

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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**Agenda Item 8**

**CX/FH 18/50/8 Add.1**

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

**Fiftieth Session**

**Panama City, Panama  
12 - 16 November 2018**

### **PROPOSED DRAFT GUIDANCE FOR THE MANAGEMENT OF (MICRO)BIOLOGICAL FOODBORNE CRISES/OUTBREAKS**

**Replies to comments at Step 3 to CL 2018/72-FH**

*Comments of Argentina, Brazil, Canada, Colombia, Cuba, Ecuador, Egypt, Gambia, Guyana, India, Iran,  
Japan, Malaysia, Morocco, New Zealand, Norway, Philippines, Senegal, Thailand, USA and IUFOST*

#### **Background**

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/72-FH issued in September 2018. 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

<b>GENERAL COMMENTS</b>	
<p>Brazil would like to thank the outstanding work carried out by Denmark, EU and Chile. With regard to the recommendations, Brazil considers the following.</p> <p>i. Brazil considers it more appropriate that Appendix I be an information document rather than a Guidance. This informational document should contain all relevant information regarding the Biological Outbreak Management mentioned in the documents listed in paragraph 14, as well as additional information already raised by the electronic group.</p> <p>ii. Brazil agrees.</p> <p>iii. a) Brazil uses the term "Food safety event". It is necessary to clarify if event, incident and emergency are synonymous and define event, crisis, incident and emergency if they are different.</p> <p>b) Brazil agrees with the use of the term biological because it is more broad.</p> <p>c) Brazil agrees with the alternative option of defining "foodborne outbreak".</p> <p>d) No comments.</p> <p>iv. Brazil is of the view that authorities and agencies involved in the management of a foodborne disease outbreak should not be included in a CCFH document but rather in a CCFICS document given its scope of action.</p> <p>For Brazil the scope / scope of the document is more comprehensive than what was approved in the draft document, since it also includes the management of situations in which the disease does not exist, but only the presence of the pathogenic microorganism. Codex documents are worldwide in scope, and closing Outbreak Management through Whole Genome Sequencing (WGS) may not be feasible for all countries. The document should also emphasize the use of other types of methods such as large-scale sequencing to identify genetic differences, virulence factors and antimicrobial resistance mechanisms.</p>	<b>Brazil</b>
<p>Canada noticed that there are missing spaces between words in the document.</p> <p><b>answer to question a:</b> The term "Food safety emergency" would be appropriate. This would adhere to the direction given at CCFH49, which stated, "This guidance intends to provide a supplement and a link to documents developed by FAO/WHO and Codex texts, as appropriate". In addition, the guidance would align with the food safety emergency definition and the scope of the CODEX document (CAC/GL 19-1995) Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations.</p> <p><b>answer to question b:</b> As per the report from CCFH49, "The scope is limited to biological hazards." As such, it is recommended that the term "biological" is used throughout the guidance instead of "(micro)biological". This would then ensure that the guidance clearly includes bacteria, viruses, parasites and other biological agents as specified in the definition in paragraph 16.</p> <p><b>answer to question c:</b> Either definition of foodborne outbreak would be acceptable. However, if we choose to be consistent with other documents referenced in this guidance, we can use the definition from The WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls".</p> <p><b>answer to question d:</b> Supportive of the use of the term "rapid risk assessment". This would align with the FAO/WHO Guide for Development and Improving National Food Recall Systems, where the wording in Section 5.1 is "Conduct a rapid risk assessment" and in Figures 2 through 5 on pages 41 to 44 is "Assessment (rapid, precedent based)."</p>	<b>Canada</b>

<p>Alternatively, we would support the term “risk assessment” but not the term "outbreak assessment". Outbreak assessment does not suggest that an assessment of the risk will be done.</p>	
<p>Cuba is grateful for the opportunity to provide the following comments on the document:</p> <ul style="list-style-type: none"> <li>- Cuba supports the document prepared by the Working Group through electronic means presided through electronic means presided over by Denmark, the European Union, and Chile.</li> <li>- Cuba considers the eWG’s recommendations to be very important in order to perfect the document when it is discussed in the Committee’s meeting.</li> <li>- In text 17, Cuba supports the alternative paragraph as it is more explicit.</li> </ul>	<b>Cuba</b>
<p>Ecuador thanks the electronic Working Group for the opportunity to provide comments on the document and wishes to support it while taking into consideration the following observations:</p> <p>(ii) Specific Comments:</p> <ul style="list-style-type: none"> <li>- Ecuador believes that the nomenclature of the bibliography should be changed from “letters” to “numbers”, as it gives rise to confusion when analyzing the document.</li> </ul> <p>Ecuador suggests including the following in paragraph 10 of Scope:</p> <p>The guidance addresses preparedness, detection, response and recovery with the intent of limiting the extent of such events. The scope is limited to (micro)biological hazards.</p> <p>Ecuador recommends supporting the alternative text proposed in paragraph 17 on Foodborne outbreaks with the following inclusion:</p> <p>A foodborne outbreak is an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness.]</p> <p>An outbreak involves the convergence of the host, the agent, and environmental factors that may be present</p> <p>[Food safety emergency] Definition is given in CXG 19-1995.</p> <p>[Food safety events] if necessary</p> <p>[Food safety incident] if necessary</p> <p>Surveillance is a systematic and ongoing collection of test results from humans, animals or foodstuffs for the purpose of applying appropriate control measures. One of the main objectives of surveillance is to follow-up unsatisfactory results with an investigation and possible enforcement action.</p> <p>Epidemiological study comprises a study of the host, the agent, and environmental factors.</p> <p>Ecuador believes that the following should be modified in paragraph 46:</p> <p>Creation of standard questionnaires surveys for this purpose may be performed electronically using one of the internet based free of charge software’s. Data can then be analyzed electronically in a standard statistical software program.</p> <p>In paragraph c) Comparing epidemiological and laboratory data, it is requested that the following be deleted from paragraph 49:</p>	<b>Ecuador</b>

<p>Although this approach can be resource consuming, it should be a key component in substantiating if the food item is the likely source of contamination and identifying the specific foods involved in the event when sufficient epidemiological and product data are available.</p> <p>- Ecuador recommends that the following be modified in paragraph 56: (...) If possible an analytical epidemiological study should be performed (e.g. a retrospective cohort or control of cases case-control study).</p> <p>Ecuador considers including the following in paragraph 58: Laboratory results can support the epidemiology but they will only be conclusive if the result is supported by at least some epidemiological information such as that obtained from the patients.</p>	
<p>India would like to appreciate the work done by EWG and observed that some cosmetic and editorial corrections need to be carried out while making final document.</p>	<b>India</b>
<p>This file needs major revision typographically and grammatically.</p> <p>Use of “incident” instead of “event” and “emergencies” is recommended everywhere.</p> <p>In the title, use of “biological” instead of microbiological and “crises” instead of “outbreaks” is recommended. Biological is general word. Furthermore, it has been mentioned in the Scope (item 10): The scope is limited to biological hazards.</p>	<b>Iran</b>
<p>The Philippines supports to consider the proposed guideline as presented in Appendix I and to continue to work on the guideline as recommended. This will provide guidance whenever a (micro)biological outbreak occurs.</p> <p>We agree to use figure or diagram as a general reference to present the required collaboration or coordination of competent authorities, food business operators and other stakeholders during food safety incidents and emergencies. The responsibilities of each sector must be provided to have a clear delineation of functions.</p>	<b>Philippines</b>
<p>1. The use of either “Food safety emergency”, “Food safety incident” or “Food safety event”</p> <p>The term “Food safety emergency” should be used so that it is in line with the existing Codex text such as Principles and Guidelines for an Exchange of Information in Food Safety Emergency Situations (CXG 19-1995).</p> <p>2. The use of the term “biological” instead of “(micro)biological” in the headline and the scope</p> <p>The term “biological” foodborne should be used. The scope of the Draft should be widened to cover other biological hazards such as poisonous mushroom and toxin from puffer fish.</p> <p>3. Which of the two definitions on foodborne outbreaks that should be used if any</p> <p>We think the definitions should be in line with the existing text such as from WHO or IHR.</p>	<b>Thailand</b>
<p><b>Scope of the document</b></p> <p>One issue to be resolved is the scope of the document. In describing the work of the eWG, paragraph 7 notes that there were different opinions on “removal of the parentheses” (around “micro”) to limit the scope to “microbiological” foodborne outbreaks, but the paragraph also addresses whether the scope of the document should go beyond foodborne outbreaks. This is further addressed in paragraph 9 with respect to the term “food safety emergencies” vs. “food safety incidents” or “food safety events.” Paragraph 9 states that “According to the project document and the scope decided upon at CCFH49 the work should cover foodborne crisis/outbreaks.” It further states that “the current draft is limited to foodborne outbreaks</p>	<b>USA</b>

and single cases in those situations where they end up as outbreaks.” We note that the project document states “the purpose of the new work is to provide guidance to competent authorities on the management of foodborne outbreaks/crises” (section 1) and “The guidance will address recommendations on preparedness for outbreaks and on their management” (section 3). We can support limiting this document to providing guidance on preparedness for and management of foodborne outbreaks (from microorganisms, as discussed in the next paragraph). It is unclear how this document provides guidance on “single cases in those situations where they end up as outbreaks.” Thus, we recommend limiting the title and scope to managing foodborne outbreaks. We recommend deleting the term “crisis” from the title as not being needed, since the guidance would be directed to all outbreaks, regardless as to whether they constitute a crisis or not. (“Crisis” is a subjective term that could be viewed differently by the entities involved, and the recommendations do not identify different procedures for outbreaks considered to be crises from those that are not so considered.)

With respect to whether the scope should be “biological” or “microbiological,” we recommend limiting the scope to microbiological foodborne outbreaks to be consistent with the other documents prepared by CCFH, such as Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30, (1999) and Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CAC/GL 63-2007). Moreover, the guidance provided seems focused on microbial foodborne outbreaks. This would cover those parasites most likely to cause an outbreak (e.g., *Cryptosporidium* and *Cyclospora*), as well as outbreaks from bacteria and viruses. Thus, we recommend this document be re-titled “Proposed Draft Guidance for the Management of Microbiological Foodborne Outbreaks.”

As a consequential change to the suggestions above for the title, there should be revision throughout of the document where terms such as “incidents,” “emergency,” “crises,” and “crisis” are used so that the document only refers to foodborne outbreaks; a similar search should be done to replace “biological” with “microbiological.” Since this would involve a majority of the paragraphs in the document, we are not including in our comments recommendations for these specific changes each place they need to be made.

Terms used in the document. With respect to the question the terms used, we offer the following comments:

**a. The use of either “Food safety emergency”, “Food safety incident” or “Food safety event” including to what extent the guideline should cover events of contamination of foodstuffs without human illness.**

As noted above, we recommend using the term “foodborne outbreak” instead of any of these terms. Each of these terms suggests a scope beyond that of a foodborne outbreak, and thus would be confusing in a document that only addresses foodborne outbreaks.

**b. The use of the term “biological” instead of “(micro)biological” in the headline and the scope.**

As noted above, we recommend using the term “microbiological.”

