

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 3(c)

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CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

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PROPOSED DRAFT GUIDELINES FOR RISK-BASED INSPECTION OF IMPORTED FOODS (Comments at step 3 received from Argentina, Canada, Colombia, Mexico, New Zealand and the United States)

(N06-2004)

Argentina

Argentina is pleased to have the opportunity to comment on the document Guidelines for Risk-Based Inspection of Imported Food.

Background

General Comments

I) Overall, Argentina agrees with the initial proposal made by the United States regarding the work presented, insofar as the stipulations of paragraph 2 of the Background are concerned. However, we should like to mention that we do not think that the wording of item b) of the original proposal is appropriate, given that it is not a question of to “ensure consistency” but rather to “guarantee the non-discrimination” between imports and national requirements for both domestic production and imported products.

II) With regard to item e), we suggest not using the word processing, because it may be misinterpreted; we suggest using the word expeditious “dispatch” of products at import.

III) Argentina would like to draw attention to the data at the bottom of page 1, as we believe it may contain an error, given that Alinorm 03/13A, paragraph 61, does not have an Appendix V, and paragraph 61 refers to the risks associated with E. Coli, which given its specific nature should not be mentioned in the background.

IV) Regarding the issue raised in point 4 of the background on the possibility of expanding the scope and content of these guidelines to include matters, such as, economic fraud, and consumer deception, Argentina does not agree with this criterion. In our opinion, while risk-based inspection programs may be considered as separate objectives to food safety, we understand that the prime function of the Codex is food safety and the protection of consumer health. Further, we consider that the manner of approaching risks differs depending on whether they are safety-related risks or those designed to guarantee other objectives. In the light of the above and bearing in mind that expanding the scope could lead to confusion in the application of the principles, we do not support expanding the scope of the application and content of the document.

V) In the light of the above point, Argentina does not agree to the inclusion in the Introduction and Scope of this document of aspects other than Safety for consideration within the context of Risk-Based Inspection Systems of Imports.

Annex I

Introduction

VI) In paragraph 1 of the Introduction, we suggest that instead of mentioning regulatory agencies, refer to the competent entities for food control face new challenges in developing an appropriate program to ensure conformance with their public health and food safety requirements.

VII) In paragraph 3 of the Introduction, a non-exhaustive list of considerations that may be taken into account to ensure conformance of a food. Argentina does not agree with the criterion of including in a program to ensure imported food conformance, the past compliance history of the grower/producer, given that in previous stages in the agri-food chain, it is possible to obtain evidence to ensure that the food that is to be imported conforms with the requirements of the importing country.

Argentina is not seeking to limit the importance of the risk handling in primary activity, but the specific nature of this information needs to be handled within the control programs of the exporting countries, taking into account the hazards that are being managed. The history of the grower lacks value with regard to the importing country's health authorities, insofar as it should take into account the history of the compliance of the exporting country, the food importer, and, depending on the type of product and associated risks for the consumer health, the history of the compliance of the plants grown in specific cases.

VIII) In the same paragraph, it is not clear to what the item "Export certification issued by the importing country's competent authority" refers. Export certification is issued by the exporting country to guarantee compliance of the product with the destination country's standards. We believe that this item may be incorrectly worded, or be open to misunderstanding, if what is referred to is the prior process in which the requirements with which a product for export to a country must comply is requested from the importing country, or simply the export certification issued by the exporting country's competent authority.

IX) Paragraphs 4 and 5 refer to the implementation of programs to inspect products when they enter the country, highlighting in particular that priority should be given to human health that should be designed and implemented to give greater attention to products that present a higher level of risk to human health. However, we do not agree that in this section, as in other parts of the document, attention be drawn to such programs that may be implemented with goals other than to guarantee the protection of human health. In this respect, we consider that, without ignoring the authority of countries to establish all the measures they consider appropriate to guarantee consumer health or other objectives, this document should only refer to the specific mandate for which the work was approved.

