

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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REP24/FH

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

*Forty-seventh Session*

*25 – 30 November 2024*

## REPORT OF THE FIFTY-FOURTH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

Nairobi, Kenya

11 – 15 March 2024

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## SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
Members, CCEXEC86 and CAC47	Adoption	Annex II on Fresh Leafy Vegetables of the <i>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</i>	CXG 99-2023	5/8	Para 52, App.II
		Annex IV on Sprouts of the <i>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</i>	CXG 99-2023	5/8	Para 52, App.III
		Annex III on Milk and Milk Products of the <i>Guidelines for the Safe Use and Reuse of Water in Food Production and Processing</i>	CXG 100-2023-	5/8	89 i., App. IV
		Proposed Draft Guidelines for Food Hygiene Control Measures in Traditional Markets for Food	-	5/8	169 App. VI
		Proposed Draft Revision of the <i>Guidelines on the Application of the General Principles of Food Hygiene to the control of Pathogenic Vibrio Species in Seafood</i>	CXG 73-2010	5	131 App. V
Members, CCEXEC86 and CAC47	Approval	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)			185 i, App. VIII
		Revision of <i>Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat</i> (CXG 78-2011)			188 i, App. IX
		Revision of <i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods</i> (CXG 61-2007)			192 i, App. X
CCEXEC86 and CAC47	Approval	Extension of timeline to complete Annex II and develop a new Annex IV to the <i>Guidelines for the Safe Use and Reuse of Water in Food Production and Processing</i> (CXG 100-2023)			91
FAO/WHO Coordinating Committees	Action	Review respective texts on street vented foods to ensure consistency with CXC 1-1969 and the <i>Guidelines for Food Hygiene Control Measures in Traditional Markets for Food</i> , once adopted and consider necessary follow-up actions e.g. revision			170, App. VI
EWG (EU, Morocco, Honduras, Mauritania, India and IDF) Members and Observers, CCFH55	Redrafting	Annex II and Annex IV of the <i>Guidelines for the Safe Use and Reuse of Water in Food Production and Processing</i>	CXG 100-2023	2/3	89 iii

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
PWG (EU, Morocco, Honduras, Mauritania, India and IDF)) Members and Observers CCFH54	Discussion	The report of the EWG on development of Annex II and Annex IV of the Guidelines for the Safe Use and Reuse of Water in Food Production and Processing	CXG 100-2023	4	90
CCFH55	Revising	CCFH should consider finalisation of or develop a plan for the completion of the work on the Draft Revision <i>Guidelines on the Application of the General Principles of Food Hygiene to the control of Pathogenic Vibrio Species in Seafood</i> upon completion of the work on Annex II of CXG 100-2023	CXG 73-2010	6/7	132
EWG (China, United Kingdom, EU) Members and Observers CCFH55	Alignment	To initiate work on the alignment of Codex texts listed in Appendix VII with the revised <i>General Principles of Food Hygiene</i> (CXC 1-1969) and liaise with the WG on the forward workplan.			177 iii
EWG (Canada and the Netherlands) CCFH55	Review / Drafting (subject to approval by CAC47)	Revision of <i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food</i> (CXG 79-2012)			185 ii, 186
EWG (USA, Australia, Brazil, Denmark, and India) CCFH55	Review / Drafting (subject to approval by CAC47)	Revision of <i>Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat</i> (CXG 78-2011)			188 ii, 189
EWG (USA, Canada, Chian and France) CCFH55	Review / Drafting (subject to approval by CAC47)	Revision of <i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods</i> (CXG 61-2007)			192 ii, 193
Members, Observers PWG (the United States of America) CCFH55	Comments/ Discussion	New work proposals / Forward workplan			196 ii
Codex Secretariat	Action	Alignment of cross-referencing to the WOAH Terrestrial Animal Health Code in the <i>Guidelines for the control of Trichinella spp. in meat of Suidae</i> (CXG 86-2015)			25
		Issue a Circular Letter requesting proposals for new work			196 iii

