

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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Organization

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PROPOSED DRAFT GUIDANCE FOR THE MANAGEMENT OF (MICRO)BIOLOGICAL

FOODBORNE ~~CRISES~~/OUTBREAKS (REVISED)

Prepared by the EWG chairs

See Annex I

F

INTRODUCTION

1. Foodborne illness can be mild with recovery in days or in some cases have severe consequences for the individuals due to long-term sequelae with serious health effects or even death. Foodborne ~~illness~~ outbreaks often can have significant socio-economic costs related to medical treatment, hospitalization and lost productivity. For food businesses the consequences can be lost markets, loss of consumer confidence and food purchases, litigation and company closures. Foodborne outbreaks can cause impediments to domestic consumption **by loss of confidence** and international trade.
2. Codex Alimentarius has issued several guidelines on hygienic practices for food businesses and competent authorities on how to ensure food safety. Those guidelines focus on, e.g. prevention, monitoring and corrective actions in case of deviations in the production processes. Despite efforts to ensure a high level of hygiene foodborne ~~illness~~ outbreaks still occur.
3. The globalized food production, trade and complex supply chains **may lead to** ~~contribute to food safety gaps/breaches and resulting~~ outbreak **situations** with a **potential** broader impact.
4. In order to be able to efficiently handle **biological foodborne safety outbreaks** ~~[emergencies/incidents/events]~~ local and national multiagency networks of preparedness should be in place. Such networks should use ~~standardized~~ **comparable** methods and interpretations; transparent exchange of results is essential. Cooperation through international networks is essential and should be a feature of any network.
5. The principles for risk analysis including risk assessment, risk management and risk communication, as described by Codex Alimentarius in *Working principles for risk analysis for food safety for application for governments* (CAC/GL 62-2007) should form the framework/basis for the establishment of a system for preparedness and management of food**borne outbreaks** ~~safety [emergencies/incidents/events]~~.
6. Molecular analytical methods contribute to link clusters of human cases with the food source. The use of specific genomic methods (e.g. whole genome sequencing) can result in improved detection of outbreaks **with more associated or linked cases** and improved ~~[outbreak /incidents/events]~~ management and **can help to** ~~enables~~ better **identify** resolution of involved **batches of food items** ~~involved~~ **hence** reducing the impact of actions taken. Use of this methodology is expected to lead to the detection of more outbreaks in the future and the need for enhanced preparedness.
7. ~~The phrase “food safety [emergencies/incidents/events] is used for simplicity throughout the document and cover such situations (regardless of size). Foodborne illness outbreaks caused by biological agents can be categorized according to the following criteria: The number of cases and spread of the outbreak; the disease severity and its consequences; the population affected; the pathogenicity of the microorganism; the distribution pattern and volumes of the food and trade implications. The risk management measures chosen will vary according to the situation.~~**The decision to categorize an outbreak as an emergency or as a crisis is at the discretion of the competent authorities and will depend on their capacity and capability of handling foodborne outbreaks and of the category of the foodborne outbreak itself. What may be a routine investigation in one country might be categorized as a crisis in another country.**
8. ~~The decision to categorize an outbreak as an emergency or as a crisis is at the discretion of the competent authorities and will depend on their capacity and capability of handling foodborne safety [emergencies/incidents/events] outbreaks and of the category of the foodborne illness outbreak itself. What may be “business as usual” a routine investigation in one country might well be categorized as an emergency or a crisis in another country.~~**Foodborne outbreaks caused by biological agents can be categorized as an emergency or crisis according to the following criteria: The number of cases and spread of the outbreak; the disease severity and its consequences; the population affected; the pathogenicity of the microorganism; the distribution pattern and volumes of the food and trade implications. The risk management measures chosen will vary according to the situation.**
9. This document **provides** ~~collects~~ guidance for **on** preparedness and management of food**borne outbreaks** ~~safety [emergencies/incidents/events]~~ with cross-references to relevant documents and **includes** ~~recommends~~ the use of new analytical technologies in outbreak investigation. ~~Relevant to this guideline is also the International Food Safety Authorities Network (INFOSAN), a global network of national food safety authorities, managed jointly by FAO and WHO, for rapid sharing of information during foodborne outbreaks (as well as other food safety emergencies) to stop the spread of contaminated food from one country to another. INFOSAN also facilitates the sharing of experiences and tested solutions in and between countries in order to optimize future interventions to protect the health of consumers.~~