In light of the above, Argentina considers that paragraphs 4 and 5 should be reworded to clearly indicate that "As part of a program to assure that imported foods meet their food safety requirements, an importing country may develop a program to inspect products when they enter a country. When such a program is used it should be based on the risks to human health where food safety is concerned. Such programs should be designed and implemented to prioritise products that present a higher level of risk to human health".

Scope

X) In paragraph 8 regarding the scope of application: Argentina considers that "food ingredients" should be deleted from the scope given that the imported food is a whole and should be considered as such within an inspection system and not in an isolated form.

XI) As we have indicated in paragraph IV) and V) of our comments, we do not agree that the scope of the guidelines include questions outside food safety and protection of consumer health. As a consequence, we suggest only retaining the first sentence of paragraph 9 of the document "The subject of these guidelines is food safety".

Objective

XII) Argentina considers that paragraph 10) needs to be clarified, indicating that it is to direct the competent health authorities".

XIII) Argentina suggest including in the listed examples agreements of mutual recognition.

Principles

XIV) With regard to the Principles set out in paragraph 12, Argentina considers that in the third bullet point the word producer should be removed as we stated in point VII) of our comments.

XV) In the fourth bullet point, we suggest changing the word “procedures” with “dispatch” to avoid confusion.

XVI) In the fourth bullet point, we consider that the words “as appropriate” should be deleted, and that the text should read: “Countries should base their inspection and certifications systems and measures on Codex standards, guidelines and recommendations”. The word “base” implies should be taken into account, which explains why we consider that “as appropriate” may indicate that Codex Members would not take Codex documents into account when implementing their systems and standards.

XVII) Argentina considers that the sixth bullet point should be changed to clarify to guarantee Codex Members that the provisions adopted are not aimed at affecting international trade or discriminating between exporting Members. In the light of which we suggest that this paragraph be worded as follows: “The inspection system and related requirements should not be applied arbitrarily or discriminatorily between the various exporting countries, nor between the latter and their nationals, and border/point of control checks of imported food should aim to reduce to a minimum the negative impact on trade, not create unjustified barriers to trade, or constitute a fraudulent restriction to international trade”.

XVIII) In the seventh and eighth bullet points, we consider that the word “acceptability” should be replaced with the words “health suitability”.

XIX) With regard to the ninth bullet point, we consider that it is important for the competent health authorities of exporting countries to provide information from the results of border control inspection, or domestic sampling plans, within a given time, and not “in a timely fashion”, in order to check the information and carry out relevant checks or corrections to the exporting country’s control systems.

Designing a risk-based program

Categories of risk

XX) Argentina suggests the following changes to paragraph 14. Border/point of control checks should be applied to particular products in proportion to the risk to human health associated with the product or types of commodity, taking into account the level of processing ~~including consideration of the processing method.~~

XXI) With regard to paragraph 15, Argentina does not understand the reason for categorising foods in terms of risks to human health for imported commodities only. In our view, this categorisation should be used for both domestic and imported commodities, basically following the same parameters. In the light of which, Argentina suggests a distinction be made between those factors used for categorisation in general and the additional factors taken into account for imported commodities.

With regard to the same paragraph, we suggest referring to the programs designed by the competent “health” authorities.

In light of the above, we suggest considering common factors to be taken into account in the program, for both domestic and imported commodities, as detailed below:

The scientifically demonstrated ability of the food product to present a public health risk⁴.

The compliance history of the food product type generally, irrespective of the source of the food.

The compliance history of the food including the compliance history with respect to:

- The primary activity and manufacturer
- The exporter
- The shipper, and
- The importer

For imported commodities, the information shall be taken into account if available.

For imported commodities the history of the exporting country or region/area of the exporting country should also be taken into account.

- The ~~adequacy~~ existence of a program 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. Argentina has suggested this last change so that it is possible to determine whether the controls are sufficient or not, or a Control System based on a specific Program under which it is possible to assess the case is required; failing which, it would be very difficult to determine whether the controls are adequate.

