

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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Organization

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PROPOSED DRAFT GUIDANCE FOR THE MANAGEMENT OF (MICRO)BIOLOGICAL CRISES/OUTBREAKS

Comments of Australia, European Union and African Union

Australia

PROPOSED DRAFT GUIDANCE FOR THE MANAGEMENT OF (MICRO)BIOLOGICAL FOODBORNE CRISES/OUTBREAKS/FOOD SAFETY EMERGENCIES/EVENTS INTRODUCTION

1. Codex Alimentarius has issued several guidelines on hygienic practice 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.
2. The globalized food production, trade and complex supply chains contribute to food safety gaps/breaches and resulting outbreaks of foodborne illness with a broader impact.
3. 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 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 and international trade.
4. In order to be able to efficiently handle biological food safety [emergencies/emergencies/incidents/events] local and national multiagency networks of preparedness should be in place to handle these situations. Such networks should use standardised methods and interpretation; transparent exchange of results is essential. Cooperation through international networks is equally essential and should be included in the structure. a feature of any network
5. The principles for risk analysis, including risk assessment, risk management and risk communication, as described by Codex Alimentarius b/c should form the framework/basis for the establishment of a system for preparedness and management of food 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 and improved [outbreak/incident/event] management and enables better resolution of involved batches 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 [emergency/incident/event]" is used for simplicity throughout the document and covers 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.
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 food safety [emergencies/incidents/events] and of the category of the foodborne illness outbreak itself. What may be "business as usual" in one country might well be categorized as an emergency or a crisis in another country.~~

Commented [PB1]: The document refers to food safety emergencies/events, and in particular "biological" ones. There needs to be consistency in terminology and clarification of scope.

Commented [PB2]: Suggest that "emergency" is used (noting it is defined in CAC/GL 19 as "a situation whether accidental or intentional, that is identified by a competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health") The use of the term is clarified under paragraph 7.

Commented [PB3]: Introducing other terminology such as crisis unnecessarily complicates things.

9. This document collects guidance for preparedness and management of food safety[emergencies/~~incidents/events~~] with cross-references to relevant documents and 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 food safety emergencies to stop the spread of contaminated food from one country to another. INFOSAN facilitates the sharing experiences and tested solutions in and between countries in order to optimize future interventions to protect the health of consumers¹.~~

SCOPE

10. These guidelines provide guidance to competent authorities on the management of food safety[emergencies/~~incidents/events~~], including the communication between national and regional programmes with international networks such as the Food Safety Authorities Network (INFOSAN). 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 and ~~collaboration in formalized~~ network structures ~~for between them at different levels. This includes C~~collaboration and communication with food business operators and other stakeholders before and during food safety [emergencies/~~incidents/events~~] ~~is also addressed. Finally some emphasis has been put on the m~~Maintenance of the structures and training methods to strengthen the response by the networks is also addressed.

USE

12. These guidelines should be used in conjunction with relevant Codex Alimentarius guidelines. References are also given to FAO/WHO guidelines providing detailed information for competent authorities on preparedness for food safety[emergencies/~~incidents/events~~] and on their management in a coordinated approach with public health authorities and if relevant other stakeholders.
13. In food 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.
14. A number of Codex Alimentarius and FAO/WHO documents 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/GLCXG 19-1995)*,¹
 - Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG-30-1999, as amended)*,²
 - Principles and Guidelines for the Conduct of Microbiological Risk Management (CXC 63-2007, as amended)*³
 - The FAO/WHO Guide for Application of Risk Analysis Principles and Procedures during Food Safety Emergencies*,⁴
 - The WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls"*,⁵
 - The FAO training Handbook on "Enhancing Early Warning Capacities and Capacities for Food Safety"*,⁶
 - The FAO/WHO framework for Developing National Food Safety Emergency Response Plans*,⁷
 - The FAO/WHO "Risk Communication Applied to Food Safety Handbook"*,⁸

