CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CRD2**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

VIRTUAL

28 February - 4 March and 9 March 2022

PROPOSED DRAFT GUIDANCE ON THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS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 EU)

INTRODUCTION

At the 49th Session of the Codex Committee in Food Hygiene (November 2017) the Committee agreed to start new work on a guideline for the Management of biological Foodborne Outbreaks chaired by Denmark and co-chaired by Chile and the EU. A draft was presented and discussed at the 50th Session of the Codex Committee on Food Hygiene and was further developed and revised by an electronic working group (eWG) during 2019. Based on the work of the eWG a revised draft was presented and discussed at the 51th Session of the Codex Committee on Food Hygiene. CAC43 adopted the draft guidance at Step 5.

After CAC43 the draft guidance was circulated for commenting to the members. In view of the postponement of CCFH52 due to the CODVID-19 pandemic, and to benefit from the additional time to continue to progress the work, Denmark, Chile and the EU, the Chair and Co-chairs, analysed and attempted to address the comments received. A revised draft guidance (CX/FH 22/52/5 Add.1) was circulated to the members in September 2021, with a deadline for commenting on 8 January 2022 through Circular Letter (CL 2021/72/OCCS/FH).

Comments were received from 20 member countries, 1 member organization and 1 observer. They have been compiled in CX/FH CX/FH 22/52/5 Add.2.

ANALYSIS AND CONSIDERATION OF COMMENTS

The majority of the comments received were editorial or comments proposing clarifying wording or elaborating the text. Those comments have largely been accepted or merged with other comments.

The definitions have been discussed in detail during the eWG and at the CCFH51 and were agreed upon at the CCFH51. The chairs have considered comments on the definitions and those that are editorial or enhance readability have been accepted. The inclusion of new definitions has not been considered appropriate at this stage.

Some comments were purely translation issues.

Substantial comments at this step were considered but in general not accepted.

1. Amendments based on the comments

Throughout the document, editorial changes as well as suggestions enhancing readability and clarity of the text have been inserted. All changes have been tracked in the revised document presented in Appendix1.

a) **Introduction:**

- In paragraph 1 the occurrence of cross-contamination events and human to human spread is addressed, and “zoonotic” was replaced by “biological hazards” because foodborne illness can be caused by agents such as norovirus.
- The text in paragraph 2 was revised to include the possibility that serious illness that occurs both immediately such as where cases can develop HUS in the acute phase of STEC infections and in the long term with chronic sequelae/conditions.
- Paragraph 3 was revised to correct the implication that vulnerable groups is related to socio-economic costs. Furthermore, the effect of foodborne illness is not just affecting tourism.

- In paragraph 5 text was added on the need for common vocabulary/definitions to ensure against misunderstandings that could jeopardise the assessment/ analysis.
- Difficulties in communication and transportation in rural areas as a complicating factor should be considered when categorising an outbreak. Text was added to address this in paragraph 9.

b) Use

- A references to the Principles and Guidelines for National Food Control Systems (CXG 82-2013) was included as it was considered to provide helpful information.

c) Foodborne outbreaks – preparedness system:

- In paragraphs 41, 42, and 43 “regional or global” was replaced by “international” for consistency.
- In paragraph 49 it was specified that WGS results can be used to identify the source of an outbreak when used in conjunction with epidemiological data (as also mentioned in paragraph 81).
- In paragraph 50, a new bullet point was added on the possibility to use existing genomic sequence data hubs.

d) Foodborne outbreaks – management

- Several additions on the information on consumed food items that should be collected from cases in an outbreak e.g. the food source (i.e. from an animal for human consumption or not), detailed food history including the nature of food (whether it is cooked, raw or minimally processed) were included in paragraph 64. In addition, a notion on food borne illnesses such as listeriosis where information on food items recently consumed may not apply has been added.
- In paragraph 73, the need for tracing back was addressed.
- In paragraph 82, a sentence was added on establishing criteria to determine sequence homology, illness attribution or environmental link, and how metadata associated with the sequence information is identified, maintained and used, where possible.
- In paragraph 87, a bullet point on procedures to identify when rumours or false information are being circulated in order to react early, was added.
- Protection of personal information was addressed in both paragraph 89 and paragraph 90. Paragraph 90 was revised accordingly.

e) Maintenance of networks

- Paragraph 96 was deleted because evaluation and joint training of local and national networks is also addressed in 100-103 (former 101-104).

e) Annex I

- Case instead of patient in the “Country” box that lists examples of stakeholders:

f) Annex II

- A sentence on the appropriateness for evaluating the need for a rapid risk assessment in each case was added in the chapeau of the table.

g) Annex III

- Comments and suggestions for additional or revised text has been included.

2. Comments that were considered, but did not result in amendments

All other comments were considered but did not result in amendments as they had been previously discussed in detail; did not appear to result in significant improvement; were different from the approach generally agreed to so far; or changed the scope or the meaning of the paragraphs. Other comments reflected issues that were covered elsewhere in the draft guidance.

Justifications for comments that were not included are listed in Appendix II.

RECOMMENDATION

It is recommended that CCFH52 consider the draft Guidelines in Appendix I as amended.

APPENDIX I - PROPOSED DRAFT GUIDELINES ON THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

INTRODUCTION

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

~~1.~~2. Biological foodborne illness usually takes the form of gastrointestinal symptoms; however, such illnesses can also have neurological, gynecological, immunological and other symptoms. The symptoms can range ~~be~~ from mild to severe in the acute phase with recovery within days or weeks but also can have severe chronic consequences for the individuals due to long-term sequelae with serious health effects or even death.

~~2.~~3. Biological foodborne outbreaks can have significant socio-economic costs~~, which may be exacerbated in populations comprised of vulnerable groups,~~ related to hospitalization and medical treatment, lost productivity and effects lost productivity and income~~on tourism.~~ In particularly, they are important for vulnerable sub-populations that have a higher risk of illness. For food businesses, the consequences can be lost markets, loss of consumer confidence, litigation and company closures. Such foodborne outbreaks can cause impediments to domestic production and international trade. Globalization of the food supply has led to the rapid and widespread international distribution of foods, further increasing opportunities for pathogens being inadvertently introduced into many geographical areas.

~~3.~~4. Codex Alimentarius has issued several guidelines for food businesses and competent authorities on hygienic practices to ensure food safety. Those guidelines focus on prevention, monitoring and corrective actions in case of deviations along the production processes. Despite efforts to ensure a high level of hygiene, foodborne outbreaks still occur.

~~4.~~5. In order to handle biological foodborne outbreaks efficiently, local and national multiagency networks of preparedness should be in place. To facilitate a common understanding and a consistent approach to these situations such networks should use comparable methods, common definitions and interpretations to the extent possible, as well as transparent exchange of information. Cooperation through international networks is essential and should be a feature of any national network.

~~5.~~6. Communication and data sharing between and among networks, food bus~~si~~ness operators nationally and internationally is fundamental for the management of foodborne outbreaks. Existing procedures on confidentiality should be used or, if not present, procedures should be developed.

~~6.~~7. The principles for risk analysis including risk assessment, risk management and risk communication, as described in the Codex *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.~~8. Within the available analytical methods, molecular methods often best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genetic methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS), Multiple-locus variable number of tandem repeat analysis (MLVA) and Multilocus Sequence Typing (MLST)) can result in improved detection of outbreaks, including detection of associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of these methods will likely lead to the detection of more ~~outbreaks~~ clusters and the need for enhanced preparedness.

~~8.~~9. The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities and~~which~~ should be consistent at both~~the~~ local and national levels. The following ~~factors~~ criteria may be used by the competent authorities to categorize the outbreak and to develop and adapt response plans.

- The number of cases, the geographic spread of the outbreak, and whether the outbreak is ongoing,.
- The disease severity and its consequences, including the number of deaths and treatment options available.
- The population affected, e.g. more vulnerable groups.