**c. Which of the two definitions on foodborne outbreaks that should be used if any.**

It is unclear what the two definitions are – “a” vs. “b”? Or “a” and “b” vs. the alternative option? We support a definition that is consistent with “b” (the occurrence of two or more cases of a similar foodborne disease resulting from the ingestion of a common food) but could accept the alternative option (A foodborne outbreak is an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness)

**d. The use of “rapid risk assessment” and/or “outbreak assessment.”**

Since the document is limited to foodborne outbreaks, we prefer the term “outbreak assessment.” We consider this to be a more appropriate term for what takes place during most foodborne outbreaks. A risk assessment should incorporate four steps, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization, leading to a risk estimate. “Rapid risk assessment” suggests that all these steps will be completed rapidly. Although this approach, which is described in the FAO/WHO Guide for Application of Risk Analysis Principles and

<p>Procedures during Food Safety Emergencies (2011), can be taken, it is not clear to us that all the steps are needed during a microbial foodborne outbreak in order to manage the risk (e.g., an exposure assessment that is based on national food consumption patterns is usually not needed). During an outbreak, assessments are made about the foods involved, the extent of their distribution, the agent involved, and the severity of likely adverse health effects, including information about virulence factors present in the microorganism where appropriate. Regardless of the term used, this document could better explain how the outcome of the assessment is to be applied, i.e., how this assessment is used to provide “a sound scientific basis for the action to be taken” (paragraph 34) when there is an ongoing foodborne outbreak (vs. a contamination event that has not been associated with illness).</p> <p>Graphic explanation/diagrams. We do not see where graphic explanations/diagrams would provide helpful information at this time. The eWG chairs use as an example for how these can be helpful “to illustrate the involved authorities and agencies and the networks described.” We question whether this would be feasible given the different authorities and agency structures in different countries.</p> <p>References to Codex and FAO/WHO documents. Paragraph 14 lists a number of documents preceded by a letter. There is no clear explanation that these letters will be used as superscripts throughout the document when relevant for obtaining additional information. (Paragraph 9 states that “This document collects guidance for preparedness and management of food safety[emergencies/incidents/events] with cross-references to relevant documents and recommends the use of new analytical technologies in outbreak investigation,” but this does not fully explain that this is done using superscripts with the letters in paragraph 14.) In fact, the superscripts appear in sentences before the list appears (e.g., in paragraphs 8 and 9) as if there is a footnote. This is very confusing and should be clarified if this format is retained.</p> <p>Moreover, we are wondering whether such a listing and extensive referencing gives the FAO/WHO documents status with respect to WTO issues. FAO/WHO documents, while developed by experts, do not incur the same inclusivity with respect to review as happens with Codex documents. In addition, we are wondering whether there is new information in this document that is not available in the many references. We do think it is useful to pull together information from these many documents into a single document, consolidating key information that is useful to national governments and/or Codex members and observers and Codex Committees. However, since the content of this document appears to be derived in large part from existing information, we suggest that this document be developed and posted as an Information Document rather than a Codex guideline.</p> <p>Communication with industry. We believe that this document can be enhanced with respect to communication with industry. In the “Preparedness” section, we recommend adding text about establishing communication links with industry that can be used to provide information about food categories potentially involved in an outbreak with respect to production and distribution practices. It is also important to communicate with industry the facts of an outbreak and the root causes in order for food businesses to learn from outbreaks. There is mention in paragraph 63 about using experts to “validate recommendations” (which we assume is primarily assessing the message in the recommendations), but involving industry experts earlier may speed the investigation (e.g., do hypotheses about what went wrong make sense given manufacturing and distribution practices?</p>	
<p>Issue/Background  <b>Para. 29: Reference to food safety emergencies/incidents/events being cause only by biological hazards</b></p> <p>Gambia recommends a modification to the sentence to read “many biological food safety [emergencies/incidents/events] are initially identified through human illness surveillance data and therefore removal of square brackets.</p> <p>Rationale          Biological hazards does not cover all causative agents of foodborne diseases</p> <p>Gambia recommends replace the term “foodborne illness” with “foodborne disease” throughout the document to ensure consistency with title</p>	<p><b>Gambia</b></p>

<p>The document is well structured. However, the sections should be numbered. The title and the scope should be widened to cover other causes of foodborne disease outbreaks other than (micro)biological.</p> <p>Issue/Background  <b>Title: Should the parenthesis in the title be deleted so the document only covers management of microbiological foodborne outbreaks?</b></p> <p>Gambia does not support the removal of brackets but recommends the title to read “Guidance for the Management of Foodborne Disease Crises/Outbreaks”</p> <p>Rationale: Outbreaks/crisis would include all foodborne disease outbreaks not only (micro)biological.</p>	
<p>Malaysia prefers the term “Biological” to be used instead of “microbiological”</p> <p>The term “biological” is broader than “microbiological” and it covers both biological agents and microbiological agents.</p> <p>Malaysia prefers the term “Food safety emergency” to be used as a general term throughout the document to cover any biological foodborne crisis/outbreak.</p> <p>This is also to be consistent with the FAO/WHO Framework for Developing National Food Safety Emergency Response Plans document.</p>	<b>Malaysia</b>
<p>The document is well structured. However, the sections should be numbered. The title and the scope should be broadened to cover causes of foodborne illnesses other than (micro)biological.</p> <p>Paragraph 5 of document CX/FH/18/50/8:</p> <p><b>Title:</b> Should the parenthesis in the title be deleted so the document covers more than just management of microbiological foodborne outbreaks?  -Morocco recommends the following title: “Guidelines for foodborne crises/illnesses”</p> <p>Rationale : Crises would encompass all foodborne illnesses, and not just those of (micro)biological origin.</p> <p>Would it be acceptable to add the words “and regional” in “Scope” to acknowledge that some regions e.g. Europe have regional alert systems for communicating both outbreaks and other food crises besides INFOSAN?</p> <p>Opinion: Yes</p> <p>Rationale: To recognize what is done at the regional level as well.</p> <p>-Is the use of the term “food safety emergencies” for all type of outbreaks feasible regardless of their severity? Opinion: No</p> <p>Rationale: Foodborne illnesses can vary depending on the degree of gravity and severity of the hazard.</p> <p>-Should we introduce graphic explanations/diagrams in the guideline although this is not normal practice in Codex text e.g. description of the network structures and monitoring?</p> <p>Yes, it is necessary to introduce graphic explanations/diagrams in the guideline.</p> <p>Rationale: To ensure improved clarity of concepts and proper comprehension of the guide.</p> <p>Is it necessary to define the terms “rapid risk assessment” and “epidemic assessment”?</p> <p>Morocco recommends defining the terms “rapid risk assessment” and “epidemic outbreak assessment”.</p>	<b>Morocco</b>

Rationale: To improve comprehension of the guide.	
<p><b>General</b></p> <p>Consider whether the term “multinational” or “international” is used throughout the guideline to refer to outbreaks that affect more than one nation. At present both terms are used</p> <p><b>Introduction</b> Discussion about requirements under the International Health Regulations (2005) needs to be included as the management of a foodborne outbreak is considered a core capacity Gives additional strength of the need to develop these systems – and countries need to be aware of the IHR requirements</p> <p><b>Para 6</b></p> <p>“... use of this methodology is expected to lead to the detection of more linked outbreaks in the future and the need for enhanced preparedness”</p> <p>The use of molecular analytical methods (such as whole genome sequencing) may lead to the detection of more associated or linked cases/incidents that form outbreaks rather than directly leading to the detection of more outbreaks in the future as suggested (ie the total number will increase).</p> <p><b>Para 10</b> “...with international networks such as the International Food Safety Authorities Network (INFOSAN) Include ‘International’ before Food Safety Authorities as the current name is incorrect</p> <p><b>Para 14</b> This is a comprehensive list for food. Consider a second list of key references for surveillance development (human health and food contamination)</p> <p>Given the documents refers to building on existing systems, it would be good to note the availability of resources on surveillance system development (human health and food contamination).</p> <p><b>Para 30</b>, bullet point 2 Amend “As not all diseases are mandatory to notify to the human health authorities’ access to information...” to “As it is not all diseases are mandatory to notify all diseases to the human health authorities’ access to information...” Clarifies wording for improved understanding</p> <p><b>Para 44</b> First bullet point – add the following at end of sentence ‘...likely to be foodborne; or’ Otherwise this statement is too broad</p> <p><b>Para 45</b> Include clarification that the case definition development should be led by the human health sector with input by food control authorities as needed Role definition helps ensure the guidelines are followed</p> <p><b>Para 41, bullet point 1</b> Establish a communication strategy, among the network members and designate official spokespersons from the government or central national network to the public and decide on the means of communication (websites, social media, radio, twitter, facebook, etc.). Delete references to Twitter and Facebook as the main social media platforms differ from country to country, also added reference to radio but could be expanded to include other forms of media</p> <p><b>Para 45</b> Include note at the end of the para that a ‘line listing should be generated and provided to the food control authority and a mechanism established to keep this information updated’. This reflects best practice.</p> <p><b>Para 51</b> “Whilst the Management of outbreaks benefits from the public health and the food and veterinary sectors being able to share and compare relevant laboratory surveillance and monitoring data in order to identify a match between a clinical isolate and a food source laboratory data is not</p>	<p><b>New Zealand .</b></p>

<p>always required and maybe secondary to robust epidemiological information.” Need to include the concept that laboratory data is not always required and is secondary to robust epidemiological information as this reflects best practice and reflects wording in para 55.</p> <p><b>Para 55</b> Delete as a repeat of para 51</p> <p><b>Para 56</b> Remove/ reword Repeat of para 45</p> <p><b>Para 59/60</b> Need to discuss in urgent situations, it is possible that the separation of risk assessment and risk management/ outbreak investigators may not be possible and is accepted if those involved are mindful about the different roles.</p> <p><b>Para 59/60</b> Include the need for a specific assessment for managing an identified affected food and appropriate actions Undertaking a rapid risk assessment is not well understood by many countries and needs additional guidance in this document. New Zealand has examples that may assist with this.</p>	
<p><b>Recommendation ii: Agree to continue the work on the guideline with the aim of elaborating a document that can be read on its own with the necessary references to other documents for more detailed guidance in relevant places.</b></p> <p>We agree to continue the work.</p> <p><b>Recommendation iii</b></p> <p><b>a): The use of either “Food safety emergency”, “Food safety incident” or “Food safety event” including to what extent the guideline should cover events of contamination of foodstuffs without human illness.</b></p> <p>In our opinion, all the terms mentioned can be used. However we prefer the term “Food safety incident”, as it corresponds the best with the established terms in outbreak investigations. The guideline should also cover events of contamination of foodstuffs without human illness.</p> <p><b>b): The use of the term “biological” instead of “(micro)biological” in the headline and the scope.</b></p> <p>We suggests using the term “biological” in the headline and the scope of the guideline. In our opinion the guideline should also include outbreaks caused by e.g. parasites.</p> <p><b>c): Which of the two definitions on foodborne outbreaks that should be used if any.</b></p> <p>Both definitions are acceptable.</p> <p><b>d): The use of “rapid risk assessment” and/or “outbreak assessment”.</b></p> <p>We would suggest the term “rapid risk assessment” as it is more precise due to established definitions.</p> <p><b>Recommendation iv: Discuss and agree on the use of graphic explanation/diagrams in the guideline e.g. to illustrate the involved authorities and agencies and the networks described.</b></p> <p>We support the use of graphic explanations/diagram to enable the reader to understand the guidance better.</p>	Norway
<p>IUFoST supports the concepts and recommended draft text, the CCFH will have to decide on final definitions.</p>	IUFOST