<b>Responsible Party</b>	<b>Purpose</b>	<b>Text/Topic</b>	<b>Code</b>	<b>Step</b>	<b>Para.</b>
Members and Observers	Action	Contribute to the discussions in CCEXEC and CAC (e.g. Sharing experience on use of SoP guidance, providing inputs to the development of the Codex Strategic Plan 2026-2031 and submit discussion papers/project documents on new work proposals on NFPS using existing mechanisms and submit any new discussion papers /new work proposals (e.g. on food allergens) in response to the relevant to Circular Letter			15 i, 196 iv

### LIST OF ACRONYMS

CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CCFL	Codex Committee on Food Labelling
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCP	Critical Control Point
CL	Circular Letter
CRD	Conference Room Document
CXC	Codex Code of Practice
CXG	Codex Guideline
CXS	Codex Standard
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FBOs	Food Business Operators
GHP	Good Hygienic Practice
HACCP	Hazard Analysis and Critical Control Point
HAV	Hepatitis A virus
IDF	International Dairy Federation
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
NFPS	New food sources and production systems
NoV	Norovirus
OCS	Online Commenting System
PWG	Physical Working Group
RTE	Ready-to-eat
SDG	Sustainable Development Goals
STEC	Shiga toxin-producing <i>Escherichia coli</i>
USA	United States of America
USDA	United States Department of Agriculture
VWG	Virtual Working Group
WHO	World Health Organization
WOAH	World Organization for Animal Health

## INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its 54th session in Nairobi, Kenya, from 11 to 15 March 2024, at the kind invitation of the Governments of Kenya and the United States of America (USA). Dr Evelyne Mbandi, Director, Microbiological and Chemical Hazards Staff, Food Safety and Inspection Service, United States Department of Agriculture (USDA) chaired the Session, and Prof George Ooko Abong, Chairman, Department of Food Science, Nutrition and Technology, University of Nairobi, co-chaired the Session, which was attended by 56 Member Countries, one Member Organization and 11 Observer Organizations. The list of participants is contained in Appendix I.

## OPENING

2. The Honourable Mithika Linturi, Cabinet Secretary, Ministry of Agriculture and Livestock Development, Government of Kenya, opened the meeting, extending a warm welcome to all participants and expressing appreciation to the USA for their support and engagement in co-hosting this important meeting. The Cabinet Secretary highlighted that food safety was key to attaining several of the United Nations' Sustainable Development Goals (SDGs), including zero hunger, health and well-being, clean water and sanitation, and responsible production; that without food safety, the SDGs would not be met and that Codex standards must continue to be the bedrock of food safety in a changing world, supporting collective efforts to end hunger and malnutrition by 2030.
3. The Honourable Nakhumicha S. Wafula, Cabinet Secretary, Ministry of Health of Kenya celebrated the international partnerships being fostered by this co-hosting collaboration, noting that together, we could build a future where safe and nutritious food was accessible to all, and where the health and well-being of communities were safeguarded through robust food hygiene standards.
4. The Honourable Rebecca Miano, Cabinet Secretary, Ministry of Investment, Trade and Industry of Kenya in welcoming delegates noted that co-hosting this session with the USA served as a vivid demonstration, dedication, and declaration of Kenya's commitment to global food safety and that this collaboration magnified the crucial role of strong international partnerships in elevating the standards of food consumed not only within their own borders but across the globe.
5. Dr José Emilio Esteban, Under Secretary for Food Safety, USA, in the opening ceremony underlined the importance of Codex work, saying that he believed Codex to be the most important food safety body in the world because everyone in the world was entitled to the same level of food safety.
6. Mr Steve Wearne, the Chairperson of the Codex Alimentarius Commission (CAC) also addressed the meeting, noting the important contribution of CCFH to the work of CAC.
7. CCFH54 observed a minute's silence in memory of the late Dr Hajime Toyofuku, Professor, Yamaguchi University, Japan, who for many years supported the work of CCFH, and provided a leadership role in areas such as the control of *Vibrio* spp. and histamine.

### Division of competence<sup>1</sup>

8. CCFH54 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)<sup>2</sup>

9. CCFH54 adopted the provisional agenda as its agenda for the Session.
10. CCFH54 also agreed to consider Agenda Items 10, 11 and 12 under Agenda Item 13 New Work/Forward Work Plan.

### MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX SUBSIDIARY BODIES TO THE COMMITTEE (Agenda Item 2)<sup>3</sup>

11. The Codex Secretariat summarised the information provided in CX/FH 24/54/2, noting that the *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, Annex I on raw beef and Annex III on raw milk and raw milk cheeses), and the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (General Section and Annex I on Fresh Produce) had been adopted by CAC46 and published as CXG 99-2023 and CXG 100-2023 respectively. CAC46 in approving the new work proposed by CCFH had requested CCFH to carefully consider the relationship between the new guidelines related to food hygiene control

<sup>1</sup> CRD01 (Division of competence and voting right between the European Union and its Member States)

<sup>2</sup> CX/FH 24/54/1; CRD22 (East African Community); CRD29 (Burundi); CRD35 (United Republic of Tanzania)

<sup>3</sup> CX/FH 24/54/2; CRD07 (European Union, Rwanda); CRD19 (Morocco); CRD20 (African Union); CRD21 (Nigeria); CRD22 (East African Community); CRD29 (Burundi); CRD35 (United Republic of Tanzania)



measures in traditional markets for food, the *General Principles of Food Hygiene* (CXC 1-1969) and the regional texts on street vended foods<sup>4</sup> (This matter was addressed under Agenda Item 8).

12. Regarding the work on the Codex Strategic Plan 2026-2031 the Codex Secretariat advised CCFH that the first draft was open for comments until 5 April 2024 and encouraged Members and Observers to respond as well as engage in the informal meetings organized at a regional level by the Chairperson and vice-Chairpersons of the Commission and the Regional Coordinators on this topic.
13. In an update on food allergens from the Codex Committee on Food Labelling (CCFL), the Codex Secretariat noted that the revised provisions relevant to allergen labelling in the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) had been adopted at step 5 and was expected to be completed this year, hence CCFH may need to consider how the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) might need to be updated to align with the revisions undertaken by CCFL.
14. Noting that the 42<sup>nd</sup> Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS42) had completed its Revision on the *Guidelines for sampling* (CXG 50-2004) and that CCFH50 had agreed to revisit work on sampling plans for histamine at that time, the Codex secretariat indicated that CCMAS would continue to develop an information document to support implementation of CXG 50-2004 over its next one to two sessions and in this context it may be appropriate for CCFH to wait for that information before revisiting the histamine sampling plans.

### Conclusion

15. CCFH54 noted the information presented and agreed to:
  - i. encourage Members and Observers to actively contribute to the discussions in CCEXEC and CAC (e.g. sharing experience on application of the draft guidance on SoP and providing inputs on the development of Codex Strategic Plan 2026-2031) and to note the encouragement to submit discussion papers or new work proposals on NFPS using existing mechanisms;
  - ii. consider the update on the food allergen work in CCFL47 under Agenda Item 13 “New work/Forward Workplan”, acknowledging that CCFH may need to follow up at its next session; and
  - iii. postpone consideration of histamine sampling plans until the work on supporting information and tools for the application of CXG 50-2004 was completed.

### MATTERS ARISING FROM THE WORK OF FAO AND WHO (INCLUDING JEMRA) (Agenda Item 3)<sup>5</sup>

16. A WHO Representative, provided a summary of some of the work undertaken by JEMRA since CCFH53, highlighting the recent JEMRA meetings, the publications on outcomes of the expert meetings on the control of *Salmonella* and *Campylobacter* in poultry meat and the quantitative risk assessment on *Listeria monocytogenes* in ready-to-eat cold smoked fish, frozen vegetables and ready-to-eat diced cantaloupe.
17. The WHO Representative informed CCFH54 of the ongoing WHO work on traditional markets for food, indicating that its particular focus was on minimizing the public health risks from live animal markets and that they considered their work to be complementary to CCFH work in this area. The WHO Representative also announced that the theme for World Food Safety Day 2024 would be “Food Safety: prepare for the unexpected” and encouraged Members and Observers to use this opportunity to engage in preparedness for management of food safety incidents.
18. An FAO Representative highlighted the outputs of the recent joint FAO/WHO scientific advice meetings addressing food allergens, noting the availability of five reports on this topic, as well as the JEMRA work on viruses in foods, in responses to prior CCFH requests. The Representative highlighted that the work on viruses to date had addressed four of the five requests for scientific advice from CCFH. The Representative also highlighted ongoing work to support low- and middle-income countries build their capacity to implement Codex standards, and to encourage and empower countries to apply risk analysis processes under a One Health umbrella to ensure food safety.