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

SCOPE

~~9.~~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) and notification to the World Health Authority (WHO) under the International Health Regulations (IHR) when it is necessary. The guidance addresses preparedness, detection and response with the intent of limiting the extent of such outbreaks. They include recommendations on the appropriate use of new analytical technologies, e.g. genetic typing methods in outbreak investigation. The scope is limited to biological hazards, as they are the predominant cause of foodborne outbreaks.

~~10.~~11. These guidelines also describe the role of competent authorities at the local, national and, where applicable, the international~~regional~~ level (e.g., groups of countries) and the collaboration among them in official network structures. Guidelines are included on collaboration and communication with food business operators and other stakeholders before and during foodborne outbreaks, as well as on post-outbreak measures and outbreak management review when an outbreak has been declared over. Maintenance of the structures and training methods to strengthen the response by the networks are also addressed.

USE

~~11.~~12. The following Codex Alimentarius documents[1] are relevant for these guidelines:

- *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995).
- *Working P~~p~~rinciples for Risk Analysis for Food Safety for Application by 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~~).
- *Principles and Guidelines for National Food Control Systems* (CXG 82-2013).

~~12.~~13. A number of FAO/WHO documents describe in more detail some of the issues presented in this guideline.

~~13.~~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

For the purpose of this document the following definitions apply:

~~14.~~15. Biological hazards: Biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include e.g. bacteria and their toxins, viruses and parasites.

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

~~15.~~16. Case-control study: An observational study in which subjects are included~~enrolled~~ on the basis of presence (cases) or absence (controls) of the foodborne illness of interest. Information is compared between cases and controls.

~~16.~~17. Case-definition: A set of criteria for determining whether a person affected by the illness under investigation should be classified as belonging to the outbreak. As such, it is an epidemiological tool for counting cases. It may include clinical and laboratory criteria, a defined period of time, and, as appropriate, limitation/restriction to a place (for example a particular event or restaurant). In some cases criteria could include a limitation based on personal characteristics (for example age).

~~17.~~18. Cluster: In epidemiological terms, it describes a group of cases linked by time or place, but with no identified common food or other source. In terms of biological hazards, isolates having the same specific molecular profile or closely related profiles identified by laboratory analyses of specimens from cases.

~~18.~~19. 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.

~~19.~~20. 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.

~~20.~~21. Foodborne outbreak: The occurrence where the observed number of cases of a particular illness that may be foodborne exceeds the expected number, OR the occurrence of two or more cases of a similar foodborne illness resulting from the ingestion of a common food and epidemiologic analysis implicates the food as the source of the illness.

~~21.~~22. Lot: A definite quantity of ingredients or of a food that is intended to have uniform character and quality, within specified limits, is produced, packaged and labelled under the same conditions, and is assigned a unique reference identification by the food business operator. It may also be referred to as a “batch”. In an outbreak situation a lot has to be separated by procedures avoiding risk of cross-contamination.

~~22.~~23. Metadata: Data that describe other data. In relation to analytical testing results metadata could be date of sample collection, identification of sample, sample size, product name, sampling site etc.

~~23.~~24. Monitoring: The performance of routine analysis aimed at detecting ~~micro~~biological contamination of e.g. food from which prevalence data may be ascertained.

~~24.~~25. Outbreak analysis: An analysis based on the information available on the foodborne outbreak as well as relevant historical data. It is used to forecast if more cases should be expected under the given circumstances and to finalize tracing information pointing to a source and comparing it with epidemiological outbreak information.

~~25.~~26. Rapid risk assessment: A risk assessment, based on the information available on the foodborne outbreak, which needs to be carried out urgently to quickly support (provisional) risk management measures and therefore may not always contain the full development of the four steps of a risk assessment described in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999).

~~26.~~27. Risk communication: The exchange of information on the biological risk among stakeholders (e.g. government, academia, industry, public, mass media and international organizations).

~~27.~~28. Surveillance: A systematic and ongoing set of observation or measurement activities, collection, analysis and interpretation of data from samples from e.g. humans, animals, feed, food or environment for early detection with the purpose of applying appropriate control measures to prevent foodborne illness.

~~28.~~29. Traceability/Product Tracing: The ability to follow the movement of a food through specified stage(s) of production, processing and distribution, where “Tracing back” refers to following the path towards its origin/source and “Tracing forward” refers to following the path towards its final distribution/to the consumer~~point of consumption~~.

FOODBORNE OUTBREAKS – PREPAREDNESS SYSTEM

~~29.~~30. To handle foodborne outbreaks in an effective way it is advisable to have and maintain preparedness structures enabling cooperation between competent authorities. In this section, such structures are described in the form of official networks at different organizational levels, along with some of the good practices and standard tools to include in the system.

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

~~30.~~31. In the following paragraphs, the composition and tasks of the networks of competent authorities within a country are described. Competent authorities, other than those at the national/federal level, are referred to as “local” and these may contain sublevels that should also be involved.

~~31.~~32. 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.~~33. 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.~~34. 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.~~35. At the national level a defined network should be established with personnel experienced in the management of foodborne outbreaks within the competence of their respective authorities/agencies. This national network should be recognized by each of the competent authorities involved, to ensure effective communication and exchange of information. The participants in the national network should be personnel from the ~~equivalent~~ authorities at the national level, equivalent to 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 national network. The role of the national network should include:

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

~~35.~~36. The networks should be based on existing structures in the participating authorities and agencies. The network should have an appropriate structure with sufficient capacity and capability. The networks and structures should be described in detail and agreed upon by the participants to ensure cooperation with respect to competences and responsibilities of each participating authority and official agency. They should allow an outbreak to be managed as soon as possible at the lowest possible administrative level, i.e. the local network should coordinate the efforts when handling local outbreaks within their area. However, local networks should ask for the support of experts from other local networks or the national network if additional competences are needed to handle a specific outbreak. When several local networks or areas are involved in an outbreak, coordination at a higher level, covering all affected areas, should be considered. This could be a task for the national level of the network. A presentation of the structure of the network is provided in Annex I.

~~36.~~37. For the networks to be effective, it is essential that the participants know whom to contact, such as the contact details for the competent authorities, have familiarity with the system and structures and use them regularly, even in the absence of a foodborne outbreak. It is recommended that participants meet or hold audio/video conferences regularly to exchange experiences and best practices, to evaluate the management of past outbreaks and to identify lessons learned.

~~37.~~38. Templates and standard tools should be developed in advance and included in the standard procedures for the network participants to use. Some of them are listed below.

- Template(s) for collecting, maintaining and reporting updated information describing the outbreak - descriptive epidemiology;

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

~~38.~~39. 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.~~40. Communication both within a network and between networks is crucial. Since network participants may have limitations on what information they may share with others in the network, these limitations should be identified and addressed in advance. Communication structures and practices should be included specifically in the documented description of the system and procedures for the network, to ensure that:

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

B. INTERNATIONAL ALERT NETWORKS AND EXCHANGE OF INFORMATION WITH THEM

~~40.~~41. Foodborne outbreaks do not respect borders. What seems to be a national outbreak at the outset may in fact be or turn into an international ~~regional or global~~ foodborne outbreak.

~~41.~~42. The national level network should have a permanent connection with ~~global~~ international networks, e.g. the INFOSAN, and, where applicable, with regional alert networks. These ~~global~~ international and/or regional networks have national emergency contact points in most countries. If there is a national contact point (person or institution), it should be actively included in foodborne outbreak investigations at the national level. The contact point at these alert networks may assist in gathering and compiling information and submitting coordinated information concerning ongoing foodborne outbreaks.

~~42.~~43. Information from ~~global~~ international networks may be useful for the work of a national network, even if the outbreak described does not concern that country, hence it should always be considered if information concerning an outbreak could be useful for other countries and therefore shared.