SPECIFIC COMMENTS	
<b>TITLE</b>	
<b>GUIDANCE FOR THE MANAGEMENT OF (MICRO)BIOLOGICAL FOODBORNE CRISES/OUTBREAKS</b>	
<b>PROPOSED DRAFT GUIDANCE FOR THE MANAGEMENT OF (MICRO)BIOLOGICAL FOODBORNE CRISES/OUTBREAKS – CRISES/ EMERGENCIES /INCIDENTS</b>	<b>Senegal</b> Incidents, emergencies, and crises would encompass all foodborne epidemic outbreaks.
<b>INTRODUCTION</b>	
<b>Paragraph 1</b>	
Codex Alimentarius has issued several guidelines on hygienic <del>practice</del> <u>practices</u> for food businesses and competent authorities on how to ensure food safety.	<b>Canada</b>
Codex Alimentarius has issued ..... Those guidelines focus on, e.g. prevention, monitoring and corrective actions in case of deviations in the production processes. Despite efforts to ensure a high level of hygiene foodborne <del>illness</del> <u>disease</u> outbreaks still occur.	<b>Japan</b>
<b>Paragraph 2</b>	
The globalized food production, trade and complex supply chains <del>contribute may lead to food safety gaps/breaches and resulting outbreaks of foodborne illness outbreak situation</del> with a broader impact.	<b>Canada</b> We suggest modifying the sentence. The focus should be on the impact of an outbreak rather than on the food safety gaps, which can also occur in local food productions and simple supply chains.
The globalized food production, trade and complex supply chains contribute to food safety breaches and resulting outbreaks of foodborne illness with a broader impact.	<b>Iran</b>
The globalized food production, trade and complex supply chains contribute to food safety gaps/breaches and resulting outbreaks of foodborne illness with a <del>broader</del> <u>potentially broad</u> impact.	<b>USA</b> Rationale: It is unclear what the outbreak is “broader” than. This may be suggesting that globalized food production, trade and complex supply chains result in outbreaks with a broader impact than localized systems, but this is not clear, nor is it necessarily true.
<b>Paragraph 3</b>	
Foodborne illness can be mild ..... Foodborne outbreaks can cause impediments to domestic <del>consumption</del> and international trade.	<b>Canada</b> Clarifications required for domestic

	consumption or suggest deletion of the word “consumption”.
Foodborne illness can be mild .... Foodborne <del>illness-disease</del> outbreaks can have significant socio-economic costs related to medical treatment, hospitalization and lost productivity.....	<b>Japan</b>
<b>Paragraph 4</b>	
In order to be able to efficiently handle food safety [emergencies/incidents/events] local and national multiagency networks of preparedness should be in <del>place to handle these situations</del> <u>place</u> .	<b>Canada</b> Consider if we need to include more information in this sentence: Such networks should use standardised methods and interpretation; (...) Is it clear what the standardised methods are?
In order to be able to efficiently handle food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u> local and national multiagency networks of preparedness should be in place to handle these situations. Such networks .....	<b>Japan</b>
<b>Paragraph 5</b>	
<del>The principles for risk analysis, including risk assessment, risk management and risk communication, as described by Codex Alimentarius <sup>b.6</sup> should form the framework/basis for the establishment of a system for preparedness and management of food safety[emergencies/incidents/events].</del>	<b>Colombia</b> Columbia suggests deleting paragraph 5.
The principles for risk analysis, including risk assessment, risk management and risk communication, as described by Codex Alimentarius  Reference source not found. should form the basis for the establishment of a system for preparedness and management of food safety incidents.	<b>Iran</b>
The principles for risk analysis, including risk assessment, risk management and risk communication, as described by Codex Alimentarius <sup>b.6</sup> should form the framework/basis for the establishment of a system for preparedness and management of food <del>safety[emergencies/incidents/events]</del> <u>safety[emergencies]</u> .	<b>Japan</b>
<b>Paragraph 6</b>	
Molecular analytical methods ..... The use of specific genomic methods (e.g. whole genome sequencing) can result in improved detection of outbreaks and improved [outbreak/incident/event] management and <del>enables-can help to</del> <u>resolution of identify</u> involved <del>batches food batches</del> , reducing the impact of actions taken. Use of this .....	<b>Canada</b> Suggest modifying the sentence because whole genome sequencing alone will not enable better resolution of involved batches unless there is systematic and representative sampling of every single batch, which does not occur. Epidemiological information and a thorough food safety investigation will still be necessary.

Molecular analytical methods contribute to link clusters of human cases with the food source. The use of specific genomic methods (e.g. whole genome sequencing) can result in improved detection of outbreaks and improved <a href="#">[outbreak/incident/event]-[emergency/incident/crisis]</a> management .....	<b>Senegal</b>
Molecular analytical methods ..... The use of specific genomic methods (e.g. whole genome sequencing) can result in improved detection of outbreaks and improved <a href="#">[outbreak/incident/event]</a> management and enables better resolution of involved batches <a href="#">of food</a> reducing the impact of actions taken. Use of this .....	<b>USA</b>
<b>Paragraph 7</b>	
The phrase “food safety <a href="#">[emergency/incident/event]</a> ” is used for simplicity throughout the document and covers <a href="#">such these</a> situations (regardless of size). Foodborne illness outbreaks caused by biological agents .....	<b>Canada</b> Suggest separating the paragraph in two so that the information on food safety emergencies is one paragraph and the information on foodborne illness outbreaks in another.
The phrase “food safety <del><a href="#">[emergency/incident/event]</a></del> <a href="#">emergency</a> ” is used <del>for simplicity throughout in the document and covers such situations (regardless guidelines to encompass possible situation regardless of size)</del> <a href="#">the size of affected consumer</a> . Foodborne illness outbreaks .....	<b>Philippines</b> We propose to delete the square bracket and to use the term “food safety incident and emergency” to be consistent with WHO’s terminologies, where food safety incident... and Food emergency....
<del>The Foodborne illness outbreaks phrase “food safety <a href="#">[emergency/incident/event]</a>” is used for simplicity throughout the document and covers such situations (regardless of size). Foodborne illness outbreaks</del> caused by biological agents can be categorized according to the following criteria: The number of cases .....	<b>USA</b> It is not needed if the single term “foodborne outbreak” is used.
The phrase “food safety <a href="#">[emergency/incident/event]</a> <a href="#">emergency</a> ” is used for simplicity throughout the document and covers such situations (regardless of size). Foodborne <del>illness disease</del> outbreaks caused by biological agents can be categorized according to the following criteria: The number of cases .....	<b>Japan</b>
<b>Paragraph 8</b>	
<b>We recommend deleting the paragraph</b> based on our recommendation to limit the document to foodborne outbreaks. If the paragraph is retained, we recommend changing “business as usual” to something like “a routine investigation.”	<b>USA</b> It is not needed if there is not specific guidance in this document for handling a foodborne outbreak as an emergency or crisis. The term “business as usual” is not clear and it could suggest that foodborne outbreaks are the norm.

<p>The decision to categorize an outbreak as an emergency or as a crisis is at the discretion of the competent authorities and will depend on their capacity and capability of handling food safety <del>[emergencies/incidents/events]</del> <del>[emergencies]</del> and of the category of the foodborne illness outbreak itself<sup>a</sup>. What may .....</p>	<p><b>Japan</b></p>
<p><b>Paragraph 9</b></p>	
<p>This document <del>collects-contains</del> guidance <del>for on</del> preparedness and management of food safety[emergencies/incidents/events] with cross-references to relevant documents and <del>recommends</del> <del>includes</del> the use of new analytical technologies in outbreak investigation. Relevant to this guideline is also the International Food Safety Authorities Network (INFOSAN), a global network of national food safety authorities, managed jointly by FAO and WHO, for rapid sharing of information during food safety emergencies to stop the spread of contaminated food from one country to another. INFOSAN <del>also</del> facilitates the sharing <del>of</del> experiences and tested solutions in and between countries in order to optimize future interventions to protect the health of consumers<sup>k,l</sup>.</p>	<p><b>Canada</b> Is there a clear position to “recommend” the use of new analytical technologies in outbreak investigations under CCFH? If not, suggest modifying the text.</p>
<p>This document collects guidance for preparedness and management of food <del>safety[emergencies/incidents/events]</del> <del>safety[emergencies]</del> with cross-references to relevant documents and recommends the use of new analytical technologies in outbreak investigation. Relevant to this ..... health of consumers<sup>k,l</sup>.</p>	<p><b>Japan</b></p>
<p>This document collects guidance for preparedness and management of ..... Relevant to this guideline is also the International Food Safety Authorities Network (INFOSAN), a global network of national food safety authorities, managed jointly by FAO and WHO, for rapid sharing of information during <del>foodborne outbreaks (as well as other</del> food safety <del>emergencies-emergencies)</del> to stop the spread of contaminated food ..... to optimize future interventions to protect the health of consumers<sup>k,l</sup>.</p>	<p><b>USA</b> As currently written, these “emergencies” would appear to go beyond the scope of the document; contaminated food is not necessarily food causing a foodborne outbreak. These sentences suggest a broader scope related to foodborne contamination incidents and not just foodborne outbreaks. (We had recommended these sentences when we thought the document would be applied to contamination events/incidents as well as foodborne outbreaks.)</p>
<p><b>SCOPE</b></p>	
<p><b>Paragraph 10</b></p>	
<p>These guidelines provide guidance to competent authorities on the management of food safety <del>[emergencies/incidents/events-emergencies]</del>, including the .....</p>	<p><b>Colombia</b> The definition involves national and international scenarios. This comment applies to the whole document.</p>
<p>These guidelines provide guidance to competent authorities on the management of food <del>safety[emergencies/incidents/events]</del> <del>safety[emergencies]</del>, including the communication between national and regional programmes with international networks such as the Food Safety Authorities Network (INFOSAN). The guidance addresses .....</p>	<p><b>Japan</b></p>