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<sup>4</sup> *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 76 R 2017).

<sup>5</sup> CX/FH 24/54/3; CRD20 (African Union); CRD21 (Nigeria); CRD22 (East African Community); CRD29 (Burundi); CRD35 (United Republic of Tanzania)

19. Following a presentation on the recently published “Good Hygiene Practices (GHP) and HACCP Toolbox for Food Safety” by FAO, which aimed to support the implementation of the *General Principles of Food Hygiene* (CXC 1-1969), there was a request that this tool be made available in French, as this would support Members efforts in implementing CXC 1-1969. The FAO Representative confirmed that translation into the official languages of FAO was underway.
20. A Member highlighted the importance of providing tailored guidance and training to all stakeholders on GHP as it was crucial to ensure that all decision-makers and stakeholders were accommodated according to their specific circumstances.

### Conclusion

21. CCFH54 noted:
  - i. the information provided by FAO and WHO and expressed appreciation for the valuable work that has been undertaken since CCFH53;
  - ii. the importance of this work in progressing the ongoing work in CCFH and scheduling new work, and that further details could be provided during the relevant Agenda Items; and
  - iii. the work of FAO on the “GHP and HACCP Toolbox for Food Safety” and encouraged Members to liaise directly with FAO with regard to the implementation and further development of this toolbox.

### INFORMATION FROM THE WORLD ORGANISATION FOR ANIMAL HEALTH (WOAH) (Agenda Item 4)

22. The Representative of the World Organisation for Animal Health (WOAH) could not join the session but submitted a statement to the meeting noting that WOAH continued to follow the work of CCFH and provided the following specific comments.
23. With regard to the possible revision of the *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011), the Representative noted that the text included references to some Glossary terms and relevant chapters of the WOAH *Terrestrial Animal Health Code (Terrestrial Code)*, and if CCFH were to begin work on the revision of these Guidelines, WOAH was willing to actively engage and also, in parallel, review the relevant standards within the *Terrestrial Code*, notably on pre-harvest control measures.
24. The Representative further highlighted that a revised Chapter 3.1.22 *Trichinellosis* (Infection with *Trichinella* spp.) of the WOAH *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* had been adopted at the 90th General Session (May 2023), and that a minor amendment of the corresponding Chapter 8.18. in the *Terrestrial Code* would be proposed for adoption at the upcoming General Session (May 2024). The Representative highlighted that the WOAH Code Commission did not consider that the changes in the *Terrestrial Code* and in the *Terrestrial Manual* would have an impact on the *Guidelines for the control of Trichinella spp. in meat of Suidae* (CXG 86-2015) but that the numbering of the *Terrestrial Manual* had been modified, and that consequently the references in the CXG 86-2015 may need to be updated, notably in points 3.2, 7.2.1 and 10.

### Conclusion

25. CCFH54 noted the ongoing commitment of WOAH to work with CCFH on relevant areas and requested the Codex Secretariat to ensure that any cross-references to the *Terrestrial Manual* and *Terrestrial Code* in the CXG 86-2015 be updated as appropriate and report back to CCFH55.

