

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

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ORGANIZATION



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Agenda Item 3 (b)

CX/FICS 05/14/4 – Add 1
November 2005

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

Fourteenth Session

Melbourne, Australia, 28 November – 2 December 2005

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR RISK-BASED INSPECTION OF
IMPORTED FOODS

(N05-2004)

Comments At Step 3

(Comments received from Argentina, Australia, Canada, India, Kenya, Malaysia, Mexico, New Zealand, the United States and Consumers International)

ARGENTINA

GENERAL COMMENTS:

Argentina wishes to thank the CCFICS and the chair of the Working Group led by the United States for the outstanding, valuable effort to progress in the design and drafting of this document, which will surely be extremely helpful to Codex Members for safety risk control of imported products.

Argentina would welcome a change in the title so that it accurately reflects that these Principles and Guidelines relating to **food safety risks**. Thus, we suggest that this issue be reflected in the title.

SPECIFIC COMMENTS:

1. In the first bullet point of paragraph 7, there are differences between the English and Spanish versions. While the English version is correct, the Spanish version provides the following translation “...inocuidad de los alimentos, **calculado** para la salud humana...” where it should say “...inocuidad de los alimentos, **evaluado** para la salud humana...” In order not to create confusion, so that the Spanish version may be understood as interpreted to mean that only quantitative methods, we suggest that the text be translated as “...inocuidad de los alimentos, **evaluado** para la salud humana...”.

2. In the third bullet point of paragraph 7, Argentina requests clarification regarding the inclusion of the compliance history of: the “producer” because within the context of the paragraph it is unclear whether the term refers to the producer of the food or the producing country. If it refers to the country, we believe it should explicitly referred to the **producing country**; but if it means the primary producer we suggest that it be deleted, as for a large number of products, particularly commodities, this disaggregated information may be available in the border.

3. In the sixth bullet point of paragraph 7, we suggest a slight change to the proposed text, which would be redrafted as follows:

“Requirements used to determine the compliance of food products in a border/point of control inspection programme should be no more stringent than the requirements imposed on the same or similar products with the same risk level in the domestic market.”

4. In paragraph 10 we suggest adding a phrase at the end; thus the paragraph would be redrafted as follows:

“The level of risk assigned to a food should be reviewed periodically or when new information that may affect the food safety risk associated with the food becomes known, **in order to maintain proportionality between the intensity of inspection and the risk assessed.**”

5. Regarding paragraph 13, Argentina does not understand exactly what kind of assurance it refers to where it states that “exporting countries (...) may provide assurance to the importing country”, as export certificates are the specific assurance of compliance with the requirements of the importing country. In addition, the items referred to in paragraph 12 also provide assurance in this respect.

We wonder whether an additional obligation is intended to be created. In view of the above, we believe that paragraph 13 should be deleted.

6. As regards paragraph 16, Argentina suggests an additional comment at the end. It would thus be redrafted as follows: “Sustained conformance with the importing country’s requirements, as demonstrated, for example, by audit results and results of border/point of control checks, provides an opportunity for importing countries to reduce the inspection intensity at the border/point of control, **in proportion to the level of compliance verified.**”

7. With regard to paragraph 17, Argentina suggests that some changes may be included. It would thus be redrafted as follows: “Foodborne illness outbreaks; epidemiological findings; results of audits conducted in the exporting country; the detection of non-compliances **with safety requirements** at the point of import and detection of pathogens, contaminants and ~~potentially~~ harmful residues in imported food; and the results of border/point of control checks, may lead an importing country to increase the intensity of inspection, or in extreme cases, to suspend the trade in that product until it is confirmed that corrective measures¹ have been introduced and are being implemented effectively. An importing country may work with an exporting country to prevent the occurrence of further outbreaks.”

8. As for paragraph 16, the phrase “competent laboratories” used in the last bullet point of this paragraph is unclear, so we do not understand its scope. We would like to know whether it refers to official laboratories or to laboratories authorized by competent authorities.

Given this potential confusion, taking into account the heading of paragraph 18, we believe that the reference to competent laboratories should be deleted. The paragraph would be redrafted as follows: “Appropriate inspection procedures, appropriate sampling techniques, and validated analytical methods.”

9. In paragraph 19, we suggest a number of changes to the wording of the first part, which would be redrafted as follows: “A range of procedures can be used to ensure that imported foods meet the importing country’s food safety requirements. **When defining these procedures to verify compliance with safety requirements, the proportionality of these measures with the level of risk of the product or group of products should be considered. These procedures may be, for example:**”

AUSTRALIA

Australia thanks the United States of America for the opportunity to comment on the Proposed Draft Guidelines for Risk-Based Inspection of Imported Foods. Australia has a number of comments and proposals for redrafting the text which we believe will improve the document.

