codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



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Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Eighteenth Session

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PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR NATIONAL

FOOD CONTROL SYSTEMS

(N06-2009)

(Comments at Step 3)

(Brazil, Bolivia, Canada, Costa Rica, Mexico, New Zealand, Panama, Philippines, South Africa, United States, FAO and OIE)

<u>Brazil</u>

General Comments

Brazil would like to congratulate Australia for the excellent work done and is pleased to forward its comments on the Proposed Draft Principles and Guidelines for National Food Control Systems.

Specific Comments

Paragraph 31

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

Rationale: Brazil proposes to eliminate this part of the sentence in order to maintain coherence with paragraph 30 which establishes that the food business operator has the primary responsibility for food safety.

<u>Bolivia</u>

General Comments

Bolivia would like to express its concern regarding the translations of CCFICS documents into Spanish, as they do not reflect the meaning expressed by the working groups, making it difficult to understand the documents and resulting in countries adopting incorrect positions.

Specific Comments

3. Fitness for purpose – [inspection systems should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required⁶.]

Justification: Bolivia does not consider it relevant to include Principle No 3 referring to the fitness for purpose. We consider that as it is already included in the document CAC/GL 20-1995 Principles for Food Import and Export Inspection and Certification, it is understood that it should be taken into account in the present document.

GUIDELINES - FRAMEWORK FOR A NATIONAL FOOD CONTROL SYSTEM

Higher level elements of a national food control system

What does the system apply to? System application

Justification: Sense of the text is clearer in relation to the subsequent points.

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

In the Spanish, replace "comerciantes minoristas" with "comercializadores". [No change to the English text]

Justification: Text clearer regarding those involved in the food control system in each country. It is not considered relevant to include academic and scientific institutions¹ as they are not part of a control system; they provide scientific information but they do not perform food safety control activities.

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

Justification: It is suggested deleting point 9, because consumers are not part of the food control system and the aim of these systems is to protect consumer health.

What does a national food control system achieve? Achievements of national food control systems

Justification: Sense of the text is clearer in relation to the subsequent points.

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

[Alternative wording for 12^2 : The requirements of national food control systems should be implemented and enforced in a uniform, coordinated and consistent manner by the competent authority(ies)]

Justification: We suggest approving the alternative text, because it is important to refer to the food control systems implementing uniform and consistent control measures. Additionally, we suggest mentioning that this control also be applied in a coordinated manner for those countries that have more than one competent control authority.

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

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

Reword the Spanish as follows: "Dicha comunicación debería incluir tomar en cuenta:" [No change to the English text]

Justification: The documents mentioned in the first bullet point are references for the communication process and so are not actually part of communication. For this reason, it is suggested including an additional point that clearly defines this concept.

33. Effort should be made to improve capacity of regulatory authorities, particularly those of developing countries_a. Capacity building for developing countries either through bilateral arrangements or with

¹ Translator's note: Spanish says "academic and scientific institutions" whereas the English says "academics and scientific institutions".

² Translator's note: Spanish text actually says 13, as in the English.

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assistance of international organizations should be directed toward implementation of these principles and guidelines³.

Justification: Clarifies the meaning of the text.

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

Justification: The legislation and procedures must always be developed to establish the extent to which the products comply with the requirements and not leave compliance or otherwise up to a country's discretion.

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

Justification: We suggest that this be the initial paragraph of the Legislative Framework in the document, so that countries give greater importance to including Codex standards in their legislation.

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

Justification: We suggest this text to ensure compliance with National Treatment provisions in WTO agreements.

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

• Approval of processors or other operators, e.g. by means of licenses or registration;

Justification: Internationally, licenses and registration are uniformly recognised as an approval document for processors or other operators.

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

Justification: Clarifies the meaning of the text.

<u>Canada</u>

Canada would like to thank Australia for leading the working group on the *Proposed Draft Principles and Guidelines for National Food Control Systems*. We are pleased to offer the following comments for consideration:

General Comments

Canada is fully supportive of the development of a Codex text highlighting Principles and Guidelines for National Food Control Systems. We view the development of this Codex text as an important undertaking, which will be of use to both developed and developing countries.

This text should provide the broad framework and high level principles guiding the development and enhancement of national food control systems. We recognize that key principles have already been developed in other CCFICS texts, but are of the opinion this work provides an opportunity to take a holistic approach/view of national food control systems including consideration of the role of official competent authorities, food businesses and other stakeholders such as consumers. This undertaking also provides an opportunity to promote the harmonization/integration of domestic (including import) control with the elements of export control systems.

At this stage of the development of this document, we believe CCFICS needs to agree on the broad framework, high level principles and key elements required in support of these principles. Once this is completed, the next step should involve the development of additional explanatory text as required.

³ Translator's note: With the suggested change, the end of the sentence no longer makes sense in Spanish or in English.

Specific Comments

For clarity and consistency, the document should refer to and employ terminology and definitions outlined in other related Codex documents, where appropriate.

Section Principles for a National Food Control System

Canada generally concurs with the four cross cutting principles that should apply to a national food control system. However, these principles would benefit from further clarification and/or articulation.

1. Protection of consumers

While we support the intent of the principle, we believe further discussion would be useful. We would be particularly interested to discuss the underlying principle related to fair practices in food trade, and its incorporation into a national food control system.

2. The national food control system should be **risk based**, **science based and harmonised** to the greatest extent possible with international standards

We support the intent of the principle. Regarding the "risk based" aspect, we agree it would be useful to reference the Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007) as it would recognize that the application of risk analysis is an integral part of a national food control system. It would also direct competent authorities to fundamental aspects/principles that should be followed in the risk assessment, risk management and risk communication activities.

With regard to the "science based" aspect of the principle, it will be necessary to identify the specific elements of the system that would support such. We view key elements such as statistics, monitoring and surveillance (found in paragraphs 18 to 20) as examples of such.

We also believe that there are some elements of a national food control system that cannot either be categorized as risk based or science based. For example, we are wondering where elements such as staffing and training processes would be categorized.

Finally, we concur with "harmonized to the greatest extent possible with international standards" and note that Paragraph 44 has a related statement in that regard. As per the question posed in relation to this paragraph, we would favour its retention in support of this high level principle.