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

~~43.~~44. Many biological foodborne outbreaks are initially identified through human illness surveillance data. In order to identify the source of a foodborne outbreak there is a need for:

- Surveillance and monitoring of the usual situation of human illnesses from biological foodborne hazards.
- Access to relevant information on cases of illnesses that do not require notification to human health authorities and an assessment of the usual level of illness. This will enable the competent authorities to define when a number of cases exceeds the expected number and may result in the identification of an outbreak.
- Timely centralization and distribution of information through early warning systems; disease notification by medical practitioners to competent authorities should be made mandatory to the extent possible.
- Analysis (e.g. weekly) of the data in order to detect outbreaks in a timely manner.

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

45.46. Data from these systems may also be used in conjunction with epidemiological data 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).

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

- New signals (increasing trends or sudden elevated numbers of analytical findings/disease reports) from these sectors and follow-up on ongoing outbreaks.
- The use of preferably harmonized and standardized laboratory methods to allow comparability and sharing of laboratory data among human health, food control and veterinary sectors.
- Tools for sharing surveillance data and epidemiological information such as databases or data sharing sites.
- Tools for comparing and presenting data, such as a phylogenetic tree, (a branching diagram or "tree" showing the evolutionary relationships of the physical or genetic characteristics of the foodborne pathogen isolateslaboratory data at hand).
- Epidemiological data to evaluate the relevance of the source and to conduct tracing back.

D. ANALYTICAL METHODS

47.48. Validated analytical methods should be used to isolate and identify causative agents. Traditional analytical methods (such as pathogen isolation) or Polymerase Chain Reaction (PCR)-based methods used for surveillance and monitoring are essential as the basis for detecting and investigating any outbreak., but often they do not allow a conclusion 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 a conclusion on a link between different human cases and between the human case and the suspected food source, but often it does not allow such a conclusionsuch linkage. When further characterization is needed for outbreak investigation purposes, molecular or genetic typing methods can be and are increasingly being used.

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

49.50. When WGS is used, consideration should be given to:

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

- Use of existing genomic sequence data hubs containing foodborne pathogens and associated tools for analysis.

~~50.~~51. There are various opportunities for collaboration between public health and food safety laboratories within a single country and across countries that could reduce WGS costs, if the necessary equipment and/or experience is missing. Collaboration between countries to carry out WGS is therefore strongly encouraged. Creation of regional hubs may be a way to optimise resources.

E. RAPID RISK ASSESSMENT – STRUCTURES FOR ASSESSING RISK

~~51.~~52. A risk assessment during a foodborne outbreak may be useful to provide a sound scientific basis to determine the appropriate risk mitigation actions. In a number of cases, a risk assessment conducted for same or similar pathogen-food combinations will be available. Adaptations to the specific outbreak circumstances may be required (within a short timeframe) based on the information from investigations and regional/local contexts (climate, consumption patterns, serving size).

~~52.~~53. If a risk assessment conducted for the same or similar pathogen-food combinations is not available, there might not be sufficient time to undertake a full assessment of the risk at hand. A ~~-~~rapid risk assessment will be more practical. It has to be taken into account that a rapid risk assessment may have a higher uncertainty and lower accuracy compared to a full risk assessment.

~~53.~~54. The rapid risk assessment is based on the data readily available at that time from the foodborne outbreak itself and, if possible, data from similar outbreaks. There might be no time for collecting additional evidence/data to fill in data gaps or to conduct larger literature studies. These types of assessments need to be updated regularly during the outbreak investigation as new information (e.g. surveillance data, analytical results, epidemiological information, information on consumption and distribution of suspected food items) becomes available.

~~54.~~55. An essential part of outbreak preparedness is to have a framework and structures in place to allow for a timely rapid risk assessment. They should include but are not limited to:

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

F. RISK COMMUNICATION SYSTEM/STRATEGY

~~55.~~56. 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.~~57. 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.~~58. In terms of risk communication, the preparedness should aim to;

- Establish a public communication strategy for the network members and, where appropriate, designate official spokespersons from the national network or the government, which includes the means of communication (websites, social media, etc.) that is appropriate to the size and nature of an outbreak. Where it is possible, the jurisdiction of each of the competent authorities should be accounted for when setting roles and responsibilities for each organisation in the risk communication strategy.
- Consider a structure to allow for the communication to be handled locally, in case of small and localised 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 time an outbreak occurs. Consider that each population group may have its own characteristics that affect how they perceive risks (e.g. religious beliefs, traditions), so understanding the audience and testing messages to ensure they are culturally and demographically appropriate is important. Consideration should be given to measures that can help prevent misinformation and the spread~~ing~~ of false information.
- Test established communication strategies on a regular basis to evaluate their efficiency.

FOODBORNE OUTBREAK – MANAGEMENT

~~58.~~59. When a foodborne outbreak occurs, the established networks and structures should be used to manage the situation with an integrated approach. Often management of foodborne outbreaks will be carried out under pressure with time and budgetary constraints. It is therefore important that each sector/participant 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.~~60. The investigation and control of biological foodborne outbreaks are multi-disciplinary tasks requiring skills and collaboration in the areas of clinical medicine, epidemiology, laboratory analysis, food microbiology, ~~food safety and food control,~~ and risk communication and management (including food safety and food control), among others. The laboratory analyses may include the analysis of e.g. the implicated food or environmental samples from the primary production and processing environment of the implicated food. The management of a biological foodborne outbreak includes the establishment and confirmation, if possible, of the likely food source by epidemiological investigations of human cases (including interviews), of food data (data on traceability of implicated food) and laboratory analysis.

~~60.~~61. Evidence from these sources should be combined to identify a potential~~find the likely~~ source and can provide input for an outbreak analysis, which serves as the basis for the communication. All aspects of an outbreak investigation, including factors considered when declaring an outbreak over, actions and communication should be documented for post-outbreak evaluation.

A. IDENTIFYING AND INVESTIGATING A FOODBORNE OUTBREAK – HUMAN HEALTH

~~61.~~62. A foodborne outbreak is typically identified by

- a national or regional surveillance system when a cluster of human cases occurs with an identical or closely related type of infection likely to be foodborne,
- food control authorities that identify a product testing positive for a pathogen and an investigation matches the pathogen to isolates from clinical illnesses in patients that have consumed the product, or
- the food control authorities when they are informed about illness related to specific products or food businesses. The information may be obtained either through consumer complaints, information from the public health sector or by the food businesses themselves e.g. a restaurant that received complaints from guests.

~~62.~~63. 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.

~~63.~~64. Depending on the information available, the public health authorities should establish a case definition. It should be used in a systematic and uniform way to identify additional cases and determine the magnitude of the outbreak. The case definition may be updated or revised if new or additional information indicates a need to do so. Cases that fall within the definition should be interviewed by trained personnel to obtain as much information as possible on food items consumed prior to illness onset. The information asked should include:

- On the food items ~~recently~~ consumed: detailed food history, ~~(if known)~~ the place (the commercial name of the establishment and the exact address) and date of purchase and the time of consumption, frequency of eating or amount of the suspected foods eaten, method of preparation, the source of the food or food product, brand name, lot/batch code. (Note that for some foodborne illnesses such as listeriosis, this information may not apply, since food causing the illness may not have been consumed recently.)

- With regards to the affected person: personal details (but shall be treated with confidentiality)~~information on travel, animal and environmental exposures, person-to-person contact~~, disease onset, symptoms, duration, hospitalization, underlying health conditions, person-to-person contact, information on travel, animal and environmental exposures, etc.

~~64.~~65. 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. It may be necessary to use several iterative rounds of questionnaires with a number of cases, beginning with a more general questionnaire such as a national hypothesis generating questionnaire, progressing to a focused or supplemental questionnaire when one or several exposures appear noteworthy, to identify a potential source~~suspect vehicle~~.

~~65.~~66. Other tools that can be used for hypothesis generation to determine the source of the outbreak~~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. Population surveys of healthy adult food consumption habits can be used as a tool for rapid hypothesis generation to identify foods eaten by people in the outbreak more often than expected.

