CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

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GUIDELINES ON THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

CXG 96-2022

Adopted in 2022

1. INTRODUCTION

Foodborne illnesses encompass a wide spectrum of illnesses and are an important public health problem. They are the result of ingestion of foodstuffs contaminated with biological hazards (biological foodborne illness) or chemicals (chemical foodborne illness). The contamination of food may occur at any stage in the process from primary production through to the consumer and can result from the presence of biological hazards in animal production and/or cross-contamination and spread to other foods by handlers, environmental contamination, equipment, water, soil, or air.

Biological foodborne illness usually takes the form of gastrointestinal symptoms; however, such illnesses can also have neurological, gynaecological, immunological, and other symptoms. The symptoms can range from mild to severe in the acute phase with recovery within days or weeks but also can have severe chronic consequences for the individuals due to long-term sequelae with serious health effects or even death.

Biological foodborne outbreaks can have significant socioeconomic costs related to hospitalization, medical treatment, and effects on productivity and income. In particular, they are important for vulnerable sub-populations that have a higher risk of illness. For food businesses, the consequences can be lost markets, loss of consumer confidence, litigation, and company closures. Such foodborne outbreaks can cause impediments to domestic production and international trade. Globalization of the food supply has led to the rapid and widespread international distribution of foods, further increasing opportunities for pathogens being inadvertently introduced into many geographical areas.

Codex Alimentarius has issued several guidelines for food businesses and competent authorities on hygienic practices to ensure food safety. Those guidelines focus on prevention, monitoring, and corrective actions in case of deviations along the production processes. Despite efforts to ensure a high level of hygiene, foodborne outbreaks still occur.

In order to handle biological foodborne outbreaks efficiently, local and national multiagency networks of preparedness should be in place. To facilitate a common understanding and a consistent approach to these situations, such networks should use comparable methods, common definitions and interpretations to the extent possible, as well as transparent exchange of information. Cooperation through international networks is essential and should be a feature of any national network.

Communication and data sharing between and among networks, food business operators – nationally and internationally – is fundamental for the management of foodborne outbreaks. Existing procedures on confidentiality should be used or, if not present, procedures should be developed.

The principles for risk analysis including risk assessment, risk management and risk communication, as described in the Codex Alimentarius *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CXG 62-2007)[1] should form the framework/basis for the establishment of a system for preparedness and management of foodborne outbreaks. The risk management measures chosen will vary according to the situation and the regulatory framework of the competent authorities.

Within the available analytical methods, molecular methods often best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genetic methods (e.g. pulsed-field gel electrophoresis [PFGE], whole genome sequencing [WGS], multiple-locus variable number of tandem repeat analysis [MLVA] and multilocus sequence typing [MLST]) can result in improved detection of outbreaks, including detection of associated or linked cases, when the country has adequate resources to implement them. The increase in the use of these methods will likely lead to the detection of more clusters and the need for enhanced preparedness.

The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities and should be consistent at both local and national level. The following criteria may be used by the competent authorities to categorize the outbreak and to develop and adapt response plans:

- the number of cases, the geographical spread of the outbreak, and whether the outbreak is ongoing;
- the disease severity and its consequences, including the number of deaths and treatment options available;
- the population affected, for example, more vulnerable groups;
- the pathogenicity (virulence/infectivity) of the microorganism;
- the source of contamination and the history of the establishment and business;

- the distribution pattern, whether the contaminated food is still available for sale or consumption, the volume of the food and national and international trade implications;
- consumer perception (e.g. referring to an outbreak as a “crisis”) can affect the consumer confidence in a product or food category clearly not belonging to the consignment implicated;
- the need to remove or reduce risk to consumers through public health action such as product recall risk communication including media alerts;
- likely exposure and consumption patterns;
- whether or not the outbreak was intentional (e.g. the consequence of fraud or bioterrorism);
- whether the hazard is known or unknown; and
- the capacity of the country and/or local entities to quickly react and limit the extent of the outbreak, considering when rural areas are involved, communication and transportation, health care providers and diagnostic resources.

2. SCOPE

These guidelines provide guidance to competent authorities on the preparedness for and management of foodborne outbreaks, including the communication with international networks, such as the International Food Safety Authorities Network (INFOSAN) and notification to the World Health Organization (WHO) under the international health regulations (IHR) when it is necessary. The guidance addresses preparedness, detection, and response with the intent of limiting the extent of such outbreaks. They include recommendations on the appropriate use of new analytical technologies, for example, genetic typing methods in outbreak investigation. The scope is limited to biological hazards, as they are the predominant cause of foodborne outbreaks.

These guidelines also describe the role of competent authorities at the local, national and, where applicable, the international level (e.g. groups of countries) and the collaboration among them in official network structures. Guidelines are included on collaboration and communication with food business operators and other stakeholders before and during foodborne outbreaks, as well as on post-outbreak measures and outbreak management review when an outbreak has been declared over. Maintenance of the structures and training methods to strengthen the response by the networks are also addressed.

3. USE

The following Codex Alimentarius documents[i] are relevant for these guidelines:

- *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995).[2]
- *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CXG 62-2007).[1]
- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999).[3]
- *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CXG 63-2007).[4]
- *Principles and Guidelines for National Food Control Systems* (CXG 82-2013).[5]

A number of FAO/WHO documents describe in more detail some of the issues presented in these guidelines.

In foodborne outbreaks involving zoonotic agents, the World Organisation for Animal Health (WOAH) standards for the prevention, detection, and control of zoonotic agents at the primary production stages should also be considered.

4. DEFINITIONS

For the purpose of this document the following definitions apply:

Biological hazards: Biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include, for example, bacteria and their toxins, viruses, and parasites.

Case-control study: An observational study in which subjects are included on the basis of presence (cases) or absence (controls) of the foodborne illness of interest. Information is compared between cases and controls.

[i] http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/

Case definition: A set of criteria for determining whether a person affected by the illness under investigation should be classified as belonging to the outbreak. As such, it is an epidemiological tool for counting cases. It may include clinical and laboratory criteria, a defined period of time, and, as appropriate, limitation/restriction to a place (for example a particular event or restaurant). In some cases criteria could include a limitation based on personal characteristics (for example age).

Cluster: In epidemiological terms, it describes a group of cases linked by time or place, but with no identified common food or other source. In terms of biological hazards, isolates having the same specific molecular profile or closely related profiles identified by laboratory analyses of specimens from cases.