3. Fitness for purpose

This terminology may be somewhat confusing, especially if "purpose" is not well understood. While recognizing that this Principle was drawn from an existing Codex text, consideration should be given to rewriting it (as per text in the Report of the Physical Working Group – paragraph 15, CX/FICS 10/18/4) and/or providing additional explanatory text.

Section Guidelines - Framework for a National Food Control System

What does the system apply to?

As a general consideration for this section, we believe the construct of this section should include different paragraphs to highlight the unique roles and responsibilities of: competent authorities, food businesses, consumers, and other interested stakeholders such as academics and scientific institutions.

Paragraph 7

We suggest this paragraph be kept as currently drafted. A separate paragraph (Paragraph 7 (bis) below) should be created to discuss the responsibilities of the competent authorities.

Paragraph 7 (bis)

We support the consideration of GL 47-2003 (paragraphs 6, 7 and 8 in particular) to draft a paragraph relating to the competent authorities. We believe the key points to highlight include: the notion of clear roles and responsibilities; the avoidance (to the fullest extent possible) of multiple inspections and duplicative testing; and the arrangement regarding the use of third party providers.

Paragraph 8

First, the role of **academics and scientific institutions** should be discussed in a separate paragraph (see paragraph 8 (bis) below), as their involvement is significantly different from food businesses. Regarding food businesses, a combination of existing paragraph 8 with alternate 8 could be considered as follows:

All those involved in food businesses from production to consumption, including farmers and growers, manufacturers and processors, food handlers, transporters, distributors, and retailers have a responsibility for complying with requirements and to ensure that food is safe and suitable for consumption.

Paragraph 8 (bis)

This new paragraph should highlight the unique role of academics and scientific institutions, and the following text may be considered:

Academics and scientific institutions also contribute to a national food control system, as they are the source of expertise and resources to support the risk based and scientific foundation of such system.

Paragraph 9

The role of consumers is of utmost importance to ensure safe food. However, we would suggest redrafting the paragraph as follows:

<u>Complementing food businesses, consumers also have a responsibility to ensure that food is safe and suitable for consumption.</u>

Section What does a national food control system achieve ?

In paragraph 19 of the Report of the Physical Working Group, it is mentioned that, when discussing what the system achieves, the working group considered that key components of a national food control system include the ability of the competent authority to verify that the system meets its objectives, is implemented in a consistent manner, is integrated and coordinated, and has appropriate notification and response procedures. We fully support this statement and believe the working group has appropriately captured some of the key components.

Referring back to CAC GL 47-2003, we suggest that due consideration be given to Paragraphs 14 and 15 of this text, as it may have significant relevance in the context of a domestic system. Paragraph 14 (CAC GL 47-2003) discusses the need for uniformity of operational procedures, and the importance of programmes and training to support this uniformity nation-wide. Paragraph 15 addresses the issue of implementation that ensures the levels of protection achieved will be consistent between domestic and imported foods.

<u>Costa Rica</u>

Costa Rica thanks the working group headed by Australia for the opportunity to raise the following comments.

1- Costa Rica proposes for paragraph 12, line 5, the following wording "and recognises that a system should consist of integrated elements related to domestic production", be replaced by "and recognises that a system should consist of integrated elements related to the **protection of the health of consumers,** domestic production..."

2- Reasoning: Although paragraph 15 includes the reference that "precedence should be given to protecting the health of consumers", Costa Rica considers it important that the overall outline of the document written by the Group, include protection of the health of consumers, in addition to domestic production, imports and exports of food products.

3- With reference to paragraph 20. Characteristics of the National Food Control System, Costa Rica proposes including:

x. Independence of scientific decisions from political influence.

Reasoning: The OIE^4 has been emphatic with regard to this recommendation and, in practice it has proven necessary to be able to guarantee product safety and the facilitation of trade. For developing countries, this recommendation is fundamental.

Appendix 1

INTRODUCTION

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS (N06-2009) (At Step 3)

For lines 1 and 2 of paragraph 2 "A national food control system consists of integrated elements related to domestic production, import and export of food products." Costa Rica proposes the following wording: <u>A</u> national food control system consists of integrated elements related to **the protection of the health of consumers,** domestic production, import and export of food products.

OBJECTIVE OF A NATIONAL FOOD CONTROL SYSTEM

PRINCIPLES FOR A NATIONAL FOOD CONTROL SYSTEM

Costa Rica proposes the following wording for paragraph 2: The national food control system should be <u>risk</u> <u>based</u>, <u>science based</u>, <u>with absolute independence from any political ppressure whatsoever</u>, <u>and</u> <u>harmonised</u> to the greatest extent possible with international standards.

Reasoning: The OIE document: The new tool for the assessment of Veterinary Services (PVS tool) based on the OIE's international standards for quality and evaluation, 28 July 2009. For developing countries, this recommendation is fundamental.

6- Costa Rica proposes the following wording for **3. Fitness for purpose** – [<u>effectiveness should be a sine</u> <u>qua non characteristic of</u> inspection systems should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required⁶].

GUIDELINES - FRAMEWORK FOR A NATIONAL FOOD CONTROL SYSTEM

Higher level elements of a national food control system

What does the system apply to?

Costa Rica proposes that the text for point 8 be retained as it appears in the proposed draft:

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

Costa Rica proposes that point 9 become point 10 following the insertion of an additional point as follows:

9. The national food inspection system is responsible for checking that all those involved in food business from production to consumption, including growers, regulators, transporters, distributors and small retailers comply with the requirements under national and international food standards.

Components of the systems

Infrastructure, programs and requirements

27. National food control systems should meet a number of operational criteria so as to ensure their impartiality and effectiveness and in particular have, or have access to, a sufficient number of qualified and experienced personnel as appropriate in areas such as: food science and technology, chemistry, biochemistry, microbiology, toxicology, veterinary science, human medicine, epidemiology, agronomic engineering, quality assurance, audit and law. Personnel should be capable and appropriately trained⁹ in the operation of national food control systems. Staff should have access to adequate facilities and equipment to undertake necessary procedures and methodologies. National food control systems should also possess adequate facilities and equipment to enable personnel to carry out their duties properly.