### 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 (Agenda Item 5)

26. Chile, as Electronic Working Group (EWG) and Physical Working Group (PWG) Chair, speaking also on behalf of co-Chairs New Zealand, Kenya, and the USA, introduced the item, recalling that the consideration of this new work had begun at CCFH49 (2017) and that it had been discussed in each of the subsequent sessions. It was recalled that the guidelines included a general section and four annexes focusing on specific food commodities and that CAC46 (2023) had adopted the General Section, Annex I on raw beef, and Annex III on raw milk and raw milk cheeses, published as CXG 99-2023.
27. The EWG/PWG Chair explained that in preparation for the PWG held prior to the plenary session, the co-Chairs had meticulously reviewed all comments received, and in addition to editorial enhancements to improve clarity and usability, substantive changes had been made to some essential paragraphs, such as recommendations on storage temperatures for fresh leafy vegetables and sprouts to mitigate the growth of Shiga toxin-producing *Escherichia coli* (STEC). The EWG/PWG Chair emphasized that consensus had been reached on all revisions during the PWG, and the updated draft annexes were presented as CRD03.
28. CCFH54 considered the revised annexes contained in CRD03 section by section.

29. CCFH54 agreed with most of the revisions in CRD03 and in addition to further editorial corrections, and amendments for clarity and consistency, CCFH54 made the following comments and decisions.

**PROPOSED DRAFT ANNEX II ON FRESH LEAFY VEGETABLES (Agenda Item 5.1)<sup>6</sup>**

Section 1 Objective - paragraph 5<sup>7</sup>

30. CCFH54 agreed to: i) insert the word "prevent" before "reduce" to clarify that the objective of this annex was to provide guidance to prevent or reduce the risk of foodborne illness from STEC; and ii) replace the words "for human consumption without cooking" with "to be consumed raw".

Section 2.3 Definition for fresh leafy vegetables

31. In response to a suggestion to change the wording in the definition for fresh leafy vegetables from "intended for consumption raw" to "intended to be consumed raw," the EWG/PWG Chair clarified that this definition was already adopted as it was included in the General Section of CXG 99-2023. The repetition of this definition in the annexes aimed to facilitate use of the document and prevent the need to refer back to the general section for definitions.
32. CCFH54 agreed to maintain the definition for fresh leafy vegetables unchanged.

Section 3.1.1 Neighbouring animal farms - paragraph 12

33. Regarding the suggestion to include "poultry farms" in this paragraph, CCFH54 noted that while poultry farms were not usually associated with STEC, other facilities like slaughterhouses could serve as potential sources of infection. As a result, CCFH54 agreed to include the wording "other similar operations" in this paragraph.

Section 3.2.3 Personnel health, hygiene, and sanitary facilities - paragraph 21

34. In response to a suggestion to reduce the risk of STEC contamination by separating personnel handling animal production from those involved in fresh leafy vegetable production, CCFH54 agreed to insert the phrase "e.g., have not had prior contact with animals" into this paragraph.
35. Regarding the suggestion to implement regular health checks for all staff to detect individuals carrying STEC, the EWG/PWG Chair explained that: i) periodic health checks might not effectively identify STEC infections; ii) imposing such health checks on individuals in primary production globally could be overly restrictive; and iii) the existing requirement prohibiting individuals known or suspected to have gastrointestinal illness from entering areas where fresh leafy vegetables were handled could adequately address this concern. Consequently, CCFH54 agreed not to include the request for regular health checks.

Section 4.3 Washing fresh leafy vegetables – paragraph 29

36. One Member questioned whether all water used for cooling and washing fresh leafy vegetables should be potable water instead of fit-for-purpose water.
37. The EWG/PWG Chair clarified that, given this section was part of the pre-processing stage, which fell under primary production, the requirement for fit-for-purpose water was adequate.
38. CCFH54 agreed to maintain this paragraph unchanged.

Section 5 Processing operations – paragraph 31

39. In response to a question regarding the inclusion of cooking as an example of a processing type in this paragraph, despite cooked vegetables being excluded from the scope, the EWG/PWG Chair clarified that, based on the JEMRA report, cooking was the only effective means of eliminating STEC, and it was important to highlight this information.

Figure 1: Process flow for fresh leafy vegetables

40. One Member proposed to: i) include farm site selection as the first step as the environmental factors around the farm site might effect the safety of the vegetables; and ii) merge transportation and cooling, as transportation of vegetables should be done under cold temperature.

