



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

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## PROPOSED DRAFT GUIDANCE ON THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

Prepared by the Electronic Working Group chaired by Denmark and  
co-chaired by Chile and the European Union

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2019/71-FH available on the Codex webpage/Circular Letters 2019:

<http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/>.

## INTRODUCTION

1. At the 49<sup>th</sup> Session of the Codex Committee in Food Hygiene (November 2017)<sup>1</sup> (CCFH) the European Union presented a project document on initiating new work to develop a guidance for the Management of Biological Foodborne Outbreaks.
2. The new work was approved by CAC41 (July 2018)<sup>2</sup>.

## TERMS OF REFERENCE

3. At CCFH50<sup>3</sup> (Panama, November 12 – 16, 2018), it was agreed to return the draft Guidance for the Management of Biological Foodborne Outbreaks to Step 2 and to establish an EWG chaired by Denmark and co-chaired by Chile and the European Union working in English and Spanish. The EWG was tasked to:
  - review and revise the draft;
  - take discussions and agreements at CCFH50 into account, and;
  - take comments received in writing into account.
4. A revised version should be provided for consideration at CCFH51.

## PARTICIPATION AND METHODOLOGY

5. All Codex members and observers were invited to participate in the EWG by email. In total 31 member countries, 1 member organisation and 4 observer organisations signed up for the EWG. A draft of the guideline based on the comments and discussions at the CCFH50 was prepared by the chairs and uploaded on the Codex online forum together with three questions of relevance for the further work. Responses to the questions as well as comments to the draft guideline were received from 14 countries (Argentina, Australia, Brazil, Canada, Ecuador, Ireland, Japan, Mexico, Peru, Spain, Switzerland, Thailand, UK and USA). Twelve countries replied to the questions (Argentina, Australia, Brazil, Canada, Ecuador, Japan, Mexico, Spain, Switzerland, Thailand, UK and USA).

## SUMMARY OF DISCUSSION

6. The questions put forward to the working group were the following:

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<sup>1</sup> REP18/FH, para 54

<sup>2</sup> REP18/CAC Appendix VI

<sup>3</sup> REP19/FH, para. 68

(i) In paragraph 37 of the guidelines (see Appendix I), we mention and describe the use of templates and tools. Examples of such templates and tools can be found in the annexes to WHO "Foodborne Disease Outbreaks: Guidelines for investigation and Controls". Should we

- a. keep the text and refer to templates in the WHO document as examples, or
- b. elaborate templates to be included in the guideline?

Re (i): In general, there was support for keeping the text and referring to the WHO document as examples. One country preferred the elaboration of templates, one country did not find templates necessary, and one country suggested keeping the text without any reference to existing templates.

(ii) As rapid risk assessments may not be widely used, we would like to know if you support the inclusion of an example of a template for asking a rapid risk assessment as an annex to the guideline?

Re (ii): There was general support for inclusion of an example of a template for asking a rapid risk assessment as an annex to the guideline; however, three countries would like to see a template before deciding.

(iii) A graphical structure of the networks described in the text is attached to the guideline as agreed on CCFH50. We would like to ask you if the graphical structure adds value to the text and if so whether it should be elaborated and proposed for inclusion as an annex or presented in the text directly?

Re (iii): There was also support for the inclusion of the graphical structure of the network described in the text. One country however did not support the inclusion and another country questioned its usefulness. The majority of responses supported the graphic to be placed in an annex.

7. The draft guideline received many comments, and has been revised accordingly. Some comments showed very different views among countries, and these are mentioned below.

8. The paragraphs emphasizing the countries' competence to categorize an outbreak as an emergency or as a crisis and giving advice on relevant criteria for doing this received many comments. Two countries questioned the need for these paragraphs. Other countries commented the wording and suggested additions or changes to the criteria.

9. The intension of the paragraphs is to give flexibility to countries on the terminology they choose to use when they categorize a foodborne outbreak. The term "foodborne outbreak" can cover both emergencies and crises, and the document should include guidance on the relevant criteria to do the categorization, which was also the outcome of the EWG in 2018. Therefore, the paragraphs are kept and has been revised according to the comments.

10. The definitions also received many comments. In general, definitions in other Codex documents or in WHO documents should be used if available and if they suit the purpose of this guideline. Some definitions were agreed on at CCFH50 and the discussions on these should not be reopened. This is the case for "Biological hazard", "Foodborne outbreak" and "Rapid risk assessment".

11. Alternative wording is proposed for the purpose of this guideline, though some definitions were already defined in the glossary of the WHO "Foodborne disease outbreaks: Guidelines for investigation and controls", alternative wording is proposed that better suits the purpose of this document:

- For "case-control study" the WHO definition includes information on earlier exposure. This is not relevant for the purpose of this guideline and might be misleading. The chosen definition is wording from the text in the mentioned WHO guideline.
- The definitions of "case-definition" and "cohort study" also differ from the glossary of the WHO guideline and again wording from the relevant text has been used. A case-definition is based on more than clinical and laboratory data and in a cohort study, for the purpose of this guideline, subjects are usually not followed over time for the development of a disease outcome of interest.
- Surveillance is also defined in the WHO "Foodborne disease outbreaks: Guidelines for investigation and controls" in relation to surveillance of human health. For the purpose of this guideline surveillance

of both humans, animals, food, feed and environment is considered relevant, and the definition has been outlined accordingly.

## **CONCLUSIONS**

12. The EWG concluded that they would:

- refer to existing templates in WHO document as examples. This does not entail that countries must use the templates, but they can serve as inspiration and guidance if needed;
- elaborate an example of a template for asking a rapid risk assessment and include it as an annex to the guideline, and;
- include the graphical structure of the network described in the text and placing it in an annex. The graphic is revised according to comments.

