JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

45th Session

21 - 25 November and 12 - 13 December 2022

REPORT OF THE 52nd SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

Virtual

28 February – 4 March and 9 March 2022
# TABLE OF CONTENTS

Summary and status of work .................................................................................................................. page ii
List of acronyms .................................................................................................................................. page iii
Report of the 52nd Session of the Codex Committee on Food Hygiene ............................................. page 1

## Paragraphs

**Introduction** .................................................................................................................................... 1

**Opening of the Session** .................................................................................................................... 2 - 5

**Adoption of the Agenda (Agenda item 1)** ....................................................................................... 6

**Matters referred by the Codex Alimentarius Commission and/or other Codex subsidiary bodies to the Committee (Agenda item 2)** ................................................................. 7

**Matters arising from the work of FAO and WHO (including JEMRA) (Agenda item 3)** ................. 8 - 12

**Information from the World Organisation for Animal Health (OIE) (Agenda item 4)** ................. 13 - 15

**Draft Guidance for the Management of Biological Foodborne Outbreaks at Step 7 (Agenda item 5)** .................................................................................................................................. 16 - 31

**Proposed draft decision tree (Revision of the General Principles of Food Hygiene (CXC 1-1969)) at Step 4 (Agenda item 6)** ..................................................................................... 32 - 52

**Proposed Draft Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef, Fresh Leafy Vegetables, Raw Milk and Raw Milk Cheeses, and Sprouts at Step 4 (Agenda item 7)** ................................................................. 53 - 70

**Proposed Draft Guidelines for the Safe Use and Re-Use of Water in Food Production at Step 4 (Agenda item 8)** ........................................................................................................... 71 - 95

**Other business and future work (Agenda item 9)** ......................................................................... 96 - 105

**Date and place of next session (Agenda item 10)** ........................................................................... 106

## Appendices

**Appendix I - List of participants** .................................................................................................... page 13

**Appendix II - Draft Guidelines on the Management of Biological Foodborne Outbreaks (at Step 8)** ........................................................................................................................... page 37

**Appendix III - Proposed revision to the General Principles of Food Hygiene (CXC 1-1969) (At Step 5/8)** ....................................................................................................................... page 56
<table>
<thead>
<tr>
<th>Responsible party</th>
<th>Purpose</th>
<th>Text/Topic</th>
<th>Code</th>
<th>Step</th>
<th>Para.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members, CCEXEC82 and CAC45</td>
<td>Adoption</td>
<td>Draft Guidelines for the Management of Biological Foodborne Outbreaks</td>
<td>-</td>
<td>8</td>
<td>31, App. II</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proposed draft revision to the <em>General Principles of Food Hygiene</em></td>
<td>CXC 1-1969</td>
<td>5/8</td>
<td>52, App. III</td>
</tr>
<tr>
<td>EWG (Chile, France, New Zealand, the United States of America) CCFH53</td>
<td>Redrafting</td>
<td>Proposed Draft Guidelines for the Control of Shiga Toxin-Producing <em>Escherichia coli</em> (STEC) in Raw Beef, Raw Milk and Raw Milk Cheeses, Fresh Leafy Vegetables, and Sprouts</td>
<td></td>
<td>2/3</td>
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</tr>
<tr>
<td>PWG (Chile, France, New Zealand, the United States of America) CCFH53</td>
<td>Revising</td>
<td></td>
<td></td>
<td>4</td>
<td>70</td>
</tr>
<tr>
<td>EWG (Honduras, Chile, and the European Union) CCFH53</td>
<td>Redrafting</td>
<td>Proposed Draft Guidelines for the Safe Use and Reuse of Water in Food Production</td>
<td></td>
<td>2/3</td>
<td>93</td>
</tr>
<tr>
<td>PWG (Honduras, Chile, and the European Union) CCFH53</td>
<td>Revising</td>
<td></td>
<td></td>
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<td>95</td>
</tr>
<tr>
<td>Members WG (the United States of America) CCFH53</td>
<td>Comments/Discussion</td>
<td>New work proposals/Forward workplan</td>
<td></td>
<td>105v</td>
<td></td>
</tr>
<tr>
<td>Japan and New Zealand CCFH53</td>
<td>Review/Drafting</td>
<td>Discussion paper on revision of the <em>Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood</em> (CXG 73-2010)</td>
<td></td>
<td>105i</td>
<td></td>
</tr>
<tr>
<td>Canada and the Netherlands CCFH53</td>
<td>Review/Drafting</td>
<td>Discussion paper on revision of the <em>Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food</em> (CXG 79-2012)</td>
<td></td>
<td>105i</td>
<td></td>
</tr>
<tr>
<td>FAO/WHO (JEMRA) CCFH53</td>
<td>Request</td>
<td>Facilitate consideration of the JEMRA outputs Additional advice on the work related to the guidelines for the safe use and re-use of water in food production Scientific advice on <em>Salmonella</em> and <em>Campylobacter</em> in chicken meat A full farm to table risk assessment for <em>Listeria monocytogenes</em> in foods</td>
<td></td>
<td>93, 105ii</td>
<td></td>
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<tr>
<td>AFoSaN</td>
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<td>Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment</td>
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INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its 52nd session virtually from 28 February – 4 March and on 9 March 2022 at the kind invitation of the Government of the United States of America. Dr Jose Emilio Esteban, Chief Scientist, Food Safety and Inspection Service, Office of Public Health Science, United States Department of Agriculture (USDA) chaired the Session, which was attended by 106 Member countries, one Member organization, 22 Observer organizations and Palestine. The list of participants is included in Appendix I.

OPENING

2. Mr Steve Wearne, the Chairperson of the Codex Alimentarius Commission (CAC), delivered opening remarks, in which he applauded the Committee’s “appetite for advancement of consensus-driven and science-based standards and texts, and the willingness to compromise where necessary in the interests of Codex and the people everywhere that our work will protect.”

3. Mr Tom Heilandt, Codex Secretary, also addressed the meeting.

4. CCFH52 held a minute of silence in memory of the recently passed Dr Claude Mosha, Tanzania, former chairperson of the CAC and Mr Otto Maldonado, Codex Contact Point Guatemala and former delegate to CCFH.

Division of competence

5. CCFH52 noted the division of competence between the European Union (EU) and its Member States, in accordance with paragraph 5, Rule II, of the Rules of Procedure of the CAC.

ADOPTION OF THE AGENDA (Agenda item 1)

6. CCFH52 adopted the provisional agenda as its agenda for the Session.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX SUBSIDIARY BODIES TO THE COMMITTEE (Agenda item 2)

7. CCFH52 noted the information provided and encouraged Members and Observers:
   i. to plan and implement activities to build awareness of Codex and to engage high level political support for Codex work on the occasion of the 60th Anniversary of the CAC in 2023;
   ii. to actively engage in opportunities to contribute to the discussions on the future of Codex and on how to address cross-cutting, overarching and emerging issues in Codex; and
   iii. to provide relevant comments on the revision to the General Guidelines on Sampling (CXG 50-2004).

MATTERS ARISING FROM THE WORK OF FAO AND WHO (INCLUDING JEMRA) (Agenda Item 3)

8. The FAO Representative, on behalf of FAO and WHO, provided a summary of work performed since CCFH51 and future joint FAO/WHO work related to CCFH and highlighted the following:

   • The Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) published, since CCFH51, full reports on: i) Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood; ii) Risk-based examples and approach for control of *Trichinella* spp. and *Taenia saginata* in meat - revised edition; iii) Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition – second report; iv) Foodborne antimicrobial resistance: role of environment, crops and biocides; v) Advances in science and risk assessment tools for *V. parahaemolyticus* and *V. vulnificus* associated with seafood; vi) Microbiological risk assessment - guidance for food; and vii) Safety and quality of water used with fresh fruits and vegetables.

   • Four JEMRA meetings were held in 2020 and 2021 on the following topics: i) Shiga toxin-producing *Escherichia coli* (STEC) associated with meat and dairy products; ii) *Listeria monocytogenes* in ready-to-eat (RTE) food: attribution, characterization and monitoring; iii) Safety and quality of water used in the production of fishery and dairy products; and iv) Prevention and control of microbiological hazards in fresh fruits and vegetables (part 1, 2 and 3). Three ad hoc expert consultations on risk assessment of food allergens (priority list of food allergens, thresholds and precautionary labelling) were also held.

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1 CRD27 (Opening speeches)
2 CRD1 (Division of competence between the European Union and its Member States)
3 CX/FH 22/52/1
4 CX/FH 22/52/2
5 CX/FH 22/52/3
in 2020 and 2021. Eight summary reports related to these meetings were published in 2020 and 2021.

9. The Representative informed CCFH52 that meeting planning for 2022 was already underway and JEMRA had scheduled meetings on prevention and control of microbiological hazards in fresh fruits and vegetables (part 4). He further noted that JEMRA would also be convening meetings on i) farm to table risk assessment of *Listeria monocytogenes*, ii) *Salmonella* in poultry, and iii) any further requests from CCFH as necessary.

10. The Representative, on behalf of both FAO and WHO, expressed appreciation to all the Members who supported the work of all the Joint FAO/WHO Scientific Advice Programmes, notably JEMRA.

11. The Representative of WHO brought the attention of CCFH52 to the re-establishment of the Foodborne Disease Burden Epidemiology Reference Group (FERG), explaining its three-year strategic framework and its main activities. The Representative also highlighted the recent activities of the joint FAO/WHO International Food Safety Authorities Network (INFOSAN) including the launch of the new INFOSAN Community Website noting that INFOSAN continued to develop and strengthen the Network as well as capacity for preparedness and response to food safety incidents.

**Conclusion**

12. CCFH52:
   i. noted the information provided by FAO and WHO and expressed appreciation for the valuable work that had been undertaken over the past two years;
   ii. encouraged FAO and WHO to publish outstanding reports as soon as possible to facilitate their consideration in ongoing work of the committee in advance of CCFH53;
   iii. noted that the work on STEC, water and other topics would be considered more extensively under agenda items 7 and 8 and possibly 9, as appropriate; and
   iv. supported the proposal that JEMRA undertake a full farm to table risk assessment on *Listeria monocytogenes* in food in order to inform a possible future revision of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods* (CXG 61-2007).

**INFORMATION FROM THE WORLD ORGANISATION FOR ANIMAL HEALTH (OIE) (Agenda item 4)**

13. CCFH noted that there was no document provided on this item.

14. The OIE Representative, recalling the past collaborative work with CCFH, including on *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011), *Guidelines for the Control of Trichinella spp. in Meat of Suidae* (CXG 86-2015), and *Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat* (CXG 87-2016), stressed the commitment of OIE to collaborate with relevant Codex committees at the international level to ensure harmonisation of both organizations’ respective standards and recommendations across the food production continuum. The Representative particularly highlighted the need for collaboration at the national level and encouraged delegates to work together with OIE counterparts to ensure alignment of their national approach to relevant standards under development by the OIE and Codex.

**Conclusion**

15. CCFH52 noted the ongoing commitment of OIE to collaborate with CCFH on areas of work relevant to OIE.

**DRAFT GUIDANCE FOR THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS AT STEP 7 (Agenda item 5)**

16. Denmark, speaking also on behalf of Chile and the EU introduced the item and recalled the aim of the Guidelines, noting that CCFH51 had advanced the guidelines to CAC43 for adoption at Step 5. CAC43 had adopted the guidelines at Step 5 and advanced them to Step 6. Taking advantage of the postponement of CCFH52 from 2021 to 2022, Denmark, Chile and the EU had addressed replies to different circular letters

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6 CX/FH 22/52/4
7 REP20/FH, Appendix III; CX/FH 22/52/5 (Argentina, Australia, Canada, Colombia, Cuba, Ecuador, Japan, Kenya, Mexico, Peru, Philippines, Thailand, Tunisia, United Arab Emirates, United States of America, Uruguay, ENCA); CX/FH 22/52/5 Add.1: CX/FH 22/52/5 Add.2 (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); CRD2 (Proposed Draft Guidance on the Management of Biological Foodborne Outbreaks - Revised by the EWG Chairs); CRD6 (Dominican Republic, New Zealand, Peru and Rwanda); CRD 11 (Indonesia); CRD 12 (Ghana); CRD 14 (Morocco); CRD 15 (Uganda); CRD 16 (East African Community); CRD 17 (Senegal); CRD 18 (Burundi); CRD 19 (United Kingdom); CRD 20 (African Union (AU)); CRD 21 (Saudi Arabia); CRD 22 (Nigeria); CRD 24 (Tanzania); CRD 25 (South Africa)
(CLs) and produced a revised draft as presented in CRD2. She explained that comments were of an editorial nature and that no major issues remained and proposed that CCFH52 consider advancing the guidelines to Step 8. She further noted that the title had been changed from “guidance” to “guidelines” for consistency with other similar CCFH texts.

**Discussion**

17. CCFH52 considered CRD2 as the basis for discussion.

18. CCFH52 agreed with the editorial amendments proposed in CRD2 for purposes of clarity and completeness, made some further editorial amendments and took the following additional decisions. Some translation issues were also highlighted (e.g. “monitoring” and “surveillance”) and CCFH52 noted that these would be addressed in the final translation of the guidelines.

**Definitions**

**Lot**

19. CCFH52 considered a proposal to amend the definition of lot to introduce the concept of separation between batches. CCFH52 agreed that the proposal was not appropriate for the definition and agreed to include this concept as a new para. 74 (section B)

20. In response to a proposal to use the definition for risk communication from the Procedural Manual, CCFH52 agreed that the current definition of risk communication was more appropriate within the context of the guidelines and did not contradict the definition in the Procedural Manual, and thus retained it unchanged.

**Risk communication**

21. CCFH52 did not agree to a proposal to insert a definition for “risk assessor”, as the term was widely used and well understood internationally. CCFH52 also considered a proposal to modify the definition for metadata, but agreed to retain the existing one, noting that for the purpose of the guidelines, it was sufficiently clear and flexible.

**Foodborne outbreaks – Preparedness system**

**C. Surveillance and monitoring systems**

22. Regarding a proposal for insertion of “packages and containers” after “food contact surfaces” in para. 45, CCFH52 agreed that “food contact surfaces” was sufficiently broad to encompass all materials that may come in contact with food, including equipment, packaging and containers, and thus agreed no additional text was needed.

**Foodborne outbreak - Management**

23. A proposal was made to insert a sentence in para. 61 to the effect that the documentation covering all aspects of the outbreak could be used in future, for example for rapid risk assessment or training. CCFH52 noted that the proposed concept was already covered in this paragraph through the reference to post-outbreak evaluation and this was further elaborated on in section F “Documentation of the outbreak and lessons learned”. Hence, CCFH52 agreed to retain the original text.

**A. Identifying and investigating a foodborne outbreak – Human health**

24. CCFH52 considered a proposal to also refer to foodborne intoxications and toxins in this section. Noting the clarification that the section reflected the typical situation, i.e. that it is related to type of infections, and that the concept of toxins was already captured within the scope of the guidelines, as it was part of the definition of biological hazards, CCFH52 agreed to retain the original text in para. 62.

**B. Substantiate hypothesis and/or handling of a foodborne outbreak – Food safety (from farm to fork)**

25. CCFH52 agreed to modify the title by replacing “from farm to fork” with “from primary production to consumption” for consistency with the terminology used in other Codex documents.

26. CCFH52 considered a number of proposals to para. 69 to provide more details. However, acknowledging that the text was intended to be generic, CCFH52 agreed to retain the original text of para. 69 with a few changes for simplification, including deleting “refrigeration and type of packaging” as an example of storage conditions, but adding “type of packaging” as information to include when taking a sample.

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* All paragraph numbers indicated in this item refer to those in Appendix II of the report.
C. Combining epidemiological and laboratory data

27. CCFH52:
- amended para. 76 to clarify that sharing of information should be timely;
- deleted reference to “consensus of experts”, as it was not clear who the experts were and there was no definition for consensus (para. 78);
- noted the reference to pathogen databases in para. 83 was intended to be comprehensive and not limited to publicly available databases in order to allow countries to use all resources available to them; and
- recognizing that during an investigation, collaboration as outlined in para. 83 may include authorities other than the public health authority, for example the agricultural authority, inserted “other authorities” to reflect this.

E. Risk communication

28. One Member expressed concern about establishing procedures for the identification of rumours and false information (para. 88 (final bullet)) and how that could be practically implemented. CCFH52, while acknowledging the challenges, agreed on the need to address rumours and false information, noting the role of social media in this regard and that failure to try to address such rumours could lead to negative consequences. The Committee agreed to add “when possible” at the beginning of the bullet in order to take practicality into account.

Annex I: Structure of networks handling foodborne outbreaks

29. CCFH52 agreed to include the African Food Safety Network (AFoSaN) as an additional example of a regional network/organization.

Annex III: Template for an outbreak analysis

30. In response to a concern about the use of a term “supplier”, which lacked a definition, CCFH52 agreed to replace it with “source” to make the guidelines as generic as possible.

Conclusion

31. Noting that there were no outstanding issues to be addressed, CCFH52 agreed to forward the draft Guidelines for the Management of Biological Foodborne Outbreaks to CAC45 for adoption at Step 8 (Appendix II).

PROPOSED DRAFT DECISION TREE (REVISION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE (CXC 1-1969)) AT STEP 4 (Agenda item 6)\(^9\)

32. Brazil introduced this item and recalled the decision of CCFH51 for Brazil, Honduras, Jamaica and Thailand to draft the decision tree for comment and consideration by CCFH52. After summarizing and analysing the comments received in response to CL 2020/55-FH and CL 2021/62-FH, Brazil explained the main amendments included in CRD3 Rev.1, and emphasized that the proposed decision tree was only one example; other decision trees that meet the general requirements as elaborated in the General Principles of Food Hygiene (CXC 1-1969) (i.e., step 7 - Principle 2 - Determine the critical control points (CCPs)) could also be used and that a chapeau had been introduced to address this point.

33. Brazil suggested that CCFH52 consider whether Q1 should be maintained in the decision tree with the new wording and whether both the decision tree and the CCP determination worksheet should be included in the General Principles of Food Hygiene (CXC 1-1969). Brazil also noted that if CCFH52 agreed to the inclusion of the decision tree and worksheet, as a new annex in the General Principles of Food Hygiene (CXC 1-1969) then a cross-reference to the annex would be needed in Section 3.7, Chapter two of CXC 1-1969.