Commented [PB4]: Covered by the previous sentence and specifically referred to in paragraph 11 under Scope

¹<http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/>

²<http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/>

³http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B63-2007%252FCXG_063e.pdf

⁴http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474_eng.pdf?ua=1

⁵http://www.who.int/foodsafety/publications/foodborne_disease/outbreak_guidelines.pdf

⁶<http://www.fao.org/3/a-i5168e.pdf>

⁷<http://www.fao.org/docrep/013/i1686e/i1686e00.pdf>

⁸<http://www.fao.org/3/a-i5863e.pdf>

- i. The WHO "Outbreak Communication. Best Practices for Communicating with the Public during an Outbreak"⁹,
 - j. The FAO "Food Traceability Guidance"¹⁰,
 - k. 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 Illness¹¹,
 - l. INFOSAN Members Guide (This document is only available for the national INFOSAN contact point members but describes the communication through the INFOSAN network),
 - m. FAO/WHO Guide for Development and Improving National Food Recall Systems¹²,
 - n. The WHO guidance "Strengthening surveillance of and response to foodborne diseases"¹³.
 - o. WHO Landscape paper "Whole genome sequencing for foodborne disease surveillance"¹⁴
15. These documents are referred to in the most relevant section(s) of the current guideline, providing more detailed recommendations on specific aspects.

DEFINITIONS

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

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 analysis implicates the food as the source of the ~~illness~~ illness.]

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

[Food safety events] if necessary

[Food safety incident] if necessary

Surveillance is a systematic and ongoing collection of test results 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 detecting 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

[Outbreak assessment] if necessary

Commented [SM5]: The choice of definition depends on the availability of epidemiological capacity in member countries.

Commented [SM6]: The definition for emergencies in CAC/GL 19-1995 is quite broad. It makes sense to be consistent and drop reference to events and incidents.

⁹http://www.who.int/csr/resources/publications/WHO_CDS_2005_32web.pdf

¹⁰<http://www.fao.org/3/a-i7665e.pdf>

¹¹ Not published yet.

¹²<http://www.who.int/foodsafety/publications/recall/en/>

¹³http://www.who.int/foodsafety/publications/foodborne_disease/surveillancemanual/en/

¹⁴http://www.who.int/foodsafety/publications/foodborne_disease/wqs_landscape/en/

1 FOOD 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^e.n.
19. National systems and structures should be in place in order to ensure early detection and to effectively manage food 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. The network should take into account e.g. surveillance and monitoring programmes for humans and food, laboratory networks 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 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". 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 ~~it~~ ~~they~~ consists of personnel usually participating in the work at local level – e.g. local food control authority, clinical microbiological laboratory, districts surgeon, community council and food/veterinary laboratory. The network contact points should ensure the exchange of information and manage the [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 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:
 - coordination of efforts to resolve large, especially complicated or serious food safety [emergencies/incidents/events],
 - 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
 - communication with international networks
24. The 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 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 they are effective.
 - There is a system in place to ensure communication channels remain open (e.g. in the event of infrastructure ~~breakake~~ down, staff absence, etc.)

- There is a practice in place for the use of external groups of experts in validation of recommendations.

b. International alert networks for food safety [emergencies/incidents/events] and human illness issues and exchange of information with them

26. Food safety [emergencies/incidents/events] do 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 food 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 and human 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 safety [emergencies/incidents/events].
28. Information from global networks may be useful for the work of the national networks even if the incidences 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 food safety [emergencies/incidents/events]

29. Many biological food safety [emergencies/incidents/events] are initially identified through human illness surveillance data. However data from surveillance and monitoring of animals, feed, food and the environment, including equipment of food businesses may also indicate an enhanced risk and are of value/assistance to help identify the source of a food safety [emergency/incident/event]. These surveillance and monitoring systems are essential tools for detecting foodborne outbreaks and should be used in an integrated approach (chapter 3).

