

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
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Agenda item 5

CX/FH 22/52/5 Add.2

January 2022

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

Codex Committee on Food Hygiene

Fifty-second Session

Virtual

28 February – 4 March and 9 March 2022

### DRAFT GUIDANCE FOR THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

Comments in reply to CL 2021/72-FH

*Comments of Australia, Brazil, Canada, Colombia, Costa Rica, Cuba, Ecuador, European Union, India, Iran, Japan, Kenya, Mexico, Norway, Philippines, Saudi Arabia, Thailand, United States of America, Uruguay and ICGMA*

#### Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/72-FH issued in October 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

#### Explanatory notes on the appendix

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

**Annex I**

<b>GENERAL COMMENTS</b>	<b>MEMBER / OBSERVER</b>
We support the progression of the guidance document to step 8 and adoption by CAC.	<b>Australia</b>
Brazil thanks the EWG chair for the excellent work and agrees that the document is ready to be advanced to Step 8 for adoption by CAC45. Below are some editorial changes, only.	<b>Brazil</b>
Overall Canada considers that the draft is ready to be advanced to Step 8 for adoption by CAC45, with the minor suggestions provided as specific comments to improve the clarity of the text.	<b>Canada</b>
Costa Rica supports the inclusion of the text in paragraph 6 and merging paragraphs 8 and 9.	<b>Costa Rica</b>
Cuba appreciates the opportunity to submit its comments on the draft guidance presented in Appendix I of document CX/FH 22/52/5 and the analysis of the comments in document CX/FH 22/52/5 Add 1. In principle, we consider the document to be very comprehensive and easier to understand by all stakeholders, and above all by the competent authorities, in terms of risk management, assessment and communication, as well as in the management of biological foodborne outbreaks.	<b>Cuba</b>
Ecuador expresses its appreciation to all the countries working and contributing towards developing the draft standard: "Draft Guidance for the Management of Biological Foodborne Outbreaks." In this regard and after having done the respective technical analysis, we agree with the proposed document and support advancing it to Step 8.	<b>Ecuador</b>
The EUMS can agree to progress this document to Step 8 for final adoption by CAC45. Some minor suggestions to improve the text have been made below.	<b>European Union</b>
Kenya thanks the Electronic Working Group (Denmark, Chile and the European Union) for its work in addressing the received comments "Draft guidance for the management of biological foodborne outbreaks". Kenya notes that the "Revised draft Guidance provided in Appendix I of CX/FH 22/52/5" took into account most of the comments previously provided by various countries, and therefore supports advancement of the draft to Step 8 for adoption by CAC45.	<b>Kenya</b>
Norway can support the proposed Draft Guidance for the Management of Biological Foodborne Outbreaks. We agree to progress this document to Step 8 for final adoption by CAC45.	<b>Norway</b>
Philippines is generally in agreement with the revised draft guidance for the management of biological foodborne outbreaks. Philippines supports the adoption of the current draft and endorsement of the current draft to Step 8.	<b>Philippines</b>
In general, Thailand agrees with the details in the Proposed draft. We have no further comment and think that it can be advanced in the Codex step process.	<b>Thailand</b>
The United States believes that these Guidelines have progressed nicely, and the changes made since the document was last circulated have improved the Guidelines so that the Committee should be able to reach conclusions at CCFH52 and forward the text to the Codex Alimentarius Commission for final adoption at Step 8. Most of the comments below are clarifications that may lead to that outcome, along with some editorial comments.	<b>United States of America</b>
Uruguay appreciates the work done. We agree with the content of the document and believe that it is ready to advance to Step 8 for adoption by CAC45. However, we have made some comments in the body of the document.	<b>Uruguay</b>

<b>SPECIFIC COMMENTS</b>	
<b>INTRODUCTION</b>	
<p>Brazil suggests the following editorial changes to the paragraphs:</p> <p>Paragraph 6. Communication and data sharing between and among networks, food bussiness operators and internationally is fundamental for the management of foodborne outbreaks. Existing procedures on confidentiality should be used or, if not present, procedures should be developed.</p> <p>Rationale: editorial</p> <p>Paragraph 9:</p> <p>Likely exposure and consumption patterns</p> <p>Rationale: editorial (Full stop)</p>	<b>Brazil</b>
<p>8. ... In particular, the use of specific genomic methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)) can result in improved detection of outbreaks, ...</p> <p>Merging terms, changing to internationally accepted acronym.</p> <p>9. The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities, which should be consistent at the local and national level. The following criteria can be used by the competent authorities to categorize outbreaks, and develop and adapt response plans:</p> <ul style="list-style-type: none"> <li>The capacity of the country and/or local or regional entities to quickly react and limit the extent of the outbreak.</li> </ul> <p>We recommend this for the last bullet point in paragraph 9:</p> <ul style="list-style-type: none"> <li>Make a reference to local or regional entities when considering the capacity to react to the outbreak, taking into account communication and transportation difficulties between rural communities and big cities due to specific geographical situations.</li> <li>Include aspects for “the capacity to quickly react to the outbreak”: in terms of hospital infrastructure, availability of diagnostic resources, communication capacity of healthcare providers with health authorities, etc.</li> </ul>	<b>Colombia</b>
<p>Costa Rica supports the changes in paragraph 3 of the introduction. However, we propose the following amendments: delete the phrase “comprised” and replace the term “litigation” with the term “dispute” in the Spanish version, so that it reads as follows:</p> <p>“Biological foodborne outbreaks can have significant socio-economic costs, which can get worse in communities with vulnerable groups, related to hospitalization and medical treatment, lost productivity and effects on tourism. For food businesses, the consequences can be lost markets, loss of consumer confidence, disputes and company closures. Such foodborne outbreaks can cause impediments to domestic production and international trade. Globalization of the food supply has led to the rapid and widespread international distribution of foods, further increasing opportunities for pathogens being inadvertently introduced into many geographical areas.</p>	<b>Costa Rica</b>
<p>India suggests to correct 'Bussioness' to Business in Paragraph no 6, Sentence 1</p> <p>India suggests to change 'participants know who to contact' to 'participants know whom to contact' in Paragraph no 37, Sentence 1</p>	<b>India</b>
<p>Para 9, add a bullet included to:</p> <p>" Informing the population about control of hazards and reducing the risk; for example, how they prepare the foods to attenuate the severity of biological virulence." Para 9, The pathogenicity (virulence/infectivity) of the microorganism and symptoms in the patients.</p>	<b>Iran</b>