13. The draft guideline has been revised according to the comments received.

## **RECOMMENDATIONS**

14. The EWG recommends CCFH51 to consider:

- the conclusions of the EWG, and
- the draft Guidance on the management of biological foodborne outbreaks in Appendix I.

**DRAFT GUIDANCE ON THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS****(Request for comments at Step 3 through CL 2019/71-FH)****INTRODUCTION**

1. Foodborne illnesses encompass a wide spectrum of illnesses and are a growing public health problem worldwide. They are the result of ingestion of foodstuffs contaminated with microorganisms (biological foodborne illness) or chemicals (chemical foodborne illness). The contamination of food may occur at any stage in the process from food production to consumption (“farm to fork”) and can result from environmental contamination, including pollution of water, soil or air.
2. Biological food-borne illness usually takes the form of gastrointestinal symptoms; however, such illnesses can also have neurological, gynecological, immunological and other symptoms, including multi organ failure. The symptoms can be mild with recovery in days or have severe consequences for the individuals due to long-term sequelae with serious health effects or even death.
3. Biological foodborne outbreaks e.g. when the illness affects more people due to a common source, can have significant socio-economic costs related to hospitalization and medical treatment, lost productivity and can affect tourism. 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.
4. Codex Alimentarius has issued several guidelines on hygienic practices for food businesses and competent authorities on how to ensure food safety. Those guidelines focus on, 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.
5. In order to handle biological foodborne outbreaks efficiently, local and national multiagency networks of preparedness should be in place. Such networks should use comparable methods and interpretations. Cooperation and transparent exchange of information through international networks is essential and should be a feature of any network.
6. The principles for risk analysis including risk assessment, risk management and risk communication, as described by Codex Alimentarius in *Working principles for risk analysis for food safety for application by governments* (CXG 62-2007) 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.
7. Within the available analytical methods, molecular methods 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 impact of actions taken and the exposure of the hazard to humans. In particular, the use of specific genomic methods (as Whole Genome Sequencing (WGS) and MLST) can result in improved detection of outbreaks with more associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of this methodology will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness.
8. The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities. There should be consistency at national level when an outbreak is declared an incident, emergency or crisis.
9. The following criteria can be used by the competent authorities to categorize biological foodborne outbreaks as an incident, emergency or crisis. An example can be found in Section 2 of the FAO/WHO framework for Developing National Food Safety Emergency Response Plans.
  - The number of cases and spread of the outbreak.
  - The disease severity and its consequences including the number of deaths and treatment options available.
  - The population affected e.g. more vulnerable groups.
  - The pathogenicity (virulence / infectivity) of the microorganism.
  - The distribution pattern, the volumes of the food and national and international trade implications.

- Consumer perception e.g. when referring to a “crisis” can affect the consumer confidence in a product or food category clearly not belonging to the consignment implicated.
- Whether or not the incident was due to fraud or the consequence of bioterrorism.
- The capacity of the country to quickly react and limit the extent of the outbreak.

## SCOPE

10. These guidelines provide guidance to competent authorities on the preparedness and management of foodborne outbreaks, including the communication with international networks, such as the International Food Safety Authorities Network (INFOSAN) when it is necessary. The guidance addresses preparedness, detection, response and recovery with the intent of limiting the extent of such outbreaks. They include recommendations on the appropriate use of new analytical technologies e.g. genetic typing methods in outbreak investigation. The scope is limited to biological hazards, as they are the predominant cause of foodborne outbreaks. However, certain recommendations might be relevant for the management of outbreaks caused by other hazards such as chemical contaminants.

11. These guidelines also describe the role of competent authorities at local, national and regional level and the collaboration between them in formalized network structures. Guidelines are included on collaboration and communication with food business operators and other stakeholders before and during foodborne outbreaks as well as recovery, post outbreak measures and “after action reviews” when an outbreak has been resolved. Maintenance of the structures and training methods to strengthen the response by the networks are also addressed.

## USE

12. The following Codex Alimentarius documents<sup>4</sup> are relevant for these guidelines:

- *Principles and Guidelines for an Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995).
- *Working principles for risk analysis for food safety for application for governments* (CXG 62-2007).
- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG-30-1999), as amended).
- *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CXG 63- 2007), as amended).

13. A number of FAO/WHO documents describe in more details some of the issues presented in this guideline. In Annex I a list of documents is given. These documents are examples of supplementary texts and may be considered for details on and clarification of specific aspects.

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

## DEFINITIONS

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

16. **Biological hazards:** Biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include e.g. bacteria, viruses and parasites.

17. **A case-control study:** An observational study in which the distribution of exposures among cases and a group of persons who do not have the illness (“controls”) are compared with each other. These studies can be valuable when no clear “cohort” of all exposed and non-exposed persons can be defined.

18. **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 includes 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).

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<sup>4</sup> <http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/>

19. 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 microbiological terms, isolates (e.g. bacteria or virus) having the same specific molecular profile or closely related profiles identified by laboratory analyses of specimens from cases.

20. A 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.

21. 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.

22. Foodborne outbreak: 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.

23. Metadata: Data that describe other data. In relation to analytical testing (e.g. molecular testing such as WGS) results metadata could be date of sample collection, identification of sample, sample size, product, sampling site etc.

24. Monitoring: The performance of routine analysis aimed at detecting microbiological contamination of e.g. food from which prevalence data may be ascertained.

25. 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 classical risk assessment.

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

27. Surveillance: A systematic and ongoing collection, analysis and interpretation of data from samples from humans, animals or food for early detection with the purpose of applying appropriate control measures to prevent foodborne illness.. One of the main objectives of surveillance is investigating unsatisfactory results, which may lead to possible enforcement action.