Cohort study: An observational study in which the occurrence of illness among those who were exposed to a suspected risk factor is compared with the occurrence among those who were not. These studies are feasible for well-defined outbreaks in which all exposed and all non-exposed persons are generally identifiable.

Descriptive epidemiology: The aspect of epidemiology concerned with organizing and summarizing health-related data according to the occurrence of disease, in terms of both geographical comparisons and descriptions of temporal trends.

Foodborne outbreak: The occurrence where the observed number of cases of a particular illness that may be foodborne exceeds the expected number, or the occurrence of two or more cases of a similar foodborne illness resulting from the ingestion of a common food and epidemiologic analysis implicates the food as the source of the illness.

Lot: A definite quantity of ingredients or of a food that is intended to have uniform character and quality, within specified limits, is produced, packaged, and labelled under the same conditions, and is assigned a unique reference identification by the food business operator. It may also be referred to as a “batch”.

Metadata: Data that describe other data. In relation to analytical testing results, metadata could be date of sample collection, identification of sample, sample size, product name, sampling site, etc.

Monitoring: The performance of routine analysis aimed at detecting biological contamination of, for example, food from which prevalence data may be ascertained.

Outbreak analysis: An analysis based on the information available on the foodborne outbreak as well as relevant historical data. It is used to forecast if more cases should be expected under the given circumstances and to finalize tracing information pointing to a source and comparing it with epidemiological outbreak information.

Rapid risk assessment: 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 the full development of the four steps of a risk assessment described in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999).[3]

Risk communication: The exchange of information on the biological risk among stakeholders (e.g. government, academia, industry, public, mass media and international organizations).

Surveillance: A systematic and ongoing set of observation or measurement activities, collection, analysis, and interpretation of data from samples from, for example, humans, animals, feed, food, or environment for early detection with the purpose of applying appropriate control measures to prevent foodborne illness.

Traceability/Product tracing: The ability to follow the movement of a food through specified stage(s) of production, processing, and distribution, where “tracing back” refers to following the path towards its origin/source and “tracing forward” refers to following the path towards its final distribution/to the consumer.

5. FOODBORNE OUTBREAKS – PREPAREDNESS SYSTEM

To handle foodborne outbreaks in an effective way, it is advisable to have and maintain preparedness structures enabling cooperation between competent authorities. In this section, such structures are described in the form of official networks at different organizational levels, along with some of the good practices and standard tools to include in the system.

5.1 Creation of official networks between human health sector and food and veterinary sectors at local and national levels

In the following paragraphs, the composition and tasks of the networks of competent authorities within a country are described. Competent authorities, other than those at the national/federal level, are referred to as “local” and these may contain sublevels that should also be involved.

At the local level, defined networks between contact points from the different relevant authorities/agencies covering the same geographical area should be formed, for example, local food control authority, local veterinary authorities, clinical microbiological laboratory, local departments of health/local health authorities, community council and food/veterinary laboratory. The contact points may be either persons or offices as long as they consist of personnel usually participating in the relevant tasks relating to the investigation of foodborne outbreaks at the local level.

The tasks of the network contact points are to ensure the exchange of information within the network and coordination of the work with the staff responsible for the various tasks involved in outbreak investigation and management. To ensure cooperation within the local network, one of the contact points should be designated as the local network contact point in charge of the network.

The local network contact points should also ensure the timely exchange of information with their respective counterparts in the national network and, if relevant, with the respective contact points in the other local networks. They should establish channels to engage stakeholders, including food business operators, where relevant, in order to exchange information to minimize adverse consequences.

At the national level, a defined network should be established with personnel experienced in the management of foodborne outbreaks within the competence of their respective authorities/agencies. This national network should be recognized by each of the competent authorities involved, to ensure effective communication and exchange of information. The participants in the national network should be personnel from the authorities at the national level, equivalent to the same authorities/agencies that participate in the local networks. In addition, representatives from other relevant institutions, for example, universities or research institutes, may be included. The authority/agency with the legal responsibility to protect public health in a foodborne outbreak situation should be designated as lead contact point in charge of the national network. The role of the national network should include:

- ensuring that communication channels among network participants at the local and national levels function effectively and efficiently;
- ensuring that coordinating efforts to resolve foodborne outbreaks, especially those that are complex, are performed;
- supporting the local networks where needed;
- assessing surveillance and monitoring data received from the participating authorities/agencies;
- assessing information received from the other levels and participants of the network as a basis for risk management decisions; and
- ensuring that communication takes place with regional and international networks, for example, through the INFOSAN emergency contact points, where necessary.

The networks should be based on existing structures in the participating authorities and agencies. The network should have an appropriate structure with sufficient capacity and capability. The networks and structures should be described in detail and agreed upon by the participants to ensure cooperation with respect to competences and responsibilities of each participating authority and official agency. They should allow an outbreak to be managed as soon as possible at the lowest possible administrative level, i.e. the local network should coordinate the efforts when handling local outbreaks within their area. However, local networks should ask for the support of experts from other local networks or the national network if additional competences are needed to handle a specific outbreak. When several local networks or areas are involved in an outbreak, coordination at a higher level, covering all affected areas, should be considered. This could be a task for the national level of the network. A presentation of the structure of the network is provided in Annex I.

For the networks to be effective, it is essential that the participants know whom to contact, such as the contact details for the competent authorities, have familiarity with the system and structures and use them regularly, even in the absence of a foodborne outbreak. It is recommended that participants meet or hold audio/video conferences regularly to exchange experiences and best practices, to evaluate the management of past outbreaks and to identify lessons learned.

Templates and standard tools should be developed in advance and included in the standard procedures for the network participants to use. Some of them are listed below:

- template(s) for collecting, maintaining, and reporting updated information describing the outbreak – descriptive epidemiology;
- standardized questionnaire(s) (including focused food consumption questionnaires) for hypothesis-generation purposes;

- template(s) for cohort and case-control questionnaires. This would allow the networks to adapt them to the specific outbreak situation and to use the questionnaires without delay. Creation of standard questionnaires for this purpose may be performed electronically using one of the Internet-based free software solutions. Data can then be analysed electronically using a standard statistical software program;
- template(s) for reporting on the outbreak and the outcome of investigations; and
- template for requesting a rapid risk assessment addressed in Section 5.5 and Annex II.

The national network may also be the forum where new tools and ways to handle outbreaks can be developed and then be made available to local networks.

