

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 5

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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PROPOSED DRAFT GUIDANCE ON THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

Comments at in reply to CL 2021/04/OCS-FH

Comments of Argentina, Australia, Canada, Colombia, Cuba, Ecuador, Japan, Kenya, Mexico, Peru, Philippines, Thailand, Tunisia, United Arab Emirates, United States of America, Uruguay, ENCA

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/04/OCS-FH issued in February 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as Annex I and are presented in table format.

GENERAL COMMENTS	
Comments	Member / Observer
<p>Argentina appreciates the opportunity to submit comments and congratulates the Electronic Working Group for the work carried out on this document.</p> <p>In response to CL 2021/4 document on the Proposed Draft Guidance on the Management of Biological Foodborne Outbreaks, Argentina agrees with the progress of the document not having observations on the proposal.</p>	Argentina
<p>Confidentiality in information sharing between networks appears to only apply to surveillance data and analytical methods. It should be noted that all information sharing during a foodborne outbreak is subject to confidentiality requirements at some level, whether local, national or international. Permission may need to be granted before certain information can be shared. Suggest adding a broad confidentiality in information sharing clause to the draft guidance paper unless captured elsewhere</p>	Australia
<p>In principle, Cuba supports the document: Proposed Draft Guidance for the Management of Biological Foodborne Outbreaks at Step 6, and we do not have comments regarding the definitions, analytical methods, rapid assessment and outbreak assessment, or on the use of combining epidemiological data, laboratory data and the annexes, which generally address much of the discussion from the previous meeting, CCFH51.</p>	Cuba
<p>Ecuador thanks the Electronic Working Group for its work relating to the document "DRAFT GUIDANCE FOR THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS." We believe that the criteria and other detailed information are generally well-structured and we, therefore, do not have any comments on the document put forward for consideration of: definitions, analytical methods, rapid assessment and outbreak assessment, combining epidemiological and laboratory data, as well as the annexes. We, thus, support continuing the work according to the respective resolutions.</p>	Ecuador
<p>Kenya welcomes and takes note of the decision of the 43rd Session of the Codex Alimentarius Commission to adopt the draft on the Guidance for the Management of Biological outbreaks at Step 5 and advanced it to Step 6 for further comments. Kenya supports the draft in general and therefore supports the advancement of the draft to the next step.</p>	Kenya
<p>Definitions- The Philippines supports the changes in the definitions as agreed on the CCFH51</p> <p>Paragraph 80- The Philippines supports the statement in paragraph 80, "Robust epidemiological evidence can be sufficiently indicative of a foodborne outbreak even without positive laboratory results from sampling to warrant an outbreak response."</p> <p>Annex 1- The Philippines supports the proposed Annex I Structure of networks handling foodborne outbreaks, as it encompasses all the key players involved in foodborne outbreaks.</p>	Philippines
<p>Thailand generally agrees with most parts of the Draft. However, we still have some specific comments in the Annex I.</p>	Thailand
<ol style="list-style-type: none"> 1. The draft takes into account comments made during CCFH51, taking into consideration comments from various countries. However, it is very important to include the idea of a regulatory threshold or criteria. (in the definitions) 2. Given the importance of analytical methods as an essential tool to detect and investigate outbreaks, Tunisia recommends adding requirements for the selection of methods and laboratories (minimum applicable capabilities and performance). 3. The revision provided increased clarity which will facilitate implementation of the guidance and alignment of intra- and 	Tunisia

<p>inter-country response procedures.</p> <p>4. The graphic (Annex I) provided added value to the written text and a simplified explanation for information sharing by competent authorities at the local, national and international level. However, principles for information sharing between food business operators (producers, manufacturers, importers, intermediary users of raw materials, wholesalers, restaurant owners, distributors, etc.) and the government are not included.</p> <p>Point 45 emphasized the importance of reporting surveillance and monitoring data, however the information sharing model is not mapped out.</p> <p>In fact, in accordance with foodstuff hygiene regulations, each food business operator must establish a health control plan HCP appropriate to its business to secure its production system and sell healthy and safe products.</p> <p>As part of the HCP, a self-inspection plan must be defined and implemented to validate, monitor and check the effectiveness of preventive control measures taken at all stages of production, processing and distribution.</p> <p>Operators must use a work method based on continuous hazard identification and must also comply with notification requirements.</p> <p>5. Annexes II and III: no specific comments</p> <p>6. It might also be useful to add an exhaustive list of known biological hazards, adding to the annex data sheets by hazard based on regulatory, scientific, epidemiological and clinical data.</p> <p>7. Tunisia recommends formalizing a procedure for initiating an epidemiological investigation and defining decision-making criteria for moving to an alert.</p> <p>8. It might be useful to add to the annex a decision-making logic diagram for epidemiological investigation and to define thresholds for initiating epidemiological investigations. This could be based on a critical threshold, the vulnerability of the affected food, the characteristics of the agent responsible for the outbreak, the consumption pattern and the size of the population likely to be exposed.</p>	
<p>Extra comments to be considered:</p> <p>1. A major challenge with outbreak investigation is the unavailability of information about the organism that caused the outbreak. This happens because most hospitals either do not collect stool for culture test before antibiotics are administered, or they completely ignore the stool test and use a rapid antibody test or similar tests that wouldn't require the pathogen to be isolated. Health authorities (assumed to be a part of the investigation) must have protocols in place that require stool culture tests for pathogen identification and isolation for the next steps to be meaningful.</p> <p>Food authorities also have a tendency to test foods and isolate anything that could be detected. It is likely that wrong pathogens are identified, specially when the cause is unknown.</p> <p>It would also be good to emphasize that finding something in the food doesn't mean that the organism that was identified caused the illness.</p> <p>2. Adding a few reference documents would be good. Include CIFOR guidelines, link to applications that can assist in epi such as Epi Data and Eli info</p>	<p>United Arab Emirates</p>
<p>Uruguay appreciates the work undertaken and agrees with the technical content of the document, including its annexes. Likewise, we would like to emphasize the importance of the content of paragraphs 52 and 83, with which we fully agree.</p>	<p>Uruguay</p>

The United States thinks these Guidelines have progressed nicely; we believe it is possible they can be finalized at CCFH52 and forwarded to the Codex Alimentarius Commission for adoption at Step 8. Most of our comments below are for clarifications that can lead to that outcome.	USA
SPECIFIC COMMENTS	
Comments / Rationale	Member / observer
INTRODUCTION Para. 1	
<p>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 food production to consumption and can result from the presence of zoonotic hazards in animal production or from handlers, environmental contamination, via equipment, water, soil or air</p> <p>Australia suggests amending the following text:</p> <p>"... The contamination of food may occur at any stage in the process from primary production through to consumption and can result from the presence of zoonotic hazards in animal production or from handlers, environmental contamination, via equipment, water, soil or air."</p>	Australia
<p>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 food production to consumption and can result from the presence of zoonotic hazards in animal production or from handlers, environmental contamination, via equipment, water, soil or air.</p> <p>We propose changing the term "hazard" to "agent."</p>	Colombia
Para. 2	
<p>Biological food-borne illness usually takes the form of gastrointestinal symptoms; however, such illnesses can also have neurological, gynecological, immunological and other symptoms. The symptoms can be mild with recovery in days or have severe consequences for the individuals due to long-term sequelae with serious health effects or even death.</p> <p>Australia suggests that the spelling for 'foodborne' is consistent throughout the document.</p>	Australia

Para. 3	
<p>Biological foodborne outbreaks can have significant socio-economic costs, <u>which are exacerbated in populations comprised of vulnerable groups</u>, related to hospitalization and medical treatment, lost productivity and effects on tourism. For food businesses, the consequences can be lost markets, loss of consumer confidence, <u>litigation</u> 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.</p> <p>The meaning of the Spanish word “pleito” can include anything from physical altercations, personal assault or quarrels, to legal disputes.</p> <p>Taking into account the context of this draft, the Spanish word “litigio” is more precise in conveying the idea when referring to legal or court disputes and is more in line with the English version.</p> <p>It is important to take vulnerable groups into consideration, given the prevailing conditions mainly in Latin America and Africa.</p>	Mexico
Para. 4	
<p>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.</p> <p>Delete the repeated Spanish word “sobre.”</p>	Colombia
<p>Codex Alimentarius has issued several guidelines for food businesses and competent authorities <u>on</u> hygienic practice 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.</p> <p>Avoid duplicate words.</p>	Mexico
<p>Codex Alimentarius has issued several guidelines for food businesses and competent authorities on hygienic practices to ensure food safety. Those guidelines focus <u>on, on</u> 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.</p>	USA
Para. 5	
<p>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 and interpretations to the extent possible, as well as a transparent exchange of information. Cooperation through international networks is essential and should be a feature of any national network.</p> <p>We propose deleting this section to avoid confusing information.</p>	Colombia
<p>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 and interpretations to the extent possible, as well as a transparent exchange of information, <u>in addition to</u></p>	Mexico

<p><u>information from experts in interventions with vulnerable groups</u>. Cooperation through international networks is essential and should be a feature of any national network.</p> <p>It is important to consider the social and economic contexts in any public health intervention, particularly with vulnerable groups, otherwise there is the risk that the planned interventions are not applicable to the population group in question.</p>	
Para. 6	
<p>The principles for risk analysis including risk assessment, risk management and risk communication, as described in the Codex Working principles <u>Principles for risk analysis-Risk Analysis for food safety-Food Safety for application-Application by governments</u> (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.</p>	USA
Para. 7	
<p>Within the available analytical methods, molecular methods best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genomic methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)) can result in improved detection of outbreaks with more associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of this methodology is relevant and will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness.</p> <p>Australia suggests amending this text to the following:</p> <p>"Within the available analytical methods, molecular methods best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genomic methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)) can result in improved detection of outbreak, including detection of additional associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of this methodology will likely lead to the detection of more outbreaks and the need for enhanced preparedness."</p>	Australia
<p>Within the available analytical methods, molecular methods best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genomic methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)) can result in improved detection of outbreaks with more associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of this methodology-these methods is relevant and will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness.</p> <p>It is unclear what "this methodology" is referring to in the last sentence. Suggest the type of method that is being referred to is specified or alternatively change to "The increase in the use of these methods (or methodologies) is relevant..."</p>	Canada
<p>Within the available analytical methods, molecular methods best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better</p>	Colombia