28. 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/point of consumption.

## **FOODBORNE OUTBREAKS – PREPAREDNESS SYSTEM**

29. 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 formalized networks at different organizational levels along with some of the routine issues and standard tools to include in the system.

### **A. CREATION OF FORMALIZED NETWORKS BETWEEN HUMAN HEALTH SECTOR AND FEED, FOOD AND VETERINARY SECTORS AT LOCAL AND NATIONAL LEVELS**

30. In the following paragraphs, the composition and tasks of the networks at any level of competent authorities within a country are described. These competent authorities, others than national/federal ones, are referred to as "local" which may contain sublevels that should all be involved.

31. At the local level defined networks between contact points from the different relevant authorities/agencies covering the same geographical area should be formed e.g. 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.

32. 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.

33. 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.

34. At the national level a defined network should be established with personnel with experience 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 communication and exchange of information. The participants in the national network should be personnel at central level from the same authorities/agencies that participate in the local networks. In addition, representatives from other relevant institutions, e.g. 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 network. The role of the network should include:

- Ensuring that communication channels between network participants at the local and national levels function effectively and efficiently;
- Ensuring that coordinating efforts to resolve , especially complicated or serious foodborne outbreaks are performed;
- Supporting the local networks where needed and maintain the communication channels;
- 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; and
- Ensuring that communication takes place with regional and international networks e.g. through the INFOSAN emergency contact points.

35. The networks and the structures should be based on existing structures in the participating authorities and agencies. They 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. It 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 II.

36. For the networks to be effective, it is essential that the participants know each other, 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-conferences regularly to exchange experiences and best practices, to evaluate the management of past outbreaks and to identify lessons learned.

37. 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 and examples can be found in Annex 3, 5 and 6 of the WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls".

- Template(s) for collecting and maintaining updated information describing the outbreak - descriptive epidemiology;
- standardized questionnaire(s) 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 analyzed electronically using a standard statistical software program;
- template(s) for reporting on the outbreak and the outcome of investigations; and
- template for the rapid risk assessment addressed in chapter e. and Annex III, which may also provide a summary template for information collected.

38. 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.

39. Communication both within a network and between networks is crucial. Communication structures and practices should be included specifically in the description of the system and procedures for the network, to ensure that:

- All available information is compiled to form as complete an overview of the situation as possible 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, etc.); and
- especially for the national network there is a mechanism in place for the potential use of external experts to reach consensus on and verify the soundness of recommendations given.

#### **B. INTERNATIONAL ALERT NETWORKS AND EXCHANGE OF INFORMATION WITH THEM**

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

41. The national level network should have a permanent connection with global networks e.g. the INFOSAN and with regional alert networks for e.g. foodborne outbreaks. These global and 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.

42. Information from global 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 should be shared.

#### **C. SURVEILLANCE AND MONITORING SYSTEMS (HUMAN, ANIMAL, FEED, FOOD, ESTABLISHMENT ENVIRONMENT) AND THEIR USE IN FOODBORNE OUTBREAK SITUATIONS**

43. Many biological foodborne outbreaks are initially identified through human illness surveillance data. In order to identify 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 for 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.
- Analysis (e.g. weekly) of the data in order to detect outbreaks in a timely manner.

44. Information from surveillance and monitoring of animals, feed, food and environment, including equipment of food businesses, may also indicate a potential risk and are essential to help identify the source of a foodborne outbreak as early as possible. These surveillance and monitoring systems are essential tools for detecting foodborne outbreaks and should preferably be used as an integrated element in the outbreak investigation.

45. Data from these systems may also be used to inform and if necessary prioritize an investigation e.g. 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).

46. 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, being a branching diagram or "tree" showing the evolutionary relationships of the physical or genetic characteristics of the laboratory data at hand.
- Epidemiological data to evaluate the relevance of the source and to conduct tracing back.

#### **D. ANALYTICAL METHODS**

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

48. Molecular 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 WGS have become widespread worldwide as biological typing tools. WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of the outbreak. 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 result require additional resources and capacity compared to other methods.

49. The use of WGS requires:

- Laboratory capacity, specific equipment (properly maintained and, where applicable, calibrated) and trained personnel.
- 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 control and veterinary authorities. Sharing of actual raw whole genome sequences and associated appropriate metadata is most useful to everyone for comparing between results obtained by various analytical methods, including both multilocus sequence typing (MLST)-based and (single-nucleotide polymorphism (SNP)-based approaches.
- Considerations of 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.
- Higher up-front costs (e.g. sequencing machine, reagents, dedicated laboratory space) than other typing methods which can be an obstacle for its implementation. Furthermore, the cost per analysis will be higher if the total number of tests is low.

50. There are various opportunities for collaboration between public health and food safety laboratories within a single country and across countries that could reduce costs, if the necessary equipment and/or experience is missing. Collaboration between countries to carry out WGS (e.g. developed countries carrying out WGS at the request of developing countries) is therefore strongly encouraged.

#### **E. RAPID RISK ASSESSMENT – STRUCTURES FOR ASSESSING RISK**

51. A risk assessment during a foodborne outbreak may be useful to provide a sound scientific basis for the actions to be taken. In a number of cases, a ready-to-use risk assessment (e.g. a risk assessment conducted for existing or similar pathogen - food combinations) will be available. Adaptations to the specific outbreak may be required (within a short timeframe) based on the information from investigations.

52. If a ready-to-use risk assessment is not available, there might not be sufficient time to ask for a full assessment of the risk at hand. A simplified version of a risk assessment - a rapid risk assessment - will be more practical.

53. The rapid risk assessment is based on the data 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. Depending on the emergency situation, several revisions of the rapid risk assessment may be needed.