General comments

Now that the working group has decided that the document should be annexed to the *Guidelines for Imported Food Control (CAC/GL 47 2003)*, Australia considers that there may be scope to focus the draft appendix on the risk based aspects of imported food control. Australia notes that there remains material in the annex that will be a repetition, rather than addition to material in the parent document. For example para 19 in the proposed annex is a partial repetition of the section “Clearly Defined and Transparent Legislation and Operating Procedures” in CAC/GL 47 -2003.

There are many other instances where general guideline information is duplicated.

¹ In such cases, the importing country will do its utmost to ensure that corrective measures put in place by the exporting country are evaluated in a reasonable interval.

Specific comments (Please see also the attached “track changes” document that takes these comments into account)

Para 7, first dot-point: Suggest deletion of “*based on...consumption of the food*” and add the sentiment to footnote 7 (under para 9). The consumption pattern of a food (level and frequency of consumption) is one of the factors considered in assessing the level of risk. It seems odd to include just that one factor in this dot-point without mentioning all the others. This detail is best left to the later para and its footnote.

para 7, page 4, third dot point – Australia considers that this dot point may not be necessary, on the basis that the first two dot-points put the case for a risk-based system, and the considerations that should be considered within that context are covered in paras 9 and 11 so do not need to be stated as principles in para 7.

Paras 8 and 9: Australia suggests removal of “*to the extent possible*” from both paras. Particularly from para 9. Codex principles for risk assessment already cover the “to the extent possible” sentiment, in that they acknowledge resource and time constraints may affect the conduct and outputs of the risk assessment process (see, eg, 14th Procedural Manual, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, paras 23 & 25, page 104. Also to be found in CAC/GL 30 - Principles and Guidelines for the Conduct of Microbiological Risk Assessment – “Any constraints that impact on the Risk Assessment such as cost, resources or time, should be identified and their possible consequences described”).

para 9, page 4, fourth dot point - the last point here is 'third party inspection bodies' - This is first mention of third party inspection bodies. Australia suggest cross referencing to existing document to provide clarification of the role and function of third party inspection bodies within a risk based imported food inspection program.

footnote 11 on page 4 - suggest that pathogens be included, so that it reads "...findings/history, pathogens, contaminants and/or residue information..."

Para 15: Australia proposes reordering as this para could be better placed within or immediately after para 11, as it relates to the assessment of risk level (covered mainly in paras 9 and 11) and the way in which uncertainty, brought about by lack of appropriate information / knowledge, can be addressed.

para 17, page 5 – In some instances it is useful to draw on border / point of control checks done by other regulatory authorities. As currently drafted it could be interpreted to be limiting a response to situations where the importing country has specific information, rather than drawing on other countries.

Footnote 9 to para 17: “*do its utmost to*” is redundant in conjunction with the use of the term “*reasonable*”, and should be deleted.

para 19, page 6, dot points - this list limits options. Australia considers that a risk based imported food inspection program can divulge significant responsibility to some sectors of industry, and then perform an audit function as a verification of industry practices. Australia suggest that including this on the list. Alternatively if the examples were needed at all, then they could be seen as a list of possibilities, not constraining other approaches, by changing the intro to the list from “*For example, in relation to direct inspection:*” to “*Examples of direct inspection procedures include:*” and then changing the “*or*” in the penultimate dot-point to an “*and*”.

Para 20: Australia would prefer to see “*has been designed using*” replaced by “*is consistent with*”.

Para 22. The current wording seems to be confusing the risk assessment determination with the change in inspection frequency that may occur because of a non-compliance. Australia suggest amending to “*The section: Frequency of Inspection and Testing of Imported Food (CAC/GL 47 2003) notes that when dealing with imports from sources of known poor compliance history, higher inspection frequency is a valid approach for an imported food control system.*”

para 24, page 6 - not sure that this is sufficiently detailed with respect to 'laboratory competency, capability and capacity' - suggest that some parameters be put around this to ensure greater integrity - or again, a cross reference to another Codex document if this has already been addressed elsewhere.