<p>identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genomic methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)) can result in improved detection of outbreaks with more associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of this methodology is relevant and will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness.</p> <p>Merging terms, changing to an internationally accepted acronym and modifying the description of the acronym for better understanding, making the changes where applicable to the document.</p> <p>We propose the following wording: In particular, the use of specific genetic typing methods (such as Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)).</p>	
<p>Within the available analytical methods, molecular methods best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genomic methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)) can result in improved detection of outbreaks with more associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of this methodology is relevant and will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness. <u>In particular, the use of genomic methods such as the Polymerase Chain Reaction (PCR) will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness. In addition, the specific methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)) can be used to identify the “genetic fingerprint” of microorganisms involved in outbreaks when the country has the adequate resources to perform it. In order to track and compare the agents involved, we recommend coordinating with the methods indicated by the international CDCs.</u></p> <p>Detection is carried out by Polymerase Chain Reactions (PCR) and not by Pulsed-Field, Sequencing or Multilocus.</p>	Mexico
<p>Within the available analytical methods, molecular methods best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genomic methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)) can result in improved detection of outbreaks with more associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of this methodology is relevant and will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness.</p> <p>(In case that some countries do not have the adequate resources to conduct such modern methods, it is proposed to mention that those countries must get regional/international required support, in order to enable them to better identify batches/lots of food involved and the root cause of the outbreaks; hence reducing the exposure of humans to hazards).</p>	United Arab Emirates
Para. 8	
<p>The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities. There should be consistency at the local and national level with respect to when an outbreak is declared an incident, emergency or crisis.</p>	Colombia

Simplify the wording so as to not make it repetitive. We propose the following: 8. The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities, which should be consistent at the local and national level.	
The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities. There should <u>There must</u> be consistency at the local and national level with respect to when an outbreak is declared an incident, emergency or crisis. "There must" is more of an obligation, while "there should" is a possibility or recommendation.	Mexico
The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities. There should be consistency at the local and national level with respect to when an outbreak is declared an incident, emergency or crisis. (the categorisation method should depend on the following criteria)	United Arab Emirates
Para. 9	
The following criteria may be used by the competent authorities to categorize biological foodborne outbreaks as an incident, emergency, or crisis and develop and adapt response plans. Australia suggests amending this text to the following: "The following factors may be used by the competent authorities to categorize biological foodborne outbreaks as an incident, emergency, or crisis and develop and adapt response plans."	Australia
Para. 9 – bullet points	
<u>6th bullet point</u> 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. Australia suggests amending this text to the following: "Consumer perception (e.g. referring to an outbreak as a "crisis") can affect the consumer confidence in a product or food category that may not clearly belong to the consignment implicated." The following criteria may be used by the competent authorities to categorize biological foodborne outbreaks as an incident, emergency, or crisis and develop and adapt response plans. Australia suggests adding the following dot points to the list: <ul style="list-style-type: none"> o The need to remove or reduce risk to consumers through public health action such as product recall risk communication including media alerts. o Likely exposure and consumption patterns 	Australia
<u>9th bullet point</u> The capacity of the country to quickly react and limit the extent of the outbreak. <u>The source of contamination and the history of the establishment and business.</u>	Mexico

For categorization, it would be useful to know if it is an isolated case or if it has occurred on several occasions.	
<u>1st bullet point</u> The number of eases and cases , the geographic spread of the outbreak, <u>and whether the outbreak is ongoing</u> .	USA
<u>2nd bullet point</u> The disease severity and its consequences consequences , including the number of deaths and treatment options available.	
<u>3rd bullet point</u> The population affected affected , e.g. more vulnerable groups.	
<u>5th bullet point</u> The distribution pattern, <u>whether the contaminated food is still available for sale or consumption, the</u> volumes of the food and national and international trade implications.	
<u>6th bullet point</u> Consumer perception 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.	
<u>3rd bullet point</u> The population affected e.g. more vulnerable groups. add: like infants. young Children or elder persons	ENCA
<u>6th bullet point</u> 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. delete: Consumer protection and health of the consumer is more important then loss of confidence	
<u>9th bullet point</u> The capacity of the country to quickly react and limit the extent of the outbreak. All countries should have the ability to react quickly and protect their consumer	ENCA
Scope Para. 10	
These guidelines provide guidance to competent authorities on the preparedness and management of foodborne outbreaks, including the communication with international networks, such as the International Food Safety Authorities Network (INFOSAN) when it is necessary. The guidance addresses preparedness, detection 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.	Australia

<p>Australia suggests amending this text to the following:</p> <p>"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) 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 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." Australia suggests including the notification to WHO in all places in the document where International Alert Networks are mentioned.</p>	
<p>These guidelines provide guidance to competent authorities on the preparedness and management of foodborne outbreaks, including the communication with international networks, such as the International Food Safety Authorities Network (INFOSAN) when it is necessary. The guidance addresses preparedness, detection 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.</p> <p>and The Global Outbreak Alert and Response Network GOARN A regional networks if available</p>	United Arab Emirates
<p>These guidelines provide guidance to competent authorities on the preparedness and management of foodborne outbreaks, including the communication with international networks, such as the International Food Safety Authorities Network (INFOSAN) when it is necessary. The guidance addresses preparedness, detection and response with the intent of limiting the extent of such outbreaks. They include recommendations on the appropriate use of new analytical technologies 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.</p>	USA
Para. 11	
<p>These guidelines also describe the role of competent authorities at the local, national and and, where applicable, the regional level (e.g., groups of countries) and the collaboration between among them in formalized network structures. Guidelines are included on collaboration and communication with food business operators and other stakeholders before and during foodborne outbreaks outbreaks, as well as on post-outbreak 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.</p>	USA
USE Para. 12 (bullet points)	
<p><i>Principles and Guidelines for the Conduct of Microbiological Risk Assessment</i> (CXG 63-2007, as amended). CODEX CAC/GL 77-2011 Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</p> <p>Add a new bullet point. In point 49 of Analytical Methods, it refers to the Whole Genome Sequencing (WGS), "...which could give AMR information." Therefore, we suggest including the CODEX document CAC/GL 77-2011 Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance.</p>	Mexico

<p><i>Principles and Guidelines for the Conduct of Microbiological Risk Assessment</i> (CXG-30-1999)(CXG-30-1999, as amended). <i>Principles and Guidelines for the Conduct of Microbiological Risk Management</i> (CXG 63- 2007)2007, as amended).</p>	USA
Para. 13	
A number of FAOWHO documents, documents describe in more detail some of the issues presented in this guideline.	USA
DEFINITIONS	
<p>We suggest putting the definitions in alphabetical order for quick user reference.</p> <p>Having the definitions in alphabetical order will help find them faster.</p>	Mexico
<p>For the purposes of this document, the following definitions are applicable:</p> <p>We suggest including the definition for epidemiological georeferencing. Within the geographic information system, the definitions of spatial georeferencing and thematic maps must be considered. Within the geographic information system, the definitions of spatial georeferencing and thematic maps must be considered.</p>	Mexico
<u>Biological hazards</u>	
<p><u>Biological hazards</u>: 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.</p> <p>Australia suggests amending this text to the following:</p> <p>"Biological hazards: Biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include bacteria and algae and their toxins, fungi, viruses and parasites."</p>	Australia
<p><u>Biological hazards</u>: 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<u>parasites and prions</u>.</p> <p>We propose including this since it is part of the biological hazards, due to its significance in the transmission of the variant Creutzfeldt–Jakob disease (vCJD).</p>	Mexico
<u>Case-control study</u>	
<p><u>Case-control study</u>: An observational study in which subjects are enrolled on the basis of presence (cases) or absence (controls) of the foodborne illness of interest. Information is compared between cases and controls.</p> <p>"Information is compared between cases and controls." - It is not clear if it should be statistically, and an OBSERVATIONAL STUDY is defined as being statistical.</p> <p>For more information on the types of OBSERVATIONAL STUDIES, a definition could be included that references literature in which such definition can be found.</p> <p><u>Case-control study</u>: An observational study in which subjects are enrolled on the basis of presence (cases) or absence (controls) of the foodborne illness of interest. <u>Statistical quantitative or qualitative</u> information is compared between cases and controls.</p>	Peru

<u>Case-definition</u>	
<p>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).</p> <p>Comment on the translation to Spanish, to change the translation of “should be” to “debería.”</p>	Peru
<p>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), or, could include a food if one has been identified.</p>	USA
<u>Case-definition</u>	
<p>Operational 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).</p> <p>There are two types of definitions: conceptual and operational. Conceptual definitions come from texts, works or dictionaries. They must set out the gender and characteristics, and differentiation must be by a characteristic or set of characteristics they have. 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. In this case, it is an operational definition.</p>	Mexico
<u>Cohort study</u>	
<p>Cohort study: A type of observational study and analytical investigation, 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.</p> <p>This better clarifies what a Cohort Study is.</p>	Peru
<u>Foodborne outbreak</u>	
<p>Foodborne outbreak: The observed number of cases of a particular illness that may be foodborne exceeds the expected number, OR the occurrence of two or more cases of a similar foodborne illness resulting from the ingestion of a common food and epidemiological analysis implicates the food as the source of the illness. Food-borne disease (FBD) outbreak: An incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiological analyses implicate the food as the source of the illness.</p> <p>More appropriate definition. Source: PAHO, Foodborne diseases https://www.paho.org/es/temas/enfermedades-transmitidas-por-alimentos</p>	Mexico