~~66.~~67. 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)

~~67.~~68. Initial epidemiological investigations (descriptive epidemiology and interviews with a number of the cases using open-ended interviews for hypothesis generation purposes) pointing to a particular food source or a site (e.g. restaurant, production facility, or farm), or a traceback of a food to a particular site, as the possible source of the outbreak should be followed by a thorough on site investigation. This on site investigation should cover all aspects of the production, storage, transport, handling, distribution and consumption to substantiate if it is possible that the food source or the production conditions are actually the source of the outbreak. If possible, the root cause of contamination should be identified and verification by sampling and analyses should be attempted.

~~68.~~69. Sampling of potential food sources and the environment of potential contamination sites can be helpful in substantiating or rejecting a hypothesis. When taking a sample, information on the product should include at least product name, comprehensive product description (e.g. animal/fish species, kind of vegetable, fresh, processed, frozen, canned), lot identification, place and date of sampling, required and actual storage conditions (refrigeration and type of packaging), in order to allow further investigations including tracing. On site investigation can include environmental sampling (e.g., swabs of a processing environment, or soil/water samples on a farm) to provide additional information on the source of the outbreak and root cause. Knowledge and correct application of sampling techniques, in particularly aseptic techniques, and of sample handling for transportation to a laboratory is~~are~~ essential to guarantee the integrity of samples taken for verification as well as confidence in the results.

~~69.~~70. If the epidemiological investigations do not identify a source, the competent authority could use other information to inform~~elaborate~~ their investigation of a potential~~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~~ supporting evidence.

~~70.~~71. 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 any other food products made with that food item or ingredient~~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 including re-processing, records~~gistrations~~ of process and product controls, identified risk factors for product contamination, 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 and other distribution paths including to institutions and via internet sales.

~~71.~~72. 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.

~~72.~~73. If the overall evidence concludes that the source of the foodborne outbreak or the affected lot(s) has been identified, appropriate risk management actions should be put in place. This includes preventing ~~the~~ further distribution of the contaminated food and removing any contaminated food already in the market~~place~~. When a recall is identified as the appropriate risk management action, tracing back and tracing ~~tracing~~ forward should be used to remove all lots implicated or suspected to be implicated. The recall should be carried out in the shortest time frame possible by the food business operator to avoid greater impact on public health and the business. The competent authority should monitor the recall to ensure compliance.

~~73.~~74. Consideration should be given to the actions required by consumers affected by ~~in~~ recalls and businesses impacted by ~~in~~ recalls and product withdrawals concerning the suspect lots. Consumers should be notified on the recalls using different appropriate communication tools (e.g. social media, newspapers, etc.). Consideration should also be given to provide advice to consumers and/or businesses about appropriate disposition of affected foods ~~and~~ which should take into account any potentially associated public health risks.

C. COMBINING EPIDEMIOLOGICAL AND LABORATORY DATA

~~74.~~75. 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 an isolate from a food ~~source~~.

~~75.~~76. Even in case of a match in serotypes, supplementary analysis by molecular methods may be necessary to draw conclusions on the likelihood of a relationship.

~~76.~~77. The decision of the degree of ~~cor~~relation between strains should be made by concensus of experts as part of the case definition. The level agreed upon may differ according to the typing method and the ~~biological hazard~~pathogen.

~~77.~~78. For example, with WGS, there are no established standard “cut-off” values in terms of degree of differences between strains (e.g. single nucleotide polymorphisms (SNP’s)) at present. In general, when the number of SNP differences, or allele differences in the case of MLST analysis, is fewer, there is the potential that the strains could share a common ancestor. If a food and clinical isolates are within a very small SNP or allele range, it is more likely that those illnesses were caused by that food. The actual number of SNP or allele differences among related outbreak strains will differ depending on a number of factors (e.g. species, length of outbreak, contamination route) and will require interpretation based on bioinformatics, epidemiological, and tracing analysis. Even with a very small SNP or allele range, it is still critical to confirm that link with epidemiology and traceback data.

~~78.~~79. The use of databases containing comparable molecular based testing results from, e.g., humans, animals, feed, food and establishment environmental sampling, may facilitate the detection and assessment of outbreaks and informs the search for the source of the contamination. The integrity of information in these databases is important as they may potentially be utilized for attribution nationally and internationally.

~~79.~~80. While robust epidemiological evidence can be sufficiently indicative of a foodborne outbreak even without positive laboratory results from sampling to warrant an outbreak response, efforts by sampling and analysis should be made to obtain laboratory results to support the epidemiological evidence. However, laboratory confirmation can be difficult to achieve for several reasons, e.g.

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

~~80.~~81. Analytical evidence, on the other hand, should always be supported by epidemiological information such as that obtained from interviewing human cases, as a match between food and human isolates may not necessarily mean that the food is the actual source of the illness.

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

D. RAPID RISK ASSESSMENT AND OUTBREAK ANALYSIS– DURING A FOODBORNE OUTBREAK

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

83.84. 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 (from both human health and food safety authorities) in order to:

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

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

- historical information on the prevalence of the hazard in different foods, particularly if the source of the ongoing foodborne outbreak is not 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;
- hazardrisk identification and characterization linked to the outbreak;
- analyses of detected hot spots (geographical areas or events with more than usual occurrence within the outbreak), guiding further investigations;
- consumer 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 food preparation instructions kill step intended by the manufacturer to achieve food safety;
- where appropriate, recommendations to the consumers and to competent authorities on how to manage the risk; and
- if the potential food source has been traced to a specific food business, information on the overall condition of the facility, such as compliance history, inspection reports, complaint records and company test results.

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

E. RISK COMMUNICATION

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

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

- Have one official communicator to speak to the public whenever practical. When more than one competent authority communicates with the public, the authorities should ensure the messages are consistent.
- Information should be simple and in plain language for key points since the public may have limited familiarity with scientific language. If more languages are used in a specific area (e.g. official national language and official local dialect/language) the information should be available in all the relevant languages.
- Acknowledge any uncertainties and make it clear that the recommendations are based on the best information available at the time. If there is a need to change the recommendations in the future, it is important to remind the public that earlier recommendations were based on information known at that time and explain why the recommendations have been changed.
- Explain to whom the recommendation applies and to whom it does not apply and why.
- ~~Do not withhold information because of a perception that it may be upsetting~~Any information regardless of perception, whether favourable or not, should not be withheld. If information is lacking or cannot be released, it is important to explain the cause (where known) and what is being done to address the situation. Information gaps that will be addressed in the future should be identified and stakeholders should be informed on the likelihood of additional communication.
- There should be a procedure in place for the consultation of external groups of experts to verify the soundness of the recommendations given.
- Repeat information when appropriate and provide updates in a timely manner.
- Monitor the effectiveness of communications and adjust as necessary.
- Establish a platform that provides the public and other stakeholders with easy access to updated information, e.g. a designated website with contact information. This includes authorities and food business operators in other countries if they may be affected. Consider non-traditional platforms used/trusted by specific subpopulations.
- Establish procedures to identify when rumors or false information are being circulated in order to reject false information early.

~~87.~~88. 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

~~88.~~89. It is important to collect and save sufficient information from the beginning of the outbreak to be able to document all relevant steps in the management of the outbreak, for example by using log books or electronic records, both when it is ongoing and afterwards. During the investigation a record should be kept that includes relevant tracing information and descriptive epidemiology, hypotheses and status of the situation. Inspection and laboratory information, as well as any regulatory actions taken should also be kept. The record should be updated as needed while the foodborne outbreak is ongoing and in a way that protects personal information. When it is over, the record can be finalized to include conclusions and can serve as an outbreak report or as basis for a summary outbreak report.

~~89.~~90. 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. ~~Procedures should be in place to protect confidentiality of people affected by the outbreak.~~

~~90.~~91. 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.