SCOPE

10. These guidelines provide guidance to competent authorities on the management of foodborne outbreaks safety [emergencies/incidents/events], including the communication between at national and regional level programmes and with international networks such as the International Food Safety Authorities Network (INFOSAN) when it is necessary. The guidance addresses preparedness, detection, response and recovery with the intent of limiting the extent of such events. The scope is limited to biological hazards.
11. The guidelines also describe the role of competent authorities at different levels and collaboration between them in formalized network structures between them at different levels. This includes collaboration and communication with food business operators and other stakeholders before and during foodborne outbreaks. safety [emergencies/incidents/events] is also addressed. Finally some emphasis has been put on the maintenance of the structures and training methods to strengthen the response by the networks are also addressed.

USE

12. These guidelines should be used in conjunction with relevant Codex Alimentarius Codes of Hygienic Practice guidelines. References are also given to FAO/WHO guidelines providing detailed information for competent authorities on preparedness for foodborne outbreaks safety [emergencies/incidents/events] and on their management in a coordinated approach with public health authorities and if relevant other stakeholders.

In foodborne outbreaks safety [emergencies/incidents/events] involving zoonotic agents it may be relevant for the decision on what risk management options to be used to take into consideration the World Organization for Animal Health (OIE) standards for the prevention, detection and control of zoonotic agents at the primary production stage, should also be considered.

13. The following A number of Codex Alimentarius and FAO/WHO documents² are specifically relevant for these guidelines and are referred to throughout the document:
- Principles and Guidelines for an Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995),*
 - Working principles for risk analysis for food safety for application for governments (CAC/GL 62-2007)**
 - Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG-30-1999, as amended),*
 - Principles and Guidelines for the Conduct of Microbiological Risk Management (CXC 63-2007, as amended)*
14. **A number of FAO/WHO documents describe in more details some issues presented in this guideline. They are listed in the annex to this document and may be consulted for more detailed recommendations on specific aspects.** These documents are referred to in the most relevant section(s) of the current guideline, providing more detailed recommendations on specific aspects.
15. **In foodborne outbreaks involving zoonotic agents the World Organization for Animal Health (OIE) standards for the prevention, detection and control of zoonotic agents at the primary production stages, should also be considered.**

DEFINITIONS

16. **Biological hazards** are biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include e.g. bacteria, **fungi** and algae, including their toxins and metabolites, viruses, natural toxins, prions, parasitic protozoa and helminths.
17. **Foodborne outbreak**
- The observed number of cases of a particular disease **that may be foodborne** exceeds the expected number, **or**
 - The occurrence of two or more cases of a similar foodborne disease resulting from the ingestion of a common food and epidemiologic analysis implicates the food as the source of the illness.**

Alternative option:

~~[A foodborne outbreak is an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analyses implicates the food as the source of the illness.~~

~~[Food safety emergency] Definition is given in CXG 19-1995~~

~~[Food safety event] if necessary~~

~~[Food safety incident] if necessary~~

Surveillance is a systematic and ongoing collection, **analysis and interpretation** of test results from samples from humans, animals or foodstuffs for the purpose of applying appropriate control measures. One of the main objectives of surveillance is to follow-up unsatisfactory results with an investigation and possible enforcement action.

Monitoring is the performance of routine analysis aimed at detection microbiological contamination of foodstuffs from which useful prevalence data may emerge.

A cluster is in epidemiological terms, an aggregation of patients with the same disease (cases) closely grouped in time and place. In microbiological terms, isolates (e.g. bacteria or virus) having the same specific molecular profile or closely related profiles identified by laboratory analyses of samples from cases.

Rapid risk assessment if necessary is a risk assessment, based on the information available on the foodborne outbreak, which needs to be carried out urgently to quickly support (provisional) risk management measures and therefore may not always contain all the full development of the four steps of a classical risk assessment.