Communication both within a network and between networks is crucial. Since network participants may have limitations on what information they may share with others in the network, these limitations should be identified and addressed in advance. Communication structures and practices should be included specifically in the documented description of the system and procedures for the network, to ensure that:

- all available information is compiled to complete as much as possible an overview of the situation and kept under review as new information becomes available;
- the appropriate information is distributed to and understood by all necessary and relevant 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 for receipt 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); and
- there is a mechanism in place for the potential use of external experts to reach consensus on and verify the soundness of recommendations, especially for the national network.

5.2 International alert networks and exchange of information with them

Foodborne outbreaks do not respect borders. What seems to be a national outbreak at the outset may in fact be or turn into an international foodborne outbreak.

The national level network should have a permanent connection with international networks, for example, the INFOSAN, and, where applicable, with regional alert networks. These international and/or regional networks have national emergency contact points in most countries. If there is a national contact point (person or institution), it should be actively included in foodborne outbreak investigations at the national level. The contact point at these alert networks may assist in gathering and compiling information and submitting coordinated information concerning ongoing foodborne outbreaks.

Information from international networks may be useful for the work of a national network, even if the outbreak described does not concern that country, hence it should always be considered if information concerning an outbreak could be useful for other countries and therefore shared.

5.3 Surveillance and monitoring systems (e.g. human, animal, feed, food, establishment environment) and their use in foodborne outbreak situations

Many biological foodborne outbreaks are initially identified through human illness surveillance data. In order to identify the source of a foodborne outbreak there is a need for:

- surveillance and monitoring of the usual situation of human illnesses from biological foodborne hazards;
- access to relevant information on cases of illnesses that do not require notification to human health authorities and an assessment of the usual level of illness. This will enable the competent authorities to define when a number of cases exceeds the expected number and may result in the identification of an outbreak;
- timely 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; and
- analysis (e.g. weekly) of the data in order to detect outbreaks in a timely manner.

Information from surveillance and monitoring of, for example, animals, feed, food, and environment, including food contact surfaces at food businesses, may also indicate a potential risk and may help identify the source of a foodborne outbreak as early as possible. Surveillance and monitoring systems are essential tools for detecting and limiting foodborne outbreaks and may help in the early identification of the source. They should preferably be used as an integrated element in the outbreak investigation.

Data from these systems may also be used in conjunction with epidemiological data to inform and if necessary, prioritize an investigation, for example, by checking if the strain found in a human outbreak has been found previously in certain reservoirs (e.g. a specific animal population, species, specific food category or environment).

For sharing of surveillance data, it is necessary that data collected are comparable among sectors and that confidentiality of personal information is maintained. Information exchange should occur both routinely and during foodborne outbreaks. There should be regular exchange of information among the human health sector, competent food authorities, and laboratories. It is recommended that the information exchange include where possible:

- 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 among human health, food control 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 a phylogenetic tree (a branching diagram or “tree” showing the evolutionary relationships of the physical or genetic characteristics of the foodborne pathogen isolates at hand); and
- epidemiological data to evaluate the relevance of the source and to conduct tracing back.

5.4 Analytical methods

Validated analytical methods should be used to isolate and identify causative agents. Traditional analytical methods (such as pathogen isolation) or polymerase chain reaction (PCR)-based methods used for surveillance and monitoring are essential as the basis for detecting and investigating any outbreak. In some cases, basic typing information such as the serotype may be enough to allow a conclusion on a link between different human cases and between the human case and the suspected food source, but often it does not allow such a conclusion. When further characterization is needed for outbreak investigation purposes, molecular or genetic typing methods can be and are increasingly being used.

Molecular typing methods include PFGE, MLVA and other genetic-based methods such as WGS. WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of an outbreak with a high degree of accuracy when used in conjunction with epidemiological data. The method can also be used to identify genetic differences, virulence factors and antimicrobial resistance mechanisms. The implementation and use of WGS and the analysis of the WGS results require additional resources and capacity compared to other methods.

When WGS is used, consideration should be given to:

- Laboratory capability, specific equipment (properly maintained and, where applicable, calibrated) and personnel trained in implementation of WGS, analysis and interpretation of WGS results. Having access to personnel with expertise in bioinformatics is critical for analysis of sequence data.
- Secure storage capacity of large amounts of metadata and sequence data and the availability of bioinformatics tools to compare data in either restricted 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 authorities and the food and veterinary authorities. Sharing of actual raw whole genome sequences and associated metadata is often most useful for comparing results obtained by various analytical methods, including MLST-based, core-genome MLST-based, and single-nucleotide polymorphism (SNP)-based approaches.
- Legal requirements for sharing of data. If data are shared in open databases, there may be a need for anonymizing the samples to ensure confidentiality of personal or business information, thus only allowing limited metadata to identify the sequences.
- Use of existing genomic sequence data hubs containing data on foodborne pathogens and associated tools for analysis.

There are various opportunities for collaboration between public health and food safety laboratories within a single country and across countries that could reduce WGS costs if the necessary equipment and/or experience is missing. Collaboration between countries to carry out WGS is therefore strongly encouraged. Creation of regional hubs may be a way to optimize resources.

5.5 Rapid risk assessment – structures for assessing risk

A risk assessment during a foodborne outbreak may be useful to provide a sound scientific basis to determine the appropriate risk mitigation actions. In a number of cases, a risk assessment conducted for same or similar pathogen-food combinations will be available. Adaptations to the specific outbreak circumstances may be required (within a short time frame) based on the information from investigations and local contexts (climate, consumption patterns, serving size).

If a risk assessment conducted for the same or similar pathogen-food combinations is not available, there might not be sufficient time to undertake a full assessment of the risk at hand. A rapid risk assessment will be more practical. It should be noted that a rapid risk assessment may have higher uncertainty and lower accuracy compared to a full risk assessment.

The rapid risk assessment is based on the data readily available at that time from the foodborne outbreak itself and, if possible, data from similar outbreaks. There might be no time for collecting additional evidence/data to fill in data gaps or to conduct larger literature studies. These types of assessments need to be updated regularly during the outbreak investigation as new information (e.g. surveillance data, analytical results, epidemiological information, information on consumption and distribution of suspected food items) becomes available.

