codex alimentarius commission





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Agenda Item 3

CX/FICS 03/3 September 2003

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

Twelfth Session

Brisbane, Australia, 1 – 5 December 2003

PROPOSED DRAFT REVISION TO THE CODEX GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD CONTROL EMERGENCY SITUATIONS

(at Step 3)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so <u>no later than 7 November 2003</u> 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 23rd Session of the Codex Alimentarius Commission, in discussing the food safety emergency situation arising from the presence of dioxins in foods, noted the lack of suitable Codex guidance on the nature of measures to be applied at import and export under such circumstances and suggested that CCFICS might consider what guidance could be developed to assist Member countries in the event of similar future unforeseen emergencies.¹ In this regard, the Commission made particular note of the Codex *Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995).
- 2. CCFICS, at its' 8th Session, considered a discussion paper on risk management guidelines for food control emergency situations.² The Committee agreed that the topic was of general interest and suggested that the Codex *Guidelines for the Exchange of Information in Food Control Emergency Situations*, as well as other texts, be examined to determine whether or not the development of guidelines would be necessary. The Committee accepted the offer of Australia to prepare a further Discussion Paper on the subject.
- 3. At its 9th Session, CCFICS reached general agreement that the elaboration of guidelines for food control emergency situations involving international trade should be undertaken in the context of a revision to CAC/GL 19-1995.³ In this regard, it was suggested that the Guidelines should include consideration of:
 - The development of a specific food emergency control plan, or alternatively, generic guidance;
 - The difficulty in applying sound risk management and risk communication practices to food control emergency situations due to the inherent lack of information and timely risk assessments:

3 ALINORM 01/30A, paras. 101-105

ALINORM 99/37, paras. 235-238

² ALINORM 01/30, paras. 70-72

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• The need to expand the application of risk communication, including a framework for feedback in the process;

- Differences and similarities between importing and exporting control measures to be taken;
- Final disposition of food products, including the concept of product tracing and third country exports;
- Texts and other documentation elaborated by international governmental and non-governmental organizations, including the future elaboration of an FAO Rapid Alert System; and
- A revised definition for food control emergency situations.
- 4. The 49th (Extraordinary) Session of the Executive Committee of the Codex Alimentarius Commission approved the revision of the *Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995) as new work.⁴
- 5. CCFICS, at its 10th Session, reviewed a revision to CAC/GL 19-1995 that had been broadened to include issues such as the importance of risk analysis in food emergency situations at various stages of food distribution and an expanded section on the specific responsibilities of exporting and importing countries.⁵ The Committee had a general discussion on the document. Several delegations expressed their reservation as to whether the purpose of the guideline was to define food emergency plans to be applied by governments or to establish principles for the exchange of information between countries in the case of food safety emergency situations. The Committee agreed to return the proposed draft Guidelines to Step 2 for revision by the Drafting Group.
- 6. At the 11th Session of CCFICS, the Committee considered a revised document that incorporated: a) modifications to existing guidance relating to information exchange in food safety emergency situations; and b) provisions relating to the management of food safety emergency situations including a "model food safety emergency plan".⁶ The Committee's discussion focused on the title, preamble and scope, as well as the initial paragraphs of the section "Considerations Relating to Food Safety Emergency Situations".⁷
- 7. The Committee discussed at length the scope of the revised Guidelines and, in particular, whether the document should focus on risk communication/information exchange related to food control emergency situations or should also consider risk management measures and the development of an action plan. While significantly different views were expressed on this issue, the Committee generally agreed that the document should preferably focus on information exchange. In this regard, the Committee agreed to a title (*Principles for the Exchange of Information in Food Safety Emergency Situations*), definition for a food safety emergency situation, and principles that would serve as basis for revision to the document. The Committee further noted that the revised document should include:
 - aspects related to both bilateral and multilateral communication
 - communication with respect to the nature of the findings, nature of the problem (including risk assessments when available) and measures taken
 - the development of an international food safety alert system
 - emphasize the need for both importing and exporting countries to provide and obtain all relevant information through official contact points and to verify the accuracy of anecdotal information
 - maintain consistency with the objectives of the Codex "Guidelines for the Exchange of Information Between Countries on Rejection of Imported Food (CAC/GL 25 1997) 8.

