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

(CAC/GL 19-1995)

Prepared by an electronic working group¹ chaired by the European Union and co-chaired by Chile

(At Step 3)

Governments and interested international organizations are invited to submit comments on the attached *Principles And Guidelines For The Exchange Of Information In Food Safety Emergency Situations (CAC/GL 19-1995) at* Step 3 (Appendix I) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see the *Procedural Manual of the Codex Alimentarius Commission*) to: Codex Australia, Australian Government Department of Agriculture & Water Resources, GPO Box 858, Canberra ACT, 2601 (email: codex.contact@agriculture.gov.au) with a copy to: The Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Rome, Italy (email codex@fao.org) by <u>15 January 2016</u>.

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers not yet doing so are requested to provide their comments in the format outlined in the Annex I to this document.

Please do not reproduce the document in track changes as this substantially increases the costs of translation and printing.

Background

- The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), at its 21st session, in 2014, agreed to submit a proposal to commence new work on the revision of the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (*CAC/GL 19-1995*). According to the proposal, the existing CAC/GL 19-1995 would be revised to include the following aspects:
 - a) The roles and responsibilities of the various parties involved in responding to food safety emergency situations;
 - b) The processes involved in preparing for and responding to food safety emergency situations;
 - c) Communications associated with food safety emergency situations; and
 - Appropriate references to: FAO/WHO's International Food Safety Authority Network (INFOSAN); FAO Emergency Prevention Systems (EMPRES Food Safety); and the WHO's International Health Regulations (2005) (IHR).
- The 21st session of CCFICS further agreed to establish an electronic working group (eWG), working in English and Spanish chaired by European Union and co-chaired by Chile, to prepare the proposed draft revision to the guidelines for circulation for comments at Step 3 and consideration at the 22nd session of CCFICS, in 2016.

¹ The electronic working group comprised representatives of Australia, Benin, Brazil, Canada, the European Union, France, India, Indonesia, Iran, Iraq, Ireland, Japan, Korea, Mauritius, Federated States of Micronesia, New Zealand, Norway, Philippines, South Africa, Spain, Thailand, the United Kingdom, the United States of America, Uruguay, Yemen, the Food and Agriculture Organization of the United Nations, OIE, IDF and FoodDrink Europe.

3. The new work was approved by CAC38 in July 2015.

Conclusions

- 4. The outcome of the eWG work can be summarized as follows:
 - a) The essential provisions of CAC/GL 19-1995 concerning the exchange of information are maintained in the revised text.
 - b) The structure of CAC/GL 19-1995 is revised in line with the layout suggested in the Codex document CX/FICS 14/21/5, which was supported by CCFICS at its 21st session (2014).
 - c) The provisions are regrouped under new headings and certain new elements/updates have been introduced, in particular:
 - i. the role of food business operators and consumers;
 - ii. references to INFOSAN, EMPRES Food Safety and WHO's International Health Regulations (2005) and relevant FAO/WHO guidance documents; and
 - iii. certain new provisions on managing food safety emergencies.

Recommendations

- 5. The Committee is invited to consider the revised text presented in Appendix I for the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995).*
- 6. The attention of the Committee is drawn in particular to the following issues:
 - a) While certain new provisions and references have been introduced on the management of food safety emergencies, the revised text still mainly addresses exchange of information. The Committee should consider whether provisions should be further extended to cover the actual management of food safety emergencies. For that purpose, the FAO/WHO Guide for Application of Risk Analysis Principles and Procedures during Food Safety Emergencies² provides useful inspiration.
 - b) The original title of the document is kept at this stage but may need to be revised if the scope is extended from the mere exchange of information to the management of food safety emergencies.
 - c) Two options are given for the Annex on information to be exchanged: the original Annex of CAC/GL 19-1995 and an alternative Annex, which contains the information required by INFOSAN. They contain essentially the same information but the original Annex goes into greater detail. The Committee is invited to consider, first, whether there is a need for an Annex containing information requirements; if so, then the Committee should consider whether to keep the original Annex or whether to align the required information with the INFOSAN requirements, as suggested in the alternative Annex.