An essential part of outbreak preparedness is to have a framework and structures in place to allow for a timely rapid risk assessment. They should include but are not limited to:

- lists of risk assessors and experts for specific hazards available with the identification of their area of competence;
- instructions clearly outlining what is expected of these risk assessors and subject matter experts, including the scope of any rapid risk assessment, taking into account the short timeline for the assessment to be completed or having a template ready to be used for such rapid risk assessment; examples of requests are provided in Annex II;
- structure to ensure the direct and immediate submission of information from the outbreak investigations to the risk assessors and for them to ask for additional clarification when required, from the investigators and/or implicated food business operators;
- availability of (international/national/local) data on consumption, consumer habits and serving sizes that is as up to date as possible; and
- procedures for rapid contact of food business operators, including maintaining contact information.

5.6 Risk communication system/strategy

Effective risk communication is essential to objectively inform on both the known data and uncertainties from an outbreak, to justify actions taken and convince affected parties of the necessity to take appropriate action when required.

Risk communication should include exchange of information with all stakeholders. Establishing communication links with food industry experts in advance of foodborne outbreaks is important in order to gather/provide information about food categories that may be linked to/potentially involved in an outbreak with respect to production, manufacturing/processing and/or distribution practices. Established relationships can enhance collaboration during the investigation.

In terms of risk communication, the preparedness should aim to:

- Establish a public communication strategy for the network members and, where appropriate, designate official spokespersons from the national network or the government, which includes the means of communication (websites, social media, etc.) that is appropriate to the size and nature of an outbreak. Where possible, the jurisdiction of each of the competent authorities should be accounted for when setting roles and responsibilities for each organization in the risk communication strategy.
- Consider a structure to allow for the communication to be handled locally, in case of small and localized outbreaks.
- Identify organizations that may be involved and make alliances and partnerships with them to ensure a coordinated message. This will minimize the risk for contradicting public statements to ensure the consumer can correctly identify the food item or cause of the outbreak.

- Draft initial messages for the different situations that could potentially arise while specific details can be filled in at the time an outbreak occurs. Consider that each population group may have its own characteristics that affect how they perceive risks (e.g. religious beliefs, traditions), so understanding the audience and testing messages to ensure they are culturally and demographically appropriate is important. Consideration should be given to measures that can help prevent misinformation and the spread of false information.
- Test established communication strategies on a regular basis to evaluate their efficiency.

6. FOODBORNE OUTBREAK – MANAGEMENT

When a foodborne outbreak occurs, the established networks and structures should be used to manage the situation with an integrated approach. Often management of foodborne outbreaks will be carried out under pressure with time and budgetary constraints. It is therefore important that each sector/participant carries out the tasks within its responsibilities according to the procedures decided upon in the networks. The following sections provide information on the basic roles of the participants in the networks.

The investigation and control of biological foodborne outbreaks are multidisciplinary tasks requiring skills and collaboration in the areas of clinical medicine, epidemiology, laboratory analysis, food microbiology, and risk communication and management (including food safety and food control), among others. The laboratory analyses may include the analysis of, for example, the implicated food or environmental samples from the primary production and processing environment of the implicated food. The management of a biological foodborne outbreak includes the establishment and confirmation, if possible, of the likely food source by epidemiological investigations of human cases (including interviews), of food data (data on traceability of implicated food) and laboratory analysis.

Evidence from these sources should be combined to identify a potential source and can provide input for an outbreak analysis, which serves as the basis for the communication. All aspects of an outbreak investigation, including factors considered when declaring an outbreak over, actions and communication should be documented for post-outbreak evaluation.

6.1 Identifying and investigating a foodborne outbreak – human health

A foodborne 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;
- food control authorities that identify a product testing positive for a pathogen and an investigation matches the pathogen to isolates from clinical illnesses in patients that have consumed the product; or
- the food control authorities when they are informed about illness related to specific products or food businesses. The information may be obtained either through consumer complaints, information from the public health sector or by the food businesses themselves such as a restaurant that received complaints from guests.

Careful description and characterization of the foodborne outbreak is an important first step in any epidemiological investigation. The initial descriptive epidemiological investigation provides an overview of the outbreak in terms of the three standard epidemiological parameters – time, place, and person.

Depending on the information available, the public health authorities should establish a case definition. It should be used in a systematic and uniform way to identify additional cases and determine the magnitude of the outbreak. The case definition may be updated or revised if new or additional information indicates a need to do so. Cases that fall within the definition should be interviewed by trained personnel to obtain as much information as possible on food items consumed prior to illness onset. The information asked should include:

- on the food items consumed: detailed food history, the place (the commercial name of the establishment and the exact address) and date of purchase and the time of consumption, frequency of eating or amount of the suspected foods eaten, method of preparation, the source of the food or food product, brand name, lot/batch code. (Note that for some foodborne illnesses such as listeriosis, this information may not apply, since food causing the illness may not have been consumed recently); and
- with regards to the affected person: personal details (to be treated with confidentiality), disease onset, symptoms, duration, hospitalization, underlying health conditions, person-to-person contact, information on travel, animal, and environmental exposures, etc.

The information should be obtained in a structured way using a standardized questionnaire for hypothesis-generation purposes when available. Data collected can be analysed using a standard statistical software program. It may be necessary to use several iterative rounds of questionnaires with a number of cases, beginning with a more general questionnaire such as a national hypothesis-generating questionnaire, progressing to a focused or supplemental questionnaire when one or several exposures appear noteworthy, to identify a potential source.

Other tools that can be used for hypothesis generation to determine the source of the outbreak in case of a foodborne outbreak include review of surveillance data, or prior sample matches, source-attribution studies, historical outbreak data and mathematical modelling. Population surveys of healthy adult food consumption habits can be used as a tool for rapid hypothesis generation to identify foods eaten by people more often than expected in the outbreak.

When a hypothesis is established, it may be appropriate, where possible, to perform analytical epidemiological investigations such as a retrospective cohort study or a case-control study. This could be the situation if the hypothesis is not very strong or if further evidence is needed to inform and back up control measures. These studies can help determine if an exposure is associated with a cluster of human cases. These investigations should not delay other ongoing investigations but can help to give them a direction.

6.2 Substantiate hypothesis and/or handling of a foodborne outbreak – food safety (from primary production to consumption)

Initial epidemiological investigations (descriptive epidemiology and interviews with a number of the cases using open-ended interviews for hypothesis-generation purposes) pointing to a particular food source or a site (e.g. restaurant, production facility, or farm), or a traceback of a food to a particular site, as the possible source of the outbreak should be followed by a thorough on-site investigation. This on-site investigation should cover all aspects of the production, storage, transport, handling, distribution, and consumption to substantiate if it is possible that the food source or the production conditions are actually the source of the outbreak. If possible, the root cause of contamination should be identified and verification by sampling and analyses should be attempted.