Attachment 1

**PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR RISK-BASED [FOOD SAFETY]
INSPECTION
OF IMPORTED FOODS
(N06-2004)**

(at Step 3 of the Elaboration Procedure)

INTRODUCTION

1. This annex elaborates on paragraphs 22-26 of the main text (CAC/GL 47-2003). While the subject of these principles and guidelines is food safety, it is recognised that the intensity of inspection of imported food could be influenced by other factors relevant for health protection and fair practices in the food trade.
2. The implementation of a risk-based imported food inspection programme enables resources to be better aligned with risk. Such a programme, therefore, provides a more effective means for addressing the food safety risks that are associated with imported food², ensuring compliance of imported foods with importing countries' food safety requirements.
3. As part of a programme to assure that imported foods meet food safety requirements, an importing country may develop a programme for carrying out border/point of control inspections to inspect products when they enter the country.
4. To increase the effectiveness of an imported food programme, the implementation of a risk-based³ design ensures that greater attention is given to products that present a higher level of risk to human health⁴.
5. This document should be read in conjunction with all relevant Codex guidelines.⁵

OBJECTIVE

6. This annex is intended to provide competent authorities with information to assist them with the design and implementation of inspection programmes for imported food, based on the food safety risks presented by the product.

PRINCIPLES

7. The following principles apply to the development and implementation of an imported food risk-based inspection programme.
 - The level of risk presented by the imported food should be based on the assessed food safety risk to human health the food presents or is likely to present based on available scientific information ~~in relation to the consumption of the food.~~
 - Requirements for an imported food risk-based inspection programme should be developed using a risk analysis approach, to the extent possible.

² Imported food in this annex also includes food ingredients.

³ A discussion paper on a proposed definition of Risk-based will be considered by the Codex Committee on General Principles in 2006

⁴ Codex defines "risk" as "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (Codex *Procedural Manual*, 14th Edition, p. 45).

⁵ *Guidelines for Food Import Control Systems* (CAC/GL 47-2003); *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995); *Guidelines for the Design, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997); *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999); *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 Rejection of Imported Food* (CAC/GL 25-1997); and, *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995, Rev.1-2004).

- **Consider deleting** The intensity⁶ of inspection of a specific imported food should be proportionate to the level of risk attributed to it and take into account, where available and when appropriate, the compliance history of: the exporting country; the producer and manufacturer; those involved with the exporting or importing of the product; and, the quality of the food control system in the exporting country. (see section “Frequency of Inspection and testing of imported food CAC GL 47 -2003)
- Sampling plans⁷ and methods of analysis should, as far as possible, be based on Codex standards, guidelines, and recommendations where they exist. In the absence of Codex sampling plans, reference should be made to internationally accepted or scientifically based sampling plans when practically feasible. (See Sampling and Analysis CAC GL 47 -2003)
- The inspection system and related requirements should not be applied arbitrarily or in a discriminatory manner. Inspection of imported food should not result in unjustified barriers to trade or any unnecessary delays. (see Scope CAC GL 47 -2003)
- Requirements used to determine the compliance of imported food products in a border/point of control inspection programme should be no more stringent than the requirements imposed on the same or similar products in the food produced domestically market. (See Requirements for imported food that are consistent with requirements for domestic food - CAC GL 47 -2003)
- Information regarding a country’s risk-based imported food inspection programme should be transparent, easily accessible, and up to date. (see Clearly defined and transparent legislation and operating procedures CAC GL 47 -2003)

DESIGNING A RISK-BASED [IMPORTED FOOD INSPECTION] PROGRAMME

8. Requirements for the inspection of imported food should be developed and implemented using a risk analysis approach ~~to the extent possible~~.
9. The competent authority should use an evidence-based approach to assess the level of risk associated with the imported food products. This should take into account, *inter alia*:
 - The scientific determination of the food safety risk to the extent possible⁸.
 - The adequacy of processing controls in place in the exporting country as evidenced by the country’s laws, regulations, and other policies; its infrastructure; and its ability to effectively enforce food safety requirements, including the findings of on-site visits⁹.
 - The compliance history of the food product type generally, irrespective of the source of the food;
 - The compliance history of the food with respect to the source of the food including, where available, the compliance history of: see Clearly defined and transparent legislation and operating procedures CAC GL 47 -2003
 - the exporting country or region/area within an exporting country;
 - the producer and manufacturer;
 - the exporter;
 - the shipper;
 - the importer; and

⁶ Intensity includes the frequency of inspection and the nature of the inspection (e.g., documentation check, visual examination, sampling and testing).

⁷ *Principles for the Establishment or Selection of Codex Sampling Procedures*, Codex Alimentarius Procedural Manual, 14th Edition, Page 82.

⁸ Risk assessments, foodborne illness outbreak and epidemiological findings/history, pathogen, contaminant and/or residue information can be key components of this information.

