

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

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PROPOSED DRAFT REVISION TO THE CODEX GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD CONTROL EMERGENCY SITUATIONS¹ (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 30 October 2002** to: Codex Australia, Agriculture Fisheries and Forestry - Australia GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; 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 10th session of the CCFICS, the Committee agreed to return the proposed draft *Guidelines for the Exchange of Information in Food Control Emergency Situations* to Step 2 for revision by a drafting group led by Australia and with the assistance of Germany, Japan, The Netherlands, Papua New Guinea, the United States and the European Commission for circulation, comment and further consideration at its current meeting.²

CONSIDERATIONS

2. The delegation of Australia, in consultation with the governments of Japan, The Netherlands, the United States, Papua New Guinea, Germany 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 drafting group proposes that the title of the guidelines be changed to *Guidelines for Food Safety Emergency Situations Involving International Trade* to more accurately reflect the broader scope and content of the document.

RECOMMENDATION

3. It is suggested that the Committee review the revised draft Guidelines and consider appropriate amendments.

¹ These draft guidelines are formed by the revision of, and are intended to replace, the *Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995).

² ALINORM 03/30, para. 94.

PROPOSED DRAFT GUIDELINES FOR FOOD SAFETY EMERGENCY SITUATIONS INVOLVING INTERNATIONAL TRADE

PREAMBLE

1. These draft guidelines are based on a revision of the guidance document CAC/GL 19-1995. This follows the agreement of CCFICS¹ that the existing Guidelines should be broadened to include information on the management of food safety emergency situations, as well as information on the exchange of information in such situations. Subsequent approval for this new work was given by the 49th session of the Executive Committee in September 2001.

SCOPE

2. These guidelines provide guidance on the exchange of information in food safety emergency situations that apply where there is a clearly identified risk or potential risk of serious untoward health effects associated with the consumption of a food or foods. These guidelines apply both when the health hazard has been identified (e.g. an identified microbiological or chemical agent) and when the health hazard had not been identified but where the association between consumption of a food and the appearance of serious untoward health effects has been established. These Guidelines also provide guidance to governments in the development of food safety emergency plans.

3. These guidelines apply to the situation where an exporting country experiences a food emergency situation and other countries that may import the implicated food are also affected by the food emergency situation. Situations may also arise where a country identifies a food emergency situation that arises from chemicals that are inherent in the food or that are produced through processing eg. acrylamide. In such cases, an international food emergency situation could arise in which other countries manufacture and consume, rather than import, the same product. The guidance provided in this document can still be utilized in handling these food emergency situations.

CONSIDERATIONS RELATING TO FOOD SAFETY EMERGENCY SITUATIONS

Nature of the health hazard

4. The nature of the health hazard should be described clearly and briefly. Whenever possible, the agent (microorganism, chemical, etc.) causing the health hazard should be identified. The food safety problem may be caused by an agent that arises from outside the food and becomes incorporated into the food product. The problem may also arise from inherent chemicals in food or chemicals produced through processing.

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

5. Whilst recognising that risk management decisions may need to be made rapidly in order to protect the health of consumers, risk analysis should be considered first and foremost to inform 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 standards².

6. A common impediment to the successful application of risk analysis principles in food safety 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-based approach difficult to implement and care should be taken to ensure that risk management measures are not disproportionate to the level of risk.

¹ Codex Committee on Import and Export Inspection and Certification Systems

² ALINORM 95/37, para 30.

7. In cases where there is a lack of information and significant scientific uncertainty in the risk assessment of food safety emergency situations, risk management measures may be applied provisionally. Recognising the need to apply risk analysis principles 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 need to ensure that these provisional risk management measures are adjusted as necessary and in a timely manner, in the light of new information.

8. Countries should keep their public informed of food safety emergency situations.

Communication of information

9. Effective communication between the exporting and importing countries is fundamental to ensuring that the response to an emerging food safety emergency situation is both appropriate and effective. It is in the interests of both the importing and exporting countries that information exchange in food safety emergency situations is rapid. 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.

10. In the event of a food safety 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.

11. A list of contacts for Food Import Control and Information Exchange in Food Safety Emergency Situations is available³ 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 *Codex Contact Point for Australia*, so that the list of contacts can be kept up-to-date.

Responsibilities of exporting countries

12. The food control authorities in exporting countries should promptly notify by telecommunication the appropriate authorities in all countries which are known to have imported, or have been the destination of, the affected foods. Where the food safety emergency situation involves composite food (eg. processed food product) which contains imported ingredients, the source countries of the ingredients should also be notified if the health hazard is potentially associated with these ingredients. Similarly, where the food safety emergency arises because contaminated feed items were imported and fed to farm animals, the source countries of these feed items should also be notified.

13. The most up-to-date information as noted in Attachment 1 should be made available, in a timely manner, to all countries which are known to have imported, or have been the destination of, the affected foods. 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.

14. To avoid any undue delay or damage to international trade, the exporting country should promptly communicate to all affected countries when the food safety emergency situation is resolved. This communication should include supporting documentation detailing how and when resolution of the food safety emergency was achieved. 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.