34. CCFH52 agreed to consider CRD3 Rev.1 as the basis for discussion.

Discussion

35. CCFH52 held a general discussion on the decision tree and noted the broad support for its inclusion in CXC 1-

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\(^9\)C/X/FH 22/52/6; C/X/FH 22/52/6 Add.1 (Argentina, Australia, Bolivia (Plurinational State of), Canada, Colombia, Costa Rica, Cuba, El Salvador, European Union, India, Iran, Iraq, Japan, Kenya, Malaysia, Mexico, New Zealand, Peru, Philippines, Republic of Korea, Saudi Arabia, Thailand, Uruguay, USA and FoodDrinkEurope, ICUMSA, IDF/FIL); CRD3 Rev.1 (Proposed draft decision tree (Revision of the General Principles of Food Hygiene (CXC 1-1969) - Revised by Brazil); CRD7 (Dominican Republic, Ecuador, Malaysia, Rwanda and ISO); CRD11 (Indonesia); CRD12 (Ghana); CRD14 (Morocco); CRD15 (Uganda); CRD16 (East African Community); CRD17 (Senegal); CRD18 (Burundi); CRD20 (African Union); CRD21 (Saudi Arabia); CRD22 (Nigeria); CRD24 (Tanzania); CRD25 (South Africa)
1969. The discussions highlighted that a decision tree was a very useful tool for both competent authorities and food business operators, in particular small and less developed businesses, in identifying CCPs, and that the decision tree in the former version of CXC 1-1969 had been globally used and understood by all users. An observer, while recognizing the support for a decision tree, highlighted the need for such tools to be clear-cut and easy to use by food business operators.

36. CCFH52, agreed with most of the revisions in CRD3 Rev.1, and in addition to editorial corrections, made the following comments and decisions:

Chapeau

37. In view of the wide support to include both the decision tree tool (CRD3 Rev.1 Annex 1a) and the CCP determination worksheet tool (CRD3 Rev.1 Annex 1b) in CXC 1-1969, CCFH52 agreed to also make reference to the CCP determination worksheet tool in the chapeau.

Annex 1a - “Example of a CCP decision tree - Apply to each step where a specified significant hazard is identified.”

Q1: Can the significant hazard be controlled to an acceptable level at this step by prerequisite programs (e.g., GHPs)?

38. One Observer was not in support of the inclusion of Q1 as in their view, some control measures (e.g., adjusting pH or water activity (a_w), chilling or cooking, metal detection and x-ray detection), which were typically identified as CCPs were all included in Section 7 (key aspects of good hygienic practices (GHPs)). Q1 as it was phrased, would lead to these control measures being excluded from CCPs. Another Observer also expressed the view that if a hazard was significant, it should be controlled by control measures at a CCP rather than by GHPs.

39. Responding to the concerns raised, it was noted that Q1 was part of a logical sequence to be applied to each identified significant hazard and assist food business operators (FBOs) in clarifying whether the significant hazards could be controlled by prerequisite programs or needed further attention. It was also clarified that because certain steps were mentioned in the section on GHPs, this did not necessarily rule them out as being eligible to be CCPs for specific significant hazards. It was further noted that a significant hazard does not automatically mean that it requires control measures at a CCP, but rather that it needs extra attention to address it whether it should be controlled by a GHP and/or a CCP.

40. Following a suggestion to include examples in Q1 for clarity, CCFH noted that such examples had been given in CXC 1-1969 Annex 1 and the decision tree, which would be incorporated in CXC 1-1969, should be read in conjunction with CXC 1-1969. The need to ensure the accuracy of the translation of the footnote to Q1 was also noted.

41. CCFH52 agreed to maintain Q1 as proposed in CRD3 Rev.1.

Q2: Do specific control measures for an identified significant hazard exist at this step?

42. There was general support for Q2 but some concerns were expressed with regard to the clarity of the guidance provided when the response to Q2 was “No”, noting that it may be necessary to remind users about evaluating subsequent steps for a CCP, and it may not always be possible to identify a CCP in a subsequent step, and further guidance on the actions to be taken in such cases should be provided, such as a modification to the process. One observer suggested that there was no added value to including Q2 and it could in fact lead to a conflict with Q4. Another Observer proposed to change the word “subsequent” to “another” in the “No” response to Q2, as in some cases it may be possible to identify a CCP at a step earlier in the process.

43. It was clarified that the decision tree should be applied at each step in the process in a sequential manner and if there were a CCP in an earlier step it would already have been identified; therefore, it was proposed to keep “subsequent step” rather than refer to “another step”. In order to address the concerns raised, and improve clarity, CCFH agreed to replace the second sentence in the text box after answering “No” with “Subsequent steps should be evaluated for a CCP” with a footnote explaining “If a CCP is not identified at questions 2 - 4, the process or product should be modified to implement a control measure and a new hazard analysis should be conducted”.

Q3. Will a subsequent step prevent or eliminate the identified significant hazard or reduce it to an acceptable level?

44. One Member proposed to change the word “should” to “could” in the textbox after answering “Yes” to Q3 as “should” appeared to be mandatory. Other Members were of the view that since the decision tree addressed significant hazards that were not controlled by prerequisite programs, if a subsequent step would prevent or eliminate the identified significant hazard or reduce it to an acceptable level, then that subsequent step should be a CCP. CCFH52 agreed to retain the word “should”.
45. Some concerns were raised regarding the relationship between Q3 and Q4 and whether in fact both were even needed. It was clarified that Q3 was needed to clarify if the significant hazard can also be controlled later in the process, or there was another control measure for the hazard at another step. If that were the case then the step being analysed should not in fact be considered as a CCP, rather the subsequent step where the hazard can be controlled would be the CCP.

46. CCFH52 agreed to retain Q3 as proposed and amended the text in the box after answering, “Yes” to read “That subsequent step should be a CCP” in order to make the connection between the subsequent step mentioned in the question and the answer.

Q4. Can this step prevent or eliminate the identified significant hazard or reduce it to an acceptable level?

47. One Observer expressed the view that it was impossible to answer “No” to Q4 if the answer to Q2 was “Yes” and there was a contradiction between Q2 and Q4.

48. In this regard, it was clarified that Q2 only asked whether specific control measures existed while Q4 asked whether the control measure was sufficient; therefore, there was a slight distinction there that did not result in a contradiction.

49. For purpose of clarity, CCFH52 agreed to insert (i) the word “specifically” in Q4; and (ii) a footnote stating, “Return to the beginning of the decision tree after a new hazard analysis” in the textbox after answering “No”.

Annex 1b - “Example of a CCP determination worksheet (Apply to each step where a specified significant hazard is identified).”

50. CCFH52 agreed to make the corresponding amendments to Annex 1b to ensure all the questions were aligned with Annex 1a and the pertinent footnotes were appropriately incorporated.

Other issues

51. CCFH52 noted that consequential changes to Section 3.7 of Chapter 2 of CXC 1-1969 should be made to reference the new annex including both the decision tree and the CCP determination worksheet. CCFH further noted that the Codex Secretariat should determine the most appropriate location for the new annex in CXC 1-1969.

Conclusion

52. CCFH52 agreed to forward:
   i. the “Tools to determine the critical control points (CCPs)” to CAC45 for adoption at Step 5/8 and subsequent inclusion as Annex 2 in the General Principles of Food Hygiene (CXC 1-1969) (Appendix III, part A); and
   ii. the consequential amendment to Section 3.7 of Chapter two of CXC 1-1969 to cross-reference Annex 2 (Appendix III, part B).

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING ESCHERICHIA COLI (STEC) IN RAW BEEF, FRESH LEAFY VEGETABLES, RAW MILK AND RAW MILK CHEESES, AND SPROUTS AT STEP 4 (Agenda item 7)\(^1\)

53. Chile, Chair of the Electronic Working Group (EWG), speaking on behalf of Co-chairs France, New Zealand and the United States of America, introduced the item and recalled that CCFH50 had agreed to recommend new work on this issue, which had been approved by CAC42. CCFH51 had considered an initial draft and agreed on the scope and names of commodities to be included in the guidelines and its annexes, namely “fresh leafy vegetables”, “raw beef”, “raw milk and raw milk cheeses” and “sprouts”. CCFH51 had also requested scientific advice to support the work and JEMRA meetings had been convened in 2020 (raw beef and raw milk) and 2021 (leafy vegetables and sprouts) to address these requests. The EWG was re-established at CCFH51 and prepared a revised version of the General Section and three of the commodity annexes, which had been circulated for comments at Step 3 (CL 2021/63-FH). The EWG co-chairs had made changes to the General section based on comments received (CX/FH 22/52/7 Add.1) and made them available

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\(^1\) CX/FH 22/52/7; CX/FH 22/52/7 Add. 1 (Canada, Colombia, Cuba, Ecuador, Egypt, European Union, India, Iran, Iraq, Japan, Malaysia, Norway, Republic of Korea, Saudi Arabia, Somalia, Thailand, Uruguay, USA and IDF/FIL, IFT); CRD4 (Proposed draft Guidelines for the Control of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef, Fresh Leafy Vegetables, Raw Milk and Raw-Milk Cheeses, and Sprouts; General Section – Prepared by the EWG co-chairs); CRD5 (Report of the Working Group on Proposed Draft Guidelines for the Control of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef, Fresh Leafy Vegetables, Raw Milk and Raw-Milk Cheeses, and Sprouts); CRD8 (Dominican Republic and Rwanda); CRD10 (El Salvador); CRD11 (Indonesia); CRD12 (Ghana); CRD13 (Argentina); CRD14 (Morocco); CRD15 (Uganda); CRD16 (East African Community); CRD17 (Senegal); CRD18 (Burundi); CRD19 (United Kingdom); CRD20 (African Union); CRD21 (Saudi Arabia); CRD22 (Nigeria); CRD24 (Tanzania); CRD25 (South Africa)
Discussion

54. Based on the comments received, the EWG Co-chair from the United States of America presented a list of issues on which input was required in order to further develop the guidelines, with reference to the proposed changes in CRD4 and discussions in the pre-session virtual working group (CRD5).

Definitions

55. CCFH52 discussed the definitions of each of the commodities and of indicator microorganism noting that an agreement on these definitions was key to ensuring the clarity and confirming the scope of the guidelines.

Fresh leafy vegetables

56. CCFH52 agreed with the definition as presented in CRD4, with delegations noting that the current proposal most accurately reflected the reality. On the question of whether this definition included microgreens, it was recalled that an annex and definition for “sprouts” was yet to be developed and that microgreens may be part of that. If that was not the case, it could be further considered in this definition at a future date, recognizing that it was important that microgreens were covered within the guidelines.

Indicator microorganism

57. There was general support for the second definition of indicator microorganism as presented in CRD4, but with some modifications proposed to improve clarity, and address the following points:

- that an indicator microorganism can also be an indicator for the conditions that would allow proliferation of pathogens as well as presence of pathogens;
- the word “lapse” may not be easily understood and could be replaced with “failure” for clarity; and
- to refer to *E. coli*, rather than total *E. coli*, as the qualifier was not necessary.

58. The definition was revised to capture these points and CCFH52 agreed to the following:

*Indicator microorganisms - microorganisms used as an indicator of quality, process efficacy, or hygienic status of food, water, or the environment, commonly used to suggest conditions that would allow the presence or the proliferation of pathogens, a failure in process hygiene or the process. Examples of indicator microorganisms include counts of total mesophilic aerobic bacteria, coliforms or faecal coliforms, *E. coli* and Enterobacteriaceae.*

Raw beef

59. CCFH52 agreed to the definition as proposed in CRD4. Responding to questions about tenderized beef, and the potential that it might extend beyond the definition of raw beef in cases where brine or other additives were included during the tenderization process, the Chair of the EWG clarified that only physically tenderized beef was included in the scope of the document; a definition for tenderized beef would be included in the raw beef annex, in line also with the recommendations of the virtual working group; and if necessary further clarity could be provided in the scope to indicate that it did not include beef tenderized with brine or other additives.

Raw milk

60. It was clarified that the definition of raw milk was based on the definition in the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004) with the exception of the text “that is intended for direct consumption or a primary input for dairy products”. CCFH52 also fully endorsed the proposal of the virtual working group to delete the last sentence of the definition and instead provide further clarity in the scope, as it was considered this sentence created confusion and may lead to incorrect assumptions regarding effective heat treatments.

61. In response to a proposal to include text in the definition to indicate that raw milk should originate from healthy animals, should not be altered and obtained by uninterrupted and hygienic milking processes, the EWG Co-chair from France clarified that these good practices were covered in other parts of the guidelines and did not need to be part of the definition. Regarding concerns that the definition of raw milk only referred to milk of bovine origin it was clarified that according to the *General Standard for the Use of Dairy Terms* (CXS 206-1999), milk was defined as “the normal mammary secretion of milking animals”, and given the inclusivity of this definition it was not necessary to make any reference to different species of milking animals within the definition.

62. CCFH52 agreed to the following definition:

*Raw milk: Milk (as defined in Codex General Standard for the Use of Dairy Terms (CXS 206-1999)) that is intended for direct consumption or a primary input for dairy products and which has not been*
heated beyond 40°C or undergone any treatment that has an equivalent effect\textsuperscript{11}.

Other definitions

63. The definitions for raw milk cheeses and Shiga toxin-producing \textit{E. coli} (STEC) were agreed as proposed. It was also noted that definitions for monitoring, verification and validation would be moved from the Raw Milk Annex into the General Section based on comments at the virtual working group meeting that these were relevant to the whole document. It was further agreed that the definitions for the commodities should appear in both the General section and in the specific commodity annex for both ease of use and to allow the commodity specific annexes to be used in a standalone manner.

“GHP-based” and “hazard-based” control measures

64. The EWG co-chairs proposed to delete “GHP-based” and “hazard-based” in front of control measures and simply refer to control measures, noting that, in their view, this did not lead to any loss of understanding of the control measures in the document, as the guidelines did not attempt to determine whether specific control measures were “GHP-based” or “hazard-based”. CCFH52 agreed with this proposal.

Section on the Laboratory Analysis Criteria – need for explanation on how virulence genes can be taken into account in corrective actions?

65. There was general support for the proposal to include guidance on how virulence genes in isolated strains can be taken into account in corrective actions. However, in doing so, it was cautioned that priority STEC virulence genes could vary from one country to another, thereby impacting the way STEC is managed and it would be important to have flexibility in the guidance developed to allow for different management approaches.

Section 6.1

66. The EWG co-chair recalled that Section 6.1 addressed development of risk-based control measures and noted that there had been some comments to delete this section, others to replace paras. 30-33 with a reference to the \textit{Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)} (CXG 63-2007) and further proposals to retain the section with modifications, with three options for para. 31 presented for consideration by CCFH52. Many delegations supported retention of the paragraphs and the third option for para. 31 proposed by the co-chair. However, some expressed concern that as the information in this section was limited it would be better to direct readers to more comprehensive information in CXG 63-2007. It was noted that such a cross-reference was already included in para. 28.

67. A further concern was expressed as to how realistic the use of such modelling tools, referred to in the proposed text for para. 31, were considering the extensive data requirements to effectively use such tools and that this challenge should be clearly communicated to the risk manager. Another Member noted that control measures also related to prevention, and this should be covered by the text, in addition to reduction and elimination of the hazard. Based on the comments received CCFH52 agreed to keep this section with the addition of the following revised text at the beginning of paragraph 31.

\begin{quote}
Risk modelling tools can be developed to assess the impact of control measures on the prevention, reduction or elimination of the hazard. The capability and limitations, including the need for quantitative data, of the tools should be clearly specified and understood by the risk manager.
\end{quote}


68. The EWG co-chairs presented CRD5 highlighting the comments provided and agreements reached during the working group. CCFH52 agreed with the proposals made in CRD5 and that these should be incorporated in the further elaboration of the guidelines. In addition, it was proposed that the future work consider the alignment of the flowcharts for beef in this guideline and the existing \textit{Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat} (CXG 87-2016).

Conclusion

69. CCFH52 agreed to:

\begin{itemize}
  \item return the proposed draft document to Step 2/3 for redrafting and circulation for comments;
  \item establish an EWG, chaired by Chile and co-chaired by France, New Zealand and the United States of America, and working in English, to:
\end{itemize}

\textsuperscript{11} For technical purposes, cheese curd might be “cooked” (i.e., by application of heat at temperatures below 40°C to expel water from the curds). The heat stresses microorganisms, making them more susceptible to other microbiological control measures. \textit{Code of Hygienic Practice for Milk and Milk Products} (CXC 57-2004), Annex II, Appendix B, p. 43.
a. update the General section and the Annexes on Raw Beef, Fresh Leafy Vegetables, and Raw Milk and Raw Milk Cheeses, taking into consideration the written comments that were submitted through the Online Commenting System (OCS) in response to the CL 2021/63-FH, and CRDs submitted at CCFH52, as well as the virtual working group (CRD5) and plenary session discussions at CCFH52;

b. draft an annex on sprouts describing interventions relevant to control of STEC; and

c. review the relevant JEMRA reports with respect to control of STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts and incorporate appropriate interventions and other changes into the annexes and general part as appropriate; and

iii. establish a Physical Working Group (PWG), chaired by Chile and co-chaired by France, New Zealand and the United States of America, working in English, French and Spanish to be held in conjunction with CCFH53 to consider all comments received and to prepare a revised proposal for consideration by plenary.

70. The report of the EWG should be made available to the Codex Secretariat at least three months before CCFH53 for circulation for comments at Step 3.

PROPOSED DRAFT GUIDELINES FOR THE SAFE USE AND RE-USE OF WATER IN FOOD PRODUCTION AT STEP 4 (Agenda item 8)12

71. The FAO Representative provided an overview of JEMRA's work related to water, addressing aspects such as microbial risk assessment and related decision tree tools, mitigation options, potential microbiological indicators, microbial monitoring and case studies for the safety and quality of water used in food processing and production. The Representative presented the specific risk assessment decision trees established for fresh fruits and vegetables, fishery products and water re-use. It was noted that JEMRA had worked on the scientific and criteria recommendations for diverse types of water, the measures used for assessing “fitness,” practical interventions to achieve an acceptable risk and case studies of different scenarios for the fresh fruits and vegetables, fishery, and dairy sectors. In conclusion, the Representative highlighted that water should be fit-for-purpose without compromising the safety of the food and that risk assessment was essential to achieving this goal.