<p>Paragraph 1 Japan proposes that "zoonotic agents" should be replaced with "biological hazards". Rationale: Some foodborne illness causing agents are not zoonotic, e.g. norovirus. Substantial nature</p> <p>Paragraph 6 Business (type error)</p>	<b>Japan</b>
<p>Paragraph 4: The Spanish word "on" is repeated - editorial [Translator's note: the change does not affect the English]</p> <p>Paragraph 8: Uruguay suggests incorporating the multiple-locus variable number of tandem repeat analysis (MLVA), which is referred to in paragraph 49 – Technical</p>	<b>Uruguay</b>
<b>SCOPE</b>	
<p>Paragraph 10: Uruguay proposes adding the abbreviation for the International Health Regulations "(IHR)" - Editorial</p>	<b>Uruguay</b>
<b>USE</b>	
<p>Paragraph 12 Japan proposes the additional relevant Codex document because GL 82 covers guidelines for laboratory, surveillance and investigations. "•Principles and Guidelines for Natiaol Food Control Systems (CXG 82-2013 )"</p>	<b>Japan</b>
<p>Paragraph 12: In the second bullet, capitalize "principles" in "Working principles for Risk Analysis for Food Safety for Application by Governments (CXG 62-2007)." Delete "as amended" in the 3<sup>rd</sup> and 4<sup>th</sup> bullets: Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG-30-1999,<del>as amended</del>). Principles and Guidelines for the Conduct of Microbiological Risk Management (CXG 63- 2007,<del>as amended</del>)</p>	<b>United States of America</b>
<b>DEFINITIONS</b>	
<p>Paragraph 22. Lot: A definite quantity of ingredients or of a food that is intended to have uniform character and quality, within specified limits, is produced, packaged and labelled under the same conditions, and is assigned a unique reference identification by the food business operator. It may also be referred to as a "batch". Rationale: editorial</p>	<b>Brazil</b>
<p>We propose new wording:</p> <p>16. Case-control study: An observational study in which subjects exposed via food consumption with potential risk are enrolled on the basis of presence (cases) or people who are not exposed via food consumption, absence (controls) of the foodborne illness of interest. Information is compared between cases and controls. We propose including the risk and confounding factors.</p> <p>26. Rapid risk assessments: Risk assessment, based on the information available on the foodborne outbreak, taking into account the risk and confounding factors, which needs to be carried out urgently to quickly support (provisional) risk management measures and therefore may not always</p>	<b>Colombia</b>

<p>contain the full development of the four steps of a risk assessment described in the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG 30-1999).</p> <p>We propose the following wording:</p> <p>29. Traceability: The ability to follow the movement of a food through specified stage(s) of production, processing and distribution, where “Tracing back” refers to following the path towards its origin/source and “Tracing forward” refers to following the path towards its final distribution/point of consumption.</p>	
<p>The EUMS consider that no substantial changes should be made to the definitions, nor new definitions introduced, unless it would substantially improve the understanding of the text.</p> <p>Paragraph 16: In the definition of “case-control study”, the meaning of “in which subjects are enrolled” is unclear. Deletion or rewording is proposed.</p> <p>Paragraph 21: A “foodborne outbreak” is not a “number”. It is proposed to reformulate as follows: “Foodborne outbreak: The occurrence where the observed number of cases ...”.</p>	<b>European Union</b>
<p>Para 23, "biological" is preferred.</p> <p>Para 24, "data" is correct.</p>	<b>Iran</b>
<p>Saudi Arabia suggests providing a definition for “Risk Assessor” as the following: "Evaluating risks associated with the food chain requires collecting information and analyses existing research and data to provide scientific advice considering the uncertainties in risk estimates, and when appropriate, alternative interpretations of the available data that may be scientifically plausible to support decision-making by risk managers without generating new scientific research or having scientific laboratories."</p>	<b>Saudi Arabia</b>
<p>Paragraph 21: We propose adding the word “that” to the following parts of this paragraph: ...may be foodborne “that” exceeds, ..... epidemiologic analysis “that” implicates</p> <p>Paragraph 25: Replace the word “buying” for “comparing” as the former does not apply here [Translator's note: the change does not affect the English].</p>	<b>Uruguay</b>
<b>FOODBORNE OUTBREAKS – PREPAREDNESS SYSTEM</b>	
<p>Costa Rica supports the proposed changes in paragraphs 40, 51 and 53.</p>	<b>Costa Rica</b>
<b>A. CREATION OF OFFICIAL NETWORKS BETWEEN HUMAN HEALTH SECTOR AND FOOD AND VETERINARY SECTIONS AT LOCAL AND NATIONAL LEVELS</b>	
<p>Paragraph 35, third sentence: It is proposed to reformulate as follows: “The participants in the national network should be personnel from the authorities at the national level, equivalent to the same authorities/agencies that participate in the local networks”.</p> <p>Paragraph 40, first bullet: It is proposed to reformulate as follows: “all available information is compiled to complete as much as possible an overview of the situation and kept...”.</p>	<b>European Union</b>
<p>Paragraph 35</p> <p>The authority/agency with the legal responsibility to protect public health in a foodborne outbreak situation should be designated as lead contact point in charge of the national network and such authority/agency must manage the safeguarding of information regarding an outbreak on a secure platform.</p> <p>Rationale:</p>	<b>Mexico</b>

Add that safeguarding information regarding an outbreak shall be managed by the competent health authorities on a secure platform. It is a priority to store all information related to a foodborne outbreak and that such information is supported by scientific studies. The authority responsible must be a government authority from the health sector.

This information can be used to predict future outbreaks.