⁹ Laboratory sampling programmes and results may provide this type of information. Audits are another way of gaining information.

- third party inspection bodies

10. The level of risk assigned to a food should be reviewed periodically or when new information that may affect the food safety risk associated with the food becomes known.

11. The competent food safety authority may establish levels of inspection intensity based on the above factors in order to determine the type and frequency of inspections at the border/point of control of a given food from a given country, producer/manufacturer, exporter, shipper, and importer. The intensity of inspection may then be adjusted according to the demonstrated compliance to food safety requirements. The levels of inspection intensity should be fully documented. (See Frequency of inspection and testing of imported food CAC GL 47 -2003)

12. When an importing country does not have prior knowledge of an exporting country's processing controls or of the product itself, that is, a compliance history is lacking or such information cannot be readily obtained, an importing country may, until there is such knowledge, initially establish a higher inspection intensity than that which it might assign to the product when such information is available.

13. For paras 12 – 17 See Recognition of Export Controls CAC GL 47 -2003)The importing country may adapt/alter the intensity of inspection of the imported food based on information from competent authorities in the exporting country regarding the exported products. This information may include:

- certificates;
- equivalence determinations;
- memoranda of understanding;
- mutual recognition agreements; or
- an assessment by the importing country's competent authority of controls its importers exercise over their suppliers.

14. Exporting countries can provide information on the control systems in place in their country and, as appropriate, may provide assurance to the importing country that a particular food product complies with the food safety requirements of the importing country.

15. Audits by the importing country may, where appropriate, verify an exporting country's inspection controls, and the information gained from these audits could be used as part of the review of the level of risk assigned to the food products from that country.

~~16. When an importing country does not have prior knowledge of an exporting country's processing controls or of the product itself, that is, a compliance history is lacking or such information cannot be readily obtained, an importing country may, until there is such knowledge, initially establish a higher inspection intensity than that which it might assign to the product when such information is available~~

17. Sustained conformance with the importing country's requirements, as demonstrated, for example, by audit results and results of border/point of control checks, provides an opportunity for importing countries to reduce the inspection intensity at the border/point of control.

18. Foodborne illness outbreaks; epidemiological findings; results of audits conducted in the exporting country; risk assessment results and information from other competent authorities or international organisations, the detection of non-compliances at the point of import and detection of pathogens, contaminants and potentially harmful residues in imported food; and the results of border/point of control checks, may lead an importing country to increase the intensity of inspection, or in extreme cases, to suspend the trade in that product until it is confirmed that corrective measures¹⁰ have been introduced and are being implemented effectively. An importing country may work with an exporting country to prevent the occurrence of further outbreaks.

¹⁰ In such cases, the importing country ~~will do its utmost~~ to ensure that corrective measures put in place by the exporting country are evaluated in a reasonable interval.

DEVELOPING REQUIREMENTS AND PROCEDURES

19. Competent authorities should take into account Codex standards, recommendations, and guidelines, when appropriate, in developing requirements for border/point of control checks of imported food and make use, when available, of:

- Relevant information from risk assessments conducted according to internationally recognized protocols for the biological, chemical, and physical hazards associated with the type of product.
- Internationally accepted or scientifically based sampling plans, to the extent possible.
- Appropriate inspection procedures, appropriate sampling techniques, and competent laboratories using validated analytical methods.

20. See “Clearly Defined and Transparent Legislation and Operating Procedures” in CAC/GL 47 - 2003) A range of procedures can be used to ensure that imported foods meet the importing country’s food safety requirements. ~~For~~ Examples of direct inspection may include:

- Checking the documentation and/or the general condition of the shipment;
- Checking documentation plus periodic product sampling (e.g., 1 in 20 or 1 in 40 shipments) to confirm the accuracy of the documentation;
- Sensory examination only;
- Random or targeted sampling and testing of, or within, shipments according to a sampling plan; ~~or~~ and
- Lot-by-lot inspection, sampling, and testing, which, in general, should be reserved for those products that present, or have the potential to present, the highest food safety risk.

IMPLEMENTING THE RISK-BASED IMPORT INSPECTION PROGRAMME

21. Countries should implement risk-based border/point of control inspection that has been designed using the above guidelines.

22. Competent authorities with responsibility for risk-based imported food inspection programs should ensure that relevant policies and procedures are implemented in a transparent, coordinated, and consistent manner. Personnel should be appropriately trained to enable such coordination, and information should be shared among competent authorities.