~~91.~~92. Outbreaks of special interest should be considered for presentations in national and international scientific forums and submission as scientific publications. INFOSAN also facilitates the sharing of experiences and lessons learned in and between countries in order to optimize future interventions to protect the health of consumers.

~~92.~~93. The documentation can be used by the competent authorities and institutions involved in foodborne outbreak management to identify lessons learned and to consider the needs of a review of existing preparedness based on the lessons learned. A special report on lessons learned can be added later on to the documentation. It can also provide input for future training activities. The learnings from outbreaks should be broadly communicated to support continuous improvement in outbreak investigations and outbreak prevention.

G. POST OUTBREAK SURVEILLANCE

~~93.~~94. Enhanced surveillance, and rapid centralization and evaluation of data, in particular from human cases, should be continued until the numbers of cases have returned to the baseline level, if known~~,~~ (or, for new biological hazards, until no further cases are observed). This allows the evaluation of the effectiveness of actions taken and the confidence of consumers and trading partners to be maintained or regained. Possible delays in analyses and reporting and possible seasonal effects should be taken into account before declaring an outbreak over.

MAINTENANCE OF THE NETWORKS

A. REVIEW OF EXISTING PREPAREDNESS

~~94.~~95. Competent authorities at the local and national level should continuously monitor, evaluate, improve and strengthen their existing networks to ensure that they are functioning effectively and efficiently. This should include ongoing strategic planning and review of objectives, priorities, needs, gaps, opportunities and challenges, including both internal processes and interagency/inter-stakeholder relations. A post-outbreak network review system for foodborne outbreaks should be implemented within the network. The results of such reviews should be documented and areas for improvement addressed to support capability and capacity of the system in place.

~~95. 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

96. The evaluation of preparedness systems can include reviews of major, serious or rare foodborne outbreaks. The evaluation should include personnel from various authorities/agencies, and if possible, also comments from relevant stakeholders such as food business operators. The review should focus on commitment in participation, the use of resources, the sharing of information, the timeline of activities, and other essential issues. The review should be used to build a stronger system or network on an international, national or local level.

97. The review could also consider whether changes may be needed to the way a food is processed (e.g. implementation of preventive strategies) or whether regulatory oversight or other regulatory change is needed to prevent future outbreaks.

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

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

99. 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

100. 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.

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

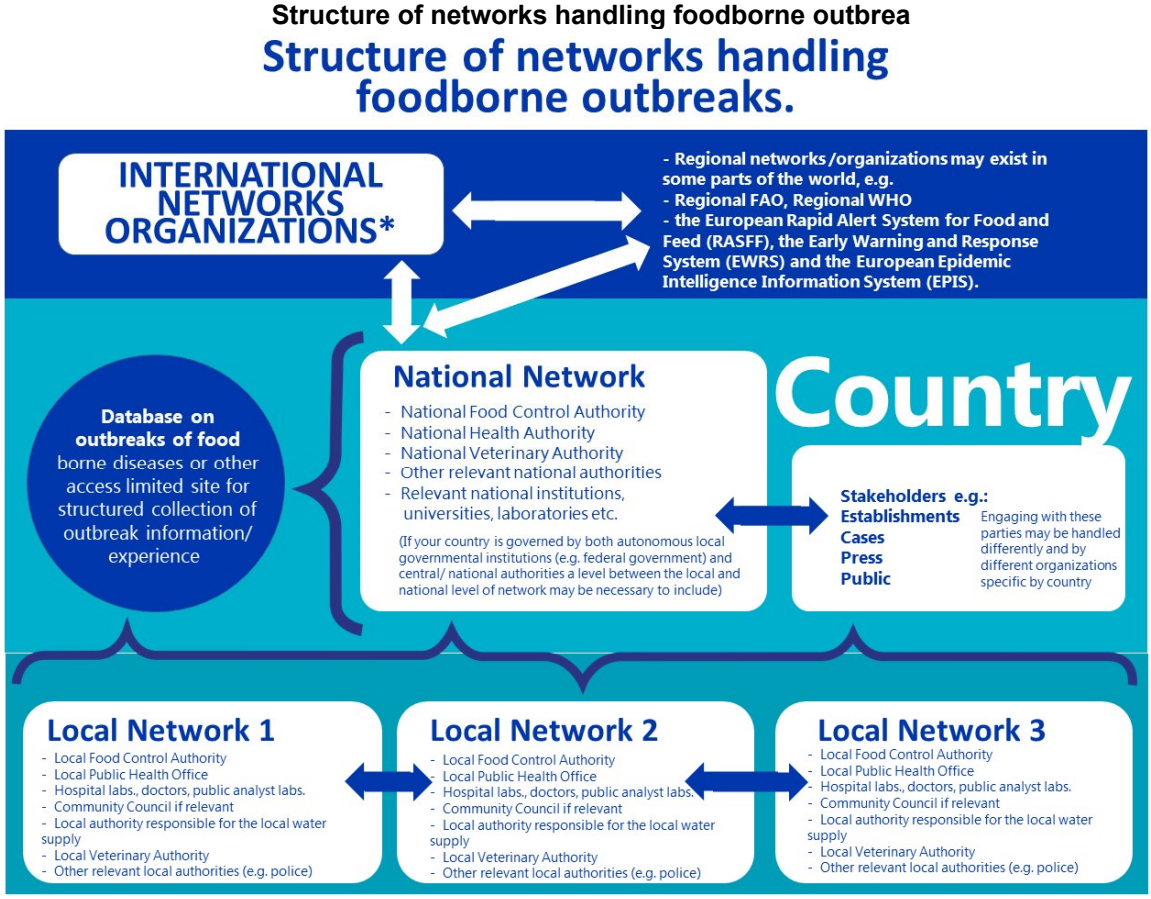
- Control/verification exercises are primarily aimed at testing the performance of the system in place and the participants' ability to carry out their responsibilities effectively, for example an expert or professional handling a particular type of method or a specific procedure. Participants should 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/development exercises are more organized, with the focus on the participants being required to achieve new competences and capabilities. The exercises may involve roles and responsibilities or the development and testing of new procedural concepts and plans. Joint simulation exercises are a proven concept in this setting. Advance notice about learning/development exercises should be given to provide participants with the opportunity to prepare, which can optimize the overall outcome and learning experience.

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

103. Regardless of type of joint training or exercise, it is important that the activity is put into a strategic perspective and that lessons learned are captured and put into a structured revision of the system where necessary.