XXII) With regard to paragraph 16, we would like to point out that the competent food safety authority should establish categories of risk based on the above factors and place a given food from a given country, ~~grower~~/producer/manufacturer, exporter, shipper, and importer into a specific category. These categories will determine the type and intensity of inspections at the border/point of control.

XXIII) With regard to paragraph 17, Argentina considers that the health authorities of exporting countries should be notified in advance of a risk category review by importing countries. For this reason, we suggest that the wording of paragraph 17 be as follows: "Countries should periodically review their categories of risk and first inform the health authorities of the exporting countries".

Additional factors for assigning food to a risk category

XXIV) Argentina suggests the following addition to paragraph 20, "When an importing country does not have prior knowledge of a product, that is, a compliance history is lacking, or cannot readily obtain such information, an importing country may place a product into a higher risk category, until such time as a risk analysis is carried out to categorise this product as a function of its origin, taking into account the delays made by the exporting country in providing the information to carry out this analysis."

XXV) Argentina considers that the second paragraph should be deleted, or changed, insofar as we consider that the later work that may be carried out should be on a case-by-case basis between both countries, and need not necessarily include an audit. In the light of this, we suggest that the paragraph be worded as follows. "Foodborne illness outbreaks and epidemiological findings may lead an importing country to place a food product in a higher risk category in the absence of information that remedial measures have been introduced and are being implemented effectively." An importing country may work with an exporting country to ensure that further outbreaks will not reoccur. ~~In some instances this may include an audit of the exporting country's procedures.~~

XXVI) With regard to paragraph 23, we consider that the words "as appropriate" should be deleted because it is understood that the categorisation of products by risk to human health is an "ordinary procedure for establishing incoming risks. In light if this, we suggest that the paragraph wording be as follows "The importing country should, ~~as appropriate,~~ verify the placement of a food into a the corresponding category of risk, as established in paragraphs 14, 15, 16 and 17. Where the importing country is satisfied with the sustained compliance ~~sustained conformance~~ of the food with the requirements (i.e., audit results, results of border/point of control inspections, etc.), the food should be placed into a lower risk category and thus reduced intensity of border/point of control inspection."

Developing Requirements and Procedures

XXVII) Argentina considers that paragraph 25 should be the following: The importing country shall ensure that the inspection system and related requirements not discriminate arbitrarily or unjustifiably against exporting countries, nor between the latter and its own territory, to ensure that the border/point of control food checks do not result in unjustifiable or unnecessary barriers to trade.

XXVIII) Argentina suggests deleting the word "credible" from the first bullet point from paragraph 26, and changing the wording to the following: "~~Credible~~ internationally accepted ~~scientific~~ risk assessments for the biological, chemical and physical hazards associated with the type of product and its level of processing."

XXIX) Argentina considers that for paragraph 27 to remain consistent with the rest of the document, it should be worded as follows: “The intensity and type of inspection performed should be determined by the potential risk to human health of the the product or type of product ~~the shipment~~, taking into account the factors noted above. In some cases, the importing country will check the documentation and general condition of each shipment. However, on the basis of the results of a risk analysis or when no information is provided by the exporting country, further examination (e.g., visual examination only, product sampling and laboratory testing) can be by random selection of shipments and of products within the shipment. In general, lot-by-lot inspection should be reserved for those products that present or have the potential to present a significant and scientifically demonstrated health risk, when determined by a risk assessment.”

XXX) Paragraph 29: Procedures for the examination of imported food should minimize the amount of product destroyed in the inspection process, for which the number of samples to be examined shall be determined by a scientifically approved statistical process.

Implementing the Risk-Based Inspection Program

XXXI) In paragraph 31, it is suggested changing the word “processing” to “dispatch”, as a consequence the wording would be as follows: “Procedures used to carry out border/point of control checks should be designed to provide expeditious ~~processing~~ dispatch of commodities at the border, and should take into account that unwarranted and excessive delays can create risks to human health, especially for fresh and/or perishable products, and may unduly increase costs to consumers, importers, and exporters.”

