

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 3(c)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Thirteenth Session

Melbourne, Australia, December 6 – 10, 2004

PROPOSED DRAFT GUIDELINES FOR RISK-BASED INSPECTION OF IMPORTED FOODS (AT STEP 3)

(Prepared by the United States with the assistance of Argentina, Australia, Austria, Canada, China, France, Indonesia, Iran, Ireland, Italy, Japan, New Zealand, Norway, Republic of Korea, South Africa and Switzerland)

(N06-2004)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 29 October 2004** 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).

BACKGROUND

1. The 12th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems undertook a discussion on possible new work for the Committee. The United States suggested that it would be helpful for the Committee to develop guidelines for carrying out risk-based inspections/border (point of control) checks of imported food products for the purpose of assuring conformance with the importing country's public health/food safety requirements. In a project document prepared by the United States, it was noted that such work would be a logical extension and further elaboration of principles and guidelines previously developed by CCFICS and adopted by the Codex Alimentarius Commission, including the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) and the *Codex Guidelines for Food Import Control Systems*¹.
2. The project document indicated that the proposed 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.

¹ ALINORM 03/13 A, para. 61 and Appendix V.

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- 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.
 - 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.

3. The Committee agreed to forward the proposed new work to the Codex Alimentarius Commission for approval and accepted the offer of the United States to lead a drafting group comprised of Argentina, Australia, Austria, Canada, China, France, Indonesia, Iran, Ireland, Italy, Japan, New Zealand, Norway, Republic of Korea, South Africa, and Switzerland to develop the document.² The Commission, at its 27th Session, approved the development of *Proposed Draft Guidelines for Risk-Based Inspection of Imported Foods*³.

4. The document presented in Annex 1 focuses on food safety but recognizes that the principles and guidance may also apply to non-safety areas (e.g., the prevention of economic fraud and consumer deception). The Committee may wish to consider whether the scope and content of the document should be expanded to include the inspection of imported foods with respect to non-safety areas.

5. The Committee **is invited** to consider the attached *Proposed Draft Guidelines for Risk-Based Inspection of Imported Foods* presented in Annex 1 with a view towards their further development.

² ALINORM 04/27/30, para. 88.

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

ANNEX 1

**PROPOSED DRAFT GUIDELINES FOR RISK-BASED INSPECTION
OF IMPORTED FOODS**

(N06-2004)

INTRODUCTION

1. 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 an appropriate program to ensure conformance with their public health and food safety requirements.

2. The food safety risk presented by a 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 these guidelines generally reference the “product”, that is, the imported food, it is important to note that the reference to the product includes the hazard(s) associated with the product.

3. A program to ensure conformance of imported foods can utilise a range of information and a range of methods for presenting information to judge, or be assured about, the acceptability of food products. For example, considerations to ensure conformance may involve:

- The past compliance history of the exporting country;
- The past compliance history of the grower/producer and manufacturer;
- The results of foodborne disease outbreak epidemiological investigations and any relevant remedial measures;
- Information obtained about the exporting country’s inspection and certification system (e.g., by audit);
- Export certification issued by the importing country’s competent authority; and
- Equivalence judgements or mutual recognition agreements.

4. As part of a program to assure that imported foods meet their public health and food safety requirements, an importing country may develop a program to inspect products when they enter the country.

5. When such a program is used it should be risk-based in order to give priority to the protection of human health; that is, it should be designed and implemented to give greater attention to products that present a higher level of risk to human health.¹

6. This document establishes principles and guidelines for developing a risk-based program for carrying out border/point of control inspections of imported food products.

7. This document should be read in conjunction with the: *Codex Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995); *Codex Guidelines for the Design, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997); *Codex Guidelines for Food Import Control Systems*²; *Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999); *Codex Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates* (CAC/GL 38-2001); and, *Codex Guidelines for the Exchange of Information Between Countries on Rejection of Imported Food* (CAC/GL 25-1997).

¹ 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*, 13th Edition, p. 52).

² ALINORM 03/30 Appendix II

SCOPE

8. These guidelines apply to all imported food (including food ingredients).
9. The subject of these guidelines is food safety. However, the concepts contained in the guidelines may also be utilized to design programs relating to non-safety areas such as the prevention of economic fraud and consumer deception. As with food safety, for non-safety areas, an evidence-based program should be designed and utilized that is proportional to the extent of the problem.

OBJECTIVE

10. These guidelines are intended to provide competent authorities with information to assist them with the design and implementation of inspection programs for imported food, based on the risk to human health presented by the product.

11. Risk-based programs can also 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.

PRINCIPLES

12. The following principles apply to the risk-based inspection of imported food:
 - Food safety requirements for food, including imported food, should be developed using a risk analysis approach.
 - The intensity³ 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.
 - 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.
 - 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.

³ Intensity includes the frequency of inspection, the proportion of product examined, and the nature of the inspection (e.g., visual examination, sampled and tested).

DESIGNING A RISK-BASED PROGRAM

13. Food safety requirements, including those for imported food, should be developed and implemented using a risk analysis approach.

Categories of risk

14. 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.

15. In designing a risk-based program, the competent authority should establish a process to categorize imported food according to a particular level of risk to human health. The level of risk will be determined by several factors, including:

- The scientifically demonstrated ability of the food product to present a public health risk.⁴
- 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 with respect to:
 - The exporting country or region/area within an exporting country;
 - The grower/producer and manufacturer
 - The exporter;
 - The shipper; and,
 - The importer.
- 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 requirements⁵.

16. 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.

17. Countries should periodically review their categories of risk.

Additional factors for assigning food to a risk category

18. 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 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.

19. 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 the appropriate risk categories for food products from that country.

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.

⁴ Risk assessments, foodborne illness outbreak and epidemiological findings/history, contaminant and/or residue information can be key components of this information.

⁵ Laboratory sampling programs and results may provide this type of information. Audits are another way of gaining information.

21. Products with a known history of compliance may be placed into a lower risk category. Sustained conformance with the importing country's requirements—demonstrated by audit results and results of border/point of control checks—provides an opportunity for importing countries to place the product into a lower risk category and to reduce the level of sampling at the border/point of control.

22. 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 countries procedures.

23. The importing country should, as appropriate, verify the placement of a food into a category of risk. Where the importing country is satisfied with the sustained conformance of the food with 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

24. Countries should take into account Codex standards, recommendations, and guidelines, whenever appropriate, in developing requirements for border/point of control checks of imported food.

25. The inspection system and related requirements should be applied consistently by the importing country to all exporting countries to ensure that border/point of control checks of imported food do not result in unjustified barriers to trade.

26. In developing requirements for border/point of control checks, importing countries should make use of available:

- Credible, internationally accepted scientific risk assessments for the biological, chemical and physical hazards associated with the type of product.
- Scientifically based food borne outbreak epidemiological programs and findings.
- Statistically valid sampling plans, acceptable for the level of risk to human health posed by the product.
- Appropriately validated inspection procedures and validated analytical methods.

27. The intensity and type of inspection performed should be determined by the potential risk to human health of 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, 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 supportable public health risk.

28. Statistically valid sampling plans will aid in providing the required level of confidence that the shipment meets the requirements of the importing country.

29. Procedures for the examination of imported food should minimize the amount of product destroyed in the inspection process.

IMPLEMENTING THE RISK-BASED IMPORT INSPECTION PROGRAM

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

31. Procedures used to carry out border/point of control checks should be designed to provide expeditious processing of commodities at the border. Unwarranted and excessive delays can create risks to human health, especially for fresh and/or perishable products, and may increase costs to consumers, importers, and exporters.

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.

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.

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.

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.

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).

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.