<u>Lot:</u>	
<p><u>Lot:</u> A definite quantity of ingredients or 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 <u>number-numeric or alphanumeric code</u> by the food business operator. It may also be referred to as a “batch”.</p> <p>When referring to a lot code, the definition of “lot” states that it is a number, however it would be appropriate to state that it is a code that is not always numerical but could also contain other characters such as letters.</p>	Peru
<u>Metadata</u>	
<p><u>Metadata:</u> Data that describe other data. In relation to analytical testing results metadata could be date of sample collection, identification of sample, sample size, product <u>name</u>, sampling site, etc.</p>	Peru
<u>Outbreak analysis</u>	
<p><u>Outbreak analysis:</u> 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.</p> <p>We suggest the following wording: Outbreak analysis: Procedure used to classify the event, in which data is gathered and systematized to allow for describing the affected population according to variables of time, place and person. It must also be analyzed by age, gender, occupation, as well as including the foods and symptoms as needed, and determination of the suspected food by calculating the specific attack rate.</p> <p>Sources: Epidemiological field research and outbreak study http://saludcapital.gov.co/sitios/VigilanciaSaludPublica/Protocolos%20de%20Vigilancia%20en%20Salud%20Publica/Investig%20de%20Campo%20y%20Estudio%20Brotos.pdf</p> <p>PAHO. Surveillance of Foodborne Disease Guide. Investigating outbreaks in persons https://www.paho.org/hq/index.php?option=com_content&view=article&id=10543:2015-capitulo-iii-investigacion-brotos-personas&Itemid=41414&lang=es</p>	Mexico
<p><u>Outbreak analysis:</u> 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.</p> <p>The original text has the Spanish word “comprarla” and it seems like it should be “comparar.”</p>	Colombia
<p><u>Outbreak analysis:</u> 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 <u>comparing it</u> with epidemiological outbreak information.</p>	Peru
<u>Risk communication</u>	
<p><u>Risk communication:</u> The exchange of information on the biological risks among stakeholders (e.g. government, academia, industry, public, mass media and international organizations) outside in the formalized network structures.</p>	Mexico

<p>We suggest the following wording: Risk communication: This refers to the real-time exchange of information, assessments and opinions by experts or officials and the people facing a threat (hazard) to their survival, health, or economic or social well-being. Its ultimate purpose is for everyone who is in danger to be able to make informed decisions to mitigate the effects of the threat, e.g. an outbreak, and to take precautionary and preventive measures. We consider this to be a more appropriate and explanatory text. Source: WHO. Risk communication training https://www.who.int/risk-communication/training/module-b/es/</p>	
<p><u>Risk communication</u>: The exchange of information on the biological risk among stakeholders (e.g. government, academia, industry, public, mass media and international organizations-outside the formalized-network-structuresorganizations).</p> <p>The United States believes that the definition should not limit risk communication to those stakeholders that are not participating in the network structure, as risk communication must also occur within the network. It is fine to talk about “risk communication to stakeholders outside the network” in section E (paragraph 86) without specifying in the definition that risk communication only applies when communicating outside the network. It is clear from the Codex Procedural Manual that risk communication also occurs in the risk management aspects of risk analysis.</p> <p>Specifically, in the 27th Edition of the Codex Procedural Manual, Section IV - Risk Analysis – Definition of Risk Analysis Terms Related to Food Safety, the definition for Risk Communication is: “The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.”</p> <p>Furthermore, under the sub-section for Risk Communication in the 27th Edition of the Codex Procedural Manual, Section IV - Risk Analysis it states the following: (ii): “Risk communication should promote consistency and transparency in formulating risk management options/recommendations (page 126).</p> <p>Its major function should be to ensure that all information and opinions required for effective risk management are incorporated into the decision-making process. (This is also in the Codex Working Principles for Risk Analysis for Food Safety for Application by Governments (CXG 62-2007).</p>	<p>USA</p>
<p><u>Surveillance</u></p>	
<p><u>Surveillance</u>: 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.</p> <p>The definition of “surveillance” could be more aligned with “monitor” as set out in the GENERAL PRINCIPLES OF FOOD HYGIENE (CXC 1-1969): Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.</p>	<p>Peru</p>

<p>Surveillance: A systematic and ongoing 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.</p> <p>The manual tackles foodborne illnesses which need AD-Hoc Surveillances and not the classical surveillance , therefore I recommend defining Ad-hoc Surveillance rather than surveillance</p>	<p>United Arab Emirates</p>
<p><u>Traceability/Product Tracing</u></p>	
<p>Traceability/Product Tracing: The ability to follow the movement of a food through specified stage(s) of production, processing and distribution. Where “Tracing back” refers to following the path towards its origin/source and “Tracing forward” refers to following the path towards its final distribution/point of consumption. <u>Foodborne Illness: Foodborne illnesses are generally infectious or toxic and are caused by bacteria, viruses, parasites or chemical substances that enter the body through contaminated food or water. - One Health: An integrated approach that recognizes that the health of animals, people, plants and the environment is interconnected, and ensures that specialists in multiple sectors work together to tackle health threats to animals, humans, plants and the environment.</u></p> <p><u>- Stakeholder analysis: A process of gathering and qualitative analysis of information to determine what interests or mandates must be taken into account when developing and/or implementing a policy or program. Stakeholders in a process are players (people or organizations) with interest or mandates in the policy or programme being promoted.</u></p> <p>The following definitions will provide better understanding of the following concepts, which are relevant:</p> <p>It is important to include Foodborne Illnesses since the main objective is to prevent them from occurring, which leads us to foodborne outbreaks.</p> <p>Based on the FAO-OIE-WHO tripartite, it is of utmost importance that any issues on public health include this holistic approach to intervention.</p> <p>In management strategy, stakeholder analysis is of utmost importance, to know the players well who will be part of the interventions required for public health problems.</p>	<p>Mexico</p>
<p>Traceability/Product Tracing: The ability to follow the movement of a food through specified stage(s) of production, processing and distribution. Where, <u>where</u> “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.</p>	<p>USA</p>
<p>FOODBORNE OUTBREAKS – PREPAREDNESS SYSTEM Para. 30</p>	
<p>To handle foodborne outbreaks in an effective way it is advisable to have and maintain preparedness structures enabling cooperation between competent authorities. In this section, such structures are described in the form of formalized networks at different organizational levels <u>levels</u>, along with some of the good practices and standard tools to include in the system.</p>	<p>USA</p>
<p>A. CREATION OF FORMALIZED NETWORKS BETWEEN HUMAN HEALTH SECTOR AND FOOD AND VETERINARY SECTORS AT LOCAL AND NATIONAL LEVELS</p>	
<p>CREATION OF FORMALIZED NETWORKS <u>OFFICIAL NETWORKS</u> BETWEEN HUMAN HEALTH SECTOR AND FOOD AND VETERINARY SECTORS AT LOCAL AND NATIONAL LEVELS</p>	<p>Mexico</p>

In management strategy, stakeholder analysis is of utmost importance, to know the players well who will be part of the interventions required for public health problems.	
Para. 32	
At the local level defined networks between contact points from the different relevant authorities/agencies covering the same geographical area should be formed 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.	USA
Para. 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 network , one of the contact points should be designated as the local network contact point in charge of the network.	USA
Para. 34	
The local network contact points should also ensure the timely exchange of information with their respective counterparts in the national network and and , if relevant relevant , with the respective contact points in the other local networks. They should establish channels to engage stakeholders stakeholders , including food business operators, where relevant, in order to exchange information to minimize adverse consequences.	USA
Para. 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 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 , <u>and such authority must manage the safeguarding of information regarding an outbreak on a secure platform.</u> The role of the national network should include: 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.	Mexico
Para. 35 bullet points	
1st bullet point Ensuring that communication channels between network participants at the local and national levels function effectively and efficiently; • <u>Performing a stakeholder analysis in accordance with the WHO.</u> • <u>Issuing guidelines and procedures for the operations of the National Epidemiological Surveillance System.</u> • <u>Establishing the basis and mechanisms for</u>	Mexico

<p><u>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 strengthen the national structure. • _____ Integrating inter-institutional groups in charge of developing and operating surveillance systems for specific programs within the country's health priorities. • _____ Ensuring training, assessment, supervision and evaluation of the surveillance system among the participating departments and entities.</u></p> <p>Stakeholder analysis at the national level will help to identify experts, whether they are institutions or persons who belong to the institutions.</p> <p>We feel it would be appropriate to supplement the framework of competence at the national level.</p>	
<p><u>5th bullet point</u></p> <p>Assessing information received from the other levels and participants of the network as <u>a</u> basis for risk management decisions; and</p>	USA
<p><u>6th bullet point</u></p> <p>Ensuring that communication takes place with regional and international <u>networks-networks</u>, e.g. through the INFOSAN emergency contact points, where necessary.</p>	
Para. 36	
<p>The networks should be based on <u>existing structures</u> 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.</p> <p>More direct wording.</p>	Mexico
<p>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 <u>level-level</u>, 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 <u>areas-areas</u>, 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.</p>	USA

Para. 37	
<p>For the networks to be effective, it is essential that the participants know each other, have familiarity with the system and structures and use them regularly, even in the absence of a foodborne outbreak. It is recommended that participants meet or hold audio-conferences regularly to exchange experiences and best practices, to evaluate the management of past outbreaks and to identify lessons learned</p> <p>Australia suggests amending this text to the following:</p> <p>"For the networks to be effective, it is essential that the participants know who 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-conferences regularly to exchange experiences and best practices, to evaluate the management of past outbreaks and to identify lessons learned." .</p>	Australia
<p>For the networks to be effective, it is essential that the participants know each other, have familiarity with the system and structures and use them regularly, even in the absence of a foodborne outbreak. It is recommended that participants meet or hold audio-conferences <u>and/or videoconferences</u> regularly to exchange experiences and best practices, to evaluate the management of past outbreaks and to identify lessons learned.</p> <p>We suggest adding this word after audio-conferences, since they are used for dealing with and tracking outbreaks.</p>	Mexico
<p>For the networks to be effective, it is essential that the participants know <u>and have rapport with</u> each other, have familiarity with the system and structures and use them regularly, even in the absence of a foodborne outbreak. It is recommended that participants meet or hold audio-conferences regularly to exchange experiences and best practices, to evaluate the management of past outbreaks and to identify lessons learned.</p>	USA
Para. 38	
<p><u>Templates-Forms</u> and standard tools should be <u>shall be</u> developed in advance and included in the standard procedures for the network participants to use. Some of them are listed below.</p> <p>We believe it would be appropriate to list the necessary forms or formats needed for a complete study and proper analysis of a foodborne illness.</p>	Mexico
Para. 38 bullet points	
<p><u>5th bullet point</u></p> <p>template for asking a rapid risk assessment addressed in Section E. and Annex II</p> <p>Australia suggests amending this text to the following:</p> <p>"o template for requesting and undertaking a rapid risk assessment addressed in Section E. and Annex II."</p>	Australia
<p><u>5th bullet point</u></p> <p>template for <u>asking-requesting</u> a rapid risk assessment addressed in Section E. and Annex II.</p> <p>To be consistent with wording used in template.</p>	Canada

