

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 7

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

Fiftieth Session

**Cleveland, Ohio, United States of America
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PROPOSED DRAFT GUIDANCE FOR THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

Comments at Step 3 in reply to CL 2019/71-FH

*Comments of Argentina, Canada, Colombia, Gambia, Iraq, Japan, Morocco Nicaragua, Peru, Thailand
United States of America, Collagen Casings Trade Association (CCTA)*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2019/71-FH issued in September 2019. 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.

ANNEX I

GENERAL COMMENTS	
Translation: Argentina believes that throughout the entire document, the word guarantee should be replaced with contribute when referring to the Health Authority, or ensure , as the case may be.	Argentina
we are agree with draft guidance and we have no comments.	Iraq
Nicaragua thanks Denmark, Chile, the European Union, and the participants of the eWG for drafting the document.	Nicaragua
In comparison with the draft during CCFH50, the text is much improved. However, we still have some comments and questions for clarification.	Thailand
<p>The United States appreciates the efforts of the electronic working group (EWG) to revise this document. We find that it has significantly improved, but we note there are issues yet to be resolved.</p> <p>Templates and standard tools.</p> <p>Paragraph 37 indicates that templates and standard tools should be developed in advance and included in the standard procedures for network participants to use. The United States agrees with this and the bulleted list of these. However, we disagree that there is a need to indicate in this document that examples can be found in Annex 3, 5 and 6 of the WHO “Foodborne Disease Outbreaks: Guidelines for Investigation and Controls.” As we commented to the EWG, there are many excellent templates available (including those provided by the U.S. Centers for Disease Control and Prevention). We recognize that providing this information does not mean that countries must use the templates, but we think including only these examples could limit the flexibility in developing templates and could limit countries from looking for other examples that may be more relevant or useful.</p> <p>Template for “rapid risk assessment.”</p> <p>In our comments on last year’s document, the United States questioned the purpose of and need for a rapid risk assessment and when it would be used, noting that it was possible that a template could help clarify our questions. This “template” has been included in Annex III of the document. It is unclear how the template in Annex III is a “risk assessment;” the annex seems to be a compilation of information on the status of an ongoing outbreak. We do think this annex is useful; however, we had recommended using the term “outbreak assessment” last year, and it would appear to still be a more appropriate term for this template. Note that changes in this terminology will also be needed in the Section E on Rapid Risk Assessment – Structures for Assessing Risk</p> <p>Graphical structure of the network. We are not opposed to including Annex II in this document, although we recommend looking at how the local networks are connected graphically to the text above, as it appears that Local Networks 1 and 2 connect to the circle and the first box and Local Networks 2 and 3 connect to the stakeholders box.</p> <p>References to Codex and FAO/WHO documents.</p> <p>References to FAO/WHO have been moved to an annex. However, questions remain about the status with respect to WTO for these documents that were not developed for CCFH. In particular, we note that paragraph 13 refers to the FAO/WHO documents as “supplementary texts” that can be considered for “details on and clarification of specific aspects,” which would seem to give these documents Codex status. When the United States raised the question at CCFH50 about the status of these reference documents in the context of how they were included, the Secretariat indicated that there was currently no specific rule in Codex on this but noted that references to external documents should be kept to a minimum and inclusion be considered on a case-by-case basis. She also reminded the Committee that the relevant information could be incorporated into the draft guidance, with the objective of removing the references in the final text. It would appear that the information needed from the FAO/WHO documents has now been included in the text, removing the need to refer to the FAO/WHO documents. Of the list of FAO/WHO documents in Annex I, only two are specifically mentioned in the document (e.g., paragraph 9 with respect to an example for categorizing outbreaks and paragraph 37 with respect to examples of templates). We believe that the text can be revised to eliminate the need for these remaining references. The references could be considered as an information document if necessary.</p>	USA

SPECIFIC COMMENTS	
INTRODUCTION	
Paragraph 1	
<p>Foodborne illnesses encompass a wide spectrum of illnesses and are a growing public health problem worldwide. They are the result of ingestion of foodstuffs contaminated with microorganisms (biological foodborne illness) or chemicals (chemical foodborne illness). The contamination of food may occur at any stage in the process from food production to consumption (“farm to fork”) and can result from <u>fecal contamination, cross contact or</u> environmental contamination, including pollution of via water, soil or air.</p>	<p>Canada As currently written it is limited to one potential source. We suggest including other sources of contamination.</p>
<p>Foodborne illnesses encompass a wide spectrum of illnesses and are a growing public health problem worldwide. They are the result of ingestion of foodstuffs contaminated with pathogenic microorganisms (biological foodborne illness) or chemicals (chemical foodborne illness). The contamination of food may occur at any stage in the process from food production to consumption (“farm to fork”) and can result from environmental contamination, including pollution of water, soil or air.</p>	<p>Colombia</p>
<p>Foodborne illnesses encompass a wide spectrum of illnesses and are a growing public health problem worldwide. They are <u>often</u> the result of ingestion of foodstuffs contaminated with microorganisms (biological foodborne illness) or chemicals (chemical foodborne illness)<u>pathogenic microorganisms</u>. The contamination of food may occur at any stage in the process from food production to consumption (“farm to fork”) and can result from environmental contamination, including pollution of water, soil or air.<u>consumption</u>.</p>	<p>USA These changes limit the paragraph to microbial pathogens, since the document is on the management of biological foodborne outbreaks, not chemical ones. We also think that the end of the paragraph sounds more like chemical contamination (“pollution” is often associated with chemicals). We think the term “farm to fork” is trite and not needed.</p>
Paragraph 3	
<p>Biological foodborne outbreaks e.g. when the illness affects more people due to a common source, can have significant socio-economic costs related to hospitalization and medical treatment, lost productivity and can affect tourism. For food businesses, the consequences can be lost markets, loss of consumer confidence, litigation and company closures. Such foodborne outbreaks can cause impediments to domestic production and international trade. Globalization of the food supply has led to the rapid and widespread international distribution of foods, further increasing opportunities for pathogens being inadvertently introduced into many geographical areas.</p>	<p>Canada Recommend removing the deleted portion as indicated as foodborne outbreaks is defined in the definition section</p>
<p>Biological foodborne outbreaks, e.g. when the illness affects more people than one person due to a common source, can have significant socio-economic costs due to hospitalization and medical treatment, lost productivity and effects on tourism. For food businesses, the consequences can be lost markets, loss of consumer confidence, litigation and company closures. Such foodborne outbreaks can cause impediments to domestic production and international trade. Globalization of the food supply has led to the rapid and widespread international distribution of foods, further increasing opportunities for pathogens to be inadvertently introduced into many geographical areas.</p>	<p>Colombia</p>
<p>Biological foodborne outbreaks e.g. when the illness affects more people due to a common source, can have significant socio-economic costs related to hospitalization and medical treatment, lost productivity and can affect effects on tourism. For food businesses, the consequences can be lost markets, loss of consumer confidence, litigation and company closures. Such foodborne outbreaks can cause impediments to domestic production and international trade. Globalization of the food supply has led to the</p>	<p>USA The “e.g.” phrase is not needed, since “foodborne outbreak” is defined. Change at the end allows each of the points to complete the term “related to.”</p>