Sampling of potential food sources and the environment of potential contamination sites can be helpful in substantiating or rejecting a hypothesis. When taking a sample, information on the product should include at least product name, manufacturer, comprehensive product description (e.g. animal/fish species, type of vegetable, fresh, processed, frozen, canned), lot identification, place, date and time of sampling and transport condition, type of packaging, required and actual storage conditions, in order to allow further investigations including tracing. On-site investigation can include environmental sampling (e.g. swabs of a processing environment, or soil/water samples on a farm) to provide additional information on the source of the outbreak and root cause. Knowledge and correct application of sampling techniques, in particular aseptic techniques, and of sample handling for transportation to a laboratory is essential to guarantee the integrity of samples taken for verification as well as confidence in the results.

If the epidemiological investigations do not identify a source, the competent authority could use other information to inform their investigation of a potential cause of an outbreak. For example, historical outbreak data, prevalence of the hazard in food, information from the cases concerning food preferences, trade patterns, knowledge of production, distribution, and consumer preferences, may be helpful to narrow down the possible food sources or sites. Such information should however be used prudently, for example to target investigations and not for communications on the outbreak source without supporting evidence.

Tracing a food item both back and forward in the food chain is an essential tool in the investigation. Tracing enables the investigators to see the full distribution of the food item, for example, going back from the lot that caused illness to the place/source of initial contamination and identify from that source any other food products made with that food item or ingredient. The following information should be collected:

- identification of the affected lot(s) for each food item suspected;
- information to identify the root cause of the contamination (raw material status, processing steps that may influence the presence of the microbiological hazard identified including re-processing, records of process and product controls, identified risk factors for product contamination, samples analysed and results, etc.);
- list of suppliers of product or raw materials; and
- list of operators who received the affected lots of the food item and other distribution paths including to institutions and via Internet sales.

The data from tracing should be gathered in a standard way using templates and business names and product descriptions curated to ensure links are not lost due to abbreviation or spelling mistakes. The information gathered should be combined with the information from the epidemiological investigations of the outbreak to see if cases are consistent with product distribution. The tracing information, as well as the findings from the on-site investigation, can also be used to determine the extent of the problem.

If the overall evidence concludes that the source of the foodborne outbreak or the affected lot(s) has been identified, appropriate risk management actions should be put in place. This includes preventing further distribution of the contaminated food and removing any contaminated food already in the market. When a recall is identified as the appropriate risk management action, tracing back and tracing forward should be used to remove all lots implicated or suspected to be implicated. The recall should be carried out in the shortest time frame possible by the food business operator to avoid greater impact on public health and the business. The competent authority should monitor the recall to ensure compliance.

The affected lot(s) should be separated from other lots by procedures that prevent cross-contamination.

Consideration should be given to the actions required by consumers affected by recalls and businesses impacted by recalls and product withdrawals concerning the suspect lots. Consumers should be notified on the recalls using different appropriate communication tools (e.g. social media, newspapers, etc.). Consideration should also be given to provide advice to consumers and/or businesses about appropriate handling of affected foods which should take into account any potentially associated public health risks.

6.3 Combining epidemiological and laboratory data

Management of outbreaks benefits from the food control and veterinary and agricultural sectors being able to share and combine relevant laboratory surveillance and monitoring data among themselves and with the public health sector in time, in order to identify a match between a clinical human isolate and an isolate from a food.

Even in the case of a match in serotypes, supplementary analysis by molecular methods may be necessary to draw conclusions on the likelihood of a relationship.

The decision of the degree of relation between strains should be made as part of the case definition. The level agreed upon may differ according to the typing method and the pathogen.

For example, with WGS, there are no established standard “cut-off” values in terms of degree of differences between strains (e.g. SNPs) at present. In general, when the number of SNP differences, or allele differences – in the case of MLST analysis, is fewer, there is the potential that the strains could share a common ancestor. If a food and clinical isolates are within a very small SNP or allele range, it is more likely that those illnesses were caused by that food. The actual number of SNP or allele differences among related outbreak strains will differ depending on a number of factors (e.g. species, length of outbreak, contamination route) and will require interpretation based on bioinformatics, epidemiological, and tracing analysis. Even with a very small SNP or allele range, it is still critical to confirm that link with epidemiology and traceback data.

The use of databases containing comparable molecular-based testing results from, for example, humans, animals, feed, food, and establishment environmental sampling, may facilitate the detection and assessment of outbreaks and informs the search for the source of the contamination. The integrity of information in these databases is important as they may potentially be utilized for attribution nationally and internationally.

While robust epidemiological evidence can be sufficiently indicative of a foodborne outbreak even without positive laboratory results from sampling to warrant an outbreak response, efforts by sampling and analysis should be made to obtain laboratory results to support the epidemiological evidence. However, laboratory confirmation can be difficult to achieve for several reasons, for example:

- pathogens that contaminate food, are not likely to be evenly distributed;
- the level of contamination may be low, hence the chance for detection is limited;
- there may not be a validated method available for detecting the pathogen in a specific food of interest; or
- the affected lot of food was consumed or removed at the end of its shelf life and therefore no longer available for testing. This may happen when a pathogen causes illness with a long incubation in humans, or the food source has a very limited shelf life (e.g. fresh produce).

Analytical evidence, on the other hand, should always be supported by epidemiological information such as that obtained from interviewing human cases, as a match between food and human isolates may not necessarily mean that the food is the actual source of the illness.

For molecular testing, and in particular WGS, it might be very useful to search for isolates in pathogen databases with similar molecular profiles as this may identify a cluster of human cases not previously linked epidemiologically. If very similar profiles are found, targeted epidemiological investigations to identify the source should be carried out to confirm or exclude a possible link. Criteria should be established to determine sequence homology, illness attribution or environmental link, and how metadata associated with the sequence information is identified, maintained and used where possible. Collaboration among public health authorities, other authorities, and relevant food business operators on sharing molecular data of pathogen isolates from ingredients and specific foods, should be encouraged. This can help hypothesis generation and potentially lead to more quickly identifying the source of an outbreak.