~~[Outbreak assessment] if necessary~~

FOODBORNE OUTBREAKS SAFETY—[EMERGENCIES/INCIDENTS/EVENTS] – PREPAREDNESS SYSTEM

A. CREATION OF FORMALIZED NETWORKS BETWEEN HUMAN HEALTH AND FOOD AND VETERINARY SECTORS AT LOCAL AND NATIONAL LEVELS

18. Foodborne illness outbreaks happen frequently and vary greatly in size and severity from local point source outbreaks restricted to a single location to prolonged diffuse national outbreaks or international outbreaks. ~~It~~
19. National systems and structures should be in place in order to ensure early detection and to effectively manage **foodborne outbreaks** ~~safety [emergencies/incidents/events]~~ and should have sufficient infrastructure, capability and capacity. The system should be a formalized network and should not be developed in isolation but be based on existing structures in the public health sector and food and veterinary control systems **and** laboratory networks. The network should ~~take into account e.g. build on existing structures for~~ **surveillance and monitoring of foodborne biological hazards in programmes for humans and food and conditions for food production and distribution.**
20. The network and structures should be described in detail and agreed upon by the participants to ensure cooperation in mutual respect of the competences and responsibilities of each participating authority and officially appointed agency and allow for an **outbreak** ~~incident~~ to be managed at the lowest possible administrative level.
21. For the networks to be operational it is necessary that the participants know each other and have familiarity with the system and structures and that they use them ~~as part of the “daily routines”~~ **regularly, even in the absence of a foodborne outbreak. Participants should also have a good knowledge of the conditions for food production and distribution.** Depending on the national structures of competent authorities, a set of contact points should be appointed at the different levels of administration.
22. At the local level defined networks between the contact points from the different relevant authorities/agencies covering the same geographical area should be formed. The contact points may be either persons or offices as long as **they consist** ~~it consists~~ of personnel usually participating in the work at local level – e.g. local food control authority, clinical microbiological laboratory, **local departments of health/local health authorities** ~~districts—surgeon~~, community council and

food/veterinary laboratory. The network contact points should ensure the exchange of information and manage the **outbreak**~~[emergency/incident/event]~~ within and between the networks. The networks should establish channels to engage stakeholders and food business operators, where relevant, in order to exchange information to minimize adverse consequences.

23. At national level a defined network should be established with senior personnel with experience in the management of food **borne outbreaks** ~~safety [emergencies/incidents/events]~~ representing their respective authorities/agencies. Guidance on the composition of such a network can be found in the description of the multiagency coordination group (MACG) described in the FAO/WHO *Framework for Developing National Food Safety Emergency Response Plans*. The role of the network should include:
- ~~coordinating~~ **coordinating** efforts to resolve large, especially complicated or serious food **borne outbreaks**, ~~safety [emergencies/incidents/events]~~,
 - **providing** support to local networks where needed
 - assessing surveillance and monitoring data information received from the participating authorities/agencies
 - assessing information received from the other levels and participants of the network as basis for management decisions
 - ~~communicating~~ **communicating** with **regional and** international networks **e.g. through the INFOSAN emergency contact points**
24. The ~~national~~ **national** ~~central~~ network may also be the forum where new tools and ways to handle outbreaks can be developed.
25. Communication between the local networks and between the local and national networks is crucial. Communication structures and practices should be included specifically in the description of the system and procedures for the network, with the following goals:
- To ensure that all available information is compiled to form as complete a picture of the **situation**~~incident~~ as possible.
 - The information is distributed to and understood by all parties in a timely manner.
 - There is only one point of contact and a backup in each of the participating authorities/agencies and interested parties of official information.
 - All parties use the established formal information channels, which are tested regularly to demonstrate that they are effective.
 - There is a system in place to ensure communication channels remain open (e.g. in the event of infrastructure break down, staff absence, etc.)
 - There is a **facility** ~~practice~~ in place for the use of external groups of experts **to verify the soundness of the** ~~in validation of recommendations~~ **given**.

B. INTERNATIONAL ALERT NETWORKS FOR ~~FOOD SAFETY INCIDENTS [EMERGENCIES/INCIDENTS/EVENTS]~~ AND HUMAN ILLNESS ISSUES AND EXCHANGE OF INFORMATION WITH THEM

26. Food **borne outbreaks** ~~safety [emergencies/incidents/events]~~ **does** not respect borders either by area of distribution or by origin of the source. What initially seems to be a national or regional incident at the outset may in fact be a ~~multinational~~ **international foodborne outbreak**, ~~safety [emergency/incident/event]~~.
27. The national level of the network should have a permanent connection with global networks including the International Food Safety Authorities Network (INFOSAN) and with regional alert networks for both food **borne outbreaks** and **associated** human **illnesses** ~~incidents~~. The ~~central~~ national level of the network should actively include the national emergency contact points for these alert networks in their work both for gathering and compiling information and for submitting coordinated information concerning active food **borne outbreaks** ~~safety [emergencies/incidents/events]~~.
28. Information from global networks may be useful for the work of the national networks even if the ~~incidents~~ **issues** described do not concern the country. A regular contact with the contact points of these regional and global networks are therefore essential.