² http://www.fao.org/docrep/014/ba0092e/ba0092e00.pdf

Annex I

GENERAL GUIDANCE FOR THE PROVISIONS OF COMMENTS

In order to facilitate the compilation of comments and prepare more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in strikethrough font.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.

Example of how comments should be prepared

SECTION 2 OBJECTIVE

Paragraph 4 - At the end of the last sentence add the words "and can be applied as relevant to any inspections of establishments or other facilities that may occur as part of an audit." So the last sentence would read "This annex applies equally to assessments carried out onsite or by documentary review alone and can be applied as relevant to any inspections of establishments or other facilities that may occur as part of an audit".

Rationale: To remove duplication of concepts – standardized and consistent. Efficiency is an outcome of following these guidelines and should be included here. To clarify the use of inspection as an associated tool not the prime focus.

Appendix I

Revision of the PRINCIPLES AND GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD SAFETY EMERGENCY SITUATIONS CAC/GL 19-1995

SECTION 1 – 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 emergency to all relevant parties, including action taken by the exporting country as expeditiously as possible to ensure prompt action can be taken to manage the food safety emergency in importing countries. This must be done in a manner that avoids unwarranted action against unaffected batches of the food or other foods from the country involved in the food safety emergency or other countries. The global nature of food trade requires that the communication occur as rapidly as possible among all relevant competent authorities of affected countries.

2. The Principles and Guidelines are consistent and should be read in conjunction with relevant Codex texts, such as the *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013) and the *Guidelines for Food Import Control System* (CAC/GL 47-2003). In addition, documents and guidance material developed by FAO and WHO are valuable resources³, in particular the *FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies*⁴ and the *FAO/WHO framework for developing national food safety emergency response plans*⁵.

3. The International Food Safety Authorities Network⁶ (INFOSAN) is a mechanism for information exchange to ensure food safety authorities are aware of events that may have international implications.

SECTION 2 – SCOPE

4. These Principles and Guidelines provide guidance for responding to food safety emergencies. They apply to situations where the competent authorities become aware of a food safety emergency, and action must be undertaken to manage and communicate the risks associated with the emergency. Due to trade globalization and increased import/export operations, the management of a food safety emergency is rarely the responsibility of a single national competent authority, and timely and coordinated collaboration among all relevant stakeholders, including food business operators and consumers, is required to ensure an effective response. The guidance applies to feed⁷ whenever the use of the feed may result in unsafe food.

5. The Principles and Guidelines apply to situations where the food safety hazard (e.g. a microbiological, chemical, radiological or physical agent) and food product has been specifically identified. They may also apply to situations where the food safety hazard has not been identified, but relevant scientific information suggests a link between consumption of a food and the appearance of serious health effects.

6. The Principles and Guidelines apply to food safety emergencies associated with imported or exported food or food that may potentially be imported or exported. The Principles and Guidelines may also apply to such emergencies where feed for food producing animals is implicated⁸.

7. The Principles and Guidelines do not apply to import rejections caused by failure to comply with importing country requirements. These situations are covered in the *Guidelines for the Exchange of Information between Countries on Rejections of Imported Food* (CAC/GL 25-1997).

³ <u>http://www.fao.org/food/food-safety-quality/publications-tools/food-safety-publications/en/</u>

⁴ http://www.fao.org/docrep/014/ba0092e/ba0092e00.pdf and

http://www.who.int/foodsafety/publications/infosan/en/

⁵ http://www.fao.org/docrep/013/i1686e/i1686e00.pdf and http://www.who.int/foodsafety/publications/infosan/en/

⁶ http://www.who.int/foodsafety/areas_work/infosan/en/

⁷ The term feed refers to both feed (feeding stuffs) and feed ingredients, as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).

⁸ Provisions for emergency situations affecting animal feed are included in the Code of Practice for Good Animal Feeding (CAC/RCP 54-2004): Section 4.3.1 "Special conditions applicable to emergency situations".

SECTION 3 – DEFINITIONS

Food Safety Emergency: A situation, whether accidental or intentional, that is identified by a competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action.