Include:

- Performing stakeholder analysis as established by the WHO.
- Issuing guidelines and procedures for the operations of the National Epidemiological Surveillance System.
- Establishing the basis and mechanisms for coordination in order to promote and support the National Epidemiological Surveillance System.
- Coordinating and carrying out epidemiological surveillance measures in accordance with the laws on epidemiological surveillance and those arising therefrom, as well as nationally mandated strategies and procedures.
- Establishing the basis and mechanisms for coordinating actions between public health departments and entities to consolidate the national structure.
- Integrating inter-institutional groups in charge of developing and operating surveillance systems for specific programs within the country's health priorities.
- Ensuring training, assessment, supervision and evaluation of the surveillance system among the participating departments and entities.

Rationale:

Stakeholder analysis at the national level will help to identify experts, whether they are institutions or persons who belong to the institutions.

We consider it appropriate to supplement the framework of competence at the national level.

Paragraph 38

Templates should be developed in advance (...). Some of them are listed below.

- Individual survey
- Record of cases of foodborne illnesses in clinics and laboratories
- Collective record of cases
- Sample collection report
- Health inspection guide for food sales
- Record of food handlers in a foodborne illness outbreak
- Attack rate of food served in a foodborne illness outbreak
- Combined attack rate by food ingested form
- Flowchart for processing suspected food
- Final report and foodborne illness outbreak guide
- A template to request rapid risk assessment as referenced in Section E and Annex II.

Rationale:

We consider it appropriate to list the necessary forms or formats needed for a complete study and proper analysis of a foodborne illness.

<p>Source: PAHO. Foodborne Disease Surveillance System and Outbreak Investigation Guide. Foodborne Disease Surveillance system forms. <a href="https://www3.paho.org/hq/index.php?option=com_content&amp;view=article&amp;id=10547:2015-anexo-b-contenido-anexo-b&amp;Itemid=41421&amp;lang=en">https://www3.paho.org/hq/index.php?option=com_content&amp;view=article&amp;id=10547:2015-anexo-b-contenido-anexo-b&amp;Itemid=41421&amp;lang=en</a></p>	
<p>Paragraph 35, first bullet: Change “between” to “among”: Ensuring that communication channels <del>between</del> <b>among</b> network participants at the local and national levels function effectively and efficiently</p> <p>Paragraph 37: Change “who” to “whom” in the first sentence: “it is essential that the participants know who to contact”</p>	<b>United States of America</b>
<b>C. SURVEILLANCE AND MONITORING SYSTEMS (E.G. HUMAN, ANIMAL, FEED, FOOD, ESTABLISHMENT ENVIRONMENT) AND THEIR USE IN FOODBORNE OUTBREAK SITUATIONS</b>	
<p>Brazil suggests the following editorial changes to the paragraphs: Paragraph 47. Tools for comparing and presenting data, such as a phylogenetic tree, (a branching diagram or “tree” showing the evolutionary relationships of the physical or genetic characteristics of the laboratory data at hand). Rationale: editorial (unnecessary comma)</p>	<b>Brazil</b>
<p>Paragraph 44 New bullet point 44. (...)In order to identify the source of a foodborne outbreak there is a need for: • Communication between government agencies in each state and country. Rationale: Communication between government bodies and between states is very important for effective coordination in managing an outbreak.</p>	<b>Mexico</b>
<b>D. ANALYTICAL METHODS</b>	
<p>Paragraph 48: The EUMS propose to revise the order of the text to facilitate readability: “48. Validated analytical methods should be used to isolate and identify causative agents. Traditional analytical methods (such as pathogen isolation) or Polymerase Chain Reaction (PCR)-based methods used for surveillance and monitoring are essential as the basis for detecting and investigating any outbreak. In some cases basic typing information such as the serotype may be enough to allow on a link between different human cases and between the human cases and the suspected food source, but often it does not allow a conclusion on such a link. When further characterization is needed for outbreak investigation purposes, molecular or genetic typing methods can be and are increasingly being used. Paragraph 49, first sentence: Abbreviations of molecular typing methods were already introduced in Paragraph 8. In addition, the link with the second sentence could be improved. Proposal for revision: “Molecular typing methods include PFGE and MLVA and other genetic based methods such as WGS.” Paragraph 50, third bullet: Core-genome MLST-based approaches are often used analytical methods and should therefore be referred to. Proposal for revision: “Sharing of WGS sequences in a form that is useful for comparison between the human health authorities and the food and veterinary authorities.</p>	<b>European Union</b>

<p>Sharing of actual raw whole genome sequences and associated metadata is often most useful for comparing results obtained by various analytical methods, including both multilocus sequence typing (MLST)-based, core-genome MLST-based, and (single-nucleotide polymorphism (SNP)-based approaches.”</p>	
<p>Paragraph 50 Laboratory capacity, specific equipment (properly maintained and calibrated) and personnel trained in implementation of WGS...</p> <p>Rationale: Laboratory equipment must be calibrated.</p> <p>Paragraph 55• • Include the list of experts and/or government agencies responsible for risk assessment available and identify their area of competence in the stakeholder analysis.</p> <p>Rationale: It is important to consider that in some countries, places or regions, there are specialized risk assessment agencies, who would be identified in the stakeholder analysis, as well as experts in the field, and the synergies they may have on the topic in question. The stakeholder analysis would help to identify them more accurately.</p>	<b>Mexico</b>
<p>Specific, Paragraph 49 Editorial accuracy Reflect the correct spelling for the word “accuracy”</p>	<b>Philippines</b>
<p>Paragraph 49: Revise the first sentence as follows: Molecular typing methods include pulsed-field gel electrophoresis (PFGE), <del>and</del> multiple-locus variable number of tandem repeat analysis (MLVA), and other genetic based methods.</p> <p>Paragraph 50, first bullet, last sentence: Having <b>access to</b> personnel with expertise in bioinformatics is critical for analysis of sequence data. Rationale: To make this broader; it should be possible to outsource data analysis and not have direct personnel.</p> <p>Paragraph 50, third bullet: Delete the open parenthesis before “single-nucleotide polymorphism” ...including both multilocus sequence typing (MLST)-based and (single-nucleotide polymorphism (SNP)-based approaches</p>	<b>United States of America</b>