<b>Paragraph 11</b>	
The guidelines describe the role of competent authorities <u>at different levels</u> and collaboration <u>between them</u> in formalized network <del>structures between them at different levels</del> <u>structures</u> . Collaboration and communication .....	<b>Canada</b>
The guidelines describe the ..... Collaboration and communication with food business operators and other stakeholders before and during food safety <del>[emergencies/incidents/events]</del> <u>is [emergencies]</u> is also addressed.....	<b>Japan</b>
The guidelines describe the role of competent authorities ..... Collaboration and communication with food business operators and other stakeholders before and during food safety <del>[emergencies/incidents/events]</del> <u>incidents/emergencies/crises</u> is also addressed .....	<b>Senegal</b>
<b>USE</b>	
Argentina believes that it is a useful document as a guide to facilitating crisis management. The scope of this document includes topics such as human health, for example the epidemiological study of outbreaks that we understand, among other aspects, would exceed the scope of the Codex. Therefore, we believe that we should have a discussion on what sort of document it would be appropriate to draw up. Additionally, Argentina believes that many documents are referenced, making it difficult to select information for the shortening and application of this document	<b>Argentina .</b>
<b>Paragraph 12</b>	
These guidelines should be used in conjunction with ..... References are also given to FAO/WHO guidelines providing detailed information for competent authorities on preparedness for food <del>safety [emergencies/incidents/events]</del> <u>and safety [emergencies]</u> and on their management in .....	<b>Japan</b>
<b>Paragraph 13</b>	
In food safety <del>[emergencies/incidents/events]</del> involving zoonotic agents <del>it may be relevant for the decision on what risk management options to be used to take into consideration the</del> World Organization for Animal Health (OIE) standards for the prevention, detection and control of zoonotic agents at the primary production stage, <u>should also be considered</u> .	<b>Canada</b>
In food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u> involving zoonotic agents it .....	<b>Japan</b>
In food safety <del>[emergencies/incidents/events]</del> <u>incidents/emergencies/crises</u> .....	<b>Senegal</b>
<b>Paragraph 14</b>	
If the list is retained here, we recommend explaining how the listed guidelines are referred to throughout the document. This is apparently done using superscript letters that correspond to the listing, but readers are left to figure this out. We recommend considering a different approach; e.g., eliminating the list and using a footnote where they are referenced (particularly when the reference superscript is more than just a letter). We also recommend deleting the INFOSAN Members Guide, since it is not widely available.	<b>USA</b> We found these superscript letters difficult to read and kept looking for corresponding footnotes or end notes. The INFOSAN Members Guide should be deleted because reference documents should not include those that are not available to all readers.

	Moreover, we are unable to determine whether the content is appropriate.
<i>Principles and Guidelines for the Conduct <del>eg of</del> Microbiological Risk Management (CXC 63-2007, as amended)</i> <sup>3</sup>	<b>Canada</b>
<b>DEFINITIONS</b>	
Argentina suggests using the term biological since it is more general and in this way, we include any biological hazard capable of producing an outbreak of foodborne illness. This would include all biological parasites and toxins (e.g. saxitoxin, cause of paralyzing poisoning by molluscs). Argentina suggests using the following option: “A foodborne outbreak is an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness.”	<b>Argentina</b>
We proposed to include the following: Food safety incident is a situation within the food safety chain where there is a possible or confirmed risk associated with the consumption of food. Food emergency is a situation, whether accidental or intentional, that is identified by a competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action.	<b>Philippines</b>
<b>Paragraph 16 Biological hazards</b>	
<u>Biological hazards</u> are biological agents..... These include e.g. <del>bacteria and algae</del> <u>bacteria</u> , including their toxins and metabolites, <del>viruses, fungi, natural toxins, viruses, prions, parasitic protozoa and helminths</del> <u>parasites and prions</u> .	<b>Colombia</b> We propose modifying in accordance with definitions from other Codex documents.
This definition and the rest of the draft did not include yeasts, molds.	<b>Egypt</b>
Iran suggests the addition of “fungi, yeasts and their toxins” into the paragraph of biological hazards as examples.	<b>Iran</b>
<u>Biological hazards</u> are biological agents including microorganisms ..... These include e.g. <del>bacteria and algae</del> <u>bacteria</u> , including their toxins and metabolites, viruses, natural toxins, <del>prions,</del> parasitic <del>protozoa</del> and <del>helminths</del> <u>protozoa</u> .	<b>USA</b> We recommend limiting the examples of biological hazards to those known to have cause foodborne outbreaks and deleting “algae,” “prions” and “helminths” from the list. Rationale: We question inclusion of algae as a biological hazard associated with foodborne illness. Prions and helminths are not microbiological hazards, and we are not aware of foodborne outbreaks from helminths.

<b>Paragraph 17 Foodborne outbreak</b>	
[A foodborne outbreak is <del>an incident</del> <u>a situation</u> in which two or more .....as the source of the illness]	<b>Colombia</b> We propose keeping the alternative definition, changing the word incident
Prefer the alternative option.	<b>Egypt</b>
The alternative option is better suited for the document but the definitions should definitely be included as a quick reference and understanding not on the grounds of 'if necessary'.	<b>Guyana</b>
<p><del>a) The observed number of cases of a particular disease exceeds the expected number.</del></p> <p><del>b) The occurrence of two or more cases of a similar foodborne disease resulting from the ingestion of a common food.]</del></p> <p>[A foodborne outbreak is an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness]</p>	<p><b>India</b></p> <p><b>India</b> We support alternative definition as it seems to be more appropriate.</p>
<p>The sentence of "b" is preferred for definition of foodborne outbreak.</p> <p>b) The occurrence of two or more cases of a similar foodborne disease resulting from the ingestion of a common food. Definition of foodborne incident is recommended.</p> <p>Rapid risk analysis" including assessment, management and rapid alert system (or communication) is recommended instead of Rapid risk assessment.</p>	<b>Iran</b>
[Foodborne <u>disease</u> outbreak]	<b>Japan</b>
<p>[Foodborne[<del>Outbreak</del> <u>Epidemic</u></p> <p>It is also necessary to define the terms food safety Emergency and incidents and the definition given in document CXG 19-1995</p> <p><del>a) The observed number of cases of a particular disease exceeds the expected number.</del></p> <p>b) <del>The occurrence of</del> <u>A foodborne epidemic is an event in which two people or more cases-of-a are affected by a similar illness resulting from the after ingestion of a common food-]. Epidemiological analysis implies that the food is the source of the illness"</u></p>	<p><b>Senegal</b> We propose keeping the terms: Incidents, emergencies and crises Rationale: Rationale The three terms can be used as needed, depending on the type of food safety situation.</p>
<p>[Foodborne outbreak</p> <p>We recommend defining an outbreak as "the occurrence of two or more cases of a similar foodborne disease resulting from the ingestion of a common food."</p>	<p><b>USA</b> This is a commonly used and understood definition of an outbreak.</p>
<b>Surveillance, monitoring and cluster</b>	
Are the definitions for surveillance, monitoring, and cluster extracted from Codex Alimentarius and/or FAO/WHO documents? Consider if the definition of surveillance needs additional concepts such as "analysis and interpretation of	<b>Canada</b>

<p>the data collected”.</p>	
<p><del>Surveillance is a the systematic collection, analysis and ongoing collection-interpretation of test results from humans, animals or foodstuffs for data essential to the purpose-planning, implementation and evaluation of applying appropriate control measures. One of public health practice, and the main objectives-timely dissemination of surveillance is to follow-up unsatisfactory results with an investigation and possible enforcement this information for public health action.</del></p>	<p><b>Philippines</b> We propose the following alternative definition from WHO Foodborne Disease Outbreaks: Guidelines for Investigation and Control</p>
<p>We recommend clarifying these definitions in a way that focuses on foodborne disease. It is unclear what the “test results” are related to in the definition of “surveillance.” Unless there is a specific reason for the limitation, we prefer to define “monitoring” more broadly than analysis aimed at detecting microbiological contamination.</p>	<p><b>USA</b> It is unclear how “monitoring” differs from “surveillance” in these definitions, and searching for other definitions did not provide us with a means of distinguishing the terms. The terms are often used together (including in this document). Some definitions we found referred to surveillance as targeting monitoring. The Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CAC/GL 63-2007) refers to surveillance in terms of human disease but also refers to “public health monitoring programs.” It also states that “Monitoring activities can include the collection and analysis of data derived from surveillance of clinical diseases in humans, as well as diseases in plants and animals that can affect humans; ... surveillance based on laboratory tests of pathogens isolated from humans, plants, animals, foods, and food processing environments for pertinent foodborne hazard...” It further states that “When establishing or re-designing monitoring systems in countries, the following aspects should be considered: A public health surveillance system should be able to estimate the proportion of illnesses and death that is truly foodborne and the major food vehicles, processes, and food handling practices</p>

	responsible for each hazard...” The MRM document uses monitoring as the “on-going gathering, analysing, and interpreting of data related to the performance of food safety control systems.”
<del>Monitoring is the performance of routine analysis aimed at detecting microbiological contamination of foodstuffs from which useful prevalence data may emerge. Monitoring refers to systematic gathering of data through the sampling of commodities as well as monitoring of foodborne diseases, collation and interpretation of collected data.</del>	<b>Philippines</b> We propose the following alternative definition to be consistent with the IRR of RA No. 10611, “Philippine Food Safety Act of 2013”
A <del>cluster conglomeration</del> is in epidemiological terms, an aggregation of patients with the same disease (cases) closely grouped in time and place. In microbiological terms, isolates (e.g. bacteria or virus) having the same specific molecular profile or closely related profiles identified by laboratory analyses of samples from cases.	<b>Colombia</b> Modify term. This term is not used in the document.
<b>[Rapid risk assessment] if necessary</b>	
<del>[Rapid risk assessment] if necessary</del>	<b>Colombia</b> Delete, since neither of the two terms has been proposed for inclusion in the document, since “rapid risk assessment” is not a methodology described by the Codex, and the use of the term, without describing the methodology behind it, could give rise to confusion.
We propose to include in the Definitions the term “Rapid Risk Assessment”	<b>Philippines</b>
<del>[Emergency risk Rapid risk assessment] if necessary</del>	<b>Senegal</b> Define the terms "Emergency risk assessment and outbreak assessment
<b>1 FOOD SAFETY [EMERGENCIES/INCIDENTS/EVENTS] – PREPAREDNESS SYSTEM</b>	
Argentina agrees with the use of the term “food incident” and we believe that the scope of this document should include food outbreaks and incidents (food contamination without human illness.)	<b>Argentina</b>
<b>FOOD SAFETY <del>[EMERGENCIES/INCIDENTS/EVENTS]</del> [EMERGENCIES] – PREPAREDNESS SYSTEM</b>	<b>Japan</b>
<b>Paragraph 18</b>	
Foodborne illness <del>outbreaks</del> <u>outbreaks</u> happen frequently and vary greatly in size ..... national outbreaks or international outbreaks <sup>e</sup> .	<b>Canada</b> Is the “e” at the end of the word outbreak supposed to be a reference to e. The

	WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls"?
Foodborne <del>illness-disease</del> outbreakshappen frequently and vary greatly in size .....national outbreaks or international outbreaks <del>e</del> .	<b>Japan</b>
Foodborne illness <del>outbreaks</del> <u>outbreaks</u> happen frequently and vary greatly in ..... national outbreaks or international outbreaks <del>e</del> .	<b>Philippines</b>
<b>Paragraph 19</b>	
National systems and structures should be in place in order to ensure early detection and to effectively manage food safety [ <del>emergencies/incidents/events</del> ] <u>[emergencies]</u> and should have sufficient infrastructure, .....	<b>Japan</b>
<b>Paragraph 20</b>	
The network and structures should be described in detail ..... and officially appointed agency <del>-and allow for an incident to be managed at the lowest possible administrative level</del> .	<b>Colombia</b> We propose deleting as it does not contribute important information within the context of the paragraph.
<b>Paragraph 21</b>	
For the networks to be operational it is necessary that the participants know each other and have familiarity with the system and structures and that they <del>use them as part of access</del> the <del>"daily routines"</del> <u>system regularly, even in the absence of a food safety outbreak</u> . Depending on .....	<b>USA</b> Rationale: Provides greater flexibility. The intent of using the networks as part of "daily routines" is unclear; "daily use" is unlikely.
<b>Paragraph 22</b>	
At the local level defined networks between ..... – e.g. local food control authority, clinical microbiological laboratory, districts <del>surgeons</del> <u>surgeon/medical officers of health</u> , community council and food/veterinary laboratory.....	<b>Canada</b> Suggest adding "medical officers of health" as not all countries have "district surgeons".
line 4: "districts physician" instead of "districts surgeon" makes more sense.	<b>Iran</b>
At the local level defined networks between the contact points from the different relevant authorities/agencies covering the same geographical area should be formed. The contact points may be either persons or offices as long as it consists of personnel usually participating in the work at local level – e.g. local food control authority, clinical microbiological laboratory, districts <del>surgeons</del> <u>surgeon/clinician</u> , community council and food/veterinary laboratory.The network contact points should ensure the exchange of information and manage the <del>[emergency/incident/event]</del> <u>[emergency]</u> within and between the networks. The networks should establish channels to engage stakeholders and food business operators, where relevant, in order to exchange information to minimize adverse consequences.	<b>Japan</b> "clinician" is used on the WHO "Foodborne Disease Outbreaks:Guidelines for Investigation and Controls"

<p>At the local level defined networks between ..... The contact points may be either persons or offices as long as <del>#</del> <del>exists</del> <del>they</del> <del>consist</del> of personnel usually participating in the work at local level – e.g. local food control authority, clinical microbiological laboratory, <del>districts surgeon, community council</del> <u>local departments of health</u> and food/veterinary laboratory. The network .....</p>	<p><b>USA</b> The first change is grammatical; “districts surgeon” does not seem to be a widely applicable term and community councils seem an unlikely contact point; “local departments of health” seems like a broader, generic term.</p>
<b>Paragrah 23</b>	
<ul style="list-style-type: none"> <li>communication with international <del>networks</del> <u>networks through INFOSAN emergency contact points</u></li> </ul>	<p><b>India</b> The food safety outbreak should be communicated to international organizations/relevant countries through INFOSAN (International Food Safety Authorities Network) by the competent national authority.</p>
<p>addition of the word “manager” is recommended as below: At national level a defined network should be established with senior manager and personnel with experience in the management of food safety</p>	<p><b>Iran</b></p>
<p>At national level a defined network should be established with senior personnel with experience in the management of food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u> representing their respective authorities/agencies. Guidance on the composition of such a network can be found in the description of the multiagency coordination group (MACG) described in the FAO/WHO <i>Framework for Developing National Food Safety Emergency Response Plans</i><sup>2</sup>. The role of the network should include:</p> <ul style="list-style-type: none"> <li>coordination of efforts to resolve large, especially complicated or serious food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u>,</li> </ul>	<p><b>Japan</b></p>
<ul style="list-style-type: none"> <li>Communication with <u>regional and</u> international networks</li> </ul>	<p><b>Morocco</b> the communication network will include “regional networks” and not only the international network. Morocco recommends that it be modified to read “communication with regional and international networks” Rationale: The regional network was missing and should be included in the scope</p>
<ul style="list-style-type: none"> <li>Communication with <del>international</del> <u>international and regional networks</u></li> </ul>	<p><b>Senegal</b> Rationale: The regional network was</p>

- <u>Post-outbreak examination</u>	missing and should be included in the scope
<ul style="list-style-type: none"> <li>• <del>ee</del><u>ordination-coordinating</u> of efforts to resolve large, especially complicated or serious food safety [emergencies/incidents/events],</li> <li>• <u>providing</u> support to local networks where needed</li> <li>• <del>o</del><u>ommunication-communicating</u> with international networks</li> </ul>	<b>USA</b>
<b>Paragraph 24</b>	
The <del>central</del> <u>-national</u> network may also be the forum where .....	<b>Canada</b> Proposed modification to align with paragraph 23 and 25. We understand that the word “central” was changed to “national” in the new draft version.
The <del>central</del> <u>-national level</u> network may also be the forum where .....	<b>Japan</b>
<b>Paragraph 25</b>	
Clarify what is meant by using external groups to “validate” recommendations in the last bullet: “There is a practice in place for the use of external groups of experts in validation of recommendations.”	<b>USA</b> It is not clear what the external groups are intended to do.
<ul style="list-style-type: none"> <li>- To ensure that all available information is compiled to form as complete a picture <del>of the incident</del><u>of the situation</u> as possible.</li> </ul>	<b>Colombia</b> We propose substituting the word incident with situation to maintain consistency throughout the text and subheadings of the document.
<ul style="list-style-type: none"> <li>- There is a practice in place for the use of external groups of experts <del>in validation of</del><u>to validate</u> recommendations.</li> </ul>	<b>Canada</b>
<b>2 FOOD SAFETY [EMERGENCIES/INCIDENTS/EVENTS] – PREPAREDNESS SYSTEM</b>	
2.1 b. International alert networks for food safety [emergencies/incidents/events] and human illness issues and exchange of information with them	
International alert networks for food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u> and human illness issues and exchange of information with them	<b>Japan</b>
<u>Exchange of information with</u> International alert networks for <del>food safety [emergencies/incidents/events]</del> <u>foodborne outbreaks</u> and <u>associated</u> human illness <del>issues and exchange of information with them</del> <u>issues.</u>	<b>USA</b>
<b>Paragraph 26</b>	

Food safety [emergencies/incidents/events] ... What initially seems to be a national or regional incident at the outset may in fact be a <del>multinational</del> <u>international</u> food safety [emergency/incident/event].	<b>Colombia</b> Modification.
Food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u> do not respect borders .....food safety [emergency/incident/event].	<b>Japan</b>
<b>Paragraph 27</b>	
The national level of the network should have ... The central national level of the network should actively include the national emergency contact points <del>k</del> for these alert networks in ..... food safety [emergencies/incidents/events].	<b>Canada</b> Is the “k” at the end of the word “points” supposed to be a reference to k. The draft Template for INFOSAN/IHR communication: National Protocol for Information Sharing with National and International Partners during Food Safety Events and Outbreaks of Foodborne Illness.
The national level of the network should have a permanent connection with global networks including the International Food Safety Authorities Network (INFOSAN) and with regional alert networks for both food and human <del>incidents</del> <u>emergency situations</u> . The central national level of .....	<b>Colombia</b> We propose substituting the word incident with situation to maintain consistency across the text and the subheadings of the document
The national level of the network should have a ..... and with regional alert networks ( <u>e.g. RASFF</u> ) for both food and human incidents. The central national level of the network should actively include the national emergency contact <del>points</del> <u>points k</u> for these alert networks in ..... food safety [emergencies/incidents/events].	<b>India</b> Propose amendment for clarity.
The national level of the network .... <del>The central</del> <u>The national level of the level</u> network should actively include the national emergency contact points <del>k</del> for these alert networks in their work both for gathering and compiling information and for submitting coordinated information concerning active food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u> .	<b>Japan</b>
The central national level of the network should actively include the national emergency contact points <del>k</del> .	<b>Philippines</b>
The national level of the network should have a permanent connection with global networks including the International Food Safety Authorities Network (INFOSAN) and with regional alert networks for both <del>food</del> <u>foodborne outbreaks</u> and <u>associated</u> human <del>incidents</del> <u>illnesses</u> . The central national level of the network should actively include the national emergency contact points <del>k</del> for these alert networks in ..... food safety [emergencies/incidents/events].	<b>USA</b>
<b>Paragraph 28</b>	
Information from global networks may be useful for the work of the national networks even if the <del>incidences</del> <u>incidents</u> described do not concern the country. A regular contact with the contact points of these regional and global networks are therefore essential <sup>a</sup> .	<b>Canada</b>

c. Surveillance and monitoring systems (human, animal, feed, food, establishment environment) and their use in food safety [emergencies/incidents/events]	
Surveillance and monitoring systems (human, animal, feed, food, establishment environment) and their use in food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u>	<b>Japan</b> Surveillance and monitoring systems (human, animal, feed, food, establishment environment) and their use in food safety [emergencies/incidents/events]
<b>Paragraph 29</b>	
Many biological food safety [emergencies/incidents/events] are initially .... <del>However-However,</del> data from surveillance and monitoring of animals, feed, food and the environment, including equipment of food businesses <del>may-can</del> also <del>indicate an enhanced risk and are be</del> of value/assistance to help identify the source of a food safety [emergency/incident/event]. These surveillance and monitoring systems are essential tools for detecting foodborne outbreaks and should be used in an integrated approach <sup>e</sup> (chapter 3).	<b>Canada</b>
Many biological food safety [emergencies/incidents/events] are initially identified through human illness surveillance data. However data from surveillance and monitoring of animals, feed, food and the environment, including equipment of food businesses may also indicate an enhanced risk and are of value/assistance to help identify the source of a food safety [emergency/incident/event]. These surveillance and monitoring systems are essential tools for detecting foodborne outbreaks and should be used in an integrated approach <sup>e</sup> (chapter 3).	<b>Japan</b> Many food safety emergencies caused by biological hazards~ ?
Many biological food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u> are initially identified through human illness surveillance data. However data from surveillance and monitoring of animals, feed, food and the environment, including equipment of food businesses may also indicate an enhanced risk and are of value/assistance to help identify the source of a food safety [emergency/incident/event]. These surveillance and monitoring systems are essential tools for detecting foodborne outbreaks and should be used in an integrated approach <sup>e</sup> (chapter 3).	
Many biological food safety [emergencies/incidents/events] are initially identified through human illness surveillance data. <del>However-However,</del> data from surveillance and monitoring of <del>animals, feed,</del> food and the <del>establishment</del> environment, including equipment of food <del>businesses-businesses,</del> may also indicate <del>an enhanced-a potential</del> risk and are of value/assistance to help identify the source of a <del>food safety [emergency/incident/event]</del> <u>foodborne outbreak</u> . These surveillance and monitoring systems are essential tools for detecting foodborne outbreaks and should be used in an integrated approach <sup>e</sup> (chapter 3).	<b>USA</b> Substantive (deletion of “feed.”) 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. Other changes are Editorial.