<sup>6</sup> CX/FH 24/54/5; CX/FH 24/54/5 Add. 1 (Argentina, Australia, Canada, Colombia, Ecuador, Egypt, European Union, Indonesia, Iraq, Japan, Kenya, Malaysia, New Zealand, Peru, Philippines, Thailand, United Arab Emirates, United Kingdom, Uruguay and USA); CRD08 (Argentina, Malaysia, Rwanda and Singapore); CRD18 (Ghana); CRD19 (Morocco); CRD21 (Nigeria); CRD22 (East African Community); CRD23 (India); CRD25 (South Africa); CRD27 (Senegal); Uganda (CRD28); CRD29 (Burundi); CRD35 (United Republic of Tanzania); CRD37 (Russian Federation)

<sup>7</sup> Unless otherwise specified, the paragraph numbers under this agenda item reflect those in CRD03

41. The EWG/PWG Chair explained that this figure was only an example, and as indicated in the footnote the diagram was intended as a generalised process flow for fresh leafy vegetables for illustrative purposes only and all of the steps might not occur in all operations and might not occur in the order presented in the flow diagram.

42. CFH54 agreed to maintain this figure unchanged.

Section 6. Microbiological testing – paragraph 37

43. In response to a comment that microbiological testing of fresh leafy vegetables could not verify the safety of the product, it was agreed to remove reference to “the safety of the product” in the middle of the paragraph for accuracy.

**PROPOSED DRAFT ANNEX IV ON SPROUTS (Agenda Item 5.2)<sup>8</sup>**

Section 1 Objective- paragraph 6

44. CCFH54 agreed to revise the wording of this paragraph consistent with that of Annex II and the scope of Annex IV by referring to “sprouts intended to be consumed raw”.

Section 5.4 Treatment and pre-germination soak of seeds for sprouting – paragraph 52

45. CCFH54 agreed to remove "antimicrobial" from this paragraph, noting that there were alternative treatment options and that comprehensive information on treatments had already been provided in this section.

Section 5.5. Rinse after seed treatment – paragraph 53

46. CCFH54 agreed to include the wording "to remove chemical residues" at the end of the first sentence in this paragraph for clarification purposes.

Section 6. Microbiological criteria and other specifications for laboratory testing and Section 6.1 Testing of seed lots before entering production

47. As for Annex II, as microbiological testing of sprouts could not verify the safety of the product, it was agreed to remove reference to “the safety of the product” in the middle of the paragraph for accuracy.

48. CCFH54 agreed to include the following paragraphs (from paragraphs 63 and 67 of CX/FH 24/54/6) in Section 6 and Section 6.1, respectively, as the information was considered important due to the nature of the sprout production system.

*Testing spent sprout irrigation water or in-process sprouts collected during sprouting increases the likelihood of detecting the pathogens that may be present in seed. It also enables early detection of contamination in the production batch before products enter the marketplace. Testing spent sprout irrigation water is preferred over testing sprouts because water may pick up bacteria as it passes through the production batch, making it easier to collect a representative sample.*

*Testing of seed lots for indicator microorganisms may be used as an indicator of potential STEC contamination. If initial testing indicates the possible presence of STEC, additional testing for STEC is recommended.*

49. CCFH54 also agreed to replace the last sentence of paragraph 65 with “This may lead to STEC not being detected when present.” for improved accuracy and clarity.

Section 6.2 Testing of sprouts and/or spent sprout irrigation water (SSIW) – paragraph 66

50. CCFH54 agreed to replace "sprouted seeds" with "sprouts" for consistency.

Section 10 Retail and foodservice – paragraph 78

51. CCFH54 agreed to delete the word "contract" from this paragraph.

**Conclusion on Agenda Items 5.1 and 5.2**

52. CCFH54 agreed to forward the proposed draft Annex II on Fresh Leafy Vegetables and Annex IV on Sprouts for adoption at Step 5/8, noting that these two annexes would be subsequently included as Annex II and Annex IV in CXG 99-2023 (Appendices II and III).