<p><u>1st bullet point</u></p> <p>Template(s) for collecting and maintaining updated information describing the outbreak - descriptive epidemiology; • 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.</p> <p>Source: PAHO. Foodborne Disease Surveillance System and Outbreak Investigation Guide. Foodborne Disease Surveillance system forms. https://www.paho.org/hq/index.php?option=com_content&view=article&id=10547:2015-anexo-b-contenido-anexo-b&Itemid=41421&lang=es</p>	Mexico
<p><u>1st bullet point</u></p> <p>Template(s) for collecting-and-collecting, maintaining and reporting updated information describing the outbreak - descriptive epidemiology;</p>	USA
<p><u>2nd bullet point</u></p> <p>standardized questionnaire(s) (including focused food consumption questionnaires) for hypothesis generation purposes;</p>	
<p><u>3rd bullet point</u></p> <p>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;</p> <p>Overall, the United States believes that there is a good amount of emphasis in this document on cohort and case control studies, which can be very resource intensive and slow to conduct. There is absolutely a role for these types of studies, but in our experience, strong descriptive epidemiology along with corroborating traceback and/or testing can get to the right answer faster, more reliably, and with more actionable specificity.</p> <p>The United States thinks the place where cohort or case control studies are absolutely critical is in investigating an outbreak associated with a single event or restaurant where you do not have the opportunity for traceback information to corroborate the epidemiology in the same way you might in a multijurisdictional outbreak.</p>	
<p><u>5th bullet point</u></p> <p>template for asking for a rapid risk assessment addressed in Section E. and Annex II.</p>	
Para. 40	
<p>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:</p>	USA

<p>Various network participants may have limitations imposed on what information they may share with others in the network. Identifying these limitations in advance, developing solutions to work within the information sharing constraints, and determining if information sharing agreements can assist, should be considered.</p> <p>Also, another thought for consideration for addition is agreement on a rhythm for when information is updated. For instance, everyone agrees to release and share updated epidemiological data on specific dates and times to facilitate a coherent national picture of the outbreak, so that the national data and local data are not inconsistent.</p>	
Para. 40 bullet points	
<p>1st bullet point</p> <p>All available information is compiled to form as complete an overview of the situation as possible and kept under review as new information becomes available;</p> <p>More direct wording.</p>	Mexico
<p><u>5th bullet point</u></p> <p>there is a system in place to ensure communication channels remain open (e.g. in the event of infrastructure break down, staff absence, etc.)absence); and</p>	USA
<p><u>6th bullet point</u></p> <p>there is a mechanism in place for the potential use of external experts to reach consensus on and verify the soundness of recommendations givenrecommendations, especially for the national network.</p>	
B. INTERNATIONAL ALERT NETWORKS AND EXCHANGE OF INFORMATION WITH THEM	
Para. 41	
<p>Foodborne outbreaks do not respect borders. <u>Therefore, it is important to implement epidemiological georeferencing methods.</u> What initially seems to be a national outbreak at the outset may in fact be or turn into a regional or global foodborne outbreak <u>more widespread event.</u></p> <p>We propose adding the text on georeferencing to locate the type of instrument used and thematic maps.</p> <p>We propose deleting the text to avoid ambiguity and give a clearer idea.</p>	Mexico
<p>Foodborne outbreaks do not respect borders. What initially seems to be a national outbreak at the outset may in fact be or turn into a regional or global foodborne outbreak.</p> <p>“Initially” and “at the outset” are redundant. Keep one or the other.</p>	USA
Para. 42	
<p>The national level network should have a permanent connection with global networks-networks, e.g. the INFOSAN-INFOSAN, and, where applicable, with regional alert networks. These global 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</p>	USA

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.	
Para. 43	
Information from global networks may be useful for the work of a national <u>network-network</u> , 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.	USA
C. SURVEILLANCE AND MONITORING SYSTEMS (E.G. HUMAN, ANIMAL, FEED, FOOD, ESTABLISHMENT ENVIRONMENT) AND THEIR USE IN FOODBORNE OUTBREAK SITUATIONS	
Para. 44	
<p><u>1st bullet point</u></p> <p>Surveillance and monitoring of the usual situation of human illnesses from biological foodborne hazards.</p> <p>All foodborne illnesses should become notifiable diseases so that an outbreak is immediately noticed Especially Enterobacter Sakazakii/Chronobacter</p>	ENCA
<p><u>4th bullet point</u></p> <p>Analysis (e.g. weekly) of the data in order to detect outbreaks in a timely manner. <u>Communication between government agencies in each state and country.</u></p> <p>Communication between government bodies and between states is very important for effective coordination in managing an outbreak.</p>	Mexico
Para. 45	
Information from surveillance and monitoring <u>of-of, e.g- ,</u> animals, feed, food and environment, including equipment of 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.	USA
D. ANALYTICAL METHODS	
Para. 48	
Validated analytical methods <u>should be-shall be</u> used to isolate and identify causative agents. Traditional analytical methods (such as pathogen isolation) or Polymerase Chain Reaction (PCR) methods used for surveillance and monitoring are essential as the basis for detecting and investigating any outbreak, but often they do not allow 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 such linkage. When further characterization is needed for outbreak investigation purposes, molecular or genetic typing methods can be and are increasingly being used. <u>This is taking into consideration the national and local economic and infrastructure conditions that the official and/or reference laboratories are in. Molecular or genetic typing methods can be used increasingly, such as Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS), and Multilocus Sequence Typing (MLST).</u>	Mexico

<p>It is important to emphasize that the infrastructure conditions of laboratories can change according to the economic and social capacities of each country or region.</p> <p>We suggest adding an example for greater understanding of the general idea behind the paragraph.</p>	
<p>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, serotype may be enough to allow-obtain such linkage. When further characterization is needed for outbreak investigation purposes, molecular or genetic typing methods can be and are increasingly being used.</p>	USA
Para. 49	
<p>Molecular typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA) but in recent years, other genetic based methods like WGS have become widespread worldwide as biological typing tools. WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of the outbreak. The method can also be used to identify genetic differences, virulence factors and antimicrobial resistance mechanisms. The implementation and use of WGS and the analysis of the WGS results require additional resources and capacity compared to other methods.</p> <p>Australia suggests amending this text to the following:</p> <p>"Molecular typing methods include pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA) and other genetic based methods like WGS. WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of the outbreak. The method can also be used to identify genetic differences, virulence factors and antimicrobial resistance mechanisms. The implementation and use of WGS and the analysis of the WGS results require additional resources and capacity compared to other methods."</p>	Australia
<p>Molecular typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA) but in recent years, other genetic based methods like WGS have become widespread worldwide as microbial typing tools. WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of the outbreak. The method can also be used to identify genetic differences, virulence factors and antimicrobial resistance mechanisms. The implementation and use of WGS and the analysis of the WGS results require additional resources and capacity compared to other methods.</p> <p>We propose modifying the description of the acronym for better understanding:</p> <p>49. Molecular typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA),</p>	Colombia
<p>Molecular typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA)-based, but in recent years, other genetic based methods like WGS have become widespread been applied worldwide as biological typing tools. WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of the outbreakan outbreak with a high degree of accuracy. The method can also be used to identify genetic differences, virulence factors and antimicrobial resistance mechanisms. The</p>	USA

implementation and use of WGS and the analysis of the WGS results require additional resources and capacity compared to other methods.	
Para. 50	
<p>When WGS is used, consideration should be given to:</p> <p>The Philippines supports the text “When WGS is used, consideration should be given to:...” This statement implies that WGS is not mandatory. Whole Genome Sequencing (WGS) is relatively new in developing countries and should not be mandatory due to limitations in capabilities and resources.</p>	Philippines
<p><u>2nd bullet point</u></p> <p>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.</p> <p>Australia suggests amending this text to the following:</p> <p>"o 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."</p>	Australia
<p><u>1st bullet point</u></p> <p>Laboratory capability, specific equipment (properly maintained and where applicable calibrated) and personnel trained in implementation of WGS, analysis and interpretation of WGS results.</p> <p>Laboratory equipment must be calibrated.</p>	Mexico
<p><u>1st bullet point</u></p> <p>Laboratory capability, specific equipment (properly maintained and, where applicable, calibrated) and personnel trained in implementation of WGS, analysis and interpretation of WGS results. <u>(Having personnel with expertise in bioinformatics is critical for analysis of sequence data.)</u></p>	USA
<p><u>3rd bullet point</u></p> <p>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 <u>often</u> most useful for comparing results obtained by various analytical methods, including both multilocus sequence typing (MLST)-based and (single-nucleotide polymorphism (SNP)-based approaches.</p> <p>Exchanging large amounts of sequence data and subsequent analysis of data by all concerned may not be a feasible approach for various reasons, including resources and time constraints.</p>	
Para. 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.	Colombia