<b>Paragraph 30</b>	
<p>In order to identify a foodborne outbreak there is a need <del>for continuous</del>for:</p> <ul style="list-style-type: none"> <li>• <del>Surveillance</del> <u>Continuous surveillance</u> and monitoring of the "business as usual" situation of human illnesses from biological hazards and foods;</li> <li>• Regular (e.g. weekly) <del>analyses</del> <u>analysis</u> of the data in order to detect outbreaks in a timely manner.</li> </ul>	<b>Canada</b>
<ul style="list-style-type: none"> <li>• Surveillance and monitoring of the "business as usual" situation of human illnesses from biological hazards <del>and in</del> foods.</li> <li>• As not all diseases <u>in humans</u> are mandatory to notify to the <u>human health</u> authorities' access to information on these cases need to be established and an assessment on the "business as usual" level should be made. This will enable .....</li> </ul>	<b>Colombia</b> Modification
<ul style="list-style-type: none"> <li>• As not all diseases are mandatory to notify to the human health authorities' <del>access a mechanism which allows the authorities to access</del> information on these cases need to be established and an assessment on <del>the "business as usual" the comparison between elevated and baseline</del> level should be made. This will .....</li> </ul>	<b>Japan</b>
<p>In order to identify a foodborne outbreak there is a need <del>for continuous</del>for:</p> <ul style="list-style-type: none"> <li>• <del>Surveillance</del> <u>Ongoing surveillance</u> and monitoring of the "<del>business as usual</del>" <u>baseline</u> situation of human illnesses from biological hazards and foods;</li> <li>• As not all diseases are mandatory to notify to the human health authorities' access to information on <del>these non-notifiable</del> cases need to be established and an assessment on the "<del>business as usual</del>" <u>baseline</u> level should be made. This will enable the competent authorities to define when a number of cases should result in a notification of an outbreak.</li> </ul>	<b>USA</b>  Each bullet needs to complete the introductory phrase "In order to identify a foodborne outbreak there is a need for:" The deletion of "continuous" is because the 4th bullet begins with "Regular (e.g., weekly)" which is not "continuous" and "quick centralization and distribution of information" is also not "continuous."
<b>Paragraph 31</b>	
<p>In order to quickly detect food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u> it is necessary .... For sharing of surveillance data, it is necessary that data collected are comparable between sectors. Information exchange should be used both routinely and during food safety <del>[emergencies/incidents/events]</del> <u>[emergencies]</u> and may include:</p>	<b>Japan</b>
<p>In order to quickly detect food safety <del>[emergencies/incidents/events]</del> <u>emergencies</u> ..... Information exchange should be used both routinely and during food safety <del>[emergencies/incidents/events]</del> <u>emergency situations</u> and may include:</p>	<b>Senegal</b>

<p>In order to quickly detect food safety [emergencies/incidents/events] it is ..... For sharing of surveillance data, it is necessary that data collected are comparable <del>between sectors</del> <u>among sectors and that confidentiality of personal information is maintained</u>. Information exchange should .....</p>	<p><b>USA</b></p>
<ul style="list-style-type: none"> <li>• The use of standardized laboratory methods to allow comparability and sharing of laboratory data between human health, food safety and veterinary sectors.</li> <li>• The use of standardized laboratory methods to allow comparability and sharing of laboratory data <del>between</del> <u>among</u> human health, food safety and veterinary sectors.</li> </ul>	<p><b>USA</b> It is important that any personal information collected during foodborne outbreak investigations be kept confidential. Other changes are Editorial “Among” is appropriate when there are more than two entities.</p>
<ul style="list-style-type: none"> <li>• <del>Sufficient epidemiological</del> <u>Epidemiological</u> data to evaluate the relevance of the source and to conduct trace back.</li> </ul>	<p><b>Canada</b> We suggest removing “sufficient” since it is not necessary and could be interpreted differently by users.</p>
<p><b>Paragraph 32</b></p>	
<ul style="list-style-type: none"> <li>• Sufficient laboratory <del>capacity</del> <u>capability</u>, specific equipment and trained personal</li> <li>• Storage capacity of large amount of meta- and sequence data and the availability of bioinformatics tools to compare data in either national or open international databases for genomics. Fast and stable internet connections are a prerequisite.</li> <li>• <u>The collection of sufficient metadata (and epidemiological information) in a standardized way</u></li> </ul>	<p><b>India</b> Sufficient laboratory capability would be more appropriate in term of qualitative requirement.</p>

<p>Except in the case of very rare foodborne <del>diseases</del><u>diseases outbreaks</u>, there might be a need for molecular testing data of the isolates to detect and demonstrate a link between different cases. For example, for <i>Salmonella</i>, the traditional way of comparing data is by using <del>serotyping</del><u>serotyping and pulsed-field gel electrophoresis (PFGE)</u>. The increasing availability of <del>such</del><u>molecular based</u> tests, including whole genome <del>sequencing</del><u>sequencing and multiple-locus variable number of tandem repeat analysis (MLVA)</u>, <del>is</del><u>are</u> expected to increase the number of links between single cases, and thereby the number of outbreaks. Because of greater ..... The use of databases containing comparable molecular <u>based</u> testing results from humans, animal, feed, food .....</p> <ul style="list-style-type: none"> <li>• Sufficient laboratory capacity, specific equipment and trained personal</li> </ul> <p><u>• No standard "cut off" values in terms of degree of differences between strains (single nucleotide polymorphisms (SNP) is established. The differences acceptable counted in SNPs differ between agents and depends on the agent analyzed. Interpretation of results will require bioinformatics specialists. Public databases can be used for comparing typing results and give information of related findings.</u></p> <ul style="list-style-type: none"> <li>• Sharing of WGS sequences in a form that is useful for comparison between the human health and the food control authorities, e.g. as cg <u>MLST-multilocus sequence typing (MLST)</u> types.</li> <li>• Considerations of <del>legal requirements</del><u>any constrains</u> for sharing of data. If data .....</li> </ul>	<p><b>Japan</b> foodborne disease outbreaks? (see para 1,3,7,8,18,44)</p>
<p>Except in the case of very rare foodborne diseases, there might be a need for molecular testing data of the isolates to detect and demonstrate a link between different cases. For example, for <i>Salmonella</i>, the traditional way of comparing data is by using serotyping. The increasing availability of such tests, including whole genome sequencing, is expected to increase the number of links between single cases, and thereby the number of outbreaks. Because of greater specificity it is possible to differentiate clusters already identified in subclusters. The use of databases containing comparable molecular testing results from humans, animal, feed, food and establishment environmental sampling facilitates the detection and assessment of outbreaks and the search for the source of the contamination.</p>	<p><b>Morocco</b> Morocco recommends rewriting paragraph 32 to take other testing methods into account.</p> <p><b>Rationale</b> It is too prescriptive and biased in favor of complete sequencing, which is expensive and unavailable in several countries</p>
<ul style="list-style-type: none"> <li>• Considerations of legal requirements for sharing of data. If data are shared in public databases there may be a need for anonymising the <del>samples</del><u>samples to ensure confidentiality of personal information</u>, thus only allowing <del>few</del><u>limited</u> metadata to follow the sequences.</li> </ul>	<p><b>USA</b> It is important that any personal information collected during foodborne outbreak investigations be kept confidential. Other changes are Editorial.</p>
<p><b>d. Risk assessment – structures for assessing risk</b></p>	
<p>Currently there is no definition in the Codex documents for “rapid risk assessment”, therefore introducing this terminology could lead to confusion.</p>	<p><b>Argentina</b> In the document titled “PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT. CA/GL 63 -2007</p>

	<p>A “risk profile” is defined as a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue. Argentina suggests using “risk profile”, which should be carried out in these crisis situations for the adoption of immediate control measures before carrying out a risk evaluation as per the principles of Codex.</p>
<p><del>Risk assessment – structures</del> - <u>Structures</u> for assessing risk emergencies</p>	<p><b>Colombia</b> We suggest modifying the subheading given that “rapid risk assessment” is not a methodology described by the Codex and the use of this term, without a description of the methodology behind it, could give rise to confusion. Likewise, the paragraphs need to be modified to not refer to rapid risk assessment or outbreak assessment. We also suggest writing a paragraph related to the assessment of emergencies and the use of existing risk assessments, but not related to the development of risk assessments during an emergency.</p>
<p>For sections d and e: Risk assessment and risk communication are subsets of risk analysis. Therefore, it would be better if these paragraphs come under the main title of risk analysis. Referring to risk management is also recommended.</p>	<p><b>Iran</b></p>
<p><b>Paragraph 34</b></p>	
<p>A risk assessment<sup>b</sup> during a food safety [emergency/incident/event] provides a ..... Risk assessments can be particularly useful when there is a contamination event that has not been associated with <del>illness</del> <u>illness</u>, in order .....</p>	<p><b>Canada</b></p>
<p>A risk assessment<sup>b</sup> during a food safety <del>[emergency/incident/event]</del> <u>[emergency]</u> provides a sound scientific basis .....</p>	<p><b>Japan</b></p>
<p>A risk assessment<sup>b</sup> during a food safety <del>[emergency/incident/event]</del> <u>emergency situation</u> provides a sound scientific basis for the actions to be taken. Risk assessments can be particularly useful when there is a contamination event that has not been associated with illness in order to .....</p>	<p><b>Senegal</b></p>

<p>A risk assessment<sup>b</sup> during a food safety [emergency/incident/event] provides a sound scientific basis for the actions to be taken. Risk assessments can be particularly useful when there is a <u>microbiological</u> contamination event .....</p>	<p><b>USA</b> The sentence addresses a “contamination event” but the eWG indicated in paragraph 9 of the Work of the eWG that the document was limited to foodborne outbreaks.</p>
<p><b>Paragraph 35</b></p>	
<p>In a number of <del>cases-cases</del>, a ready-to-use risk assessment will be available, however adaptations to the specific incident will be required (within a short timeframe) based on the information from investigations<sup>b,d</sup> (especially chapter 3).</p>	<p><b>Canada</b></p>
<p>In a number of cases a ready-to-use risk assessment will be available, however adaptations to the specific incident will be required (within a short timeframe) based on the information from investigations<sup>b,d</sup> (especially chapter 3) <u>and regional/local contexts (climate, consumption pattern, serving size)</u>.</p>	<p><b>India</b> As, some of the data required for these adaptations, may not be available. So the data has to be collected through literature review/conducting experiments. In some cases, the adaptations may not be feasible thus rendering the ready to use risk assessment, unfeasible.</p>
<p>In a number of cases a ready-to-use risk assessment will be available, however adaptations to the specific <u>incident situation</u> will be required (within a short timeframe) based on the information from investigations<sup>b,d</sup> (especially chapter 3).</p>	<p><b>Senegal</b></p>
<p><b>Paragraph 36</b></p>	
<p>If a risk assessment is not available, there .... A “light” version of a risk assessment <u>known as-- a-an emergency rapid</u> risk assessment -- or and outbreak assessment will be more practical.</p>	<p><b>Senegal</b></p>
<p>If a risk assessment is not available ..... <del>A “light” version of a risk assessment -- a rapid risk assessment -- or and An</del> outbreak assessment will be more practical.</p>	<p><b>USA</b> “Outbreak assessment” is more appropriate than the terms “light risk assessment” and “rapid risk assessment”.</p>
<p><b>Paragraph 37</b></p>	
<p>In case of time constraints, food intake data (including concentration and consumption) could be updated regularly to make a structure for rapid risk assessment. It would be better to write some words about data updating.</p>	<p><b>Iran</b></p>
<p>The <u>emergency risk rapid risk</u> assessment or outbreak assessment includes the steps of a risk assessment but is based on the current data from the <u>[emergency/incident/event]-situation itself at hand</u> and if possible data from similar incidents<sup>b,d</sup>. There is no time for collecting new evidence/data .....</p>	<p><b>Senegal</b></p>
<p>The <del>rapid risk assessment or</del> outbreak assessment <u>includes-may or may not include</u> the steps of a risk assessment but is based on the current data from the [emergency/incident/event] itself and if possible data from similar incidents<sup>b,d</sup>. There is no time for collecting new evidence/data to fill in data gaps or to conduct larger literature studies.....</p>	<p><b>USA</b> An outbreak assessment may not include all the steps of a risk assessment, since some of the steps</p>