6.4 Rapid risk assessment and outbreak analysis – during a foodborne outbreak

A rapid risk assessment is useful when answers to specific questions are needed (examples are given in Annex II). When possible, a risk assessment or adaptation of an existing risk assessment to the specific outbreak situation should be carried out. Since risk management actions might be needed urgently, a full risk assessment might not be practical, but a simplified rapid risk assessment can be helpful to correctly target risk management activities.

Rapid risk assessments can be carried out and updated at any time during the outbreak investigation. Constant communication should be ensured between the risk assessors and the risk managers (from both human health and food safety authorities) in order to:

- ensure that the most recent information is available to the risk assessors;
- formulate targeted questions; and
- identify gaps in information.

An outbreak analysis is a prognosis in an outbreak situation and is based on historical data and data generated in the investigation. It is used to forecast if more cases should be expected in a given scenario and to finalize tracing information pointing to a source. It provides a summary of the information collected during the investigations, thereby identifies gaps to be filled, and provides relevant background information and input for the risk communication. In particular, it includes the following (see template in Annex III for more details):

- historical information on the prevalence of the hazard in different foods, particularly if the source of the ongoing foodborne outbreak is not yet confirmed;
- 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 and food (including tracing back) investigations;
- hazard identification and characterization linked to the outbreak;
- analyses of detected hot spots (geographical areas or events with more than usual occurrence within the outbreak), guiding further investigations;
- consumer behaviour and adherence to intended use and preparation of foods, for example, use of frozen ready-to-cook vegetables and/or fruit, as a ready-to-eat product, not observing the food preparation instructions intended by the manufacturer to achieve food safety;
- where appropriate, recommendations to the consumers and to competent authorities on how to manage the risk; and
- if the potential food source has been traced to a specific food business, information on the overall condition of the facility, such as compliance history, inspection reports, complaint records and company test results.

Parts of the information from the outbreak analysis may be needed for risk assessors to reply to the specific question in the rapid risk assessment.

6.5 Risk communication

Ideally, risk communication will provide stakeholders outside the official network structure, including consumers, with the information they need to make informed decisions and take appropriate action. At the beginning of an outbreak, during the period when information is being gathered, there may be confusion and intense public and media interest. Therefore, it may be necessary to conduct risk communication even if the source of the outbreak is unknown. Such early communication should include information on the ongoing investigations and advice on general food hygiene measures consumers could take.

Most relevant practices that should be considered when conveying the risk communication message to the public and/or food industry sector include, but are not limited to:

- have 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 (e.g. official national language and official local dialect/language) 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 have been changed;
- explain to whom the recommendation applies and to whom it does not apply and why;
- any information regardless of perception, whether favourable or not, should not be withheld. If information is lacking or cannot be released, it is important to explain the cause (where known) and what is being done to address the situation. Information gaps that will be addressed in the future should be identified and stakeholders should be informed on the likelihood of additional communication;
- there should be a procedure in place for the consultation of external groups of experts to verify the soundness of the recommendations given;
- repeat information when appropriate and provide updates in a timely manner;
- monitor the effectiveness of communications and adjust as necessary;
- establish a platform that provides the public and other stakeholders with easy access to updated information, for example, a designated website with contact information. This includes authorities and food business operators in other countries if they may be affected. Consider non-traditional platforms used/trusted by specific subpopulations; and
- when possible, establish procedures to identify when rumours or false information are being circulated in order to reject false information early.

Foodborne outbreaks may start in one country but can spread rapidly to other countries/regions and require rapid and clear response in terms of communication. INFOSAN or other similar networks 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.

6.6 Documentation of the outbreak and lessons learned

It is important to collect and save sufficient information from the beginning of the outbreak to be able to document all relevant steps in the management of the outbreak, for example by using logbooks or electronic records, both when it is ongoing and afterwards. During the investigation a record should be kept that includes relevant tracing information and descriptive epidemiology, hypotheses, and status of the situation. Inspection and laboratory information, as well as any regulatory actions taken should also be kept. The record should be updated as needed while the foodborne outbreak 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 report or as the basis for a summary outbreak report.

For the documentation to be of future use, 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 or in a shared file system accessible only to the relevant personnel/competent authorities.

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.

Outbreaks of special interest should be considered for presentations in national and international scientific forums and submission as scientific publications. INFOSAN also facilitates the sharing of experiences and lessons learned in and between countries in order to optimize future interventions to protect the health of consumers.

The documentation can be used by the competent authorities and institutions involved in foodborne outbreak management to identify lessons learned and to consider the needs of a review of existing preparedness based on the lessons learned. A special report on lessons learned can be added later on to the documentation. It can also provide input for future training activities. The learnings from outbreaks should be broadly communicated to support continuous improvement in outbreak investigations and outbreak prevention.

6.7 Post-outbreak surveillance

Enhanced surveillance, and rapid centralization and evaluation of data, in particular from human cases, should be continued until the numbers of cases have returned to the baseline level, if known (or, for new biological hazards, until no further cases are observed). This allows the evaluation of the effectiveness of actions taken and the confidence of consumers and trading partners to be maintained or regained. Possible delays in analyses and reporting and possible seasonal effects should be taken into account before declaring an outbreak over.

7. MAINTENANCE OF THE NETWORKS

7.1 Review of existing preparedness

Competent authorities at the local and national level should continuously monitor, evaluate, improve, and strengthen their existing networks to ensure that they are 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. A post-outbreak network review system for foodborne outbreaks should be implemented within the network. The results of such reviews should be documented and areas for improvement addressed to support capability and capacity of the system in place.

7.2 Implementation of lessons learned

The evaluation of preparedness systems can include reviews of major, serious, or rare foodborne outbreaks. The evaluation should include personnel from various authorities/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, the timeline of activities, 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 could also consider whether changes may be needed to the way a food is processed (e.g. implementation of preventive strategies) or whether regulatory oversight or other regulatory change is needed to prevent future outbreaks.

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 outbreak that others may learn from?
- What were some of the most difficult challenges faced and how were they overcome (or not)?
- What changes, if any, to the national structure, procedures or analytical methods are recommended?
- What was not done to your satisfaction during the outbreak investigation and what could be the points to be improved next time?

The lessons learned should be included in the ongoing development of capacity and capabilities of the international, national, and local system.

7.3 Joint training on foodborne outbreak preparedness and management

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.

The exercises can aim at control/verification or learning/development.