<b>E. RAPID RISK ASSESSMENT – STRUCTURES FOR ASSESSING RISK</b>	
<p>Brazil suggests the following editorial changes to the Paragraph 53:</p> <p>If a risk assessment conducted for same or similar pathogen-food combinations is not available, there might not be sufficient time to undertake a full assessment of the risk at hand. A -rapid risk assessment will be more practical. It has to be taken into account that a rapid risk assessment may have a higher uncertainty and lower accuracy compared to a full risk assessment.</p> <p>Rationale: editorial (remove unnecessary hyphen)</p>	<b>Brazil</b>
<p>53. Second sentence - There is a hyphen in front “-rapid” that shouldn’t be there.</p>	<b>Canada</b>
<p>Paragraph 53:</p> <p>Add “the” in the first sentence: “If a risk assessment conducted for <b>the</b> same or similar pathogen-food combinations...”</p> <p>Delete the hyphen before “rapid risk assessment”: “A -rapid risk assessment will...”</p>	<b>United States of America</b>
<b>F. RISK COMMUNICATION SYSTEM/STRATEGY</b>	
<p>Paragraph 58</p> <p>New bullet point.</p> <p>58. In terms of risk communication, the preparedness should aim to:</p> <ul style="list-style-type: none"> <li>* Prevent misinformation and spreading false information or rumors</li> </ul> <p>Rationale:</p> <p>It is important to include guidance that shows the importance of combating the infodemic, which is the spread of supposed treatments or false information on social media that makes it difficult to control the outbreak and could even increase the level of risk to the population.</p>	<b>Mexico</b>
<p>Paragraph 58, next to last bullet, last sentence:</p> <p>Consideration should be given to <b>measures that can help</b> prevent misinformation and <b>the spread of</b> <del>spreading</del> false information.</p> <p>Rationale: clarification</p>	<b>United States of America</b>
<b>FOODBORNE OUTBREAK – MANAGEMENT</b>	
<p>Paragraph60, " food safety and food control, and risk communication and management, " -&gt; " and risk communication and management(including food safety and food control ), "</p> <p>Japan proposes this amendment since food safety and food control are part of risk management.</p>	<b>Japan</b>
<p>Para 60, Addition of below sentence is recommended at the end of this part:</p> <p>"The documents would be used for further outbreaks and rapid risk assessments if required."</p> <p>Para 60, line 5, "distribution" is also important here.</p>	<b>Iran</b>

<b>A. IDENTIFYING AND INVESTIGATING A FOODBORNE OUTBREAK – HUMAN HEALTH</b>	
64. First bullet - Recommend removing “recently” as it could be misleading for investigations for pathogens such as <i>Listeria monocytogenes</i> or HAV which could have a very long incubation period. The period of interest for the questionnaire/interview should match the etiology of the pathogen being investigated	<b>Canada</b>
Para 63, line 12, Add this sentence at the end of the first bullet: and frequency of eating or amount of the suspected foods eaten by the impacted people during the outbreak.	<b>Iran</b>
<p>Paragraph 64</p> <ul style="list-style-type: none"> <li>On the food items consumed (if known): the place (the commercial name of the establishment and the exact address) and date of purchase and time of consumption, method of preparation, brand name, lot/batch code, the source of the food or food product.</li> </ul> <p>Rationale:</p> <p>We propose adding the source of the food, for example to identify whether it is an animal not recognized for human consumption, whether the food products were purchased in bulk or packaged, and where, since the place could be a source of contamination.</p> <p>Depending on the information available, the public health authorities must establish an operational case definition. It must be used in a systematic and uniform way to identify additional cases and determine the magnitude of the outbreak. The operational case definition may be updated or revised if new or additional information indicate a need to do so.</p> <p>Rationale:</p> <p>Operational definitions are built or adapted from others, based on the observable characteristics of the phenomenon; they indicate the specific, empirical or indicative elements of what is being investigated.</p> <p>It is important to replace “should” with “must,” which we recommend throughout the document.</p> <p>Paragraph 67</p> <p>When a hypothesis is established, it may be appropriate where possible to perform analytical epidemiological investigations such as a prospective cohort study or a retrospective case-control study.</p> <p>Rationale:</p> <p>Cohort studies are longitudinal and prospective, not retrospective.</p>	<b>Mexico</b>

<p>Specific, Paragraph 64, bullet 1</p> <p>On the food items recently consumed: <i>detailed food history including the nature of food, (if known) the place (the commercial name of the establishment and the exact address) and date of purchase and the time of consumption, method of preparation, brand name, lot/batch code.</i></p> <ul style="list-style-type: none"> <li>- Addition of the phrase “detailed food history including the nature of food” to give emphasis and importance to the nature of food (whether it is cooked, raw or minimally processed) that may be vital in the conduct of investigation of foodborne outbreak.</li> </ul> <p>We propose the deletion of “(if known)” since the place and date of purchase are important information and must not be optional.</p> <p>Specific, Paragraph 64, bullet 2</p> <p>With regards to the affected person: <i>personal details (but shall be treated with confidentiality), information on travel, animal and environmental exposures, person-to-person contact, disease onset, symptoms, duration, hospitalization, underlying health conditions, etc. person-to-person contact, information on travel, animal and environmental exposures, etc</i></p> <ul style="list-style-type: none"> <li>- We propose adding the personal details of the affected person as both their identification and demographic information were deemed important as stated in the previously provided WHO guidelines, provided it should be confidential.</li> <li>- Proposal to restate the information in the bullet by order of importance in relation to the biological FBDO. The first four information are clinical information related to the biological FBDO while the person to person contact is still related to the biological FBDO and is an important information for the tracing of affected persons. The information on travel and animal exposures may just serve as supporting details of other possible causes.</li> </ul>	<p><b>Philippines</b></p>
<p>Paragraph 62, second bullet:</p> <p>Add the following at the end of the second bullet:</p> <ul style="list-style-type: none"> <li>• food control authorities that identify a product testing positive for a pathogen and an investigation matches the pathogen to isolates from clinical illnesses <b><u>in patients that have consumed the product, or</u></b></li> </ul> <p>Rationale: clarification to reflect the ultimate need to have an epidemiological link</p> <p>Paragraph 64, first bullet:</p> <p>Add the following at the end of the bullet:</p> <p><b><u>(Note that for some foodborne illnesses such as listeriosis, this information may not apply, since food causing the illness may not have been consumed recently.)</u></b></p>	<p><b>United States of America</b></p>
<p><b>B. SUBSTANTIATE HYPOTHESIS AND/OR HANDLING OF A FOODBORNE OUTBREAK – FOOD SAFETY (FROM FARM TO FORK)</b></p>	
<p>68. Second Sentence - (This onsite) Change to “on site” for consistency with the rest of the document. All other instances of “on site” are two separate words.</p> <p>73. Third sentence - Remove duplicate "tracing"</p> <p>74. Minor wording changes to para 74 to clarify meaning so that it reads as follows:</p>	<p><b>Canada</b></p>