Proposed wording: “... if the necessary equipment and/or experience is missing.”	
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. (What are the recommendations/ alternatives, in case of these methods are not currently available in some countries?)	United Arab Emirates
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. <u>Creation of regional hubs may be a way to maximise resources.</u>	USA
E. RAPID RISK ASSESSMENT – STRUCTURES FOR ASSESSING RISK	
Para. 52	
A risk assessment during a foodborne outbreak may be useful to provide a sound scientific basis to determine the appropriate risk mitigation actions to be taken. 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). The words “to be taken” are not needed.	Colombia
A risk assessment during a foodborne outbreak may be useful to provide a sound scientific basis to determine the appropriate risk mitigation actions to be taken. 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). We would like to emphasize the importance of the content of the first paragraph we shared.	Uruguay
A risk assessment during a foodborne outbreak may be useful to provide a sound scientific basis to determine the appropriate risk mitigation actions to be taken. In a number of cases, a risk assessment conducted for same or similar <u>pathogen—food pathogen-food</u> 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).	USA
Para. 53	
If a risk assessment conducted for same or similar pathogen - food combinations is not available, there might not be sufficient time to ask for a full assessment of the risk at hand. A simplified version of a risk assessment - a rapid risk assessment - will be more practical. it is recommended to follow the WHO manual on Rapid Risk Assessment of Acute Public Health Events.	United Arab Emirates

<p>If a risk assessment conducted for same or similar pathogen–feed-pathogen-food combinations is not available, there might not be sufficient time to ask for a full assessment of the risk at hand. A simplified version of a risk assessment - a rapid risk assessment - will be more practical.</p>	USA
<p>If a risk assessment conducted for same or similar pathogen - food combinations is not available, there might not be sufficient time to ask for a full assessment of the risk at hand. A simplified version of a risk assessment - a rapid risk assessment - will be more practical.</p> <p>Australia suggests amending this text to the following:</p> <p>"If a risk assessment conducted for 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 simplified version of a risk assessment - a rapid risk assessment - will be more practical."</p>	Australia
<p>If a risk assessment conducted for same or similar pathogen - food combinations is not available, there might not be sufficient time to ask for a full assessment of the risk at hand. A simplified version of a risk assessment—rapid risk assessment —will be more practical.</p> <p>We propose deleting this because in paragraph 26, the term “rapid risk assessment” is already defined.</p>	Mexico
<p>If a risk assessment conducted for same or similar pathogen - food combinations is not available, there might not be sufficient time to ask for a full assessment of the risk at hand. A simplified version of a risk assessment - a rapid risk assessment - will be more practical.</p> <p>We suggest mentioning the disadvantages of rapid risk assessments.</p> <p>Indicate that a major disadvantage in rapid risk assessments is that uncertainty would increase in 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.</p> <p>This is so that they are not overused by wanting to use them in every case.</p>	Mexico
Para. 54	
<p>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.</p> <p>We deleted the word “readily” as it is redundant in rapid assessment.</p>	Peru
Para. 55	
<p><u>1st bullet point</u></p> <p>Lists of risk assessors and experts for specific hazards available with the identification of their area of competence. Include the list of experts and/or government agencies responsible for risk assessment available and identify their area of competence in the stakeholder analysis.</p>	Mexico

<p>It is important to consider that in some countries, places or regions, there are specialized risk assessment agencies, that 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.</p>	
<p><u>5th bullet point</u> Procedures for rapid contact of food business operators<u>operators</u>, including maintaining contact information.</p>	<p>USA</p>
<p>Para. 58</p>	
<p>In terms of risk communication, the preparedness should aim to: We propose new wording: In terms of risk communication, as part of the preparedness, the advisory group or group of experts should aim to: <u>3rd bullet point</u> 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. Delete the Spanish word "de"</p>	<p>Colombia</p>
<p>In terms of risk communication, the preparedness should aim to: <u>* Prevent misinformation and spreading false information or rumors.</u> 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. <u>1st bullet point</u> 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. <u>Deliver information in a coordinated way and only through the official spokesperson.</u> Using an official spokesperson will make it possible to find the official source of rumors.</p>	<p>Mexico</p>

<p><u>1st bullet point</u></p> <p>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-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.</p> <p><u>4th bullet point</u></p> <p>Draft initial messages for the different situations that could potentially arise while specific details can be filled at the moment 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.</p>	<p>USA</p>
<p>FOODBORNE OUTBREAK – MANAGEMENT</p>	
<p>We suggest including or describing how a risk management approach must be carried out. Consider getting the risk committee involved to explain what to do with an identified risk that has been classified and evaluated in order to eliminate, mitigate or control it.</p>	<p>Mexico</p>
<p>Para. 60</p>	
<p>The investigation and control of biological foodborne outbreaks are multi-disciplinary tasks requiring skills and collaboration in the areas of clinical medicine, epidemiology, laboratory medicine, food microbiology, food safety and food control, and risk communication and management among others. 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, of food data (traceability of implicated food data) and laboratory analysis</p> <p>Australia suggests adding detail to this paragraph to outline what the laboratory will be analysing e.g. the implicated food or environmental samples from the primary production and processing environment of the implicated food.</p>	<p>Australia</p>
<p>The investigation and control of biological foodborne outbreaks are multi-disciplinary tasks requiring skills and collaboration in the areas of clinical medicine, epidemiology, laboratory medicine, food microbiology, food safety and food control, and risk communication and management among others. 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, of food data (traceability of implicated food data) and laboratory analysis.</p> <p>We propose adding “consultations.”</p>	<p>Colombia</p>
<p>The investigation and control of biological foodborne outbreaks are multi-disciplinary tasks requiring skills and collaboration in the areas of clinical medicine, epidemiology, laboratory medicineanalysis, food microbiology, food safety and food control, and risk communication and management-management, among others. 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, of food data (#traceability-(data on traceability of implicated food-data)-food) and laboratory analysis.</p>	<p>USA</p>
<p>A. IDENTIFYING AND INVESTIGATING A FOODBORNE OUTBREAK – HUMAN HEALTH</p>	

Para. 62	
<p><u>1st bullet point</u></p> <p>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, <u>•food control authorities that identify a product testing positive for a pathogen and an investigation matches the pathogen to isolates from clinical illnesses, or</u></p> <p>This is becoming a common means of detecting an outbreak.</p>	USA
Para. 64	
<p><u>1st bullet point</u></p> <p>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.</p> <p>Delete the Spanish word "de"</p>	Colombia
<p>Depending on the information available, the public health authorities should-must establish a-an operational case definition. It should-must be used in a systematic and uniform way to identify additional cases and determine the magnitude of the outbreak. The <u>operational</u> case definition may be updated or revised if new or additional information indicate 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:</p> <p>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.</p> <p>It is important to replace "should" with "must," which we recommend throughout the document.</p> <p><u>1st bullet point</u></p> <p>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, <u>the source of the food or food product.</u></p> <p>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.</p>	Mexico
<p>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 <u>indicate-indicates</u> 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:</p>	USA

<p><u>1st bullet point</u></p> <p>On the food items consumed: (if known) the place (the commercial name of the establishment and the exact address) and date of purchase and <u>the</u> time of consumption, method of preparation, brand name, lot/batch code.</p> <p><u>2nd bullet point</u></p> <p>With regards to the affected person: information on travel, animal and environmental exposures, person-to-person contact, disease onset, symptoms, duration, hospitalization, underlying health concerns<u>conditions</u>, etc.</p>	USA
Para. 65	
<p>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. <u>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 suspect vehicle.</u></p> <p>See comment on paragraph 68.</p>	USA
Para. 66	
<p>Other tools that can be used for hypothesis generation to determine the source of attribution in case of a foodborne outbreak include review of surveillance data, or prior sample matches, source attribution studies, historical outbreak data and mathematical modelling. <u>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.</u></p> <p>Several countries, including the United States, use this approach in which the healthy adult consumption acts as a type of control</p>	USA
Para. 67	
<p>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. 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.</p> <p>Cohort studies are longitudinal and prospective, not retrospective.</p>	Mexico
<p>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.</p> <p>Often during outbreak investigations, case-control or cohort studies may be too time intensive or resource intensive. In the United States, to assess the strength of a food vehicle hypothesis, we often compare the proportion of cases in the outbreak reporting that food to background consumption data from a national population survey administered through our FoodNet</p>	USA

<p>program. This allows for a quick assessment of the relative significance of that exposure frequency in the cluster. We have added this point in paragraph 66.</p>	
<p>B. SUBSTANTIATE HYPOTHESIS AND/OR HANDLING OF A FOODBORNE OUTBREAK – FOOD SAFETY (FROM FARM TO FORK)</p>	
<p>Para. 68</p>	
<p>Initial epidemiological investigations (descriptive epidemiology and interviews with a few-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 farms-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 onsite investigation should cover all aspects of the production, storage, transport, handling, distribution and consumption to substantiate if it is possible that the food source or the production conditions are actually the source of the outbreak. If possible, the root cause of contamination should be identified and verification by sampling and analyses should be attempted.</p> <p>Often in the United States, we use several iterative rounds of questionnaires with many cases (not just a few, depending on the size of the outbreak), 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 suspect vehicle. Then there is follow up at the facility or farm then follows to confirm if that food in fact caused the outbreak (confirmation is based on the epidemiologic evidence as well as at least one other line of evidence, either arising from tracing back food exposures from cases to a common source, or laboratory sampling identifying the matching strain of the pathogen in a food product or environment). Open ended interviews are used as more of a last resort when no food item has emerged from the first round of interviews and cases continue to occur. We captured some of this in paragraph 65.</p> <p>In many instances, there is an additional step between the epidemiologic investigation, which may identify a vehicle (romaine lettuce) and the farm investigation – traceback. This step is critical to narrowing down a very broad food vehicle such as romaine to (ideally) a specific farm where it was grown. The United States recommends the inserted text regarding traceback to capture this.</p> <p>In order to get to a site investigation, there would either need to be traceback performed to identify the site, or perhaps product or environmental testing that linked the outbreak strain to that site. In many cases there is a step or two in between hypothesis generation and the site investigation. In the United States we usually refer to that phase as confirming or corroborating the hypothesis. The site investigation can also provide additional evidence for the hypothesis and yield important “root cause” information that could inform future, prevention/mitigation measures.</p>	<p>USA</p>
<p>Para. 69</p>	
<p>When taking a sample, information on the product should include at least product name, comprehensive product description (e.g. animal/fish species, kind of vegetable, fresh, processed, frozen, canned), lot identification, place and date of sampling, in order to allow further investigations including tracing.</p> <p>Philippines proposes the additional text based on FAO’s Risked-Based Food Inspection Manual, emphasizing the importance of proper sampling in ensuring integrity of the sample for laboratory testing.</p> <p>In relation to text in paragraph 69 on sampling, the Philippines proposes additional text/sentence to read: “Knowledge of</p>	<p>Philippines</p>