54. 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. An example is provided in Annex III and in Annex I of the WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls".
- 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 information analysis tools e.g. to detect hot spots (geographical areas, food establishments, or events with more than usual occurrence within the outbreak).
- Availability of (regional/national/local) data on consumption and serving sizes that is as up to date as possible.
- Procedures for rapid contact to food business operators including maintaining information on contact information.

#### **F. RISK COMMUNICATION SYSTEM/STRATEGY**

55. 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.

56. 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.

57. In terms of risk communication, the preparedness should aim to;

- Establish a communication strategy among the network members, designate official spokespersons from the national network or the government to the public and decide on the means of communication (websites, social media etc.). Where it is possible, the jurisdiction of each of the competent authorities should be taken into account to set the roles of each one in the risk communication strategy.
- Consider a structure to allow for the communication to be handled locally, in case of small and local 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 at the moment the 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.
- Test established communication strategies on a regular basis to evaluate their efficiency.

## **FOODBORNE OUTBREAK – MANAGEMENT**

58. When a foodborne outbreak occur, the networks and structures established should be used to manage the situation in 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 carry out the tasks within their responsibilities according to the procedures decided upon in the networks. The following sections give information of the basic roles of the participants in the networks.

59. The investigation and control of biological foodborne outbreaks are multi-disciplinary tasks requiring skills in the areas of clinical medicine, epidemiology, laboratory medicine, food microbiology, food safety and food control, and risk communication and management. When establishing a hypothesis about the likely source of the outbreak, three lines of investigation are used; epidemiological investigation, traceability of implicated food items, and microbiological analysis. Evidence from all three lines is used to identify the likely source.

### **A. IDENTIFYING AND INVESTIGATING A FOODBORNE OUTBREAK – HUMAN HEALTH**

60. 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, 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 e.g. a restaurant that received complaints from guests.

61. 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.

62. 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 indicate a need to do so. Cases, which 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: the place (the commercial name of the establishment and the exact address) and date of purchase and consumption, brand name, lot/batch code if known.
- With regards to the affected person: information on travel, animal and environmental exposures, person-to-person contact, disease onset, symptoms, duration etc.

63. The information should be obtained in a structured way using a standardized questionnaire for hypothesis generation purposes when available. Data collected can be analyzed using a standard statistical software program.

64. Other tools that can be used for hypothesis generation to determine the source of attribution in case of a foodborne outbreak include review of surveillance data, or prior sample matches, source attribution studies, historical outbreak data and mathematical modelling.

65. 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 a direction to them.

### **B. SUBSTANTIATE HYPOTHESIS AND/OR HANDLING OF A FOODBORNE OUTBREAK – FOOD SAFETY (FROM FARM TO FORK)**

66. Initial epidemiological investigations (descriptive epidemiology and interviews with a few 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 farms) as the possible source of the outbreak should be followed by a thorough on site investigation. This onsite 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.

67. When taking a sample, information on the product should include at least product name, comprehensive product description (e.g. animal/fish species, kind of vegetable, fresh, processed, frozen, canned), lot identification, place and date of sampling, in order to allow further investigations including tracing.

68. If the epidemiological investigations do not identify a source, the competent authority could use other information to elaborate their investigation of the 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 e.g. to target investigations and not for communications on the outbreak source without additional evidence.

69. 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 e.g. going back from the lot that caused illness to the place/source of initial contamination and identify from that source on, the distribution of all products made with that lot. 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, registrations of process and product controls, identified shortcomings, samples analyzed and results etc.)
- List of suppliers of product or raw materials
- List of operators who received the affected lots of the food item.

70. 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.

71. 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. 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 to avoid greater impact on public health and the economy of food business operators. The competent authority should monitor the recall to ensure compliance.

72. Consideration should be given to the actions required by consumers in recalls and businesses in product withdrawals concerning the suspect lots. Consideration should also be given to provide advice to consumers and/or businesses about appropriate disposal of affected risky foods linked to the outbreak and subsequent potential environmental risks or public health risks as a result of recycling.

### **C. COMBINING EPIDEMIOLOGICAL AND LABORATORY DATA**

73. 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 order to identify a match between a clinical human isolate and a food source.

74. Even in case of a match in serotypes, supplementary analysis by molecular methods may be necessary to conclude on the probability of a relationship.

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

76. For WGS for example, no standard “cut-off” values in terms of degree of differences between strains (e.g. single nucleotide polymorphisms (SNP’s)) are established. In general, the fewer the number of SNP differences, the more likely the strains are originating from the same source (e.g., the same facility). The actual number of SNP 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.

77. The use of databases containing comparable molecular based testing results from humans, animals, feed, food and establishment environmental sampling, facilitates the detection and assessment of outbreaks and informs the search for the source of the contamination.

78. Robust epidemiological evidence can be conclusive of a foodborne outbreak even without positive laboratory results from sampling. Efforts by sampling and analysis should be made to allow laboratory results to support the epidemiological evidence. It is however important to note that sampling is not always needed to draw conclusions on the source of the outbreak. Laboratory confirmation can be difficult to achieve for several reasons e.g.

- contaminations in food are not likely to be evenly distributed,

- the contamination may be low level hence the chance for detection is limited,
- there may not be a standard method available for detecting the biological hazard in a specific food responsible for the outbreak, or
- the affected lot of food is consumed or removed at the end of its shelf life and therefore no longer available for testing, in particular when a hazard causes illness with a long incubation in humans.

79. Analytical evidence on the other hand should always be supported by some 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.

80. For molecular testing, and in particular WGS, it might be very useful to search for isolates in food databases with similar molecular profiles as in a cluster of human cases. If very similar profiles are found, targeted epidemiological investigations to identify the source should be carried out to confirm or exclude a possible link.