30. In order to identify a foodborne outbreak there is a need for 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' a~~ Access to information on ~~these cases need to be established~~ and an assessment on the "business as usual" level ~~should be made. This 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.
- ~~Quick-Timely~~ centralisation 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) a~~ Analyses ~~(e.g. weekly)~~ of the data in order to detect outbreaks in a timely manner.

31. In order to quickly detect food 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 sectors. Information exchange should be used both routinely and during food safety [emergencies/incidents/events] and 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 standardized laboratory methods to allow comparability and sharing of laboratory data between 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 epidemiological 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. The increasing availability of such tests, including whole genome sequencing, is 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 testing results from humans, animal, feed, food and establishment environmental sampling facilitates the detection and assessment of outbreaks and the search for the source of the contamination.

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 amount of meta- 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 cg MLST types.
- Considerations of legal requirements for sharing of data. If data are shared in public databases there may be a need for anonymising the samples thus only allowing few metadata to follow the sequences.

33. Whole genome sequencing methods (WGS) 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.

d. Risk assessment – structures for assessing risk

34. A risk assessment during a food 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.
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 b d (especially chapter 3).
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 includes the steps of a risk assessment but is based on the current data from the [emergency/incident/event] itself and if possible data from similar incidents b d. 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 structures in place to allow 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 what is expected for these risk assessors and subject matter experts, including the scope of any risk assessment, taking into account the short deadline 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).

e. Risk communication system/strategy

39. In the context of a biological food safety [emergency/incident/event], the term "risk communication" means the exchange of information on the biological risk among stakeholders (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 incident, and this should include exchange of information with all stakeholders.
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 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.

2 FOOD SAFETY [EMERGENCY/INCIDENT/EVENT] - MANAGEMENT

42. When a food 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 restraints. 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 food safety [emergency/incident/event] – human health side

43. Careful description and characterization of the food safety emergency/incident/event is an important first step in any epidemiological investigation. Descriptive epidemiology provides a picture of the [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 or,
 - the food control authorities when they are informed about illness 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 a case definition should be created. Cases that fall within the definition should be interviewed 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 (especially chapter 4.1 and 4.2).

46. Creation of standard questionnaires for this purpose may be performed electronically using one of the internet based free of charge software's. Data can then be analyzed electronically in a standard statistical software program.

b. Substantiate hypothesis and/or handling of a food safety [emergency/incident/event] – food safety side

47. Food safety [emergencies/incidents/events] where a food source or a location has been identified during the epidemiological investigations should be followed by a thorough on site investigation covering all aspects of the production, storage, transport, distribution and consumption to substantiate if it is possible that the food source or the location is 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 (specifically chapters 4.3 and 4.4).

48. Food safety incidents where the source of the outbreak is not yet known are challenging. If the epidemiological investigations do not reveal a source, the competent authority could use other information to inform their investigation of the cause of an outbreak. For example, historical outbreak data, information from the cases concerning food preferences, trade patterns, and knowledge of production, distribution, and consumer preferences may be helpful to narrow down the possible sources or locations causing the situation.
49. Tracing a food item both backwards and forwards in the food chain is an essential tool in the investigation. This does not initially include a recall of the food item from the consumers or a withdrawal from the market. The process should be used to enable the investigators to see the full distribution of the food item or products produced in a single production site. Although this approach can be resource consuming, it should be a key component in substantiating if the food item is the likely source of contamination and identifying the specific foods involved in the event when sufficient epidemiological and product data are available. The information gathered should be compared with the epidemiological information of the outbreak to see if cases are consistent with product distribution.
50. If the overall evidence is strong enough that the source of the incident has been identified, appropriate risk management actions should be put in place. When a recall is identified as the appropriate risk management action, the same procedures of tracing back and forward in the food chain should be used in recalling the food item/batches of the food item from consumers, thus removing the source of the incident.