Annex I

Structure of networks handling foodborne outbrea



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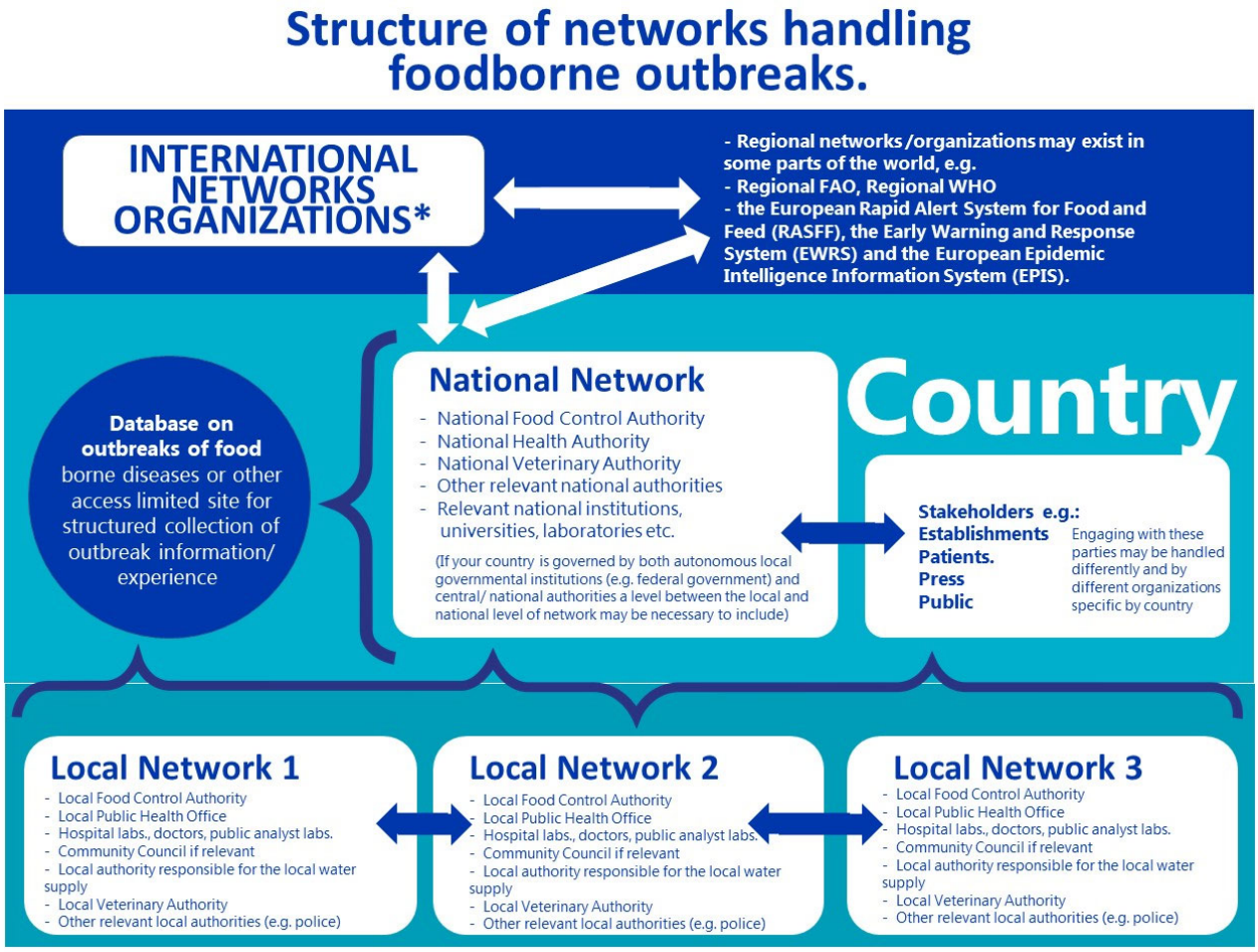
*** INFOSAN and International Health Regulations (IHR)**



Annex II

Examples of requests for rapid risk assessments

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

The scope of a rapid risk assessment is to answer a specific question or assess a specific risk in relation to an outbreak ,~~item~~ for which additional information is required for decision making ~~in relation to an outbreak~~. The need for a rapid risk assessment should be evaluated on each case scenario.

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

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

Annex III

Template for an outbreak analysis

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

Outbreak information/ Descriptive epidemiology	Case definition Number of confirmed cases Number of probable cases not yet verified as part of the outbreak Geographical location (cases per area/jurisdiction) / place of suspected or confirmed exposure~~contamination~~ Age and gender distribution Affected vulnerable subgroups (e.g. elderly, children) Epi-curve (number of cases per day/week or month) Other descriptive information available of the outbreak size and distribution area.
Analytical information Human cases	Agent involved – characteristics of the agent Overview of human cases reported including severity of illness (e.g. hospitalisations, disabillity, fetal loss and deaths).
Outbreak background information	Questions such as~~like~~ the following should be answered: How was the outbreak initially detected? Are there any common foods (or ingredients) identified as being consumed by the human cases? Is there any correlation between the distribution of the cases and the distribution of the potentially implicated food? How have the human cases initially been linked to a certain food source? Has outbreak information been reported to the public and how?
Illness background information	Historical data from previous monitoring and isolations in food might help target investigations towards the source if not known yet. Historical data, not related to the ongoing outbreak, on the hazard, e.g.; • occurrence in humans • outbreaks in the past at local, national, regional or international level. • occurrence in different types of food The purpose is to indicate if human cases/outbreaks with the involved pathogens are rare or occurring from time to time. Historical data from previous monitoring and isolations in food might target investigations towards the source when not known yet. When possible, these data should be targeted to the pathogen with the same virulence factors/serotypes as the one in the ongoing outbreak. Historical data may also be valuable when determining if / how the agent involved behaves differently than previously seen.
Investigation of human cases	This may include, but not be limited to results of the investigations performed: • hypotheses generating interviews • food exposures that appear higher than expected based on available surveys of food consumption habits~~.~~ • subclusters~~subcultures~~ where two or more cases not part of the same family ate at the same event, restaurant, etc. • Case-control or cohort investigation
Investigations in food	• Information on samples taken – items, places of sampling, open or closed sample, lot code, any storage or cooking instructions provided on package, etc. • Analytical methods used. • Outcome of the laboratory analyses. • Information on tracing of the affected food/food ingredients, e.g. starting from the food/establishment initially linked to the human cases: ○ Tracing back the food/ingredients to the supplier; ○ Tracing forward the distribution; ○ To be repeated for each affected establishment along the food supply chain ○ Data gaps should be identified (e.g. establishments to which the affected food was sent, but where there is no information on investigations carried out in that establishment) ○ Are there any identified ~~Have any~~ common suppliers of the affected food product~~ of interest been identified~~? • Assessing if the distribution of the suspected food item can explain the outbreak (distribution area, amount of the food on the market in relation to the distribution and number of cases in the outbreak)

	• Description of production conditions in affected establishments (e.g. hygiene conditions), applicable steps influencing the presence of the hazards (e.g. heat treatments or possibilities for cross-contamination) • Information on consumer behaviour and eating habits, e.g., not following the manufacturer's instructions for storage (e.g., refrigerate, use-by date) or for the cooking intended by the manufacturer to achieve food safety. How much time elapsed between preparation and consumption?
Background information concerning the strain in food, feed, animal or environment samples	Has the strain been seen previously? If yes, please describe further the time, place etc. If isolates are available for comparison, sample identification should be provided. If a specific production or process is suspected to be the source of the outbreak, a detailed description of the ingredients, their treatment, production processes etc. need to be ~~described~~ developed / documented to assess whether deviations in the production may be implicated. Possible significant family or community event that may have been an opportunity for outbreaks to occur (e.g. family event, birthday parties, fiesta, festivals, holiday celebrations~~Christmas parties,~~ etc.)
Linking epidemiological food trace back and laboratory data in humans and food	An attempt should be made to graphically present and link the data from human cases, retailers, distributors, processors back to suppliers of raw materials, indicating the link between them when existing and the results of laboratory testing if carried out and available. When available, results from whole genome sequencing can be added, and a single-linkage tree including all human and non-human isolates should be made, illustrating the core gene allelic differences.
Data not available / not yet available	Any u~~U~~ncertainties on the existing data and data gaps should be indicated. If any data /information is necessary for the assessors but not yet available, it should be indicated when the data will be available. If any data is~~are~~ not available, this should be clearly stated when asking for the outbreak analysis, as the missing data may be vital for the outcome of the analysis.
Communication	Clear information on the communication strategy targeted towards consumers, affected operators and other stakeholders should be given. It is also a good idea to agree upon a strategy for communication in case the assessors are approached by the press or public – agree on what can be said, by whom and when.
Annexes	References

Prognosis / summary

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

APPENDIX II - Comments to the draft guidance on the management of foodborne outbreaks that did not lead to amendments in the text and justifications from the chairs