⁴: OIE, The new tool for the assessment of Veterinary Services (PVS tool) based on the OIE's international standards for quality and evaluation, 28 July 2009

Reasoning: Unnecessary.

28. Es fundamental contra contar con sistemas de transporte y comunicación confiables para garantizar la prestación de los servicios donde y cuando se los necesita y para trasladar muestras a los laboratorios.

Reasoning: Typing error in the Spanish. [No change to the English]

Costa Rica proposes joining paragraphs 30 and 31 as follows:

30. The food industry is responsible for developing and managing systems to ensure that the food supplied complies with the requirements set by the competent authority. The food business operator has primary responsibility for food safety. **Notwithstanding**, the competent authority retains the fundamental responsibility to verify and provide assurances as to the conformity of food and the associated production with requirements.

Mexico

Mexico is grateful for the opportunity to make the following comments about the document:

Para. 2.- It is suggested moving the text of paragraph 44 to the end of the first sentence: <u>Member countries</u> should use Codex standards and related texts whenever appropriate as it is an overarching principle of <u>Codex</u>.

• It is necessary to clarify whether the text in parentheses after paragraph 2 is part of the document or if it is a temporary note. Also, we agree to the reference to the Codex *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).

Principle 3.- Referring to inspection systems, and although it is an exact quotation of paragraph 6 of the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995), it is suggested adjusting this passage to be in line with the rest of the document by referring to **national food inspection** systems.

Para. 7.- The reference to paragraphs 6 and 8 are from CAC/*GL* 47-2003, but not the reference to paragraph 7.

Para. 8.- It is suggested using the alternative paragraph 8, and including a separate reference to academics and scientific institutions (in paragraph 20, given their significant risk assessment role).

Para. 12.- It is suggested adopting the alternate paragraph 12 (the same concept is repeated in paragraph 24, clarification is required).

Para. 13.- It is suggested changing as follows: "Verification \underline{by} of the national food control system...". This is because it refers to verification activities \underline{by} the control system and not an evaluation of the system itself.

Para. 15.- It is suggested changing the order of the bullet points given the scope of its application:

(1) Communication strategies...

(2) Food safety education and information to consumers

(3) Following the *Principles*...

Para. 16.- It is suggested deleting this paragraph. It does not comply with the objectives of the Codex, quoted in para. 6 and in Principle 1.

Para. 19.- The following changes are suggested: "...la información mencionada <u>previamente</u> precedentemente. Un sistema nacional ... y [la existencia de] prácticas leales de comercio." [No changes to the English text]

Para. 20.- Include a bullet point that refers to the following:

Ties to academic and scientific institutions.

Para. 21, 3rd bullet point – It is suggested <u>deleting</u> the words: "**import country findings**", given that it is implicit in the words: "<u>results of foreign assessments</u>"

Para. 22.- The reference to "competent authority" is repeated in paragraph 23.

Para. 24.- It is suggested deleting, as it is a repeat of paragraph 12.

Para. 28.- Change: "Es fundamental contra contar con..." [Typing error. No change to the English text]

Para.- 29.- Change: "… reconocimiento oficial, de modo de **para** garantizar la existencia…" [No change to the English text]

Para. 34.- Repeated in 22 and 23; clarify the meaning of this repetition.

Para. 35.- The concepts are repeated in paragraph 23.

Para. 37. Add a comma: "... en conocimientos científicos sólidos, desarrollados mediante..." [No change to the English] These ideas are repeated in paragraph 49.

Para. 38.- Repeated in 42.

Para. 39.- Replace the words "de transparencia" with "transparente". [No change to the English text]

Para. 40.- Delete. Corresponds to operations/implementation.

Para. 41.- Align with paragraph 52 and quote: "...including potential for fraud <u>or deception of consumers</u>". The prior text if there are differences between the concepts defined by Codex, if not, retain "or deception of consumers" in both paragraphs).

Para. 42.- Repeated in 38.

Para. 43.- Change: "...se refieren a <u>la protección de</u> proteger la salud de los consumidores..." [No change to the English text]

Para. 44.- It is suggested repositioning as a general principle to become part of paragraph 2 or in a separate paragraph.

Para. 46.- Inappropriate. This statement corresponds to texts about imports and exports. It is suggested considering the alternative wording with the following changes: "National food control systems should be designated and operated such that <u>control systems for food for</u> domestic <u>consumption</u> (including import<u>ed food</u>) and for export<u>ed</u> food are harmonized and integrated to the fullest extent possible."

Para. 48.- Change as follows: "The national food control system should be fully documented, including a description of its scope and operation, responsibilities <u>functions</u> and actions for staff, in order that all parties involved <u>are aware of their responsibilities</u> know what is expected of them..."

Para. 49.- The same as paragraph 37, clarify the meaning.

Operations/implementation

• It is suggested moving paragraph 40 to this section.

Para. 50.- Clarify the meaning of the last bullet point: certification based on evaluations by third parties? In which case, reword as follows:

• Certification with the recognition that food businesses meet national requirements through their registration listing, <u>based on declarations</u> through to attestations to other parties. in this regard

Para. 51.- It is suggested adopting a positive approach: "A number of these responsibilities should provide proactive **promotion of compliance with** prevention of breaches of a national food control system". Unless the intent is to make an express reference to preventing breaches.

Para. 52.- It is suggested replacing the word "descubre" with "<u>detecta</u>" and the expression "de modo de" with the word "<u>para</u>". [No changes to the English text] Additionally, refer to the comments regarding the words "**fraud**" and "**deception**" in paragraph 41.

Para. 54.- Replace the word "cursar" with "proveer". [No change to the English text]

Subtitle: Verification/maintenance and Improvement. It is suggested replacing the word "Verification" with "Evaluation".

Para. 56.- It is suggested deleting this paragraph. It corresponds to operations/implementation and is dealt with under Mexico's proposal to move paragraph 40 to the relevant section.

Para. 58.- It is suggested moving this paragraph to the end of the document.

