bullets as follows: **Elements/components include:**

Rationale: editorial change.

Insert “**Assessment and Evaluation**” Section (paragraphs 44bis, 45, 46, 47) after the “Training” section and before the “Surveillance, Investigation and Response” Section.

Rationale: Better logic flow of the document.

Paragraph 60. b) Review and response: Add a new third bullet as follows:

- **Implement appropriate response (i.e., product recall or other interventions).**

Rationale: adds additional guidance that is missing from paragraph.

Add a new paragraph 60 bis as follows.

60. bis National food safety authorities should have in place an effective emergency response system that should take into account and, as appropriate, be linked to: food recall systems, risk assessment systems and specialists, laboratory systems, and enforcement and intelligence systems and agencies.

Rationale: Provides additional guidance regarding the inclusion of an emergency response system in a national food control system.

Add two new paragraphs, 64 bis and 64 bis bis as follows:

64. bis The national food control system should have in place a system that fosters communication and information exchange among regulators, industry, consumers, and academia including actively participating in meetings, outreach events, and educational events related to food safety, which may include food safety investigation strategies (including stakeholder engagement), regulatory processes, or other topics.

64 bis bis Stakeholder engagement in the development and improvement of many elements of a national food control system is essential, and in particular, in the development of laws, standards, regulations, guidances, and educational material. National food control systems should have adequate programs in this regard.

Rationale: Provides additional guidance regarding stakeholder engagement.

Paragraph 65. In the second sentence delete the word “always”; the sentence would read: “Consumers should ~~always~~ be promptly, “

Rationale: It is not necessary to notify consumers of each and every contaminated food incident or food recall through an alert system.

Paragraph 69. Reorganize this paragraph by modifying the first sentence and separating the rest of the paragraph into a new paragraph 69 bis with new introductory wording as indicated.

69. Effective implementation of control programmes requires that all **participants** staff are fully aware of what is expected of them (Principle 4).

69 bis. With respect to the competent authority(ies), it is essential that all staff are fully aware of what is expected of them and have objectives clearly communicate to them . . . (rest of paragraph stays the same).

Rationale: Principle 4 refers to all parties and implementation should, in fact, take into account the responsibilities of all parties, not just staff. This change takes into account this aspect but retains the original construct relating to the role of the staff of competent authorities.

Add a new paragraph 70 bis as follows:

70. bis. The regulatory foundation and legislative framework includes laws, regulations, rules, ordinances, official guidance, or other authorities and regulatory requirements that govern the operation of the food control system.

Rationale: Provides additional guidance covering the nature of legislation—wording was obtained from the section heading of the prior version of the text.

Add a new paragraph 73 bis as follows:

73. bis Legislation should be reviewed on a periodic basis to ensure that it reflects current food production and manufacturing practices and current policy and thinking regarding approaches to ensuring food safety.

Rationale: Provides additional guidance on legislation

Delete paragraph 74 and the associated heading.

Continuous Improvement

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

Rationale: Substance of paragraph is covered in the “Continuous Improvement” section at the end of the text. The heading and paragraph can be deleted.

Add 9 new paragraphs beginning at 77bis, as follows.

77bis. Control programs should be implemented that:

- **Maintain basic surveillance of the entire food safety system, from production to manufacturing and transportation.**
- **Focus inspection resources on high risk plants, products, and processes. The criteria for classification of risk for food processors include: type of processing, type of food, volume of product manufactured/distributed, target population, and compliance history.**
- **Utilize sampling and analysis to support inspectional programs. Sampling should take into account the level of risk, including the type of commodity to be sampled.**
- **Obtain immediate corrections and long-term improvements.**
- **Respond efficiently to prevent unsafe products from reaching consumers or to remove unsafe food from the human food system.**

(Note: The following additional eight (8) paragraphs follow in order).

77 bis (a) National food control programs should, as part of their inspection and control program, include:

- **Inspecting premises and processes;**
- **Evaluating HACCP plans;**
- **Sampling and testing food as appropriate; for example, during harvest, processing, storage, transport, or at the point of sale;**
- **Responding to non-compliance with food laws;**
- **Recognizing hazardous and/or spoiled food that is unfit for human consumption;**
- **Procedures to address patterns of consumer complaints that indicate food safety or fraud issues are occurring.**

77 bis (b) Inspections, as a component of control programs, should ensure that controls cover, as appropriate:

- **establishments, installations, means of transport, equipment, and material;**
- **raw materials, ingredients, technological aids, and other products used for the preparation and production of foodstuffs;**
- **semi-finished and finished products;**
- **materials and objects intended to come into contact with foodstuffs;**
- **cleaning and maintenance products and processes, and pesticides;**

- processes used for the manufacture or processing of foodstuffs;
- the application and integrity of health, grading and certification marks;
- preserving methods;
- labeling integrity and claims

77 bis (c) The frequency and intensity of controls should be designed so as to take account of risk and the reliability of controls already carried out by those handling the products including producers, manufacturers, importers, exporters, and distributors.