72. Honduras, Chair of the EWG, speaking also on behalf of the co-Chairs, Chile, Denmark, the EU, and India, introduced the item and recalled that CCFH51 had agreed to undertake this new work and tasked the EWG to develop the guidelines. The EWG Chair explained that CX/FH 22/52/8 consisted of three parts (i.e., General Part, Annex I Fresh produce and Annex II Fishery products) and that a third annex on the dairy sector from milk harvest to manufacturing, would be elaborated. The EWG Chair highlighted that there was overall support for the proposed Guidelines and specific inputs on several issues including definitions, retention of certain text, organization of the information, decision support systems and other practical examples had been collected. The EWG Chair further proposed that, to facilitate development of the Guidelines, CCFH52 should focus their discussions on providing guidance on key issues identified by the EWG and defining the request for scientific advice from FAO/WHO.

73. CCFH52 agreed with the proposed approach and discussed the key issues identified by the EWG.

General part

Relevant terminology – the use of “potable water” or “drinking water” throughout the document

74. There was extensive support to use the term “potable water” throughout the document, as it has been previously defined and widely used in Codex documents.

75. One Observer proposed to include both terms in the document given that the term “potable” might have a number of localized interpretations across the world while another Observer, supporting the use of the term “potable water”, also suggested consideration of the use of “drinking water” defined by WHO when water of that quality was being referred to.

76. CCFH52 agreed to use the term “potable water” throughout the document.

12 CX/FH 22/52/8; CX/FH 22/52/8 Add.1 (Argentina, Australia, Brazil, Canada, Colombia, Costa Rica, Cuba, Egypt, European Union, India, Iran, Japan, Kenya, Malaysia, Mexico, New Zealand, Norway, Peru, Republic of Korea, Saudi Arabia, Thailand, Uruguay, USA and Food Industry Asia, FoodDrinkEurope, IGBA, ICGMA, ICUMSA, IDF/FIL, IFT, IFU); CRD9 (Dominican Republic, Ecuador, Malaysia, Philippines and Rwanda); CRD 10 (El Salvador); CRD11 (Indonesia); CRD12 (Ghana); CRD14 (Morocco); CRD15 (Uganda); CRD16 (East African Community); CRD17 (Senegal); CRD18 (Burundi); CRD20 (African Union); CRD21 (Saudi Arabia); CRD22 (Nigeria); CRD23 (the Republic of Korea); CRD24 (Tanzania); CRD25 (South Africa); CRD28 (United Kingdom)
Annex I Fresh produce

Key issue 1: Determine whether to keep the revised paragraphs 5 to 36 as adapted to the scope of these guidelines, or to replace with a cross-reference to CXC 53-2003

77. Most Members supported maintaining the paragraphs. Some suggested that paras. 5 to 36 should be replaced by a cross-reference to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003) to avoid duplication while others suggested that the revised paras. 5 to 36, adapted to the scope of these guidelines, should be retained, making the document more user friendly and easier to implement.

78. CCFH52 noted that FAO/WHO had been re-evaluating the scientific evidence on prevention and control of microbiological hazards in fresh fruits and vegetables, which might identify the need for a revision to CXC 53-2003. It was further noted that as these guidelines were still under development and there was also work ongoing on fresh leafy vegetables in the context of the elaboration of the draft guidelines for the control of STEC, it may be more appropriate to review all relevant texts when the current work had been completed and the relevant JEMRA report was available and then take a decision on any updates to CXC 53-2003 and appropriate cross-referencing.

79. In view of this, CCFH52 agreed to retain these paragraphs for the time being.

Key issue 2: Appropriate examples and decision trees

80. Most Members expressed overall support for the examples/decision trees. Some proposed that the examples, as well as the examples of decision-support systems such as decision trees should be moved to an appendix, while others suggested they should be replaced with references to the relevant national/local guidance.

81. Noting that the examples, as well as the examples of decision-support systems such as decision trees were important and helpful in understanding factors in determining whether water was fit for purpose, CCFH52 agreed to retain them for now, conduct further consultation with FAO/WHO JEMRA and subsequently consider how to appropriately include them in the document in terms of both their content and location.

Key issue 3: Request to FAO/WHO to validate/critically review examples and give concrete recommendations on thresholds and sampling frequencies

82. The Chairperson clarified that FAO/WHO could be asked to critically review rather than validate these examples in paras. 58-72 and provide recommendations on how they could be adapted in different countries/regions in a flexible manner, if possible, in countries with water scarcity and/or limited resources without putting food safety at stake.

83. Following a suggestion that the specificities of mitigation options such as filtering and peeling in para. 59 should also be reviewed by FAO/WHO, the FAO Representative, while understanding the request and being willing to provide inputs if needed, expressed concern that there were many different risk management measures and providing specificities on all or many of these might be challenging.

84. CCFH52 noted that the level of specificity required would be addressed in the further development of the guidelines.

85. CCFH52 agreed to request the EWG co-Chairs and FAO/WHO to work together to facilitate the use of the JEMRA outputs and identify other relevant issues where expert advice might be needed.

Annex II Fishery products

Key issue 1: Choose the most appropriate definitions for fishery products, harvesting and fit for purpose water from the proposed definitions in Section 4

Fishery products

86. With reference to their written comments, Members expressed divergent views in terms of their preferred option for the definition of fishery products. Members also made specific suggestions for modification of the proposed definitions (e.g., inclusion of echinoderm and other aquatic animals, removal of aquatic reptile and plants).

87. CCFH52 agreed to ask the EWG to continue the discussion on this matter.

Harvesting

88. CCFH52 agreed to ask the EWG to continue the discussion on the definition of harvesting.

Fit for purpose water

89. CCFH52 agreed to eliminate the definition from the annex and maintain it at the general part.

Other considerations
90. CCFH52 agreed to:
   - reduce the number of definitions and delete definitions for those terms that were well understood; and
   - conduct further consultation with FAO/WHO JEMRA on potential examples.

**Annex III Dairy sector**

91. CCFH52 noted that this annex would be developed upon confirmation of the co-Chair leading this task. The International Dairy Federation (IDF) expressed their willingness to assist in drafting this annex.

92. CCFH52 further noted that if it was not possible to progress all the annexes in advance of CCFH53, the annexes might move forward at different rates.

**Conclusion**

93. CCFH52 agreed:
   i. to return the proposed draft document to Step 2/3 for redrafting and circulation for comments;
   ii. to establish an EWG, chaired by Honduras and co-chaired by Chile and the EU, working in English to continue developing the proposed draft guidelines, and annexes (fresh produce, fishery products and dairy sector), considering all written comments submitted to CCFH52 and the decisions and comments made at CCFH52; and
   iii. that the EWG co-Chairs and FAO/WHO would schedule regular communications to facilitate consideration of the JEMRA outputs and get advice on any relevant issues in the document (e.g., critical review of examples, examples of decision-support systems currently included in the document, recommendations on how to adapt examples to different countries including those with water scarcity and/or limited resources, examples of specific risk mitigation strategies, etc.).

94. The report of the EWG should be made available to the Codex Secretariat at least three months before CCFH53 for circulation for comments at Step 3.

95. CCFH52 further agreed to convene a PWG, chaired by Honduras and co-chaired by Chile and the EU and working in English, French and Spanish, to meet in conjunction with CCFH53 to consider comments received at Step 3 and prepare recommendations for consideration by the plenary.

**OTHER BUSINESS AND FUTURE WORK (Agenda item 9)**

96. The Chairperson recalled that it was over two years since CCFH had last met and that CCFH53 was scheduled to meet in approximately 8 months’ time, and this presented difficulties for work planning. He therefore highlighted the need to plan strategically, starting immediately, for future sessions both in terms of potential newwork and the need for scientific advice.

**Discussion papers**

97. The Chairperson recalled that CCFH51 had agreed to consider discussion papers on Vibrio species in seafood and viruses in food at its next session, but this had not been possible due to the time constraints and abridged agenda of this virtual session. He therefore requested the Members who had agreed to develop these discussion papers to confirm if they were still able to develop these papers for CCFH53.

98. Japan confirmed their willingness to provide a discussion paper for CCFH53 on the possible revision to the Guidelines on the Application of the General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood (CXG 73-2010) together with New Zealand. The Member noted that they were reviewing the JEMRA work on this topic, which provided useful information on potential interventions especially on live bivalve molluscs, and this would be considered in their discussion paper.

99. Canada confirmed their commitment to work with the Netherlands to prepare a discussion paper on the possible revision of the Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (CXG 79-2012). The Member noted that they would only be presenting a discussion paper for CCFH53, but that a project document could be developed at a later stage depending on the outcome of discussions at CCFH53.

100. The Chairperson expressed appreciation for the ongoing commitments to prepare the discussion papers and highlighted the importance of both using the available scientific information and identifying any scientific advice needs in their development.

**Potential new work proposals and requests for scientific advice**

101. One Member noted that there were several texts that had been developed by CCFH that potentially needed

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13 CRD26 (The Global Alliance for Improved Nutrition (GAIN))
updating due to advances in science, including the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods* (CXG 61-2007) and the *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011). However, before any new work proposals could be submitted, an update to the scientific advice, which was more than a decade old, was required. In this regard CCFH52 recalled that it had already supported the proposal that JEMRA undertake a full farm to table risk assessment on *Listeria monocytogenes* in food which would then enable CCFH to consider an approach to updating CXG 61-2007 (see Agenda Item 3). Recalling the scientific developments that had taken place over the last decade, CCFH52 also agreed to request JEMRA to compile available information related to both *Salmonella* and *Campylobacter* in chicken meat to determine the kind of update that would be needed for CXG 78-2011.

102. The Global Alliance for Improved Nutrition (GAIN) referred to CRD26 and drew attention of delegates to the need for international guidelines on food safety for traditional food markets. She referred to existing Codex regional texts,\(^\text{14}\) and requested support from Members for a new work proposal to elaborate global guidelines for traditional food markets. Bolivia, Indonesia, Kenya, Nigeria and Peru, highlighted their interest in this work and willingness to develop a proposal in collaboration with GAIN.

103. The Codex Secretariat reminded CCFH52 that a CL would be distributed to request submissions for new work proposals after CCFH52, and Members were encouraged to provide any proposals in response to this CL.

*Working group on CCFH work priorities*

104. The United States of America confirmed their willingness to continue to serve as Chair of the working group.

**Conclusion**

105. CCFH52:

i. noted the willingness of those Members who committed to prepare discussion papers at the last session, namely on *Vibrio* and viruses, to present those for consideration at CCFH53;

ii. requested JEMRA to collate the relevant scientific information on *Salmonella* and *Campylobacter* in chicken meat in preparation for an update of the existing *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011) and recalled their support for JEMRA to develop a full farm to table risk assessment for *Listeria monocytogenes* in foods that would inform any update of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods* (CXG 61-2007);

iii. reminded delegates that a CL calling for new work proposals would be issued shortly after CCFH52 and that any proposals for new work should clearly identify needs for scientific advice;

iv. noted the support of several members to the proposal of GAIN to develop a new work proposal on food safety in traditional markets and encouraged interested parties to work together to submit such a proposal in response to the aforementioned CL for consideration by CCFH53; and

v. established a working group on CCFH work priorities, chaired by the United States of America, to be held in conjunction with CCFH53, working in English, French and Spanish to consider any proposals for new work and update the committee’s forward work plan.

**DATE AND PLACE OF THE NEXT SESSION (Agenda item 10)**

106. CCFH52 was informed that CCFH53 was scheduled to take place the week starting 28th November 2022, in San Diego, United States of America. However, due to the ongoing uncertainties, the exact time and format of the meeting would be determined by the host Government in consultation with the Codex Secretariat and communicated in due course.

APPENDIX I

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

CHAIRPERSON – PRÉSIDENT - PRESIDENTE

Dr Jose Emilio Esteban
Chief Scientist
Food Safety and Inspection Service
U.S. Department of Agriculture
Washington, DC

CHAIR’S ASSISTANTS – ASSISTANTES DU PRÉSIDENT – ASISTENTES DEL PRESIDENTE

Ms Kristen Hendricks
International Issues Analyst
U.S. Codex Office
U.S. Department of Agriculture
Washington, DC

Mrs Heather Selig
International Issues Analyst
U.S. Codex Office
U.S. Department of Agriculture
Washington, DC

MEMBERS NATIONS AND MEMBER ORGANIZATIONS
ÉTATS MEMBRES ET ORGANISATIONS MEMBRES
ESTADOS MIEMBROS Y ORGANIZACIONES MIEMBROS

ARGENTINA - ARGENTINE

Dr Maria Esther Carullo
Secretaria Técnica del Comité Nacional del Codex sobre Higiene de los Alimentos
Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA)

Ms Josefina Cabrera
Jefa Laboratorio Nacional de Referencia
Instituto Nacional de Alimentos

Ms Erika J. Marco
Jefa del Servicio de Análisis Integrado de Vigilancia
Departamento Vigilancia Sanitaria y Nutricional de los Alimentos
Instituto Nacional de Alimentos

Eng Silvia Santos
Asesora
Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA)

Ms Soledad Sarniguet
Jefa Servicio Microbiología
Instituto Nacional de Alimentos

AUSTRALIA - AUSTRALIE

Dr Nora Galway
Director
Food Standards Australia New Zealand
Canberra

Dr Hong Jin
Senior Scientist
Food Standards Australia New Zealand
Canberra

Ms Lauren Kolstad
Senior Food Safety Coordinator
Food Standards Australia New Zealand
Majura Park, ACT

AUSTRIA - AUTRICHE

Dr Carolin Krejci
Head of Division
Federal Ministry of Social Affairs, Health, Care and Consumer Protection
Vienna

BAHAMAS

Ms Patricia Johnson
Standards Officer
Bahamas

BANGLADESH

Mrs Esmat Jahan
Assistant Director
Bangladesh Standards and Testing Institution
Dhaka
BARBADOS - BARBADE
Mrs Cheryl Lewis
Technical Officer
Barbados National Standards Institution (BNSI)
St. Michael

BELGIUM - BELGIQUE - BÉLGICA
Ms Katrien De Pauw
Regulatory Expert
Federal public service of Health, Food Chain Safety and Environment
Brussels
Ms Vera Cantaert
Expert Contaminants
Federal Agency for the Safety of the Food Chain
Brussels
Mr Bert Colpaert
Attaché
Federal Agency for the Safety of the Food Chain
Brussels
Mrs Elien De Boeck
Regulatory Expert
Federal public service of Health, Food Chain Safety and Environment
Brussels

BELIZE - BELICE
Mrs Lisa Sanchez Marin
Senior Public Health Inspector
Ministry of Health
Belize City
Mr Endhir Sosa
Senior Inspector
Belize Agriculture Health Services
Belize

BOLIVIA (PLURINATIONAL STATE OF) – BOLIVIE (ÉTAT PLURINATIONAL DE) – BOLIVIA (ESTADO PLURINACIONAL DE)
Eng Maria Lourdes Abularach
Coordinadora
Colegio de Ingenieros de Alimentos
Santa Cruz de la Sierra
Ms Maria Cristina Ríos Gomez
Responsable Nacional de Vigilancia y Control de Residuos Contaminantes en Alimentos
SENASAG
La Paz
Eng Wilder Fernando Aguilar Quispe
Punto de Contacto
Ministerio de Desarrollo Productivo y Economía Plural
La Paz
Eng Marcela Sandra Aliaga Belmonte
Delegada
Ministerio de Desarrollo Productivo y Economía Plural
La Paz

BOTSWANA
Ms Lephutshe Ada Senwelo
CCP
Ministry of Health and Wellness
Gaborone

BRAZIL - BRÉSIL - BRASIL
Mrs Lígia Schreiner
Specialist on Regulation and Health Surveillance
Brazilian Health Surveillance Agency - ANVISA
Brasília
Ms Angela Maria Queiroz Pellegrino Missaglia
Consultant
Brazilian Association of Feed Manufacturers
Brasília
Mr Lúcio Akio Kikuchi
Head Special Programs Coordination – DIPOA/MAPA
Ministry of Agriculture, Livestock and Supply
Ms Carolina Araujo Vieira
Specialist on Regulation and Health Surveillance
Brazilian Health Surveillance Agency - ANVISA
Brasília
Prof Eduardo Cesar Tondo
Full Professor
Institute of Food Science and Technology of the Federal University of Rio Grande do Sul
Porto Alegre

BRAZILIAN FOOD INDUSTRY ASSOCIATION
Mr Rafael Ribeiro Goncalves Barrocas
Federal Inspector
Ministry of Agriculture, Livestock and Food Supply - MAPA
Brasília

BURKINA FASO
Mr Dominique Ouedraogo
Ingénieur Agronome
Ministère en charge de l’Agriculture
Ouagadougou
Mrs Estelle Bambara  
Director of Nutrition  
Ministry of Health  
Ouagadougou  

Dr Giséle Pare  
Director of veterinary services  
Ministry of animal resources  
Ouagadougou  

Mr Alain Yaguibou  
Food Technology Engineer  
ABNORM  
Ouagadougou  

CABO VERDE  

Mrs Edmilson Semedo  
Técnico de Regulação da ERIS  
ERIS  
Praia  

Ms Edira Baptista  
Técnico de Regulação da ERIS  
ERIS  
Praia  

Ms Maria Da Luz Lima  
Presidente do Instituto Nacional de Saúde Pública  
INSP  
Praia  

CAMBODIA - CAMBODGE - CAMBOYA  

Mr Dim Theng  
Deputy Director General  
Ministry of Commerce  
Phnom Penh  

Mr Aing Hoksrun  
Chief  
Food Safety Bureau, Ministry of Health  
Phnom Penh  

CAMEROON - CAMEROUN - CAMERÚN  

Mrs Hélène Carole Edima  
Maître de Conférences  
Université de Ngaoundere  

Mr Awal Mohamadou  
Agence des Normes et de la Qualité  
Yaoundé  

Mr Medi Moungui  
Ambassade du Cameroun  
Rome  

Mr Pouedoogo Pouedoogo  
Attaché  
Services du Premier Ministre  
Yaoundé  

Mr Indongo Yves Laret  
Directeur du Développement de la Qualité  
Ministère des Mines, de l’industrie et du développement Technologique  
Yaoundé  