⁷ ALINORM 03/30A, paras. 21-39.

⁴ ALINORM 03/3, para. 24 and Appendix III

⁵ ALINORM 03/30, paras. 85-93.

⁶ CX/FICS 02/11/5.

The Drafting Group considered the relationship between this document being developed and *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* CAC/GL 25-1997 and decided that it was important to maintain the links between the two documents but that they should remain as separate documents to reflect differences in objectives and scope.

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8. The Committee returned the document to Step 2 for revision by the Drafting Group based on the Committee's discussion and comments submitted, submittal for country comments, and further consideration by the 12^{th} Session of the Committee.

- 9. At the subsequent meeting of the Drafting Group a number of issues were discussed in relation to matters that were proposed for either inclusion or exclusion in the draft paper. A summary of these issues follows.
 - a. The Drafting Group discussed the proposed title and considered that incorporation of the words "and Guidelines" more appropriately reflected the content of the paper and was consistent with the style and content of existing CCFICS texts.
 - b. The Drafting Group noted the public health issues associated with the identification of a food safety emergency as is reflected in paragraph 1, Preamble, and, while having regard for the dual mandate of Codex, considered that public health was the first priority for the exchange of information in such situations. Although the Drafting Group discussed the importance of ensuring minimal disruption to trade in safe food in food safety emergency situations, it was considered that the obligation was understood and it was not necessary to specifically address the issue in the document. However it was noted that this issue was specifically addressed in paragraph 4, Preamble, of CAC/GL 19-1995.
 - c. The Drafting Group discussed inclusion of the term "Regional Economic Integration Organisations" in addition to "national governments" following the amendments to the Rules of Procedure adopted by the 26th session of the Commission and noted that the mechanism for referencing the term in Codex texts was not of the competence of the Drafting Group. The Drafting Group therefore placed the term in square brackets in paragraph 2, Preamble, to enable clarification and advice to be sought from the Commission and discussion to be undertaken in CCFICS 12 regarding the appropriateness of inclusion of the term in the text of the document.
 - d. The Drafting Group considered the scope of the document and agreed that it was important that the paper reflect the exchange of information in food emergency situations and that the paper note the difference with respect to routine imported food rejections where food is rejected because importing country requirements have not been met, for example, where nitrofurans or chloramphenical residues are detected. Accordingly, paragraph 6 was included in the Scope.
 - e. The importance of food safety emergency situations that often arise from the consumption of feedstuffs by animals that are ultimately a source of human food was discussed by the Drafting Group. The Working Group considered that it was important for governments to note that the document could be equally applied to situations where the basis of the food emergency was the consumption of certain feedstuffs by animals intended for food use. Appropriate words were added to paragraph 5, Scope. The Working Group was divided on the need to also include words regarding the role of animal feedstuffs in the definition. Some delegations felt that the addition of such words would weaken the primary focus of the document which relates to the exchange of information in emergency situations in relation to food that might be consumed by people and that the reference to animal feedstuffs in paragraph 5, Scope, was sufficient.
 - f. The Drafting Group was divided on the appropriateness of including wording in relation to traceability in the document. Some delegations felt that it was important to reflect the recent recommendations of the WHO that national food tracing systems and mandatory market recalls are critical authorities for responding to food safety emergencies and other contamination incidents. Other delegations felt that the inclusion of comment on traceability changed the focus of the paper and expanded the mandate of the Drafting Group to include risk management as well as risk communication. It was noted by the Drafting Group that there had been considerable discussion on this issue by CCFICS 11 and that the mandate of the Drafting Group was to cover risk communication.

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g. The Drafting Group was divided on the appropriateness of including the term 'risk assessment' in relevant sections of the document (paragraph 16 and attachment 1). Some delegations considered that the term 'risk assessment' might be considered synonymous with the detailed, scientifically based, extensive consultative process undertaken as part of a routine risk analysis process. The potential to confuse such a process with a more general understanding of the concept of 'risk assessment' and the need to quickly gather and convey the available information with urgency in a food safety emergency was considered such a concern that some felt the term should not be specifically included in the document. The Drafting Group noted that the elements of a risk assessment that would be conducted in a food safety emergency situation were included in paragraph 16 and attachment 1.