Para. 60.- Replace the phrase "suficiencia de la" with "adecuada" [No change to the English text]

New Zealand

New Zealand was a member of the working group that developed this draft. We would like to thank the United States of America for hosting the working group meeting held in Miami, Florida and also acknowledge the leadership of Australia and the Chair of CCFICS in facilitating the work undertaken.

General Comment

New Zealand supports the continuation of this work and believes that the development of principles and guidelines for national food control systems will be of significant assistance to all Codex members.

Once completed such guidelines will assist members, particularly developing countries, in applying a consistent level of protection between imports and domestically produced foods, and ensure consistency with international standards.

Codex guidelines against which national systems can be assessed will also be of assist in undertaking determination of equivalence, and in assisting importing countries in determining whether or not products can and do meet their requirements.

New Zealand considers that the working group has produced an appropriate framework for this document. New Zealand supports the key principles identified, the characteristics and components as outlined.

New Zealand looks forward to the discussion of this draft during the 18th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems.

New Zealand will make specific comments on the content of the draft during that discussion.

Panama

General comments

As the document serves as a basis for countries to establish a national service under the Codex standards, and as a fundamental document without which it would not be possible to structure an import and export inspection and certification system, we consider that we are only at the very early stages with this step and that greater analysis is required.

Given that one of the concerns of CC/FICS is to ensure that national systems serve as a basis for structuring import and export systems, we recommend drawing up a proposal to change the mandate of CCFICS, factoring in the WTO's Principles of Non-Discrimination and National Treatment, avoiding approaches that focus on the differences between national systems and food import and export inspection and certification systems.

We consider it necessary to include guidelines to help countries implement these recommendations in their national food control systems.

Specific comments

The specific comments are set out below:

Paragraph 13. Retain the alternative text

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

Justification: Food control is the responsibility of the relevant official authorities, even though the activities performed to exercise this control may be delegated to other recognised organisations at any relevant point in the food chain. As a result, it is up to the relevant official authorities to ensure the systems are "implemented and enforced", as stated in the alternative text.

Philippines

General Comments

We generally support the development of a guideline document that will assist developing countries in developing and revising their national food control system. We commend the Physical Working Group in coming up with a document that can based used as a starting point. The PWG was able to identify the elements that need to go within an ideal national food control system.

However, the Committee has to determine what the documents intends to provide. If the document intends to provide general principles and guidelines for national food control systems, then it should cover all the five (5) essential components of a food control system namely (1) food control management, (2) food legislation, (3) food inspection, (4) official food control laboratories and (5) IEC as outlined in the FAO publication on "Strengthening National Food Control Systems Guidelines to Assess the Capacity Building Needs." Otherwise, it may be necessary to refine the title of the document to reduce its scope.

Specific Comments

Introduction

Paragraph 1

An effective national food control system is <u>a necessity for every nation in order to</u> <u>one that is able to</u> protect its consumers (national and international) against foods, <u>whether produced domestically or</u> <u>imported</u>, that are contaminated, adulterated or in any ways injurious to health, or which are incorrectly packaged or labelled <u>as prescribed by law</u>.

Rationale: A country may have in some ways or means a food control system, although some countries may only have control over a particular part of the food chain. Even if this is the case, some semblance of control is in place. We do recognize that it is a necessity, however, the focus of the document should be on the matters that it needs to address which to protect its consumers from products that are contaminated, etc. These goods may be those that are produced domestically or imported.

The proposal to insert the phrase "as prescribed by law" is to emphasize that the foremost responsibility of food control is to enforce the food laws protecting the consumers against unsafe, impure and fraudulently presented food as stated in the FAO publication (FAO Food and Nutrition Paper 76).

Scope

Paragraph 4

These principles and guidelines provide a framework to assist national government in the development and operation, and improvement of an existing of a national food control system. Such systems are...

Rationale: There should also be provisions on how countries can further improve their existing national food control systems, i.e. streamlining of functions, etc.

Principles for a National Food Control System

1- Protection of consumers

In the design of national food control systems, precedence should be given to protecting the health of consumers...

Rationale: This is already reflected in the Objective section. This can be merged with paragraph 6.

Principles for a National Food Control System

5 – Cooperation: There should be cooperation between and among concerned national government agencies, especially if there are several competent authorities concerned in having control over a specific part of the production chain

Rationale: In our experience, where there are cases that responsibilities are not properly delineated, we have come up with a solution that there should be great cooperation among and between government agencies in order to effectively implement a technical regulation. We believe that this should be included in the principles.

What does the system apply to?

<u>Insert a new paragraph after paragraph 7: "The competent authorities, particularly government agencies, are responsible for establishing and managing an enabling institutional, policy and regulatory framework for food safety."</u>

Rationale: While the different stakeholders have interconnected and interdependent responsibilities, it is the government agencies that provide the legal/regulatory framework of a national food control system.

Guidelines – Framework for a National Food Control System

Higher level elements of a national food control system

Paragraph 87

All those involved in food business from production to consumption, including <u>These include</u> growers, processors, regulators, transporters, distributors, retailer, <u>[academics and scientific institutions, maybe a separate bullet point]</u> which have primary responsibility for complying with <u>technical</u> requirements and ensuring <u>food safety</u> safe food on those aspects of food which are under their control.

Rationale: This should be put after 1st sentence in paragraph 7. Technical requirements are those that are mandatory in nature and which have to be complied with by the food business sector. We also believe that the aspects of the national food control system basically apply to the competent authorities and establishments. They may be included in the succeeding paragraphs of the documents and should be put in a separate bullet.

Paragraph 9

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

Rationale: May not be applicable to be put under this heading.

What does a national food control system achieve?

Paragraph 14

The competent authority(ies) involved in the national system should have clearly defined responsibilities. Where different authorities in the same country have jurisdiction over the different parts of the food, multiple inspections of duplication of testing should be avoided. a harmonized and coordinated inspection should be implemented. There should also be clear delineation of responsibilities in such cases. Strategies on how this can be resolved should be explored.

Rationale: To encourage countries with multiple agencies involved in food inspection to assess weaknesses in their respective inspection systems and develop a harmonized risk-based inspection that cuts across all commodities and product forms. Strategies will help avoid miscommunications and duplication of work.

Characteristics of the national food control system

Paragraph 18, 1st bullet

Statistical data on production, trade (both domestic and international) and consumption.