<p>Consideration should be given to the actions required by consumers affected by recalls and businesses impacted by recalls and product withdrawals concerning the suspect lots. Consumers should be notified on the recalls using different communication tools (e.g. social media, newspapers, etc). Consideration should also be given to provide advice to consumers and/or businesses about appropriate disposition of affected foods which should take into account any potentially associated public health risks.</p>	
<p>We propose adding “(such as sample selection or collection)”</p> <p>69. ... Knowledge of sampling techniques (such as sample selection or collection), particularly aseptic techniques, and of sample handling for transportation to a laboratory are essential to guarantee the integrity of samples taken for verification.</p> <p>We propose deleting “controls” since the registrations kept are not only from the process controls.</p> <p>71. Tracing a food item...</p> <ul style="list-style-type: none"> <li>- Information to identify the root cause of the contamination (raw material status, processing steps that may influence the presence of the microbiological hazard identified including re-processing, registrations of the process and product, identified risk factors for product contamination, samples analyzed and results etc.).</li> </ul> <p>Delete the words “from an outbreak” since they are repeated.</p>	<b>Colombia</b>
<p>Costa Rica supports the expanded text in paragraph 69.</p>	<b>Costa Rica</b>
<p>Paragraph 73</p> <p>Japan proposes that "marketplace" should be replaced with "market". Rationale: To be consistent with GPFH section 7.5 "Recall Procedures - removal from the market of unsafe food"</p>	<b>Japan</b>
<p>Para 73, line 4, tracing repeated twice. One of them should be deleted.</p> <p>Para 74, line 3, The parenthesis was open here.</p>	<b>Iran</b>
<p>Paragraph 73</p> <p>When a recall is identified as the appropriate risk management action, tracing back and tracing forward should be used to remove all lots implicated or suspected to be implicated. The food business operator should carry out the recall in the shortest time frame possible to avoid greater impact on public health and the company. The competent authority should monitor the final disposal of the products to ensure compliance.</p> <p>Rationale:</p> <p>Improve the wording and highlight the importance of considering the “destination of the products” recalled, such as destroying them, etc.</p>	<b>Mexico</b>
<p>Paragraph 73</p> <p>When a recall is identified as the appropriate risk management action, tracing <del>tracing</del> forward</p> <p>Removal of the word tracing as it is redundant</p> <p>Paragraph 74</p> <p>Consumers should be notified on the recalls using <del>different</del> appropriate communication tools (e.g. social media, newspapers, etc.).</p> <p>Propose to use the term “appropriate” instead of “different”</p>	<b>Philippines</b>

<p>Paragraph 69: In the last sentence change “are essential” to “is essential” (the subject of the sentence is “knowledge”)</p> <p>Paragraph 71, second bullet: Change “registrations of” to “records of”: Information to identify the root cause of the contamination (raw material status, processing steps that may influence the presence of the microbiological hazard identified including re-processing, <del>registrations of</del> <b>records of</b> process and product controls, identified risk factors for product contamination, samples analyzed and results etc.) Rationale: clarification</p> <p>Paragraph 73: Delete the duplicated word “tracing”: When a recall is identified as the appropriate risk management action, tracing <del>tracing</del>-forward... Rational: editorial</p> <p>Paragraph 74: Correct the spelling of “newspapers” and close the parenthesis after “etc.”: (e.g. social media, newspapers, etc.) Consideration... Rationale: editorial</p>	<p><b>United States of America</b></p>
<p><b>C. COMBINING EPIDEMIOLOGICAL AND LABORATORY DATA</b></p>	
<p>77. First sentence - Recommend using "relation" instead of "correlation". Correlation is a word usually used to indicate cause or an established interdependence between two things which might not be the case with WGS. A food isolate and a clinical isolate could have matching related WGS but not be correlated to each other.</p>	<p><b>Canada</b></p>
<p>A revision has been added in paragraph 82 Costa Rica supports adding a sentence calling for collaboration between public health and food manufacturers to share molecular data on specific ingredients and foods. However, we propose replacing the Spanish term “sanidad” for the term “salud” so that it reads as follows: [Translator’s note: the change does not affect the English as both are translated as “health”] “For molecular testing, and in particular WGS, it might be very useful to search for isolates in food databases with similar molecular profiles as in a cluster of human cases. If very similar profiles are found, targeted epidemiological investigations to identify the source should be carried out to confirm or exclude a possible link. Collaboration between public health and food manufacturers on sharing molecular data from specific ingredients and foods should be encouraged. This can help hypothesis generation and potentially lead to more quickly identifying the source of an outbreak.</p>	<p><b>Costa Rica</b></p>
<p>Paragraph 82, "manufacturers" -&gt; "relevant food business operators" Japan proposes this amendment since the target of collaboration is not limited to manufacturers, and could be importers.</p>	<p><b>Japan</b></p>