- Control/verification exercises are primarily aimed at testing the performance of the system in place and the participant’s ability to carry out their responsibilities effectively, for example an expert or professional handling a particular type of method or a specific procedure. Participants should not be notified in advance of the exercise content. These exercises can vary in both complexity of organization, in number of participants and in length in time and size.

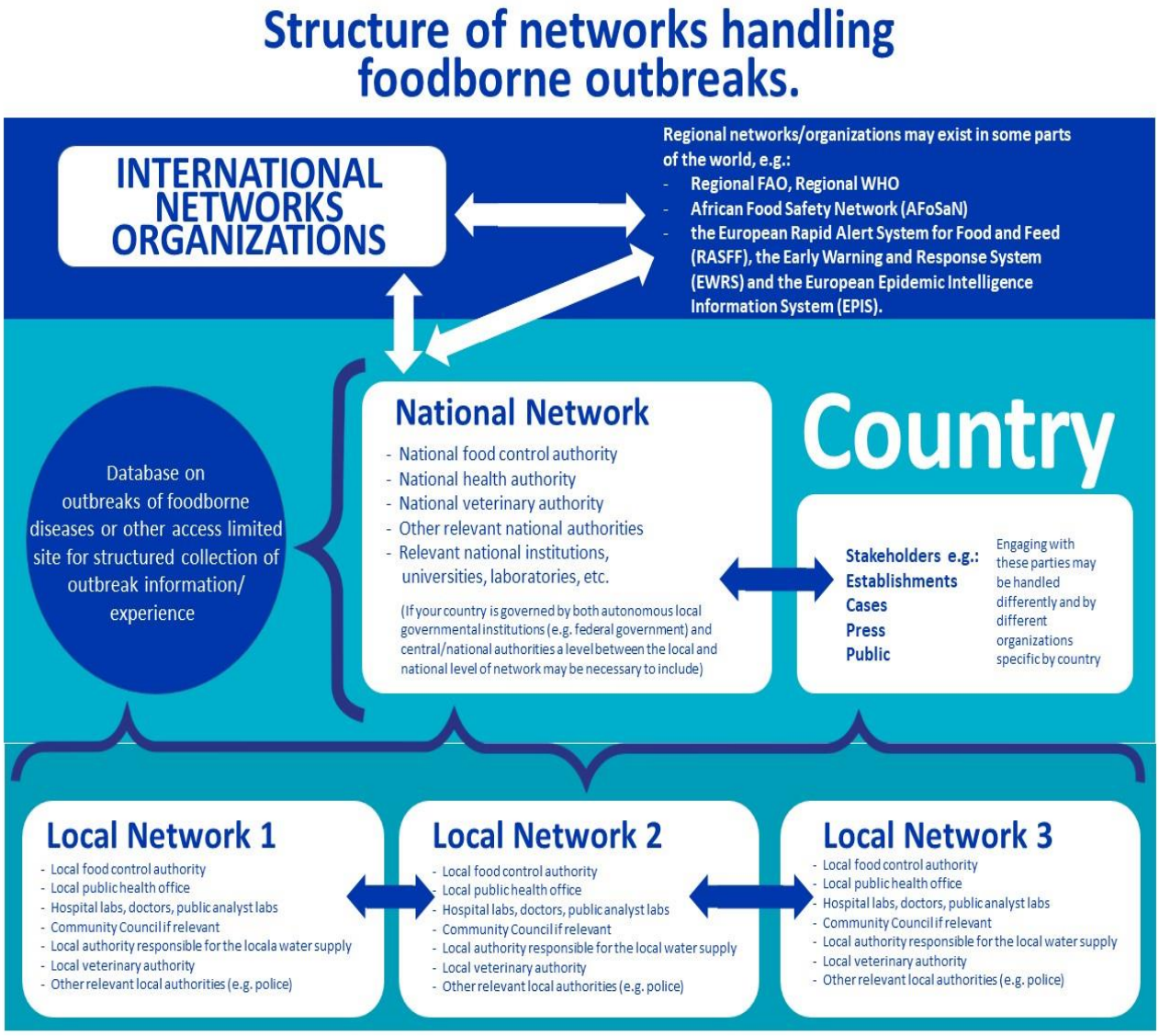
- Learning/development exercises are more organized, with the focus on the participants being required to achieve new competences and capabilities. The exercises may involve roles and responsibilities or the development and testing of new procedural concepts and plans. Joint simulation exercises are 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.

The exercise type should be varied to include exercises concerning the procedures in place (procedural exercises), exercises addressing specific difficult issues/topics and crisis management exercises. The exercises can be done both in a live environment like a laboratory or in a tabletop form.

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.

Annex I

Structure of networks handling foodborne outbreaks



*INFOSAN and international health regulations (IHR)

Annex II

Examples of requests for rapid risk assessments

Rapid risk assessment – Examples of questions to be clarified/risk to be assessed

The scope of a rapid risk assessment is to answer a specific question or assess a specific risk in relation to an outbreak, for which additional information is required for decision-making.

The topics and listed questions are only examples. The list is not exhaustive.

Possible question(s) related to the suspected food item, a production process etc.	1. Is it possible that the "food item X" produced under the "specific circumstances described" could have caused the outbreak? 2. The outbreak agent has been detected in an unopened sample of the "food item X" acquired in a private household. Is it likely that other items of the same food may carry the same risk? (In other words, are the production and storage requirements of this food item described sufficiently to eliminate the specific risk?)
Possible question(s) related to the agent causing the outbreak	3. A certain strain of "bacterium Y" is causing an outbreak that is suspected of being foodborne. The strain has not been previously seen in food items, but a closely related strain has been detected in a feed sample. An assessment of the strain relatedness and stability in the environment could be requested to determine if there could be a reservoir in the husbandry sector using the feed in question. 4. A certain strain of "bacterium Y" is causing an outbreak that is suspected of being foodborne. The strain has not been previously seen in food items. What is the most likely reservoir for these bacteria Y? What may be the most likely production(s) that these bacteria may be found in? 5. "Bacterium Y" is causing an outbreak that is suspected to be caused by products from one or more specific production facilities. However, samples from the facilities turned out to be negative with standard testing methods. What would be the optimal testing method and number of samples required to be able to determine whether the facilities are the source of the outbreak? 6. A certain strain of 'bacterium Y' is causing an outbreak. This strain has been linked to other foodborne outbreaks in the past. Interviews point at different food items as the source. Based on the data from interviews and previous outbreaks, what is the most likely food implicated in the outbreak and where in the food supply chain may the contamination event have occurred?
Possible question(s) related to the use of certain food items and consumer eating habits	7. An outbreak caused by *Listeria monocytogenes* seems to be caused by frozen small meatballs for soup. The meatballs are cooked prior to freezing. Normally they are heat treated when preparing the soup prior to eating. A kitchen added the frozen meatballs to the hot soup prior to chilling and storage. The soup portions are distributed as a chilled product ready to heat and serve. Is this process adequate to prevent illness from *Listeria monocytogenes*?