XXXII) Argentina suggests the following wording for paragraph 36: When the results of border/point of control checks indicate failure of a shipment to meet the requirements of the importing country designed to guarantee product safety and consumer health, ~~the exporter or the food control authorities~~ the food control authorities of the exporting country and, if appropriate, the exporter should be promptly notified of the reason for the rejection in order to facilitate correction of the problem. Notification to the exporting country should be immediate ~~for violations involving potential risk to consumers~~. Countries should refer, as appropriate, to the Codex *Guidelines fore the Exchange of Information Between Countries of 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*.

XXXIII). Finally, Argentina suggests the following changes to paragraph 37: “Changes to procedures should be notified to exporting countries in advance of implementation, to allow the exporter sufficient time for compliance ~~allow sufficient time to facilitate exporter compliance~~ and allow necessary policy or procedural adjustments by authorities in the exporting country. Countries should use existing means of communicating changes, such as the WTO/SPS notification process ~~or press releases~~ or reliable communication with the governments with which they have historic records, and should provide an opportunity for exporting countries to submit comments on proposed changes. ~~Direct communications to foreign governments outlining changes to procedures can supplement these more public notifications.~~”

Canada

Canada thanks the United States for taking the lead in redrafting the *Proposed Draft Guidelines for Risk Based Inspections*. Canada is pleased to offer the following comments.

GENERAL COMMENTS:

Canada believes that many elements of the proposed draft guidelines are closely linked to the recommendations developed in the “Codex Guidelines for Food Import Control Systems” (CAC/GL 47-2003). We would welcome a discussion by the Committee, at an early stage, on the purpose(s) and scope of the “Proposed Draft Guidelines for Risk-based Inspection of Imported Foods” to access whether it should be a stand alone document or whether it should be an annex to the “Codex Guidelines for Food Import Control Systems.” Canada would prefer the latter option as we believe that there would be greater consistency and improved user-friendliness as well as reduced repetitiveness.

Canada notes the reference made to “*categorization of risk*” and its linkage to intensity of inspection as the approach to determine border/point of control inspection activities. However, the text does not sufficiently elaborate on this concept and therefore we recommend that further guidance regarding the application of this concept be developed.

Canada notes that these guidelines suggest that “risk based” means giving “greater attention to products that present a higher level of risk to human health” (See Paragraph 5). This is not consistent with the definition being considered by the Codex Committee on Meat Hygiene, i.e., “containing performance and/or process criteria developed according to risk analysis principles.” Canada would welcome a broad discussion on the meaning of “risk-based” in the context of these guidelines, and the degree to which this Committee’s definition should be aligned with that of CCMH.

SPECIFIC COMMENTS:

INTRODUCTION

Paragraphs 1 and 2

Canada recommends the realignment of paragraphs 1 and 2 to more clearly establish the rationale for the guidelines, by placing paragraph 2 before paragraph 1 as follows:

Paragraph 1

The food safety risk presented by **an imported** food is dependent upon a number of factors, including the nature of the food, the presence and concentration of a hazard, and the handling conditions to which the product is subjected. While...

Paragraph 2

As trade in food grows, as more countries engage in producing food for the world market, as the variety of food products increases, and as concerns with ensuring the safety of food increases, regulatory agencies face new challenges in developing appropriate systems to ensure conformance of imported foods with the importing country’s health and food safety requirements.

Paragraph 3

Canada notes that the information in paragraph 3 is more appropriately included in the section entitled “Designing a Risk-based Program: Categories of risk”. To reduce duplication and improve interpretation of these provisions, Canada recommends deleting paragraph 3 and incorporating these elements into paragraph 15 of the document.

Paragraph 4

Canada suggests the following revision for editorial clarity.

“As part of ~~an program~~ **food import inspection system** to assure that imported foods meet their public health and food safety requirements, an importing country may develop a program of border/point of control inspections for foods destined to enter the country.”