C. SURVEILLANCE AND MONITORING SYSTEMS (HUMAN, ANIMAL, FEED, FOOD, ESTABLISHMENT ENVIRONMENT) AND THEIR USE IN

FOODBORNE OUTBREAK SITUATIONS SAFETY [EMERGENCIES/INCIDENTS/EVENTS]

29. Many biological food borne outbreaks ~~safety [emergencies/incidents/events]~~ are initially identified through human illness surveillance data. However, data from surveillance and monitoring of animals, feed, food and the establishment environment, including equipment of food businesses, may also indicate a potential ~~an enhanced~~ risk and are essential ~~of value/assistance~~ to help identify the source of a food borne outbreak ~~safety [emergency/incident/event]~~. These surveillance and monitoring systems are essential tools for detecting foodborne outbreaks and should be used in an integrated approach.
30. In order to identify a foodborne outbreak there is a need for: ~~continuous~~:
- **Continuous** surveillance and monitoring of the "business as usual" situation of human illnesses from biological hazards and foods;
 - ~~As not all diseases are mandatory to notify to the human health authorities~~ Access to information on these cases ~~need to be established~~ and an assessment of the baseline "business as usual" level should be made. **This is especially important in the case for diseases that are not required to be notified to human health authorities.** This will enable the competent authorities to define when a number of cases should result in a notification of an outbreak.
 - **Timely** Quick centralization and distribution of information through early warning systems; disease notification by medical practitioners to competent authorities should be made mandatory to the extent possible.
 - ~~Regular (e.g. weekly)~~ **Analysis** (e.g. weekly) of the data in order to detect outbreaks in a timely manner.
31. In order to quickly detect food borne outbreaks ~~safety [emergencies/incidents/events]~~ it is necessary to establish structures to exchange information between public health, food safety and veterinary authorities. For sharing of surveillance data, it is necessary that data collected are comparable ~~between~~ among sectors **and that confidentiality of personal information is maintained.** Information exchange should be used both routinely and during food borne outbreaks ~~safety [emergencies/incidents/events]~~ and **it is recommended that they include where possible** ~~may include~~:
- Regular exchange of information between the human health sector, competent food authorities and laboratories. The information should include new signals (increasing trends or sudden elevated numbers of analytical findings/disease reports) from these sectors and follow-up on ongoing outbreaks.
 - The use of **preferably harmonized and** standardized laboratory methods to allow comparability and sharing of laboratory data ~~between~~ among human health, food safety and veterinary sectors.
 - Tools for sharing surveillance data and epidemiological information such as databases or data-sharing-sites.
 - Tools for comparing and presenting data, such as phylogenetic trees can be used if surveillance data are based on genetic methods.
 - ~~Sufficient~~ eEpidemiological data to evaluate the relevance of the source and to conduct trace back.
32. Except in the case of very rare foodborne diseases, there might be a need for molecular testing data of the isolates to detect and demonstrate a link between different cases. For example, for *Salmonella*, the traditional way of comparing data is by using serotyping, **pulsed-field gel electrophoresis (PFGE) and multiple locus variable number of tandem repeats analysis (MLVA).** The increasing availability of such molecular based tests, including whole genome sequencing, ~~is~~ **are** expected to increase the number of links between single cases, and thereby the number of outbreaks. Because of greater specificity it is possible to differentiate clusters already identified in subclusters. The use of databases containing comparable molecular based testing results from humans, animals, feed, food and establishment environmental sampling facilitates the detection and assessment of outbreaks and the search for the source of the contamination.
33. **An increased use of whole genome sequencing (WGS) as molecular method is encouraged. The method can also be used to identify genetic differences, virulence factors and antimicrobial**

resistance mechanisms.

The use of whole genome sequencing methods (WGS) for surveillance and monitoring purposes requires:

- Sufficient laboratory capacity, specific equipment and trained personnel
- Storage capacity of large amounts of metadata and sequence data and the availability of bioinformatics tools to compare data in either national or open international databases for genomics. Fast and stable internet connections are a prerequisite.
- Sharing of WGS sequences in a form that is useful for comparison between the human health and the food control authorities, e.g. as **multilocus sequence types (MLST) or core genome multilocus sequence types (cgMLST)**.
- Considerations of legal requirements for sharing of data. If data are shared in public databases there may be a need for anonymizing the samples **to ensure confidentiality of personal information**, thus only allowing **limited** few metadata to follow the sequences.
- WGS methods are more costly than other typing methods which can be an obstacle for their implementation. Furthermore the cost per analysis will be higher if the total number of tests is low. **Collaboration between countries to carry out WGS is therefore strongly encouraged.**

d. Rapid risk assessment – structures for assessing risk

34. A risk assessment during a **foodborne outbreak** safety [~~emergency/incident/event~~] provides a sound scientific basis for the actions to be taken. ~~Risk assessments can be particularly useful when there is a contamination event that has not been associated with illness, in order to evaluate the potential for illness and to inform decisions on appropriate actions to mitigate risk.~~ **In a number of cases, a ready-to-use risk assessment will be available, however adaptations to the specific incident will be required (within a short timeframe) based on the information from investigations**
- ~~35. In a number of cases, a ready-to-use risk assessment will be available, however adaptations to the specific incident will be required (within a short timeframe) based on the information from investigations.~~
36. If a risk assessment is not available there might not be sufficient time to ask for a full assessment of the risk at hand. A “light” version of a risk assessment - a rapid risk assessment - ~~or and outbreak assessment~~ will be more practical.
37. The rapid risk assessment ~~or outbreak assessment~~ **may or may not** includes the steps of a risk assessment but is based on the current data from the [~~emergency/incident/event~~] **foodborne outbreak** itself and if possible data from similar **outbreaks** incidents. There is no time for collecting new evidence/data to fill in data gaps or to conduct larger literature studies. These types of assessments need to be updated regularly during the incident as information becomes available.
38. Having **framework** structures in place to allow a timely rapid risk/~~outbreak~~ assessment are therefore an essential part of incident preparedness. They include but are not limited to:
- lists of risk assessors and subject matter experts for specific hazards available with their area of competence;
 - clearly prepared instructions ~~on~~ **outlining** what is expected ~~for~~ **of** these risk assessors and subject matter experts, including the scope of any risk assessment, taking into account the short ~~deadline~~ **timeline** for the assessment;
 - structure to ensure the direct and immediate submission of information from the outbreak investigations to the risk assessors and the possibility for them to ask for additional clarification from the investigators and/or implicated food business operators;
 - availability of information analysis tools e.g. to detect hot spots (geographical areas or events with more than usual activity within the outbreak);
 - **availability of up-to-date (regional/local) data on consumption and serving sizes.**

E. RISK COMMUNICATION SYSTEM/STRATEGY

39. In the context of a **foodborne outbreak caused by biological hazards** ~~biological food safety~~ [~~emergency/incident/event~~], the term “risk communication” means the exchange of information on the biological risk among stakeholders (e.g. government, academia, industry, public, mass media and

international organizations) outside the formalized network structure, with the aim to inform and motivate to action.

40. Effective communication is essential and requires preparation in advance of an ~~outbreak~~ incident, and this should include exchange of information with all stakeholders. **Establishing communication links with food industry experts in advance of foodborne outbreaks are important to gather/provide information about food categories that may be linked to/potentially involved in an outbreak with respect to production and distribution practices.**
41. In terms of risk communication, the preparedness should aim to;
 - Establish a communication strategy among the network members and designate official spokespersons from the government or the ~~central~~-national network to the public and decide on the means of communication (websites, ~~twitter, facebook~~ **social media** etc.). Where it is possible, the jurisdiction of each of the competent authorities should be taken into account to set the roles of each one in the risk communication strategy.
 - Identify all the types of organizations that may be involved and make alliances and partnerships with them to ensure that they will speak in a coordinated manner to deliver appropriate information needed to minimize the risk to public health.
 - Draft initial messages for the different situations that could potentially arise; specific details can be filled in later. Consider that each population group may have its own characteristics that affect how they perceive risks (e.g. religious beliefs, traditions), so ~~that~~ understanding the audience and testing messages to ensure they are culturally and demographically appropriate is important.
 - Test established communication strategies on a regular basis to evaluate their efficiency.

FOODBORNE OUTBREAK SAFETY [EMERGENCY/INCIDENT/EVENT] – MANAGEMENT

42. When a food ~~borne outbreak~~ safety [emergency/incident/event] occurs, the networks and structures established should be used to manage the situation in an integrated approach. Management of foodborne outbreaks will often be carried out under big pressure and time **and budgetary** ~~re~~ **con**straints. It is therefore important that each sector/participant carries out the tasks within their responsibilities according to the procedures decided upon for the networks. The following sections give information of the basic roles of the participants in the networks.