77 bis (d) When physical checks are to be undertaken, sampling should take into account the level of risk, including the presentation and type of commodity to be sampled.

77 bis (e) Where quality assurance systems and food safety plans and/or preventative control plans are used by food businesses, the national food control system should take them into account when such systems relate to protecting consumer health and ensuring fair practices in the food trade. The voluntary utilization of food safety and/or quality assurance systems by food businesses should be encouraged in order to achieve greater confidence in the safety and quality of products.

77 bis (f) Administrative procedures should be in place to ensure that controls system are carried out:

- regularly in proportion to risk;
- where non-compliance is suspected or identified;
- in a coordinated manner between different authorities, if several exist;
- re-inspection carried out when non-compliance is found.

77 bis (g) The effectiveness and appropriateness of control programs should be reviewed. Criteria for review should be established and inspection programs should be reviewed when new information becomes available e.g. emerging hazard or changes in susceptible population.

77 bis (h) Inspectors and other officials involved in control programs should continuously be provided with updated knowledge regarding hazards in food and new technologies, etc. to ensure their ongoing competency.

Rationale: Provides additional guidance relating to control programs.

Assessment and Evaluation: The United States notes the Secretariat's note within the box regarding the placement of this section. We prefer the section to be a stand-alone section, both because of its importance and because of its distinct nature, separate from other activities.

This section can be moved down to follow the training section. Additionally, the heading phrase can be removed for consistency of heading formatting and used to create a new paragraph 77 (i), just preceding paragraph 78, as follows.

77 bis (i). Assessment and evaluation includes, as appropriate, audits, inspections or other tools to evaluate the effectiveness of the food control programme, including the recognition of trends.

Rationale: For consistency of formatting, the phrase accompanying the section heading should be removed but the content works well as an introductory paragraph to this section.

Paragraph 80. Redraft as follows: "Assessment of the efficacy of the national food control system should **take into account food safety outcomes, and** be targeted at the most appropriate stages in the food chain, based on risk analysis...".

Rationale: additional component that should be considered in the assessment of a national food control system.

Add a new paragraph 80bis as follows.

80bis The assessment of programs should cover issues such as:

- **Effectiveness of control procedures;**

- **Suitability in achieving objectives; and**
- **Whether the program has covered relevant stages in the production chain, taking into account risk factors.**

Rationale: Provides additional guidance relating to assessment and evaluation.

Add a new paragraph 81 bis as follows:

81bis The results of the evaluations, including the results of self-assessment and third-party audits should be taken into account in further development of the system, and corrective actions should be taken as appropriate.

Rationale: Provides additional guidance relating assessment and evaluation.

Paragraph 83. Delete the final phrase regarding legislation: “In verifying compliance with requirements, competent authorities should acknowledge that different means can be used to achieve the same objectives ~~unless the means have been explicitly prescribed in legislation.~~”

Rationale: Codex standards are voluntary, and countries can utilize them as appropriate. Specific provisions relating to national legislation are unnecessary in Codex texts.

Delete 4.31. Heading- **4.3.1 RESOURCES (INCLUDES LABORATORIES, STAFF, TRAINING, ETC)**

Rationale: Laboratories, resources, training, and surveillance-investigation-response should be individual sections and not combined under “resources” as they have an importance that is generally the same as other sections of this part of the document.

Create a heading “Laboratories” before paragraph 52, as follows:

Laboratories

Rationale: The section on laboratories requires its own heading.

Paragraph 87. Redraft the first sentence to read: “The Laboratories should have adequate facilities for physical, microbiological and chemical analyses as well as technical capability to perform reliable testing.”

Rationale: Adds important provision relating to technical capability.

Delete the phrase after “Resources” and place in a new introductory paragraph to this section, as follows:

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

92bis Competent authorities operating national food control systems should, on a continuing and comprehensive basis, have adequate resources, including staffing, equipment, facilities, and funding.