#### **D. RAPID RISK ASSESSMENT – DURING A FOODBORNE OUTBREAK**

81. 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. It provides a summary of the information collected during the investigations described in a) to c), thereby identifies gaps to be filled, and provides relevant background information and input for the risk communication in e). In particular, it includes (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 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 and food safety (including tracing back) investigations;
- risk identification and characterization linked to the outbreak;
- consumer behavior and adherence to intended use and preparation of foods, e.g. use of frozen ready-to-cook vegetables and/or fruit, as a ready-to-eat product, not observing the kill step intended by the manufacturer to achieve food safety; and
- where appropriate, recommendations to the consumers and to competent authorities on how to manage the risk.

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

- ensure that the most recent information is available to the risk assessors;
- formulate targeted questions; and
- allow the risk assessors to point investigators to gaps of information or hot spots (geographical areas or events with more than usual occurrence within the outbreak) detected, guiding further investigations.

#### **E. RISK COMMUNICATION**

83. Ideally, risk communication will provide stakeholders including consumers outside the formalized network structure 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 still unknown. Such early communication should include information on the ongoing investigations and advice on general food hygiene measures consumers could take (cook thoroughly, wash vegetables/fruit, follow product durability information, appropriate chilling in the home, good kitchen hygiene (clean/disinfect, avoid cross-contamination etc.)).

84. 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 were changed.
- Explain to whom the recommendation applies and to whom it does not apply and why.
- Do not withhold information just because it may be upsetting. If information is lacking or cannot be released, it is important to explain the cause (where known) and what is being done to address this 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.
- A facility to provide easy access for the public and other stakeholders to updated information e.g. a designated website with contact information. This includes easy access for authorities and food business operators in other countries if they may be affected.

85. 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.

#### **F. DOCUMENTATION OF THE OUTBREAK AND LESSONS LEARNED**

86. 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 using e.g. log books, both when it is ongoing and afterwards. During the investigation a record should be kept, which include relevant tracing information and descriptive epidemiology, hypotheses and status of the situation. 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 basis for a summary outbreak report.

87. 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.

88. 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.

89. Outbreaks of special interest should be considered for 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.

90. 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.

#### **G. POST OUTBREAK SURVEILLANCE**

91. 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, (or, for new biological hazards, until no further cases are observed). This allows to evaluate the effect of actions taken and to maintain/regain the confidence of consumers and trading partners. Possible delays in analyses and reporting and possible seasonal effects should be taken into account before declaring an outbreak over.

## **MAINTENANCE OF THE NETWORKS**

### **A. REVIEW OF EXISTING PREPAREDNESS**

92. Competent authorities at 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. An “after action 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.

93. Evaluation of the local and national network structures and associated procedures can be facilitated by joint training to focus on specific objectives, priorities, needs, gaps, opportunities and challenges.

### **B. IMPLEMENTATION OF LESSONS LEARNED**

94. The evaluation of preparedness systems can include “after action 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.

95. The review could also consider whether changes may be needed to the way a food is processed or whether regulatory oversight or other regulatory change is needed to prevent future outbreaks.

96. 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?
- 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?

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

### **C. JOINT TRAINING ON FOODBORNE OUTBREAK PREPAREDNESS AND MANAGEMENT**

98. 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.

99. 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 participants' 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 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.

100. 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 table top form.

101. 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.

**List of FAO/WHO documents and other relevant documents**

- a. *The FAO/WHO Guide for Application of Risk Analysis Principles and Procedures during Food Safety Emergencies*<sup>5</sup>.
- b. *The WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls"*<sup>6</sup>.
- c. *The FAO training Handbook on "Enhancing Early Warning Capacities and Capacities for Food Safety"*<sup>7</sup>.
- d. *The FAO/WHO framework for Developing National Food Safety Emergency Response Plans*<sup>8</sup>.
- e. *The FAO/WHO "Risk Communication Applied to Food Safety Handbook"*<sup>8</sup>.
- f. *The WHO "Outbreak Communication. Best Practices for Communicating with the Public during an Outbreak"*<sup>9</sup>.
- g. *The FAO "Food Traceability Guidance"*<sup>10</sup>.
- h. *The draft Template for INFOSAN/IHR communication: National Protocol for Information Sharing with National and International Partners during Food Safety Events and Outbreaks of Foodborne Illness*<sup>11</sup>.
- i. *FAO/WHO Guide for Development and Improving National Food Recall Systems*<sup>12</sup>.
- j. *The WHO guidance "Strengthening surveillance of and response to foodborne diseases"*<sup>13</sup>.
- k. *WHO Landscape paper "Whole genome sequencing for foodborne disease surveillance"*<sup>14</sup>.

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<sup>5</sup> [http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474_eng.pdf?ua=1)

<sup>6</sup> [http://www.who.int/foodsafety/publications/foodborne\\_disease/outbreak\\_guidelines.pdf](http://www.who.int/foodsafety/publications/foodborne_disease/outbreak_guidelines.pdf)

<sup>7</sup> <http://www.fao.org/3/a-i5168e.pdf>

<sup>8</sup> <http://www.fao.org/docrep/013/i1686e/i1686e00.pdf>

<sup>9</sup> <http://www.fao.org/3/a-i5863e.pdf>

<sup>10</sup> [http://www.who.int/csr/resources/publications/WHO\\_CDS\\_2005\\_32web.pdf](http://www.who.int/csr/resources/publications/WHO_CDS_2005_32web.pdf)

