codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/FICS 02/7**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS
Tenth Session
Brisbane, Australia, 25 February – 1 March 2002

Proposed Draft Revision to the Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995)

(At Step 3)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 18 February 2002** to: Codex Australia, Agriculture, Fisheries and Forestry – Australia, GPO Box 858, Canberra ACT, 2601 (telefax: +61.2.62723103; E-mail: codex.contact@affa.gov.au) with a copy to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail codex@fao.org).

BACKGROUND

1. At the 23rd Session of the Codex Alimentarius Commission (CAC), Rome, 28 June to 3 July 1999, the Delegation of Belgium provided the Commission with information on the contamination of poultry, cattle and pigs and derived products with dioxin and dioxin-like polychlorinated biphenyls (PCBs). The incident had resulted in widespread concern among consumers, and significant disruption to international trade[1].

2. The Commission noted that the incident drew attention to the lack of suitable Codex guidance on the nature of measures to be applied at import and export under such circumstances, whilst acknowledging the existence of the Codex Guidelines for the *Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995).

[1] ALINORM 99/37 para 235.

3. The Secretariat suggested that the Committee on Food Import and Export Inspection and Certification Systems (CCFICs) might consider developing a draft guidance document to assist Member countries in the event of similar future unforseen emergencies[2].

4. At the 8th session of the CCFICs, the Australian delegation presented a discussion paper entitled "*Risk Management Guidelines for Food Control Emergency Situations involving International Trade*." The Committee accepted Australia's offer to revise the paper for presentation at the next CCFICs meeting and asked that the paper outline the issues involved in food emergency situations and that the revised paper address the adequacy of the existing *Codex Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995), as well as related texts to determine whether or not the development of addition guidelines are necessary[3].

5. At the 9th session of the CCFICs, the Australian delegation presented a revised discussion paper which emphasised potential future work in the application of risk analysis to food emergency situations and information exchange; model food emergency response plans; levels (extent) of food distribution; re-export of food to third countries; and, communication between exporting and importing countries.

6. The Committee agreed that the existing *Codex Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995), whilst outlining a broad framework for information exchange between importing and exporting countries in Food Emergency Situations, required further elaboration. The Committee also noted that the experience of some countries following recent Food Emergency Situations, such as the contamination of certain animal products with dioxin and dioxin-like polychlorinated biphenyls (PCBs), is that information is still not being exchanged through official channels in timeframes that meet the needs of the importing countries. In these cases, the media has remained the main source of information in the first few days of Food Emergency Situations. The Committee also agreed that a number of other issues were not adequately addressed within the current text, including: the importance of scientific risk analysis in Food Emergency Situations; the consideration of the level of food distribution once the food products have entered the importing country, and the obligation of the importing country in cases where they allow re-export of food that is subject to a Food Emergency Situation.

7. The Committee agreed that these inadequately addressed issues should be addressed in the context of a revision of CAC/GL 19-1995. The Committee accepted the offer of Australia, with assistance provided by Japan, the Netherlands, the United States and the European Commission, to elaborate guidance on the expansion of CAC/GL 19-1995, to include elements related to generic guidance and/or specific food emergency control plans on the basis of the Committee's discussions and written comments submitted for consideration at its next session[4].

8. At the 49th session of the Executive Committee in September 2001, approval was given for the progression of this new work by the CCFICS[5].

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[2] ALINORM 99/37 para 237
[3] ALINORM 01/30 paras 70 - 72
[4] ALINORM 01/30 para 105.
[5] ALINORM 03/3 Appendix III

CONSIDERATION

9. The delegation of Australia, in consultation with the governments of Japan, the Netherlands, the United States and the European Commission, have revised the existing Guidelines for the *Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995). In undertaking this work, the majority of the members of the drafting group are proposing that the title of the document be changed to *Guidelines for Food Emergency Situations Involving International Trade*. This document is attached at Annex 1.

RECOMMENDATION

10. That the Committee review the revised draft guidelines and consider appropriate amendments.

PROPOSED DRAFT GUIDELINES FOR FOOD EMERGENCY SITUATIONS INVOLVING INTERNATIONAL TRADE (At Step 3)

PREAMBLE

1. These guidelines replace, and broaden the scope of, the Codex *Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995).

2. For the purposes of these guidelines the term 'food emergency situations' is taken to mean situations where there is a clearly identified risk of serious untoward health effects associated with the consumption of certain foods. In most cases the nature of the agent causing such health effects will be known (e.g. an identified microbiological or chemical agent). However, emergency situations may arise where consumption of a certain foodstuff is associated with serious health effects but the agent causing these effects has not been identified. Such situations are also covered by these guidelines.