Paragraph 6

We suggest this paragraph would more properly belong to the Scope section of the document

SCOPE

Paragraph 8

We suggest to incorporate former paragraph 6 into this paragraph as follows:

“~~These~~ **This document establishes principles and** guidelines ~~apply to~~ **for developing a risk-based program for carrying out border/point of control inspections of** all imported food (including food ingredients).”

OBJECTIVES

Paragraph 11

Canada suggests that Paragraph 11 be split in two separate provisions as follows:

“Risk based programs help countries to focus resources on those products presenting the greatest potential public health threat to consumers. ~~Additionally, A risk-based approach can support the recognition that information can be provided or gathered in a variety of ways and that various forms of assurances of conformity can be utilised (e.g., certification, system audits, equivalence determinations), allowing additional potential for products to be placed in a lower risk category or to warrant a reduced level of inspection.~~ **to assist in placing products into different risk categories with intensity of inspection which is proportionate to this risk.**“

Paragraph (11 bis)

“Various forms of assurance of conformity can then be utilised (e.g., certification, system audits, equivalence determinations) **to allow for further refinement to the level of risk and hence, the intensity of the inspection.**”

These revisions attempt to delineate the process of risk categorization related to the product *per se* from the reduction in risk expected from the various forms of assurances of conformity which should result in a reduction in the intensity of inspection.

PRINCIPLES

Paragraph 12 - Bullet 5

Canada questions whether this principle should be included in this document. It does not relate to the issue of “risk-based” inspection and it is adequately addressed in other Codex documents as well as WTO agreements.

Paragraph 12 - Bullet 9

Canada questions whether this bullet is actually a principle of risk based inspection of imported foods and recommends that it be deleted.

The exchange of information on rejections resulting from inspection is already discussed as outlined in the “*Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997)*.” In many cases, foodborne illness outbreak investigations and results of border/point of control inspections may not be linked.

If retained, this principle needs to be addressed elsewhere in the document to ensure that the purpose and practical implications of this principle are clearly understood and defined.

Designing a Risk Based Program

Paragraph 13

Canada notes that this paragraph is identical to bullet 1 in paragraph 12 under Principles. We prefer its placement in the Principles section and therefore suggest it be deleted from this section in order to prevent duplication.

Paragraph 14

Canada recommends that this paragraph, as amended below, be moved up under the general section entitled “Designing a Risk Based Program”, as it reflects both the initial categorization of risk and the consideration of additional factors.

“Border/point of control checks should be applied to particular commodities in proportion to the risk to human health associated with the commodity or types of commodities, including consideration of the processing method. **The category of risk and hence the intensity of inspection may be adjusted according to demonstrated compliance to food safety requirements.**”

Categories of risk

Paragraph 16

Canada suggests the following editorial change for clarity:

“The competent food safety authority should establish categories of risk based on the above factors and place a given food ~~from a given country, grower/producer/manufacture, exporter, shipper, and importer~~ into a specific category. The type and intensity of inspections at the border/point of control for each of these categories should be specified.”

We are of the view that the inclusion of a prescriptive list of factors seems repetitive and that the clause “*based on the above factors*” provides adequate reference for application.

Additional factors for assigning food to risk category

Paragraph 18

We suggest Paragraph 18 be revised as follow:

"Any certifications made by the competent authorities in the exporting country regarding the exported products, or the existence of equivalence determinations and programs involving the use of memoranda of understanding and mutual recognition agreements, **or a program where the competent authority assesses the controls their importers implement over their suppliers**, may enable the importing country to place an imported food subject to these programs into a lower category of risk. They can provide information on the systems and controls in place in the exporting country and can also provide a form of assurance to the importing country that a particular food product complies with the food safety requirements of the importing country."