Food Safety Emergency Response: A process of assessing the risk, making risk management decisions, and communicating risks in the face of time constraints, and possible incomplete data and knowledge.

SECTION 4 – PRINCIPLES

8. Many food safety emergencies have international implications and may be reportable to the WHO under the International Health Regulations (2005)⁹ (IHR) and INFOSAN. A Food Safety Emergency Response should follow the risk analysis principles recognized by the Codex Alimentarius,¹⁰ while recognizing that due to time constraints risk management measures may have to be taken on the basis of limited information and before the completion of a full risk assessment.

- 9. Key principles include:
 - a) A primary official contact point should be designated by each country involved in a food safety emergency to facilitate and manage a response. Preparedness and response to food safety emergencies may require coordination between competent authorities responsible for different parts of the food chain and public health, depending on the emergency.
 - b) Information on the nature and extent of the food safety emergency, including a risk assessment when completed, should, where possible, be clearly and completely described by the relevant competent authorities. If the basis for the food safety emergency is related to the use of feed, the specific nature of the feed related problem and its impact on food safety should be indicated.
 - c) In circumstances where the specific food safety hazard has not been precisely identified, any clear and substantial association between the consumption of a food and the appearance of serious public health effects should be provided by the competent authority.
 - d) Risk management measures should be reviewed, performed within a reasonable time and modified as appropriate when new information comes available.
 - e) The exchange of information on food safety emergencies should be between official contact points designated by the competent authorities in accordance with section 6.2. A channel providing the most rapid and effective information flow should be used.
 - f) A country detecting a food safety emergency should inform all known affected and potentially affected countries without delay utilizing existing mechanisms and international agreements (e.g. INFOSAN or IHR (2005), as appropriate). If the country detecting the emergency is not the exporting country, the exporting country must be informed as a matter of priority.
 - g) All relevant information should be shared by competent authorities detecting a food safety emergency to enable all affected and potentially affected countries to take informed risk assessment, risk management and/or risk communication decisions.
 - h) Competent authorities should also provide clear, relevant, factual and timely information to relevant stakeholders.
 - i) Information flow should be transparent and continue during all phases of the food safety emergency to enable continuous evaluation and development of the emergency response.
 - j) Food should not be placed in international trade for the purpose of disposing of unsafe or unsuitable food as described in 3.2 of the Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979).

⁹ http://www.who.int/ihr/about/en/

¹⁰ Working Principles for Risk analysis for Food Safety for Application by Governments (CAC/GL 62-2007).

SECTION 5 – STAKEHOLDERS AND THEIR RESPECTIVE ROLES

5.1 Competent authorities

10. The competent authorities are responsible for managing and communicating food safety emergencies in accordance with the principles outlined in paragraph 9.

11. Upon identification of a food safety emergency, the competent authority identifying the emergency should promptly communicate with official contact point(s) (i.e. the INFOSAN Emergency Contact Point) of the country and the appropriate competent authority/ies of other affected or potentially 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 and veracity of the scientific and other information regarding a food safety emergency should be verified to assist in carrying out of risk assessment, risk management and risk communication. Any misinformation should be promptly corrected by competent authorities.

12. Competent authorities should provide clear, relevant, factual and timely information to their industry, consumers, other stakeholders and the media on the status of the food safety emergency. The development of a communications plan that includes the use of social media may also be useful.

5.2 International Food Safety Authorities Network (INFOSAN)

13. The INFOSAN Emergency Contact Point is responsible for reporting urgent food safety events of potential international significance to the INFOSAN Secretariat. INFOSAN is the FAO/WHO network for the dissemination of important information about food safety issues globally. INFOSAN maintains a network of official contact points from national government authorities involved in food safety. This includes one Emergency Contact Point from the authority responsible for national food safety emergency response, and additional focal points from other national agencies involved in food safety (in accordance with section 6.2). During food safety incidents, INFOSAN liaises with relevant national authorities to collect, validate and if required share factual information at the international level. INFOSAN should be considered a key information resource for support during emergencies. Many food safety emergencies have serious international implications and may also be reportable to WHO under the International Health Regulations (2005).