A. IDENTIFYING AND INVESTIGATING A FOODBORNE OUTBREAK SAFETY [EMERGENCY/INCIDENT/EVENT] – HUMAN HEALTH

43. Careful description and characterization of the food ~~borne outbreak~~ safety [emergency/incident/event] is an important first step in any epidemiological investigation. Descriptive epidemiology provides a picture of the **outbreak** ~~[emergency/incident/event]~~ in terms of the three standard epidemiological parameters – time, place and person.
44. A foodborne ~~illness~~ outbreak is typically identified by
 - a national or regional surveillance system when a cluster of human cases occurs with an identical or closely related type of infection **likely to be foodborne** or,
 - the food control authorities when they are informed about ~~illnesses~~ es related to specific products or companies. The information may be provided by consumer complaints, information from public health sector or by the companies or businesses themselves e.g. a restaurant.
45. Depending on the information available **the health authorities should initiate the creation of** a case definition. ~~should be created.~~ Cases that fall within the definition should be interviewed **by trained personnel** to obtain as much information concerning food items consumed prior to illness onset, place and date of purchase, brand name as well as information on travel, animal and environmental exposures, person to person contact etc. If possible, a standardized questionnaire for hypothesis generation purposes or standard epidemiological study methods such as case-control and cohort studies should be used to obtain information in a structured way.
46. Creation of standard questionnaires for this purpose may be performed electronically using one of the internet based free of charge software. Data can then be analyzed electronically in a standard statistical software program.

B. SUBSTANTIATE HYPOTHESIS AND/OR HANDLING OF A

study).

57. Other tools that can be used for hypothesis generation to determine the source of attribution in case of a **foodborne outbreak** ~~safety incident~~ are sample monitoring, surveillance data, source attribution studies and mathematical modelling. More detailed information on epidemiological tools can be found in the *WHO Foodborne Disease Outbreaks: Guidelines for Outbreak Investigation and Controls*.
58. Robust epidemiological evidence may be conclusive of **a foodborne outbreak** ~~the food safety incident~~ even without positive laboratory results. **Efforts by sampling and analysis should be made to allow laboratory results to support the epidemiological evidence** but they will only be conclusive if the result is **Analytical evidence should always be** supported by at least some epidemiological information such as that obtained from the patients. **For molecular testing and in particular WGS, it might be very useful to search for isolates in food databases with similar molecular profiles as in a cluster of human cases. If very similar profiles are found, targeted epidemiological investigations to identify the source should be carried out to confirm or exclude a possible link.**

D. [OUTBREAK ASSESSMENT / RAPID RISK ASSESSMENT] – DURING A FOODBORNE OUTBREAK

59. **When possible** ~~In most cases~~, a risk assessment or adaptation of an existing risk assessment to the emergency specific situation should be carried out. Since risk management actions are needed urgently, a full risk assessment is not practical, but a simplified rapid risk assessment or "**outbreak assessment**" can be helpful to correctly target risk management activities. It includes:
- historical information on the prevalence of the hazard in different food, in particular if the source of the ongoing **foodborne outbreak** ~~safety incident~~ is not confirmed yet;
 - results from epidemiological and microbiological investigations of human outbreak cases, considering severity, possible mortality, spread of cases and affected subgroups (e.g. elderly);
 - laboratory results and results from the epidemiological (including tracing back) investigations;
 - risk **identification and** characterization linked to the outbreak;
 - if possible, recommendations to the consumers and to competent authorities on how to **manage** the risk.
60. Since such rapid risk assessments ~~outbreak assessments~~ are likely to be carried out at any time in the outbreak investigation, constant communication should be ensured between the risk assessors and the **risk managers (outbreak investigators from both human health and food safety institutions)** ~~on human cases and on food investigations~~:
- to ensure that most recent information is available to the risk assessors;
 - to formulate targeted questions;
 - to allow the risk assessors to point investigators to gaps of information or hot spots (geographical areas or events with more than usual activity within the outbreak) detected, guiding further investigations.