Canada believes that the provisions outlined in the Food Import Control Systems document ("Other Considerations" section), which recognizes "*agreements where the competent authority assesses the controls that importers implement over suppliers and the procedures that are in place to verify compliance of suppliers*," have relevance to a risk based inspection program. These system controls of importers are designed to meet, at a minimum, the importing country's requirements and takes into account their assessment of an exporter's food safety and quality control system (i.e. HACCP system at the processors side). Our proposal incorporates the (CAC/GL 47-2003) concept.

Paragraph 19

We suggest to replace “to determine” with “in the determination of” as follows:

“Production controls, inspection, sampling, and analysis may be verified or determined by audits of the foreign country’s inspection controls, where appropriate, and the information gained from these audits should be used ~~to determine~~ **in the determination of** the appropriate risk categories for food products from that country.”

Paragraph 22

Canada suggests the following change to improve clarity:

“Foodborne illness outbreaks and epidemiological findings **from a particular country** may lead an importing country to place a food product **from that country** into a higher risk category in the absence of information that remedial measures have been introduced and are being implemented effectively. An importing country may work with an exporting country to ensure that further outbreaks will not reoccur. In some instances this may include an audit of the exporting countries procedures.”

Developing Requirements and Procedures

Paragraph 25

Canada notes that the recommendation in paragraph 25 is already addressed in bullet 6 in the “Principles” section. Hence, Canada recommends deleting paragraph 25.

Paragraph 29 and Paragraph 31

Canada recommends deleting both paragraphs 29 and 31. We note that these two paragraphs deal with issues not related to risk-based inspections and that they are adequately addressed under the “Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) - Paragraph 19, Section regarding Control and Inspection Procedures.”

Implementing the Risk-Based Import Inspection System

Paragraph 34

Canada suggests modifications to indicate that in some cases it is adequate to simply modify the importing country’s response to subsequent imports of the product. In other cases, more stringent activities will need to occur, including, prohibition of further imports until assurances of conformity can be provided by the exporting country.

“Actions of an importing country with respect to failure of an exporting country to meet the requirements of the importing country should be proportional to the risk to human health. **In some cases**, placement of **subsequent shipments** of the product into a higher risk category is an appropriate response. ~~Product detention combined with enhanced sampling and testing from the processing establishment involved, or in certain instances, from the country, may also be an appropriate response.~~ **Depending on the category of risk, this may result in product detention combined with enhanced sampling and testing from the establishment involved, or in some instances, from the country.** Prohibition.....”

Paragraph 36

Canada suggests modifications to indicate that importers should also be notified of product rejections as they also have a stake in corrective actions (such as maintaining product identity, product disposition, etc).

“When the results of border/point of control checks indicate failure of a shipment to meet the requirements of the importing country, **the importer and** the exporter or the food control authorities of the exporting country should be promptly notified of the reason for the rejection in order to facilitate correction of the problem. Notification . . . “

Colombia

Colombia considers that the proposed document is relevant insofar as it provides Colombia with an opportunity to improve the health inspection and certification system.

Iran

Comments of Iranian Codex Committee on Food Import and Export Inspection and Certification Systems, regarding " Proposed Draft Guidelines for Risk Based Inspection of Imported Foods " (CX/FICS 04/13/5)

Please find our comments about the document on “ Proposed draft guidelines for risk based inspection of imported foods ” as follows:

1. Clause 4, page 2: We suggest that the phrase “ When they enter the country ” should be replaced by “ at border/point of control ” .
2. Clause 15, page 4: The following addition is suggested under bullet # 3 as an additional sub-bullet:
 - The third party inspection bodies.
3. Clause 31, page 5: We propose the addition of “ /point of control ” at the end of the first sentence, after “ at the border “, for consistency .
4. Clause 33, page 6 : It is recommended to revise the last sentence as below :

Training that includes statistical sampling techniques and sufficient knowledge of food production and distribution processes will enhance the ability of the inspectors to fulfil their responsibilities .

Mexico

Mexico views as positive the preparation of guidelines for the risk-based inspection of imported products, and requests that the following comments be taken into consideration:

Para. 3, 5th bullet point.- Clarification is requested that each time export certification is mentioned it is issued by the importing country.