<sup>11</sup> <http://www.fao.org/3/a-i7665e.pdf>

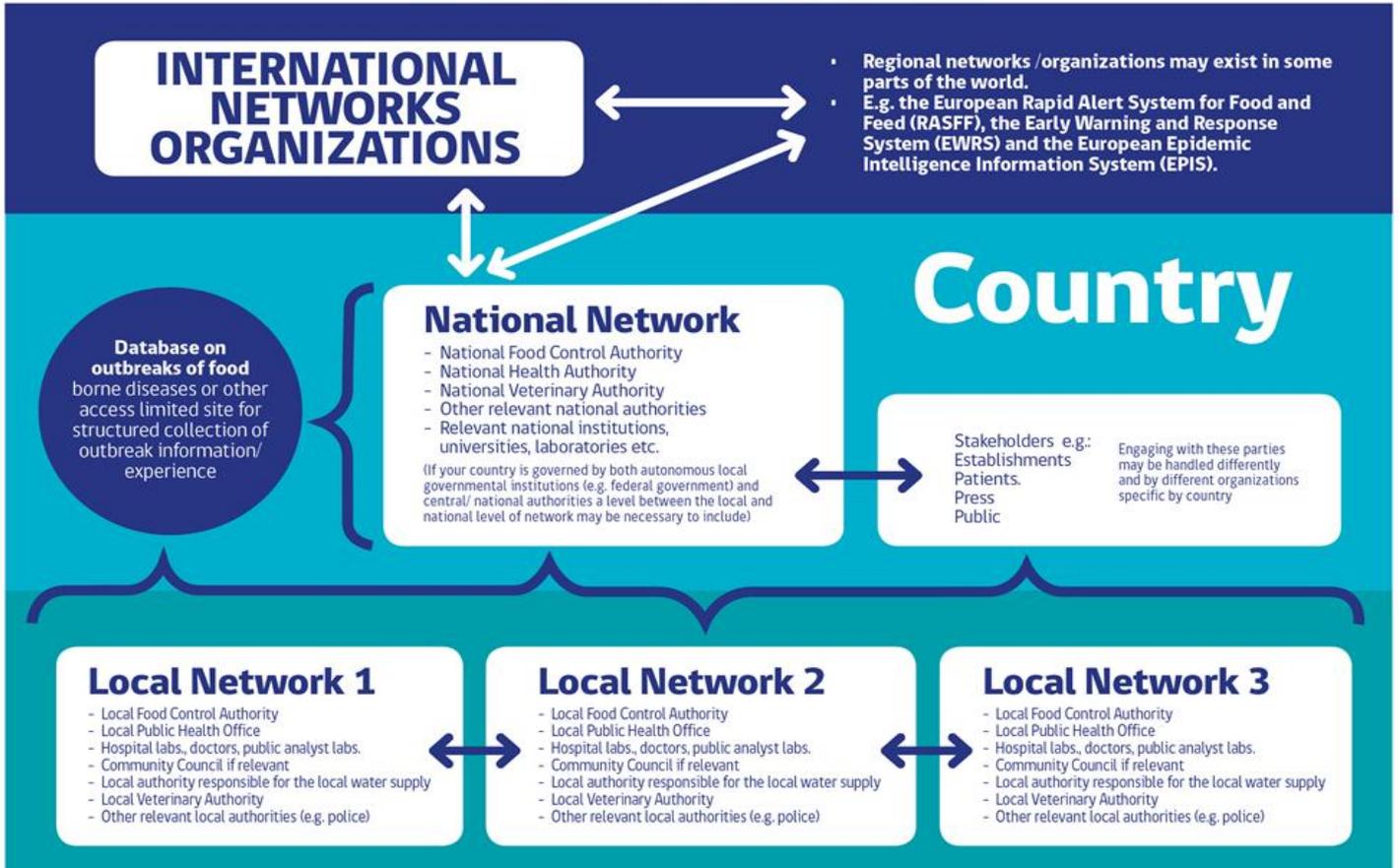
<sup>12</sup> <http://www.who.int/foodsafety/publications/recall/en/>

<sup>13</sup> [http://www.who.int/foodsafety/publications/foodborne\\_disease/surveillancemanual/en/](http://www.who.int/foodsafety/publications/foodborne_disease/surveillancemanual/en/)

<sup>14</sup> [http://www.who.int/foodsafety/publications/foodborne\\_disease/wgs\\_landscape/en/](http://www.who.int/foodsafety/publications/foodborne_disease/wgs_landscape/en/)

Structure of networks handling foodborne outbreaks

# Structure of networks handling foodborne outbreaks.



## Annex III

## Template for rapid risk assessments

Topic	Possible content
Summary	<p>Overview of involved countries at local, national or regional level. Overview of human cases reported including hospitalisations and deaths</p> <p>Summary of investigations on food source and actions taken (e.g. withdrawal) and planned.</p> <p>Short and clear communication message to consumers, affected operators and trade partners.</p>
Illness background information	<p>Historical data, not related to the ongoing outbreak, on the hazard e.g.;</p> <ul style="list-style-type: none"> <li>• occurrence in humans</li> <li>• outbreaks in the past at local, national or regional level.</li> <li>• occurrence in different type of food</li> </ul> <p>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 known yet.</p>
Outbreak background information	<p>Questions like; How was the outbreak initially detected? How has initial information on human cases and on affected food been distributed? How have the human cases initially been linked to a certain food source? should be answered in this part.</p>
Investigation of human cases	<p>This should include, but not be limited to:</p> <ul style="list-style-type: none"> <li>- Outbreak case definition</li> <li>- Number of human cases detected so far, fitting the case definition <ul style="list-style-type: none"> <li>o Per country/county</li> <li>o Per time/month of onset</li> <li>o Additional information (age groups, hospitalisations, mortality)</li> </ul> </li> <li>- Information from interviews of patients, case control or cohort studies.</li> </ul>
Investigations in food	<ul style="list-style-type: none"> <li>- Information on outcomes of laboratory analyses in food, animals, production environment, ... matching the outbreak strain: type of food, place of origin, identification of batches and operator (can be kept anonymously), time of production, time of sampling, shelf-life of batch, amounts of pathogens found in sample, ...</li> <li>- 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)</li> <li>- Information on tracing of the affected food/food ingredients, e.g. starting from the food/establishment initially linked to the human cases: <ul style="list-style-type: none"> <li>o Tracing back the food/ingredients;</li> <li>o Tracing forward the distribution;</li> <li>o To be repeated for each affected establishment along the chain</li> <li>o 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)</li> </ul> </li> <li>- Consumer behaviour and eating habits e.g. use of frozen ready-to-cook vegetables and/or fruit, as a ready-to-eat product, not observing the kill step intended by the manufacturer to achieve food safety.</li> </ul>
Linking epidemiological and laboratory data in humans and food	<p>An attempt should be made to graphically present and link the data from human cases, retailers, distributors, processors until suppliers of raw materials, indicating the link between them when existing and the results of laboratory testing if carried out and available.</p> <p>When available, results from 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.</p>