<p>rapid and widespread international distribution of foods, further increasing opportunities for pathogens being inadvertently introduced into many geographical areas.</p>	
<p>Paragraph 4</p>	
<p>Codex Alimentarius has issued several guidelines on hygienic practices for food businesses and competent authorities on how 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>Canada</p>
<p>Paragraph 5</p>	
<p>In order to handle biological foodborne outbreaks efficiently, local and national multiagency networks of preparedness should be in place. Such networks should use comparable methods and interpretations interpretations to facilitate a common understanding and a consistent approach to these situations. Cooperation and transparent exchange of information through international networks is also essential and should be a feature of any network.</p>	<p>Canada We propose new text to explain why this is recommended.</p>
<p>In order to handle biological foodborne outbreaks efficiently, local and national multiagency networks of preparedness should be in place. Such networks should use comparable methods and interpretations interpretations to the extent possible. Cooperation and transparent exchange of information through international networks is essential and should be a feature of any network.</p>	<p>USA Provides flexibility.</p>
<p>Paragraph 7</p>	
<p>Among the available analytical methods, molecular methods best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the impact of actions taken and the exposure of humans to the hazard. In particular, the use of specific genomic-genotypic methods (such as pulsed-field gel electrophoresis (PFGE), multilocus sequence typing (MLST) or whole genome sequencing (WGS) and MLST-(WGS) can result in improved detection of outbreaks with more associated or linked cases, when the country has the adequate resources to perform it. Use of this methodology is expected to lead to the detection of more outbreaks in the future and the need for enhanced preparedness-.</p>	<p>Colombia Not all laboratories have the capacity or budget to implement WGS technology, but some can analyze outbreaks through PFGE and determine the genetic relationships between the food and human isolates.</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 impact of actions taken exposure of the hazard to humans. In particular, the use of specific genomic methods (such as 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 will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness, and the exposure of the hazard to humans. In particular, the use of specific genomic methods (as Whole Genome Sequencing (WGS) and MLST) can result in improved detection of outbreaks with more associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of this methodology will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness.</p>	<p>USA We do not want to reduce the impact of actions taken when investigating an outbreak.</p>
<p>Paragraph 8</p>	
<p>The decision to categorize an outbreak as an incident, an emergency or a crisis is at the discretion of the competent authorities. There should be consistency at the local and national level when an outbreak is declared an incident, emergency or categorized.</p>	<p>Canada Recommend the inclusion of “local”. Alternatively, may wish to state “at all levels (local, national, regional and international)” to ensure consistency.</p>

<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 national level with respect to when an outbreak is declared an incident, emergency or crisis.</p>	<p>USA</p>
<p>Paragraph 9</p>	
<p>The following criteria can be used by the competent authorities to categorize biological foodborne outbreaks as an incident, emergency or crisis. An example can be found in Section 2 of the FAO/WHO framework for Developing National Food Safety Emergency Response Plans.</p>	<p>Canada As this is the Introduction, such a reference may not be necessary here. In addition, the supplementary use of FAO/WHO documents is noted in paragraph 13.</p>
<p>The following criteria can be used by the competent authorities to categorize biological foodborne outbreaks as an incident, emergency or crisis. An example can be found in Section 2 of the FAO/WHO Framework for Developing National Food Safety Emergency Response Plans:</p>	<p>Colombia</p>
<p>The following criteria can be used by the competent authorities to categorize biological foodborne outbreaks as an incident, emergency or crisis. An example can be found in Section 2 Response plans should reflect the need to adapt the response based on the severity of the FAO/WHO framework for Developing National Food Safety Emergency Response Plans outbreak.</p>	<p>USA Section 2 of “Developing National Food Safety Emergency Response Plans” (Defining ‘food safety emergency’) describes factors that influence how an event is approached (many of which are captured in the criteria listed in the bullets of paragraph 9). It does not provide an example of how to categorize an outbreak, but shows a pyramid in Figure 1 in which the response is scaled up from “business as usual” to “incident” to “emergency” to “crisis.” The text related to the figure says that the figure “illustrates how the more severe (and less frequent) events have escalating needs for resources, centralized coordination and decision-making at a senior level. Response plans should reflect the need to adapt the response either up or down to meet the needs of the event.” We think the substitute sentence we are recommending captures this point and eliminates the need for a reference.</p>
<p>Paragraph 9 bullet points</p> <ul style="list-style-type: none"> The number of cases and spread of the outbreak 	
<p>The number of cases and spread of the geographic outbreak.</p>	<p>Canada</p>
<ul style="list-style-type: none"> Consumer perception, e.g. when referring to a “crisis” can affect the consumer confidence in a product or food category clearly not belonging to the consignment implicated 	

Consumer perception-perception , e.g. when , referring to <u>an outbreak as</u> a “crisis” can affect the consumer confidence in a product or food category clearly not belonging to the consignment implicated.	USA This document is about outbreaks and should use that term consistently.
• Whether or not the incident was due to fraud or the consequence of bioterrorism	
Whether or not the incident was due to intentional (e.g. side effect of fraud or the consequence of bioterrorism bioterrorism).	Canada Fraud and terrorism are different concepts; therefore we recommend the wording is amended as shown.
Whether or not the incident-outbreak was due to fraud or the consequence of bioterrorism.	USA This document is about outbreaks and should use that term consistently.
SCOPE	
Paragraph 10	
These guidelines provide guidance to competent authorities on the preparedness and management of foodborne outbreaks, including the communication with international networks, such as the International Food Safety Authorities Network (INFOSAN) when it is necessary. The guidance addresses preparedness, detection, response and recovery with the intent of limiting the extent of such outbreaks. They include recommendations on the appropriate use of new analytical technologies e.g. genetic typing methods in outbreak investigation. The scope is limited to biological hazards, as they are the predominant cause of foodborne outbreaks. However, certain recommendations might be relevant for the management of outbreaks caused by other hazards such as chemical contaminants.	USA This sentence is not needed. Since chemical contamination issues may be very different from biological ones, many of the recommendations here may not apply. Moreover, CCFH agreed to limit the scope of the document to biological contaminants.
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 guidelines address preparedness, detection, response and recovery with the intent of limiting the extent of such outbreaks. They include recommendations on the appropriate use of new analytical technologies e.g. genetic typing genotypic methods in outbreak investigation. The scope is limited to biological hazards, as they are the predominant cause of foodborne outbreaks. However, certain recommendations might be relevant for the management of outbreaks caused by other hazards such as chemical contaminants.	Colombia It is important to standardize the terminology used in the text for the analytical laboratory methods.
Paragraph 11	
These guidelines also describe the role of competent authorities at <u>the</u> local, national and <u>where applicable, the</u> regional level and the collaboration between them in formalized network structures. Guidelines are included on collaboration and communication with food business operators and other stakeholders before and during foodborne outbreaks as well as recovery, on post outbreak measures and “after action reviews” when an outbreak has been resolved declared over. Maintenance of the structures and training methods to strengthen the response by the networks are also addressed.	Canada Suggest adding “where applicable” since not all countries have a formal regional network.
USE	
Paragraph 12	
The following Codex Alimentarius documents ¹ are relevant for these guidelines:	Gambia Position for bullet 1: The Gambia recommends to keep the text and refer to the