SPECIFIC COMMENTS		
INTRODUCTION	**MEMBER/OBSERVER**	**JUSTIFICATION**
Para 9, add a bullet included to: " Informing the population about control of hazards and reducing the risk; for example, how they prepare the foods to attenuate the severity of biological virulence." Para 9, The pathogenicity (virulence/infectivity) of the microorganism and symptoms in the patients.	**Iran**	The paragraph is on when and how to define an outbreak as an incident, an emergency or as a crisis, so the proposed guidance does not fit in here.
DEFINITIONS **General comment from chairs:** The document is at stage 5, and definitions have been discussed in earlier rounds. Some definitions were agreed upon at CCFH51. Comments that are editorial or enhance readability are accepted. New definitions are not accepted at this stage, unless there is an obvious need.		
We propose new wording: 16. Case-control study: An observational study in which subjects exposed via food consumption with potential risk are enrolled on the basis of presence (cases) or people who are not exposed via food consumption, absence (controls) of the foodborne illness of interest. Information is compared between cases and controls. We propose including the risk and confounding factors. 26. Rapid risk assessments: Risk assessment, based on the information available on the foodborne outbreak, taking into account the risk and confounding factors, which needs to be carried out urgently to quickly support (provisional) risk management measures and therefore may not always contain the full development of the four steps of a risk assessment described in the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG 30-1999). We propose the following wording: 29. Traceability: 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.	**Colombia**	16. This definition was agreed on at CCFH51 and broad in line with the WHO definition. 26. See general comment from chairs. 29. We consider this a translation issue.
Saudi Arabia suggests providing a definition for “Risk Assessor” as the following: "Evaluating risks associated with the food chain requires collecting information and analyses existing research and data to provide scientific advice considering the uncertainties in risk estimates, and when appropriate, alternative interpretations of the available data that may be scientifically plausible to support decision-making by risk managers without generating new scientific research or having scientific laboratories."	**Saudi Arabia**	See general comment.

FOODBORNE OUTBREAKS – PREPAREDNESS SYSTEM		
A. CREATION OF OFFICIAL NETWORKS BETWEEN HUMAN HEALTH SECTOR AND FOOD AND VETERINARY SECTIONS AT LOCAL AND NATIONAL LEVELS		**B.**
New bullet point: Coordinating any communications released to the media Also include the coordination of any communications released to the media	**New Zealand**	Paragraph 35 is on communication between networks nationally and internationally. Risk-communication is adressed in para 58 in another chapter
Paragraph 35 The authority/agency with the legal responsibility to protect public health in a foodborne outbreak situation should be designated as lead contact point in charge of the national network and such authority/agency must manage the safeguarding of information regarding an outbreak on a secure platform. Rationale: Add that safeguarding information regarding an outbreak shall be managed by the competent health authorities on a secure platform. It is a priority to store all information related to a foodborne outbreak and that such information is supported by scientific studies. The authority responsible must be a government authority from the health sector. This information can be used to predict future outbreaks. Include: • Performing stakeholder analysis as established by the WHO. • Issuing guidelines and procedures for the operations of the National Epidemiological Surveillance System. • Establishing the basis and mechanisms for coordination in order to promote and support the National Epidemiological Surveillance System. • Coordinating and carrying out epidemiological surveillance measures in accordance with the laws on epidemiological surveillance and those arising therefrom, as well as nationally mandated strategies and procedures. • Establishing the basis and mechanisms for coordinating actions between public health departments and entities to consolidate the national structure. • Integrating inter-institutional groups in charge of developing and operating surveillance systems for specific programs within the country's health priorities.	**Mexico**	35. There is a general recommendation on procedures ensuring data confidentiallity in the introduction, so this would be a repetition.. This section is on preparedness and on establishing networks. The proposed wording does not fit in here, as it more or less covers and summarises all sections of the guideline.

• Ensuring training, assessment, supervision and evaluation of the surveillance system among the participating departments and entities. Rationale: Stakeholder analysis at the national level will help to identify experts, whether they are institutions or persons who belong to the institutions. We consider it appropriate to supplement the framework of competence at the national level. Paragraph 38 Templates should be developed in advance (...). Some of them are listed below. • Individual survey • Record of cases of foodborne illnesses in clinics and laboratories • Collective record of cases • Sample collection report • Health inspection guide for food sales • Record of food handlers in a foodborne illness outbreak • Attack rate of food served in a foodborne illness outbreak • Combined attack rate by food ingested form • Flowchart for processing suspected food • Final report and foodborne illness outbreak guide • A template to request rapid risk assessment as referenced in Section E and Annex II. Rationale: We consider it appropriate to list the necessary forms or formats needed for a complete study and proper analysis of a foodborne illness. Source: PAHO. Foodborne Disease Surveillance System and Outbreak Investigation Guide. Foodborne Disease Surveillance system forms. https://www3.paho.org/hq/index.php?option=com_content&view=article&id=10547:2015-anexo-b-contenido-anexo-b&Itemid=41421&lang=en		38. This paragraph is on preparedness, where the most important and commonly used templates, specific for outbreak investigations, should be outlined on beforehand. The intension is not to mention all possible templates, but there is of course flexibility for countries to adapt the list to their needs.
C. SURVEILLANCE AND MONITORING SYSTEMS (E.G. HUMAN, ANIMAL, FEED, FOOD, ESTABLISHMENT ENVIRONMNET) AND THEI USE IN FOODBORN OUTBREAK SITUATIONS		
Paragraph 44 New bullet point 44. (…)In order to identify the source of a foodborne outbreak there is a need for: • Communication between government agencies in each state and country.	**Mexico**	This paragraph is on basic surveillance/monitoring needed to identify outbreaks. Communication is

Rationale: Communication between government bodies and between states is very important for effective coordination in managing an outbreak.		important and is covered in several paragraphs (e.g. 5, 33, 34, 35 and 47).
D. ANALYTICAL METHODS		
Paragraph 50 Laboratory capacity, specific equipment (properly maintained and calibrated) and personnel trained in implementation of WGS... Rationale: Laboratory equipment must be calibrated. Paragraph 55• • Include the list of experts and/or government agencies responsible for risk assessment available and identify their area of competence in the stakeholder analysis. Rationale: It is important to consider that in some countries, places or regions, there are specialized risk assessment agencies, who would be identified in the stakeholder analysis, as well as experts in the field, and the synergies they may have on the topic in question. The stakeholder analysis would help to identify them more accurately.	**Mexico**	50. Where applicable" refers to “equipment”, which should be calibrated if it is a measuring equipment. Not all kinds of equipment can be calibrated. 55. The suggestion changes the meaning of the paragraph. Furthermore there is no mention on 'stakeholder analysis' elsewhere in the draft.
F. RISK COMMUNICATION SYSTEM/STRATEGY		
Paragraph 58 New bullet point. 58. In terms of risk communication, the preparedness should aim to: * Prevent misinformation and spreading false information or rumors Rationale: It is important to include guidance that shows the importance of combating the infodemic, which is the spread of supposed treatments or false information on social media that makes it difficult to control the outbreak and could even increase the level of risk to the population.	**Mexico**	This is already included in the fourth bulletpoint.
FOODBORNE OUTBREAK – MANAGEMENT		
Para 60, Addition of below sentence is recommended at the end of this part: "The documents would be used for further outbreaks and rapid risk assessments if required." Para 60, line 5, "distribution" is also important here.	**Iran**	This is covered by paragraph 89-93.