10. Annex 1 contains a revised document for the Committee's consideration.

RECOMMENDATION

11. It is recommended that the Committee review the revised document with a view towards progressing the document in the Codex Step Procedure.

Annex 1

PRINCIPLES AND GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD SAFETY EMERGENCY SITUATIONS

(**Step 3**)

PREAMBLE

- 1. When a food safety emergency arises, in order to minimize potential adverse public health effects, it is essential to communicate the nature and extent of the food safety problem to all relevant parties as expeditiously as possible. The global nature of food trade often requires that this communication occur between nations at a government level.
- 2. This document provides guidance for use by national governments [and regional economic integration organisations] for the exchange of information in food safety emergency situations. These guidelines replace guidance presented in the Codex *Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995).

SCOPE

- 3. These Guidelines apply to situations where the competent authorities become aware of a food safety emergency situation, and communication of the information and risks surrounding the emergency situation must be undertaken.
- 4. The Guidelines apply to situations where the food safety hazard (e.g., a microbiological, chemical, or physical agent) has been specifically identified, as well as to situations where the food safety hazard has not been identified, but association has been established between consumption of a food and the appearance of serious health effects.
- 5. The Guidelines apply to food safety emergencies associated with imported or exported food or food that may potentially be imported or exported. The guidelines may also apply to such emergencies where feeding stuffs for food producing animals are implicated.
- 6. The Guidelines do not apply to routine food rejections where importing country standards have not been met. These situations are covered in the *Guidelines for the Exchange of Information between Countries on Rejections of Imported Food* (CAC/GL 25-1997).

DEFINITIONS

- 7. **Food Safety Emergency:** A situation, whether accidental or intentional, that exists when a competent authority:
 - identifies a serious risk or threat to the health of consumers associated with the consumption of food:
 - determines that the threat may not be contained/controlled or its extent may be unknown; and,
 - determines that urgent action is required.

PRINCIPLES

- 8. In the event that a food safety emergency is identified, the following principles apply to the exchange of information:
 - a) The nature and extent of the food safety emergency should, to the extent possible, be clearly and completely described by the competent authority.
 - b) The exchange of information on food safety emergencies should be between competent authorities who should designate official contact points.
 - c) A country detecting a food safety emergency situation, whether it is an importing or an exporting country, should inform all potentially affected trading partners without delay.

d) All relevant information should be shared to enable potentially affected countries to make informed risk management decisions.

- e) Competent authorities should provide clear, relevant, factual and timely information to all stakeholders.
- f) Information flow should be transparent and continue during all phases of the risk analysis process (risk assessment as appropriate to the circumstances, risk management and risk communication) to enable continuous evaluation and development of the emergency response.

NATURE OF THE FOOD SAFETY EMERGENCY

- 9. The nature of the food safety emergency including its scientific basis as it becomes available should be described in a clear, concise and accurate manner. Whenever possible, the food safety hazard, e.g. microbiological contamination or chemical or physical agent, and the source of the contamination causing the food safety hazard should be identified. Any clear and substantial association between the consumption of a food and the appearance of serious adverse health effects should be reported by the competent authority in accordance with the principles outlined in paragraph 8 even in circumstances where the specific food safety hazard has not been precisely identified.
- 10. In cases where the food safety hazard is associated with a specific food or foods, these foods should be identified in as much detail as is available to facilitate the identification and location of the affected foods. In other cases, where a food safety hazard affects many different categories of foods and potentially involves a large geographical area, all affected foods should be identified.