CANADA - CANADÁ  

Dr Martin Duplessis  
Director  
Government of Canada  
Ottawa  

Mrs Cathy Breau  
Scientific Evaluator  
Government of Canada  
Ottawa  

Dr Marie Breton  
Section Head  
Health Canada  
Ottawa  

Mr Paul Ciras  
Chef, politiques et programmes  
Agence Canadienne d’Inspection des Aliments  
Ottawa  

Dr Jorge Correa  
Vice President, Market Access and Technical Affairs  
Canadian Meat Council  
Ottawa  

Mrs Kristin Hill  
A/National Manager, Process Management and Liaison, Office of Food Safety and Recall  
Canadian Food Inspection Agency  
Ottawa  

Ms Nancy Ing  
Regulatory Policy and Risk Management Specialist  
Health Canada  
Ottawa  

Dr Annie Locas  
National Manager  
Canadian Food Inspection Agency  
Ottawa  

CHILE - CHILI  

Ms Constanza Vergara E.  
Asesora Técnico  
ACHIPIA - Ministerio de Agricultura  
Santiago  

Mr David Guerra Maldonado  
Profesional de la División de Protección Pecuaria  
Ministerio de Agricultura  
Santiago  

Mrs Luisa Kipreos Garcia  
Asesora Técnica  
Ministerio de Salud  
Santiago  

Mr Diego Varela  
Coordinador Asuntos Internacionales  
Ministerio de Agricultura  
Santiago  

CHINA - CHINE  

Mrs Li Bai  
Researcher  
China National Center for Food Safety Risk Assessment  
Beijing
Mr Kwok Ching Chan
Chief Health Inspector (Food Surveillance)
Centre for Food Safety, Food and Environmental Hygiene Department, HKSAR Government
Hong Kong

Mr Wai Yip Chan
Chief Health Inspector (Import/Export)
Centre for Food Safety, Food and Environmental Hygiene Department, HKSAR Government
Hong Kong

Mr Xiao Chen
Research Assistant
China National Center for Food Safety Risk Assessment
Beijing

Mrs Yung Yung Melva Chen
Scientific Officer (Programme Planning)
Centre for Food Safety, Food and Environmental Hygiene Department, HKSAR Government
Hong Kong

Dr Tsz Kit Chong
Scientific Officer (Microbiology)
Centre for Food Safety, Food and Environmental Hygiene Department, HKSAR Government
Hong Kong

Mrs Hao Ding
Associate Researcher
China National Center for Food Safety Risk Assessment
Beijing

Prof Yunchang GUO
Professor/Director of Risk Surveillance Division II
China National Center for Food Safety Risk Assessment
Beijing

Mr Yang Jiao
Senior Engineer
International Inspection and Quarantine Standards and Technical Regulations Research Center of General Administration of Customs
Beijing

Mr Feng Jin
Deputy Director
Ningbo Customs, P.R. China

Mrs Weiwei Li
Associate Researcher
China National Center for Food Safety Risk Assessment
Beijing

Mr Yu Li
Chief Technology Officer
China National Food Industry Association
Beijing

Mr Jikai Liu
Assistant Researcher
China National Center for Food Safety Risk Assessment
Beijing

Mrs Hanyang Lyu
Assistant Researcher
China National Center for Food Safety Risk Assessment
Beijing

Mr Gensheng Shi
Investigator
Department of Food Safety Standards, Risk Surveillance and Assessment, National Health Commission of the People's Republic of China
Beijing

Mrs Jing Tian
Researcher
China National Center for Food Safety Risk Assessment
Beijing

Prof Jun Wang
Professor/Researcher
China National Center for Food Safety Risk Assessment
Beijing

Mrs Jiaqi Wang
Research Assistant
China National Center for Food Safety Risk Assessment
Beijing

Prof Jing Zeng
Professor
Science and Technology Center of China Customs
Beijing

COLOMBIA - COLOMBIE

Eng Blanca Cristina Olarte Pinilla
Profesional especializada
Ministerio de Salud y Protección Social
Bogotá

Mr Wilmer Humberto Fajardo Jiménez
Chemical Food "Official Food Inspection Functionary"
INVIMA
Bogotá

Prof Lorena Aydee Herreño Téllez
Asesora
Ministerio de Comercio, Industria y Comercio
Bogotá

Eng Norma Soto Tarquino
Profesional especializada
Instituto Nacional de Vigilancia de Medicamentos y Alimentos - Invima
Bogotá

COSTA RICA

Mrs Carolina Quesada Rojas
Ingeniera de Alimentos
Coordinadora del CCFH
Ministerio de Salud
San José

Mrs Alejandra Chaverri Esquivel
Nutricionista
Ministerio de Salud
San José
Mrs Amanda Lasso Cruz
Asesora Codex
Ministerio de Economía Industria y Comercio
San José

Mrs Rebeca López Clavo
Área de especialidad: Gestión de la calidad e inocuidad y microbiología
Universidad de Costa Rica
San José, San Pedro

CROATIA - CROATIE - CROACIA
Dr Sandra Gutić
Head of Service
Ministry of Agriculture of the Republic of Croatia
Zagreb

CUBA
Mrs María Victoria Luna Martínez
Investigadora del Departamento de Registro Nacional de Alimentos
Ministerio de Salud Pública
La Habana

Dr Jorge Félix Medina Pérez
Secretario Codex Cuba
Ministerio de Ciencia, Tecnología y Medio ambiente/CITMA
La Habana

CZECH REPUBLIC - RÉPUBLIQUE TCHÈQUE - REPÚBLICA CHECA
Dr Dana Triska
Head of Food Chain Unit
Ministry of Agriculture of the Czech Republic
Prague 1

Mrs Alena Triskova
National Expert
Ministry of Agriculture of the Czech Republic
Prague 1

CÔTE D'IVOIRE
Ms Rose Kouassi
Chef de Service
Ministère d’Etat, Ministère de l’Agriculture et du Développement Rural
Abidjan

Mrs Adeline Sanogo Epse Gale
Sous-Directeur
Ministère de l’Agriculture et du Développement Rural

DENMARK - DANEMARK - DINAMARCA
Mrs Gudrun Sandø
Special Veterinary Adviser
Danish Veterinary and Food Administration
Glostrup

DOMINICAN REPUBLIC – RÉPUBLIQUE DOMINICAINE – REPÚBLICA DOMINICANA
Dr Luís Martínez
Encargado departamento de alimentos
Dirección General Medicamentos, Alimentos y Productos Sanitarios, en Ministerio de Salud Pública
Santo Domingo, D.N.

Dr Svetlana Afanasieva
Coordinadora del programa de alimentación hospitalaria
Ministerio de Salud Pública y Asistencia Social
Santo Domingo

Eng Pedro De Padua
Supervisor Nacional Alimentos
Ministerio de Salud Pública y Asistencia Social (MSP)
Santo Domingo, D. N.

Mr Modesto Buenaventura Pérez Blanco
Coordinador Normas Alimenticias
Ministerio de Salud Pública y Asistencia Social (MSP)
Santo Domingo

Mrs Fredesvinda Selmo
Técnica Normalización
Instituto Dominicano para la Calidad (INDOCAL)
Santo Domingo, D.N.

Mrs Ángela Urbáez
Enc. Departamento Normalización
Instituto Dominicano para la Calidad (INDOCAL)
Santo Domingo, D.N.

ECUADOR - ÉQUATEUR
Mr Miguel Ortiz
Analista
Ministerio de Salud Pública del Ecuador
Quito

Mr Ismael Cuichán
Analista
Agencia de Regulación y Control Fito y Zoosanitaria-AGROCALIDAD
Quito

Mrs Tatiana Gallegos
Analista
Ministerio de Salud Pública
Ms Andrea Segovia
Analista de la Dirección de Gestión
Ministerio de Producción, Comercio Exterior, Inversiones y Pesca
Quito

Ms Daniela Vivero
Analista de certificación de producción primaria y buenas prácticas
Agencia de Regulación y Control Fito y Zoosanitario - AGROCALIDAD
Quito
Mr Cristian Yépez
Analista
Ministerio de Producción, Comercio Exterior, Inversiones y Pesca
Quito

EGYPT - ÉGYPTE - EGIPTO
Dr Zienab Mosad Abdelrazik Abdelrahman
Food Standards Specialist
Egyptian Organization for Standardization and Quality (EOS)
Cairo
Prof Afaf Amin
Prof. of Food Safety and Microbiology
National Nutrition Institute (NNI)
Cairo
Dr Mostafa Diab
Head of Regulatory and Scientific Affairs
Juhayna Food Industries
Giza
Dr Kareem Ismail
Technical Manager for Microbiological lab
Alexandria Water Company
Alexandria
Dr Nayra Mehanna
Director of Food Safety Unit
National Research Center (NRC)
Giza
Dr Shaimaa Zaid
Manager of Microbiology Lab.
Chemical Administration
Cairo

EL SALVADOR
Mrs Claudia Guzmán
Jefa de Punto de Contacto Codex Alimentarius
OSARTEC
San Salvador
Mr Josué Daniel López Torres
Especialista Codex Alimentarius
Organismo Salvadoreño de Reglamentación
Técnica-OSARTEC
San Salvador

ESTONIA - ESTONIE
Ms Katrin Kempi
Adviser
Ministry of Rural Affairs
Tallinn
Mrs Elsa Peipman
Chief Specialist
Ministry of Rural Affairs
Tallinn

ESWATINI
Mr Sigpho Emmanuel Shongwe
Chief Environmental Health Officer/Codex Contact Point
Ministry of Health
Mbabane

Mr Funwako Elias Dlamini
Deputy Chief Environmental Health Officer
Ministry of Health
Manzini
Ms Glorious Hloniphile Dlamini
Programme Manager
Ministry of Health
Mbabane
Mrs Senteni Mamba
Environmental Health Officer
Ministry of Health
Mbabane
Ms Setsabile Mamba
Environmental Health Officer
Mbabane City Council
Manzini
Ms Ellen Matsenjwa
Senior Environmental Health Officer
Municipal Council of Mbabane
Mbabane
Mr Simon Mkhwana
Senior Environmental Health Officer
Ministry of Health
Siteki
Mr Sibusiso Mncina
Environmental Health Officer
Ezulwini Town Council
Ezulwini
Dr Courage Mudyanavana
Veterinary Officer
Ministry of Agriculture
Mbabane
Mr Musa Nsibandze
Senior Environmental Health Officer
Matsapha Town Council
Matsapha

EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA
Mr Risto Holma
Senior Administrator
European Commission
Brussels
Mr Kris De Smet
Administrator
European Commission
Brussels
Ms Patricia Herrero Sancho
Legislative Officer
European Commission
Brussels
Ms Judit Krommer
Administrator
European Commission
BRUSSELS
Mr Martial Plantady
Team Leader
European Commission
Brussels
**FINLAND - FINLANDE - FINLANDIA**
Dr Sebastian Hielm
Food Safety Director
Ministry of Agriculture and Forestry

**FRANCE - FRANCIA**
Mr Quentin Guyonnet-Dupérat
Adjoint au sous-directeur
Ministère de l'agriculture et de l'alimentation

Mrs Louise Dangy
Point de contact national
SGAE
Paris

Mrs Cécile Balon
chargée d'études
Ministère de l'agriculture et de l'alimentation

Mr Eric Dumoulin
Sous-directeur
Ministère de l'agriculture et de l'alimentation

Mr David Hicham
Adjoint au chef de bureau
Ministère de l'agriculture et de l'alimentation

Mrs Mylène Molitor
Chargée de mission
Ministère de l'économie

Dr Laurent Noel
Chef de bureau
Ministère de l'agriculture et de l'alimentation
Paris

Mrs Yasmine Petit
Rédactrice au bureau 4B – qualité et valorisation des denrées alimentaires
Ministère de l'économie et des finances

Mrs Stéphanie Rivier
Chargée d'études
Ministère de l'agriculture et de l'alimentation

Mrs Delphine Sergentet
Experte nationale
ANSES

Mrs Outi Tyni
Officer
Council of the EU General Secretariat

**GERMANY - ALLEMAGNE - ALEMANIA**
Dr Niels Bandick
Head of Unit
Food Hygiene and Technologies, Supply Chains, Food Defense Deputy Head of Department
Biological Safety
Federal Institute for Risk Assessment
Berlin

Ms Anne Beutling
Officer
Federal Ministry of Food and Agriculture
Berlin

Dr Lueppo Ellerbroek
Director and Professor
Federal Ministry of Food and Agriculture
Berlin

Dr Klaus Lorenz
Head of Unit
Federal Office of Consumer Protection and Food Safety Berlin

**GHANA**
Prof Kwasi Addo
HEAD
Noguchi Memorial Institute for Medical Research
Accra

Ms Pokuua Appiah-Kusi
Deputy Codex Contact Point Manager
Ghana Standards Authority
Accra

Mr Edward Worlanyo Archer
Principal Regulatory Officer
Food and Drugs Authority
Accra

Dr Bashiru Bawise Boi Kikimoto
Head, Public Health & Food Safety Division
Ministry of Food and Agriculture
Accra

Mr Andrew Larney
Codex Contact Point Manager
Ghana Standards Authority
Accra

Ms Lilian Kabukuor Manor
Scientific Officer
Ghana Standards Authority
Accra

Prof Charles Tortoe
Director
Centre for Scientific and Industrial Research, FRI
Accra

Mrs Regina Yawa Vowotor
Director, Biochemical Science Directorate
Ghana Standards Authority
Accra

**GREECE - GRÈCE - GRECIA**
Mrs Soultana Tatsika
Head of Department
Hellenic Food Authority
Thessaloniki

**GRENADA - GRENADE - GRANADA**
Mr Andre Worne
Chief Environmental Health Officer
Ministry of Health
St. George's

Mr Kenneth Hazard
Environmental Health Officer
Ministry of Health
St. George's

**GUATEMALA**
Mr Mario Álvarez Orellana
Inspector de Alimentos
Ministerio de Salud Pública y Asistencia Social
Guatemala
GUINEA-BISSAU - GUINÉE-BISSAU
Mr Jose Mora N’sume
Directeur des Services d’Information et de la Communication et Point Contact de Comité National du Codex Alimentarius Institut National de la Recherche Agricole Bissau

GUYANA
Ms Tandeka Barton
Principal Analytical Scientific Officer
Government Analyst Food and Drug Department Georgetown

Ms Bevon Mcdonald
Senior Foreign Service Officer
Ministry of Foreign Affairs and International Cooperation

Ms Grace Parris
Lecturer/Manager of Agro-Processing Unit
Guyana School of Agriculture Georgetown

Ms Maya Phillips
Quality Assurance Officer
Guyana Marketing Corporation Georgetown

Mr Roy Porter
Senior Food and Agro-Processing Inspector
Guyana Food Safety Authority, Ministry of Agriculture

Mr Robert Ross
Quality Assurance Manager/ Business Development Manager
Guyana Manufacturers & Services Association Georgetown

HONDURAS
Ms Maria Eugenia Sevilla
Coordinadora de CCFH Honduras SENASA

Mrs Mirian Yamileth Bueno Almendarez
Directora Técnica de Inocuidad Agroalimentaria SENASA Tegucigalpa

Ms Fany Cárcamo
Jefa de Reglamentación Técnica Secretaría de Desarrollo Económico Tegucigalpa

Mrs Daniela Raquel Figueroa
Pasante Secretaría Técnica de Codex Honduras SENASA Tegucigalpa

HUNGARY - HONGRIE - HUNGRÍA
Ms Kitti Annamária Bognár
Food Safety Officer Ministry of Agriculture Budapest

Ms Maya Phillips
Quality Assurance Officer
Guyana Marketing Corporation Georgetown

Mr Roy Porter
Senior Food and Agro-Processing Inspector
Guyana Food Safety Authority, Ministry of Agriculture

Mr Robert Ross
Quality Assurance Manager/ Business Development Manager
Guyana Manufacturers & Services Association Georgetown

INDIA - INDE
Dr Bhaskar Narayan
Advisor Food Safety and Standards Authority of India New Delhi

Ms Rheeabe Abraham
Assistant General Manager Agricultural and Processed Food Products Export Development Authority (APEDA)

Dr K M Ansari
Principal Scientist CSIR-Indian Institute of Toxicology Research

Ms Reeba Abraham
Technical Officer Food Safety and Standards Authority of India New Delhi

Dr Naresh Kumar
Principal Scientist ICAR-National Dairy Research Institute

Ms Amrutha M Kaimal
Regulatory Support Executive Diageo India

Dr Bhavesh Modi
MD, PGDHHM, MPH, MBA, FIAPSM Professor & Head Department of Community & Family Medicine All India Institute of Medical Sciences Rajkot, Gujarat, India
Dr Asish Kumar Mukhopadhyay  
Scientist-F  
ICMR-National Institute of Cholera and Enteric Diseases, Kolkata, India

Dr V. Sudershan Rao  
Scientist-E (Rtd.)  
National Institute of Nutrition  
Hyderabad

Dr Sandeep Kumar Sharma  
Senior Scientist  
CSIR-Indian Institute of Toxicology Research  
Lucknow

Mr Jitender Singh  
Scientist III  
National Dairy Development Board

Ms Dhanya Suresh  
Technical Officer  
Food Safety and Standards Authority of India  
New Delhi

Mr Shashi Prakash Tripathi  
Technical Officer  
Export Inspection Council (EIC)

INDONESIA - INDONÉSIE

Dr Anas Ma’aruf  
Director of Environmental Health Department  
Ministry of Health  
DKI Jakarta

Mrs Duma Olivia Bernadette  
Product Quality Assurance Supervisor  
Ministry of Trade Republic of Indonesia  
Jakarta

Mrs Ela Edithya  
Sanitarian  
Ministry of Health Republic of Indonesia  
Jakarta

Mrs Fetnayeti Fetnayeti  
Product Quality Assurance Senior Manager  
Ministry of Trade Republic of Indonesia  
Jakarta

Mrs Bety Wahyu Hapsari  
Secretariat of the Codex Contact Point of Indonesia  
National Standardization Agency of Indonesia  
Jakarta