Rationale: To emphasize that there is a need to separate trade data for purposes of developing national risk assessment studies.

Paragraph 20, 1st bullet

Monitoring and surveillance programs for **foodborne** diseases and **food safety** hazards, as appropriate

Rationale: To emphasize that the monitoring and surveillance programs should focus only on those that are food-related.

Paragraph 20, 4th bullet

Efficient use of resources by means of risk categorization, **<u>implementing risk-based inspections</u>** and adjusting the intensity and/or frequency of controls according to risk category

Rationale: To encourage countries to implement risk-based food inspection to reduce minimize the use of resources.

Paragraph 23

As appropriate, clearly defined and transparent legislation and operating procedures should be developed <u>or</u> <u>updated</u> which <u>allows for the establishment of the competent authority(ies)</u> and the processes...

Rationale: The word 'updated' covers where there is an existing legislation.

Legislative framework

Paragraph 41

Insert a new bullet: "Marketing characteristics (large volumes reaching all populations, destined for infants, especially products, etc.)

Rationale: Marketing characteristics is also an important factor to consider when deciding on the nature and frequency of audit/inspection.

South Africa

General Comments

1. Most developing countries do not have a National Food Control System and food control is still fragmented. The ultimate aim is to establish such a National Food Control System, but it is a slow and complicated process. Currently the various authorities interact and cooperate with one another and is aware of each others responsibilities. The possible fear consequently exists that these Guidelines can be used against such developing countries during assessments by some exporting countries, once approved by CAC, in terms of the SPS Agreement. Some clarity would be required on this issue.

2. HACCP is not nationally mandatory in many countries as HACCP systems can be costly if properly implemented (certification costs, audit costs, etc.). Food safety systems are, however, required by the relevant authorities based on the PRP's of HACCP.

Specific Comments

Paragraph 6. Add It should also be designed in such a way that evidence is provided that the requirements of the National Food Control System are being met.

Paragraph 8. We prefer the wording of **Alternate 8** as it more clearly states the responsibility of safe and wholesome food by the food business operators.

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*. While we believe that the current working document provides much of the needed guidance, we also think that substantial redrafting of the text is needed to provide clarity and coherence to the guidance.

The United States believes the document should be developed for use as a stand-alone Codex text. In that regard, we note that certain portions of the guidance currently exist in existing food import/export texts previously developed by CCFICS. To the extent needed for clarity and completeness, the United States, in this instance, does not mind repeating certain guidance rather than cross-referencing the information. The United States notes that, since food import/export control systems are a sub-component of national food control systems, in the future it might be useful to consider whether the current text under development could become the primary text for guidance on food control systems generally and that existing guidance on such areas as guidelines for food import control systems, traceability/product tracing, the production and issuance of official certificates, the exchange of information in food safety emergency situations, and the exchange of information between countries on the rejections of imported food, could be incorporated as annexes into this overarching text on national food control systems.

The United States believes that the *Proposed Draft Principles and Guidelines for National Food Control Systems* should consist of the following broad sections: Introduction; Scope; Objective (of a national food control system); Principles; Characteristics; Components; and, Implementation. In our specific comments below, we present an outline of the construct of such a document, noting those paragraphs in the current working document that apply to the particular component in the outline. We suggest that work of the Committee at this session should be used to clarify the overall framework/organization of the document, identify the specific items/elements of each section, and determine whether text in the working document exists that can be placed in each item/element.

Specific Comments

The following is a suggested organizational outline for the *Proposed Draft Principles and Guidelines for National Food Control Systems.* For the Principles section, additional principles are suggested. For other sections of the document, if language exists in the current text, this is indicated.

Title

The United States supports the existing title.

Introduction

At this stage, the United States supports the existing introduction.

Scope

The United States supports the existing wording of paragraph 4. We believe the first sentence of paragraph 5 is unnecessary and the last sentence of paragraph 5 can be added to the end of existing paragraph 4. The scope statement would then read:

These principles and guidelines provide a framework to assist national governments in the development and operation of a national food control system. Such systems are intended to ensure that requirements for food, and the associated production systems, achieve or contribute to the achievement of the protection of the health of consumers and ensuring fair practices in the food trade. Competent authorities may apply these principles and guidelines, where appropriate, according to their particular situations.

Objective of a National Food Control System

The United States can support existing paragraph 6, noting that it may be worthwhile to consider whether the Scope and Objective sections can be combined.

We note that paragraph 6 (the current Objective paragraph) is substantively the same as the current paragraph 10. We also suggest that the current paragraph 12 could be incorporated into this section. If this were done, the Objective would then read:

The national food control system should be designed and maintained with the main objective of protecting the health of consumers and second, to ensure fair practices in trade. National food control systems should be developed and implemented to ensure consistent delivery by the competent authority(ies).

Definitions

The United States suggests that the need for this section and the specific definitions to be included can be determined at a later point in the development of the document.

Principles for a National Food Control System

The United States supports the inclusion of a clear and succinct set of overarching principles and suggests the following for consideration.

Protection of Consumers

National food control systems should be designed and maintained with the primary goal to protect the health of consumers, while ensuring fair practices in the food trade.

Fitness for Purpose

National food control systems should be effective in achieving the appropriate level of protection.

Legislative and Regulatory Framework

National food control systems should be authorized through appropriate and adequate legislation and implemented through appropriate regulations, guidelines, policies and procedures.

Based on Science

Food safety components of national food control systems should be designed and operated on the basis of objective risk analysis, appropriate to the circumstances.

Transparency

The principles and operations of national food control systems should be transparent and open to scrutiny by all interested parties, respecting legitimate concerns to preserve confidentiality.

Control Throughout the Food Chain

National food control systems should operate at any point in the food chain necessary to ensure the protection of consumers, in a manner that is not more restrictive than is necessary to achieve the appropriate level of protection.

Uniform Application

National food control systems should be developed and implemented in a manner that ensures uniform application by competent authorities.

Clearly Defined Responsibilities

The competent authority(ies) involved in national food control should have clearly defined responsibilities and authority.

Adequate Means

Competent authorities and other parties implementing national food control systems should have adequate means to perform their tasks.