	<p>templates in WHO "Foodborne Disease Outbreaks: Guidelines for investigation and Controls, as example and incorporate them as Annex in the guidelines.</p> <p>Rationale: The existing template in WHO "Foodborne Disease Outbreaks: Guidelines for investigation and Controls sufficiently provides the relevant information but need to be consolidated in one document.</p> <p>Position for bullet 2: The Gambia supports the recommendation to elaborate an example of a template for asking a rapid risk assessment as an annex to the guideline. This will facilitate implementation of rapid risk assessment</p> <p>Position for Bullet 3: The Gambia supports the inclusion of the graphical structure of the network described in the text and placing it in an annex. This will enhance on the key elements to be considered when establishing networks at national and international levels.</p>
<p>Bullet points</p> <ul style="list-style-type: none"> • <i>Principles and Guidelines for an Exchange of Information in Food Safety Emergency Situations (CXG 19-1995)</i> • <i>Working principles for risk analysis for food safety for application for governments (CXG 62-2007)</i> • <i>Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG 30-1999), as amended</i> • <i>Principles and Guidelines for the Conduct of Microbiological Risk Management (CXG 63-2007), as amended</i> 	
<p><i>Principles and Guidelines for an the Exchange of Information in Food Safety Emergency Situations (CXG 19-1995).</i></p>	<p>Canada</p> <p>The titles of the Codex references should be modified to be accurate.</p>
<p><i>Working principles Principles for risk analysis Risk Analysis for food safety Food Safety for application for governments Application by Governments (CXG 62-2007).</i></p>	<p>Morocco</p> <p>Morocco supports the recommendation to elaborate an example of a template for rapid risk assessment and place it in an annex. This will facilitate implementation of rapid risk assessment.</p>

<p><i>Principles and Guidelines for the Conduct of Microbiological Risk Assessment</i> (CXG-30-1999, as amended).</p>	<p>Morocco Morocco supports the inclusion of the graphical structure of the network described in the text and placing it in an annex. This will reinforce the key elements to be considered when establishing networks at national and international levels.</p>
<p>Paragraph 13</p>	
<p>A number of FAO/WHO documents documents, listed in Annex I, describe in more details detail some of the issues presented in this guideline. In Annex I a list of documents is given. These documents are examples of supplementary texts and may be considered for details on and clarification of specific aspects.</p>	<p>Canada</p>
<p>A number of FAO/WHO documents describe in more details some of the issues presented in this guideline. In Annex I a list of documents is given. These documents are examples of supplementary texts and may be considered for details on and clarification of specific aspects.</p>	<p>USA Delete the paragraph. We think that this document captures the essential information from the FAO/WHO documents and there is no need to include the list of documents in Annex I. Referring to these as “supplementary texts” and including them in the annex may give them status similar to that of a Codex document. If there is a desire to maintain this list, it could possibly be turned into an information document</p>
<p>DEFINITIONS</p>	
	<p>Japan WGS should also be defined. Japan proposes the following definition. :the process of determining the order of the four chemical bases (A, G, T, and C) for the entire genome of an organism. Which provides possible microbial subtyping resolution.</p>
<p>DEFINITIONS <u>RISK: A FUNCTION OF THE PROBABILITY OF AN ADVERSE HEALTH EFFECT AND THE SEVERITY OF THAT EFFECT, CONSEQUENTIAL TO A HAZARD(S) IN FOOD.</u></p>	<p>Nicaragua Considering that this document addresses the topic of risk, we propose including its definition. Reference: CAC/GL 30-1999 Nicaragua suggests listing the definitions in alphabetical order.</p>

<p>DEFINITIONS</p> <p><u>PFGE: PULSED-FIELD GEL ELECTROPHORESIS.</u></p> <p><u>MLST: Multilocus sequence typing.</u></p> <p><u>WGS: Whole genome sequencing</u></p> <p><u>Genotypic methods: also known as genetic typing or molecular subtyping, are methods that use nucleic acid sequences to identify relations or grades of genetic identity between two or more microorganisms. E.g. MLST, MLVA, PFGE, WGS, etc.</u></p>	<p>Colombia</p> <p>Make the definitions of the terminology and acronyms that are used in the document clear.</p>
<p>Lot</p>	
<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 <u>produced, packaged or labelled</u> under the same conditions, and is assigned a unique reference identification number by the food business operator. It may also be referred to as a “batch”.</p>	<p>Canada</p> <p>As the definitions are listed alphabetically, this definition of lot should be moved further down the list as appropriate.</p> <p>Suggest inclusion of “packaged or labelled” as companies who repackage product may use that to define a lot.</p>
<p>Biological hazards</p>	
<p><u>Biological hazards</u>: Biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include e.g. bacteria, viruses <u>viruses, toxins, parasites</u> and parasites <u>others</u>.</p>	<p>Colombia</p>
<p><u>Biological hazards</u>: Biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include e.g. bacteria, viruses and parasites.</p>	<p>Gambia</p> <p>Issue - Definitions Para. 16, the definition of Biological hazards i.e. “Biological hazards”: agents including microorganisms that have the capacity to cause harmful effects in humans.”</p> <p>Position: The Gambia seeks clarification whether “biological hazards” include metabolites of microorganism such as biotoxin.</p> <p>Rationale: The definition provided seem to suggest that there may be other agents apart from microorganisms.</p>
<p><u>Biological hazards</u>: Biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include e.g. bacteria, viruses and parasites.</p>	<p>Morocco</p> <p>Morocco asks whether “biological hazards” also include metabolites of microorganisms such as biotoxins.</p> <p>Rationale: the definition provided seems to suggest that there may be other agents apart from microorganisms.</p>

Case control study	
A case-control Case-control study : An observational study in which the distribution of exposures among cases and a group of persons who do not have the illness (“controls”) are compared with each other. These studies can be valuable when no clear “cohort” of all exposed and non-exposed persons can be defined.	Canada
A case-control study : An observational study in which the distribution of exposures among cases and a group of persons who do not have the illness (“controls”) are compared with each other. These studies can be valuable when no clear “cohort” of all exposed and non-exposed persons can be defined.	Japan Japan supports the definition in the glossary of the WHO FBD outbreak investigation manual.
Cluster	
Cluster : In epidemiological terms, it describes a group of cases linked by time or place, but without a common food or other source having been identified. In microbiological microbiological terms, viruses isolates (e.g., bacteria or virus) bacteria, parasites or fungi having the same specific molecular profile or closely related profiles identified by laboratory analyses of samples from cases.	Nicaragua
Descriptive epidemiology	
Descriptive epidemiology : The aspect of epidemiology concerned with organizing and summarizing health-related data according to the occurrence of disease time, in terms of both geographical comparisons place and descriptions of temporal trends person characteristics .	Thailand As the co-chairs mentioned, the definitions in Codex or WHO documents should be used if available. So, we would like to propose the amendment of the definition of the words ‘descriptive epidemiology’ to be in line with the glossary of the WHO “Foodborne disease outbreaks: Guidelines for investigation and controls”
Foodborne outbreak	
Foodborne outbreak : An incident in which two or more persons experience a similar illness after ingestion of a common food, and paremiologic analyses implicate the food as the source of the illness. The observed number of cases of a particular disease that can be foodborne exceeds the expected number, OR the presence of two or more cases of a similar foodborne illness as a result of ingesting a common food and an epidemiological analysis implicates the food as the source of the illness.	Colombia We consider this definition simpler, taken from the PAHO page: https://www.paho.org/col/ https://www.paho.org/hq/index.php?option=com_content&view=article&id=10836:2015-enfermedades-transmitidas-por-alimentos-eta&Itemid=41432&lang=es <i>Category : SUBSTANTIVE</i>
Metadata	
Metadata : Data that describe other data. In relation to analytical testing (e.g., molecular testing genotypic methods such as SGC WGS), metadata of the results could be date of sample collection, identification of sample, sample size, product, sampling site, etc.	Colombia Standardize the terminology.