<p>Specific, Paragraph 82</p> <p>Collaboration between public health <i>authorities</i> and food manufacturers on sharing molecular data from ingredients and specific foods, should be encouraged.</p> <p>Addition of the word “authorities” to the term public health</p>	<p><b>Philippines</b></p>
<p>Paragraph 77:</p> <p>Add text to explain who determines the level of relatedness needed to consider that strains are likely related and should be considered part of an outbreak.</p> <p>77. The decision of the degree of correlation between strains should be made <b><u>by consensus of experts</u></b> as part of the case definition. The level agreed upon may differ according to the typing method and the biological hazard.</p> <p>Rationale: clarification</p> <p>Paragraph 80, 3rd bullet:</p> <p>Change “standard method” to “validated method”:</p> <ul style="list-style-type: none"> <li>• there may not be a <del>standard</del> <b><u>validated</u></b> method available for detecting the biological hazard in a specific food of interest, or</li> </ul> <p>Rationale: for consistency with paragraph 48, which refers to use of “validated analytical methods”</p>	<p><b>United States of America</b></p>
<p>Paragraph 77: We need guidance on what are established standard “cut-offs” prior to the use of WGS as a regulatory tool. It is important to recognize that WGS is an evolving technology and sole reliance on WGS results may be inappropriately applied in a regulatory framework.</p> <p>77. Proposed edits:</p> <p>The decision of the degree of correlation between strains should be made as part of the case definition. The level agreed upon may differ according to the typing method and the biological hazard. For example, with WGS, there are no established standard “cut-off” values in terms of degree of differences between strains (e.g. single nucleotide polymorphisms (SNP’s)) at present. In general, when the number of SNP differences, or allele differences in the case of MLST analysis, is fewer, there is the potential that the strains could share a common ancestor. The actual number of SNP or allele differences among related outbreak strains will differ depending on a number of factors (e.g. species, length of outbreak, contamination route) and will require interpretation based on bioinformatics, epidemiological, and tracing analysis.</p> <p>78. Proposed edits:</p> <p>Delete text here as it is covered in 77.</p> <p>ICGMA Comment on 79: Integrity of sequence data in the databases is critical. See proposed text to 79.</p> <p>79. Proposed edits:</p> <p>The use of databases containing comparable molecular based testing results from e.g. humans, animals, feed, food and establishment environmental sampling, facilitates the detection and assessment of outbreaks and informs the search for the source of the contamination. The integrity of information in these databases is critical and should be of high quality and fidelity as they may potentially be utilized for attribution regionally, nationally, and globally.</p> <p>ICGMA Comment on 81: Analytical tools such as WGS and related results should be used in the context of epidemiological evidence (illnesses). We are supportive of this approach.</p>	<p><b>ICGMA</b></p>

<p>ICGMA Comment on 82: Rules of engagement need to be outlined – to establish criteria for sequence homology, source attribution, use of metadata. See proposed text to 82.</p> <p>82. Proposed edits:</p> <p>For molecular testing, and in particular WGS, it might be very useful to search for isolates in food databases with similar molecular profiles as in a cluster of human cases. If very similar profiles are found, targeted epidemiological investigations to identify the source should be carried out to confirm or exclude a possible link. It is important to establish criteria to determine sequence homology, illness attribution or environmental link, and how metadata associated with the sequence information is identified, maintained and used.</p>	
<b>D. RAPID RISK ASSESSMENT AND OUTBREAK ANALYSIS – DURING A FOODBORNE OUTBREAK</b>	
<p>Brazil suggests the following editorial changes to paragraph 85:</p> <ul style="list-style-type: none"> <li>• analyses of detected hot spots (geographical areas or events with more than usual occurrence within the outbreak), guiding further investigations;</li> </ul> <p>Rationale: editorial (add semicolon)</p> <p>Brazil suggests the following editorial changes to paragraph 92:</p> <p>Outbreaks of special interest should be considered for presentations in national and international scientific forums and submission as scientific publications. INFOSAN also facilitates the sharing of experiences and lessons learned in and between countries in order to optimize future interventions to protect the health of consumers.</p> <p>Rationale: editorial (unnecessary tab)</p> <p>Brazil suggests the following editorial changes to paragraph 94:</p> <p>Enhanced surveillance, and rapid centralization and evaluation of data, in particular from human cases, should be continued until the numbers of cases have returned to the baseline level, if known, (or, for new biological hazards, until no further cases are observed). This allows the evaluation of the effectiveness of actions taken and the confidence of consumers and trading partners to be maintained or regained. Possible delays in analyses and reporting and possible seasonal effects should be taken into account before declaring an outbreak over.</p> <p>Rationale: editorial (unnecessary comma)</p>	<b>Brazil</b>
<p>83. First sentence - "specific question" - Suggest to reference Annex II in this paragraph.</p>	<b>Canada</b>
<p>We propose adding "(such as sample selection or collection)"</p> <p>85. An outbreak analysis is a prognosis in an outbreak situation and is based on historical data and data generated in the investigation.</p>	<b>Colombia</b>
<p>Paragraph 85, 4th bullet: The EUMS propose to amend "risk identification" into "hazard identification" to better align with WHO/FAO terminology.</p>	<b>European Union</b>
<p>Paragraph 83</p> <p>We suggest mentioning the disadvantages of rapid risk assessments.</p> <p>Rationale:</p>	<b>Mexico</b>

Indicate that a major disadvantage in rapid risk assessments is that uncertainty would increase the in tail probabilities in a response-exposure assessment such that the study's effectiveness would be affected, as well as the lack of data due to missing some of the methodological steps. This is so that they are not overused by wanting to use them in every case.	
<p>Paragraph 85:</p> <p>Clarification is needed for bullets 2 and 3, which appear to be somewhat duplicative in that both refer to results from epidemiological investigations.</p> <ul style="list-style-type: none"> <li>• results from epidemiological and microbiological investigations of human outbreak cases, considering severity, possible mortality, spread of cases and affected subgroups (e.g. elderly);</li> <li>• laboratory results and results from the epidemiological and food safety (including tracing back) investigations;</li> </ul>	<b>United States of America</b>
<p>ICGMA Comment on 85 bullet 6:</p> <p>Scientific evidence rather than anecdotal or historical consumer behaviors should be utilized here. Food processors must be encouraged to develop and clearly display validated cooking instructions on packaging for foods that should be cooked prior to safe consumption.</p>	<b>ICGMA</b>
<b>E. RISK COMMUNICATION</b>	
<p>Paragraph 87: The introductory sentence does not seem to fit with the bullet points below. Some redrafting should be considered. The introductory sentence could read: "Most relevant practices that should be considered when conveying the risk communication message to the public and/ or food industry sector</p>	<b>European Union</b>
<p>Paragraph 87</p> <p>Practices that should be considered when conveying the risk communication message to the public and/or food industry sector include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Identify when rumors or false information are being circulated and prevent them from spreading. Social media and other forms of informal communication can be manipulated to disseminate erroneous information about the outbreak or its handling, which would put the population at risk. It is appropriate to monitor this phenomenon in order to debunk false information early.</li> </ul> <p>Rationale:</p> <p>It is important to include guidance that shows the importance of combating the infodemic, which is the spread of supposed treatments or false information on social media that makes it difficult to control the outbreak and could even increase the level of risk to the population.</p> <p>During the COVID-19 pandemic, there were health effects registered, such as poisoning, due to dissemination of supposed treatments against the disease.</p>	<b>Mexico</b>
<p>Paragraph 87, bullet 5</p> <p><del>Do not withhold information just because of a perception that it may be upsetting. Any information regardless of perception, whether favorable or not, should not be withheld.</del></p> <p>Change the sentence to convey a clearer message.</p>	<b>Philippines</b>
<b>F. DOCUMENTATION OF THE OUTBREAK AND LESSONS LEARNED</b>	