<p>sampling techniques, particularly aseptic techniques, and of sample handling for transportation to a laboratory are essential to guarantee the integrity of samples taken for verification.”</p>	
<p><u>Sampling of potential food sources and the environment of potential contamination sites can be helpful in substantiating or rejecting a hypothesis.</u> When taking a sample, information on the product should include at least product name, comprehensive product description (e.g. animal/fish species, kind of vegetable, fresh, processed, frozen, canned), lot identification, place and date of sampling, in order to allow further investigations including tracing. <u>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.</u></p> <p>This seems particular to product sampling. The United States often uses environmental sampling (swabs of a processing environment, or soil/water samples on a farm, for example) as part of our response activities. A suggested addition is provided.</p>	<p>USA</p>
<p>Para. 71</p>	
<p>Tracing a food item both back and forward in the food chain is an essential tool in the investigation. Tracing enables the investigators to see the full distribution of the food item e.g. going back from the lot that caused illness to the place/source of initial contamination and identify from that source on, the distribution of all products made with that lot. The following information should be collected:</p> <p>Traceback is also one of the primary tools that the United States uses to confirm a food vehicle hypothesis identified during an epidemiologic investigation, as the cause of an outbreak. By tracing a specific food item back from points of purchase by ill cases to its source, and comparing this information across multiple cases (or even better, subclusters of cases who purchased the product ate at the same restaurant or shopped at the same grocery store), we can confirm that this product was the likely source of the outbreak. The traceback investigation can also be used to identify locations for additional product or environmental sampling (which are important both in confirming the food vehicle as well as root cause analysis).</p> <p><u>2nd bullet point</u></p> <p>Information to identify the root cause of the contamination (raw material status, processing steps that may influence the presence of the microbiological hazard identified<u>identified (including use of rework)</u>, registrations of process and product controls, identified shortcomings, samples analyzed and results etc.)</p> <p>This seems more relevant for a root cause analysis, as opposed to a traceback investigation. The United States would suggest moving this elsewhere. Root cause should be covered in a separate paragraph.</p> <p>The word “shortcomings” is confusing. The United States takes this to mean “opportunities for product contamination,” but request clarification.</p>	<p>USA</p>
<p>Para. 73</p>	
<p>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. <u>This includes preventing the distribution of the contaminated food and removing any contaminated food already in the marketplace.</u> When a recall is identified as the appropriate risk management action, tracing back and tracing forward should be used to remove all lots implicated or suspected to be implicated. The recall should be carried out in the shortest time frame possible by the food business operator to avoid greater impact on public health and the business. The competent authority should monitor the recall to ensure compliance.</p>	<p>USA</p>

<p>Paragraphs 73 and 74 only address recall and communications as a means of controlling an outbreak. Another important aspect to stopping an outbreak is implementing some type of corrective action at the responsible location, to halt the introduction of contaminated product into commerce. In the United States (for U.S. Food and Drug Administration (FDA)-regulated products), this can run the range from a firm voluntarily shutting down and performing a deep clean/root cause analysis themselves, to FDA suspending a firm's ability to ship product or barring them from further manufacturing via an injunction. While we do not think it appropriate to address regulatory actions, it would be appropriate to end this section with a paragraph on determination of root cause and corrective actions to prevent reoccurrence of the problems leading to the outbreak.</p> <p>Once the food causing the outbreak is identified, then the implicated lots of food need to be traced forward. If the situation involves the use of a contaminated ingredient from another source that needs to be traced back and then forward to other foods from businesses that used that ingredient, more discussion would be needed here, but those foods have not been identified as the source of the outbreak</p>	
Para. 74	
<p>Consideration should be given to the actions required by consumers in recalls and businesses in recalls and product withdrawals concerning the suspect lots. Consideration should also be given to provide advice to consumers and/or businesses about appropriate disposition of affected foods and should take into account any potentially associated public health risks.</p> <p>Australia suggests including a sentence about the importance of notifying consumers of a food recall including the use of different communication tools (e.g. social media, media releases, newspapers etc.).</p>	Australia
C. COMBINING EPIDEMIOLOGICAL AND LABORATORY DATA	
Para. 78	
<p>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.</p> <p>Delete the Spanish word "de"</p>	Colombia
<p>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. <u>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.</u> 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. <u>Even with a very small SNP or allele range, it is still critical to confirm that link with epidemiology and traceback data.</u></p> <p>Even in situations where the single nucleotide polymorphisms (SNP) or allele differences are not very close, in theory isolates in the same sequencing tree could still share a common ancestor, just further back in evolutionary time. The United States thinks what this point is getting at is, the more genetically similar two isolates are, the higher the likelihood that they share a very recent source. Therefore, if there are two clinicals that are within a very small SNP or allele range, they probably were exposed to the</p>	USA

<p>same food that made them sick. If a food and clinical isolates are within a very small SNP or allele range, it's more likely that those illnesses were caused by that food. However, even with a very small SNP or allele range, it's still critical to confirm that link with epidemiology and traceback data. We have seen multiple instances of product or environmental isolates that are virtually identical to clinical isolates, but ultimately did not cause the illness in those particular individuals.</p>	
<p>Para. 79</p>	
<p>The use of databases containing comparable molecular based testing results from e.g. humans, animals, feed, food and establishment environmental sampling, <u>may</u> facilitates the detection and assessment of outbreaks and informs the search for the source of the contamination.</p> <p>Suggest "may" is added to be less definitive</p>	<p>Canada</p>
<p>The use of databases containing comparable molecular based testing results from 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.</p>	<p>USA</p>
<p>Para. 80</p>	
<p><u>4th bullet point</u></p> <p>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 hazard causes illness with a long incubation in humans or the food source has a very limited shelf life (e.g. fresh berries).</p> <p>Australia suggests amending this text to the following: "o 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 hazard causes illness with a long incubation in humans or the food source has a very limited shelf life (e.g. fresh produce)."</p>	<p>Australia</p>
<p><u>While robust obust</u> epidemiological evidence can be sufficiently indicative of a foodborne outbreak even without positive laboratory results from sampling to warrant an outbreak response. Efforts, efforts by sampling and analysis should be made to allow laboratory results to support the epidemiological evidence. Laboratory <u>However, laboratory</u> confirmation can be difficult to achieve for several reasons, e.g.</p> <p>To better connect the concepts under discussion.</p>	<p>Canada</p>
<p><u>1st bullet point</u></p> <p>Biological contaminants in food are not likely to be evenly distributed,</p> <p>Align the terms in the document: Biological hazards that contaminate food are not likely to be evenly distributed,</p>	<p>Colombia</p>
<p><u>2nd bullet point</u></p> <p>The level of contamination may be low hence the chance for detection is limited,</p>	<p>Peru</p>

<p>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 allow-obtain laboratory results to support the epidemiological evidence. Laboratory confirmation can be difficult to achieve for several reasons, e.g.</p> <p>The United States agrees with this first sentence. We frequently initiate outbreak investigations based on epidemiologic hypotheses alone. A positive laboratory result may help confirm the outbreak vehicle, but it is not required in order to initiate an investigation.</p> <p><u>2nd bullet point</u></p> <p>the level of contamination may be low-low, hence the chance for detection is limited,</p>	<p>USA</p>
<p>Para. 81</p>	
<p>Analytical evidence on the other hand should always be supported by some epidemiological information such as that obtained from interviewing human cases, as a match between food and human isolates may not necessarily mean that the food is the actual source of the illness.</p> <p>Molecular testing between food and human isolates are performed based on epidemiological criteria rather than by matching genetic similarities that may be found. We propose the following wording: to perform molecular testing between food and human isolates and establish the possible existing genetic relationships.</p>	<p>Colombia</p>
<p>Analytical evidence-evidence, on the other hand-hand, should always be supported by some epidemiological information such as that obtained from interviewing human cases, as a match between food and human isolates may not necessarily mean that the food is the actual source of the illness.</p>	<p>USA</p>
<p>Para. 82</p>	
<p>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. <u>To this end, it would be good to encourage collaboration between public health and food manufacturers on sharing molecular data from ingredients and specific foods, which can help with hypothesis generation and potentially lead to more quickly identifying the source of an outbreak.</u></p>	<p>USA</p>
<p>D. RAPID RISK ASSESSMENT AND OUTBREAK ANALYSIS— DURING A FOODBORNE OUTBREAK</p>	
<p>Para. 83</p>	
<p>A rapid risk assessment is useful when answers to specific questions are needed. 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. We would like to emphasize the importance of the content of the first paragraph we shared.</p>	<p>Uruguay</p>

Para. 84	
<u>1st bullet point</u> Ensure that the most recent information is available to the risk assessors; Delete the Spanish word "de"	Colombia
Para. 85	
An outbreak analysis is a prognosis in an outbreak situation and is based on historical data and data generated in the outbreak 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 (see template in Annex III for more details): Delete "outbreak" so it is not redundant. <u>5th bullet point</u> 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. Change the Spanish word "de" to "que"	Colombia
An outbreak analysis is a prognosis in an outbreak situation and is based on historical data and data generated in the outbreak 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 <u>the following</u> (see template in Annex III for more details): <u>5th bullet point</u> analyses of <u>detected</u> hot spots (geographical areas or events with more than usual occurrence within the <u>outbreak</u>) detected outbreak , guiding further investigations;	USA
E. RISK COMMUNICATION	
Para. 87	
<u>5th bullet point</u> Do not withhold information just because it may be upsetting. If information is lacking or cannot be released, it is important to explain the cause (where known) and what is being done to address 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. Australia suggests amending this text to the following: "o Do not withhold information because of a perception that it may be upsetting. If information is lacking or cannot be released, it is important to explain the cause (where known) and what is being done to address the situation. Information gaps	Australia