<p><u>Metadata</u>: Data that describe other data. In relation to analytical testing (e.g., All descriptive information on the context, molecular testing such as SGC) quality, metadata condition or characteristics of the results could be the date of sample collection a resource, data or object that has the identification purpose of sample enabling its recovery, sample size authentication, product evaluation, sampling site, etc. preservation and/or interoperability.</p>	<p>Nicaragua Nicaragua proposes a clearer and more precise definition of metadata. Reference: https://www.sedic.es/autoformacion/metadatos/tema1.htm</p>
<p><u>Metadata</u>: Data that describe other data. In relation to analytical testing <u>results</u> (e.g. <u>results from</u> molecular testing such as <u>WGS</u> <u>results</u> <u>WGS</u>), metadata could be date of sample collection, identification of sample, sample size, product, sampling <u>site</u> <u>site</u>, etc.</p>	<p>USA Makes the definition easier to read.</p>
<p>Rapid risk assessment</p>	
<p><u>Rapid risk assessment</u>: A risk assessment, based on the information available on the foodborne outbreak, which needs to be carried out urgently to quickly support (provisional) risk management measures and therefore may not always contain the full development of the four steps of a classical-risk assessment <u>assessment described in the CAC GL-30</u>.</p>	<p>Japan To clarify four steps in a risk assessment</p>
<p>Risk communication</p>	
<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) <u>outside-in</u> the formalized network structure.</p>	<p>Colombia This definition should be reviewed. Taking the context into account, it would be the risk information or communication in the event of an outbreak, so the information should be official, and provided by the health authorities.</p>
<p>Surveillance</p>	
<p><u>Surveillance</u>: A <u>The</u> systematic and ongoing collection, analysis and interpretation of data from samples from humans, animals or food for early detection with the purpose of applying appropriate control measures to prevent foodborne illness. One of the main objectives of surveillance is investigating unsatisfactory results, which may lead to possible enforcement action.</p>	<p>Canada We would recommend removing the last sentence. Surveillance has different goals for different competent authorities and could also include: verifying compliance, for market access, systems equivalencies, etc. Also, investigating unsatisfactory results is a consequence of surveillance (not its goal).</p>
<p><u>Monitoring</u>: A <u>Systematic</u> and ongoing collection, analysis and interpretation of data from samples from humans, animals or food for early detection with the purpose of applying appropriate control measures to prevent foodborne illness. One of the main objectives of monitoring is investigating unsatisfactory results, which may lead to possible enforcement action.</p>	<p>Colombia</p>
<p><u>Surveillance</u>: A systematic and ongoing collection, analysis and interpretation of data from samples from humans, animals or food for early detection with the purpose of applying appropriate control measures to prevent foodborne illness. One of the main objectives of surveillance is investigating unsatisfactory results, which may lead to possible enforcement action.</p>	<p>Japan According to the comments of the eWG chair, the sample includes feed and environment. Feed and environment should be included.</p>

<p>Surveillance: A systematic and ongoing collection, analysis and interpretation of data from samples from humans, animals or food for early detection with the purpose of applying appropriate control measures to prevent foodborne illness. One of the main objectives of surveillance is investigating unsatisfactory results, which may lead to possible enforcement action.</p>	<p>USA The objective of surveillance should not be part of the definition.</p>
<p>Traceability/Product Tracing</p>	
<p>Traceability/Product Tracing: The ability to follow the movement of a food through specified stage(s) of production, processing and distribution. "Traceability/product tracing backwards" refers to following the flow to its origin or source and "traceability/product tracing forward" refers to following the flow to its final distribution or point of consumption. <u>29. COMPETENT AUTHORITY: THE OFFICIAL BODY AUTHORIZED BY THE GOVERNMENT WITH THE CONTROL OF FOOD HYGIENE, INCLUDING SETTING AND ENFORCING REGULATORY FOOD SAFETY REQUIREMENTS.</u></p>	<p>Nicaragua We propose including the definition of competent authority.</p>
<p>FOODBORNE OUTBREAKS – PREPAREDNESS SYSTEM</p>	
<p>Paragraph 29</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 along with some of the routine issues <u>good practices</u> and standard tools to include in the system.</p>	<p>Canada We suggest removing the word "issues" as it implies problems, and replace with "good practices".</p>
<p>A. CREATION OF FORMALIZED NETWORKS BETWEEN HUMAN HEALTH SECTOR AND FEED, FOOD AND VETERINARY SECTORS AT LOCAL AND NATIONAL LEVELS</p>	
<p>CREATION OF FORMALIZED NETWORKS BETWEEN HUMAN HEALTH SECTOR AND FEED, FOOD <u>CONTROL</u> AND VETERINARY SECTORS AT LOCAL AND NATIONAL LEVELS</p>	<p>Japan For the consistency with the latter part of this document</p>
<p>CREATION OF FORMALIZED NETWORKS BETWEEN HUMAN HEALTH SECTOR AND FEED, FOOD AND VETERINARY SECTORS AT LOCAL AND NATIONAL LEVELS</p>	<p>USA The feed sector relates to animal health, not human health.</p>
<p>Paragraph 30</p>	
<p>In the following paragraphs, the composition and tasks of the networks at any level of competent authorities within a country are described. These competent authorities, others other than <u>those at the</u> national/federal ones <u>level</u>, are referred to as "local" which <u>and</u> may contain sublevels that should all <u>also</u> be involved.</p>	<p>Canada</p>
<p>In the following paragraphs, the composition and tasks of the networks at any level of competent authorities within a country are described. These competent authorities, others other than national/federal ones, are referred to as "local" "<u>local</u>," which may contain sublevels that should all be involved.</p>	<p>USA</p>
<p>Paragraph 32</p>	
<p>The tasks of the <u>These local</u> network contact points are <u>responsible for the coordination of relevant tasks to ensure be completed within their authority/agency, as well as for</u> 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 <u>network</u>. To ensure cooperation <u>and transparency</u> within the local network <u>network</u>, one of the contact points should be designated as the local network contact point in charge of the network.</p>	<p>Canada We modified the text so the roles of the contact points are outlined but less prescriptive.</p>
<p>Paragraph 34</p>	
<p>At the national level a defined network should be established with personnel with experience <u>experienced</u> in the management of foodborne outbreaks within the competence of their respective authorities/agencies. This national network should be recognized by</p>	<p>Canada The meaning of "central level" level is</p>