³ 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.

Responsibilities of importing countries

15. When the food control authorities in importing countries detect problems during import control or distribution of foodstuffs, which they consider to pose a significant risk to the health of consumers, they should promptly notify the relevant exporting country authority.

16. The most up-to-date information, as noted in Attachment 1, 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 the health of consumers. 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 consumer health.

18. The appropriateness of the available 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 safety emergency situation.

19. Importing countries should ensure that their risk management measures are based on all available information. Where the food safety emergency situation is hindered by the lack of relevant information, the importing country should ensure that their risk management measures are provisional, such that they can be amended or discontinued in a timely fashion on the provision of further information.

Level of food distribution

20. In deciding on the appropriate risk management measures to apply, food control authorities should consider the quantity of food that is involved, the stage 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 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, or is likely to have 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. The competent authorities of the country of origin to which the goods are being sent should be notified in accordance with CAC/GL 25-1997⁴.

23. The affected food should not be re-exported to a third country, unless the competent authority of the third country has been fully informed about the nature of the food safety emergency situation and their consent obtained before shipment. Consent to receive the affected food may be granted by a third country where, for example, their appropriate level of protection is lower than in the importing country, or where the third country intends to apply a treatment that will render the food safe.

⁴ Guidelines for the Exchange of Information between Countries on Rejection of Imported Food. (CAC/GL 25-1997)

24. In cases of a major risk to the health of consumers, the importing country should consider the destruction of the food or require that food be destroyed, rather than re-export, in accordance with CAC/RCP 20-1979 (Rev. 1 – 1985)⁵, in order to ensure that the food does not end up being consumed.

Role of FAO and WHO

25. Although the information exchange components of these guidelines are primarily intended for use between 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 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 SAFETY EMERGENCY SITUATIONS

26. 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 also available 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. The most important information elements, which should be included in any alternative formats, are discussed below.

Nature of the health hazard

27. The nature of the health hazard should be clearly described. If possible, the agent/substance (microorganism, chemical etc.) causing the health hazard should be identified. However, any clear and substantial association between the consumption of a food and the appearance of serious adverse health effects should be reported even in circumstances where the agent causing the effects has not been unequivocally identified.

Details of the foods concerned

28. 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

29. The action taken to reduce and eliminate the hazard should be reported briefly. The minimum information that should be provided is:

- 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

30. Competent authorities 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

⁵ Codex Code of Ethics for International Trade in Food. (CAC/RCP 20-1979 (Rev. 1 – 1985). Paragraph 4.2a) states “subject to the provisions of article 5, no food should be in international trade which has in or upon it any substance in an amount which renders it poisonous, harmful or otherwise injurious to health”.

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 SAFETY EMERGENCY PLAN

31. Importing and exporting countries should develop a national food safety emergency plan, which would indicate the procedure to be followed in the case of a food safety emergency situation. The plan needs to recognise that each food safety 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 Safety Emergency Situations are given as Attachment 2. This is intended to assist governments in the development of national food safety emergency plans.

STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD SAFETY EMERGENCY SITUATIONS

1. Emergency situations

The following should constitute the advice provided by both exporting and importing countries in food safety emergency situations.

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);
- 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 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, 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 and identification of premises where last packed or processed;
- other identification marks/stamps (e.g. UPC codes);
- container and shipping details;
- 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 countries to which the product has been exported should also be provided, where this is known, 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 or importing 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
- measure taken regarding final disposition.

5. Contact point(s) for further information

Full contact details including: name, address, telephone, facsimile 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.

MODEL FOOD SAFETY EMERGENCY PLAN

PRINCIPLES

A plan for use in food safety emergency situations should incorporate the following principles:

- Measures must be based on 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 should be designed to ensure the protection of consumer health, while avoiding 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 communication of measures to be applied; and
- A review of the response measures to assist with planning for possible future emergencies.

PHASES INVOLVED IN A MODEL FOOD SAFETY EMERGENCY PLAN

Model food safety emergency plans commonly contain the following phases:

- a) scoping the problem and information gathering
- b) risk assessment
- c) risk management and communication phase; and
- d) implementation and review phase.

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.

Risk assessment phase

The essential elements of this phase are as follows:

- confirmation of hazard identification. 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;

- 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 safety 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 assessment decisions may be taken based on the best judgement of trained and experienced food control officials rather than a formal risk assessment approach.

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 between the exporting country and importing 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.

In undertaking risk management in food safety emergency situations, it is recognized that there is often the need to take provisional risk management measures that are based on the best judgment of trained and experienced food control officials. Countries should ensure that these provisional risk management measures are adjusted as necessary in a timely manner, in the light of new information.

Implementation and review phase

The essential elements of this phase are as follows:

- implementation of the risk management measures by the importing and exporting countries;
- notification, by member countries, of these measures to the WTO in relevant cases;
- continuing communication between the exporting and importing countries 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 safety emergency plan that was used and the risk management measures that were applied; and
- the design and application, as appropriate, of measures leading to the prevention of similar problems reoccurring.