<p>that will be addressed in the future should be identified and stakeholders should be informed on the likelihood of additional communication."</p>	
<p><u>1st bullet point</u> 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. Delete the Spanish word "de" <u>5th bullet point</u> Do not withhold information just because it may be upsetting. If information is lacking or cannot be released, it is important to explain the cause (where known) and what is being done to address 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. Delete the Spanish word "de"</p>	<p>Colombia Colombia</p>
<p><u>1st bullet point</u> Have one official communicator to speak to the public whenever practical. When more than one competent authority communicates with the public-public, the authorities should ensure the messages are consistent. <u>3rd bullet point</u> Acknowledge any uncertainties and make it clear that the recommendations are based on the best information available at the time. If there is a need to change the recommendations in the future, it is important to remind the public that earlier recommendations were based on information known at that time and explain why the recommendations were <u>have been</u> changed. <u>9th bullet point</u> <u>Establish a</u> 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. <u>Consider non-traditional platforms used/trusted by specific subpopulations.</u></p>	<p>USA</p>
<p><u>9th bullet point</u> 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. This platform should be accessible through different ways not to exclude consumers which are less literate or have no internet access.</p>	<p>ENCA</p>
<p>F. DOCUMENTATION OF THE OUTBREAK AND LESSONS LEARNED</p>	
<p>Para. 89</p>	

<p>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 <u>booksbooks or electronic records</u>, 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. <u>Inspectional and laboratory information, as well as any regulatory actions taken should also be kept.</u> The record should be updated as needed while the foodborne outbreak is ongoing and in a <u>way-way</u> 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.</p> <p>The United States is not sure what the difference is for an “outbreak report” and a “summary outbreak report.” Please provide a brief explanation of the difference between the two.</p>	USA
Para. 90	
<p>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. <u>Procedures should be in place to protect confidentiality of people affected by the outbreak.</u></p>	USA
Para. 92	
<p>Outbreaks of special interest should be considered for <u>presentations in national and international scientific forums and</u> 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.</p>	USA
G. POST OUTBREAK SURVEILLANCE	
<p>POST OUTBREAK SURVEILLANCE</p> <p>Consumers should receive communication on the steps taken and on any outcomes as well as further investigations on the source of the outbreak</p>	ENCA
<p><u>OUTBREAK AND POST OUTBREAK SURVEILLANCE</u>POST-OUTBREAK SURVEILLANCE</p> <p>This paragraph is titled “post outbreak” but seems to be describing activities that should occur during the on-going investigation before the outbreak is over and post outbreak activities commence.</p>	USA
Para. 94	
<p>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, <u>if known,</u> (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.</p> <p>It is quite possible that such data may not be available in many countries with limited resources.</p>	USA
MAINTENANCE OF THE NETWORKS	
A. REVIEW OF EXISTING PREPAREDNESS	

Para. 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. An “after action review system” for foodborne outbreaks should be implemented within the network. The results of such reviews should be documented and areas for improvement addressed to support capability and capacity of the system in place. Delete the Spanish word "de"	Colombia
B. IMPLEMENTATION OF LESSONS LEARNED	
Para. 97	
The evaluation of preparedness systems can include reviews of major, serious or rare foodborne outbreaks. The evaluation should include personnel from various authorities/agencies <u>authorities/agencies</u> , and if possible <u>possible</u> , 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.	USA
Para. 98	
The review could also consider whether changes may be needed to the way a food is processed (<u>e.g. implementation of preventive strategies</u>) or whether regulatory oversight or other regulatory change is needed to prevent future outbreaks.	USA
Para. 99	
<u>2nd bullet point</u> What were some of the most difficult challenges faced and how were they overcome <u>overcome (or not)</u> ?	USA
<u>3rd bullet point</u> What changes, if any, to the national structure, procedures or analytical methods are recommended? Delete the Spanish word "de"	Colombia
C. JOINT TRAINING ON FOODBORNE OUTBREAK PREPAREDNESS AND MANAGEMENT	
Para. 102	
<u>2nd bullet point</u> Learning and 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. Delete the Spanish word "de"	Colombia

<p><u>2nd bullet point</u></p> <p>Learning and development <u>Learning/development</u> exercises are more organized <u>organized</u>, 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.</p>	<p>USA</p>
<p>Para. 103</p>	
<p>The exercise type should be varied to include exercises concerning the procedures in place (procedural exercises), exercises addressing specific difficult issues/topics and crisis management exercises. The exercises can be done both in a live environment like a laboratory or in a table-top <u>tabletop</u> form.</p>	<p>USA</p>
<p>Annex I</p>	
<p>[1. In the National Network, include Regional and Local Authorities. Comment: In our country's structure, there is this type of decentralization and the information they have on foodborne outbreaks must be obtained.</p>	<p>Peru</p>
<p><u>GENERAL COMMENT</u> Suggest the line in the arrow between National network and Regional Network is dotted (- - -) rather than solid as not all countries report to a regional network. A key could be added to indicate that the dotted line represents "where applicable". EDITORIAL Suggest INFOSAN is cited as an example of an international network. To mirror format of description for Regional Networks</p>	<p>Canada</p>
<p>Based on the fact that INFOSAN appears many times in the text as a mechanism for international information exchange, and the results of the November meeting, We think that E.g. INFOSAN should be added to the figure INTERNATIONAL NETWORKS ORGANIZATION.</p>	<p>Japan</p>
<p>The example of international networks organizations should also be included such as the International Health Regulations (IHR), International Food Safety Authority Network (INFOSAN). Furthermore, the regional networks/organizations should include the Regional WHO, and Regional FAO.</p>	<p>Thailand</p>

Annex II	
<p><u>Examples of requests for rapid risk assessments</u></p> <p>Australia suggest that it may be more appropriate to align these with the approach in the WHO rapid risk assessment guidelines which includes a broader review of the whole situation including hazard assessment, exposure assessment and context assessment.</p> <p>WHO rapid risk assessment of acute public health events https://www.who.int/csr/resources/publications/HSE_GAR_ARO_2012_1/en/</p> <p>Australia suggests in the table above to include a question about when 'bacteria Y' has been linked to foodborne outbreaks in the past. This may assist in determining the potential implicated food and where in the supply chain the contamination event may have occurred.</p>	<p>Australia</p>
<p><u>General Comment:</u></p> <p>It appears that the purpose of Annex II is to provide examples of how a request for a rapid risk assessment could be phrased. However, it gives no guidance on the type of information to be provided to the risk assessor. Suggest that the annex is expanded to include examples of the type of information to be provided, e.g. the questions on the food investigation findings that are covered in the outbreak analysis annex, or a reference to Annex III is included.</p> <p><u>The outbreak agent has been detected in an unopened sample of the “food item x” acquired in a private household. An unopened sample of the “food item x” acquired in a private household has been tested positive with the outbreak agent.</u> Is it likely that other items of the same food may carry the same risk? – in other words is the production and storage requirements of this food item described</p> <p>A certain strain of “bacteria Y” is causing an outbreak that is suspected of being foodborne. The strain is<u>has</u> not been previously seen in food items, but a closely related strain has been detected in a feed sample. To<u>An assessment of the strain relatedness and stability in the environment could be able requested to conclude whether a reservoir determine if there could be a reservoir</u> in the husbandry sector using the feed in question an assessment on the strain relatedness and stability in the environment could be asked<u>question.</u></p> <p>A certain strain of “bacteria Y” is causing an outbreak that is suspected of being foodborne. The strain is<u>has</u> not been previously seen in food items. What is the most likely reservoir for this bacteria Y? What may be the most likely production(s) that this bacteria<u>bacterium</u> may be found in?</p>	<p>Canada</p>

<p>The scope of a rapid risk assessment is to answer a specific question or assess a specific risk item in relation to an outbreak. Since not all outbreaks will require a rapid risk assessment, it is necessary to clarify in which cases such a request is required. Therefore, we recommend clarifying that it is only when there is a need to answer a specific question or assess a specific risk item in relation to an outbreak for which additional information is required. We propose the following wording: (...) The scope of a rapid risk assessment is to answer a specific question or assess a specific risk item, for which additional information is required for decision making in relation to the outbreak.</p> <p>Considering the information on the epidemiological investigation of the outbreak in question, prior to the request, the need for a rapid risk assessment must be assessed, primarily when there is no knowledge on how to properly address it or if it is a situation that will result in a national or international alert. (...)</p> <p>Related to the suspected food item, a production process etc.</p> <p>Since the scope is to answer a specific question or assess a specific risk item, we recommend modifying the wording of the text referenced in the table. Proposed wording: If the question is related to the suspected food item, a production process etc.</p> <p>Related to the agent causing the outbreak Proposed wording: If the question is related to the agent causing the outbreak</p> <p>Related to the use of certain food items and consumer eating habits Proposed wording: If the question is related to the use of certain food items and consumer eating habits</p>	<p>Colombia</p>
<p>A certain strain of “bacteria Y” is causing an outbreak that is suspected of being foodborne. The strain is not previously seen in food items, but a closely related strain has been detected in a feed sample. To be able to conclude whether a reservoir could be in the husbandry sector using the feed in question an assessment on the strain relatedness and stability in the environment could be asked.</p> <p>We thought that the RRA also needs to take into account the magnitude of harm caused by pathogenic substances.</p>	<p>Japan</p>
<ol style="list-style-type: none"> 1. Suspected food item. Include the following question: Has the product been consumed directly or mixed with other foods? Comment: To determine if the mixture triggered the outbreak. 2. Related to the agent causing the outbreak. Include the following question: Could the bacteria have come into contact with the product from the packaging used? Comment: In order to rule out that the bacteria came in the product or was due to a subsequent contamination from the packaging. 3. Was the person in charge of preparation in good health during the preparation? Did they have any symptoms and did they wash their hands after doing any activities other than food preparation? Comment: In order to rule out that the cause of recontamination is the staff preparing or serving the food. 4. Was the packaging sealed, or did it have any dents or micro leaks? Comment: In order to rule out that the cause of recontamination was via the packaging. 5. Consumer eating habits. Include the following question: Are frozen products (in this case, frozen fruits or vegetables) consumed directly after thawing or do they require further processing? Comment: Processing conditions have more requirements when the product is for direct consumption. 6. How was the product thawed and how much time elapsed before it was processed further? Comment: Due to the possibility of microorganism growth. 	<p>Peru</p>

7. When the products were unpackaged, did the person preparing the food comply with good hygiene practices? Comment: Due to the possibility of recontamination by the food handler.