Conclusion	The conclusion should summarise and indicate the robustness (or uncertainty) of the information on the source. It could indicate if the outbreak is considered under control by the actions take or if more human cases should be expected. It should fairly indicate uncertainties and data gaps and make recommendations, in the first place to consumers, but also, if considered appropriate, to public health and food authorities, public health and food operators, and to trade partners.
Names of consulted experts	Experts that contributed to the rapid risk assessment and its affiliation should (or can) be listed in this part.

## Appendix II

## List of Participants

1	Australia	Food Standards Australia New Zealand (FSANZ)	Angela Davies	Angela.Davies@foodstandards.gov.au
2	Australia	Food Standards Australia New Zealand(FSANZ)	Lauren Kolstad	
3	Australia	Department of Agriculture and Water Resources, Codex Secretariat	Stacey McIntosh	
4	Argentina	Dto Vigilancia Alimentaria, Instituto Nacional de Alimentos	Erika J. Marco	emarco@anmat.gov.ar
5	Argentina	Servicio de Microbiología, Instituto Nacional de Alimentos Argentina	Josefina Cabrera	josefina@anmat.gov.ar
6	Argentina	Secretary of Argentina CCFH	Maria Esther Carullo	mcarullo@senasa.gov.ar
7	Armenia	Food Safety Inspection Body under the Government of the Republic of Armenia	Elvira Mirzoyan	e.mirzoyan@ssfs.am
8	Armenia	Food Safety Risk assessment and Analysis Scientific Center	Satenik Kharatyan	satenik.kharatyan@mail.ru
9	Armenia	Health Department, Ministry of Health of the Republic of Armenia	Kristina Gyurjyan	k_gyurjyan@moh.am
10	Armenia	National Center for Disease Control and Prevention" SNCO, Ministry of Health of the Republic of Armenia	Romella Abovyan	rabovyan75@gmail.com
11	Armenia	Scientific Centre of Drug and Medical Technology Expertise	Lilit Ghazaryan	lili@pharm.am
12	Brazil	Brazilian Health Regulatory Agency	Ligia Lindner Schreiner	Ligia.Schreiner@anvisa.gov.br
13	Brazil	Brazilian Health Regulatory Agency	Carolina Araújo Vieira	Carolina.Vieira@anvisa.gov.br
14	Canada	Health Canada	Cathy Breau	Cathy.breau@canada.ca
15	Canada	Canadian Research Institute for Food Safety	Jeffrey Farber	jfarber@uoguelph.ca
16	Chile	Ministry of Agriculture, Achipia	Constanza Vergara	Constanza.vergara@achipia.gob.cl
17	Colombia	Ministry of Health and Social Protection of Colombia.	Blanca Cristina Olarte Pinilla	bolarte@minsalud.gov.co
18	Costa Rica	Ministerio de Economía Industria y Comercio	Amanda Lasso Cruz	alasso@meic.go.cr
19	Cuba	Ministerio de Salud Pública (MINSAP)	Oswaldo Vladimir Puñales Sosa M. Sc	ovps@infomed.sld.cu
20	Denmark	Danish Veterinary and Food administration	Gudrun Sandø	gus@fvst.dk
21	Denmark	Danish Veterinary and Food administration	Tenna Jensen	teje@fvst.dk

22	Ecuador	Ministerio de Salud Pública	Mónica Quinatoa Osejos	monica.quinatoa@msp.gob.ec
23	European Union	European Commission	Kris De Smet	Kris.DE-SMET@ec.europa.eu
24	Germany	Federal Ministry of Food and Agriculture.	Udo Wiemer	udo.wiemer@bmel.bund.de
25	Germany	Federal Ministry of Food and Agriculture	Lüppo Ellerbroek	Lueppo.ellerbroek@bmel.bund.de
26	Germany	Federal Office of Consumer Protection and Food Safety	Petra Luber	petra.luber@bvl.bund.de
27	India	National Dairy Development Board, Anand	D.K. Sharma	dksharma@nddb.coop
28	India	Principal Scientist, ICAR-National Dairy Research Institute	Naresh Kumar	nrshgoyal@yahoo.com
29	Ireland	Food Safety Authority of Ireland.	Kilian Unger	kilian.unger@agriculture.gov.ie
30	Ireland	Food Safety Authority of Ireland	Wayne Anderson	wanderson@fsai.ie
31	Japan	Food Inspection and Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare	Tsuyoshi Arai	codexj@mhlw.go.jp
32	Japan	Food Safety Policy Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries	Tomotaro Yoshida	tomotaro_yoshida880@maff.go.jp
33	Japan	Joint Faculty of Veterinary Medicine Yamaguchi University	Hajime Toyofuku	toyofuku@yamaguchi-u.ac.jp
34	Republic of Korea	Ministry of Agriculture Food and Rural Affairs (MAFRA), Republic of Korea	Kim Nana	khn0166@korea.kr
35	Republic of Korea	Animal and Plant Quarantine Agency, Republic of Korea	Kichan Lee	noanoa33@korea.kr
36	Republic of Korea	Rural Development Administration(RDA), Republic of Korea	Eunjung Roh	rosalia51@korea.kr
37	Republic of Korea	Ministry of Food and Drug Safety(MFDS), Republic of Korea	Yongmu Kim	ymkim73@korea.kr
38	Republic of Korea	Ministry of Food and Drug Safety(MFDS), Republic of Korea	Jinhyok Son	sontoly33@korea.kr
39	Republic of Korea	Ministry of Food and Drug Safety(MFDS), Republic of Korea	Sujin Jo	codexkorea@korea.kr
40	Malaysia	Ministry of Health Malaysia Principal Assistant Director	Raizawanis Abdul Rahman	raizawanis@moh.gov.my