OFFICIAL CONTACT POINTS FOR INFORMATION EXCHANGE

- 11. The designated contact points for the competent authorities responsible for coordinating the response to the food safety emergency should be clearly identified. Necessary information includes the name of the competent authority and name, address, phone and facsimile numbers, and email address of the persons or offices that are responsible for managing the emergency situation and who can provide further details about the hazard, the foods concerned, actions taken and other relevant information. A website address should also be provided if this is used to provide up-to-date information.
- 12. A list of official contact points for the exchange of information in food safety emergency situations as mentioned in point 8.b is available¹ and an update is distributed to governments on a periodic basis. It is the responsibility of all countries to ensure that they regularly provide updated information on their country contact points to the *[organisation to be determined]*, so that the list of contacts can be kept up-to-date. Although the official contact point is the first contact, it is understood that in a given food safety emergency national governments may wish to designate a specific contact point for that emergency.

INFORMING POTENTIALLY AFFECTED TRADING PARTNERS

- 13. Given the global nature of food trade, the impact of a food safety emergency may be widespread. The competent authority of the country where the food safety emergency is identified should, to the best of its ability, determines all potential recipient countries of the implicated food(s) and all countries from which the potentially contaminated food or its ingredients was imported. All relevant information in relation to the food safety emergency should be provided to the competent authorities of the countries thus identified.
- 14. Communication should be made by the most expedient means, as early as possible, and with verification of receipt by key parties. Communications by telephone, email, facsimile and regular mail should all be considered to achieve early communication and to ensure that the message is received by the competent authorities as quickly as possible.
- 15. It is recognised that the initial information provided may often be incomplete and it is therefore the responsibility of the country identifying the food emergency to ensure that the initial communication is supplemented by further notification(s), as and when more detailed information becomes available.

The list of contacts for Food Import Control and Information Exchange in Food Control Emergency Situations is maintained by the Codex Contact Point for Australia, Australian Government Department of Agriculture, Fisheries and Forestry, GPO Box 858, Canberra, ACT 2601, Australia, email: codex.contact@affa.gov.au.

INFORMATION TO BE EXCHANGED

16. Competent authorities should exchange with affected trading partners the following information, as relevant upon identification of a food safety emergency.

- a. The nature of the food safety emergency including the hazards and risks identified, the methodology used and assumptions made
- b. Detailed identification of the food or foods concerned including product markings, certificate information
- c. The affected populations group(s)
- d. Shipping and related information, e.g. the name and contact information for the exporter, importer, consignee and shippers
- e. Action taken to reduce or eliminate the hazard
- 17. The communication regarding the nature and extent of a food safety emergency should include relevant scientific substantiation and assessment of risk as they become available, including how international standards have been taken into account.
- 18. A standard format for the relevant information to be exchanged is recommended for use by both the importing and exporting countries. A model standard format for information exchange in food safety emergency situations is provided as Attachment 1. Where alternative formats are used, care should be taken to ensure that all the relevant information is included and is clearly presented.

ROLE OF COMPETENT AUTHORITY

19. Upon identification of a food safety emergency, the competent authority identifying the emergency should promptly communicate with and consult the appropriate competent authority/ies of other affected country/ies. The competent authorities responsible for coordinating the response should update countries receiving the affected food of action taken, as appropriate. The accuracy of the scientific and other information regarding a food safety emergency should be verified. Any misinformation should be promptly corrected by competent authorities.

INFORMATION FLOW

20. Communications between exporting and importing countries should be transparent and continue through all phases of the emergency situation, from initial notification of the food safety problem including details of any relevant risk assessments that have been used through to notification of the resolution of the problem. This will enable countries to re-assess their risk assessment, risk management and risk communication strategies as the situation changes.

COMMUNICATION WITH OTHER PARTIES

21. It is also essential that all other relevant parties be kept informed, as appropriate, of the nature and status of the food safety emergency. Competent authorities should therefore provide clear, relevant, factual and timely information to their industry, consumers, other stakeholders and the media on the status of the food safety emergency.

OTHER CONSIDERATIONS FOR INFORMATION EXCHANGE

Level of food distribution

22. In deciding on the appropriate communication measures to apply, the competent authorities should consider the quantity of food that is involved, the extent of its distribution and the level (e.g. wholesale, retail) at which it has been distributed. In some cases, the affected food may not yet have entered the importing country and communication will focus on the importers. However, in other cases the food will have entered and been distributed within the country. In these cases, the competent authority should take account of whether the food has been, or is likely to have been, distributed at the wholesale, retail or consumer level, and implement risk management and communication measures accordingly, including a notice of recall at one or more of these levels of food distribution.