Shared Responsibility

Responsibility for food safety should be shared by all involved parties from production to consumption including regulators, growers, processors, distributors, retailers and consumers.

Harmonization

National food control systems should be based on international standards, guidelines and recommendations when they exist.

Characteristics of a National Food Control System

The United States supports the inclusion of a section providing guidance on the characteristics of a national food control system. The following is a listing of characteristics that we believe should be included. Where the current text provides language to elaborate on the characteristic, this is indicated by providing the pertinent paragraphs in parens.

- Precedence to the protection of consumers.
- Risk-based and proactive
- Based on prevention, intervention and response
- Clearly defined and transparent legislation, regulations, guidelines, policies and procedures.
- Clearly defined roles and responsibilities for the competent authorities.
- Uniform national implementation
- Sufficient infrastructure and resources
- Adequate performance and enforcement capabilities

- Means to identify food safety problems
- Means to respond to food safety emergencies.
- Adaptive, responsive to change with mechanisms to review and update the food control systems
- Use of harmonized international standards to the extent possible

Components of a National Food Control System

The United States supports having a clearly identified section of the document that presents information on the components of a national food control system. While the document currently provides much of this information in paragraphs 25-24, we suggest that, for clarity, this part of the document be in a separate, clearly identified section. The specific elements of this section would be the following (numbers in parens refer to paragraphs of the current text that contain the guidance).

- Infrastructure, programs and requirements (25, 26, 27, 28, 29, 30, 31, 33, 33)
- Legislative framework (34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46)
- Design and development (47, 48, 49)

Implementation of a National Food Control System

The United States supports having a separate section on implementation of a national food control systems. The elements of this section are itemized below along with sections of the current document that contains some of the needed explanatory narrative (see paragraph numbers in parens that contain portions of needed guidance).

- Point of control
- Approval processes including recognition procedures, licensing procedures, auditing, use of certification, and similar mechanisms (50).
- Undertaking risk assessment and make risk management decisions.
- Conducting inspections, including frequency of inspection and testing and sampling/analytical requirements
- Product tracing and recall.
- Decision-making and corrective action/enforcement procedures.
- Documentation
- System verification (56-60)
- Maintenance and improvement (56-60)
- Dealing with emergency situations
- Information exchange and arrangements
- Professional development and training

Food and Agriculture Organization (FAO)

While thanking the physical Working Group and the Australian Secretariat for the preparation of the proposed draft principles, and acknowledging the eventual usefulness of a guidance document in this regard, FAO wishes to raise a question about the specific purpose of the document.

Is it intended to propose:

- relevant principles for modern food control systems and general guidance for their application, or,
- detailed guidelines, specific enough to help developing countries (in particular) to strengthen their national food control systems?

In its present state, the document does not clearly correspond to either of these purposes. The text is too detailed in some sections for general guidance, without being practical enough to help developing countries

to set up their food control system, or provide them with a self assessment tool. Furthermore, there is a good deal of repetition that presently disturbs the logical flow of the document.

In keeping with the spirit of Codex texts, FAO would recommend the preparation of an overarching document that establishes principles for national food control systems, and that provides a **concise** overall framework for the other, already existing, FICS – texts (Principles for food import and export inspection and certification, Guidelines for food import control systems, etc).

As a first step it would be important to define what a food control system is, and its main components, stating that it includes also non regulatory elements (information and communication, capacity building of small and medium size enterprises etc). This should be reflected under the "introduction" or "scope" section, in a concise statement, as well as in the discussion of the "components of a food control system" (assuming that this subsection remains after the structure of the document has been reconsidered).

In the currently proposed draft principles, the focus is almost entirely on the mandatory regulatory approach (with major emphasis of regulations, inspection and laboratory services, and with some reference made to the need for coordination). Taking the needs of developing countries into account means recognizing the major effort they have to make in upgrading the very heterogeneous food producing sector, varying from informal to industry-size businesses, with a majority of family size producing units, where the need for training is crucial, and where mandatory regulatory approaches are not sufficient. For reference, Food control systems are described in the FAO/WHO publications (as mentioned in the proposed draft principles) as "the integration of a mandatory regulatory approach with preventive and educational strategies that protect the whole food chain". Food control systems can be described around five building blocks : (i) Food law and regulations, (ii) food control management (more specifically than coordination among Competent Authorities), (iii) food inspection services, (iv) laboratory services (for food monitoring and epidemiological data) and (v) information, education, communication and training.

Once the specific purpose of the document is clarified, and a more balanced view is provided of the different components of food control systems, consideration should be given to simplifying the structure of the document. This could serve to reduce the unhelpful repetition among sections. It should also be noted that the text under various subheadings does not always correspond to the intent of the subheading itself.

World Organisation for Animal Health (OIE)

General comments

The international standard setting organisations referenced in the SPS Agreement for animal health and food safety are the OIE and the CAC and the relevant Codes and guidelines should be clearly referenced as standards. The documents published by the FAO and other international organisations provide useful guidance - they do not have the same legal status under the WTO SPS Agreement as the normative publications of the OIE and CAC.

In keeping with the WTO SPS Agreement, respect for the relevant recommendations of ISSOs is a key principle for international trade. The international standard setting organisations referenced in the SPS Agreement for animal health/zoonotic diseases and food safety are the OIE and the CAC respectively.

The relevant standards for Veterinary Services and for the management at the production level of food safety hazards are set out in the Codes for terrestrial and aquatic animals. The standards and guidelines of the World Organisation for Animal Health (OIE) are the legal basis for the quality of veterinary services and aquatic animal health services, covering animal health and animal production food safety and all related activities of veterinary services, including legislation. This point should be addressed as one of the principles of National Food Control Systems and appropriate references made to the OIE standards elsewhere in the draft text.

OIE Members have showed strong support for the evaluation of the quality of veterinary services using the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool). To date, more than 100 countries have been evaluated and several have requested follow up activities aimed at strengthening infrastructure, eg veterinary legislation, and securing investments for sustainable capacity building. Recommendations in this text pertaining to National Food Control Systems, insofar as these are relevant to the on-farm phase of food production (terrestrial and aquatic animals) should make reference to the OIE PVS procedures.