CONSIDERATIONS RELATING TO FOOD EMERGENCY SITUATIONS

Nature of the health hazard

3. The nature of the health hazard should be described clearly and briefly. If possible, the agent (microorganism, chemical, etc.) causing the health hazard should be identified. However, if there is a clear association between consumption of a food and the appearance of serious untoward health effects this should be reported even though the agent causing the effects has not been unequivocally identified.

The application of risk analysis to food emergency situations and information exchange

4. Whilst recognising that risk management decisions may need to be made rapidly in order to protect public health and safety, risk analysis should be considered first and foremost as a tool for informed decision-making by countries in the management of food safety incidents. The risk analysis process should follow a structured approach comprising the three components of risk analysis (risk assessment, risk management and risk communication). The risk analysis framework has recently been elaborated by the Codex Alimentarius Commission in the development of food standards[1].

5. A common impediment to the successful application of risk analysis principles in food emergency situations is the lack of timely provision of detailed information on the situation by the exporting country to the importing countries. In these circumstances, importing countries can find that their main information sources are through anecdotal reports including the media, and reports from third countries. This lack of data can make the application of a truly risk-based and evidence-approach difficult to implement and care should be taken to ensure that risk management measures are not disproportionate to the level of risk.

[1] ALINORM 95/37, para 30.

6. In cases where there is a lack of information and significant scientific uncertainty in the risk assessment of food emergency situations, risk management measures may be applied provisionally. Recognising the need to apply risk analysis to the extent possible, provisional risk management decisions in these circumstances will need to be made using the best judgement of trained and experienced food control officials. Countries should ensure that these provisional risk management measures are adjusted, in a timely manner, in the light of new information.

7. Countries should keep their public informed of food emergency situations.

Communication of information

8. Effective communication between the exporting and all importing countries is fundamental to ensuring the success and appropriateness of an effective response to emerging food emergency situations. It is in the interests of both the importing and exporting countries that there is rapid information exchange in food emergency situations. In this way, risks to human health can be minimised and the foodstuffs concerned can be quickly identified and removed from the market. This helps to prevent unwarranted action being taken against other foods that are not involved in the emergency situation.

9. In the event of a food emergency situation, communication by telephone or facsimile is recommended in order to ensure the early receipt by the country contact point. Where initial contact is made by telephone, this should be followed up by information contained in a written form such as facsimile or e-mail. Communication by e-mail should also be considered as an alternative to telephone or facsimile, where it is known that the recipient regularly checks for new e-mails.

10. A list of contacts for Food Import Control and Information Exchange in Food Emergency Situations is available[2] and an update 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 *Codex Contact Point for Australia*, so that the list of contacts can be kept up to date.

Responsibilities of exporting countries

11. The food control authorities in exporting countries should promptly notify by telecommunication the appropriate authorities in all countries which have imported or are the destination of the affected foods. Where the food emergency situation involves composite food (eg. processed food product) which contains imported ingredients, the source countries of the ingredients should also be notified wherever the health hazard may be associated with these ingredients.

12. The most up-to-date information, including any scientific data (eg. concentrations of contaminants) and the products likely to be affected, should be made available to all importing countries in a timely manner. It is recognised, however, that the initial information may often be incomplete and it is therefore the responsibility of the exporting country to ensure that the initial communication is supplemented by further notification(s) as and when the situation develops and more detailed information becomes available.

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[2] 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, Agriculture, Fisheries and Forestry – Australia, GPO Box 858, Canberra, ACT 2601, Australia, email: codex.contact@affa.gov.au .

13. To avoid any undue delay or damage to international trade, the exporting country should promptly communicate to all affected countries when the food emergency situation is finished. This will enable the national authorities of the importing or destination countries to lift the emergency risk management measures on future imports from the exporting country.

Responsibilities of importing countries

14. When the food control authorities in importing countries detect problems during import control or distribution of foodstuffs, which they consider to be so serious as to indicate a food emergency situation, they should promptly notify the relevant exporting country authority.

15. Where an imported composite food (eg. processed food product) is affected by an emergency situation, the relevant authorities in the source countries of the ingredients should also be notified, where they can be identified and where the health hazard may be associated with these imported ingredients.

16. The most up-to-date information, including any scientific data (eg. concentrations of contaminants) and the products likely to be affected, should be made available to the exporting country in a timely manner. The initial communication should be supplemented by further information as and when the situation develops and more detailed information becomes available.

17. It is also the responsibility of the importing country to ensure that their risk management response is proportionate to the risk to public health and safety. On receipt of information from the exporting country, the importing country has a responsibility to ensure that risk analysis principles are applied to the extent possible and that the risk management measures that are put into effect, are no more stringent than are necessary to ensure the protection of public health and safety.

