

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP22/FH

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

45th Session

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

Virtual

28 February – 4 March and 9 March 2022

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SUMMARY AND STATUS OF WORK

Responsible party	Purpose	Text/Topic	Code	Step	Para.
Members, CCEXEC82 and CAC45	Adoption	Draft Guidelines for the Management of Biological Foodborne Outbreaks	-	8	31, App. II
		Proposed draft revision to the <i>General Principles of Food Hygiene</i>	CXC 1-1969	5/8	52, App. III
EWG (Chile, France, New Zealand, the United States of America) CCFH53	Redrafting	Proposed Draft Guidelines for the Control of Shiga Toxin-Producing <i>Escherichia coli</i> (STEC) in Raw Beef, Raw Milk and Raw Milk Cheeses, Fresh Leafy Vegetables, and Sprouts		2/3	69
PWG (Chile, France, New Zealand, the United States of America) CCFH53	Revising			4	70
EWG (Honduras, Chile, and the European Union) CCFH53	Redrafting	Proposed Draft Guidelines for the Safe Use and Reuse of Water in Food Production		2/3	93
PWG (Honduras, Chile, and the European Union) CCFH53	Revising			4	95
Members WG (the United States of America) CCFH53	Comments/ Discussion	New work proposals/Forward workplan			105v
Japan and New Zealand CCFH53	Review/Drafting	Discussion paper on revision of the <i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood</i> (CXG 73-2010)			105i
Canada and the Netherlands CCFH53	Review/Drafting	Discussion paper on revision of the <i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food</i> (CXG 79-2012)			105i
FAO/WHO (JEMRA) CCFH53	Request	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 <i>Salmonella</i> and <i>Campylobacter</i> in chicken meat A full farm to table risk assessment for <i>Listeria monocytogenes</i> in foods			93, 105ii

LIST OF ACRONYMS

AFoSaN	African Food Safety Network
a_w	Water activity
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CCP	Critical Control Point
CL	Circular Letter
CRD	Conference Room Document
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FBOs	Food Business Operators
FERG	Foodborne Disease Burden Epidemiology Reference Group
GAIN	Global Alliance for Improved Nutrition
GHP	Good Hygienic Practice
HACCP	Hazard Analysis and Critical Control Point
IDF	International Dairy Federation
INFOSAN	International Food Safety Authorities Network
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
OIE	World Organization for Animal Health
OCS	Online Commenting System
PWG	Physical Working Group
RTE	Ready-to-eat
STEC	Shiga toxin-producing <i>Escherichia coli</i>
USDA	United States Department of Agriculture
WHO	World Health Organization

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.

OPENING¹

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 Moshia, Tanzania, former chairperson of the CAC and Mr Otto Maldonado, Codex Contact Point Guatemala and former delegate to CCFH.

Division of competence²

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)³

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)⁴

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)⁵

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

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)⁶

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)⁷

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

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)⁸ as more appropriate.

Risk communication

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.

Other matters

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.

⁸ 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-

⁹ CX/FH 22/52/6; CX/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); CRD03 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)¹⁰

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

¹⁰ 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)

in CRD4.

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 effect¹¹.

Other definitions

63. The definitions for raw milk cheeses and Shiga toxin-producing *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 *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.

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.

Report of the Working Group on the 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 (CRD5)

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 *Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat* (CXG 87-2016).

Conclusion

69. CCFH52 agreed to:
- i. return the proposed draft document to Step 2/3 for redrafting and circulation for comments;
 - ii. establish an EWG, chaired by Chile and co-chaired by France, New Zealand and the United States of America, and working in English, to:

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. *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, ICBA, 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)¹³

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 new work 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

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,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.

¹⁴ *Regional Guidelines for the Design of Control Measures for Street-Vended Foods (Africa)* (CXG 22R-1997); *Regional Code of Hygienic Practice for the Preparation and Sale of Street Foods (Latin America and the Caribbean)* (CXC 43R-1995); *Regional Code of Practice for Street-vended Foods (Near East)* (CXC 71R-2013); *Regional Code of Hygienic Practice for Street-Vended Foods in Asia* (CXC 76R-2017)

APPENDIX I

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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 documents¹⁵ are relevant for these guidelines:

- *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995).
- *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CXG 62-2007).
- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG-30-1999).

¹⁵ <http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/>

- *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.