Prof Purwiyatno Hariyadi  
Professor  
IPB University (Bogor Agricultural University)  
Bogor

Mr Singgih Harjanto  
Secretariat of the Codex Contact Point of Indonesia  
National Standardization Agency of Indonesia  
Jakarta

Mrs Eti Kurniaiwati  
Laboratory Analyst  
Ministry of Marine Affairs and Fisheries of Republic of Indonesia  
Jakarta

Prof Harsi Dewantari Kusumaningrum  
Professor  
IPB University

Mrs Deksa Presiana  
Coordinator of Food Additives, Processing Aids, Packaging, Contaminant Standardization and Good Retail Practices  
Indonesian Food and Drug Authority  
Jakarta

Ms Tika Nur Pusparani  
Technical Manager of Quality Testing Laboratory  
Ministry of Trade Republic of Indonesia  
Jakarta

Mr Adhi Sambodo  
Sub-Coordinator of Food Safety  
Ministry of Health Republic of Indonesia  
DKI Jakarta

Ms Lia Sugihartini  
Coordinator of Standardization  
Ministry of Marine Affairs and Fisheries of Republic of Indonesia  
Jakarta

Mr Dasep Wahidin  
Sub-Coordinator of Food Contaminant Standardization and Good Retail Practices  
Indonesian Food and Drug Authority  
Jakarta

Mrs Tutut Indra Wahyuni  
Coordinator of Food Safety  
Ministry of Health Republic of Indonesia  
DKI Jakarta

Mrs Endang Widyastuti  
Sub-Coordinator of Food Safety  
Ministry of Health Republic of Indonesia  
Jakarta

Mrs Nuri Wulansari  
Secretariat of the Codex Contact Point of Indonesia  
National Standardization Agency of Indonesia  
Jakarta

Mrs Yuliana Yuliana  
Trade Analyst  
Ministry of Trade Republic of Indonesia  
Jakarta

Mr Jamal Zamrudi  
Food Safety Trainer  
Catalyst Consulting  
Banten

IRAN (ISLAMIC REPUBLIC OF) –  
IRAN (REPUBLIQUE ISLAMIQUE D’) –  
IRÁN (REPUBLICA ISLÁMICA DEL)

Mrs Farahnaz Ghollasi Moud  
Codex Contact Point  
Iranian National Standardization Organization (INSO)  
Tehran

Prof Abolghassem Djazayery  
Professor of Nutritional Sciences and co-Chair of CCFH in Iran  
Tehran University of Medical Sciences
Mrs Samaneh Eghtedari  
Expert of Codex Group in Iran  
Iranian National Standards Organization (INSO)  
Tehran  

Dr Masoumeh Moslemi  
Chair National Codex Committee CCFH in Iran  
Ministry of Health and Medical Education  

Mrs Leila Nasiri  
Codex Contact Point  
Iranian National Standardization Organization (INSO)  
Tehran  

IRELAND - IRLANDE - IRLANDA  

Mr Denis Carroll  
Senior Veterinary Inspector  
Department of Agriculture, Food and the Marine (DAFM)  
Dublin  

Mr Wayne Anderson  
Director of Food Science and Standards  
Food Safety Authority of Ireland  
Dublin  

Dr Lisa O’Connor  
Chief Specialist of Biological Safety  
Food Safety Authority of Ireland  
Dublin  

ITALY - ITALIE - ITALIA  

Mr Giulio Cardini  
Official  
Ministry of Agricultural Food and Forestry Policies  
Rome  

Ms Anna Beatrice Ciorba  
Official Veterinarian  
Ministry of Health  
Rome  

Dr Francesca Ponti  
Official  
Ministry of Agricultural Food and Forestry Policies  
Rome  

Mr Nicola Santini  
Doctor of Veterinary Medicine  
Ministry of Health  
Rome  

JAMAICA - JAMÂIQUE  

Dr Linnette Peters  
Director  
Ministry of Health  

JAPAN - JAPON - JAPÓN  

Ms Yoriko Onozawa  
Deputy Director, Office of HACCP Promotion  
Ministry of Health, Labour and Welfare  
Tokyo  

Mr Takumi Adachi  
Associate Director  
Ministry of Agriculture, Forestry and Fisheries  
Tokyo  

Dr Takateru Daikai  
Science Officer  
Ministry of Agriculture, Forestry and Fisheries  
Tokyo  

Mr Masafumi Dobashi  
Section chief  
Ministry of Health, Labour and Welfare  
Tokyo  

Mr Toyohiro Egawa  
Associate Director  
Ministry of Agriculture, Forestry and Fisheries  
Tokyo  

Ms Yoko Fukunaga-Nagano  
Associate Director  
Ministry of Agriculture, Forestry and Fisheries  
Tokyo  

Ms Tomoko Goshima-Matsuta  
Associate Director  
Ministry of Agriculture, Forestry and Fisheries  
Tokyo  

Ms Takao Mizuno  
Deputy Director  
Food Safety Commission  
Tokyo  

Dr Noriko Mizutani  
Risk Assessment Senior Expert Officer  
Food Safety Commission  
Tokyo  

Ms Misato Nakamura  
Section Chief  
Food Safety Commission  
Tokyo  

Ms Makoto Otsuka  
Chief of food safety subsection  
Ministry of Health, Labour and Welfare  
Tokyo  

Mr Nobuhiko Sato  
Chief of meat and dairy product safety subsection  
Ministry of Health, Labour and Welfare  
Tokyo  

Dr Hajime Toyofuku  
Professor  
Yamaguchi University  
Yamaguchi
Mr Yuki Yamazaki  
Technical Officer, Office of Foodborne Disease Surveillance  
Food Inspection and Safety Division  
Ministry of Health, Labour and Welfare  
Tokyo

Mr Tomotaro Yoshida  
Associate Director  
Ministry of Agriculture, Forestry and Fisheries  
Tokyo

KENYA

Mr Leonard Kimtai  
Food safety officer  
Ministry of Health  
Nairobi

Dr George Abong  
Senior Lecturer  
University of Nairobi  
Nairobi

Ms Maryann Kindiki  
Manager, National Codex Contact Point  
Kenya Bureau of Standards  
Nairobi

Ms Naomi Mariach  
Principal Standards Officer  
Kenya Bureau of Standards  
Nairobi

Mr Danset Moranga  
Senior Standards Officer  
KENYA BUREAU OF STANDARDS  
Nairobi

KUWAIT - KOWEÏT

Ms Maryam Al-Najjar  
Technical Nutritionist  
The Public Authority for Food and Nutrition

Eng Badria Al-Shammari  
Chemical Engineer  
The Public Authority for Food and Nutrition - Kuwait

Dr Jeehan Alestad  
First Secretary  
Permanent Representation of Kuwait to FAO & WFP

Eng Noor Sadeqi  
Chemical Engineer  
The Public Authority for Food and Nutrition

LAO PEOPLE’S DEMOCRATIC REPUBLIC - REPUBLIQUE DÉMOCRATIQUE POPULAIRE  
LAO – REPÚBLICA DEMOCRÁTICA POPULAR  
LAO

Mrs Viengxay Vansilalom  
Deputy Director General  
Ministry of Public Health  
Vientiane capital

LEBANON - LIBAN - LÍBANO

Ms Mariam Eid  
Head Agro-Industries Department  
Ministry of Agriculture

LITHUANIA - LITUANIE - LITUANIA

Mrs Jolanta Jasunskaite  
Adviser  
State Food and Veterinary Service  
Vilnius

MADAGASCAR

Mrs Lantomalala Raharinosy  
Point de contact national du Codex  
Ministère de l’industrialisation du commerce et de la consommation  
Antananarivo

MALAWI

Mr Demster Kumvenji  
Certification Officer  
Malawi Bureau of Standards  
Blantyre

MALAYSIA - MALAISIE - MALASIA

Ms Tosiah Abdullah  
Deputy Director  
Ministry of Health Malaysia  
Putrajaya

Ms Hanizah Abdol Karim  
Senior Auditor  
SIRIM QAS International SDN. BHD.  
Shah Alam

Dr Tariq Jaafar  
Veterinary Officer  
Dept. of Veterinary Services, Malaysia  
Putrajaya

Ms Faridah Malik Shari  
Deputy Director  
Ministry of Health Malaysia  
Wilayah Persekutuan Putrajaya

Ms Sakhiah Md Yusof  
Assistant Director  
Ministry of Health Malaysia  
Putrajaya

Dr Rohaizan Mohd Anuar  
Veterinary Officer  
Veterinary Public Health Division, Department of Veterinary Services  
Putrajaya

Ms Shazlina Mohd Zaini  
Principal Assistant Director  
Ministry of Health Malaysia  
Wilayah Persekutuan Putrajaya

Ms Rafeah Sibil  
Senior Principal Assistant Director  
Ministry of Health Malaysia  
Putrajaya
MAURITANIA - MAURITANIE
Dr Niang Amadou Mamadou
Directeur adjoint de l'ONISPA
ONISPA
Nouadhibou
Prof Sidi Mohamed Laghdaf
Directeur Général - Point focal du Codex Alimentarius, Mauritanie
Institut National pour la Recherche en Santé Publique (INRSP)
Nouakchott
Dr Bilal Mohamed Lemine
Conseiller directeur ONISPA
ONISPA
Nouadhibou

MAURITIUS - MAURICE - MAURICIO
Dr Shalini Neeliah
CCP
Ministry of Agro-Industry and FS

MEXICO - MEXIQUE - MÉXICO
Ms Penélope Elaine Sorchini Castro
Verificadora Dictaminadora Especializada
Comisión Federal para la Protección contra Riesgos Sanitarios COFEPRIS
Ms María Guadalupe Arizmendi Ramírez
Verificadora Dictaminadora Especializada
Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS
Ms Verónica Berrones Zapata
Directora Ejecutiva de Programas Especiales
Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS
Ms Mariana Jiménez Lucas
Verificadora Dictaminadora Especializada
Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS
Ms Esmeralda Paz Lemus
Gerente de Desarrollo de Proyectos
LEFIX y Asociados

MOROCCO - MAROC - MARRUECOS
Dr El Hariri Oleya
Veterinarian, Head of Fishery product service
National Food Safety Office
Rabat
Mr Abdelkrim Berrada
Head of division
Direction des Industries de la Pêche
Rabat
Dr Abdellah El Abbadi
Head of Control Service for Animal Products and By-Products and Animal Food
ONSSA
Rabat
Mr Mohamed El Amine El Amrani
Chef de la Division de la Législation et des Etudes Juridiques
Direction des Affaires Administratives et Juridiques
Rabat
Mrs Fedwa Hihi
Head of Service of Quality and Certification National Office of Fisheries, (Office National des Pêches)
Casablanca
Eng Khadija Kadiri
Chef du Service de la Normalisation et du Codex Alimentarius
Office National de la Sécurité Sanitaire des Produits Alimentaires
Rabat
Mr Najib Layachi
Conseiller
Fédération des Industries de la Conserves des Produits Agricoles du Maroc (FICOPAM)

NEPAL - NÉPAL
Mr Sanjay Bhandari
Senior Food Research Officer
Department of Food Technology and Quality Control, Ministry of Agriculture and Livestock Development
Kathmandu

NETHERLANDS - PAYS-BAS - PAÍSES BAJOS
Mrs Ana Viloria
Senior Policy Officer
Ministry of Health, Welfare and Sport
The Hague
NEW ZEALAND - NOUVELLE-ZÉLANDE –
NUEVA ZELANDIA
Ms Marion Castle
Manager
Ministry for Primary Industries
Wellington
Dr Roger Cook
Director
Ministry for Primary Industries
Wellington
Ms Lisa Ralph
Manager
Ministry for Primary Industries
Wellington

NIGERIA - NIGÉRIA
Mr Olugbemiga John Atanda
DD/NC Food Safety and Quality Programme
Federal Ministry of Health
Abuja
Mrs Miriam Datol
Assistant Director
National Agency for Food and Drug Administration and Control (NAFDAC)
Mrs Ovuakporoye Irivwegu
Scientific Officer
Federal Ministry of Science, Technology and Innovation
Abuja
Mrs Oluwatoyin Motunrayo Jegede
Chief Scientific Officer
Federal Ministry of Science, Technology and Innovation
Abuja
Ms Philomena Ngozi Nwobosi
Assistant Chief Scientific Officer
Federal Ministry of Health
Abuja
Prof Adewale Olusegun Obadina
Lecturing
Federal University of Agriculture, Abeokuta
Abeokuta
Dr Omolara Ibiwumi Okunlola
Director
Standards Organisation of Nigeria
Lagos
Ms Helen Ugwu
Assistant Chief Regulatory Officer
National Agency for Food and Drug Administration and Control (NAFDAC)

NORWAY - NORVÈGE - NORUEGA
Mrs Randi Edvardsen
Senior Adviser
Norwegian Food Safety Authority
Sandnes
Mrs Turid Michelle Berglund
Senior Adviser
Norwegian Food Safety Authority
Oslo
Mrs Åsne Sangolt
Senior Adviser
Norwegian Food Safety Authority
Bergen

PANAMA - PANAMÁ
Eng Joseph Gallardo
Ingeniero de Alimentos / Punto de Contacto Codex
Ministerio de Comercio e Industrias
Panamá
Eng Aracelis Arosemena De Vergara
Ingeniera Agrónoma / Inspección de Plantas
Ministerio de Salud
Panamá
Mrs Edilma López
Sub Directora Nacional de Protección al Consumidor
Autoridad de Protección al Consumidor y Defensa de la Competencia
Panamá
Eng Omaris Vergara
Directora de la Escuela de Ciencias y Tecnología de Alimentos
UP (Universidad de Panamá)
Panamá

PARAGUAY
Prof Elva Patricia Maldonado
Técnica
Instituto Nacional de Alimentación y Nutrición - INAN
Asunción
Mrs Estela Chamorro
Profesional de Alimentos
Instituto Nacional de Alimentación y Nutrición - INAN
Asunción
Mrs Librada Gamarra  
Técnica  
CEPALI  
Asunción  

Mrs María Inés Ibarra Colmán  
Punto de Contacto del Codex, Paraguay  
Instituto Nacional de Tecnología, Normalización y Metrología - INTN  
Asunción  

Mr Carlos Insfran  
Técnico  
UIP  
Asunción  

Mrs Marizela López Cattebeke  
Técnica  
Instituto Nacional de Alimentación y Nutrición  
Asunción  

Mr Víctor Silva  
Técnico  
CEPALI  
Asunción  

Mrs María Alejandra Zaracho  
Técnica  
Instituto Nacional de Tecnología, Normalización y Metrología - INTN  
Asunción  

PERU - PEROU - PERÚ  

Mrs Giovanna Galarza Silva  
Coordinadora Titular de la Comisión Técnica de Higiene de Alimentos  
MINISTERIO DE SALUD - DIGESA  
Lima  

Eng Romina Sofia Cerro Quintana  
Miembro de la Comisión Técnica de Higiene de Alimentos  
ALICORP SAA  
Lima  

Mrs Sonia Cordova Jara  
Coordinadora Alterna de la Comisión de Higiene de alimentos-Perú  
Digesa/Minsa  
Lima  

Eng Ernesto José Dávila Taboada  
Miembro de la Comisión técnica de Higiene de Alimentos  
ADEX (Asociación de exportadores)  
Lima  

Eng Ana Mercado Del Pino  
Miembro de la Comisión Técnica de Higiene de Alimentos  
Colegio de Ingenieros del Perú  
Lima  

Eng Hugo Valdez Osorio  
Miembro de la Comisión Técnica de Higiene de Alimentos  
Sierra y Selva Exportadora  
Lima  

PHILIPPINES - FILIPINAS  

Ms Kris Jenelyn De Las Peñas  
Chairperson, NCO Sub-Committee on Food Hygiene (NCO-SCFH)  
Food and Drug Administration-Department of Health  

Ms Cristina Almonte  
Member, NCO-SCFH  
Philippine Association of Food Technologists, Inc.  

Ms Riza Jane Banicod  
Member, NCO-SCFH  
National Fisheries Research and Development Institute-Department of Agriculture  

Ms Portia Crisostomo  
Member, NCO-SCFH  
Food Development Center-Department of Agriculture  

Eng Elizabeth De Leon-Lim  
Member, NCO-SCFH  
Philippine Chamber of Food Manufacturers, Inc.  

Ms Christian Grace Estimada  
Member, NCO-SCFH  
Food and Drug Administration-Department of Health  

Mr Niño Carlo Isnit  
Member, NCO-SCFH  
Bureau of Fisheries and Aquatic Resources-Department of Agriculture  

Mr Roeder Jon Jareño  
Member, NCO-SCFH  
Food and Drug Administration-Department of Health  

Mr Ariel Joshua Madrid  
Member, NCO-SCFH  
National Fisheries Research and Development Institute-Department of Agriculture  

Ms Minglanilla Mendoza  
Member, NCO-SCFH  
Philippine Association of Food Technologists, Inc.  

Ms Deserie Peralta  
Member, NCO-SCFH  
Philippine Chamber of Food Manufacturers, Inc.  