An unopened sample of the “food item x” acquired in a private household has been tested positive with the outbreak agent. 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? [3. Has the product been consumed directly or mixed with other foods?](#)

To be able to determine if the mixture triggered the outbreak.

“Bacteria Y” is causing an outbreak and 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. Could the bacteria have come into contact with the product from the packaging used?](#) [7. Was the person in charge of preparation in good health during the preparation? Did they have any symptoms and did they wash their hands after doing any activities other than food preparation?](#) [8. Was the packaging sealed, or did it have any dents or micro leaks?](#)

6. In order to rule out that the bacteria came in the product or was due to a subsequent contamination from the packaging.

7. In order to rule out that the cause of recontamination is the staff preparing or serving the food.

8. In order to rule out that the cause of recontamination was via the packaging.

[9.](#) 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 insufficient to avoid growth of *Listeria monocytogenes*? [10. Are frozen products \(in this case, frozen fruits or vegetables\) consumed directly after thawing or do they require further processing?](#) [11. How was the product thawed and how much time elapsed before it was processed further?](#) [12. When the products were unpackaged, did the person preparing the food comply with good hygiene practices?](#)

10. Processing conditions have more requirements when the product is for direct consumption. 11. Due to the possibility of microorganism growth. 12. Due to the possibility of recontamination by the food handler.

<p>An unopened sample of the “food item x” acquired in a private household has been-tested positive with the outbreak agent. Is it likely that other items of the same food may carry the same risk? —in—(lin other words is-are the production and storage requirements of this food item described sufficient to eliminate the specific risk?)</p> <p>A certain strain of “bacteria-“bacterium Y” is causing an outbreak that is suspected of being foodborne. The strain is-has not previously been seen in food items, but a closely related strain has been detected in a feed sample. To be able to conclude whether a reservoir could be in the husbandry sector using the feed in question an assessment on the strain relatedness and stability in the environment could be askedrequested.</p> <p>A certain strain of “bacteria-“bacterium Y” is causing an outbreak that is suspected of being foodborne. The strain is-has not previously been seen in food items. What is the most likely reservoir for this-bacteria-Ythese bacteria? What may be the most likely production(s) that this-these bacteria may be found in?</p> <p>The United States would like additional clarification on what this means. Since the strain has not been seen in food, there is no information that would really lead to an answer to this question. Is the question really “ Based on how this food is produced, are their other products at risk for contamination with these bacteria?”</p> <p>Note “bacteria” is plural; the singular is “bacterium.”</p> <p>“Bacteria-“Bacterium Y” is causing an outbreak and-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?</p> <p>An outbreak caused by <i>Listeria monocytogenes</i> 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 insufficient-inadequate to avoid growth of <i>Listeria monocytogenes</i>?</p>	<p>USA</p>
<p>Annex III</p>	
<p><u>Investigating of human cases</u></p> <p>Australia suggests amending dot point 2 to the following:</p> <p>"• outbreaks in the past at local, national, regional or international level."</p>	<p>Australia</p>
<p>Questions like the following should be answered: How was the outbreak initially detected? <u>Are there any common foods identified as being consumed by the cases?</u> 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?</p> <p>Often in outbreak investigations, there may be no obvious potential food source that is common to the cases or there are several. As such, suggest the inclusion of a question about common foods.</p> <p><u>Investigations in food</u></p> <p>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)</p>	<p>Canada</p>

<p>Suggest the order of the information is adjusted as trace back activities often have to occur first to determine if there are any commonalities between the suppliers/growers of the food item consumed by the cases.</p> <p>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) <u>o Have any common suppliers of the food of interest been identified?</u></p> <p>Suggest the inclusion of a question on relating to common suppliers of interest as on occasion although common food items are reported by cases, trace back activities (from the various stores or for the brands identified) may not always lead to common suppliers being identified.</p> <p>Assessing if the distribution of the suspected food item can explain the outbreak (areal distribution, amount of the food on the market in relation to the distribution and number of cases in the outbreak)• <u>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)</u></p> <p>Has the strain been seen previously? +<u>If</u> yes, please describe <u>further</u> the time, place etc. further. If isolates are available for comparison, sample identification should be provided.</p> <p>Linking epidemiological <u>food trace back</u> and laboratory data in humans and food</p> <p>Suggest the title of this section is amended to more accurately describe the information to be captured in the diagram.</p> <p>If data is not available, it should be clearly stated when asking for the assessment as the missing data may be vital for the outcome of the assessment.</p> <p>It is unclear whether “assessment” is referring to the “outbreak analysis” or the “rapid risk assessment”.</p> <p>Overview of involved geographic areas/jurisdictions at local, national or regional level. Overview of human cases reported including hospitalisations and deaths</p> <p>“Overview of human cases reported including hospitalisations and deaths” should be captured on a new line rather than immediately following the first sentence as it is a separate concept.</p> <p>Short and clear communication message to consumers (recommendations on buying and preparing food), affected operators, other stakeholders and trade partners, including possible uncertainties<u>uncertainties where applicable</u>.</p> <p>“Where applicable” is added to the sentence on communications as public communication may not always undertaken for all outbreak investigations depending on the findings.</p> <p>Should<u>Could</u> more cases be expected in near future or can it be assumed that the outbreak is over?</p>	
<p>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.</p> <p>Delete the Spanish word "de"</p>	<p>Colombia</p>

<p>Data gaps <u>Uncertainties on the existing data</u> should be identified <u>indicated</u> (e.g. establishments to which the affected food was sent, but where there is no information on investigations carried out in that establishment).</p> <p>Information on consumer behaviour and eating habits, e.g., not following the manufacturer's instructions for storage (e.g., refrigerate, use-by date) or cooking not intended by the manufacturer to achieve food safety.</p> <p>Information on consumer behaviour and eating habits, e.g., not following the manufacturer's instructions for storage (e.g., refrigerate, use-by date) or cooking not intended by the manufacturer to achieve food safety. <u>How much time lapsed between preparation and consumption?</u></p> <p>Information on consumer behaviour and eating habits, e.g., not following the manufacturer's instructions for storage (e.g., refrigerate, use-by date) or cooking not intended by the manufacturer to achieve food safety.</p> <p>Include unintended use.</p>	Peru
<p>Based on the study on Foodborne Disease Outbreaks in the Philippines from 2005-2018, most foodborne outbreaks occurred during household and community gatherings such as birthdays, fiestas, Christmas parties, and the like.</p> <p>Include additional background information on possible significant family or community event that may have been an opportunity for outbreaks to occur (e.g. birthdays, fiesta, Christmas parties etc.)</p>	Philippines
<p>Other descriptive information available of the outbreak size and areal distribution <u>distribution area</u>.</p> <p>Overview of human cases reported including hospitalisations <u>severity of illness (hospitalisations, Hemolytic uremic syndromes (HUS), fetal loss</u> and deaths – the severity of the illness.</p> <p>It is unclear why this is not part of the outbreak information</p> <p>Questions like the following should be answered: How was the outbreak initially detected? <u>Has a food been implicated?</u> 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?</p> <p>Historical data, not related to the ongoing outbreak, on the hazard <u>hazard</u>, e.g.;</p> <p>outbreaks in the past at local, national <u>national</u>, regional <u>regional</u>, or regional <u>international</u> level.</p> <p>hypotheses generating interviews • <u>food exposures that appear higher than expected based on available surveys of food consumption habits</u> • <u>subcultures where two or more cases not part of the same family ate at the same event, restaurant, etc.</u></p> <p>Assessing if the distribution of the suspected food item can explain the outbreak (areal distribution <u>distribution area</u>, amount of the food on the market in relation to the distribution and number of cases in the outbreak)</p> <p>Information on consumer behaviour and eating habits, e.g., not following the manufacturer's instructions for storage (e.g., refrigerate, use-by date) or <u>for the</u> cooking not intended by the manufacturer to achieve food safety.</p> <p>Has the strain been seen previously? <u>If</u> yes, please describe the time, place etc. further. If isolates are available for comparison, sample identification should be provided.</p>	USA

If a specific production or process is suspected to be the source of the ~~outbreak-outbreak~~, a detailed description of the ingredients, their treatment, production processes etc. need to be described / documented to assess ~~if-whether~~ deviations in the production may be implicated.

An attempt should be made to graphically present and link the data from human cases, retailers, distributors, processors ~~until~~ ~~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-added~~, and a single-linkage tree including all human and non-human ~~isolates,-isolates~~ should be made, illustrating the core gene allelic differences.

If data /information is necessary for the assessors but not yet ~~available-available~~, it should be indicated when the data will be available.

If data ~~is-are~~ not available, ~~it-this~~ should be clearly stated when asking for the ~~assessment-assessment~~, as the missing data may be vital for the outcome of the assessment.

Overview of involved geographic areas/jurisdictions at local, national or regional level. Overview of human cases ~~reported~~ ~~reported~~, including hospitalisations and deaths.

Short and clear communication message to consumers (recommendations on buying and preparing food), affected operators, other stakeholders and trade partners, including possible uncertainties.

Should more cases be expected in near future or can it be ~~assumed-assumed/stated~~ that the outbreak is over?