Re-export of food subject to an emergency situation.

23. Food that is refused entry into a country, or in some cases food that is recalled after entry, should be dealt with in accordance with CAC/GL 25-1997² and taking into account the *Code of Ethics for International Trade in Foods* that is currently under revision by the Codex Committee on General Principles.

Rapid Alert System

24. A rapid alert system can be an important component of a food safety emergency information exchange system. A rapid alert system should contain elements that both help to identify the existence of a food safety emergency situation and to communicate the existence of the food safety problem to competent authorities.

Food Safety Emergency Action Plan

25. Importing and exporting countries should develop a national food safety emergency plan that would indicate the procedures to be followed in the case of a food safety emergency. The plan should contain specific provision relating to the exchange of information including keeping their public informed, as appropriate, of food safety emergency.

Role of FAO and WHO

26. Although the information exchange components of these guidelines are primarily intended for use between the competent authorities of the importing and exporting countries, copies or summaries of selected information regarding the emergency should be provided to FAO, WHO or other international organizations on request, to assist in international food safety emergency. In these situations, the FAO and WHO, may be able to offer technical advice and assistance to one or more of the affected countries or countries yet to be affected.

Guidelines for the Exchange of Information between Countries on Rejection of Imported Food. (CAC/GL 25-1997)

STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD SAFETY EMERGENCY SITUATIONS

The following constitutes the advice that should be provided by both exporting and importing countries in a food safety emergency. A food safety emergency situation exists when a competent authority identifies a serious risk or threat to the health of consumers associated with the consumption of a food or foods that requires urgent action³.

1. Nature of the food safety emergency

The nature of the hazard causing the food safety emergency should be described, as appropriate, according to the list below:

- biological/microbiological contamination (specify organism or toxin of concern);
- chemical contamination, e.g. toxic levels of residues of pesticides, drugs, industrial chemicals, environmental contaminants;
- radionuclide contamination (specify radionuclide(s) of concern);
- undeclared allergen (the allergen should be explicitly named);
- other identified hazards (e.g. foreign bodies, inherent chemicals in foods or produced through processing, processing/packaging faults);
- unknown agent specify serious adverse health effects associated with consumption of specified foods.

In each of the above cases the specific hazard and its level or prevalence based on available information and, as appropriate, the sampling and methods of analysis used, and any assumptions made should be notified.

2. Identification of foods concerned

The foods concerned should be described as completely as possible. The following information should be provided if available, as appropriate to the product:

- description and quantity of product(s) including brand, the name(s) of the product listed on the label, grade, and preservation method (i.e. chilled or frozen);
- type and size of package(s);
- lot identification, including lot code, dates of production and processing, and identification of premises where last packed or processed;
- other identification marks/stamps (e.g. UPC codes);
- name and address of producer, manufacturer, packer, seller, exporter or importer as appropriate;
- pictorial image;
- export certificate(s) reference number(s)

An indication of the countries to which the product has been exported should also be provided, as soon as it is known, to enable countries to quickly identify whether they are likely to be affected, and to help locate the affected foods.

3. Affected population group(s)

Food emergency situations may predominantly affect certain segments of a population e.g. children, pregnant women, immune compromised persons or the elderly. In such instances, this information should be communicated.

It should be noted that the guidelines may also apply to such emergencies where feeding stuffs for food producing animals are implicated

4. Shipping and Related Information

Information on the following should be provided:

- Exporter name and contact information;
- Importer name and contact information
- Container and shipping details;
- Consignee(s) and shipper(s) and contact information.

5. Action taken by exporting or importing country

- Information on action taken, such as: measures taken to identify and prevent the sale and export of the food;
- measures taken to recall food from markets including whether these recalls are voluntary or mandatory;
- measures taken, at the source, to prevent further problems;
- measures taken regarding final disposition (e.g., destruction of the food).

6. Competent authority contact point(s) for further information

Full contact details including: the name of the competent authority, address, telephone, email address and facsimile numbers of persons or offices that can supply further information. A website address should also be provided if this is used to provide up-to-date information.