Dr Rona Regina Reyes  
Co-Chairperson, NCO-SCFH  
National Meat Inspection Service-Department of Agriculture  

Ms Karen Kristine Roscom  
Member, NCO-SCFH  
Bureau of Agriculture and Fisheries Standards-Department of Agriculture  

Mr Bryan Tanyag  
Member, NCO-SCFH  
National Fisheries Research and Development Institute-Department of Agriculture
Ms Gemie Rose Zabala  
Member, NCO-SCFH  
Food and Drug Administration-Department of Health

**POLAND - POLOGNE - POLONIA**

Ms Aneta Klusek  
Chief Specialist  
Ministry of Agriculture and Rural Development  
Warsaw

Ms Maja Czerwinska  
Chief Specialist  
General Veterinary Inspectorate  
Warsaw

**PORTUGAL**

Mrs Sara Godinho  
Senior Technician  
Directorate-General for Food and Veterinary (DGAV)  
Lisboa

Dr Francisco Santos  
Senior technician  
Directorate-General for Food and Veterinary (DGAV)  
Lisboa

**REPUBLIC OF KOREA - RÉPUBLIQUE DE COREE - REPÚBLICA DE COREA**

Ms Ho Jin An  
Deputy Director  
Animal and Plant Quarantine Agency (APQA)  
Animal Quarantine Division

Dr Won Young Choi  
Deputy Director  
Ministry of Food and Drug Safety

Ms Eunsong Cho  
SPS Researcher  
Ministry of Agriculture, Food and Rural Affairs  
Sejong

Ms Song-yi Choi  
Senior Researcher  
Rural Development Administration  
Wanju-gun

Dr Sang-do Ha  
Professor  
Chung-Ang University

Mr Minkwan Han  
Assistant Director  
Animal and Plant Quarantine Agency (APQA)  
Animal Quarantine Division

Ms Eun Jeong Heo  
Scientific Officer  
Food Safety Evaluation Department

Ms Sung-Youn Kim  
Agricultural Research Official  
NAQS/ Ministry of Agriculture  
Gimcheon-si

Ms Jooyeon Kim  
Researcher  
Ministry of Food and Drug Safety

Ms Jihye Yang  
SPS Researcher  
Ministry of Oceans and Fisheries

**ROMANIA - ROUMANIE - RUMANIA**

Mrs Denisa Cojocaru  
Counselor  
National Sanitary Veterinary and Food Safety Authority  
Bucharest

**RUSSIAN FEDERATION – FÉDÉRATION DE RUSSIE – FEDERACIÓN DE RUSIA**

Ms Natalia Efimochkina  
Leading Researcher  
Federal Research Centre of Nutrition, Biotechnology and Food Safety  
MOSCOW

Ms Anna Koroleva  
Consultant  
Federal Service for Surveillance on Consumer Rights Protection and Human Well-being

Mr Vyacheslav Smirnov  
Expert Chemist  
FBHI “Federal Center for Hygiene and Epidemiology”

Mr Dmitri Suvorov  
Junior Researcher  
FBSI “Federal Scientific Center for Medical and Preventive Health Risk Management Technologies”.

Mr Sergey Zclenkin  
Junior Researcher  
FBSI “Federal Scientific Center for Medical and Preventive Health Risk Management Technologies”.

**RWANDA**

Mr Justin Manzi Muhire  
Analyst  
Rwanda Food and Drugs Authority

Mrs Athanasie Mukeshiyaremye  
NSD Manager  
Rwanda Standards Board  
Kigali
Mr Jerome Ndahimana
Ag. Director of Food and Agriculture, Chemistry, Environment, Services Unit
Rwanda Standards Board

Mr Moses Ndayisenga
Operations Manager
MINIMEX Ltd

Ms Rosine Niyonshuti
Codex Contact Point
Rwanda Standards Board

SAUDI ARABIA - ARABIE SAUDITE – ARABIA SAUDITA

Ms Sarah Alfaifi
Risk Assessment Specialist I
Saudi Food and Drug Authority
Riyadh

Mr Abdullah Al Dakheelallah
Head of Microbial Risks
Saudi Food and Drug Authority
Riyadh

Mr Suliman Al Otabi
A Second Risk Assessment Specialist
Saudi Food and Drug Authority
Riyadh

Mr Mazen Al-Seghayer
Monitoring Expert
Saudi Food and Drug Authority
Riyadh

Mr Meshari Alshardan
Monitoring Expert
Saudi Food and Drug Authority
Riyadh

Mr Ali Duham
Head of Food Products Specifications Section
Saudi Food and Drug Authority
Riyadh

Ms Nada Saeed
Senior specifications and regulations Specialist |
Saudi Food and Drug Authority
Riyadh

SENÉGAL - SÉNÉGAL

Mr Moustapha Kane
Chef de Division
SERVICE NATIONAL DE L’HYGIENE
Dakar

Dr Raphael Coly
Expert SSA
Comité National Codex
Dakar

Dr Abdoulaye Diawara
Inspecteur Technique
Cabinet Ministère
Dakar

Mrs Ndeye Diop
Chef De Division
Association Sénégalaise De Normalisation
Dakar

Mrs Mame Diarra Faye Leye
Point De Contact National
Direction Générale de la Santé
Dakar

Dr Mamadou Ndiaye
Expert SSA
Comité National Codex
Dakar

Mrs Fatou Beye Sarre
Chef Section Microbiologie
Laboratoire National d’Analyses et de Contrôle
Dakar

Mrs Maimouna Sow
Chef de Division
Service National de l’Hygiène
Dakar

Mr Aïta Sylla
Agent
Centre Anti-Poison
Dakar

Dr Adama Abdoulaye Thiam
Directeur Adjoint
Sopasen
Dakar

Mr Abdallah Thiam
Agent
Direction Service Vétérinaire

SINGAPORE - SINGAPOUR - SINGAPUR

Ms Shirley Chua
Director
Singapore Food Agency

Dr Joanna Khoo
Director
Singapore Food Agency

Ms Yi Ling Tan
Senior Manager
Singapore Food Agency

Ms Jannie Wan
Deputy Director
Singapore Food Agency

Dr Yelin Wong
Acting Director
Singapore Food Agency

SLOVAKIA - SLOVAQUIE - ESLOVAQUIA

Ms Gabriela Virgalová
Senior Officer
State Veterinary and Food Administration of the Slovak Republic
Bratislava

SOUTH AFRICA - AFRIQUE DU SUD - SUDÁFRICA

Mrs Penny Campbell
Director: Food Control
Department of Health
Pretoria
Mr Deon Jacobs
Principal Inspector
National Regulator for Compulsory Specifications
Cape Town

Dr Kudakwashe Magwedere
State Veterinarian/Technical Specialist
Department of Agriculture, Land Reform and Rural Development
Pretoria

Mr Malose Daniel Matlala
Deputy Director: Food Control
Department of Health
Pretoria

SPAIN - ESPAGNE - ESPAÑA

Ms Paloma Sánchez Vázquez De Prada
Jefa del Área de Gestión de Riesgos Biológicos y Legislación Veterinaria
Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)-Ministerio de Consumo
Madrid

Ms Mónica María Alfaro Iznala
Técnica Superior
Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)-Ministerio de Consumo
Madrid

Ms Clara Castellano García
Técnica Superior
Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)-Ministerio de Consumo
Madrid

Ms María Cristina Ocerín Cañón
Jefa de Servicio
Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)-Ministerio de Consumo
Madrid

Ms Blanca Ortega Medina
Técnica Superior
Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)-Ministerio de Consumo
Madrid

Ms Ana Lorena Solar De Frutos
Jefa del Servicio
Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)-Ministerio de Consumo
Madrid

Ms Alicia Yagüe Martín
Jefa de Servicio
Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)-Ministerio de Consumo
Madrid

SRI LANKA

Dr Vithanage Thilak Sisira Kumara Siriwardana
Director, Environmental & Occupational Health and Food Safety
Ministry of Health
Colombo

Dr Madalagama Appuhamilage Roshan Priyantha
Veterinary Research Officer
Sri Lanka

Dr Sharmila Jayatilake
Senior Lecturer
Wayamba University of Sri Lanka
Wayamba

Mr Chathudina Janitha Liyanage
Senior Lecturer
Sabaragamuwa University of Sri Lanka
Belihuloya

Prof Eresha Mendis
Professor
University of Peradeniya, Sri Lanka
Peradeniya

Mrs Sujatha Pathirage
Consultant Microbiologist
Ministry of Health
Colombo

Mr Rasika Waduge
Deputy Director
Sri Lanka Standard Institution
Colombo

SUDAN - SOUDAN - SUDÁN

Mrs Amel Ahmed
Head inspection Unit
Sudanese Standard & Metrology Organization
Khartoum

Mrs Enas Elhussan
Head of Microbiology and contaminant Unit
Sudanese Standards and Metrology Organisation
Khartoum

Mrs Nahla Mohammed Abdullah
Quality control inspector
Ministry of Agriculture
Khartoum

SURINAME

Mrs Ratna Ramrattansing
Codex Focal Point
Ministry of Agriculture animal Husbandry and Fisheries

SWEDEN - SUÈDE - SUECIA

Dr Camilla Wallander
DVM, PhD, Head of Section
Government Offices of Sweden
Stockholm

Mrs Viveka Larsson
Principal Regulatory Officer, DVM
Swedish Food Agency
Uppsala
Ms Satu Salmela
Principal Regulatory Officer, DVM, M.Sc. PolSci
Swedish Food Agency
Uppsala

**SWITZERLAND - SUISSE - SUIZA**

Mr Mark Stauber
Head, Food Hygiene
Federal Food Safety and Veterinary Office FSVO
Bern

Mrs Awilo Ochieng Pernet
Former Chairperson, Codex Alimentarius Commission
International Affairs
Bern

**SYRIAN ARAB REPUBLIC – RÉPUBLIQUE ARABE SYRIENNE – REPÚBLICA ÁRABE SIRIA**

Dr Ayman Al-Mariri
Research Director of Microbiology and Immunology Division
Atomic Energy Commission
Damascus

Eng Maisaa Abo Alshamat
Head of Plants Standard Department
Syrian Arab Organization for Standardization and Metrology
Damascus

Prof Ahed Abo Younes
Professor in Damascus University Damascus University Damascus

Dr Balsam Jreikous
Quality Manager
Syndian Company
Latakia

**THAILAND - THAÏLANDE - TAILANDIA**

Mr Pisan Pongsapitch
Secretary General
Ministry of Agriculture and Cooperatives
Bangkok

Ms Pitchaporn Achawawongtip
Executive Director
Thai Food Processors' Association
Bangkok

Ms Chitrilada Booncharoen
Standards Officer
National Bureau of Agricultural Commodity and Food Standards (ACFS)
Bangkok

Ms Orasa Chongworagun
Food and Drug Technical Officer
Food and Drug Administration
Nonthaburi

Ms Jeerajit Dissana
Standards Officer
National Bureau of Agricultural Commodity and Food Standards
Bangkok

Ms Umaporn Kamolmattayakul
Representatives of the Federation of Thai Industries
The Federation of Thai Industries
Bangkok

Ms Kunnanut Klaharn
Veterinary Officer
Ministry of Agriculture and Cooperatives
Bangkok

Dr Pichet Koompa
Veterinarian, Senior Professional Level
Ministry of Agriculture and Cooperatives Pathumthani

Ms Virachnee Lohachoompol
Standards Officer
Ministry of Agriculture and Cooperatives
Bangkok

Ms Nattakarn Nammakuna
Standard Officer
National Bureau of Agricultural Commodity and Food Standards
Bangkok

Mrs Manusawee Onyaem
Standards Officer
National Bureau of Agricultural Commodity and Food Standards, ACFS

Ms Pommpanida Poochinda
Standards Officer
National Bureau of Agricultural Commodity and Food Standards, ACFS

Ms Tasrun Ratanathusnee
Scientist, Senior Professional Level
Ministry of Agriculture and Cooperatives
Bangkok

Dr Kingduean Somjit
Food Technologist, Senior Professional Level
Ministry of Agriculture and Cooperatives
Bangkok

Ms Maneeporn Sungkaram
Standards Officer
National Bureau of Agricultural Commodity and Food Standards; ACFS,

Mrs Jitpaga Yuktanun
Standards Officer
National Bureau of Agricultural Commodity and Food Standards, ACFS

**TRINIDAD AND TOBAGO - TRINITÉ-ET-TOBAGO - TRINIDAD Y TABAGO**

Mr Neil Rampersad
Chief Public Health Inspector
Ministry of Health
<table>
<thead>
<tr>
<th>Country</th>
<th>Representative</th>
</tr>
</thead>
</table>
| TURKEY - TURQUIE - TURQUIA      | Mr Gürkan Karaca  
Engineer  
Ministry of Agriculture and Forestry  
Ankara  
Mrs Hatice Aykir  
Engineer  
Ministry of Agriculture and Forestry  
Ankara  
Mr Eray Elçiım  
Food Engineer  
Ministry of Agriculture and Forestry  
Ankara |
| UGANDA - OUGANDA                | Mrs Irene Mwesigwa  
Principal Food Safety Officer  
National Drug Authority  
Kampala Uganda  
Ms Night Carolyne  
General Manager  
Kike Tropical Fruits LTD  
Kampala  
Mr Edward Kizza  
Standards Officer  
Uganda National Bureau of Standards  
Kampala Uganda  
Dr Moses Matovu  
Senior Research Officer  
National Agricultural Research Organization  
Kampala  
Ms Rehema Meeme  
Standards Officer  
Uganda National Bureau of Standards  
Kampala  
Mr Hakim Mufumbiro Baligeya  
Principal Standards Officer  
Uganda National Bureau of Standards  
Kampala  
Prof George Nasinyama  
Vice Chancellor  
UNICAF University  
Kampala  
Mr Johnson Ssubi  
Technical Executive Assistant  
Uganda National Bureau of Standards  
Kampala |
| UNITED ARAB EMIRATES – EMIRATS ARABES UNIS – EMIRATOS ARABES UNIDOS | Eng Muhammed Altaf  
Principle Food Inspection Specialist  
MOIAT |
| UNITED KINGDOM - ROYAUME-UNI – REINO UNIDO                     | Mr David Alexander  
Head of General Food Hygiene Policy  
Food Standards Agency  
London  
Mr Steve Weame  
Director of Global Affairs  
Food Standards Agency  
London  
Mr Ian Woods  
Senior Policy Advisor  
Food Standards Agency  
Cardiff |
| UNITED REPUBLIC OF TANZANIA – RÉPUBLIQUE-UNIE DE TANZANIE – REPÚBLICA UNIDA DE TANZANÍA | Dr Lilian Daniel  
Lecturer  
University of Dar Es Salaam  
Ms Lilian Gabriel Peter  
Senior Standards Officer  
Tanzania Bureau of Standards  
Dr Analice Kamala  
Researcher  
Tanzania Food and Nutrition Centre  
Mr Roman Mmanda  
Lecturer  
University of Dar Es Salaam  
Ms Stella Mrosso  
Senior Quality Assurance Officer  
Tanzania Bureau of Standards (TBS)  
Dar Es Salaam  
Ms Mary Ottaru  
Standards Officer  
Tanzania Bureau of Standards (TBS)  
Dar Es Salaam |
| UNITED STATES OF AMERICA – ÉTATS-UNIS D’AMÉRIQUE – ESTADOS UNIDOS DE AMÉRICA | Ms Jenny Scott  
Senior Advisor, Office of Food Safety  
U.S. Food and Drug Administration  
College Park, MD  
Dr Alexandra Calle  
Assistant Professor of Microbiology  
Texas Tech University  
Lubbock, TX  
Mr Chase Decoite  
Director, Animal Health & Food Safety Policy  
National Cattlemen's Beef Association  
Washington, DC  
Dr James Dickson  
Professor  
Iowa State University  
Ames, IA |
Dr Emily Griep  
VP, Regulatory Compliance & Global Food Safety Standards  
International Fresh Produce Association  
Washington, DC  

Dr Bala Kottapalli  
Director, Food Safety Science  
Walmart  
Omaha, NE  

Ms Mary Frances Lowe  
U.S. Manager for Codex Alimentarius  
U.S. Codex Office  
U.S. Department of Agriculture  
Washington, DC  

Dr William Shaw  
Director, Risk, Innovations, and Management Staff  
Food Safety and Inspection Service  
U.S. Department of Agriculture  
Washington, DC  

Dr Eric Stevens  
International Policy Analyst  
U.S. Food and Drug Administration  
College Park, MD  

Dr John Surak  
Principal  
John Surak and Associates  
Clemson, SC  

Dr Benjamin Warren  
Senior Science Advisor for Food Safety  
U.S. Food and Drug Administration  
College Park, MD  

Dr E. Noelia Williams  
Biologist  
U.S. Food and Drug Administration  
College Park, MD  

Mr Andrew Chi Yuen Yeung  
Consumer Safety Officer  
U.S. Food and Drug Administration  
College Park, MD  

URUGUAY  
Mrs Rossana Bruzzone  
Evaluadora  
Ministerio de Salud Pública  
Montevideo  

Dr Norman Bennett  
Gerente de Inocuidad  
Ministerio de Ganadería, Agricultura y Pesca  
Montevideo  

Dr Cecilia Dieste  
Asistente Técnica  
Ministerio de Ganadería, Agricultura y Pesca  
Montevideo  

Eng Nora Enrich  
Técnica  
Dirección General de la Granja  
Montevideo  

Mrs Inés Martínez  
Investigadora  
Latitud  
Montevideo  

Dr Diego Moreira  
Técnico  
Ministerio de Ganadería, Agricultura y Pesca  
Montevideo  

Eng Fabiana Osorio  
Técnica  
Ministerio de Ganadería Agricultura y Pesca  
Montevideo  

Eng Natalia Pastorino  
Técnica  
Intendencia de Montevideo  
Montevideo  

Dr María Andrea Pollak  
Técnica  
Ministerio de Ganadería, Agricultura y Pesca  
Montevideo  

Dr Sylvia Vázquez  
Técnica  
Intendencia Montevideo  
Montevideo
VENEZUELA (BOLIVARIAN REPUBLIC OF) - VENEZUELA (RÉPUBLIQUE BOLIVARIENNE DU) - VENEZUELA (REPÚBLICA BOLIVARIANA DE)

Mrs Roxana Abreu
Directora
SENCAMER
Caracas

Mrs Milady Barrios Farias
Coordinadora
SACS, Servicio Autónomo de Contraloría Sanitaria
Caracas

Mrs Marilyn Hernández
Jefa de División
Servicio Desconcentrado de Normalización, Calidad, Metrología y Reglamentos Técnicos (SENCAMER)
Caracas

Mrs Maybelyn Iglesias
Farmacéutica Jefa I
SACS, Servicio Autónomo de Contraloría Sanitaria
Caracas

Mrs Lysmar Sánchez
Directora
Servicio Desconcentrado de Normalización, Calidad, Metrología y Reglamentos Técnicos (SENCAMER)
Caracas

PALESTINE - PALESTINA

Mr Adib M. I. Alqaimari
Head
Palestine Standards Institution
OBSEVERS – OBSERVATEURS - OBSERVADORES
INTERNATIONAL GOVERNMENTAL ORGANIZATIONS –
ORGANISATIONS GOUVERNEMENTALES INTERNATIONALES –
ORGANIZACIONES GUBERNAMENTALES INTERNACIONALES