c. Comparing epidemiological and laboratory data

51. Management of outbreaks benefits from the public health and the food and veterinary sectors being able to share and compare relevant laboratory surveillance and monitoring data in order to identify a match between a clinical isolate and a food source.
52. In case of a match in serotypes, supplementary analysis is necessary to determine the probability of relationship. Typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA) but in recent years, genetic based methods like Whole Genome Sequencing (WGS) have become widespread worldwide as microbial typing tools. These methods have several advantages over traditional typing methods: as WGS reveals the entire bacterial genome and provides very accurate information which makes it possible to determine when isolates are highly related and thereby enhances the possibility to identify the source of the outbreak.
53. The decision of the degree of correlation between strains should be decided upon as part of the case definition. The decided level may differ according to the typing method. For WGS no standard "cut-off" values in terms of degree of differences between strains (single nucleotide polymorphisms (SNP) is established. The differences acceptable counted in SNPs differ between agents and depends on the agent analyzed. Interpretation of results will require bioinformatics specialists. Public databases can be used for comparing typing results and give information of related findings.
54. Enough data to ensure traceability of the product sampled should be collected and this should at least include animal species, product type, batch identification and place of sampling.
55. Food safety [emergencies/incidents/events] involving illnesses cannot be solved solely based on laboratory data but must always be linked to epidemiological data for confirmation.
56. Descriptive epidemiological data such as structured information on food consumed, disease onset, symptoms, duration etc. should be collected as part of the foodborne outbreak investigation. If possible an analytical epidemiological study should be performed (e.g. a retrospective cohort or case-control study).
57. Other tools that can be used for hypothesis generation to determine the source of attribution in case of a food 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 Control.
58. Robust epidemiological evidence may be conclusive of the food safety incident even without positive laboratory results. Laboratory results can support the epidemiology but they will only be conclusive if the result is supported by at least some epidemiological information such as that obtained from the patients.

d. [Outbreak assessment / rapid risk assessment]

59. 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 food 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 characterisation linked to the outbreak
- If possible recommendations to the consumers and to competent authorities on how to mitigate 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 outbreak investigators (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. Food 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 food safety incident.

62. At the beginning of an incident, during the period when information is being gathered, there maybe 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 toh;

- 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.
- 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.
- If possible, assemble a group of experts to validate recommendations within their domain of expertise.
- 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 incidenta 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 safety [emergency/incident/event] is ongoing. When it is over, the record can be finalized to include conclusions and can serve as an [emergency/incident/event] report.

65. For the documentation to be of future use to the competent authorities and institutions involved in food 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 in targeting official control efforts f.g.n.
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.

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 centralisation 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;
- Possible seasonal effect

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 review should be documented and areas for improvement addressed to support capability and capacity of the system in place f.g.
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 food 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.
 - 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 safety [emergencies/incidents/events]. The evaluation should include both competent authorities and 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 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.

European Union

The EUMS very much appreciate the work done and consider that the drafts has an added value in guiding competent authorities in being prepared for and manage biological foodborne outbreaks. A number of comments, mainly for editorial/consistency/clarity purposes, are provided below and need to be considered to further improve the draft.

Recommendations of the eWG

The EUMS agree to continue this work. The EUMS in particular support the interdisciplinary approach and international cooperation in crisis preparedness that is given due prominence in the document.

As regards the scope and the terms used:

- a. and c.

The EUMS welcome a debate on the terminology "foodborne outbreak", "foodborne illness outbreak", "food safety emergency", "food safety event" and "food safety incident". The EUMS has no fixed position on this terminology and are willing to consider all options. However, the following remarks should be taken into account:

- Clear differentiation should be made between "outbreaks", which always include the detection of human cases, and broader wording (emergency, event, incident, crisis), which may include emergencies/events/incidents without detected human cases but where the detection of a serious biological hazard in food, already largely distributed to consumers may indicate a substantial risk to a large group of consumers.

- Since the wording/definition "foodborne outbreak" already includes the detection of human illness cases, the wording "foodborne illness outbreaks" does not seem relevant.