23. [A failure of food shipments to meet importing country food safety requirements might, besides other actions, trigger a change in the level of food safety risk for the product concerned. The response could include product being held pending final judgment combined with enhanced sampling and testing from the establishment involved or, in certain instances, from other exporting establishments from the same country producing similar products. “ The section: *Frequency of Inspection and Testing of Imported Food (CAC/GL 47 2003)* notes that when dealing with imports from sources of known poor compliance history, higher inspection frequency is a valid approach for an imported food control system.

24. When the results of border/point of control checks indicate failure of a shipment to meet the requirements of the importing country, competent authorities of the importing countries should consider action as described in the *Codex Guidelines for the Exchange of Information Between Countries on Rejection of Imported Food (CAC/GL 25-1997)* or to the *Codex Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995, Rev 1-2004)*.

25. (See Sampling and Analysis CAC/GL 47 2003)Competent authorities should ensure adequate laboratory competency, capability and capacity is available to conduct the testing of imported food.

CANADA

Canada thanks the United States for leading the Working Group, and for preparing the revised proposed draft principles.

General Comments

Canada supports the recommendation to develop the “Proposed Draft Guidelines for Risk-Based Inspection of Imported Foods” document as an annex to the Codex Guidelines for Food Import Control Systems (CAC/GL 47-2003).

Canada recommends that the Committee develop a coherent approach to the terminology regarding risk-based inspection. By Codex definition and, further, through elaboration in the introduction, it should be understood that Risk Based Inspection deals with (and is restricted to) food safety. Therefore the square brackets around “food safety” in the title of the document should be removed.

Further, the placement of the various adjectives in phrases such as “imported food risk-based inspection programme” (second bullet point of Paragraph 7) should be standardised. We suggest that “risk-based inspection of imported foods” is the appropriate terminology, along with “risk-based inspection programmes for imported foods”. Once an agreed terminology is established, all similar instances in the text should be modified to reflect this approach.

Specific Comments

Paragraph 5 - footnote 8

Following the CCFICS Working Group meeting in Brussels on “Risk-based Inspection of Imported Foods”, the Working Group on “Traceability” met and discussed a similar situation as to the appropriateness of a footnote listing a number of existing texts. The WG on Traceability agreed not to provide a general list of Codex texts with which the traceability document should be read. We recommend a similar approach be taken for this document, i.e., removal of footnote 8.

Paragraph 7 - Bullet point 2

Bullet point 2 should be placed before bullet point 1 to enhance the logical flow of these principles. The wording of former bullet point 2 should be changed to “Requirements for a risk based inspection programme for imported food should be developed using a risk analysis approach, to the extent possible.”

Former bullet 1 should reflect the wording in Paragraph 10, which describes “the level of risk assigned to a food”. Therefore, bullet 1 should be modified to read: “In determining the level of risk assigned to an imported food, an importing country should consider the assessed food safety risk to human health the food presents.....”. This would more clearly delineate between the level of risk assigned to a food versus the food safety risk calculated according to risk assessment procedures.

Paragraph 7 - Bullet point 6

It is unclear whether the first reference to “requirements” in this bullet refers to the criteria set down by the competent authorities for the imported foods, or the criteria set down by the competent authority for the border/point of control inspection programme. If the latter is intended, we would agree that similar inspection activities (e.g., sampling plans) should be no more stringent for imported products than for the same or similar domestic products. However, the same degree of stringency may not be possible if different inspection activities are employed; e.g., if compliance of imported products is verified through a sampling and testing program, but compliance of domestic products is verified through a HACCP monitoring plan.

Canada suggests that the Committee should discuss the intent of this bullet and revise the language as necessary.

Paragraph 8

In the title preceding this paragraph, we believe the square brackets should be around the words “imported food”, rather than “imported food inspection”. Concerns related to this title may be resolved during the discussion on appropriate terminology.

Paragraph 12

We believe the 5th bullet, beginning with “*an assessment by the importing country’s ...*”, more properly belongs to information gathered by the importing country’s competent authority and differs from the other bullets which directly involve the competent authority in the exporting

country. Therefore, we suggest this bullet be made a paragraph on its own and be appended as new paragraph “17bis”. The new paragraph would read as follows:

“The importing country may also adapt/alter the intensity of inspection of the imported food product based on assessments by the importing country’s competent authority of controls its importers exercise over their suppliers.”

In addition, we suggest that a new bullet be added to allow flexibility for countries to communicate relevant information on amending the intensity of inspection of an imported food.