AFRICAN UNION (AU)
Mr John Oppong-Otoo
Food Safety Officer
AFRICAN UNION INTERAFRICAN BUREAU FOR
ANIMAL RESOURCES
Nairobi

INTER-AMERICAN INSTITUTE FOR
COOPERATION ON AGRICULTURE (IICA)
Mrs Alejandra Díaz
Especialista internacional en Sanidad Agropecuaria
e Inocuidad de Alimentos
Instituto Interamericano de Cooperación para la
Agricultura
Llorente, Tibás. San José

WORLD ORGANIZATION FOR ANIMAL HEALTH
(OIE)
Dr Lisa Harrynanan
Agricultural Health and Food Safety Specialist
Inter-American Institute for Cooperation on
Agriculture (IICA)
Couva

NON-GOVERNMENTAL ORGANIZATIONS –
ORGANISATIONS NON GOUVERNEMENTALES –
ORGANIZACIONES NO GUBERNAMENTALES

THE CONSUMER GOODS FORUM (CGF)
Ms Anne Gerardi
Senior Project Manager
The Consumer Goods Forum

Ms Marie-Claude Quentin
Senior Technical Manager
Consumer Goods Forum

Mrs Sandra Stanley
CGF GFSI CODEX Committee Chair
The Consumer Goods Forum

EUROPEAN FEDERATION OF ALLERGY AND
AIRWAYS DISEASES PATIENTS’
ASSOCIATIONS (EFA)
Mrs Marcia Podestà
Vice President
European Federation of Allergy and Airways
Diseases Patient's Associations
Brussels

Mrs Sabine Schnadt
Member of EFA delegation to CAC
European Federation of Allergy and Airways
Diseases Patients’ Associations - EFA
Brussels

FOOD INDUSTRY ASIA (FIA)
Mr Justin Ng
Regulatory Affairs
FIA

FOODDRINKEUROPE
Mr Luca Terzi
Manager
FoodDrinkEurope
Etterbeek

GLOBAL ALLIANCE FOR IMPROVED
NUTRITION (GAIN)
Ms Caroline Smith Dewaal
Senior Manager
GAIN
Silver Spring

GOOD FOOD INSTITUTE (GFI)
Ms Laura Braden
Lead Regulatory Counsel
The Good Food Institute

INTERNATIONAL CO-OPERATIVE ALLIANCE
(ICA)
Mr Kazuo Onitake
Senior Scientist, Department of Quality Assurance
International Co-operative Alliance
Tokyo
Mr Yuji Gejo
Officer
International Co-operative Alliance
Tokyo
INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATIONS (ICBA)
Ms Kimberly Turner
Manager, Food Safety
The Coca-Cola Company
Atlanta
Ms Elaine Berkovich
Manager, Food Regulations & Standards
The Coca-Cola Company
Ms Jacqueline Dillon
Senior Manager
PepsiCo
Chicago, IL
Dr Trevor Phister
Principal Scientist
PepsiCo
Leicester

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)
Dr Sanjay Gummalla
Senior Vice President, Scientific Affairs
American Frozen Food Institute
Ms Naz Ahmed
Coordinator, Regulatory & Technical Affairs
Consumer Brands Association
Mr Jonathan Clifford
Head of Regulatory Affairs, Food & Refreshment
Unilever Canada Inc.

INTERNATIONAL COMMISSION ON MICROBIOLOGICAL SPECIFICATIONS FOR FOODS (ICMSF)
Dr Leon Gorris
Secretary
International Commission on Microbiological Specifications of Foods (ICMSF)
Nijmegen
Dr Jeffrey Farber
Adjunct Professor
University of Guelph
Guelph

INTERNATIONAL DAIRY FEDERATION (IDF/FIL)
Ms Choreh Farrokh
Head of Food Safety Unit / Science & Technology
CNIEL
Paris
Mr Claus Heggum
Chief Consultant
Danish Agriculture and Food Council
Aarhus
Mr François Bourdichon
Principal Consultant
Food Safety, Microbiology and Hygiene
Paris
Mr Aurélie Dubois
Science and Standards Programme Manager
International Dairy Federation
Brussels

Mr Allen Sayler
Managing Director
Center for Food Safety and Regulatory Solutions
Woodbridge, Virginia

INTERNATIONAL FROZEN FOODS ASSOCIATION (IFFA)
Dr Donna Garren
Executive Vice President, Science and Policy
International Frozen Food Association
Arlington

INSTITUTE OF FOOD TECHNOLOGISTS (IFT)
Mr Bruce Ferree
Chief Food Scientist
Insight Food Safety
Sutter Creek
Dr Ruth Petran
Consultant
Ruth Petran Consulting, LLC
Eagan

INTERNATIONAL FRUIT AND VEGETABLE JUICE ASSOCIATION (IFU)
Mr John Collins
Executive Director
International Fruit and Vegetable Juice Association
Paris
Dr David Hammond
Chair Legislation Commission
International Fruit and Vegetable Juice Association (IFU)
Paris

INTERNATIONAL MEAT SECRETARIAT (IMS)
Ms Trachelle Carr
International Technical Services Specialist
International Meat Secretariat
Washington, DC

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)
Mr Paul Besseling
ISO/TC 34/SC 17 Expert
ISO
Bunnik
INTERNATIONAL UNION OF FOOD SCIENCE AND TECHNOLOGY (IUFoST)

Prof Samuel Godefroy
Chair, Codex Committee, IUFoST
International Union of Food Science and Technology (IUFoST)
Quebec City

SSAFE

Dr Himanshu Gupta
Vice President of SSAFE
SSAFE

Mr Daniel Hammer
Member of SSAFE
SSAFE

FAO

Ms Christine Kopko
ESF - Scientific Advice
Food and Agriculture Organization of the UN Roma

Mr Jeffrey Lejeune
Food Safety and Quality Officer
Food and Agriculture Organization of the UN Roma

Mr Kang Zhou
Food Safety and Quality Officer
Food and Agriculture Organization of the UN Roma

Ms Cornelia Boesch
Food Safety and Quality Officer
Food and Agriculture Organization of the UN Roma

WHO

Dr Moez Sanaa
Unit Head
World Health Organization (WHO) Geneva

Ms Haruka Igarashi
Technical Officer
World Health Organization (WHO) Geneva

CCFH SECRETARIAT

Ms Marie Maratos Bhat
International Issues Analyst
U.S. Codex Office
U.S. Department of Agriculture
Washington, DC

Mr Kenneth Lowery
Senior International Issues Analyst
U.S. Codex Office
U.S. Department of Agriculture
Washington, DC

CODEX SECRETARIAT

Mr Tom Heilandt
Codex Secretary
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO) Rome

Dr Sarah Cahill
Senior Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO) Rome

Ms Lingping Zhang
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO) Rome

Mr Goro Maruno
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO) Rome

Mr David Massey
Special Adviser - Codex
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO) Rome

Ms Ilaria Tarquinio
Programme Assistant
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO) Rome

Ms Elaine Raher
Office Assistant
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO) Rome

Ms Jocelyne Farruggia
Office Assistant
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO) Rome
APPENDIX II

GUIDELINES ON THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

(For adoption at Step 8)

INTRODUCTION

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

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

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

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

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

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

7. The principles for risk analysis including risk assessment, risk management and risk communication, as described in the Codex Working Principles for Risk Analysis for Food Safety for Application by Governments (CXG 62-2007) should form the framework/basis for the establishment of a system for preparedness and management of foodborne outbreaks. The risk management measures chosen will vary according to the situation and the regulatory framework of the competent authorities.

8. Within the available analytical methods, molecular methods often best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genetic methods (e.g. pulsed-field gel electrophoresis (PFGE), whole genome sequencing (WGS), multiple-locus variable number of tandem repeat analysis (MLVA) and multilocus sequence typing (MLST)) can result in improved detection of outbreaks, including detection of associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of these methods will likely lead to the detection of more clusters and the need for enhanced preparedness.

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

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

SCOPE

10. These guidelines provide guidance to competent authorities on the preparedness for and management of foodborne outbreaks, including the communication with international networks, such as the International Food Safety Authorities Network (INFOSAN) and notification to the World Health Organization (WHO) under the international health regulations (IHR) when it is necessary. The guidance addresses preparedness, detection and response with the intent of limiting the extent of such outbreaks. They include recommendations on the appropriate use of new analytical technologies, for example, genetic typing methods in outbreak investigation. The scope is limited to biological hazards, as they are the predominant cause of foodborne outbreaks.

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

USE

12. The following Codex Alimentarius documents\(^{15}\) are relevant for these guidelines:


• Principles and Guidelines for the Conduct of Microbiological Risk Management (CXG 63-2007).
• Principles and Guidelines for National Food Control Systems (CXG 82-2013).

13. A number of FAO/WHO documents describe in more detail some of the issues presented in these guidelines.

14. In foodborne outbreaks involving zoonotic agents, the World Organisation for Animal Health (OIE) standards for the prevention, detection and control of zoonotic agents at the primary production stages should also be considered.

DEFINITIONS

For the purpose of this document the following definitions apply:

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

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

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

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

19. Cohort study: An observational study in which the occurrence of illness among those who were exposed to a suspected risk factor is compared with the occurrence among those who were not. These studies are feasible for well-defined outbreaks in which all exposed and all non-exposed persons are generally identifiable.

20. Descriptive epidemiology: The aspect of epidemiology concerned with organizing and summarizing health-related data according to the occurrence of disease, in terms of both geographical comparisons and descriptions of temporal trends.

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

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”.

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

24. Monitoring: The performance of routine analysis aimed at detecting biological contamination of, for example, food from which prevalence data may be ascertained.

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

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

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

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

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

**FOODBORNE OUTBREAKS – PREPAREDNESS SYSTEM**

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

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

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

32. At the local level defined networks between contact points from the different relevant authorities/agencies covering the same geographical area should be formed, for example, local food control authority, local veterinary authorities, clinical microbiological laboratory, local departments of health/local health authorities, community council and food/veterinary laboratory. The contact points may be either persons or offices as long as they consist of personnel usually participating in the relevant tasks relating to the investigation of foodborne outbreaks at the local level.

33. The tasks of the network contact points are to ensure the exchange of information within the network and coordination of the work with the staff responsible for the various tasks involved in outbreak investigation and management. To ensure cooperation within the local network, one of the contact points should be designated as the local network contact point in charge of the network.

34. The local network contact points should also ensure the timely exchange of information with their respective counterparts in the national network and, if relevant, with the respective contact points in the other local networks. They should establish channels to engage stakeholders, including food business operators, where relevant, in order to exchange information to minimize adverse consequences.

35. At the national level a defined network should be established with personnel experienced in the management of foodborne outbreaks within the competence of their respective authorities/agencies. This national network should be recognized by each of the competent authorities involved, to ensure effective communication and exchange of information. The participants in the national network should be personnel from the authorities at the national level, equivalent to the same authorities/agencies that participate in the local networks. In addition, representatives from other relevant institutions, for example, universities or research institutes, may be included. The authority/agency with the legal responsibility to protect public health in a foodborne outbreak situation should be designated as lead contact point in charge of the national network. The role of the national network should include:

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

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

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

38. Templates and standard tools should be developed in advance and included in the standard procedures for the network participants to use. Some of them are listed below:
• template(s) for collecting, maintaining and reporting updated information describing the outbreak – descriptive epidemiology;
• standardized questionnaire(s) (including focused food consumption questionnaires) for hypothesis generation purposes;
• template(s) for cohort and case-control questionnaires. This would allow the networks to adapt them to the specific outbreak situation and to use the questionnaires without delay. Creation of standard questionnaires for this purpose may be performed electronically using one of the Internet-based free software solutions. Data can then be analysed electronically using a standard statistical software program;
• template(s) for reporting on the outbreak and the outcome of investigations; and
• template for requesting a rapid risk assessment addressed in Section E. and Annex II.

39. The national network may also be the forum where new tools and ways to handle outbreaks can be developed and then be made available to local networks.

40. Communication both within a network and between networks is crucial. Since network participants may have limitations on what information they may share with others in the network, these limitations should be identified and addressed in advance. Communication structures and practices should be included specifically in the documented description of the system and procedures for the network, to ensure that:
• all available information is compiled to complete as much as possible an overview of the situation and kept under review as new information becomes available;
• the appropriate information is distributed to and understood by all necessary and relevant parties in a timely manner;
• there is only one point of contact and a backup in each of the participating authorities/agencies and interested parties for receipt of official information;
• all parties use the established formal information channels, which are tested regularly to demonstrate that they are effective;
• there is a system in place to ensure communication channels remain open (e.g. in the event of infrastructure break down, staff absence); and
• there is a mechanism in place for the potential use of external experts to reach consensus on and verify the soundness of recommendations, especially for the national network.
B. INTERNATIONAL ALERT NETWORKS AND EXCHANGE OF INFORMATION WITH THEM

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

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

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

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

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

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

46. Data from these systems may also be used in conjunction with epidemiological data to inform and if necessary prioritize an investigation, for example, by checking if the strain found in a human outbreak has been found previously in certain reservoirs (e.g. a specific animal population, species, specific food category or environment).

47. For sharing of surveillance data, it is necessary that data collected are comparable among sectors and that confidentiality of personal information is maintained. Information exchange should occur both routinely and during foodborne outbreaks. There should be regular exchange of information among the human health sector, competent food authorities, and laboratories. It is recommended that the information exchange include where possible:
   - New signals (increasing trends or sudden elevated numbers of analytical findings/disease reports) from these sectors and follow-up on ongoing outbreaks.
   - The use of preferably harmonized and standardized laboratory methods to allow comparability and sharing of laboratory data among human health, food control and veterinary sectors.
   - Tools for sharing surveillance data and epidemiological information such as databases or data sharing sites.
   - Tools for comparing and presenting data, such as a phylogenetic tree (a branching diagram or "tree" showing the evolutionary relationships of the physical or genetic characteristics of the foodborne pathogen isolates at hand).
   - Epidemiological data to evaluate the relevance of the source and to conduct tracing back.
D. ANALYTICAL METHODS

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 a conclusion on a link between different human cases and between the human case and the suspected food source, but often it does not allow such a conclusion. When further characterization is needed for outbreak investigation purposes, molecular or genetic typing methods can be and are increasingly being used.

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

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

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

E. RAPID RISK ASSESSMENT – STRUCTURES FOR ASSESSING RISK

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

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

54. The rapid risk assessment is based on the data readily available at that time from the foodborne outbreak itself and, if possible, data from similar outbreaks. There might be no time for collecting additional evidence/data to fill in data gaps or to conduct larger literature studies. These types of assessments need to be updated regularly during the outbreak investigation as new information (e.g., surveillance data, analytical results, epidemiological information, information on consumption and distribution of suspected food items) becomes available.
55. An essential part of outbreak preparedness is to have a framework and structures in place to allow for a timely rapid risk assessment. They should include but are not limited to:

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

F. RISK COMMUNICATION SYSTEM/STRATEGY

56. Effective risk communication is essential to objectively inform on both the known data and uncertainties from an outbreak, to justify actions taken and convince affected parties of the necessity to take appropriate action when required.

57. Risk communication should include exchange of information with all stakeholders. Establishing communication links with food industry experts in advance of foodborne outbreaks is important in order to gather/provide information about food categories that may be linked to/potentially involved in an outbreak with respect to production, manufacturing/processing and/or distribution practices. Established relationships can enhance collaboration during the investigation.

58. In terms of risk communication, the preparedness should aim to:

- Establish a public communication strategy for the network members and, where appropriate, designate official spokespersons from the national network or the government, which includes the means of communication (websites, social media, etc.) that is appropriate to the size and nature of an outbreak. Where it is possible, the jurisdiction of each of the competent authorities should be accounted for when setting roles and responsibilities for each organization in the risk communication strategy.
- Consider a structure to allow for the communication to be handled locally, in case of small and localized outbreaks.
- Identify organizations that may be involved and make alliances and partnerships with them to ensure a coordinated message. This will minimize the risk for contradicting public statements to ensure the consumer can correctly identify the food item or cause of the outbreak.
- Draft initial messages for the different situations that could potentially arise while specific details can be filled in at the time an outbreak occurs. Consider that each population group may have its own characteristics that affect how they perceive risks (e.g. religious beliefs, traditions), so understanding the audience and testing messages to ensure they are culturally and demographically appropriate is important. Consideration should be given to measures that can help prevent misinformation and the spread of false information.
- Test established communication strategies on a regular basis to evaluate their efficiency.

FOODBORNE OUTBREAK – MANAGEMENT

59. When a foodborne outbreak occurs, the established networks and structures should be used to manage the situation with an integrated approach. Often management of foodborne outbreaks will be carried out under pressure with time and budgetary constraints. It is therefore important that each sector/participant carries out the tasks within its responsibilities according to the procedures decided upon in the networks. The following sections give information of the basic roles of the participants in the networks.

60. The investigation and control of biological foodborne outbreaks are multidisciplinary tasks requiring skills and collaboration in the areas of clinical medicine, epidemiology, laboratory analysis, food microbiology, and risk communication and management (including food safety and food control),
among others. The laboratory analyses may include the analysis of, for example, the implicated food or environmental samples from the primary production and processing environment of the implicated food. The management of a biological foodborne outbreak includes the establishment and confirmation, if possible, of the likely food source by epidemiological investigations of human cases (including interviews), of food data (data on traceability of implicated food) and laboratory analysis.

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

A. IDENTIFYING AND INVESTIGATING A FOODBORNE OUTBREAK — HUMAN HEALTH

62. A foodborne outbreak is typically identified by:

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

63. Careful description and characterization of the foodborne outbreak is an important first step in any epidemiological investigation. The initial descriptive epidemiological investigation provides an overview of the outbreak in terms of the three standard epidemiological parameters – time, place and person.

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

- On the food items consumed: detailed food history, the place (the commercial name of the establishment and the exact address) and date of purchase and the time of consumption, frequency of eating or amount of the suspected foods eaten, method of preparation, the source of the food or food product, brand name, lot/batch code. (Note that for some foodborne illnesses such as listeriosis, this information may not apply, since food causing the illness may not have been consumed recently).
- With regards to the affected person: personal details (to be treated with confidentiality), disease onset, symptoms, duration, hospitalisation, underlying health conditions, person-to-person contact, information on travel, animal and environmental exposures, etc.