This document seems to address primarily food safety and labelling, not food security. Food security is mentioned in para 16 (seemingly the only reference in the document). If this document is intended to cover food security, the principles and guidelines should be broadened to address social, economic and development issues.

Similar to the observation in point 5., there is a single mention in the document of 'capacity building' (para 33). This would seem to be outside the scope of the document and, if to be covered, needs to be properly considered and addressed.

References to 'food business operators' are found throughout the document (eg para 30 and para 50). If this document is intended to cover the whole food chain, clear reference should be made to both producers (the on farm level) and processors (post farm gate), and appropriate references be made to the standards of the OIE and CAC, as appropriate.

The Committee should reconsider the placement of references to the ALOP concept. The reference to ALOP in para 37 is poorly worded and could give the impression that ALOP is a constraint on the use of science and risk analysis. The OIE recommends that the concept of ALOP be addressed in the introduction to the document. In dealing with ALOP it should be made clear that while it is the right of countries to apply the ALOP, they also have relevant obligations under the SPS Agreement. The use of ALOP is not a 'back door' to avoid the application of international standards and/or risk analysis. Once the ALOP concept has been presented (in the introductory part of the document) it should not be necessary to include references in paras dealing with scientific issues and international standards (eg para 37).

The OIE does not agree that countries should '...have their effectiveness evaluated by third parties'. What is the rationale for countries accepting review by unidentified third parties?

In connection with the evaluation of national systems for inspection and control, there are three specific points that should be addressed, i.e.

- i. in the context of market access requests, the exporting country should be open to review by potential importing countries, following an established framework (e.g. as being developed in CX/FICS 10/18/4);
- ii. the reviews undertaken by ISSOs are of central importance. They are relevant to self evaluations, to evaluations undertaken in the context of market access negotiations and, more broadly, in the context of strengthening national inspection and control systems.
- iii. in relation to the on-farm part of the food chain, and veterinary services, the OIE PVS Evaluation is the most relevant independent mechanism for review and is well accepted by Members - more than 100 formal evaluations using the OIE PVS Tool have been carried out at Members' request to November 2009. For assessments relating to on farm controls and/or veterinary services, the findings of an evaluation by the OIE should be taken into account.

The OIE finds the proposed new system for providing comments to Codex to be unduly time consuming and laborious. The OIE routinely handles comments on draft texts in a more streamlined manner. The impact of this proposed system on countries, particularly developing countries, should be assessed before deciding to adopt this approach.

Specific comments

Introduction

New paragraph

The standards and guidelines of the World Organisation for Animal Health (OIE) are the legal basis for the quality of veterinary services and aquatic animal health services, covering animal health and animal production food safety.

<u>Rationale:</u> The OIE is one of the three international standard setting organisations referenced in the WTO SPS Agreement. The publications of the FAO and other international organisations are advisory in nature.

Paragraph 3

In addition, the Food and Agricultural Organisation (FAO) publications *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems* (FAO food and nutrition paper 76), *Strengthening National Food Control Systems Guidelines to Assess Capacity Building Needs.* and the relevant standards and guidelines developed by the World Organisation for Animal Health (OIE) are valuable resources for member governments and organizations.

<u>Rationale:</u> The OIE is one of the three international standard setting organisations referenced in the WTO SPS Agreement. The publications of the FAO and other international organisations are advisory in nature.

Principles for a national food control system

New point 5

Alignment with relevant international standards

The relevant guidelines published by international standard setting bodies should be respected in the design and operation of national food control systems, to facilitate safe international trade and consumer confidence.

<u>Rationale</u>: WTO Members should be reminded of the obligation to respect the international standards of the three sisters and encouraged to implement relevant standards to facilitate safe international trade. The OIE standards and guidelines relevant to on farm control of food safety hazards and the activities of veterinary services are found in the Terrestrial and Aquatic Health Codes, for terrestrial and aquatic animals respectively.

Paragraph 7

The national food control system applies to competent authorities and food business <u>across</u> <u>throughout</u> the value chain from production to consumption.

Rationale: improved grammar

Paragraph 8

All those involved in food businesses from production to consumption, including growers, processors, regulators, transporters, distributors, retailers, <u>laboratories</u>, <u>{academics and scientific institutions - maybe a separate bullet point}</u>}</u> have the primary responsibility for complying with requirements and ensuring safe food on those aspects of food which are under their control.

<u>Rationale:</u> laboratories are directly relevant. The relevance of academics and scientific institutions more generally is arguable.

Paragraph 12

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

The requirements of national food control systems should be implemented and enforced in a uniform and consistent manner by the competent authority(ies), having regard to the relevant standards established by the OIE and Codex Alimentarius Commission]

Rationale: WTO Members should respect the OIE and CAC standards.

Paragraph 16

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

Rationale: Food security is outside the scope of this standard.

Paragraph 20

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

• Monitoring and surveillance programs for disease and hazards, including pathogens, as appropriate;

Rationale: 'hazards' includes pathogens.

• Mechanisms to identify emerging risks, in particular, factors indicating increased risk of noncompliance due to commercial incentives, <u>climatic extremes</u> etc.;

<u>Rationale</u>: Many other examples could be given, e.g. climatic extremes endangering the preservation of the cold chain. The single example given seems to place undue emphasis on commercial factors.

Paragraph 22

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

Rationale: the same point is covered in more detail in paragraph 23.

Paragraph 23

As appropriate, clearly defined and transparent legislation and operating procedures should be developed which allows for the establishment of the competent authority(ies) and the processes and procedures required to verify the conformity of products against requirements. <u>Uniformity</u> <u>Standardisation</u> of operational procedures is particularly important. Programmes and training manuals should be developed and implemented to ensure <u>uniform</u> <u>consistent</u> application <u>of requirements</u>⁵.

<u>Rationale</u>: It is more appropriate and feasible to identify standardisation and consistency as the goals, rather than uniformity.

Paragraph 24.

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

Rationale: this para seems superfluous as the points are covered in the previous paras.

Paragraph 30

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

<u>Rationale</u>: If this document covers the whole food chain, clear reference should be made to both producers (the on farm level) and processors (post farm gate).