<p>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 central-the national level from-to the same authorities/agencies that participate in the local networks. In addition, representatives from other relevant institutions, e.g. universities or research institutes, may be included. The authority/agency with the legal responsibility to protect public health in a foodborne outbreak situation should be designated as lead contact point in charge of the national network. The role of the national network should include:</p>	<p>unclear. Suggest “central level” is removed and the sentence is modified as shown.</p>
<p>Paragraph 34: Bullet points</p>	
<ul style="list-style-type: none"> Ensuring that coordinating efforts to resolve foodborne outbreaks, especially complicated or serious foodborne outbreaks those that are complex, are performed; 	<p>Canada We propose to replace “Serious” with “those that are complex”. The meaning of serious in this context is unclear.</p>
<ul style="list-style-type: none"> Ensuring that coordinating efforts to resolve ,especially complicated or serious foodborne outbreaks are performed; 	<p>USA</p>
<ul style="list-style-type: none"> Supporting the local networks where needed and maintain-maintaining the communication channels; 	<p>Canada</p>
<ul style="list-style-type: none"> Supporting the local networks where needed and maintain-maintaining the communication channels; 	<p>USA</p>
<ul style="list-style-type: none"> Assessing surveillance and monitoring data information received from the participating authorities/agencies; 	<p>Canada</p>
<ul style="list-style-type: none"> Assessing surveillance and monitoring data information data received from the participating authorities/agencies; 	<p>USA</p>
<ul style="list-style-type: none"> Assessing information received from the other levels and participants of the network as basis for risk management decisions; and 	<p>Canada</p>
<ul style="list-style-type: none"> Assessing information received from the other levels and participants of the network as a basis for management decisions; and 	<p>USA</p>
<ul style="list-style-type: none"> Ensuring that communication takes place with regional and international networks e.g. through the INFOSAN emergency contact points, where necessary. 	<p>Canada</p>
<p>Paragraph 35</p>	
<p>The networks and the structures should be based on existing structures in the participating authorities and agencies. They-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. It-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 II.</p>	<p>USA Clarify what the pronouns refer to.</p>
<p>Paragraph 37</p>	
<p>Templates and standard tools should be developed in advance and included in the standard procedures for the network participants to use. Some of them are listed below and examples can be found in Annex 3, 5 and 6 of the WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls" below.</p>	<p>USA As noted in our general comments, there are many excellent templates available and we</p>

	think this statement limits the flexibility in developing templates and looking for other examples that may be more relevant.
Paragraph 37 bullet points	
<ul style="list-style-type: none"> template for the rapid risk assessment addressed in chapter e- Section E and Annex III, which may also provide a summary template for information collected. 	Canada
<ul style="list-style-type: none"> template for the rapid risk outbreak assessment addressed in chapter e- Section E and Annex III, which may also provide provides a summary template for information collected. 	USA We do not see the template provided as a “rapid risk assessment” but rather as a template for summarizing the information available on an outbreak (and is described here as a “summary template”).
Paragraph 39	
Communication both within a network and between networks is crucial. Communication structures and practices should be included specifically in the <u>documented</u> description of the system and procedures for the network, to ensure that:	Canada
Paragraph 39, bullet points	
<ul style="list-style-type: none"> especially for the national network there is a mechanism in place for the potential use of external experts to reach consensus on and verify the soundness of recommendations given, <u>especially for the national network</u>. 	Canada
Paragraph 41	
The national level network should have a permanent connection with global networks e.g. the INFOSAN and-and, where applicable, with regional alert networks for e.g. foodborne outbreaks. These global and-and/or regional networks have national emergency contact points in most countries. If there is a national contact point (person or institution), it should be actively included in foodborne outbreak investigations at the national level. The contact point at these alert networks may assist in gathering and compiling information and submitting coordinated information concerning ongoing foodborne outbreaks.	Canada
Paragraph 42	
Information from global networks may be useful for the work of a national network even if the outbreak described does not concern that country, hence it should always be considered if information concerning an outbreak could be useful for other countries and therefore should be shared.	Canada
C. SURVEILLANCE AND MONITORING SYSTEMS (HUMAN, ANIMAL, FEED, FOOD, ESTABLISHMENT ENVIRONMENT) AND THEIR USE IN	
FOODBORNE OUTBREAK SITUATIONS	
SURVEILLANCE AND MONITORING SYSTEMS (HUMAN, ANIMAL, FEED, FOOD, ESTABLISHMENT ENVIRONMENT) AND THEIR USE IN FOODBORNE OUTBREAK SITUATIONS	USA Surveillance of feed relates to animal health (rather than foodborne outbreaks in humans) and is out of scope for CCFH. We also question the inclusion of animal surveillance and would like the document to be more

	specific in how such surveillance relates to human foodborne outbreaks if this is retained.
Paragraph 44	
Information from surveillance and monitoring of animals, feed, food and environment, including equipment of food businesses, may also indicate a potential risk and are essential to help identify the source of a foodborne outbreak as early as possible. These surveillance and monitoring systems are essential tools for detecting and preventing foodborne outbreaks and may help in the early identification of its source . They should preferably be used as an integrated element in the outbreak investigation.	Canada
Information from surveillance and monitoring of animals, food and, feed where appropriate, food and the environment, including equipment of food businesses, may also indicate a potential risk and are essential to help identify the source of a foodborne outbreak as early as possible. These surveillance and monitoring systems are essential tools for detecting foodborne outbreaks and should preferably be used as an integrated element in the outbreak investigation.	USA As noted for Subheader C, surveillance of feed relates to animal health (rather than foodborne outbreaks in humans) and is out of scope for CCFH. We also question the inclusion of animal surveillance and would like the document to be more specific in how such surveillance relates to human foodborne outbreaks if this is retained.
Paragraph 45	
Data from these systems may also be used in conjunction with epidemiological data to inform and if necessary prioritize an investigation-investigation , e.g., by checking if the strain found in a human outbreak has been found previously in certain reservoirs (e.g. a specific animal population, species, specific food category or environment).	USA Clarification that data from surveillance and monitoring should be used in conjunction with epidemiological data when investigating an outbreak.
Paragraph 46	
To share monitoring data, it is necessary that the data collected be comparable between different sectors and that personal information on people as well as plants/industries and commercial brands related to the case be kept confidential . Information should be shared both routinely and during foodborne outbreaks. There should be a regular exchange of information between the human health sector, competent food authorities and laboratories. It is recommended that the exchange of information include, whenever possible:	Colombia
Paragraph 46, bullet points	
<ul style="list-style-type: none"> Tools for comparing and presenting data, such as a phylogenetic tree, being a tree (a branching diagram or "tree" showing the evolutionary relationships of the physical or genetic characteristics of the laboratory data at hand). 	USA
ANALYTICAL METHODS	
Paragraph 47	
Validated analytical methods should be used to isolate and identify causative agents. Traditional analytical methods (such as pathogen isolation) or Polymerase Chain Reaction (PCR) methods used for surveillance and monitoring are essential as the basis for detecting and investigating any outbreak, but often they do not allow to conclude 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.	USA

Validated analytical methods should be used to isolate and identify causative agents. Traditional analytical methods (such as pathogen isolation) or Polymerase Chain Reaction (PCR) methods used for surveillance and monitoring are essential as the basis for detecting and investigating any outbreak, but often they do not establish 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 establish such a linkage. When further characterization is needed for outbreak investigation purposes, molecular or genetic typing <u>genotypic</u> methods can and are increasingly being used.	Colombia Standardize the terminology.
Paragraph 48	
Molecular typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA) but in recent years, genetic based methods like WGS have become widespread worldwide as biological typing tools. WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of the outbreak. The method can also be used to identify genetic differences, virulence factors and antimicrobial resistance mechanisms. The implementation and use of WGS and the analysis of the WGS <u>result</u> results require additional resources and capacity compared to other methods.	USA
Molecular typing <u>Genotypic</u> methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of (MLVA), but in recent years, - genetic based methods like Whole Genome Sequencing (WGS) - multiple-locus variable number of tandem repeat analysis have become widespread worldwide as microbial typing tools (MLVA). WGS typing <u>genotyping</u> 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 require additional resources and capacity compared to other methods.	Colombia
Paragraph 49	
The use of WGS requires:	Gambia Issue – Analytical Methods Para 49 on Whole Genome Sequencing Position: The Gambia recommends to delete para. 49 as the information provided is not relevant to the document.
The use of whole genome sequencing requires:	Morocco Morocco recommends deleting para. 49 as the information provided is not relevant to the document.
Paragraph 49, bullet points	
<ul style="list-style-type: none"> Laboratory capacity, specific equipment (properly maintained and, where applicable, calibrated) and <u>personnel</u> trained personnel <u>in implementation of WGS, analysis and interpretation of WGS results.</u> 	Japan For clarity. Supplementary explanation on “trained personnel” is needed.
<ul style="list-style-type: none"> Sharing of WGS sequences in a form that is useful for comparison between the human health authorities and the food control and veterinary authorities. Sharing of actual raw whole genome sequences and associated appropriate metadata is most useful to everyone for comparing between results obtained by various analytical methods, including both multilocus sequence typing (MLST)-based and (single-nucleotide polymorphism (SNP)-based approaches. 	Canada