E. RISK COMMUNICATION

61. **Foodborne outbreaks** ~~safety [emergencies/incidents/events]~~ may start in one country but can travel rapidly to other regions and require rapid and clear response in terms of communication. INFOSAN can be used as a resource for risk communication messages in such instances to ensure factual information is being shared about an international **foodborne outbreak** ~~safety incident~~.
62. At the beginning of an **outbreak** ~~incident~~, during the period when information is being gathered, there may be confusion and intense public and media interest. Ideally, risk communication will provide stakeholders outside the formalized network structure with the information they need to make informed decisions.
63. Some good practices that should be considered when elaborating the risk communication message to the public include, but are not limited to;
- **Having** one official communicator to speak to the public whenever practical. When more than one competent authority communicates with the public the authorities should ensure the messages are consistent.
 - Information should be simple and in plain language for key points since the public may have limited familiarity with scientific language. **If more languages are used in a specific area the information should be available in all the relevant languages.**

- Acknowledge any uncertainties and make it clear that the recommendations are based on the best information available at the time. If there is a need to change the recommendations in the future, it is important to remind the public that earlier recommendations were based on information known at that time and explain why the recommendations were changed.
- Explanation of who the recommendation applies to and who it does not apply to and why.
- Do not withhold information just because it may be upsetting. If information is lacking or cannot be released, an explanation of the cause and what is being done to address this situation is important. Identifying information gaps that will be addressed in the future informs stakeholders on the likelihood of additional communication.
- There is a **facility practice** in place for the use of external groups of experts **to verify the soundness of the** ~~in-validation of~~ recommendations **given**.
- Repeat information and provide updates in a timely manner.
- Monitor effectiveness of communications and adjust as necessary.

F. DOCUMENTATION OF THE OUTBREAK

64. It is important to collect and save sufficient information to be able to document all relevant steps in the management of the outbreak using e.g. log books, both when it is ongoing and afterwards. During the ~~outbreak~~ **incident** a record should be kept which includes relevant trace back information and descriptive epidemiology, hypotheses and status of the situation. The record should be updated as needed while the food ~~borne outbreak~~ **safety [emergency/incident/event]** is ongoing **and in a way that protects personal information**. When it is over, the record can be finalized to include conclusions and can serve as an ~~outbreak~~ **[emergency/incident/event]** report.
65. For the documentation to be of future use to the competent authorities and institutions involved in food ~~borne outbreaks~~ **safety [emergency/incident/event]** management it should be kept in a structured way and accessible at all times for the personnel involved in the work. This could be in the form of a database structure or in a shared file system accessible only to the relevant personnel/competent authorities.
66. Information from the shared system should be reviewed regularly by the competent authorities. The information can be valuable for the food control authorities when targeting official control efforts.
67. Outbreaks ~~or [emergencies/incidents/events]~~ of special interest should be considered for submission as scientific publications. ~~—and shared through INFOSAN so that other food safety authorities can learn from the experiences.~~ **Relevant to this guideline is also the International Food Safety Authorities Network (INFOSAN) for rapid sharing of information during foodborne outbreaks (as well as other food safety emergencies) to stop the spread of contaminated food from one country to another. INFOSAN also facilitates the sharing of experiences and tested solutions in and between countries in order to optimize future interventions to protect the health of consumers**

G. POST OUTBREAK SURVEILLANCE

68. In order to evaluate the effect of actions taken and to maintain the confidence of consumers and trading partners, enhanced surveillance, rapid centralization and evaluation of data, in particular for human cases, should be continued until the baseline level has been reached or for new agents no further cases are observed, taking into account the delays in analyses and reporting and possible seasonal effects.

MAINTENANCE OF THE NETWORKS

A. REVIEW OF EXISTING PREPAREDNESS

69. Competent authorities should continuously monitor, evaluate, improve and strengthen their existing network to ensure that it is functioning effectively and efficiently. This should include ongoing strategic planning and review of objectives, priorities, needs, gaps, opportunities and challenges, including both internal processes and interagency/ inter-stakeholder relations. The results of such reviews should be documented and areas for improvement addressed to support capability and capacity of the system in place.

70. Evaluation of the local and national network structures and associated procedures can be facilitated by joint training or joint exercises, to focus on specific objectives, priorities, needs, gaps, opportunities and challenges. An “after action review system” for food safety incidents should be implemented within the network.
71. Evaluation of the national network, the member entities of the network and the efficiency of the network should be done on a regular basis. Restructuring and development in a governance system should be reflected in the network.