- In the EU experience, in the case of biological hazards, foodborne emergencies/events/incident are always accompanied by human cases, and therefore "foodborne outbreak" is considered as the most relevant term within the context of this guidance document.

- Additionally, the use of "emergency/event/incident" to cover also "linked cases" without detected human cases, might open the scope too widely, covering any case where a biological hazard is detected in food.

- b.

The EUMS believe that all biological hazards should be covered by the scope of this guidance; however specific emphasis should be given to microbiological hazards as microbiological hazards are most frequently the source of foodborne outbreaks.

- d.

The definition of "rapid risk assessment" in the WHO guidance "Strengthening surveillance of and response to foodborne diseases" should be used if considered appropriate within this draft (preferred option). If not

appropriate within this draft, the wording "rapid outbreak assessment" should be used and defined to differentiate from the WHO wording. Only one term should be used in any case.

Other general comments

References

The EUMS suggest consulting the Codex secretariat on the way references to existing Codex Alimentarius and FAO/WHO documents are made (references in superscript). Spelling out these documents in the relevant sections might be more appropriate.

Specific comments

- Paragraph 3: It might be considered to move this paragraph to the beginning and the following revision of the second sentence is proposed: "Foodborne ~~illness~~ outbreaks **contain several human cases of illness and** can have ..."

Rationale: See general comment + to make a better link to the first sentence.

- Paragraphs 7 and 8: Pending on the outcome of the discussion on the terminology (see first general comment) these paragraphs need to be redrafted. The EUMS support that these paragraphs should explain that only one term is used throughout the draft but different wordings might be used at the discretion of competent authorities depending on a number of factors such as the extent and severity of human cases, perception by consumers and trade implications.

Rationale: Editorial, for clarification and simplification.

- Paragraph 9: it is proposed to amend the first sentence as follows: "This document ~~collects~~ **provides** guidance ..."

Rationale: Editorial.

- Paragraph 12: it is proposed to amend the first sentence at the end: "Codex Alimentarius ~~guidelines~~ **Codes of Hygienic Practice**."

Rationale: Differentiation from guidelines referred to in second sentence. The EUMS consider that it is relevant to refer to these codes since they are the most relevant tools to prevent outbreaks.

- Paragraph 15: it is proposed to amend as follows: "of the current guidelines, ~~providing~~ **to provide** more detailed..."

Rationale: editorial (not clear if "providing" refers to "guideline" or "documents").

- Paragraph 17:

- see first general comment. The following definitions of a foodborne outbreak is proposed:

"A foodborne outbreak is

- **an incident of two or more human cases of the same disease and/or infection, or a situation in which the observed number of cases exceeds the expected number, and**
- **where the cases are linked or probably linked to the same food source."**

Rationale: the observation of an increase of human cases should be considered as an outbreak. In addition there must at least be a probable link with a food source to call the outbreak "foodborne".

- The definition of "monitoring" in CAC/GL 69-2008 could be considered instead of the proposed one.

Rationale: consistency of terminology with other guidelines.

- Paragraph 19: it is proposed to replace the last sentence as follows: "The network should ~~take into account e.g.~~ **build on existing networks for** surveillance and monitoring **foodborne biological hazards in** programmes for humans and food ~~and laboratory networks and conditions for food production and distribution.~~

Rationale: editorial; the last part is proposed for insertion in paragraph 21 (see below).

- Paragraph 21: it is proposed to add the following sentence after "daily routines": "**Participants should also have a good knowledge of the conditions for food production and distribution.**"

Rationale: moved from paragraph 19.

- Paragraph 22: it is proposed to replace "surgeon" by "local health authority"

Rationale: editorial.

- Paragraph 25 last bullet: it is proposed to amend as follows: "There is a ~~practice~~ **facility** in place..."

Rationale: It may not always be necessary to use an external group of experts.

- Paragraph 29: it is proposed to amend the second sentence as follows "However data from surveillance and monitoring of animals, feed, food and the environment, including equipment of food businesses ~~may also indicate an enhanced risk and are of value/assistance~~ **are essential** to help identify the source of a food safety [emergency/incident/event]".