<ul style="list-style-type: none"> Sharing of WGS sequences in a form that is useful for comparison between the human health authorities and the food control and veterinary authorities. Sharing of actual raw whole genome sequences and associated metadata is most useful to everyone for comparing between results obtained by various analytical<u>genotypic</u> methods, including both multilocus sequence typing (MLST) -based- and <u>analysis of</u> single-nucleotide polymorphism (SNP) -based approaches-. 	<p>Colombia</p>
<ul style="list-style-type: none"> <u>Higher WGS involves higher</u> up-front costs (e.g. sequencing machine, reagents, dedicated laboratory space) than other typing methods<u>methods</u>, which can be an obstacle for its implementation. Furthermore, the cost per analysis will be higher if the total number of tests is low. 	<p>USA We propose to make this a separate paragraph rather than a bullet. Each of the bullets completes the phrase “The use of WGS requires.” The fact that the costs may be higher is not a requirement for conducting such analyses.</p>
<p>E. RAPID RISK ASSESSMENT – STRUCTURES FOR ASSESSING RISK</p>	
	<p>USA Clarify exactly what the outcome of the “rapid risk assessment” is. This assessment is applied during an outbreak, so it is already clear there is a risk to public health. We had hoped the template would clarify the concept of a “rapid risk assessment” for us, but the template seems to be a compilation of the information available related to the outbreak (which is clearly a useful document). A risk assessment involves hazard identification, hazard characterization, exposure assessment and risk characterization; it is not clear how the “rapid risk assessment” as described here and in the template addresses all these components, in particular the “risk characterization.” We are unable to fully comment on this section without a greater understanding of this.</p>
<p>Paragraph 51</p>	
<p>A risk assessment during a foodborne outbreak may be useful to provide a sound scientific basis for to determine the <u>appropriate risk mitigation</u> actions to be taken. In a number of cases, a ready-to-use risk assessment (e.g. a risk assessment conducted for existing or similar pathogen - food combinations) will be available. Adaptations to the specific outbreak may be required (within a short timeframe) based on the information from investigations.</p>	<p>Canada Recommend that the type of action is specified.</p>
<p>Paragraph 53</p>	

<p>The rapid risk assessment is based on the data available at that time from the foodborne outbreak itself and, if possible, data from similar outbreaks. There might be no time for collecting additional evidence/data to fill in data gaps or to conduct larger literature studies. These types of assessments need to be updated regularly during the outbreak investigation as new information (e.g. surveillance data, analytical results, epidemiological information, information on consumption and distribution of suspected food items) becomes available. Depending on the <u>emergency</u> situation, several revisions of the rapid risk assessment may be needed.</p>	<p>USA This document is about outbreaks. Not all outbreaks are emergencies.</p>
<p>Paragraph 54, bullet points</p>	
<p>Instructions clearly outlining what is expected of these risk assessors and subject matter experts, including the scope of any rapid risk assessment, taking into account the short timeline for the assessment to be completed or having a template ready to be used for such rapid risk assessment. An example is provided in Annex III and in Annex I of the WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls" III.</p>	<p>USA There is no need to refer to the FAO/WHO document since an example is provided in an Annex.</p>
<p>Availability of information analysis tools e.g. to detect hot spots (geographical areas, <u>food establishments/sites (e.g. restaurant, production facility, or farms) or</u> events with more than usual occurrence within the outbreak).</p>	<p>Canada To align with wording used in Paragraph 66.</p>
<p>Availability of (regional/national/local) data on consumption <u>habits</u> and serving sizes that is as up to date as possible.</p>	<p>Canada</p>
<p>Procedures for rapid contact to <u>of</u> food business operators including maintaining information on contact information.</p>	<p>USA</p>
<p>Paragraph 58</p>	
<p>When a foodborne outbreak occurs <u>occurs</u>, the <u>established</u> networks and structures established should be used to manage the situation in <u>with</u> an integrated approach. Often management of foodborne outbreaks will be carried out under pressure with time and budgetary constraints. It is therefore important that each sector/participant carry out the tasks within their responsibilities according to the procedures decided upon in the networks. The following sections give information of the basic roles of the participants in the networks.</p>	<p>Canada</p>
<p>When a foodborne outbreak occurs <u>occurs</u>, the networks and structures established should be used to manage the situation in an integrated approach. Often management of foodborne outbreaks will be carried out under pressure with time and budgetary constraints. It is therefore important that each sector/participant carry out the tasks within their responsibilities according to the procedures decided upon in the networks. The following sections give information of the basic roles of the participants in the networks.</p>	<p>USA</p>
<p>When a foodborne outbreak occurs <u>occurs</u>, the networks and structures established should be used to manage the situation in an integrated approach. Often management of foodborne outbreaks will be carried out under pressure with time and budgetary constraints. It is therefore important that each sector/participant carry out the tasks within their responsibilities according to the procedures decided upon in the networks. The following sections give information of the basic roles of the participants in the networks.</p>	<p>CCTA</p>
<p>Paragraph 62</p>	
<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 indicate a need to do so. Cases, which <u>Cases that</u> 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>USA</p>
<p>Paragraph 62, bullet points</p>	