Rationale: To provide consistency of heading formatting and to retain the content of the phrase which is useful as an introductory paragraph to this section.

Add two new paragraphs, 94bis and 94 bis bis, as follows.

94bis Funded programs should include those relating to regular inspection and compliance/enforcement, laboratory operations, standards development including risk assessment/risk management activities, training and development, and community outreach and education.

94bis bis With respect to program operation and, in particular, with respect to risk management, in the choice of control measures, there should be regard to costs to consumers and to the costs in money and time to the affected food industry and government consulting with interested bodies as appropriate.

Rationale: Provides additional guidance relating to resources

Paragraph 96- Add a new sentence and associated bullets to the paragraph as follows:

96. Programmes and training manuals should be developed, implemented and maintained to ensure consistent application of requirements. **Documentation of a national food control system should include:**

- **An organizational chart of the official control system;**
- **Roles of each level in the hierarchy (including other relevant jurisdictions; i.e., State, Provincial);**
- **Job functions and qualifications as appropriate;**
- **Operating procedures including methods of inspection and control, sampling, and testing;**
- **Relevant legislation and requirements;**
- **Arrangements for coordination with key officials in relevant ministries and private sector organisations;**
- **Relevant information about food contamination and food control;**
- **Procedures for conducting food recalls and investigations;**
- **Relevant information on staff training; and**
- **Programmes and training manuals should be developed and implemented to ensure uniform application.**

Rationale: Provides additional guidance relating to training programmes.

Insert “**Assessment and Evaluation**” Section (paragraphs 78, 79, 80, 80 bis, 81, 81bis) following the “Training” section and before the “Surveillance, Investigation and Response” Section.

Rationale: Better logic flow of the document.

Paragraph 98- Add a new sentence to the end of this paragraph:

98. The competent authority(ies)...from foodborne disease information. **Foodborne illness and outbreak information should be used to inform the risk analysis activities of competent authorities.**

Rationale: Provides additional guidance relating to the use of surveillance information.

Paragraph 99. Add a new sentence at the end of this paragraph:

99. The competent authority should ensure... implemented for this purpose. **Emergency response systems should be tested periodically to ensure that the communication and response system works effectively.**

Rationale: Provides additional guidance relating to maintaining response systems.

Section 4.4. Continuous Improvement. The United States can accept this section noting related changes made earlier in the text.

Paragraph 105. Modify the second sentence as follows: “These changes may also require amendments to legislation; changes to control programmes and/or laboratory practices **including their design.**”

Rationale: Provides additional clarification on elements that should be taken into account in regard to continuous improvement.

IACFO

General comments

IACFO strongly supports Principle 1 and Principle 3. Overall, while the Principles have been fully shaped by the Working Group in preparation of the Committee meeting, the Framework document lacks some clarity. From the standpoint of creating a true framework for use by developing countries and others, IACFO proposes that certain paragraphs of the Framework be removed into an Appendix. This would greatly improve the clarity of the framework and put important theoretical considerations that support the framework into a single section, so they could be read together.

The paragraphs that would fit in such an appendix are:

32, 33, 34, 35, 38, 54.

Additionally, several important components of a national food system need to be clearly characterized. For example, recall is referenced in paragraphs 58, 65 and 98 but nowhere described in the framework. Tracing food is similarly discussed in paragraphs 29, 30 and 60, but not described. IACFO will propose definitions for recall and traceability and propose their placement in the Compliance and Enforcement section of the framework.

Specific comments:

Paragraphs 32, 33, 34, 35, 38, 54

IACFO recommends removing these paragraphs to an appendix to improve readability of the document.

Rationale: While these paragraphs contain many important concepts that should be considered in system design, they do not in fact provide core components of a national food safety system. In addition, a more streamlined document would improve its readability.

Paragraph 38, Legislation

IACFO supports restructuring these paragraphs to be more concise and descriptive. Specifically, the paragraphs set up a system where each country has national “objectives” (i.e. “legislation should set overarching objectives”, “specific or lower objectives”). This term implies that each country’s “objectives” will be different, and potentially inconsistent with the Principals outlined earlier in the document.

IACFO recommends the adoption of the following definition at the beginning of the legislation section and the following new section to replace paragraph 38:

Legislation - Regulatory foundation and legislative framework, including the laws, regulations, rules, ordinances, or other authorities and regulatory requirements that govern the operation of a national food control system.