Paragraph 89 and 90: There seems to be some duplication between “and in a way that protects personal information” (paragraph 89) and “Procedures should be in place to protect confidentiality of people affected by the outbreak.” (paragraph 90). It is therefore proposed to delete the wording in paragraph 89.	<b>European Union</b>
Paragraph 93: We recommend adding a sentence at the end that says: <b><u>“The learnings from outbreaks should be broadly communicated to support continuous improvement in outbreak investigations and outbreak prevention.”</u></b> Rationale: Emphasize the benefits of learnings from outbreaks.	<b>United States of America</b>
<b>G. POST OUTBREAK SURVEILLANCE</b>	
Paragraph 94 There needs to be a definition or explanation of the concept of enhanced surveillance. Rationale: Have greater clarity about the features of enhanced surveillance.	<b>Mexico</b>
<b>MAINTENANCE OF THE NETWORKS</b>	
Paragraph 96: the deletion of this paragraph can be considered since fully developed in paragraphs 101 to 104.	<b>European Union</b>
What were some of the most difficult challenges faced and how were they overcome ( <del>or not</del> )? To delete (or not) at the end of the sentence as it may cause confusion.	<b>Philippines</b>
<b>ANNEX I</b>	
In the “Country” box that lists examples of stakeholders: Suggest that the word “cases” is used instead of “patients”.	<b>Canada</b>
Costa Rica supports including the reference to INFOSAN in Annex I.	<b>Costa Rica</b>
<b>ANNEX II</b>	
Brazil suggests the following editorial changes to the items: 6. A certain strain of 'bacterium Y' is causing an outbreak. This strain has been linked to other foodborne outbreaks in the past. Interviews point at different food items as the source. Based on the data from interviews and former outbreaks, what is the most likely food implicated in the outbreak and where in the supply chain may the contamination event have occurred? Rationale: editorial 7. An outbreak caused by <i>Listeria monocytogenes</i> seems to be caused by frozen small meatballs for soup. The meatballs are cooked prior to freezing. Normally they are heat treated when preparing the soup prior to eating. A kitchen added the frozen meatballs to the hot soup prior to chilling and storage. The soup portions are distributed as a chilled product ready to heat and serve. Is this process adequate to avoid growth of <i>Listeria monocytogenes</i> ?	<b>Brazil</b>

Rationale: editorial	
<p>Since not all outbreaks will require a rapid risk assessment, it is necessary to clarify in which cases such a request is required. Therefore, we recommend clarifying that it is only when there is a need to answer a specific question or assess a specific risk item in relation to an outbreak for which additional information is required.</p> <p>(...) The scope of a rapid risk assessment is to answer a specific question or assess a specific risk item in relation to an outbreak, for which additional information is required for decision making in relation to the outbreak.</p> <p>Therefore, prior to requesting it, the need for a rapid risk assessment must be evaluated, taking into consideration the information from the epidemiological investigation of the outbreak in question.</p> <p>(...)</p>	<b>Colombia</b>
Costa Rica supports including question 3.	<b>Costa Rica</b>
In the first column, a slight reformulation could be considered (3 times): "Possible question(s) related to..."	<b>European Union</b>
In the table, para 3, The parenthesis was open here.	<b>Iran</b>
<p>Annex II, "risk item"</p> <p>Japan proposes the deletion of "item" since "risk item" and "food item" could cause confusions for readers of this document.</p>	<b>Japan</b>
<p>Annex II</p> <p>Put a table or columns of advantages and disadvantages for each case, giving an example in comparison with a "normal" risk assessment study.</p> <p>Rationale:</p> <p>Improve knowledge and understanding as well as providing information for a more informed decision.</p>	<b>Mexico</b>
<p>A certain strain of 'bacteria bacterium Y' is causing an outbreak. This strain has been linked to other foodborne outbreaks in the past. Interviews point at different food items as the source. Based on the data from interviews and <del>former</del> previous outbreaks, what is the most likely food implicated in the outbreak and where in the food supply chain may the contamination event have occurred? To use singular term for bacteria since it only pertains to a certain strain "bacterium Y"</p> <p>To use the term "previous" instead of "former"</p> <p>To use the term "food supply chain" to be more specific</p>	<b>Philippines</b>
Saudi Arabia suggests identifying competencies, experience and other requirements to qualify as a Risk Assessor, and these criteria considerations should be within the jurisdiction of the local competent authority.	<b>Saudi Arabia</b>
<p>Annex II</p> <p>In Question 6 change "bacteria Y" to "bacterium Y."</p> <p>Rationale: editorial</p> <p>In Question 7 change "to avoid growth of <i>Listeria monocytogenes</i>" to "<b>to prevent illness from <i>Listeria monocytogenes</i></b>" in the last sentence.</p>	<b>United States of America</b>