Para. 9.- It is considered that no reference should be made to different aspects of safety, even if some of the guideline concepts may apply to the design of inspection programs for other areas, given that the guidelines are specifically for risk-based inspection.

Para. 22.- To avoid unjustified measures, it is suggested including, in reference to food safety emergency situations, that any changes in sampling size should not be extended to other products (including the brand, country or region of origin, etc.), beyond those which have been identified as being the cause or the possible cause of the emergency situation.

Linguistic comments:

Given the recommendatory nature of the document, it is suggested that in the Spanish version “debería” be used instead of “debe” wherever the English version uses “should”.

Para. 11.- Replace the word “posible” with “potencial”.

Para 12, 4th bullet point, and Para 31- Replace the word “procesamiento” with “despacho”.

8th bullet point.- Change the phrase “de fácil acceso y actualizadas” to “estar disponible y mantenerse actualizada”.

Para 15, 1st bullet point.- With a view to clarification, it is suggested changing the wording as follows: “The available scientific evidence demonstrating that the food product presents a public health risk”.

Para. 34.- It is suggested changing the wording as follows: “... Product detention from the processing establishment involved, or in certain instances, from the country, combined with enhanced sampling and testing, may also be an appropriate response. ...”.

New Zealand

The New Zealand Government would like to make the following comments:

New Zealand supports the development of the draft guidelines for risk-based inspection of imported foods and has welcomed the opportunity to participate in the drafting group that developed Annex 1 to CX/FICS 04/13/5.

New Zealand made substantive comment during the development of the draft and believes that the proposed draft guidelines are a good starting document for the Committee to consider.

We would like to make the following specific comments on the draft guidelines for consideration by the Committee:

Principles (paragraph 12)

New Zealand suggests that the principles could be refined and reordered as follows to further improve their clarity and to remove duplication:

- ~~Food safety requirements for food, including imported food, should be developed using a risk analysis approach. (This principle is self evident given the title of these proposed guidelines)~~
- The intensity of inspection of an imported food should be based on the risk to human health the product presents or is likely to present based on available scientific information (e.g., epidemiological foodborne disease data, contaminant and/or residue data).
- The intensity of inspection of a specific imported food should take into account, where available and ~~when~~ appropriate, the compliance history of: the exporting country; the grower, producer and manufacturer; and, those involved with the exporting or importing of the product.

- ~~Border/point of control inspection procedures should allow for expeditious processing of commodities. (This has been combined with another principle)~~
- Countries should, as appropriate, base their inspection and certification systems and measures on Codex standards, guidelines and recommendations.
- The inspection system and related requirements should be applied consistently to all exporting countries and border/point of control checks of imported food should not result in unjustified barriers to trade **or any unnecessary delays in processing of commodities.**
- Requirements used to determine the acceptability of food products in a border/point of control inspection program should be no more stringent than the requirements imposed on the same or similar products in the domestic market.
- Information about the systems and requirements used to determine the acceptability of food products and information about the clearance procedures for imported food products should be transparent, easily accessible and up to date.
- Information about the results of border/point of control inspections and, when appropriate, risk-based domestic sampling/testing programs arising from foodborne illness outbreaks, should be shared in a timely fashion with the exporting country's competent food safety authorities.

Developing Requirements and Procedures

Paragraph 26 – 4th bullet point – we suggest a small addition to this bullet to improve clarity. The amended bullet point would read:

- Appropriately validated inspection procedures, **appropriate sampling techniques** and **competent laboratories using** validated analytical methods.

Paragraph 27 – New Zealand suggests that this paragraph should be reformatted to provide a list of examples of procedures, as currently drafted this paragraph is too prescriptive. A revised paragraph could be:

27. The intensity and type of inspection performed should be determined by the potential risk to human health of the ~~shipment~~ **imported food and the category of risk the food has been placed into;** ~~taking into account the factors noted above.~~ ***A range of procedures can be used for clearance of imported foods, for example:***

- checking the documentation and general condition of the shipment
- **checking documentation plus periodic product sampling (e.g. 1-20 or 1-40 shipments) to confirm the accuracy of the documentation**
- visual examination only
- random product sampling and laboratory testing of shipments
- random product sampling and laboratory testing within shipments
- lot-by-lot inspection, sampling and laboratory testing.