18. The appropriate risk management options available to the regulatory authorities in the importing country, will be dependent on the level of distribution of the affected products, combined with the time between the arrival of the food and the first communication identifying the food emergency situation.

19. Importing countries should ensure that their risk management measures are sufficiently flexible, such that they may be amended in a timely fashion on the provision of further information. This is particularly the case where the original application of risk analysis principles to the food emergency situation was hindered by the lack of relevant information.

Level of food distribution

20. In deciding on the appropriate risk management measures to apply, Food Control Authorities should consider both the quantity of food that is involved, the stage of its distribution and the level (eg. wholesale, retail) at which it has been distributed. In some cases, the affected food may not yet have entered the importing country and risk management measures will focus on import controls and testing of these foods where appropriate. However, in other cases the food will have entered and been distributed within the country. In these cases, the Food Control Authority should take account of whether the food has been distributed at the wholesale, retail or consumer level, which may necessitate a recall at one or more of these levels of food distribution.

21. A wholesale recall involves recovery of the product from wholesalers, distribution centres and importers. A retail recall involves recovery of the product from supermarkets, grocery stores,

hospitals, restaurants and other major catering establishments, and retail outlets such as take-away and health food stores. A consumer level recall involves the recovery of the product from consumers.

Re-export of food subject to an emergency situation.

22. Food that is refused entry into a country as a result of the application of appropriate risk management measures, or in some cases food that is recalled after entry, may be sent back to the country of origin or to a third country. In either case, the competent authorities of the country to which the goods are being exported should be notified. When re-exported to a third party country the reason for the refusal of entry or recall should be given and their consent in principle to receiving the food should be obtained before shipment. In cases of a major risk to public health and safety, the importing country may consider the destruction of the food, rather than re-export, in order to ensure that the food does not end up being consumed.

Role of the FAO and WHO

23. Although these guidelines are primarily intended for information exchange between importing and exporting countries, copies or summaries of selected information should be provided to FAO, WHO or other international organizations on request, to assist in international food emergency situations. [Details of the specific program office of the FAO and WHO to be added.] 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.

STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD EMERGENCY SITUATIONS

24. The use of a standard format for information exchange is recommended for use by both the importing and exporting countries. A model standard format for information exchange in food emergency situations is also available at Attachment 1. Where alternative formats are used, care should be taken to ensure that all the relevant information is included and is clearly presented. The most important information elements to be considered are discussed below.

Nature of the health hazard

25. The nature of the health hazard should be clearly described. If possible, the agent (microorganism, chemical etc.) causing the health hazard should be identified. However, if there is a clear association between the consumption of a food and the appearance of serious adverse health effects this should be reported even though the agent causing the effects has not been unequivocally identified.

Details of the foods concerned

26. In cases where the health or safety hazard is associated with a specific food or foods these should be identified in detail in accordance with the standard format annexed to these guidelines, to facilitate the identification and location of the affected foods. In other cases, where contamination is spread over a wide area and affects many different categories of foods, all such affected foods should be identified.

Action taken

27. The action taken to reduce and eliminate the hazard should be reported briefly. This may include, for affected food, at least the following:

- measures taken to identify and prevent the sale and (where this has occurred) export of the food;
- measures taken, at source, to prevent further problems;
- identification of agencies responsible for supervising recall from the market detaining the product; and
- supervising its final disposition.

Contact point(s) for further information

28. Agencies responsible for coordinating the response should keep countries receiving the affected food notified of action taken, and provide the name, address, telephone/facsimile number and e-mail address of the persons or organizations who can provide further details about the hazard, the foods concerned, action taken and other relevant information.

MODEL FOOD EMERGENCY PLAN

29. Importing countries should develop a national food emergency plan, which would outline the procedure to be followed in the case of a food emergency situation. This needs to recognise that each food emergency is different and should therefore provide sufficient flexibility to respond to each situation on a case-by-case basis. Principles and elements of a generic plan for use in Food Emergency Situations are given as Attachment 2. This is intended to assist governments in the development of national food emergency plans.

ATTACHMENT 1

STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD EMERGENCY SITUATIONS

1. Emergency Situations

The following should constitute the advice provided by countries in food emergency situations that have exported affected or potentially affected product to other countries that may have received such product.

2. Nature of the health hazard

The nature of the health hazard should be described as outlined 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).
- Other identified hazards (e.g. foreign bodies).
- Unknown agent - specify serious adverse health effects associated with consumption of specified foods.
- Processing/packaging faults i.e. under processing of retorted product.

In each of the above cases, the specific hazard and its level or prevalence based on available information should be notified.