The revised paragraph 12 would read as follows:

“The importing country may adapt/alter the intensity of inspection of the imported food based on information from competent authorities in the exporting country regarding the exported products. This information may include:

- certificates;
- equivalence determinations;
- memoranda of understanding;
- mutual recognition agreements; or
- an assessment by the importing country’s competent authority of controls its importers exercise over their suppliers.
- other appropriate means acceptable between countries.

Paragraph 17 - Footnote 13

This footnote would be more appropriately placed at the end of the sentence, since it refers to action that occurs after introduction and implementation of the corrective actions. Also, we recommend either expanding on or removing the last sentence of this paragraph. The objective of this principle is not readily apparent from the text, and without greater clarification, we feel that the sentence does not add sufficiently to the text.

Paragraph 19

Canada is concerned that a number of elements related to inspection procedures already exist in the “Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and

Export Inspection and Certification Systems (CAC/GL 26-1997, para 26)¹¹. To avoid duplication, paragraph 19 should be deleted.

Paragraph 20

We recommend this principle be either removed or modified significantly. In its current form, the paragraph does not significantly contribute to the text.

¹¹ The elements of a control programme should include, as appropriate:

- inspection;
- sampling and analysis;
- checks on hygiene, including personal cleanliness 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.

Paragraph 22

We recommend removal of the square brackets around this paragraph, and modifications to the first two sentences of the paragraph. In the first sentence, we suggest replacing “trigger a change in the level of food safety risk for the product concerned.” with the following wording: “trigger a change in the inspection intensity for the product concerned.”

In the second sentence, we suggest adding a reference to the importing country after the first two words, i.e., “The response of *the importing country* could include.....”

Paragraph 24

Similar to the comment made regarding Paragraph 19, we believe this paragraph should be deleted as it is not an element of information specific to risk-based inspection of imported foods and is repetition of text found in other CCFICS text.

INDIA**Attachment 1**

Clause 1 - Delete the following words as given in the last line:

“ and fair practices in the food trade”

The reason for proposing this deletion is that this document is related to risk based or food safety inspections and not to fair practices in the food trade.

Clause 7**Second bullet**

Second bullet to be modified as follows:

“Requirement for an imported food risk-based inspection programme should be developed using a risk analysis approach, to the extent possible, and the same should be made available to the exporting country on request.”

Third bullet

Modify the last line as follows to substitute ‘quality’ by ‘nature and extent’:

“.....the nature and extent of the food control systems in the exporting country”.

Add the following additional bullets at the end:

- “Keeping in mind the broad aim of working towards reduction of risks due to imported foods, it may require the developed importing countries to provide technical assistance to the developing exporting countries to put in place an appropriate system to address the risk. This should further ensure that no unjustified barriers to trade are imposed. “
- The inspection system and related requirements should take into account previously established equivalence determination or mutual recognition Agreements.”

Clause 9, fourth bullet - Add the following at the end:

“.....or official/officially recognized export certification body”

Clause 17 - Add the following at the end:

“Where necessary, the importing country should design and provide technical assistance to an exporting country to enable the latter to comply with the food safety requirements”

Clause 22 - Add the following before the last sentence:

“Destruction should not be resorted unless it has been agreed to by the exporter/Competent Authority of the exporting country” and add “including third party examination” at the end.

Clause 24 - Modify “capability and capacity” to read as “capability, capacity and transparency”.

KENYA**PRINCIPLES****Clause 7, bullet 3****Kenya proposes that;**

- The phrase **“and when appropriate”** in the second line of bullet number three in clause 7 **be deleted because this could be have different interpretations hence lead to misuse. The phrase “where available” is adequate.** The Statement to read as follows;

The intensity of inspection of a specific imported food should be proportionate to the level of risk attributed to it and take into account, where available, the compliance history of:

DESIGNING A RISK-BASED [IMPORTED FOOD INSPECTION] PROGRAMME**Clause 9, bullet 4****Kenya proposes that;**

- The word **“Recognized”** be inserted at the beginning of the last **item to ensure competence. The statement to read as follows;**
 - **recognized** third party inspection bodies

DEVELOPING REQUIREMENTS AND PROCEDURES**Clause 18, bullet 1**

Kenya proposes that while developing procedures, “Radiology” be considered in risk assessments in order to minimize risks associated with radio-active hazards.

MALAYSIA**TITLE**

We propose the removal of square brackets and retention of the term “food safety”

INTRODUCTION**Paragraph No.9**

Malaysia has reservations about using the term “evidence based approach “. Though widely used in clinical context, the term has not been elaborated or defined in Codex.

Paragraph No.22

We propose the removal of square brackets and retention of text in the square brackets.