Increasing the intensity and type of inspection performed should also be related to the risk to human health of the imported food and the category of risk the food has been placed into. In general, lot-by-lot inspection should be reserved for those products that present or have the potential to present a significant and scientifically supportable public health risk.

Paragraph 28 – we suggest an addition to the end of this paragraph for completeness. The amended paragraph would read:

28 Statistically valid sampling plans will aid in providing the required level of confidence that the shipment meets the requirements of the importing country **and provide a sound basis for decisions on conformity, non-conformity and further action, when necessary.**

Paragraph 31 – this paragraph should be moved into the section 'Developing requirements and procedures' as it relates to design of procedures.

Implementing the Risk-Based Import Inspection Program

New Zealand suggests that paragraphs 32 – 37 of this section should be reordered to improve the flow and clarity of the information presented. The text of the paragraphs would remain the same. The reordered section (with original paragraph numbers for ease of identification) would read as follows:

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

35. Requirements and procedures for carrying out border/point of control checks should be transparent so that exporting countries will have access to them and to their application. The inspection procedures should be documented in a manner that is accessible to exporting countries and other interested parties, such as through the Internet or available upon request.

37. Changes to procedures should be notified to exporting countries in advance of implementation to allow sufficient time to facilitate exporter compliance and allow necessary policy or procedural adjustments by authorities in the exporting country. Countries should use existing means of communicating changes, such as the WTO/SPS notification process or press releases and should provide an opportunity for exporting countries to submit comments on proposed changes. Direct communications to foreign governments outlining changes to procedures can supplement these more public notifications.

34. Actions of an importing country with respect to failure of an exporting country to meet the requirements of the importing country should be proportional to the risk to human health. Placement of a product into a higher risk category is an appropriate response. Product detention combined with enhanced sampling and testing from the processing establishment involved, or in certain instances, from the country, may also be an appropriate response. Prohibition of an exporting country's product by an importing country should be reserved only for those rare situations where an extreme public health threat exists.

36. When the results of border/point of control checks indicate failure of a shipment to meet the requirements of the importing country, the exporter or the food control authorities of the exporting country should be promptly notified of the reason for the rejection in order to facilitate correction of the problem. Notification to the exporting country should be immediate for violations involving potential health risk to consumers. Countries should refer, as appropriate, to 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 (ALINORM 04/27/30, Appendix II).

33. Inspection personnel performing the border/point of control checks need to be adequately trained in the importing country's procedures and in the ability to recognize abnormalities that present public health risks. Training that includes statistical sampling techniques and food production and distribution will enhance the ability of the inspectors to fulfil their responsibilities.

32. It is recognized that multiple government agencies may have responsibilities at the border/point of control of importing countries. In these cases, procedures and policies that impact imported food should be implemented in a coordinated and consistent manner. Personnel should be cross-trained, when appropriate, and information should be shared among agencies and importers transparently so that delays are reduced and movement of products is facilitated.

United States

The United States supports the development of the *Proposed Draft Guidelines for Risk-Based Inspection of Imported Foods*. We believe the document, as drafted, presents helpful information to governments on the design and implementation of inspection programs for imported food.

Venezuela

Venezuela's comments on the document "Proposed Draft Guidelines for Risk-Based Inspection of Imported Foods".

- In point 12 of the document, the following working is recommended: "The following risk-based principles apply to the inspection of imported food".
- In the first sub-paragraph of point 12, the following wording is recommended: "Imported food safety requirements should be developed using a risk analysis approach".
- In point 37 the following wording is recommended: "Changes to procedures [...] Direct communications to foreign governments outlining changes made can supplement these notifications".