B. JOINT TRAINING ON FOODBORNE OUTBREAK SAFETY [EMERGENCY/INCIDENT/EVENT]

72. A key part of capability and capacity building is the training of experts and professionals. The training should be extended across different competent authorities and key stakeholders. The purpose should be to develop a common understanding of the entire system for local, national, and international preparedness. As part of the capability and capacity building joint simulation exercises should be put in place.
73. The exercises can aim at control/verification or learning/ development.
- Control/verification exercises are primarily aimed at testing the performance of the plan/system in place and the participants' ability to carry out their responsibilities effectively, for example an expert or professional handling a particular type of method or a procedure in the contingency plan. Participants should not be notified in advance of the exercise. These exercises can vary in both complexity, ~~length in time and size~~ of organization, in number of participants **and in length in time and size**.
 - Learning and development exercises are more organized with the focus on the participants being required to achieve new competences and capabilities. It may involve roles and responsibilities or the development and testing of new procedural concepts and plans. Joint simulation exercises are a proven concept in this setting. Advance notice about learning/development exercises should be given to provide participants with the opportunity to prepare, which can optimize the overall outcome and learning experience.
74. The exercise type should be varied to include procedural exercises, dilemma exercises and crisis management exercises. The different types of exercises can achieve different objectives, both in a control/ verification setting and in a learning/ development setting. The exercises can be done both in a live environment like a laboratory or in a table top form.
75. Regardless of type of joint training or exercise, it is important that the activity is put into a strategic perspective and that lessons learned are captured and put into a structured revision of the system where necessary.

C. IMPLEMENTATION OF LESSONS LEARNED

76. The evaluation of national preparedness systems can include “after action reviews” of major, serious or rare food **borne outbreaks safety** ~~[emergencies/incidents/events]~~. The evaluation should include ~~both~~ competent authorities and **personnel from various** agencies and if possible also comments from relevant stakeholders such as food business operators. The review should focus on commitment in participation, the use of resources, the sharing of information, and other essential issues. The review should be used to build a stronger system or network on an international, national or local level.

The review should also address whether changes are needed to the way a food is processed or whether regulatory oversight or other regulatory change is needed.

The review should be disseminated in order to share the lessons learned broadly within the system. Ideally, dissemination would include information such as:

- What was the most notable success in the management of the incident that others may learn from?
 - What were some of the most difficult challenges faced and how were they overcome?
 - What changes, if any, to the national structure, procedures or analytical methods are recommended?
 - What was not done to your satisfaction and what could be done differently next time?
77. The lessons learned should be included in the ongoing development of capacity and capabilities of the

international, national, and local system.

ANNEX

List of FAO/WHO documents and other relevant documents

- a. *The FAO/WHO Guide for Application of Risk Analysis Principles and Procedures during Food Safety Emergencies*¹,
- b. *The WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls"*²,
- c. *The FAO training Handbook on "Enhancing Early Warning Capacities and Capacities for Food Safety"*³,
- d. *The FAO/WHO framework for Developing National Food Safety Emergency Response Plans*⁸,
- e. *The FAO/WHO "Risk Communication Applied to Food Safety Handbook"*⁴,
- f. *The WHO "Outbreak Communication. Best Practices for Communicating with the Public during an Outbreak"*⁵,
- g. *The FAO "Food Traceability Guidance"*⁶,
- h. *The draft Template for INFOSAN/IHR communication: National Protocol for Information Sharing with National and International Partners during Food Safety Events and Outbreaks of Foodborne Illness*⁷,
- i. *INFOSAN Members Guide (This document is only available for the national INFOSAN contact point members but describes the communication through the INFOSAN network)*⁸,
- j. *FAO/WHO Guide for Development and Improving National Food Recall Systems*⁹,
- k. *The WHO guidance "Strengthening surveillance of and response to foodborne diseases"*¹⁰.
- l. *WHO Landscape paper "Whole genome sequencing for foodborne disease surveillance"*¹¹

¹ http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474_eng.pdf?ua=1

² http://www.who.int/foodsafety/publications/foodborne_disease/outbreak_guidelines.pdf

³ <http://www.fao.org/3/a-i5168e.pdf>

⁴ <http://www.fao.org/docrep/013/i1686e/i1686e00.pdf>

⁵ <http://www.fao.org/3/a-i5863e.pdf>

⁶ http://www.who.int/csr/resources/publications/WHO_CDS_2005_32web.pdf

⁷ <http://www.fao.org/3/a-i7665e.pdf>

⁸ Not published yet.

⁹ <http://www.who.int/foodsafety/publications/recall/en/>

¹⁰ http://www.who.int/foodsafety/publications/foodborne_disease/surveillancemanual/en/

¹¹ http://www.who.int/foodsafety/publications/foodborne_disease/wgs_landscape/en/