<p>Rationale: The focus should be on whether the process can contribute to illness; the assessment of the process would include whether growth could occur, but it should not be limited to that.</p>	
<b>ANNEX III</b>	
<p>Brazil suggests the following editorial changes to the item 'Investigation of human cases':</p> <ul style="list-style-type: none"> <li>• subcultures where two or more cases not part of the same family ate at the same event, restaurant, etc.</li> </ul> <p>Rationale: editorial (enter a tab)</p>	<b>Brazil</b>
<p>Suggestion of different words for precision.</p> <p>In the section Illness background information - the sentence should read: "Historical data from previous monitoring and isolations in food might help target investigations towards the source if not known yet."</p> <p>Suggestion of different words for precision.</p> <p>Under the Outbreak information/Descriptive epidemiology, fourth point: Replace "contamination" with "suspected or confirmed exposure" so that it reads: "- / place of suspected or confirmed exposure".</p> <p>Comment - Suggest those additional examples that are often used in Canada's food investigations.</p> <p>In section Investigations in food - in the first bullet, to read: "• Information on samples taken – items, places of sampling, open or closed sample, lot code, any storage or cooking instructions provided on package, etc."</p> <p>In the Summary / prognosis section, fifth sentence add the word "any" before "data gaps" so that it reads: "Summary of considerations that resulted in the conclusions including any data gaps."</p> <p>Suggestion of an additional example.</p> <p>In the Summary / prognosis section, third sentence added "recall" in the examples so that it reads: "Summary of investigations on food sources and actions taken (e.g. recall , withdrawal) and actions planned."</p> <p>Comment - One of the level (i.e. international) appears to be missing.</p> <p>in the section Summary / prognosis, first sentence, it should read: "Overview of involved geographic areas/jurisdictions at local, national regional or international level."</p> <p>Suggest "Summary" is more suitable for the section title</p> <p>In the section titled "Prognosis/Summary", the word "prognosis" should be deleted.</p> <p>Minor wording change to clarify the meaning.</p> <p>In the section Communication - to read as follows:</p>	<b>Canada</b>

<p>"Clear information on the communication strategy targeted towards consumers, affected operators and other stakeholders should be given. It is also a good idea to agree upon a communication strategy in case the assessors are approached by the press or public – agree on what can be said, by whom and when."</p> <p>Minor wording change for clarification.</p> <p>In the section Data not available / not yet available - To read:</p> <p>"Any uncertainties on the existing data and data gaps should be indicated.</p> <p>If any data /information required for the assessment is not yet available, it should be indicated when the data will be available. If any data are not available, this should be clearly stated when asking for the outbreak analysis, as the missing data may be vital for the outcome of the analysis."</p> <p>Minor wording change and addition for precision.</p> <p>In the section Background information concerning the strain in food, feed, animal or environment samples - last sentence to read:</p> <p>"Possible significant gathering or community event that may have been an opportunity for the outbreaks to occur (e.g. family event, birthdays parties, fiesta, festivals, holiday celebrations, etc.)"</p> <p>Suggestion of additional wording for precision.</p> <p>in the section Investigations in food in the first sub-bullet of the fourth bullet, add at the end "to the supplier" so that it reads:</p> <ul style="list-style-type: none"> <li>o Tracing back the food/ingredients to the supplier ;</li> </ul> <p>Comment - In section Investigation of human cases - We believe the term is "subclusters" not "subcultures".</p> <p>This should be moved as a third bullet on its own line instead of combined with the second bullet.</p> <p>Suggestion of different words for precision.</p> <p>In the section Outbreak background information - In the first sentence replace the word "like" with "such as".</p> <p>Comment - Addition of a point that is often captured during an outbreak analysis.</p> <p>In the section Outbreak information/Descriptive epidemiology, add as a third point - "Number of hospitalizations and deaths"</p>	
<p>We propose adding the following question: Were the confounding factors related?</p> <p>The confounding factors are related to health conditions, socioeconomic conditions, etc.</p> <p>Annex III</p> <p>Contextual information about the outbreak</p> <p>Questions such as the following should be answered: How was the outbreak initially detected? Has the consumption of any common food been identified among the cases? Is there any correlation between the case distribution and distribution of the foods potentially involved? How were the cases in humans initially linked to a particular food source? Were the confounding factors related? Has the public been notified about the outbreak? How was this carried out?</p>	<p><b>Colombia</b></p>
<p>Annex III</p>	<p><b>Mexico</b></p>

<p>Operational case-definition</p> <p>Rationale:</p> <p>Operational definitions are built or adapted from others, based on the observable characteristics of the phenomenon; they indicate the specific, empirical or indicative elements of what is being investigated.</p>	
<p>Annex III, Outbreak background information</p> <p>Are there any common foods identified as being consumed by the human cases?</p> <p>Add the word “human” to refer to human cases for consistency</p> <p>Annex III, Investigation of human cases</p> <ul style="list-style-type: none"> <li>• subcultures where two or more cases not part of the same family ate at the same event, restaurant, etc.</li> </ul> <p>Transfer to next bullet</p> <p>Annex III, Investigations in food, 3rd sub-bullet</p> <p>To be repeated for each affected establishment along <i>the food supply</i> chain</p> <p>To use the term “food supply chain” to be more specific</p> <p>Annex III, Investigations in food, 5<sup>th</sup> sub-bullet</p> <p><del>Have any common suppliers of the food of interest been identified?</del></p> <p><i>Are there any identified common suppliers of the affected food product?</i></p> <p>To rephrase the question for clearer statement of the question</p>	<b>Philippines</b>
<p>Annex III</p> <p>In the row on Investigations in food, in the last sentence of the last bullet, change “lapsed” to “elapsed”: How much time <del>lapsed</del> <b>elapsed</b> between preparation and consumption?</p> <p>In the row on Background information concerning the strain in food, revise the second sentence as follows:</p> <p>“...a detailed description of the ingredients, their treatment, production processes etc. <del>needs</del> <b>is</b> to be <del>described</del> <b>developed</b>/ documented to assess...”</p> <p>(to avoid saying a “description” needs to be “described”).</p> <p>In the row on Data not available, change the “is” to “are”:</p> <p>If data /information <del>is</del> <b>are</b> necessary for the assessors but not yet available...</p>	<b>United States of America</b>