<ul style="list-style-type: none"> On the food items<u>items consumed</u>: the place (the commercial name of the establishment and the exact address) and date of purchase and consumption, <u>method of preparation</u>, brand name, lot/batch code if known. 	Canada
<ul style="list-style-type: none"> On the food items: the place (the commercial name of the establishment and the exact address) and date of purchase and <u>time of</u> consumption, brand name, lot/batch code if known. 	Thailand To be more specific on the information during interview
<ul style="list-style-type: none"> On the food items: (<u>if known</u>) the place (the commercial name of the establishment and the exact address) and date of purchase and consumption, brand name, lot/batch code if known<u>code</u>. 	USA To make it clear that “if known” applies to all of this information, not just lot code.
<ul style="list-style-type: none"> On the food items: the place (the commercial name of the establishment and the exact address) and as well as date of purchaseand <u>time of consumption</u>purchase, brand name, lot/batch code if known. 	Colombia
<ul style="list-style-type: none"> With regards to the affected person: information on travel, animal and environmental exposures, person-to-person contact, disease onset, symptoms, duration<u>duration</u>, <u>hospitalization</u>, <u>underlying health concerns</u>, etc. 	Canada
<ul style="list-style-type: none"> With regards to the affected person: information on travel, animal and environmental exposures, person-to-person contact, disease onset, symptoms, duration, <u>time and date of consumption</u>, etc. 	Colombia
B. SUBSTANTIATE HYPOTHESIS AND/OR HANDLING OF A FOODBORNE OUTBREAK – FOOD SAFETY (FROM FRAM TO FORK)	
SUBSTANTIATE HYPOTHESIS AND/OR HANDLING OF A FOODBORNE OUTBREAK – FOOD SAFETY (FROM FARM TO FORK)	USA
Paragraph 68	
If the epidemiological investigations do not identify a source, the competent authority could use other information to elaborate their investigation of the cause of an outbreak. For example, historical outbreak data, prevalence of the hazard in food, information from the cases concerning food preferences, trade patterns, knowledge of production, distribution, and consumer preferences, may be helpful to narrow down the possible food sources or sites. Such information should however be used prudently <u>prudently</u> , e.g., to target investigations and not for communications on the outbreak source without additional <u>supporting</u> evidence.	USA
Paragraph 69, bullet points	
<ul style="list-style-type: none"> List of operators who received the affected lots of the food item<u>item and other distribution paths including to institutions and via internet sales</u>. 	Canada
Paragraph 71	
If the overall evidence concludes that the source of the foodborne outbreak or the affected lot(s) has been identified, appropriate risk management actions should be put in place. When a recall removal is identified as the appropriate risk management action, tracing back and tracing forward_bookmark12 should be used to remove all lots implicated or suspected to be implicated. The recall The removal should be carried out in the shortest time frame possible to avoid greater impact on public health and the economy of food business operators. The competent authority should monitor the recall the removal to ensure compliance. Rationale: The Spanish version should replace recall with removal . The other change does not affect the English.	Argentina
If the overall evidence concludes that the source of the foodborne outbreak or the affected lot(s) has been identified, appropriate risk management actions should be put in place. When a recall is identified as the appropriate risk management action, tracing back and tracing forward_should be used to remove all lots implicated or suspected to be implicated <u>lots</u> . The recall should be carried out	Canada Suggest removing "suspected to be implicated" to provide flexibility in how the removal of products is done in each country.

<p>in the shortest time frame possible to avoid greater impact on public health and the economy of food business operatorseconomy. The competent authority should monitor the recall to ensure compliance.</p>	
<p>Paragraph 72</p>	
<p>Consideration should be given to the actions required by consumers in recalls and businesses in <u>recalls or</u> product withdrawals concerning the suspect lots. Consideration should also be given to provide advice to consumers and/or businesses about appropriate <u>methods of</u> disposal of affected riskyfoods linked to the outbreak and subsequent potential should take into account <u>any potentially associated</u> environmental risks or public health risksrisks, for example such as a result of those related to recycling.</p>	<p>Canada Countries may not have the same definition of recall and product withdrawal.</p>
<p>Paragraph 74</p>	
<p>Even in case of a match in serotypes, supplementary analysis by molecular methods may be necessary to conclude<u>draw</u> <u>conclusions</u> on the probability of a relationship.</p>	<p>USA</p>
<p>Paragraph 76</p>	
<p>For WGSfor example, <u>with WGS, there are no</u> established standard “cut-off” values in terms of degree of differences between strains (e.g. single nucleotide polymorphisms (SNP’s)) are established(SNP’s)). In general, <u>when the fewer the</u> number of SNP differences<u>differences is fewer, there is the more likely potential that</u> the strains are originating from the same source (e.g., the same facility) could share a common ancestor. The actual number of SNP differences among related outbreak strains will differ depending on a number of factors (e.g. species, length of outbreak, contamination route) and will require interpretation based on bioinformatics, epidemiological, and tracing analysis.</p>	<p>Canada For information, 2 strains can have minimal SNP differences but not be from the same source. They likely have a common ancestor though. WGS alone is not sufficient to establish a definitive link and caution should be taken in this document.</p>
<p>Paragraph 77</p>	
<p>The use of databases containing comparable molecular based testing results from humans, animals, feed, food and establishment environmental sampling, facilitates the detection and assessment of outbreaks and informs the search for the source of the contamination.</p>	<p>USA Molecular testing of isolates from feed is relevant to animal health.</p>
<p>Paragraph 78</p>	
<p>Robust epidemiological evidence can be conclusive of a foodborne outbreak even without positive laboratory results from sampling. Efforts by sampling and analysis should be made to allow laboratory results to support the epidemiological evidence. It is however important to note that sampling is not always needed to draw conclusions on the source of the outbreak.Laboratory confirmation can be difficult to achieve for several reasonsreasons, e.g.-.</p>	<p>USA This is covered by the first sentence.</p>
<p>Robust epidemiological evidence can be conclusive of a foodborne outbreak even without positive laboratory results from sampling. Sampling and analysis should be carried out to allow laboratory results to support the epidemiological evidence. It is however important to note that sampling is not always needed to drawreach conclusions on the source of the outbreak. Laboratory confirmation can be difficult to achieve for several reasons, e.g.</p>	<p>Colombia</p>
<p>Paragraph 78, bullet points</p>	
<p>contaminations<u>biological contaminants</u> in food are not likely to be evenly distributed,</p>	<p>USA The term used should be “contaminants”; this document is about biological contaminants as a source of outbreaks, not all contaminants.</p>
<p>the <u>level of</u> contamination may be low levelhence the chance for detection is limited,</p>	<p>Canada</p>

<p>there may not be a standard method available for detecting the biological hazard in a specific food <u>responsible for the outbreak of interest</u>, or</p>	<p>Canada</p>
<p>the affected lot of food <u>is/was</u> consumed or removed at the end of its shelf life and therefore no longer available for testing, <u>in particular</u>. <u>This may happen</u> when a hazard causes illness with a long incubation in <u>humans/humans or the food source has a very limited shelf life (e.g., fresh berries)</u>.</p>	<p>Canada</p>
<p>D. RAPID RISK ASSESSMENT – DURING A FOODBORNE OUTBREAK</p>	
<p>RAPID RISK ASSESSMENT – DURING A FOODBORNE OUTBREAK</p>	<p>USA Provide clarification and see earlier comments on “rapid risk assessment.” As noted, it is unclear how most of the information listed here, while clearly important to have and assess during an outbreak, constitutes a “risk assessment.” We note that the 4th bullet refers to “risk identification and characterization” linked to the outbreak. It is unclear what specific information would be included in this assessment; “hazard identification” and “risk characterization” are components of a risk assessment, so the terms “risk identification and characterization” seem inconsistent with risk assessment terminology.</p>
<p>Paragraph 81, bullet points</p>	
<p>where appropriate, recommendations to the consumers and to competent authorities on how to manage the risk. • <u>If the potential food source has been traced to a specific food business, information on the overall condition of the facility, such as compliance history, inspection reports, complaint records and company test results.</u></p>	<p>Canada Suggest adding a new bullet.</p>
<p>Paragraph 82, bullet points</p>	
<p><u>allow the risk assessors to point investigators to identify</u> gaps <u>of in</u> information or hot spots (geographical areas or events with more than usual occurrence within the outbreak) detected, guiding further investigations.</p>	<p>Canada This information could be provided by many involved in the investigation, not necessarily just the risk assessors.</p>
<p>E. RISK COMMUNICATION</p>	
<p>Paragraph 83</p>	
<p>Ideally, risk communication will provide stakeholders including consumers outside the formalized network structure with the information they need to make informed decisions and take appropriate action. At the beginning of an outbreak, during the period when information is being gathered, there may be confusion and intense public and media interest. Therefore, it may be necessary to conduct risk communication even if the source of the outbreak is still unknown. Such early communication should include information on the ongoing investigations and advice on general food hygiene measures consumers could <u>take (cook thoroughly,</u></p>	<p>Canada Suggest that there is no need to expand on the concept of “hygienic practices” in this document.</p>