5.3 Food business operators

14. Food business operators have the primary responsibility for ensuring food safety and are thus responsible for contributing to manage food safety emergencies related to their products. They are also responsible for having in place traceability systems capable of effective tracing of food lots and for providing timely and relevant information to the competent authorities and other relevant stakeholders, including customers and/or consumers, on matters of relevance for managing food safety emergencies. They are also responsible for providing training or instruction to staff and for internal communication. These provisions also apply to feed business operators if the food safety emergency is associated with feed.

15. In relation to food receipt, a food business operator must be able to provide information about what food it has on the premises and where it came from.

5.4 Consumers

16. Consumers can enhance both their personal health and public health in general by adhering to, remaining informed of and following food safety-related instructions that have a role in managing those aspects of food safety emergencies which are under their control. They should be provided with information on how to achieve this. Multiple methods of providing such information to consumers should be prepared by the authorities. The information should concern health effects on the most sensitive groups (children, elderly people and people with reduced immune system) and how the affected food/foods can be identified and handled in order to reduce further spreading of risk (e.g. information to travellers about food in luggage).

SECTION 6 – PROCESSES FOR FOOD SAFETY EMERGENCY RESPONSE

17. This section should be read in conjunction with FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies – especially section 2 Preliminary risk management activities, section 3 Risk assessment during emergencies, section 4 Risk management during emergencies and section 5 Risk communication during emergencies.

6.1 Food Safety Emergency Plan

18. The competent authorities should develop a national food safety emergency plan indicating procedures to be followed in the case of a food safety emergency, including specific provisions relating to communication. The plan should also establish coordination arrangements with links to public health authorities, law enforcement agencies, food recall systems, risk assessment bodies, food business operators and other relevant stakeholders. Useful guidance on establishing a food safety emergency plan can be found in the FAO/WHO framework for developing national food safety emergency response plans¹¹.

6.2 Designated official contact points for information exchange

19. Each country should designate a primary official contact point for food safety emergency situations, which can act as the national focal point for information exchange in such situations. Although the primary 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. Updated information on the primary official contact points should be provided to INFOSAN. Any change in the contact point should be swiftly communicated to INFOSAN. Necessary information includes the name of the competent authority and the contact details, including name, address, phone numbers, facsimile numbers and email addresses, of the persons or offices responsible for managing the specific food safety emergency and who can provide further details about the hazard, the foods or, as appropriate, the feed concerned, actions taken and other relevant information. A website address should also be provided if such a resource is used to provide up-to-date information.

6.3 Level of food distribution

20. The competent authority should take account of whether the food or, as appropriate, feed involved, has or is likely to have been distributed at the wholesale, retail or consumer level, whether it may be in transit to a trading partner, the quantity of food distributed and implement risk management and communication measures accordingly, including a notice of recall at one or more of these levels of food distribution. Useful guidance for this is available in the *FAO/WHO* guide for developing and improving national food recall systems¹².

21. In some cases, the affected food may not yet have entered an importing country, and risk management and communication measures of the importing country competent authority will focus on the importers and border controls. However, in other cases, the food will have entered and been distributed within a country or transhipped to other countries, and risk management and communication measures by both the exporting and importing country competent authorities will need to be amended accordingly.

6.4 Information management

22. 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 and in cooperation with other competent authorities, determine all potential recipient countries of the implicated food and all countries from which the potentially contaminated food or, when appropriate, feed 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.

23. Communication should be made by the most expedient means, as early as possible, and with verification of receipt by primary official contact points. Communications by telephone (of particular importance outside office hours at the receiving end) or electronic means should be considered to achieve early communication and to ensure that the message is received by the competent authorities as quickly as possible.

24. 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 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 determined geographical area, all affected foods should be identified. If the food safety hazard is associated with feed, the feed should be clearly identified.