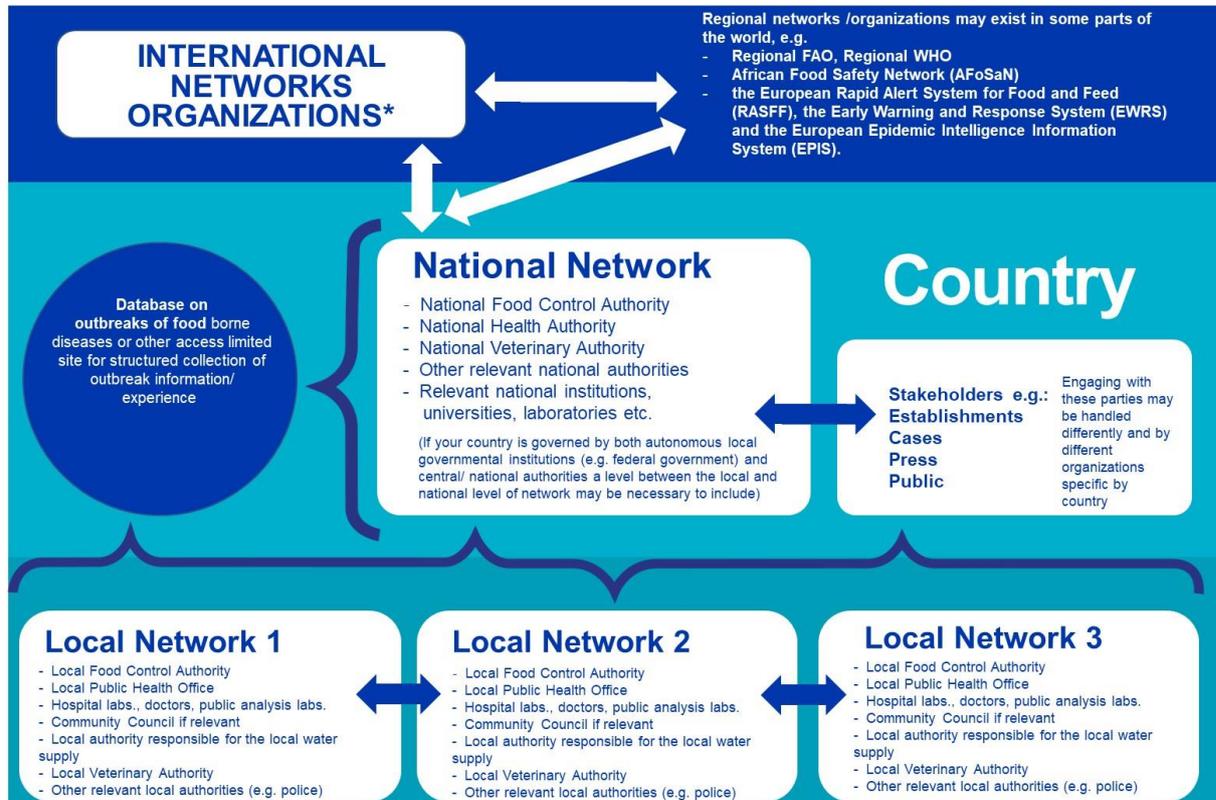
- Control/verification exercises are primarily aimed at testing the performance of the system in place and the participants' ability to carry out their responsibilities effectively, for example an expert or professional handling a particular type of method or a specific procedure. Participants should 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)

Annex II

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.

Possible question(s) related to the suspected food item, a production process etc.	<ol style="list-style-type: none"> 1. Is it possible that the “food item X” produced under the “specific circumstances described” could have caused the outbreak? 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?)
Possible question(s) related to the agent causing the outbreak	<ol style="list-style-type: none"> 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. 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? 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? 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?
Possible question(s) related to the use of certain food items and consumer eating habits	<ol style="list-style-type: none"> 7. An outbreak caused by <i>Listeria monocytogenes</i> seems to be caused by frozen small meatballs for soup. The meatballs are cooked prior to freezing. Normally they are heat treated when preparing the soup prior to eating. A kitchen added the frozen meatballs to the hot soup prior to chilling and storage. The soup portions are distributed as a chilled product ready to heat and serve. Is this process adequate to prevent illness from <i>Listeria monocytogenes</i>?

Annex III

Template for an outbreak analysis

Template for an outbreak analysis – fill in as much information as is available.

Outbreak information/ Descriptive epidemiology	<p>Case definition</p> <p>Number of confirmed cases</p> <p>Number of probable cases not yet verified as part of the outbreak</p> <p>Geographical location (cases per area/jurisdiction)/Place of suspected or confirmed exposure</p> <p>Age and gender distribution</p> <p>Affected vulnerable subgroups (e.g. elderly, children)</p> <p>Epi-curve (number of cases per day/week or month)</p> <p>Other descriptive information available of the outbreak size and distribution area.</p>
Analytical information Human cases	<p>Agent involved – characteristics of the agent</p> <p>Overview of human cases reported including severity of illness (e.g. hospitalisations, disability, foetal loss and deaths).</p>
Outbreak background information	<p>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?</p>
Illness background information	<p>Historical data from previous monitoring and isolations in food might help target investigations towards the source if not known yet.</p> <p>Historical data, not related to the ongoing outbreak, on the hazard, for example:</p> <ul style="list-style-type: none"> • occurrence in humans • outbreaks in the past at local, national, regional or international level • occurrence in different types of food <p>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.</p> <p>Historical data may also be valuable when determining if/how the agent involved behaves differently than previously seen.</p>
Investigation of human cases	<p>This may include, but not be limited to results of the investigations performed:</p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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?