	may not be applicable, e.g., where there are no data to determine an exposure assessment.
<b>Paragraph 38</b>	
<ul style="list-style-type: none"> <li>Clearly prepared instructions <del>on outlining</del> what is expected <del>for of</del> these risk assessors and subject matter experts, including the scope of any risk assessment, taking into account the short <del>deadline</del> <u>timeline</u> for the assessment;</li> </ul>	<b>Canada</b>
<p>Having <del>structures</del> <u>a structural framework</u> in place to allow timely rapid risk/outbreak assessment are therefore an essential part of incident preparedness.....</p> <ul style="list-style-type: none"> <li>Lists of risk assessors and <del>subject matter experts</del> <u>people who are experts in the subject matter</u> for .....</li> <li>Structure to ensure the direct and immediate submission of information from the outbreak investigations to the risk assessors and the possibility for them to ask for additional clarification from the <del>investigators</del> <u>competent authorities</u> .....</li> </ul>	<b>Senegal</b>
<b>d. Risk communication system/strategy</b>	
<del>Risk communication system/strategy</del> <b>Communication of risks</b>	<b>Colombia</b> We propose that the suheading be left general for the communication of risks
<del>Risk communication system/strategy</del> <u>strategy</u>	<b>Senegal</b>
<b>Paragraph 39</b>	
In the context of a biological food safety <del>[emergency/incident/event]</del> <u>[emergency]</u> , the term “risk communication” means .....	<b>Japan</b> In the context of a food safety emergency caused by biological hazard ~
<b>Paragraph 40</b>	
<p>Effective communication is essential and requires preparation in advance of an incident, and this should include exchange of information with all stakeholders<sup>h</sup>.</p> <p><u>Establishing communication links with food industry experts in advance of foodborne outbreaks is important to gather/provide information about food categories that may be linked to/potentially involved in an outbreak with respect to production and distribution practices.h<sup>i</sup>.</u></p>	<b>USA</b> Establishing industry contacts before foodborne outbreaks should be part of preparedness.

<b>Paragraph 41</b>	
<ul style="list-style-type: none"> <li>Establish a communication strategy among the network members ..... means of communication (websites, <u>twitter, facebook social media</u> etc.).Where it is possible, .....</li> <li>Draft initial messages for the different situations ..... they perceive risks (e.g. religious beliefs, traditions), so <del>that</del> understanding the audience .....</li> </ul>	<b>Canada</b> Change was suggested to be more general and flexible with the social media currently available and the expansion of new ones.
<ul style="list-style-type: none"> <li>Establish a communication strategy among the network members and designate official spokespersons from the government or the central national network to the public and decide on <del>the means</del> <u>the channels</u> of communication (websites, twitter, facebook etc.) Where it is .....</li> </ul>	<b>Colombia</b> Modification
<b>3 FOOD SAFETY [EMERGENCY/INCIDENT/EVENT] - MANAGEMENT</b>	
Argentina believes that as the writing of the document progresses, if necessary, these tools can be used to clarify structures, processes, sequences, etc.	<b>Argentina</b>
<b>Paragraph 42</b>	
When a food safety [emergency/incident/event] occurs, ..... Management of foodborne outbreaks will often be carried out under <u>big</u> pressure and time <del>restraints</del> <u>constraints</u> . It is therefore .....	<b>Canada</b>
When a food safety incident occurs, the networks and structures established should be used to manage the situation in an integrated approach. Management of foodborne outbreaks will often be carried out under big pressure and time restraints. It is therefore important that each sector/participant stakeholder carries out the tasks within their responsibilities according to the procedures decided upon for the networks. The following sections give information of the basic roles of the participants in the networks.	<b>Iran</b>
When a food safety <del>[emergency/incident/event]</del> <u>[emergency]</u> occurs, the networks and structures established should be used to manage the situation in an integrated approach. Management of foodborne outbreaks .....	<b>Japan</b>
When a food safety [emergency/incident/event] occurs..... integrated approach. Management of foodborne outbreaks will often be carried out under big pressure and <del>time</del> <u>time and budgetary</u> restraints. It is therefore .....	<b>Argentina</b>
<b>a. Identifying and investigating a food safety [emergency/incident/event] – human health side<sup>e</sup></b>	
<b>Identifying and investigating a food safety <del>[emergency/incident/event]</del><u>[emergency]</u> – human health side<sup>e</sup></b>	<b>Japan</b>
<b>Paragraph 43</b>	
Careful description and characterization of ..... in any epidemiological investigation. Descriptive epidemiology provides a picture of the <del>[emergency/incident/event]</del> <u>[emergency]</u> in terms of .....	<b>Japan</b>
<b>Paragraph 44</b>	
<ul style="list-style-type: none"> <li>the food control authorities when they are informed about <del>illness</del><u>illnesses</u> related to specific products or companies. The information .....e.g. a restaurant.</li> </ul>	<b>Canada</b>

<p>The food control authorities when they are informed about <del>illness</del> <u>biological contamination</u> related to specific products or companies. The information may .....e.g. a restaurant.</p>	<p><b>Colombia</b> We propose that the text be modified to increase its scope.</p>
<p><b>Paragraph 45</b></p>	
<p>Depending on the information available a case definition should be created. Cases that fall within the definition should be interviewed <u>preferably by regulatory representative qualified to conduct health survey to</u> obtain ..... If possible, a standardized questionnaire for hypothesis generation purposes or standard epidemiological study methods such as case-control and cohort studies should be used to obtain information in a structured way<sup>e</sup> (especially chapter 4.1 and 4.2).</p>	<p><b>India</b> There might be particular training required for the interviewers based on their expertise and experience. (E.g.: if done by a regulatory officers then they might require training for questions pertaining to the health aspects of the incident)</p>
<p>Depending on the information available a case definition should be created. Cases that fall within the definition should be interviewed to obtain as much information concerning food items consumed prior to illness onset, place and date of purchase, preparation method, brand name as well as information on travel, animal and environmental exposures, person to person contact etc. If possible, a standardized questionnaire for hypothesis generation purposes or standard epidemiological study methods such as case-control and cohort studies should be used to obtain information in a structured way<sup>e</sup> Reference source not found. (especially chapter 4.1 and 4.2).</p>	<p><b>Iran</b></p>
<p>Depending on the information available a case definition should be created..... in a structured way<sup>e</sup> (especially chapter 4.1 and 4.2). <u>There should be a strong legal framework and procedures when implementing necessary measures to respond to food safety incidents and emergencies. A National Traceability and Recall System must be in place to facilitate decision making and implementation of all stakeholders involved.</u></p>	<p><b>Philippines</b> We propose the following statement to be consistent with the IRR of RA No. 10611, the “Philippine Food Safety Act of 2013”.</p>
<p><b>Paragraph 46</b></p>	
<p>Creation of standard questionnaires for this purpose may be..... Data can then be analyzed electronically in a standard statistical software <del>program</del><u>program by using standard protocols.</u></p>	<p><b>India</b> Standard procedures for data analysis can be set as sample, subjected to modification depending on the incident.</p>
<p>Creation of standard questionnaires for this purpose may be performed electronically using one of the internet based free of charge <del>software's</del><u>software</u>. Data can then .....</p>	<p><b>USA</b></p>
<p><b>Paragraph 47</b></p>	
<p>Food safety <u>emergencies</u> [<del>emergencies/incidents/events</del>] where a food source or a location has been identified during the epidemiological investigations should be followed by a thorough on site investigation covering all aspects of the production, storage, transport, <del>distribution</del> <u>distribution, handling</u> and consumption to substantiate if it is possible that the food source or the location is actually the source of the outbreak. If possible the root cause of contamination should be identified and verification by sampling and analyses should be attempted<sup>e</sup> (specifically chapters 4.3 and 4.4).</p>	<p><b>Colombia</b> We propose this inclusion given its importance as a risk factor in food contamination.</p>

Food safety [ <del>emergencies/incidents/events</del> ][ <del>emergencies</del> ] where a food source or a location has been identified ..... If possible the root cause of contamination should be identified and verification by sampling and analyses should be attempted <sup>e</sup> (specifically chapters 4.3 and 4.4).	<b>Japan</b>
Food safety [emergencies/incidents/events] where a food source or <del>a location</del> <del>bad practices have</del> been identified during the epidemiological investigations should be followed by a thorough on site investigation covering all aspects of the production, storage, transport, distribution and consumption to substantiate if it is possible that the food source or <del>the location</del> <del>the practices are</del> 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 <sup>e</sup> (specifically chapters 4.3 and 4.4).	<b>Senegal</b>
Food safety [emergencies/incidents/events] where a food source or a location has been identified during the epidemiological investigations should be followed by a thorough on site investigation covering all aspects of the production, storage, transport, distribution and consumption to substantiate if it is possible that the food source or <del>the location</del> <del>production conditions are</del> 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 <sup>e</sup> (specifically chapters 4.3 and 4.4).	<b>Senegal</b>
<b>Paragraph 49</b>	
Tracing a food item both backwards and forwards in the food chain is an essential tool in the investigation <sup>l,l,m</sup> . This does not initially include a recall of the food item from the consumers or a withdrawal from the market. The process <del>should be is</del> used to enable the investigators to see the full distribution of the food item or products produced in a single production site.....	<b>Canada</b>
<b>Paragraph 50</b>	
If the overall evidence <del>is strong enough concludes</del> that the source of the incident has been identified, appropriate risk management actions should be put in place. When a recall is identified as the appropriate risk management action, the same procedures of tracing back and forward in the food chain <sup>i</sup> should be used in recalling the food item/batches of the food item from consumers, thus removing the source of the incident.	<b>Canada</b>  Paragraph 50 addresses risk management. Therefore, we suggest moving paragraph 50 under a new sub-heading (Risk management).  Suggest defining “strong enough”. What is the proposed scale of terms? Reference document for scale of terms: Scientific Opinion on Risk Assessment Terminology, EFSA Scientific Committee, EFSA Journal 2012; 10(5):2664. Alternatively, if strong enough is not defined, we suggest modifying the text as proposed in the previous column.
If the overall evidence is strong enough that the source of the incident has been identified, appropriate risk management actions should be put in place. When a recall is identified as the appropriate risk management action, the	<b>Colombia</b> The addition is proposed in order to