38. The national legislation should define the structure of the food-control management system, including providing clarity as to the roles and responsibilities of **government and industry** participants in the food chain. Legislation should **set forth the core responsibilities of that system including: establishing regulatory measures, monitoring system performance, facilitating continuous improvement, and providing overall guidance.** Consideration **should be given to adequately identifying** the risk of **specific** food **categories** and resources available in the design of the system and the application of the following elements.

Rationale: The definition following the heading is consistent with other sections in the document, e.g. Assessment and Evaluation; Compliance and Enforcement; Resources.

The proposed new paragraph 38 includes some elements from the previous version, but sets forth a much clearer description of the components of legislation, including its importance in defining the structure of the food-control management system.

Paragraph 39,

IACFO recommends deleting this paragraph, or moving it to an Appendix.

Rationale: With the change from Inspection to Control Systems, this paragraph lacks clarity. The phrase “flexibility in the nature and frequency of control programs” seems unclear. This is also entirely inconsistent with much existing national legislation. IACFO strongly objects to the retention of this paragraph.

Paragraph 45 to 47, Assessment and Evaluation

IACFO recommends the addition of a new paragraph in the section covering Assessment and Evaluation:

#. Countries 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 health sector.

Rationale: The present draft lacks a provision covering evaluation of national surveillance systems. These systems are essential to assuring effective public health protection, especially in a food emergency, such as an outbreak of disease linked to contaminated food stuffs.

Paragraphs 48 to 50, Compliance and Enforcement

IACFO observes that while the concepts of recall and traceability are referenced elsewhere in the text (recall, para. 58, 65, 98; traceability, paras. 29, 30, 60), the concepts are not defined as components of a national food safety system. This deficiency can be remedied by adding text to the Compliance and Enforcement section.

A. The national food safety system should have comprehensive procedures covering the prompt removal of contaminated and mislabeled food products from the domestic market. Recalled products that are deemed to be unsafe should be properly disposed of and not exported to other countries. Where distribution has occurred, appropriate consumer notification should be given.

B. Tracing systems are necessary to identify the source of food linked to a disease outbreak to facilitate its rapid market withdrawal. Tracing systems should be designed to start with food production, and should encompass appropriate tracking information (lot numbers, time and date marking) to allow for prompt identification.

C. Recall systems and other market withdrawal systems should be a coordinated effort between the national government and food business operators. If the government 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 from national governments.

Rationale: The concepts of recall and traceability appear in many places in the document, but are not defined in the text. These additional paragraphs will give national governments a clear concept of the importance of these systems, and how they should be designed.

IACFO recommends the addition of a new section on food emergencies:

#. In order to respond to food safety emergencies, consideration should be given to the establishment of a national food safety emergency coordination body with links to law enforcement and intelligence agencies, food-recall systems, risk assessment specialists, the food industry, and others. These systems should be periodically tested to ensure that the communication and response systems work effectively.

Rationale: The last paragraph was derived from a World Health Organization report on responding to food emergencies.

Paragraph 54,

IACFO recommends that this paragraph be moved to an Appendix. It is commentary on the application of the previous paragraphs 52 and 53. The framework should include the essential elements, and commentary should be addressed elsewhere.

Paragraph 55, Resources

IACFO recommends replacing paragraph 55 with the following paragraph:

#. National food safety programs must be funded sufficiently and transparently to enable the programs to conduct regular inspections of food-processing facilities and imports; to conduct laboratory tests of both domestic and imported food; and to set standards and perform risk analyses, as well as many other functions. The nature of the funding must not compromise the program's integrity and independence.

Rationale: As currently written, paragraph 55 seems more concerned with the “effective and efficient” use of resources than the common problem of absence of resources. In addition, paragraph 55 reverts to the previously referenced language on “objective of the national food control system” that is vague and unclear. The bullets of the existing paragraph seem to repeat earlier text in the document, with the possible exception of the final bullet point. This could be rewritten as a new paragraph:

#. Resources can be leveraged by undertaking agreements with other countries' competent authorities, including the establishment of equivalence agreements.

Paragraph 60,

IACFO applauds the government of Japan on providing highly descriptive language regarding the elements of the surveillance, investigation and response system. We would like to propose one minor addition to b) as follows:

b) Review and response:

- Correlate and analyze data, **including food attribution data to facilitate outbreak response and prevention.**

Rationale: Food attribution information available from outbreak investigations provides essential information for implementing HACCP systems (particular for doing the Hazard Analysis) and for evaluating the effectiveness of the various components of the national food safety system.

