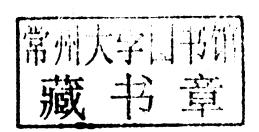
FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies





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Acronyms

FAO Food and Agriculture Organization of the United Nations **FSER** Food safety emergency response **GMP** Good manufacturing practice International Health Regulations (WHO)1 IHR The International Food Safety Authorities **INFOSAN** Network MACG Multiagency coordination group RA Risk analysis RASFF Rapid Alert System for Food and Feed Standard operating procedure SOP WHO World Health Organization WTO World Trade Organization

http://www.who.int/topics/international_health_regulations/en/

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1. Introduction

1.1 Background

An essential part of the Food Safety Emergency Response (FSER) is the process of assessing the risk, making risk management decisions, and communicating risk in the face of time constraints, lack of data and knowledge gaps. While the elements for conducting a risk analysis have been documented by Codex (2007), the process of applying the risk analysis concept operationally during an emergency has not been addressed thoroughly. Some countries do, however, have well-defined procedures for assessing, managing and communicating food safety risks in the context of emergency situations, from which best practices may be derived.

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have developed this document to support countries in applying risk analysis principles and procedures during emergencies in their own national food control systems, as risk analysis is a key component of national FSER planning.

1.2 Purpose of the document

This document was developed to assist countries in understanding essential elements in the application of risk analysis during emergencies, within the framework of their FSER plan. The principles and procedures may also apply to other food safety events that are not necessarily emergencies but that require action to be taken under time constraints and uncertainly.

1.3 Target audience

The target audience includes all national food safety authorities. While it was developed mainly for government agencies, this document may also be useful to organizations that engage in activities in the area of food safety. Recognizing the

importance of relying on effective national food control systems when applying food safety risk analysis during emergencies, the document also addresses the specific needs of countries that are in the process of developing their national food control systems.

1.4 Scope of the document

The document outlines best practice for the application of risk analysis during food safety emergencies, and suggests practical ways of incorporating such processes into existing systems. The food safety risks described in this document include biological, chemical and physical risks associated with food consumption.

This document should not be regarded as a standard, additional to the already established Codex guidelines and related texts on food safety risk analysis, but rather as guidance that is based on a collection of examples of best practice provided by experts from various parts of the world.

1.5 How to use the document

This document provides guidance on how to apply the principles of food safety risk analysis during food safety emergencies. It does not suggest the establishment of new and different risk analysis principles and procedures only for emergencies. Rather, the aim of this document is to provide technical advice on considerations specific to the emergency situation, and to describe useful tools for the application of risk analysis in this context. All components of risk analysis, namely risk assessment, risk management and risk communication, are conducted in an iterative manner both under normal circumstances and during emergencies; therefore, the order of the chapters in this document does not necessarily reflect the timeline of an event.

In order to deliver the functions outlined in the document effectively, food safety authorities must be adequately prepared with arrangements in place before an emergency occurs. These arrangements, including well developed procedures and staff training, form a crucial part of incident preparedness. In this document, major tips on preparedness that are relevant to the particular chapters are summarized in green-shaded boxes with a light bulb logo. In order to facilitate greater understanding of key issues, some real-life examples are included in grey-shaded boxes with a star logo. In addition, relevant advice is highlighted in light green-shaded boxes with an exclamation mark logo.

There are six chapters in this document. The first (current) chapter is the introduction, which describes the background, purposes, target audience and scope, and also outlines two key concepts that are significant to the basis of the document.

The second chapter introduces preliminary activities in risk management, including the initial steps after the recognition of an emergency or an urgent event. The third chapter, "Risk assessment during emergencies", outlines specific issues to consider in the process of assessing risks during an emergency. The fourth chapter, "Risk management during emergencies", discusses the key issues and considerations that are particular to emergencies and that are necessary to consider in the management of food safety risks. The fifth chapter, "Risk communication during emergencies", summarizes the main factors that are critical in the risk analysis process when applied during emergencies. The last chapter concludes the document and provides overall guidance for the application of risk analysis during food safety emergencies.