MEXICO

Mexico is pleased to have the opportunity to comment on the following document:

Specific comments

Paragraph 7. - first bullet point. - The following change is suggested: “The level of risk ~~presented by~~ attributed to the imported food...”

Paragraph 8. - Is the same as the second bullet point of Paragraph 7, it is suggested deleting Paragraph 8.

Paragraph 10. - Change the tense of the verb from “podría” to “pudiera” [No change to the English].

Paragraph 12. - It is suggested changing the word “alter” to “change”.

Paragraph 17. - It is recommended changing the word “conclusiones” to “información” (the term used in the English text is “findings”), as it indicates the results of scientific study rather than those from a permanent system of supervision.

Paragraph 18. - bullet point 3.- In accordance with Paragraph 22 of the document CAC/GL 47-2003, laboratories must be official or officially recognised (this comment is also applicable to Paragraph 24).

It is suggested changing the word “convalidados” to “validados”. [No change to the English.]

Paragraph 19. - Expand the text in square brackets from “1-20 ó 1-40 envíos” to “1 de cada 20 envíos, 1 de cada 40 envíos”. [No change to the English.]

Paragraph 22. - It is suggested changing the word “hazard” to “risk”.

Paragraph 24.- See comment regarding Paragraph 18, bullet point 3.

It is suggested including a paragraph after paragraph 22, as follows:

“The degree of adjustment/change to the level of inspection applied to a food product should be proportional to the change in the level of risk experienced for the food product in question, assessed on the basis of available scientific evidence and consistent with the changes detected in the compliance with food safety requirements”.

NEW ZEALAND

New Zealand supports the development of draft *Guidelines for Risk-based Inspection of Imported Foods* and has welcomed the opportunity to participate in the working group that undertook this work.

We believe that work on the draft guidelines has made good progress but suggest that some further work is needed before the draft progresses in the Codex step process. In particular New Zealand suggests:

- the Principles need further clarification and refinement;
- the importance of compliance needs clarifying;
- the concepts of ‘frequency’ of inspection and the ‘nature’ of inspection need separating – these are different and should probably have separate principles and be discussed separately in the paper; and
- the concept that intervention at the border may not always be the most effective or efficient point for ensuring food safety and/or compliance with importing country requirements needs discussion, for example control mechanisms in the exporting country or intervention after importation and prior to end use may be more cost efficient, practical or effective.

New Zealand supports the attachment of the draft guidelines as an annex to the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003). The draft guidelines do focus on food safety matters and therefore it is appropriate for ‘Food Safety’ to be in the title, the square brackets should therefore be removed.

We note that the Codex Committee on General Principles (CCGP) expects to consider a paper on the terms ‘Risk-based’ and ‘Science-based’ at its next meeting. New Zealand believes that it is important for there to be a clear understanding of what ‘risk-based’ in connection with imported foods inspection means. Such understanding needs to fit into the overall Codex understanding of this term and therefore the work of CCGP may impact on these draft guidelines.

New Zealand does not suggest that work on further development of the *Proposed Draft Guidelines for Risk-based Inspection of Imported Foods* be delayed until CCGP have completed their deliberations, rather that CCFICS needs to be aware that such work is underway and may need to be taken into account as we progress our own work.

New Zealand is working on specific suggestions for amendments to the text of the draft appendices and expects to offer these at the 14th Session of CCFICS.

UNITED STATES**GENERAL COMMENTS**

The United States appreciates the assistance of the drafting group in the preparation of the *Proposed Draft Principles and Guidelines for Risk-Based Inspection of Imported Foods*.

With minor modifications as shown in the specific comments below, the United States supports the document and believes it will provide useful information to countries for the design and operation of their food import control systems.

We support advancement of the document in Codex Step Process. Additionally, as drafted and with the recommended modifications, we would support advancement to Steps 5/8 of the Accelerated Step Procedure.

SPECIFIC COMMENTS**Title**

Delete the bracketed text ([food safety]).

Rationale: The food safety scope of the document is stated in paragraph 1; there is no need to include it in the title.

Paragraph 7**4th Bullet**

Substitute “available” for “practically feasible” so that the second sentence reads: “*In the absence of Codex sampling plans, reference should be made to internationally accepted or scientifically based sampling plans, when available.*”

Rationale: Internationally accepted or scientifically based texts are normally feasible and should be used when available.

6th Bullet

Redraft the bullet to read: “*Requirements used to determine the compliance of food products in a border/point of control inspection programme should be no more stringent than the requirements imposed on the same or similar products in the domestic market where like conditions prevail.*”

Rationale: To make the provision consistent with provisions of the SPS Agreement provisions.