41	Malaysia	Ministry of Health Malaysia Assistant Director	Sakhiah Md Yusof	sakhiah@moh.gov.my
42	Mexico	Secretaría de Economía	Tania Daniela Fosado Soriano	codexmex@economia.gob.mx
43	Mexico	COFEPRIS	Mariana Jimenez Lucas	mjimenez@cofepris.gob.mx
44	Mexico	COFEPRIS	María Guadalupe Arizmendi Ramírez	mgarizmendi@cofepris.gob.mx
45	Morocco	Fishery Products Department at ONSSA.	EL HARIRI Oleya	oleyaflour@yahoo.fr.
46	Morocco	Division of Plant and Plant Control at ONSSA	ELHAJJAB Amina	amelhajjab@gmail.com.
47	Morocco	Supervision Service of the Establishments at ONSSA.	EL GHAZI Khadija	khadijaghazi1@gmail.com
48	Myanmar	Yangon Technological University	Swe Swe Win	ageipi08s7@gmail.com
49	New Zealand	Food Regulation Ministry for Primary Industries	Marion Castle	Marion.Casele@mpi.govt.nz
50	New Zealand	Food Compliance Liaison.Coordination Ministry for Primary Industries	Jenny Bishop	Jenny.Bishop@mpi.govt.nz
51	Norway	Norwegian Food Safety Authority	Randi Edvardsen	randi.edvardsen@mattilsynet.no
52	Peru	DIGESA ( Dirección General de Salud Ambiental)/Minsa	Maria Eugenia Nieva Muzurrieta	mnieva@minsa.gob.pe
53	Peru	DIGESA ( Dirección General de Salud Ambiental)/Minsa	Sonia Susana Cordova Jara	scordova@minsa.gob.pe
54	Peru	DIGESA ( Dirección General de Salud Ambiental)/Minsa	Juan Carlos Huiza Trujillo	codex@minsa.gob.pe
55	Poland	Codex Contact Point, Poland	Magdalena Kowalska	
56	Singapore	Agri-Food and Veterinary Authority, Singapore	Tay Geng Yu	tay_geng_yu@ava.gov.sg
57	Singapore	Agri-Food and Veterinary Authority, Singapore	Sylvester Lee	sylvester_lee@ava.gov.sg
58	Singapore	Observer Organization Food Industry Asia	Jianf YiFan	codex@foodindustry.asia
59	Spain	Centro Nacional de Epidemiología- Instituto de Salud Carlos III - España.	Carmen Varela Martínez	mvarelam@isciii.es
60	Sweden	National Food Agency Sweden	Viveka Larsson	viveka.larsson@slv.se
61	Switzerland	Federal Food Safety and Veterinary Office FSVO	Karin Hulliger	Karin.Hulliger@blv.admin.ch
62	Switzerland	Federal Food Safety and Veterinary Office FSVO	Thomas Lüthi	Thomas.Luethi@blv.admin.ch
63	Switzerland	Federal Food Safety and Veterinary Office FSVO	Françoise Fridez	francoise.fridez@blv.admin.ch

64	Thailand	National Bureau of Agricultural Commodity and Food Standards (ACFS)	Virachnee Lohachoompol	virachnee@acfs.go.th
65	United Kingdom	Policy Incidents Handling and Engagement Food Standards Agency	Liz Stretton	Liz.Stretton@food.gov.uk
66	United States of America	Center for Food Safety & Applied Nutrition U.S. Food and Drug Administration	Jenny Scott	Jenny.Scott@fda.hhs.gov
67	United States of America	U.S. Food and Drug Administration	Andrew Yeung	Andrew.Yeung@fda.hhs.gov
68	United States of America	U.S. Food and Drug Administration	Caroline Smith Dewaal	
69	United States of America	U.S. Department of Agriculture	William Shaw	William.Shaw@fsis.usda.gov
70	United States of America	U.S. Department of Agriculture	Bonnie Kissler	Bonnie.Kissler@fsis.usda.gov
71	United States of America	U.S. Department of Agriculture	Marie Maratos	Marie.Maratos@osec.usda.gov

#### OBSERVER ORGANISATIONS

International Council of Grocery Manufacturers (ICGMA)	Ai Kataoka	akataoka@gmaonline.org
Institute of Food Technologists	Rosetta Newsome	<a href="mailto:rnewsome@ift.org">rnewsome@ift.org</a>
African Union, Interafrican Bureau for Animal Resources	Oppong-Otoo	<a href="mailto:john.oppong-otoo@au-ibar.org">john.oppong-otoo@au-ibar.org</a>

WHO Department of Food Safety and Zoonoses	Satoko Murakami	<a href="mailto:murakamis@who.int">murakamis@who.int</a>
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