It is important for readers to study all the chapters in order to capture all the key elements to consider during an emergency. For example, although the chapter on risk assessment provides key advice for risk assessors, the chapter also provides useful and essential information for risk managers and risk communicators, and reading the chapters on risk management and risk communication is also important and useful for risk assessors.

1.6 Key concepts

Although this document can be used as a stand-alone resource, it is strongly recommended that it is read in conjunction with the FAO/WHO guidance entitled "FAO/WHO framework for developing national food safety emergency response plans" (FAO/WHO, 2010; see <u>Resources</u>).

In addition, it is important to understand the principles for food safety risk analysis in order to apply this guidance document to risk analysis procedures during food safety emergencies. Therefore, it is also strongly recommended that the FAO/WHO document entitled "Food safety risk analysis: a guide for national food safety authorities" (FAO/WHO, 2006; see Resources) is studied to increase understanding of the general principles and processes needed to arrive at risk-based decisions in food control systems.

1.6.1 National food safety emergency response planning

Food safety emergencies are very diverse and may be described differently according to the food control systems of a particular country. The response to a food safety emergency is scalable, and it may range from "business as usual" to "incident", "emergency" and "crisis". However, good planning will foster an effective and timely response.

In a given country, a single body (agency, committee, authority, etc.) theoretically could be mandated to lead the FSER. However, given that food safety emergencies often call for a multidisciplinary approach, FAO and WHO recommend that member states provide the mandate to establish a multiagency coordination group (MACG) to ensure a coordinated approach during emergencies, which should involve relevant government agencies (FAO/WHO, 2010; see Resources). This document refers to the MACG when discussing decisions and activities that may best be handled in a coordinated manner by multiple agencies.

The risk analysis framework offers a tool that national food safety authorities can use to make significant gains in food safety. Risk analysis encompasses three major components: risk assessment, risk management and risk communication. Risk analysis provides a systematic approach to estimating the risks, in order to identify and implement appropriate measures to control the risks, and to communicate information about the risks and the control measures applied.

It is important to be familiar with all the principles of food safety analysis in order to understand the specific procedures to be considered when applying them in the situation of a food safety emergency or an urgent food safety event (FAO/WHO, 2006; see Resources).

2. Preliminary risk management activities

Prior to any food safety emergency, it is useful for the national food safety authority to have in place criteria to define what is considered an emergency and a strategy for gathering the necessary information to determine whether a food safety incident meets those criteria. Emergencies may evolve from standard non-emergency food safety situations or may emerge as sudden events.

2.1 Preparedness for food safety emergencies

During a food safety emergency, risk management options may be limited and decisions must be made rapidly. Defining the available risk management options and choosing the most appropriate response may not be straightforward in situations where timelines are constricted and information may not be complete.

Preparedness tip 1

When responding to food safety emergencies, preparedness is key. Creation of various tools, such as templates for data gathering, situation report templates and decision trees, as well as clear and concise reference materials for use during emergencies, can limit the number of decisions that the emergency risk managers will have to make under time constraints. This allows the team to focus on the emergency at hand, and to be able to make decisions on key questions that arise during the event. The use of decision trees¹ and/or templates may also be useful when using established criteria to determine whether a food safety event qualifies as an emergency and to ensure that critical processes are not overlooked.

The objective of any FSER is to prevent further illnesses and maintain public confidence in the food supply. However, during the event itself, the optimal course of

¹ See Figures 2, 3, 4 and 5 on pages 18, 23, 24 and 25.

action may not be evident, and risk managers can benefit from effective tools to simplify the process of choosing risk management options.

2.2 Initial steps after identifying a food safety event

When a national food safety authority receives initial reports of a food safety event that appears to be widespread, difficult to control and/or of serious health consequence, it is necessary to determine: i) the likely magnitude of the event; ii) the need to inform/involve higher officials; and iii) whether the emergency response plan needs to be activated. The following factors may be considered in this context.