IIR

The International Institute of Refrigeration (IIR) would like to thank the working party that has developed draft principles and directives for national food-control systems.

General Comments

It would be useful to specifically mention temperature and humidity control (on a per-product basis) in the principles and directives. Indeed, many foodstuffs that are not preserved under good conditions can be detrimental to health in a number of different ways: enzymatic breakdown, contamination with toxins produced by pathogens, growth of pathogenic bacteria.... Foodstuffs may also be totally lost or may lose part of their nutritional quality.

Controls, analysis and measurements must not be confined to the final condition of the foodstuffs; means are also vital and control of the means implemented is also vital.

Given that temperature is involved, the main sources of faults are the following: offloading (without forgetting the last halt before export), the beginning of the chain (collection, where production is very dispersed) and the final link (the store), but of course the latter does not concern exports.

Good risk analysis should focus on:

- Transport, storage-site, measuring and control equipment...
- Maintenance management (ability to repair rapidly and maintain on a regular basis)
- Temporary solutions in the case of a breakdown (degree of insulation....)
- Organization or definition of responsibilities within the chain (with a particular focus on links where no-one is in charge: for instance, containers left in a parking area by a transporter when a warehouse is closed)
- Staff and operator training and awareness-raising (for producers, handlers, carriers, warehouse managers, etc.)
- Implementation of control (recorders, TTI, inspection...) and checks on those in charge of controls.

OIE**General comments**

The OIE recommends that the Working Group consider some adjustments to the text, as set out below, to highlight the importance of coordination between authorities responsible for food safety and animal health. This is a key consideration to enable the development and implementation of programmes for the control of food born hazards that must be implemented wholly or in part at the on-farm level, e.g. veterinary drug residues, salmonella, trichinellosis.

The OIE supports the proposal to define the term 'competent authority' and notes that this matter was referred to CCGP (see paragraph 23). We note that this term was defined in CAC/GL 71-2009 as 'official government organisation/agency(ies) having jurisdiction'.

The OIE defines the term Competent Authority in the *Terrestrial Animal Health Code* and the *Aquatic Animal Health Code* as:

‘the Veterinary Authority or other Governmental Authority of a Member having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the *Terrestrial Code* and in the OIE *Aquatic Animal Health Code* in the whole territory.’

Specific comments

Paragraph 61 Where appropriate, the national competent authority should utilize the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19/1995), the International Health Regulations (IHR), ~~and~~ the International Food Safety Authorities Network (INFOSAN) for national and international emergency notification and response. [Japan/Canada] **The authority should also take steps to facilitate reporting of OIE listed zoonotic diseases according to the relevant OIE disease reporting obligations**

Rationale: Some foodborne zoonotic diseases are listed by the OIE. It is important to encourage collaboration and coordination between the Food Safety Agency and the Veterinary Services at the national level, particularly for diseases in relation to which control measures must be implemented wholly or in part at the farm level.

Paragraphs 91 and 92

91. The effective linkages should be established between laboratories in food control agencies and those in the public health system to utilize information on foodborne diseases for developing risk based food control policies. (FAO Food and Nutrition Paper 76, page 8 last para modified) [Japan]. **Effective procedures for communication should be established between laboratories within food safety/public health agencies and the Veterinary Services, to ensure coordination and to facilitate investigation and management of food safety hazards arising on the farm.**

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

Rationale: clear communication between public health agencies and Veterinary Services enables development and revision of programmes for the control of hazards at the on-farm level, e.g. veterinary drug residues, salmonella, trichinellosis.

Paragraph 98 The competent authority(ies) should utilize information gained from the surveillance of foodborne illness as a risk management tool in the operation of their food control systems. Food recalls and adjustments to food production and processing operations, including emergency responses, may be based on information obtained from foodborne disease information. [US] **The competent authority(ies) for food safety should establish effective coordination with the Veterinary Services to facilitate the development and implementation of appropriate on-farm control programmes, as appropriate.**

Rationale: clear communication between public health agencies and Veterinary Services enables development and revision of programmes for the control of hazards at the on-farm level, e.g. veterinary drug residues, salmonella, trichinellosis.

Paragraphs 38 and 51

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

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

Comment: The term '**authorised providers**' is not clear and should be explained or defined.