3. Identification of foods concerned

The details of the foods concerned should be described as outlined below:

- Description and quantity of product(s) including brand, grade, preservation method (i.e. chilled or frozen);
- Type and size of package(s);
- Lot identification, including lot code and identification of premises where last packed or processed;
- Other identification marks/stamps;
- Container and shipping details; and
- Name and address of producer, manufacturer, seller or importer as appropriate.

Where possible a pictorial image of food in its wholesale and/or retail package should be provided.

An indication of the international distribution of the product should also be provided to enable countries to quickly identify whether they are likely to be affected, and to help locate the affected foods.

4. Action taken by exporting country

Information on action taken (e.g. recall and/or destruction of food concern, prohibition on sale of food from certain area or establishment)

- measures taken to identify and prevent the sale and export of the food;
- measures taken, at source, to prevent further problems;
- measures taken to recall food from markets and to detain products and recall products from the market; and
- measures taken regarding final disposition.

5. Contact point(s) for further Information

Full contact details including: name, address, telephone/telefax number and email address of persons or organizations who can supply further information. Also provide a website address if this is used to provide up to date information.

ATTACHMENT 2

MODEL FOOD EMERGENCY PLAN

1. A plan for use in Food Emergency Situations should incorporate the following principles:

    - measures must be based on scientific risk analysis;
    - to the extent that lack of information and significant scientific uncertainty may be a factor in the risk assessment, risk management measures may be applied provisionally and adjusted in a flexible and timely manner in the light of new information;
    - the risk management measures applied are the minimum that will ensure the protection of public health and safety, in order to avoid unnecessary disruption to trade;
    - there is maximum transparency between exporting and importing country authorities and relevant stakeholders;
    - full cooperation between exporting and importing country authorities, including in respect of sampling/testing matters, evaluation of scientific evidence and risk communication; and
    - a review of the response measures to assist with planning for possible future emergencies.

2. Model Food Emergency Plans commonly contain the following broad phases:

    a) Scoping the problem and Information Gathering
    b) Risk Assessment
    c) Risk Management and Communication Phase
    d) Implementation and Review Phase

3. Scoping the problem and information gathering

The essential elements of this phase are as follows:

- Initial report(s) precipitating the emergency management response;
- Information gathering around the issue including contacting the exporting country as appropriate;
- Hazard identification including the determination of the food commodities affected;
- Quantification and/or characterisation of the food hazard where possible;
- Identification and notification of relevant national and regulatory authorities and industry;
- Mobilisation of a national response team with expertise appropriate for the particular food hazard;
- Gathering of existing monitoring, surveillance and trade data on the food hazard in the identified food commodities;
- Obtaining information of the risk management measures put in place by the exporting country to reduce the risk; and
- Determination of the laboratory testing capacity for the food hazard where relevant.

4. Risk Assessment phase

The essential elements of this phase are as follows:

- Confirmation of Hazard Identification. Suspected contaminant identified and levels independently characterised/quantified;
- Hazard characterization in order to evaluate the nature of the adverse effects associated with biological, chemical and physical agents that may be present in food;
- Exposure assessment where relevant, eg. for chemical residues in food; and
- Risk characterization based on the hazard identification, hazard characterisation and exposure assessment. This should allow an estimation of any adverse effects that may be likely in any given population, including attendant uncertainties.

In undertaking risk assessments in food emergency situations, it is recognised that there is sometimes a lack of information. In these cases, recognising the need to utilise the essential principles of risk assessment to the extent possible, provisional risk management measures may depend on the best judgement of trained and experienced food control officials rather than a formal risk assessment approach. However, countries should ensure that the risk assessment phase is revisited, and provisional risk management measures adjusted, in a timely manner, in the light of new information.

5. Risk management and communication phase

The essential elements of this phase are as follows:

- The weighing of policy alternatives by the national response team to decide what risk management measures may be needed. This risk management process should use the risk characterisation derived from the above risk assessment phase in order to determine the adequacy of corrective action;
- Consultation with the exporting country on the risk management measures that have been identified as being appropriate; and
- Communication with importers, other international trading partners and major stakeholders on the measures to be applied.

6. Implementation and review phase

The essential elements of this phase are as follows:

- Implementation of the Risk Management Measures by the importing country;
- Notification, by member countries, of these measures to the WTO in relevant cases;
- Continuing communication with the exporting country to ensure full exchange of information;
- Generation of targeted testing data, as well as routine monitoring and surveillance, to evaluate the success of the Risk Management measures;
- As new information and testing data becomes available, regular review of the Risk Management Measures put into place with a revised risk assessment wherever appropriate;
- Removal of the Risk Management Measures once the primary reason(s) for the food safety emergency have been corrected and evidence of effectiveness provided; and
- Evaluation of the success of the Food Emergency Plan that was used and the risk management measures that were applied.