• The source of the initial report;

Example: Initial source of information

- Media reports
- · Official food inspectors
- · Laboratory test results
- Alerts from regional/international partners (INFOSAN, RASFF, etc.)
- · Consumer complaints etc.
- Verification/validation of initial reports by a credible source or through testing;
- Initiating food safety and epidemiological investigations to determine:
 - Whether food is potentially contaminated with a food hazard
 - Whether severe illness or death is involved
 - Whether the event appears to be localized or widespread
 - · Whether the source of the hazard has been identified
 - The involvement of a particular food source
 - The likely scope of distribution of the product (e.g. local, regional, national, international)
 - · Whether taking no action could result in widespread illness

Important: Documentation of the outcomes of the risk analysis activities

It is important to document the outcome of these initial steps and the entire process of risk analysis during an emergency. A documentation system should also involve archiving of e-mails, building a database and use of a geographical information system for spatial analysis of the outbreak. These records can be useful when evaluating the emergency response after closure of the event, and are essential when identifying any gaps and needs for improvement.

2.3 Activation of emergency response

Once a food safety emergency has been identified, the national food safety authority will no longer be conducting "business as usual". Typically, the standard procedures involved in a non-emergency food safety event include all the components of risk analysis. In emergency situations, the risk analysis process generally follows the same order but may be more dynamic and intense, and risk management actions may be taken before the completion of risk assessment.

Once the event has been established to be an emergency, the FSER plan should be activated and a multiagency coordination group (MACG) established. The plan should have defined the roles and responsibilities of those involved in managing emergencies in sufficient detail so that individuals clearly understand their roles, and ambiguity and duplication are prevented. The group should include an expert in communications from the beginning of the process, so that they can develop risk communication materials as required.

In addition, the risk manager should:

- Identify the objectives for that particular emergency response and the data that need to be gathered;
- Evaluate what other relevant factors need to be taken into account;
- Consider the need for inclusion of other relevant agencies/ministries in the MACG;
- Determine which stakeholders may need to be notified (e.g. senior officials, other agencies, affected private-sector establishments); and
- Consider the inclusion of a decision tree to model the initial steps and resulting outcomes.

During the investigation phase of a food safety emergency, an overview of the context and the background information should be developed rapidly for use in further communications.

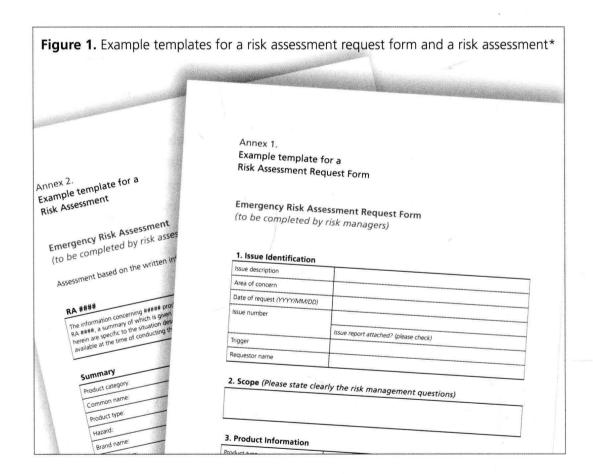
2.4 Formulating targeted questions for risk assessors

During a food safety emergency, interactions between risk assessors and risk managers are likely to be much more rapid, frequent and may be initiated earlier than those that occur during non-emergency situations. At the outset of investigations, the following should be conducted as thoroughly as possible in order to formulate targeted questions for risk assessors.

 Formally engage relevant partners prior to asking the questions, in order to gather additional information that may support the assessment

- Begin to collect and focus information for risk assessment components such as hazard characterization
- For novel/unusual hazards such as particularly virulent pathogens, emphasis should be placed on collecting field data, as far as is possible in an abbreviated time period
- It is useful to have standardised terminologies commonly used by industry and understood by risk assessors and risk managers to reduce any potential miscommunication, delays or errors

Targeted questions should be presented to risk assessors in a standard format (Figure 1; a full example is provided in Annex 1) and clearly defined questions based on currently available evidence should be included.



See full details of these examples in Annexes 1 and 2 (pages 45 and 49).