¹¹ http://www.fao.org/docrep/013/i1686e/i1686e00.pdf

¹² http://www.fao.org/docrep/017/i3006e/i3006e.pdf and www.who.int/foodsafety/publications/recall/en/

25. It is recognized that the initial information provided may often be incomplete, and it is therefore the responsibility of the country identifying the food safety emergency to ensure that the initial communication is supplemented by further notification(s), as and when more detailed information becomes available. This may mean that further information is provided directly by the exporting country where the country identifying the emergency is not the exporting country.

26. Competent authorities should also provide clear, relevant, updated, factual and timely communication to all relevant stakeholders and the media on the status of the food safety emergency. The development of a communication plan that includes the use of social media may also be useful.

6.5 Information to be exchanged

27. 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 emergencies is provided in the Annex.

6.6 Information flow

28. The information flow at the initial stages of the process will likely include presumptions and a level of precaution with regards to the measures implemented. This information should be refined as further detail on the nature of the food safety emergency becomes available. Communications between designated official contact points should be transparent and continue through all phases of the food safety emergency, from initial notification of the food safety problem including, whenever possible, details of any relevant risk assessments that have been used through to notification of the resolution of the problem. This will enable countries to review their risk assessment, risk management and risk communication strategies as the situation changes.

6.8 Early warning systems

29. Consideration should be given for setting up early warning systems. The FAO Emergency Prevention System for Food Safety¹³ (EMPRES Food Safety) may provide assistance in setting up such systems.

¹³ http://www.fao.org/food/food-safety-quality/empres-food-safety/en/

ANNEX

STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD SAFETY EMERGENCIES

The following constitutes the information that should be exchanged between competent authorities of both exporting and importing countries involved in a food safety emergency. A food safety emergency is a situation, whether accidental or intentional, that is identified by a competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action.

1. Nature of the food safety emergency

The nature of the food safety hazard causing the food safety emergency should be described, and may include the following:

- biological/microbiological contamination (specify organism or toxin of concern);
- chemical contamination (e.g. pesticides, drugs, industrial chemicals, environmental contaminants);
- physical contamination (e.g. foreign bodies);
- radionuclide contamination (specify radionuclide(s) of concern);
- undeclared allergen (the allergen should be explicitly named);
- other identified hazards (e.g. 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 food safety 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.

The nature and extent of any adverse health effects associated with a food safety emergency should be described, e.g. incubation period, severity, other epidemiological data.

2. Identification of foods or, as appropriate, feeds concerned

The foods or feeds concerned should be described completely. 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, preservation method (e.g. chilled or frozen) and shelf life;
- 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. bar codes, UPC codes);
- name and address of producer, manufacturer, packer, seller, exporter or importer, as appropriate;
- pictorial image;
- export certificate(s) reference number(s), official name and mark.

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 or potentially affected population group(s)

Food safety emergencies 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.

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, including port of origin and destination; and
- 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 to prevent further problems;
- measures taken to reduce the risk by appropriate physical treatment;
- methods of diagnosis and treatment of affected persons;
- measures taken regarding final disposition (e.g. destruction of the food);
- laboratory analyses.

6. Details of the designated primary official contact point and of the relevant competent authority

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 that may be sought by affected or potentially affected countries to assist in the management of the food safety emergency. A website address should be used where available to provide up-to-date information.

Alternative ANNEX

INFORMATION TO BE EXCHANGED IN FOOD SAFETY EMERGENCIES

The following information should be exchanged between competent authorities of exporting and importing countries involved in a food safety emergency. This information should also be supplied to INFOSAN.

- details of the food and hazard (suspected or confirmed);
- a short summary of the food safety or foodborne disease event;
- the source of the information; and
- a list of countries that have (or may have) received or exported the affected product or alternatively, clarification that distribution cannot be confirmed.

Further detailed information, if available, should include:

- any epidemiological information;
- any laboratory information (clinical or food related, including PFGE file if relevant and available);
- lot or batch identification of the affected product;
- detailed identification of the food packaging and any labelling present;
- shipping and related information, e.g. the name and contact information for the exporter, importer, consignee and shippers; and
- any additional information that may be useful to assess the risk of this event.