<sup>8</sup> CX/FH 24/54/6; CX/FH 24/54/6 Add. 1 (Argentina, Australia, Canada, Colombia, Ecuador, Egypt, European Union, Indonesia, Iraq, Japan, Kenya, Malaysia, New Zealand, Peru, Thailand, United Arab Emirates, United Kingdom, Uruguay and USA); CRD09 (Argentina, Malaysia, Rwanda and Singapore); CRD18 (Ghana); CRD19 (Morocco); CRD21 (Nigeria); CRD22 (East African Community); CRD23 (India); CRD25 (South Africa); CRD27 (Senegal); CRD28 (Uganda); CRD29 (Burundi); CRD35 (United Republic of Tanzania); CRD37 (Russian Federation)

**GUIDELINES FOR THE SAFE USE AND REUSE OF WATER IN FOOD PRODUCTION AND PROCESSING (ANNEX II ON FISHERY PRODUCTS AND ANNEX III ON DAIRY PRODUCTS) (Agenda Item 6)<sup>9</sup>**

53. The European Union (EU) as Chair of the EWG and the PWG, speaking also on behalf of the co-Chairs, Chile and the International Dairy Federation (IDF), introduced the item providing a brief history of the work, noting that the General section and Annex I of the *Guidelines for the safe use and re-use of water in food production and processing* (CXG100-2023) had been adopted by CAC46 and that the work had been underpinned by the scientific advice provided by JEMRA.
54. With reference to the reports of the EWG (CX/FH 24/54/7) and the PWG (CRD04), the EWG/PWG Chair highlighted the progress made and some key agreements reached, including on modifications to the annex titles (II: Fish and Fishery Products and III: Milk and Milk Products), changes to ensure consistency of structure across the annexes, and the addition of a new annex to address technologies, which although originating in the Annex on Milk and Milk Products, was considered to be relevant to the other parts of the guidelines document as well. The EWG/PWG Chair noted that comments suggested general support for this new annex but proposed that more time was needed in the EWG for its further elaboration.
55. Recalling the report of the PWG, and the key issues outlined therein, the EWG/PWG Chair highlighted that paragraphs 32 to 63 of the Annex on Milk and Milk Products (CRD04) were cross-cutting as they addressed water fit-for-purpose assessment and safety management and that the PWG agreed these should also be moved to the new annex. The PWG had extensively discussed the decision tools in the Annex on Fish and Fishery Products, but the EWG/PWG Chair noted that these still required further consideration.

**Discussion**

56. Having expressed appreciation for the work of the EWG/PWG Chair and co-Chairs and all those that participated in the work, CCFH54 agreed to consider the revised Annexes as presented in CRD04 and to discuss section by section.

**Annex II Fish and Fishery Products**

57. CCFH54 made the following comments and decisions, in addition to editorial corrections, and amendments for clarity and consistency.

1. Introduction

58. The deleted paragraph 2 was reintroduced as some Members considered it important to provide an overview of the different water sources to be considered in the fish and fisheries product sector at the outset of this Annex.
59. Paragraph 5<sup>10</sup>: “a level of comprehensive risk assessment” was replaced with “an appropriate risk assessment” for clarity.

2. Purpose and Scope

60. It was noted that this section and in particular the last sentence might have to be revised pending discussion on the use of decision tools in this annex.

4. Definitions

61. Fish and Fishery Products: The text in the parenthesis after molluscs was revised for accuracy and completeness to (bivalve molluscs, gastropods and cephalopods).

6. Water use, Paragraph 11

62. Following concerns that use of the term “indigenous” in reference to microorganisms was not clear, other terms such as “endemic” and “autochthonous” were considered, but for ease of understanding, CCFH54 agreed to change the term to “naturally occurring” in this paragraph and throughout the document.
63. 6. Water use: Paragraph 15: As “some distance” from the shore was considered to be vague and subjective, it was changed to “sufficiently distant” for clarity and at the end of the paragraph “or other objectionable substances” was added to the list of things to avoid, for inclusiveness.