65. The information should be obtained in a structured way using a standardized questionnaire for hypothesis generation purposes when available. Data collected can be analysed using a standard statistical software program. It may be necessary to use several iterative rounds of questionnaires with a number of cases, beginning with a more general questionnaire such as a national hypothesis generating questionnaire, progressing to a focused or supplemental questionnaire when one or several exposures appear noteworthy, to identify a potential source.

66. Other tools that can be used for hypothesis generation to determine the source of the outbreak in case of a foodborne outbreak include: review of surveillance data, or prior sample matches, source attribution studies, historical outbreak data and mathematical modelling. Population surveys of healthy adult food consumption habits can be used as a tool for rapid hypothesis generation to identify foods eaten by people in the outbreak more often than expected.

67. When a hypothesis is established, it may be appropriate, where possible, to perform analytical epidemiological investigations such as a retrospective cohort study or a case-control study. This could be the situation if the hypothesis is not very strong or if further evidence is needed to inform and back up control measures. These studies can help determine if an exposure is associated with a cluster of
human cases. These investigations should not delay other ongoing investigations but can help to give a direction to them.

B. **Substantiate Hypothesis and/or Handling of a Foodborne Outbreak — Food Safety (From Primary Production to Consumption)**

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

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

70. If the epidemiological investigations do not identify a source, the competent authority could use other information to inform their investigation of a potential cause of an outbreak. For example, historical outbreak data, prevalence of the hazard in food, information from the cases concerning food preferences, trade patterns, knowledge of production, distribution, and consumer preferences, may be helpful to narrow down the possible food sources or sites. Such information should however be used prudently, for example to target investigations and not for communications on the outbreak source without supporting evidence.

71. Tracing a food item both back and forward in the food chain is an essential tool in the investigation. Tracing enables the investigators to see the full distribution of the food item, for example, going back from the lot that caused illness to the place/source of initial contamination and identify from that source any other food products made with that food item or ingredient. The following information should be collected:

- Identification of the affected lot(s) for each food item suspected.
- Information to identify the root cause of the contamination (raw material status, processing steps that may influence the presence of the microbiological hazard identified including re-processing, records of process and product controls, identified risk factors for product contamination, samples analysed and results etc.).
- List of suppliers of product or raw materials.
- List of operators who received the affected lots of the food item and other distribution paths including to institutions and via Internet sales.

72. The data from tracing should be gathered in a standard way using templates and business names and product descriptions curated to ensure links are not lost due to abbreviation or spelling mistakes. The information gathered should be combined with the information from the epidemiological investigations of the outbreak to see if cases are consistent with product distribution. The tracing information, as well as the findings from the on-site investigation, can also be used to determine the extent of the problem.

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

74. The affected lot(s) should be separated from other lots by procedures that prevent cross-contamination.

75. 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 appropriate communication tools (e.g. social media, newspapers, etc.). Consideration should also be given to provide advice to consumers and/or businesses about appropriate handling of affected foods which should take into account any potentially associated public health risks.

C. COMBINING EPIDEMIOLOGICAL AND LABORATORY DATA

76. Management of outbreaks benefits from the food control and veterinary and agricultural sectors being able to share and combine relevant laboratory surveillance and monitoring data among themselves and with the public health sector in time, in order to identify a match between a clinical human isolate and an isolate from a food.

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

78. The decision of the degree of relation between strains should be made as part of the case definition. The level agreed upon may differ according to the typing method and the pathogen.

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

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

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

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

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

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

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

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

85. Rapid risk assessments can be carried out and updated at any time during the outbreak investigation. Constant communication should be ensured between the risk assessors and the risk managers (from both human health and food safety authorities) in order to:

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

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

- Historical information on the prevalence of the hazard in different foods, particularly if the source of the ongoing foodborne outbreak is not yet confirmed.
- Results from epidemiological and microbiological investigations of human outbreak cases, considering severity, possible mortality, spread of cases and affected subgroups (e.g. elderly).
- Laboratory results and results from the epidemiological and food (including tracing back) investigations.
- Hazard identification and characterization linked to the outbreak.
- Analyses of detected hot spots (geographical areas or events with more than usual occurrence within the outbreak), guiding further investigations.
- Consumer behaviour and adherence to intended use and preparation of foods, for example, use of frozen ready-to-cook vegetables and/or fruit, as a ready-to-eat product, not observing the food preparation instructions intended by the manufacturer to achieve food safety.
- Where appropriate, recommendations to the consumers and to competent authorities on how to manage the risk.
- If the potential food source has been traced to a specific food business, information on the overall condition of the facility, such as compliance history, inspection reports, complaint records and company test results.

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

E. RISK COMMUNICATION

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

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

89. Foodborne outbreaks may start in one country but can spread rapidly to other countries/regions and require rapid and clear response in terms of communication. INFOSAN or other similar networks can be used as a resource for risk communication messages in such instances to ensure factual information is being shared about an international foodborne outbreak.

F. DOCUMENTATION OF THE OUTBREAK AND LESSONS LEARNED

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

91. For the documentation to be of future use it should be kept in a structured way and accessible at all times for the personnel involved in the work. This could be in the form of a database or in a shared file system accessible only to the relevant personnel/competent authorities.

92. Information from the shared system should be reviewed regularly by the competent authorities. The information can be valuable for the food control authorities when targeting official control efforts.

93. 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.

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

G. POST-OUTBREAK SURVEILLANCE

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

MAINTENANCE OF THE NETWORKS

A. REVIEW OF EXISTING PREPAREDNESS

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

B. IMPLEMENTATION OF LESSONS LEARNED

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

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

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

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

100. The lessons learned should be included in the ongoing development of capacity and capabilities of the international, national, and local system.

C. JOINT TRAINING ON FOODBORNE OUTBREAK PREPAREDNESS AND MANAGEMENT

101. A key part of capability and capacity-building is the training of experts and professionals. The training should be extended across different competent authorities and key stakeholders. The purpose should be to develop a common understanding of the entire system for local, national, and international preparedness. As part of the capability and capacity, building joint simulation exercises should be put in place.

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

- Control/verification exercises are primarily aimed at testing the performance of the system in place and the participants' ability to carry out their responsibilities effectively, for example an expert or professional handling a particular type of method or a specific procedure. Participants should not be notified in advance of the exercise content. These exercises can vary in both complexity of organization, in number of participants and in length in time and size.
Learning/development exercises are more organized, with the focus on the participants being required to achieve new competences and capabilities. The exercises may involve roles and responsibilities or the development and testing of new procedural concepts and plans. Joint simulation exercises are a proven concept in this setting. Advance notice about learning/development exercises should be given to provide participants with the opportunity to prepare, which can optimize the overall outcome and learning experience.

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

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

*INFOSAN and international health regulations (IHR)
### Examples of requests for rapid risk assessments

**Rapid risk assessment – Examples of questions to be clarified/risk to be assessed**

The scope of a rapid risk assessment is to answer a specific question or assess a specific risk in relation to an outbreak, for which additional information is required for decision-making.

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

<table>
<thead>
<tr>
<th>Possible question(s) related to the suspected food item, a production process etc.</th>
<th>1. Is it possible that the “food item X” produced under the “specific circumstances described” could have caused the outbreak?</th>
<th>2. The outbreak agent has been detected in an unopened sample of the “food item X” acquired in a private household. Is it likely that other items of the same food may carry the same risk? (In other words, are the production and storage requirements of this food item described sufficiently to eliminate the specific risk?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible question(s) related to the agent causing the outbreak</td>
<td>3. A certain strain of “bacterium Y” is causing an outbreak that is suspected of being foodborne. The strain has not been previously seen in food items, but a closely related strain has been detected in a feed sample. An assessment of the strain relatedness and stability in the environment could be requested to determine if there could be a reservoir in the husbandry sector using the feed in question.</td>
<td>4. A certain strain of “bacterium Y” is causing an outbreak that is suspected of being foodborne. The strain has not been previously seen in food items. What is the most likely reservoir for these bacteria Y? What may be the most likely production(s) that these bacteria may be found in?</td>
</tr>
<tr>
<td></td>
<td>5. “Bacterium Y” is causing an outbreak that is suspected to be caused by products from one or more specific production facilities. However, samples from the facilities turned out to be negative with standard testing methods. What would be the optimal testing method and number of samples required to be able to determine whether the facilities are the source of the outbreak?</td>
<td>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 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?</td>
</tr>
<tr>
<td>Possible question(s) related to the use of certain food items and consumer eating habits</td>
<td>7. An outbreak caused by <em>Listeria monocytogenes</em> 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 prevent illness from <em>Listeria monocytogenes</em>?</td>
<td></td>
</tr>
</tbody>
</table>
### Template for an outbreak analysis

**Outbreak information**

<table>
<thead>
<tr>
<th>Case definition</th>
<th>Number of confirmed cases</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of probable cases not yet verified as part of the outbreak</td>
</tr>
<tr>
<td>Geographical location (cases per area/jurisdiction)</td>
<td>Place of suspected or confirmed exposure</td>
</tr>
<tr>
<td>Age and gender distribution</td>
<td>Affected vulnerable subgroups (e.g. elderly, children)</td>
</tr>
<tr>
<td>Epi-curve (number of cases per day/week or month)</td>
<td>Other descriptive information available of the outbreak size and distribution area.</td>
</tr>
</tbody>
</table>

**Analytical information**

<table>
<thead>
<tr>
<th>Human cases</th>
<th>Agent involved – characteristics of the agent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overview of human cases reported including severity of illness (e.g. hospitalisations, disability, foetal loss and deaths).</td>
</tr>
</tbody>
</table>

**Outbreak background information**

| Questions such as the following should be answered | How was the outbreak initially detected? Are there any common foods (or ingredients) identified as being consumed by the human cases? Is there any correlation between the distribution of the cases and the distribution of the potentially implicated food? How have the human cases initially been linked to a certain food source? Has outbreak information been reported to the public and how? |

**Illness background information**

| Historical data from previous monitoring and isolations in food might help target investigations towards the source if not known yet. Historical data, not related to the ongoing outbreak, on the hazard, for example: occurrence in humans, outbreaks in the past at local, national, regional or international level, occurrence in different types of food | The purpose is to indicate if human cases/outbreaks with the involved pathogens are rare or occurring from time to time. Historical data from previous monitoring and isolations in food might target investigations towards the source when not yet known. When possible, these data should be targeted to the pathogen with the same virulence factors/serotypes as the one in the ongoing outbreak. Historical data may also be valuable when determining if/how the agent involved behaves differently than previously seen. |

**Investigation of human cases**

| This may include, but not be limited to results of the investigations performed: hypotheses generating interviews, food exposures that appear higher than expected based on available surveys of food consumption habits, subclusters where two or more cases not part of the same family ate at the same event, restaurant, etc. case-control or cohort investigation | |

**Investigations in food**

| Information on samples taken – items, places of sampling, open or closed sample, lot code, any storage or cooking instructions provided on package, etc. Analytical methods used Outcome of the laboratory analyses Information on tracing of the affected food/food ingredients, for example, starting from the food/establishment initially linked to the human cases: tracing back the food/ingredients to the source, tracing forward the distribution, to be repeated for each affected establishment along the food chain, data gaps should be identified (e.g. establishments to which the affected food was sent, but where there is no information on investigations carried out in that establishment), are there any identified common suppliers of the affected food product? | |
- Assessing if the distribution of the suspected food item can explain the outbreak (distribution area, amount of the food on the market in relation to the distribution and number of cases in the outbreak)
- Description of production conditions in affected establishments (e.g. hygiene conditions), applicable steps influencing the presence of the hazards (e.g. heat treatments or possibilities for cross-contamination)
- Information on consumer behaviour and eating habits, for example, not following the manufacturer’s instructions for storage (e.g. refrigerate, use-by date) or for the cooking intended by the manufacturer to achieve food safety. How much time elapsed between preparation and consumption?

<table>
<thead>
<tr>
<th>Background information concerning the strain in food, feed, animal or environment samples</th>
<th>Has the strain been seen previously? If yes, please describe further the time, place etc. If isolates are available for comparison, sample identification should be provided. If a specific production or process is suspected to be the source of the outbreak, a detailed description of the ingredients, their treatment, production processes etc. needs to be developed/document to assess whether deviations in the production may be implicated. Possible significant family or community event that may have been an opportunity for outbreaks to occur (e.g. family events, birthday parties, fiestas, festivals, holiday celebrations, etc.).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linking epidemiological food trace back and laboratory data in humans and food</td>
<td>An attempt should be made to graphically present and link the data from human cases, retailers, distributors, processors back to suppliers of raw materials, indicating the link between them when existing and the results of laboratory testing if carried out and available. When available, results from whole genome sequencing can be added, and a single-linkage tree including all human and non-human isolates should be made, illustrating the core gene allelic differences.</td>
</tr>
<tr>
<td>Data not available / not yet available</td>
<td>Any uncertainties on the existing data and data gaps should be indicated. If any data/information is necessary for the assessors but not yet available, it should be indicated when the data will be available. If any data is 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.</td>
</tr>
<tr>
<td>Communication</td>
<td>Clear information on the communication strategy targeted towards consumers, affected operators and other stakeholders should be given. It is also a good idea to agree upon a strategy for communication in case the assessors are approached by the press or public – agree on what can be said, by whom and when.</td>
</tr>
</tbody>
</table>

**Annexes**

**References**

**Prognosis/Summary**

**Summary**

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

PROPOSED REVISION TO THE GENERAL PRINCIPLES OF FOOD HYGIENE (CXC1-1969)

Part A: Tools to determine the critical control points (CCPs)

(For adoption at Step 5/8)

The following are examples of a decision tree and CCP worksheet tools that can be used in the determination of a CCP. Such examples are not unique and other tools can be used as long as the general requirements as elaborated in CXC 1-1969 (i.e., Step 7 - Principle 2 - Determine the critical control points (CCPs)) have been met.

A.1. Example of a CCP decision tree - Apply to each step where a specified significant hazard is identified

Q1. Can the significant hazard be controlled to an acceptable level at this step by prerequisite programs (e.g. GHPs)?

Yes → This step is not a CCP

No → Q2. Do specific control measures for the identified significant hazard exist at this step?

No → This step is not a CCP. Subsequent steps should be evaluated for a CCP

Yes → Q3. Will a subsequent step prevent or eliminate the identified significant hazard or reduce it to an acceptable level?

No → Q4. Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?

No → Modify the step, process or product to implement a control measure

Yes → This step is a CCP

Yes → That subsequent step should be a CCP

* Consider the significance of the hazard (i.e., the likelihood of occurrence in the absence of control and the severity of impact of the hazard) and whether it could be sufficiently controlled by prerequisite programs such as GHPs. GHPs could be routine GHPs or GHPs that require greater attention to control the hazard (e.g. monitoring and recording).

** If a CCP is not identified at questions 2-4, the process or product should be modified to implement a control measure and a new hazard analysis should be conducted.

***Consider whether the control measure at this step works in combination with a control measure at another step to control the same hazard, in which case both steps should be considered as CCPs.

****Return to the beginning of the decision tree after a new hazard analysis.
**A.2. Example of a CCP determination worksheet (Apply to each step where a specified significant hazard is identified)**

<table>
<thead>
<tr>
<th>Process step</th>
<th>Significant hazards</th>
<th>Q1. Can the significant hazard be controlled to an acceptable level at this step by prerequisite programs (e.g. GHPs)*?</th>
<th>Q2. Do specific control measures for the identified significant hazard exist at this step?</th>
<th>Q3. Will a subsequent step prevent or eliminate the identified significant hazard or reduce it to an acceptable level?</th>
<th>Q4. Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level? ***</th>
<th>CCP number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify process step</td>
<td>Describe hazard and cause</td>
<td>If yes, this step is not a CCP. If no, proceed to Q2.</td>
<td>If yes, proceed to Q3. If no, this step is not a CCP. Subsequent steps should be evaluated for a CCP**.</td>
<td>If yes, that subsequent step should be a CCP. If no, proceed to Q4.</td>
<td>If yes, this step is a CCP. If no, modify the step, process or product to implement a control measure ****</td>
<td>Number the CCP and include in HACCP worksheet</td>
</tr>
</tbody>
</table>

* Consider the significance of the hazard (i.e., the likelihood of occurrence in the absence of control and the severity of impact of the hazard) and whether it could be sufficiently controlled by prerequisite programs such as GHPs. GHPs could be routine GHPs or GHPs that require greater attention to control the hazard (e.g. monitoring and recording).

** If a CCP is not identified at questions 2-4, the process or product should be modified to implement a control measure and a new hazard analysis should be conducted.

***Consider whether the control measure at this step works in combination with a control measure at another step to control the same hazard, in which case both steps should be considered as CCPs.

****Return to the beginning of the decision tree after a new hazard analysis.
Part B: Consequential amendment to Section 3.7 of Chapter two of CXC 1-1969

(For adoption)

The proposed changes are shown in **bold/underlined** font.

3.7  **Determine the critical control points (Step 7/Principle 2)**

The FBO should consider which among the available control measures listed during Step 6, Principle 1 should be applied at a CCP. Critical control points are to be determined only for hazards identified as significant as of the result of a hazard analysis. CCPs are established at steps where control is essential and where a deviation could result in the production of a potentially unsafe food. The control measures at CCPs should result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens). Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be helped by using a decision tree or a CCP determination worksheet (see Annex 2). A decision tree should be flexible, given whether it is for use in production, slaughter, processing, storage, distribution or other processes. Other approaches such as expert consultation may be used.

To identify a CCP, whether using a decision tree or other approach, the following should be considered:

- Assess whether the control measure can be used at the process step being analysed:
  - If the control measure cannot be used at this step, then this step should not be considered as a CCP for the significant hazard.
  - If the control measure can be used at the step being analysed, but can also be used later in the process, or there is another control measure for the hazard at another step, the step being analysed should not be considered as a CCP.

- Determine whether a control measure at a step is used in combination with a control measure at another step to control the same hazard; if so, both steps should be considered as CCPs.

The CCPs identified could be summarized in tabular format e.g. the HACCP worksheet presented in Diagram 3, as well as highlighted at the appropriate step on the flow diagram.

If no control measures exist at any step for an identified significant hazard, then the product or process should be modified.