Rationale: while to essential role of surveillance and monitoring of animals, feed, food and the environment is recognised, the detection of hazards in them without human cases should not be identified as a foodborne outbreak.

- Paragraph 31,
 - End of introductory part: It is proposed to replace "and may include" by "and it is recommended that they include where possible"
 - second bullet: it is proposed to amend as follows "The use of **preferably harmonised and** standardized laboratory methods to allow comparability..."

Rationale: Methods should not only be standardized but also harmonised to the extent possible.

- Paragraphs 32 and 33:
 - It is proposed to limit paragraph 32 to molecular testing in general (e.g. first paragraph only). Paragraph 33 should cover specifically WGS and could be:

"An increasing use of very specific whole genome sequencing as molecular typing is encouraged and expected to become more and more important in the next few years. The use of WGS for surveillance *(continue with the rest of the second paragraph of paragraph 32).*

- ~~Whole genome sequencing methods (WGS) methods~~ **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.**"

- A definition of "metadata" should be considered.

Rationale: Recommendations on the use of molecular methods in general should be included separately as not everybody may have access to WGS. Considering the increasing importance of WGS, but the difficulties some countries may have to use it, it should be treated separately and collaboration encouraged.

- A definition of "metadata" should be considered.
- It is proposed to replace (2x) "molecular testing" by "molecular typing".
- It is proposed to amend the end of the 4th bullet of paragraph 32 as follows: "... the samples thus only ~~allowing few metadata to follow the sequences~~ **providing a small amount of metadata with the published sequence.**"

- Headings below paragraph 42 and 46

It is proposed to replace "side" by "approach" or delete the word

Rationale: editorial

- Paragraph 47: the wording "food source or a location" is not clear. Does it refer to food sourced at a specific place?

Rationale: Clarification needed.

- Paragraph 49:
 - It might be useful to define or describe "tracing backwards" and "tracing forwards".

Rationale: Clarity of understanding

- The last sentence should be amended as follows: "The information gathered should be compared with the epidemiological information of the outbreak **on the human cases** to see if cases are consistent with product distribution.

Rationale: clarity.

○ It is proposed to add an additional sentence after "... and product data are available": "**For data to be useful, it should be gathered in a standard way using templates and business names and product descriptions curated to ensure that links are not lost due to abbreviation or spelling mistakes.**"

• Paragraph 53, second sentence: the EUMS propose the following amendment: "The ~~decided~~ **agreed** level may ..."

Rationale: editorial

• Paragraph 55: the EUMS propose to delete this paragraph

Rationale: Repetition (addressed in paragraph 58).

• Paragraph 58: It is proposed to redraft this paragraph as follows: "Robust epidemiological evidence may be conclusive of the food safety incident even without positive laboratory results. **Efforts by sampling and analysis should be made to allow** laboratory results ~~can~~ **to** support the ~~epidemiology~~ **epidemiological evidence**, but they will only be conclusive if the result is. Analytical evidence **should** be supported by ~~at least~~ some epidemiological information such as that obtained from the patients. **Since molecular testing and in particular WGS is becoming more and more specific, it might be very useful to search for isolates in food data bases 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.**"

Rationale: It is proposed to elaborate the guidance in this paragraph based on experiences gained.

• Paragraph 59:

○ The paragraph should be redrafted since there seems to be some contradiction between the first sentence (a risk assessment should be carried out) and the second sentence (a risk assessment or outbreak assessment can be helpful).

○ The Committee may consider the usefulness for a model/template of a rapid risk/outbreak assessment.

Rationale: Urgent action is needed. Therefore, a ready-to-use template may facilitate quick action by competent authorities.

• Paragraph 61: in section e. Risk communication, a reference to the Principles and guidelines for the exchange of information in food safety emergency situations (CXG 19-1995) should be included.