	<ul style="list-style-type: none"> 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?
Background information concerning the strain in food, feed, animal or environment samples	<p>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.</p> <p>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/documentated to assess whether deviations in the production may be implicated.</p> <p>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.).</p>
Linking epidemiological food trace back and laboratory data in humans and food	<p>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.</p> <p>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.</p>
Data not available / not yet available	<p>Any uncertainties on the existing data and data gaps should be indicated.</p> <p>If any data/information is necessary for the assessors but not yet available, it should be indicated when the data will be available.</p> <p>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.</p>
Communication	<p>Clear information on the communication strategy targeted towards consumers, affected operators and other stakeholders should be given.</p> <p>It is also a good idea to agree upon a strategy for communication in case the assessors are approached by the press or public – agree on what can be said, by whom and when.</p>
Annexes	References

Prognosis/Summary

Summary	<p>Overview of involved geographical areas/jurisdictions at local, national or international level.</p> <p>Overview of human cases reported, including hospitalisations and deaths.</p> <p>Summary of investigations on food sources and actions taken (e.g. recall, withdrawal) and actions planned.</p> <p>Short and clear communication message to consumers (recommendations on buying and preparing food), affected operators, other stakeholders and trade partners, including possible uncertainties where applicable.</p> <p>Summary of considerations that resulted in the conclusions including any data gaps.</p> <p>Could more cases be expected in near future or can it be assumed/stated that the outbreak is over?</p>
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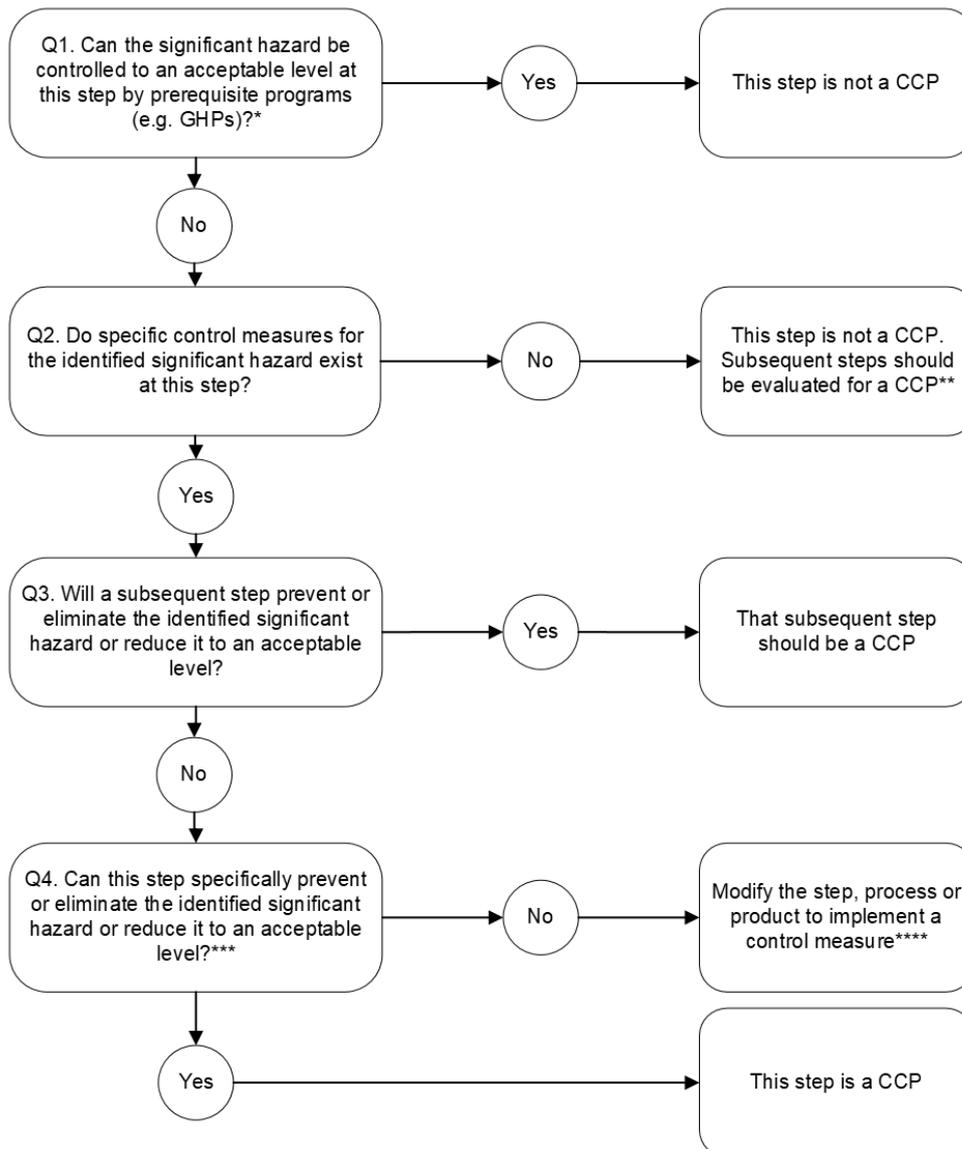
PROPOSED REVISION TO THE GENERAL PRINCIPLES OF FOOD HYGIENE (CXC1- 1969)

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



* 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)

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

* 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.