Evidence from these sources should be combined to identify a potential source and can provide input for an outbreak analysis, which serves as the basis for communication, particularly if a food product recall is required. Alternative wording. Need to consider in the management that a food recall may be required, and this would be a priority if a source has been determined.	**New Zealand**	"potential source" is included. The addition on recalls can give the wrong impression that it is less important to combine evidence as input for an outbreak analysis, that can be a basis for risk communication in situations where a recall is not required. Recall is adressed in 73
A. IDENTIFYING AND INVESTIGATING A FOODBORNE OUTBREAK – HUMAN HEALTH		**B.**
Paragraph 64 • On the food items consumed (if known): the place (the commercial name of the establishment and the exact address) and date of purchase and time of consumption, method of preparation, brand name, lot/batch code, the source of the food or food product. Rationale: We propose adding the source of the food, for example to identify whether it is an animal not recognized for human consumption, whether the food products were purchased in bulk or packaged, and where, since the place could be a source of contamination. Depending on the information available, the public health authorities must establish an operational case definition. It must be used in a systematic and uniform way to identify additional cases and determine the magnitude of the outbreak. The operational case definition may be updated or revised if new or additional information indicate a need to do so. Rationale: Operational definitions are built or adapted from others, based on the observable characteristics of the phenomenon; they indicate the specific, empirical or indicative elements of what is being investigated. It is important to replace "should" with "must," which we recommend throughout the document. Paragraph 67	**Mexico**	64. "The source of the food" is included. "Must" does not fit in a Codex guidance document. 67. Both could be prospective or retrospective - in

When a hypothesis is established, it may be appropriate where possible to perform analytical epidemiological investigations such as a retrospective prospective cohort study or a retrospective case-control study. Rationale: Cohort studies are longitudinal and prospective, not retrospective.		outbreak situations it is mostly retrospective.
This could be the situation if the hypothesis is not very strong or if further evidence is needed to inform and back up long-term control measures.	**New Zealand**	Both long-term and short-term control measures may be required, so there is no need to limit the use.
C. SUBSTANTIATE HYPOTHESIS AND/OR HANDLING OF A FOODBORNE OUTBREAK – FOOD SAFETY (FROM FARM TO FORK)		**D.**
We propose adding "(such as sample selection or collection)" 69. ... Knowledge of sampling techniques (such as sample selection or collection), particularly aseptic techniques, and of sample handling for transportation to a laboratory are essential to guarantee the integrity of samples taken for verification. We propose deleting "controls" since the registrations kept are not only from the process controls. 71. Tracing a food item… - Information to identify the root cause of the contamination (raw material status, processing steps that may influence the presence of the microbiological hazard identified including re-processing, registrations of the process and product, identified risk factors for product contamination, samples analyzed and results etc.). Delete the words "from an outbreak" since they are repeated.	**Colombia**	69. It is not necessary for the understanding of the paragraph, and may complicate and confuse. Sampling techniques include sample selction and collection, but this should be obvious. 71. Chairs couldn't understand the intention of the comment, and no change is made.
E. COMBINING EPIDEMIOLOGICAL AND LABORATORY DATA		**F.**
Paragraph 77: We need guidance on what are established standard "cut-offs" prior to the use of WGS as a regulatory tool. It is important to recognize that WGS is an evolving technology and sole reliance on WGS results may be inappropriately applied in a regulatory framework. 77. Proposed edits: 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. For example, with WGS, there are no established standard "cut-off" values in terms of degree of differences between strains (e.g. single nucleotide polymorphisms (SNP's)) at present. In general, when the number of SNP differences, or allele differences in the case of MLST analysis, is fewer, there is the potential that the strains could share a common ancestor. The actual number of SNP or allele differences among related outbreak strains will differ depending on a number of factors (e.g. species, length of outbreak, contamination route) and will require interpretation based on bioinformatics, epidemiological, and tracing analysis.	**ICGMA**	77. and 78.The proposal is to merge two paragraphs and delete a sentence. This sentence provides useful information and should be maintained. 79 and 82. Included, language softened.

78. Proposed edits: Delete text here as it is covered in 77. ICGMA Comment on 79: Integrity of sequence data in the databases is critical. See proposed text to 79. 79. Proposed edits: The use of databases containing comparable molecular based testing results from e.g. 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. The integrity of information in these databases is critical and should be of high quality and fidelity as they may potentially be utilized for attribution regionally, nationally, and globally. ICGMA Comment on 81: Analytical tools such as WGS and related results should be used in the context of epidemiological evidence (illnesses). We are supportive of this approach. ICGMA Comment on 82: Rules of engagement need to be outlined – to establish criteria for sequence homology, source attribution, use of metadata. See proposed text to 82. 82. Proposed edits: 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. It is important to establish criteria to determine sequence homology, illness attribution or environmental link, and how metadata associated with the sequence information is identified, maintained and used.		
Collaboration between public health and food manufacturers should be encouraged to share molecular **and/or traceability** data for specific ingredients and foods. This can aid in hypothesis generation and potentially lead to faster identification of the source of an outbreak. Access to molecular tests by AEOs is limited. In this sense, the most practical form of collaboration is to make information available on the traceability of specific ingredients and foods; for the competent authority to proceed with generating molecular data for strains involved in biological outbreaks	**Peru**	Paragraph 82 is specifically on molecular testing.
G. RAPID RISK ASSESSMENT AND OUTBREAK ANALYSIS – DURING A FOODBORNE OUTBREAK		**H.**
We propose adding “(such as sample selection or collection)” 85. An outbreak analysis is a prognosis in an outbreak situation and is based on historical data and data generated in the investigation.	**Colombia**	Chairs couldn’t understand the intention of the comment, and no change is made.
Paragraph 83 We suggest mentioning the disadvantages of rapid risk assessments.	**Mexico**	The disadvantages are mentioned in paragraph 53.

Rationale: Indicate that a major disadvantage in rapid risk assessments is that uncertainty would increase the in tail probabilities in a response-exposure assessment such that the study's effectiveness would be affected, as well as the lack of data due to missing some of the methodological steps. This is so that they are not overused by wanting to use them in every case.		
ICGMA Comment on 85 bullet 6: Scientific evidence rather than anecdotal or historical consumer behaviors should be utilized here. Food processors must be encouraged to develop and clearly display validated cooking instructions on packaging for foods that should be cooked prior to safe consumption.	**ICGMA**	The proposed wording changes the meaning of the bulletpoint. The term 'food preparation instructions' i sinserted instead of 'killing step'
I. POST OUTBREAK SURVEILLANCE		
Paragraph 94 There needs to be a definition or explanation of the concept of enhanced surveillance. Rationale: Have greater clarity about the features of enhanced surveillance.	**Mexico**	It is not considered necessary to define enhanced surveillance.
MAINTENANCE OF THE NETWORKS		
What were some of the most difficult challenges faced and how were they overcome ~~(or not)~~? To delete (or not) at the end of the sentence as it may cause confusion.	**Philippines**	It can also be useful and instructive to include experiences on challenges that where not solved in the review.
ANNEX II		
Annex II Put a table or columns of advantages and disadvantages for each case, giving an example in comparison with a “normal” risk assessment study. Rationale: Improve knowledge and understanding as well as providing information for a more informed decision.	**Mexico**	This proposal is quite substantial at this step in the proces. Furthermore, disadvantages and advantages when issuing a rapid risk assessment, is described elsewhere in the guideline.

Saudi Arabia suggests identifying competencies, experience and other requirements to qualify as a Risk Assessor, and these criteria considerations should be within the jurisdiction of the local competent authority.	**Saudi Arabia**	This is the competence of the competent authorities and not up to Codex.
ANNEX III		
Comment - Addition of a point that is often captured during an outbreak analysis. In the section Outbreak information/Descriptive epidemiology, add as a third point - "Number of hospitalizations and deaths"	**Canada**	This information is included in the following section (Analytical information Human cases).
We propose adding the following question: Were the confounding factors related? The confounding factors are related to health conditions, socioeconomic conditions, etc. Annex III Contextual information about the outbreak Questions such as the following should be answered: How was the outbreak initially detected? Has the consumption of any common food been identified among the cases? Is there any correlation between the case distribution and distribution of the foods potentially involved? How were the cases in humans initially linked to a particular food source? Were the confounding factors related? Has the public been notified about the outbreak? How was this carried out?	**Colombia**	The question on this section should support or guide the outbreak investigation, confounding factors are part of the statistical analysis to detect associations that can be made.
Annex III Operational case-definition Rationale: Operational definitions are built or adapted from others, based on the observable characteristics of the phenomenon; they indicate the specific, empirical or indicative elements of what is being investigated.	**Mexico**	Case-definition is used as a general term, not necessay to specify as operational.