wash vegetables/fruit, follow product durability information, appropriate chilling in the home, good kitchen hygiene (clean/disinfect, avoid cross-contamination etc.etc.)).	
Ideally, risk communication will provide stakeholders including consumers outside the formalized network structure structure, <u>including consumers,</u> with the information they need to make informed decisions and take appropriate action. At the beginning of an outbreak, during the period when information is being gathered, there may be confusion and intense public and media interest. Therefore, it may be necessary to conduct risk communication even if the source of the outbreak is still unknown. Such early communication should include information on the ongoing investigations and advice on general food hygiene measures consumers could take (cook thoroughly, wash vegetables/fruit, follow product durability information, appropriate chilling in the home, good kitchen hygiene (clean/disinfect, avoid cross-contamination etc.)).	USA To clarify that this refers to all stakeholders outside the formalized network structure, not just consumers outside the network structure.
Paragraph 84, bullet points	
Do not withhold information just because it may be upsetting. If information is lacking or cannot be released, it is important to explain the cause (where known) and what is being done to address this 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.	Canada
A facility to provide easy access for platform that provides the public and other stakeholders <u>with easy access</u> to updated information e.g. a designated website with contact information. This includes easy access for authorities and food business operators in other countries if they may be affected.	Canada
A facility to provide <u>Provide</u> easy access for the public and other stakeholders to updated information information, e.g., a designated website with contact information. This includes easy access for authorities and food business operators in other countries if they may be affected.	USA Make the bullet consistent with the others.
A facility means of communication to provide easy access for the public and other stakeholders to updated information e.g. a designated website with contact information. This includes easy access for authorities and food business operators in other countries if they may be affected.	Colombia
Paragraph 85	
Foodborne outbreaks may begin in one country but can quickly spread to other countries or regions and require a quick and clear response in terms of communication. INFOSAN or other similar networks can be used as a resource for risk communication messages in such instances to ensure factual current information is being shared about an international foodborne outbreak.	Colombia
F. DOCUMENTATION OF THE OUTBREAK AND LESSONS LEARNED	
Paragraph 86	
It is important to collect and save sufficient information from the beginning of the outbreak to be able to document all relevant steps in the management of the outbreak outbreak, for example by using e.g. log books, both when it is ongoing and afterwards. During the investigation a record should be kept, which include kept that includes relevant tracing information and descriptive epidemiology, hypotheses and status of the situation. The record should be updated as needed while the foodborne outbreak is ongoing and in a way, that protects personal information. When it is over, the record can be finalized to include conclusions and can serve as an outbreak report or as basis for a summary outbreak report.	USA
G. POST OUTBREAK SURVEILLANCE	
Paragraph 91	
Enhanced surveillance, and rapid centralization and evaluation of data, in particular from human cases, should be continued until the numbers of cases have returned to the baseline level, (or, for new biological hazards, until no further cases are observed). This allows to evaluate the effect evaluation of the effectiveness of actions taken and to maintain/regain the confidence of consumers	Canada

and trading partners <u>partners to be maintained or regained</u> . Possible delays in analyses and reporting and possible seasonal effects should be taken into account before declaring an outbreak over.	
Enhanced surveillance, and rapid centralization and evaluation of data, in particular from human cases, should be continued until the numbers of cases have returned to the baseline level, (or, for new biological hazards, until no further cases are observed). This allows to evaluate an evaluation of the effect of actions taken and to maintain/regain the confidence of consumers and trading partner <u>taken</u> . Possible delays in analyses and reporting and possible seasonal effects should be taken into account before declaring an outbreak over.	USA It is unclear how this enhanced surveillance allows maintaining/regaining confidence.
MAINTENANCE OF THE NETWORKS A. REVIEW OF EXISTING PREPAREDNESS	
Paragraph 92	
Competent authorities at <u>the</u> 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.	USA
Paragraph 99, bullet points	
<ul style="list-style-type: none"> Learning and development exercises are more organized with the focus on the participants being required to achieve new competences and capabilities. †<u>The exercises</u> 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. 	USA
ANNEX II - STRUCTURE OF NETWORKS HANDLING FOODBORNE OUTBREAKS	
Comments for the Spanish-language document: The networks structure graphic should have the following replaced: In LOCAL NETWORK 1, 2 and 3, where it says NATIONAL, it should be replaced with LOCAL as that is the level being referred to.	Argentina
	Thailand The example of international networks organizations should include International Health Regulations (IHR), International Food Safety Authority Network (INFOSAN), Regional WHO, and Regional FAO.
ANNEX III – TEMPLATE FOR RAPID RISK ASSESSMENT	
	Colombia In investigations of human cases, change county to local. On the topic of linking epidemiological and laboratory data in humans and food, the possible content of the last sentence would

	<p>be "... thus illustrating the allele differences in the main genes."</p>
	<p>Thailand We would like to add 'Prognosis' as one of the topic in the Template. The disease prediction, if available, can be used to forecast the possibility of disease spreading and population that may be affected.</p>
	<p>USA Outbreak background information Revise as follows: Questions such as the following should be answered in this part: How was the outbreak initially detected? How has initial information on human cases and on affected food been distributed? How have the human cases initially been linked to a certain food source? Investigations in food (last bullet) Revise as follows: 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>Summary</p>	
	<p>Canada Proposed text for Annex III Summary (to add precision): Overview of involved geographical areas/jurisdictions at local, national or regional level. Summary of investigations on food source and any risk mitigation actions taken (e.g. withdrawal) and planned. Short and clear communication message to consumers, affected food business operators and other stakeholders, and trade partners.</p>
<p>Illness background information</p>	

	<p>Proposed text for Annex III Illness background information: Historical data on the hazard, not related to the ongoing outbreak, on the hazard e.g.;</p> <ul style="list-style-type: none"> • occurrence in different types of food <p>Historical data from previous monitoring and isolations in food might help target investigations towards the potential source if the source is not known yet.</p>
<p>Outbreak background information</p>	
	<p>Proposed text for Annex III Outbreak background information: Questions which should be answered in this part, such as: How was the outbreak initially detected? How has initial information on human cases and on affected food been distributed? How have the human cases initially been linked to a certain food source? Canada's comments on this section are that the intent of the second question as written is unclear. Should it read: "Is there any correlation between the distribution of the cases and the distribution of the potentially implicated food?"</p>
<p>Investigation of human cases</p>	
	<p>Canada Proposed text for Annex III Investigation of human cases: Per geographical area/jurisdiction (e.g. county, province/state, country) Additional information (age groups, hospitalisations, severity of symptoms (e.g. hemolytic uremic syndrome), mortality)</p>
<p>Conclusion</p>	
	<p>Canada <u>Proposed text for Annex III Conclusion:</u> It should indicate uncertainties and data gaps and make recommendations, in the first place to consumers, but also, if considered</p>

	<p>appropriate, to public health and food authorities, public health and food business operators, and to trade partners.</p>
	<p>Canada</p> <p>Canada suggests that some of the information in paragraph 81 should also be included in the template. Especially bullet 2, 3, 4 and 6.</p> <ul style="list-style-type: none"> • results from epidemiological and microbiological investigations of human outbreak cases, considering severity, possible mortality, spread of cases and affected subgroups (e.g. elderly); • laboratory results and results from the epidemiological and food safety (including tracing back) investigations; • risk identification and characterization linked to the outbreak; • where appropriate, recommendations to the consumers and to competent authorities on how to manage the risk.