Paragraph 9 (Design)**4th Bullet, 6th dash point:**

Move “third party inspection bodies” to a separate bulleted item which would read “Information from third party inspection bodies”.

Rationale: It appears that, inadvertently, this item was incorporated as a dash point under a bulleted item rather than as a separate bullet.

Paragraph 17

Merge paragraph 22 with this paragraph. New paragraph to read:

“*The following may lead to an importing country to increase the intensity of inspections:*

- *foodborne illness outbreaks;*
- *epidemiological findings;*
- *results of audits conducted in the exporting country;*
- *the detection of non-compliances at the point of import; and,*
- *the results of border/point of control checks.*

The country's response could include product being held pending final judgment combined with enhanced sampling and testing from the establishment involved or, in certain instances, from other exporting establishments from the same country producing similar products. In extreme cases, it may be warranted to suspend the trade in that product until it is confirmed that corrective measures have been introduced and are being implemented effectively. An importing country may work with an exporting country to prevent the occurrence of further outbreaks or food safety problems."

Rationale: These two paragraphs have similar concepts, which are related to design. Reformatting is for clarity.

Footnote 13

Revise to read: *"Confirmation may include certification by the exporting country that corrective measures have been placed, and, within a reasonable interval, evaluation by the importing country that the measures are sufficient."*

Rationale: Rewording to provide greater flexibility in confirming the corrective measures have been introduced and are being implemented.

Paragraph 22

Delete

Rationale: These are design issues that can be incorporated in to paragraph 17. See above comment.

Paragraph 24

Insert "of the importing country" after "competent authorities" so the sentence reads: *"Competent authorities of the importing country should ensure adequate laboratory competency, capability, and capacity is available to conduct the testing of imported food."*

Rationale: For clarification purposes.

Thank you for the opportunity to provide these comments.

CONSUMERS INTERNATIONAL

General comments:

Consumers International considers risk-based inspections as an important tool to help Codex Members identify and focus on those products that present the greatest potential public health risk to consumers. Consumers International took part in the working group on risk-based inspections and would like to contribute to the further progress of the document.

We would have liked to see the scope of the document include other than health aspects, e.g. fair trade and consumer protection, since deceptive trade practices, fraudulent or misleading labelling, can have public health consequences.

Consumers International believes that the "Draft Principles and Guidelines" should be elaborated to ensure that competent authorities retain operative capacity, as well as legal authority, over inspection requirements and practices. Even though it is possible for the competent authorities to use third party providers as officially recognised inspection or certification bodies (as described in paragraph 8 of the main document CAC/CL 47/2003) it is crucial that the competent authorities retain legal responsibility.

Detailed comments:

Paragraph 2:

Delete "enables resources to be better aligned with risk" and substitute with "helps competent authorities to focus resources on those products presenting the greatest potential public health risk to consumers".

Rationale: The primary objective of the guidelines should not be to better align resources, i.e. to save money, but to increase food safety.

Footnote 5:

This footnote appears to be very important and therefore should remain in the main text as a new paragraph 6.

Paragraph 3:

Replace “may” with “should.” if absolutely necessary because it refers only to a guideline and not to a Standard.

Paragraph 4:

Instead of having this sentence as a separate paragraph it should be included in paragraph 3 (at the end). (for clarity reasons)

Paragraph 9:

Following “requirements” in the second bullet point, delete the rest of the sentence and substitute by “as may be verified by audits and on-site visits of establishments by the competent authority of the importing country”.

Paragraph 11:

Delete “The intensity of inspection may then be adjusted according to the demonstrated compliance to food safety requirements.”

Rationale: This notion of compliance is confusing as it is already covered in one of the bullets points that should be taken into account when considering the level of risk (paragraph 9).

Paragraph 12:

Substitute “the importing country” with “The competent food safety authority of the importing country”.
Rationale: for reasons of clarity and consistency with paragraph 11

Paragraph 20:

Substitute “Countries” with “Competent authorities”

Paragraph 22:

Replace the last two sentences with the following sentences: “In cases where competent authorities determine that imported food products pose a demonstrable risk to human health, those authorities should prohibit the importing of those products until such time as competent authorities of the exporting country can demonstrate that the risk to human health of the prohibited product has been reduced to a level equivalent to that allowed in the importing country. The determination of an import prohibition should include information on how to appeal the import prohibition decision and how to satisfy importing country requirements for the prohibited product.”

Paragraph 23:

Substitute “consider” in line 2 with “take”