Paragraph 33

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

Rationale: Outside the scope of this document.

Paragraph 35

Add new para 35bis The legislation supporting the activities of Veterinary Services, particularly for on farm food safety, should be consistent with the OIE standards and guidelines on veterinary legislation.

<u>Rationale</u>: The OIE has developed relevant standards and guidelines and WTO Members should be encouraged to respect the OIE standards, according to obligations of the WTO SPS Agreement.

Paragraph 37

Requirements, including food regulations, standards and codes of practice should be based on sound science,

⁵ Guidelines for Food Import Control Systems CAC/GL 47-2003 paragraph 14

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developed using risk analysis principles⁶ and to the extent possible, be consistent with international standards where such requirements achieve the appropriate level of protection established by the competent authority.

<u>Rationale</u>: the inclusion of the phrase 'to the extent possible' covers the possibility of countries establishing more restrictive standards if considered appropriate based on their ALOP. If ALOP is to be specifically mentioned in this context, it should also be explicitly stated that countries have relevant obligations when exercising this right.

Paragraph 44

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

<u>Rationale</u>: WTO Members are obliged to respect both Codex and OIE standards under the WTO SPS Agreement. While OIE standards relate to animal health and zoonoses and are not in themselves WTO SPS references for food safety, this document sets out to cover the whole food production chain, therefore the OIE standards should be mentioned.

Paragraph 46

Use the proposed alternative, ie National food control systems should be designated and operated such that domestic (including import) and export food control system are harmonized and integrated to the fullest extent possible.

<u>Rationale:</u> this wording is clearer.

Paragraph 48

The national food control system should be fully documented, including a description of its scope and operation, responsibilities and actions for staff, in order that all parties involved know what is expected of them. Documented procedures assist in ensuring that the controls are carried out consistently and uniformly.

Documentation of a national food control system should include:

- An organizational chart of the official control system;
- Roles of each level in the hierarchy (including other relevant jurisdictions i.e., State, Provincial);
- Job functions as appropriate;
- Operating procedures including methods of **inspection and control, sampling and testing**;

Rationale: Wording re-ordered to make it more complete and clear.

- Relevant legislation and requirements;
- <u>Arrangements for coordination with key officials in relevant ministries and private sector</u> <u>organisations</u> <u>Important contacts</u>;

Rationale: the point was not clear: suggested rewording to clarify meaning.

Paragraph 50

• Recognizing accredited or accreditation of laboratories in accordance with internationally recognized standards;

Rationale: grammatical requirement.

• Providing for <u>the identification and</u> tracing of food products7 and for the recall of unsafe products;

Rationale: both identification and tracing are required in this point.

⁶ FAO–WHO Food Safety Risk Analysis: A guide for national food safety authorities (FAO Food and Nutrition Paper 87)

⁷ Principles for Traceability/Product tracing as a tool within a food inspection and certification system CAC/GL 60-2006

- Implementing administrative and/or judicial measures when specific requirements are not satisfied; and
- Certification with the recognition that **food producers and** processors **and associated** businesses meet national requirements through their registration listing, including the provision of through to attestations to other parties in this regard⁸

Rationale: Reworded to clarify the meaning.

Rationale: need to make it clear that both producers (ie farms, aquaculture establishments) and those handling the animal product beyond the farm gate are responsible for complying with national requirements.

Delegation of activities to the private sector, as appropriate and as provided for under the • relevant legislation.

Rationale: in many countries some official responsibilities are delegated to individuals or organisations in the private sector. If this is not covered already, this point should be added.

Paragraph 52

Where a product or process is found not to be in conformity, the competent authority should shall take action to ensure that the operator remedies the situation. The resulting measures should take into account any repeated non-conformity of the same product or process to ensure that any action is proportionate to the degree of public health risk, potential fraud or deception of consumers.

Rationale: use of should is preferred in a document of this nature; the word shall is not found elsewhere.

Paragraph 53

The specific measures applied with regard to future production may include:

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

Rationale: need to make it clear that both producers (ie farms, aquaculture establishments) and those handling the animal product beyond the farm gate are responsible for complying with national requirements.

Paragraph 55

Where the competent authorities use third⁹ party providers as officially accredited bodies to implement controls, to be officially accredited, the third party provider should be assessed against objective criteria and officially accredited. The performance of the third party provider should be monitored by the **Competent Authority.**

Rationale: sentence reworded to be more clear and complete.

Paragraph 59

The competent authority(ies) implementing the national food control system should carry out periodic selfevaluation and should request formal evaluations by international standard setting bodies, where such evaluations are available. In the context of market access negotiations, the competent authorities should allow access by importing countries to assess the or have their effectiveness of their national food control system evaluated by third parties.

Rationale: What is the rationale for countries accepting review by unidentified third parties? The key point is that in the context of market access requests, the exporting country should be open to review by potential importing countries.

⁸ Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems CAC/GL 26-1997 paragraph 22 Guidelines for Design, Production, Issuance and Use of Generic Official Certificates CAC/GL 38-2001 ⁹ Guidelines for Food Import Control Systems CAC/GL 47-2003 paragraph 8

In relation to the on farm part of the food chain, the OIE PVS Evaluation is the most relevant independent mechanism for auditing veterinary services and is well accepted by Members - more than 100 formal evaluations using the OIE PVS Tool have been carried out at Members' request (to November 2009).

In addition, para 60 duplicates para 59; either the two paras should be merged or the three different concepts should be clearly separated: i.e., self evaluation; versus evaluation by an independent organisation, in particular an ISSO; versus evaluation by a trading partner.

Paragraph 60

Self-assessment or third party <u>audits/evaluations by international standard setting bodies or other</u> <u>relevant organisations</u> should be carried out periodically at various levels of the national food control system, using internationally-recognized procedures. The national food control services of a country may undertake self-assessment for such purposes as assuring the adequacy of consumer protection and other matters of national interest or improving internal efficiency.

<u>Rationale</u>: In relation to the on farm part of the food chain, the OIE PVS Evaluation is the most relevant independent mechanism for auditing veterinary services and is well accepted by Members - more than 100 formal evaluations using the OIE PVS Tool have been carried out at Members' request to November 2009.