• Paragraph 62: The following redrafting is proposed: "At the beginning of an incident, during the period when information is being gathered ~~and the source is not known yet~~, there may be ~~be confusion~~ **uncertainty for the public and media interest may be difficult to handle. In such situations, it is extremely important to strictly follow the recommendations in this section on risk communication. Any premature announcement which might have to be recalled when not confirmed, may create a lot of confusion, fear and more uncertainty of consumers and trade partners.** ~~Ideally, risk communication will provide stakeholders outside the formalized network structure with the information they need to make informed decisions.~~

Rationale: It is proposed to expand this paragraph providing more guidance. A revision of the last sentence seems more appropriate in paragraph 63.

• Paragraph 63:

○ The nomination of an official communicator could be addressed in paragraph 41 on preparedness.

Rationale: can be considered as part of preparedness.

○ It is proposed to add the following bullet point: "**Inform before the communication all relevant partners in order to allow them to be prepared for such communication and to provide to the extent possible the same message. Relevant partners include affected food business operators, affected competent authorities within the country (regional-central level, other regions where the affected food was distributed), affected competent authorities in other countries.**"

Rationale: It is important to coordinate communication with all affected partners.

○ The need for one central website where people can find information about the outbreak should be included.

○ Fifth bullet: the following amendment is proposed: "... an explanation of the cause, **where known**, and what is being done ..."

Rationale: the cause may not be known (yet).

African Union

General Comment

The document is well structured, however, the sections should be numbered. African Union recognizes that there are other causes of foodborne outbreaks e.g. from chemical hazards (pesticides, mycotoxins) which would also require guidance on their management. Considering that the principles for foodborne disease outbreak management is generally applicable to all foodborne hazards, the Codex Alimentarius Commission should focus on developing a comprehensive guidance document that addresses all forms of foodborne disease outbreaks. In this regard, African Union recommends that the scope of the current document should be widened to cover other causes of foodborne disease outbreaks other than (micro)biological, consequently, the title will have to be modified to reflect other forms of hazards. CCFH50 should also give consideration to engaging other relevant Codex committees such as CCCF, CCPR, CCRVDF and CCFA in the development of a holistic document that addresses all food safety hazards that could be associated with foodborne disease outbreaks.

Issue

Title: Should the parenthesis in the title be deleted so the document only covers management of microbiological foodborne outbreaks?

Position

African Union does not support the removal of brackets but recommends that the title should read as follows ***Guidance for the Management of Foodborne Disease Crises/Outbreaks***

Rationale: Outbreaks/crisis would include all foodborne disease outbreaks not only (micro)biological.

Issue

Par. 5, Bullet 1: Is the structure of the document appropriate?

Position

Yes, it's appropriate. However, some modification will be helpful to improve the content of this paragraph.

Issue

Is the use of the term **“food safety emergencies”** for all type of outbreaks feasible regardless of their severity?

Position: No

Rationale

Foodborne disease may vary in their degree of severity.

Issue

Is the balance between text and references to underlying documents appropriate?

Position

No, there is no balance. African Union recommends that relevant applicable sections of referenced text should be incorporated in this document.

Rationale

The vital information that have been referenced in this document, have not been incorporated in this text. They have been referenced and need to be read before applying the guide.

Issue

Par. 5, Bullet 7: Should we introduce graphic explanations/diagrams in the guideline although this is not normal practice in Codex text e.g. description of the network structures and monitoring?

Position

Yes, there is need to introduce graphic explanations/diagrams in the guideline

Rationale

To enhance clarity of concepts and understanding of the guide.

Issue

Use of the term “foodborne illness” outbreaks

Position

African Union recommends to replace the term “**foodborne illness**” with “**foodborne disease**” throughout the document.

Rationale

To ensure consistency with the title.

Issue

Para.4 & 5: Use of the terms “[emergencies/incidents/events]”

Position

African Union recommends removal of the square bracket.

Rationale

Information on emergency, incidences or events need to be communicated.