Annex III

Template for an outbreak analysis

Template for an outbreak analysis – fill in as much information as is available.

Outbreak information/ Descriptive epidemiology	Case definition Number of confirmed cases Number of probable cases not yet verified as part of the outbreak Geographical location (cases per area/jurisdiction)/Place of suspected or confirmed exposure Age and gender distribution Affected vulnerable subgroups (e.g. elderly, children) Epi-curve (number of cases per day/week or month) Other descriptive information available of the outbreak size and distribution area.
Analytical information Human cases	Agent involved – characteristics of the agent Overview of human cases reported including severity of illness (e.g. hospitalizations, disability, foetal loss and deaths).
Outbreak background information	Questions such as the following should be answered: How was the outbreak initially detected? Are there any common foods (or ingredients) identified as being consumed by the human cases? Is there any correlation between the distribution of the cases and the distribution of the potentially implicated food? How have the human cases initially been linked to a certain food source? Has outbreak information been reported to the public and how?
Illness background information	Historical data from previous monitoring and isolations in food might help target investigations towards the source if not known yet. Historical data, not related to the ongoing outbreak, on the hazard, for example: • occurrence in humans; • outbreaks in the past at local, national, regional, or international level; and • occurrence in different types of food. The purpose is to indicate if human cases/outbreaks with the involved pathogens are rare or occurring from time to time. Historical data from previous monitoring and isolations in food might target investigations towards the source when not yet known. When possible, these data should be targeted to the pathogen with the same virulence factors/serotypes as the one in the ongoing outbreak. Historical data may also be valuable when determining if/how the agent involved behaves differently than previously seen.
Investigation of human cases	This may include, but not be limited to results of the investigations performed: • hypotheses-generating interviews; • food exposures that appear higher than expected based on available surveys of food consumption habits; • subclusters where two or more cases not part of the same family ate at the same event, restaurant, etc.; and • case-control or cohort investigation.
Investigations in food	• information on samples taken – items, places of sampling, open or closed sample, lot code, any storage or cooking instructions provided on package, etc.; • analytical methods used; • outcome of the laboratory analyses; • information on tracing of the affected food/food ingredients, for example, starting from the food/establishment initially linked to the human cases: o tracing back the food/ingredients to the source; o tracing forward the distribution; o to be repeated for each affected establishment along the food chain;

	○ data gaps should be identified (e.g. establishments to which the affected food was sent, but where there is no information on investigations carried out in that establishment); and ○ are there any identified common suppliers of the affected food product? • assessing if the distribution of the suspected food item can explain the outbreak (distribution area, amount of the food on the market in relation to the distribution and number of cases in the outbreak); • description of production conditions in affected establishments (e.g. hygiene conditions), applicable steps influencing the presence of the hazards (e.g. heat treatments or possibilities for cross-contamination); • information on consumer behaviour and eating habits, for example, not following the manufacturer's instructions for storage (e.g. refrigerate, use-by date) or for the cooking intended by the manufacturer to achieve food safety. How much time elapsed between preparation and consumption?
Background information concerning the strain in food, feed, animal, or environment samples	Has the strain been seen previously? If yes, please describe further the time, place, etc. If isolates are available for comparison, sample identification should be provided. If a specific production or process is suspected to be the source of the outbreak, a detailed description of the ingredients, their treatment, production processes, etc. needs to be developed/documented to assess whether deviations in the production may be implicated. Possible significant family or community event that may have been an opportunity for outbreaks to occur (e.g. family events, birthday parties, fiestas, festivals, holiday celebrations, etc.).
Linking epidemiological food trace back and laboratory data in humans and food	An attempt should be made to graphically present and link the data from human cases, retailers, distributors, processors back to suppliers of raw materials, indicating the link between them, when existing, and the results of laboratory testing if carried out and available. When available, results from whole genome sequencing can be added, and a single-linkage tree including all human and non-human isolates should be made, illustrating the core gene allelic differences.
Data not available/not yet available	Any uncertainties on the existing data and data gaps should be indicated. If any data/information is necessary for the assessors but not yet available, it should be indicated when the data will be available. If any data is not available, this should be clearly stated when asking for the outbreak analysis, as the missing data may be vital for the outcome of the analysis.
Communication	Clear information on the communication strategy targeted towards consumers, affected operators and other stakeholders should be given. It is also a good idea to agree upon a strategy for communication in case the assessors are approached by the press or public – agree on what can be said, by whom and when.
Annexes	References

Prognosis/Summary

Summary	Overview of involved geographical areas/jurisdictions at local, national, or international level. Overview of human cases reported, including hospitalizations and deaths. Summary of investigations on food sources and actions taken (e.g. recall, withdrawal) and actions planned. Short and clear communication message to consumers (recommendations on buying and preparing food), affected operators, other stakeholders, and trade partners, including possible uncertainties where applicable. Summary of considerations that resulted in the conclusions including any data gaps. Could more cases be expected in near future, or can it be assumed/stated that the outbreak is over?

NOTES

[1] FAO and WHO. 2007. *Working Principles for Risk Analysis for Food Safety for Application by Governments*. Codex Alimentarius Guideline, No. CXG 62-2007. Codex Alimentarius Commission. Rome.

[2] FAO and WHO. 1995. *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations*. Codex Alimentarius Guideline, No. CXG 19-1995. Codex Alimentarius Commission. Rome.

[3] FAO and WHO. 1999. *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*. Codex Alimentarius Guideline, No. CXG 30-1999. Codex Alimentarius Commission. Rome.

[4] FAO and WHO. 2007. *Principles and Guidelines for the Conduct of Microbiological Risk Management*. Codex Alimentarius Guideline, No. CXG 63-2007. Codex Alimentarius Commission. Rome.

[5] FAO and WHO. 2013. *Principles and Guidelines for National Food Control Systems*. Codex Alimentarius Guideline, No. CXG 82-2013. Codex Alimentarius Commission. Rome.