

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 3 (b)

CX/FICS 05/14/4  
October 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)**

**At Step 3**

**(Prepared by the United States with the assistance of Argentina, Australia, Canada, Chile, China, Costa Rica, European Community, France, Haiti, India, Iran, Ireland, Japan, Malaysia, New Zealand, Republic of Korea, Singapore, Switzerland, Thailand)**

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 1 November 2005** to: Codex Australia, Australian Government Department of Agriculture Fisheries and Forestry GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; E-mail: codex.contact@affa.gov.au), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: [codex@fao.org](mailto:codex@fao.org)).

## **BACKGROUND**

1. The 12<sup>th</sup> Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) agreed to undertake new work to develop guidelines for carrying out risk-based inspections of imported food products for the purpose of assuring conformance with the importing country's public health/food safety requirements<sup>1</sup>. The Committee accepted the offer of the United States to lead a Working Group<sup>2</sup> to prepare an initial draft document. The project document submitted to the Codex Alimentarius Commission indicated that the proposed new work would address the following main aspects.

- a) The need for transparency and harmonization with international science-based standards.
- b) The need to ensure consistency between import and domestic requirements.
- c) The importance of science-based decision-making to: 1) identify risk and appropriate checks; and 2) establish sampling frequencies based on the risk inherent in the product.
- d) Consideration of the exporting country's inspection controls in determining the level of inspection needed at import.

<sup>1</sup> ALINORM 04/24/30, para. 88.

<sup>2</sup> Argentina, Australia, Austria, Canada, China, France, Indonesia, Iran, Ireland, Italy, Japan, New Zealand, Norway, Republic of Korea, South Africa, Switzerland.

- e) The need for expeditious processing of commodities at import.
- f) The importance of coordination among border control agencies to share information and reduce delays.

2. The Codex Alimentarius Commission, at its 27<sup>th</sup> Session, approved the development of *Proposed Draft Guidelines for Risk-Based Inspection of Imported Food*.<sup>3</sup>

3. CCFICS, at its 13<sup>th</sup> Session, considered at length a draft document developed by the Working Group.<sup>4</sup> The Committee made numerous technical changes to the text and returned it to Step 3 for further development on the basis of discussion at the 13<sup>th</sup> Session, written comments submitted at Step 3, and revision by a Working Group led by the United States and comprised of Argentina, Australia, Canada, Chile, China, Costa Rica, European Community, France, Haiti, India, Iran, Ireland, Japan, Malaysia, New Zealand, Republic of Korea, Singapore, Switzerland and Thailand.

4. The Working Group met in Brussels, Belgium, September 8-9, 2005, to revise the document. A list of participants can be found at Attachment 2. The Working Group agreed that the document should be developed as an Annex to the Codex *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) rather than as a stand-alone text and modified the structure of the document accordingly. The Working Group also agreed that the subject of the document should be food safety and recommended a change to the title to reflect this fact. Additionally, the Working Group recognized that the intensity of inspection of imported foods could be influenced by other factors relevant for health protection and fair practices in the food trade and incorporated this aspect into the introduction section of the document. The Working Group generally did not agree with provisions in the text relating to the categorization of food based on the risk presented although the Working Group recognized that there could be levels of inspection intensity based on various factors (e.g., processing controls in place in the exporting country, compliance history of the food), and modified the text accordingly. The Working Group also revised the document to reduce redundancy both with respect to the document and with respect to other Codex texts, and made other technical changes.

5. The revised *Proposed Draft Principles and Guidelines for Risk-Based Inspection of Imported Foods*, developed as Annex to CAC/GL 47-2003, is presented in Attachment 1.

## **RECOMMENDATION**

6. The Committee is invited to consider the attached *Proposed Draft Principles and Guidelines for Risk-Based Inspection of Imported Foods* as an Annex to the Codex *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) with a view towards its further progression in the Codex Step Procedure.

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<sup>3</sup> ALINORM 04/27/4, para 88 and Appendix VI.

<sup>4</sup> ALINORM 05/28/30, para 38-80.

**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 food<sup>5</sup>, 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-based<sup>6</sup> design ensures that greater attention is given to products that present a higher level of risk to human health<sup>7</sup>.
5. This document should be read in conjunction with all relevant Codex guidelines.<sup>8</sup>

## **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.

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<sup>5</sup> Imported food in this annex also includes food ingredients.

<sup>6</sup> A discussion paper on a proposed definition of Risk-based will be considered by the Codex Committee on General Principles in 2006

<sup>7</sup> 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*, 14<sup>th</sup> Edition, p. 45).

<sup>8</sup> *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).

- The intensity<sup>9</sup> 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.
- Sampling plans<sup>10</sup> 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.
- 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.
- 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.
- Information regarding a country's risk-based imported food inspection programme should be transparent, easily accessible, and up to date.

### **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 possible<sup>11</sup>.
- 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 visits<sup>12</sup>.
- 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:
  - the exporting country or region/area within an exporting country;
  - the producer and manufacturer;
  - the exporter;
  - the shipper;
  - the importer; and
  - 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.

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<sup>9</sup> Intensity includes the frequency of inspection and the nature of the inspection (e.g., documentation check, visual examination, sampling and testing).

<sup>10</sup> *Principles for the Establishment or Selection of Codex Sampling Procedures*, Codex Alimentarius Procedural Manual, 14th Edition, Page 82.

<sup>11</sup> Risk assessments, foodborne illness outbreak and epidemiological findings/history, contaminant and/or residue information can be key components of this information.

<sup>12</sup> Laboratory sampling programmes and results may provide this type of information. Audits are another way of gaining information.

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.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

17. Foodborne illness outbreaks; epidemiological findings; results of audits conducted in the exporting country; 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 measures<sup>13</sup> have been introduced and are being implemented effectively. An importing country may work with an exporting country to prevent the occurrence of further outbreaks.

## **DEVELOPING REQUIREMENTS AND PROCEDURES**

18. 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.

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<sup>13</sup> 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.

19. A range of procedures can be used to ensure that imported foods meet the importing country's food safety requirements. For example:

- 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
- 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**

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

21. 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.

22. [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 suspension of the importation of a product by an importing country should be reserved only for those situations involving a serious food safety hazard. Procedures should provide for appeal.]

23. 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).

24. Competent authorities should ensure adequate laboratory competency, capability and capacity is available to conduct the testing of imported food.

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