Issue

Para. 6: The logical flow of the paragraph and repetition.

Position

African Union recommends the removal of square brackets and rephrasing of the second sentence in Par. 6 to read “The use of specific genomic methods (e.g. whole genome sequencing) can result in improved detection ~~and management of and improved~~ outbreak/incident/event ~~management~~ and enables better resolution of involved batches reducing the impact of actions taken.”

Rationale

To improve logical flow.

Issues

Para. 7: The use of terms “[**emergency/incident/event**]”

Position

AU recommends the removal of square brackets on “[**emergency/incident/event**]” throughout the document.

Rationale: The three terms can be used depending on the type of food safety situation.

Issue

Para. 16: Definition of biological hazard is repetitive and omits fungi as part of the biological hazards.

Position

AU recommends the definition of biological hazards to read as “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”.

Rationale: To avoid repetition and to include “fungi” in the definition for biological hazards which was missing.

Issue

Para. 17: Is it necessary to define the terms “**Food safety events**” and “**food safety incident**?”

Position

Yes, African Union recommends to define “**Food safety events:**” and “**food safety incident**”. This is necessary to ensure a common understanding of the terms.

Issue

Is it necessary to define the terms “**rapid risk assessment**” and “**outbreak assessment**”?

Position

African Union recommends that “rapid risk assessment” and “outbreak assessment” should be defined to ensure a common understanding of the terms.

Issue

Para. 23, bullet 5: Communication network to include “**regional networks**” and not just international network.

Position

AU recommends modification to the bullet to read “communication with regional and international networks”

Rationale

Due to the transboundary nature of foodborne disease outbreaks, communication with all networks at national, regional and international level is critical in the effective management of outbreaks.

Issue

Para. 29: Reference to food safety emergencies/incidents/events being cause only by biological hazards

Position

African Union recommends a modification to the sentence to read “many ~~biological~~ food safety [emergencies/incidents/events] are initially identified through human illness surveillance data and therefore removal of square brackets.

Rationale

Biological hazards do not cover all causative agents of foodborne diseases

Issue

Para. 32: Use of molecular analysis and genome sequencing.

Position

African Union recommends the redrafting of para.32 to take into account other available test methods.

Rationale

The current text is too prescriptive and biased towards the use of whole genome sequencing which is expensive and not available to many countries.

Issue

Para. 39: Reference to food safety emergencies/incidents/events being caused only by biological hazards.

Position

African Union recommends a modification to the sentence to read “In the context of a ~~biological~~ food safety [emergency/incident/event], the term “risk communication” means the exchange of information on the biological risk among stakeholders (government, academia, industry, public, mass media and international organizations) outside the formalized network structure, with the aim to inform and motivate to action.”

Rationale: Biological hazards do not cover all causative agents of foodborne diseases.

Issue

Para. 50: The issue of “**overall evidence being strong enough**”-in the paragraph

Position

African Union recommends to modify the 1st sentence of para.50 to read as follows “If ~~the overall evidence is strong enough that~~ the source of the incident has been identified, appropriate risk management actions should be put in place.”

Rationale

For clarity.

Issue

Para. 52 & 53: Recommendation of a particular method of analysis to be used.

Position

African Union recommends that para. 52 should be redrafted to remove any preference to any one particular method of analysis.

Rationale

Codex text should not show any indication of preference for one method over another especially in situations where different methods may achieve the same performance criteria outcomes.

Issue

Para. 58: Use of the term “**robust**”

Position

African Union recommends the deletion of the word ‘**robust**’ as its meaning is unclear. The sentence should read as follows: **Robust** “Epidemiological evidence may be conclusive of the food safety incident even without positive laboratory results.”

Issue

Para 58: Removal of square brackets from the term “[**Outbreak assessment / rapid risk assessment**]”

Position

AU recommends the terms should remain in square brackets

Rationale

A decision can only be made as to whether the two terms should be retained in the document or not only after the definitions of the two terms have been articulated.