<p>same procedures of tracing back and forward in the food chain <sup>i</sup> should be used in recalling the food item/batches of the food item from consumers, thus removing the source of the incident. <u>The recall of these products should be carried out in the shortest time frame possible to avoid greater impact, and the competent authority should monitor compliance.</u></p>	<p>specify and highlight the importance of response times and the role of the competent authority.</p>
<p>If the overall evidence is strong enough that the source of the incident has been identified, appropriate risk management actions should be put in place. When a recall is identified as the appropriate risk management action, the <del>same procedures of tracing back and forward in the food chain</del> <u>standard recall protocols</u> <sup>i</sup> should be used in recalling the food item/batches <u>from different stages</u> of the food <del>item from chain including</del> consumers, thus removing the source of the incident.</p>	<p><b>India</b> As recall is a part of risk management The same procedures for tracing food items would not be appropriate in case of consumer for tracing food items from consumer. Hence, proposed to revise</p>
<p><b>Paragraph 52</b></p>	
<p>In case of a match in serotypes, supplementary analysis is necessary ..... and thereby enhances the possibility to identify the source of the <del>outbreak</del> <u>outbreak(see para32)</u>.</p>	<p><b>Japan</b></p>
<p>In case of a match in serotypes, supplementary analysis is necessary to determine the probability of relationship. Typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA) but in recent years, genetic based methods like Whole Genome Sequencing (WGS) have become widespread worldwide as microbial typing tools. These methods have several advantages over traditional typing methods<sup>2</sup>: as WGS reveals the entire bacterial genome and provides very accurate information which makes it possible to determine when isolates are highly related and thereby enhances the possibility to identify the source of the outbreak.</p>	<p><b>Morocco</b> Morocco recommends that paragraph 52 be rewritten to remove any preference for a particular analysis method.  Rationale The Codex text should not indicate a preference for any particular analysis method.</p>
<p><b>Paragraph 53</b></p>	
<p>The decision of the degree of correlation between strains ..... The differences acceptable counted in SNPs differ between agents and depends on the agent analyzed.-, <u>sampling time between agents and the conditions to which the agent was exposed</u> Interpretation of results will require bioinformatics <del>specialists</del> <u>specialists and microbiologists</u>. [Validated/Credible] Public databases .....</p>	<p><b>India</b> Results from different databases may vary. Selecting standard databases for use in all applications will avoid this ambiguity in results.</p>
<p><b>Paragraph 54</b></p>	
<p>Enough data to ensure traceability of the product sampled should be collected and this should at least include <del>animal</del> <u>animal</u> species, product type, batch identification and place of sampling.</p>	<p><b>Philippines</b></p>
<p>Enough data to ensure traceability of the product sampled should be collected and this should at least include <del>animal</del> <u>product type, batch identification and place of sampling.</u> <del>species, product type, batch identification and place of sampling.</del></p>	<p><b>USA</b> Editorial. Unclear how this is relevant</p>
<p><b>Paragraph 55</b></p>	
<p>Food safety [<del>emergencies/incidents/events</del>] <u>[emergencies]</u> involving illnesses cannot be solved solely based on laboratory data but must always be linked to epidemiological data for confirmation.</p>	<p><b>Japan</b></p>

<b>Paragraph 58</b>	
Robust eEpidemiological evidence may be conclusive of the food safety incident even without positive laboratory results.....	<b>Senegal</b>
Robust epidemiological evidence may be conclusive of the <del>food safety incident</del> <u>foodborne outbreak</u> even without positive laboratory results.....	<b>USA</b> Clarify that the “incident” is an outbreak.
<b>d. [Outbreak assessment / rapid risk assessment]</b>	
<b>[Emergency Outbreak assessment /rapid risk assessment]</b>	<p><b>Colombia</b></p> <p>We believe it necessary to modify the paragraphs to not refer to rapid risk assessment or outbreak assessment.</p> <p>We suggest that emergency assessment should be moved forward considering at least:</p> <ul style="list-style-type: none"> <li>• magnitude (geographic distribution-quantity of product/number of affected persons),</li> <li>• gravity (identification of biological hazard, hospitalizations, demand for healthcare services),</li> <li>• impact(distribution of product for recall/mortality).</li> </ul> <p>The emergency assessment should be carried out at the beginning of the situation (when it presents/is detected) and updated during and at the end of the situation in order to close.</p> <p>A paragraph should also be included to specify that the management measures should be proportional, justified and modified, as necessary, based on the results of the emergency assessment.</p>
<b>[Outbreak assessment / rapid risk assessment]Rapid Risk Assessment</b>	<p><b>Philippines</b></p> <p>We propose to use the term “Rapid Risk Assessment” instead of “outbreak assessment” since the term outbreak may differ from one member country to</p>

	<p>another.</p> <p>However, some steps in risk assessment may not be included during rapid risk assessment therefore, selected criteria/ steps must be identified. After initial investigation, an incident may also not be considered as an outbreak hence, a more general term may be used.</p>
<b>Paragraph 59</b>	
<ul style="list-style-type: none"> <li>Laboratory results and results from the epidemiological <del>(including and food safety (including</del> tracing back) investigations</li> </ul>	<p><b>Canada</b></p> <p>We believe the word “food safety” was deleted by mistake, considering the word “tracing back” was kept in the sentence.</p>
<p>bullet 4: risk identification is prior to characterization. Therefore, recommended change is as below:</p> <ul style="list-style-type: none"> <li>Risk identification and characterisation linked to the outbreak.</li> </ul>	<p><b>Iran</b></p>
<ul style="list-style-type: none"> <li>If possible recommendations to the consumers and to competent authorities on <del>how to mitigate the</del> risk <u>management measures.</u></li> </ul>	<p><b>Senegal</b></p>
<b>e. Risk Communication</b>	
<p>Proposed text:</p> <p>d.(bis) Risk management</p> <p>If the overall evidence is strong enough concludes that the source of the incident has been identified, appropriate risk management actions should be put in place. When a recall is identified as the appropriate risk management action, the same procedures of tracing back and forward in the food chain should be used in recalling the food item/batches of the food item from consumers, thus removing the source of the incident.</p> <p>The risk management action should be based on the risk assessment and other relevant factors.</p> <p>The response may include a number of control measures, including recalling the product and other actions available to the competent authority with respect to the food’s production and distribution. Risk communication to consumers and to competent authorities on how to mitigate the risk should also be considered.</p> <p>More details can be found in the FAO/WHO Guide for Development and Improving National Food Recall Systems and in the WHO "Foodborne Disease Outbreaks: Guidelines for Investigation and Controls.</p>	<p><b>Canada</b></p> <p>Suggest adding a sub-heading between paragraph 60 and 61 and suggest moving paragraph 50 under this new sub-heading.</p> <p>The proposed new heading is to cover this component of risk analysis in the document. Additional text is provided for consideration.</p>

<b>Paragraph 61</b>	
Food safety <del>[emergencies/incidents/events]</del> <del>[emergencies]</del> may start in one country but can travel rapidly to other regions and require rapid and clear response in terms of communication. INFOSAN can .....	<b>Japan</b>
<ul style="list-style-type: none"> <li>Information should be simple and in plain language (<u>regional language, wherever applicable</u>) for key points since the public may have limited familiarity with scientific language.</li> </ul>	<b>India</b> We propose this as the risk communication should be deciphered in national/regional/local language so that food safety risks shall be intimated appropriately for better understanding in countries like India where multiple languages are followed.
<b>Paragraph 63</b>	
If possible, assemble a group of experts to validate recommendations within their domain of expertise.	<b>USA</b> Recommendation: Clarify how experts validate recommendations. If possible, assemble a group of experts to validate recommendations within their domain of expertise.  Rationale: It is not clear what the experts do to “validate” recommendations.
<b>Paragraph 64</b>	
It is important to collect and save ..... During the incident a record should be kept which includes relevant trace back information and descriptive epidemiology, hypotheses and status of the situation. The record should be updated as needed while the <del>food safety [emergency/incident/event]</del> <u>foodborne outbreak is ongoing and that protects personal information.</u> .....	<b>USA</b> Rationale: Substantive. Clarify that information collected during an outbreak should be reported in a way to protect personal information.
<b>Paragraph 66</b>	
The information can be valuable for the food control authorities in targeting official control effortsf.	<b>Philippines</b>
<b>Paragraph 67</b>	
Outbreaks or <del>[emergencies/incidents/events]</del> <del>[emergencies]</del> of special interest should be considered .....	<b>Japan</b>
<b>Paragraph 68</b>	
Consider introducing the two bullets in paragraph 68 using a sentence instead.	<b>Canada</b>
<b>Paragraph 69</b>	

<p>Competent authorities should ..... The results of such review should be documented and areas for improvement addressed to support capability and capacity of the system in place<del>f</del>.g.</p>	<p><b>Canada</b> Is the “f” at the end of the word “in place” supposed to be a reference to f. The FAO training Handbook on "Enhancing Early Warning Capacities and Capacities for Food Safety"</p>
<p>In MAINTENANCE OF THE NETWORKS, the title of paragraph c should be changed to “Application of lessons learned for future incidents”. Moreover, addition of “Was timely action taken?” as a new bullet is recommended.</p>	<p><b>Iran</b></p>
<p><b>Paragraph 73</b></p>	
<ul style="list-style-type: none"> <li>Control/verification exercises are primarily aimed at testing the performance of the plan/system in place and the participants' ability to carry out their responsibilities effectively, for example an expert or professional handling a particular type of method or a procedure in the contingency plan<sup>a</sup>. Participants should not be notified in advance of the exercise. These exercises can vary in <del>both</del>-complexity, length in time and <del>size of organization</del> in number of participants.</li> </ul>	<p><b>Canada</b> The following sentence could be improved, but we are not sure we have captured the meaning with our proposed changes</p>
<p><b>Paragraph 76</b></p>	
<p>The evaluation of national preparedness systems can include “after action reviews” of major, serious or rare food safety [<del>emergencies/incidents/events</del>][<del>emergencies</del>]. The evaluation .....</p>	<p><b>Japan</b></p>
<p>The evaluation of national preparedness systems can include “after action reviews” of major, serious or rare food safety [emergencies/incidents/events]. The evaluation should include <del>both</del>-competent authorities and <u>personnel from various</u> agencies and if possible also comments from relevant stakeholders such as food business operators. The review should focus on commitment in participation, the use of resources, the sharing of information, and other essential issues. The review should be used to build a stronger system or network on an international, national or local level.</p> <p><u>The review should also address whether changes are needed to the way a food is processed or whether regulatory oversight or other regulatory change is needed.</u></p>	<p><b>USA</b> Rationale: Editorial. Competent authorities may also be part of agencies.</p> <p>Recommendation: Add a sentence at the end of paragraph 76: Rationale: Substantive. More emphasis should be placed on communication with industry with respect to information/learnings that can be used to improve industry food safety practices. It may be that this would be better captured elsewhere, since this is the section on maintaining the network, but currently the document lacks a section on disseminating information about an outbreak and lessons learned outside of the network.</p>