<sup>9</sup> CX/FH 24/54/7; CX/FH 24/54/7 Add.1 (Argentina, Australia, Canada, Colombia, Ecuador, India, Japan, Kenya, Morocco, New Zealand, Norway, Peru, Philippines, Saudi Arabia, United Arab Emirates, United Kingdom, Uruguay, USA, ICBA and IDF/FIL), CRD 04 (PWG); CRD 10 (Argentina, European Union, Malaysia, Republic of Korea, Singapore, Thailand); CRD 18 (Ghana); CRD19 (Morocco); CRD20 (African Union); CRD21 (Nigeria); CRD22 (East African Community); CRD24 (Institute of Food Technologists); CRD25 (South Africa); CRD26 (El Salvador); CRD28 (Uganda); CRD29 (Burundi); CRD31 (Guyana); CRD33 (FAO/WHO); CRD35 (United Republic of Tanzania); CRD37 (Russian Federation)

<sup>10</sup> Unless otherwise specified, the paragraph numbers under this agenda item reflect those in CRD04

### 8. Water use or reuse fit-for-purpose assessment

64. Recalling that this section revolved around decision tools, and that the PWG had identified a number of problems in understanding the originally proposed tools and had deleted some of them, the EWG/PWG Chair requested CCFH54 to consider some new decision tools published as CRD33 which had been prepared taking into account the comments received at the PWG, informal consultations after the PWG and in collaboration with the JEMRA secretariat. CCFH54 agreed to review the four decision tools for suitability for inclusion in the annex.
65. CCFH54 generally agreed that the new tools presented in CRD33 were much improved and understandable and were in general agreement with their inclusion for further discussion and development. Delegates also provided the following additional comments and issues for clarification:
- Clarify the titles of the figures to specifically explain that they were related to fish that were likely to be consumed raw or insufficiently cooked.
  - After the boxes that indicate low risk, high risk, add another box to indicate the water status and possible risk management action e.g., in case of low risk, the additional box would indicate that water was fit for purpose while in case of high risk, it would indicate that water was not fit for purpose and that additional control measures needed to be taken to make it fit for purpose.
  - Indicate that these were examples of decision tools and not the only tools that could be used, using language similar to that which had been used elsewhere in CXG 100-2023 as well as in CXC 1-1969.
  - Ensure consistency of terminology in the figures with that in the main text e.g. replace “degutting” with “evisceration”, as well as within the figures themselves e.g. use “excreta” or “faeces” but not both.
  - Rephrase the text in some of the boxes to ensure the text was clear and phrased as questions.
  - In figure 2, clarify what was meant by “nearby”, review the arrows leading from question 2 to indicate whether sewage nearby meant it could enter the open system with or without rainwater; revise the “no” arrow from question 2 to question 4 (on whether there was surface water run-off) rather than question 3; and consider using “higher” risk instead of “high” risk in all figures as how high the risk might be will depend on the level of contamination.
  - Include more granularity in figure 4 to facilitate good decision making, for example by building in additional questions on whether potable water or seawater was used and in the case of seawater, whether that was collected offshore or in coastal areas, with corresponding risk level outcomes.
  - In figure 5, clarify the risk outcome of the “no” arrows from activities like fish degutting and transport on ice as currently, even though no water was involved, these lead to “high risk” but should be changed to “not applicable”.

### 9. Water Safety Management

66. Paragraph 45: There were mixed views on whether reference to Annex IV on technologies, which was currently under development, should be included as a reference and it was agreed to reconsider such cross-references throughout the text once Annex IV was further elaborated.
67. Paragraph 48: Reference to irradiation was removed so as to have consistent reference to biological, chemical and physical water treatments across paragraphs.
68. Paragraph 49: Concerns were expressed regarding a lack of clarity, in particular around microbiological testing potentially ensuring safety in cases of non-conformities, which was considered to be inaccurate. After some discussion, the paragraph was fully revised for clarity as follows:
- Implement operational monitoring, including periodic microbiological testing, of water used in the production and processing of fish and fishery products to provide insight into the performance of the water safety management process. Such monitoring can enable rapid identification of potential nonconformities and inform corrective actions, which may include additional microbiological testing of the process and/or the fish and fishery products.*
69. Paragraph 51: The first sentence was edited for clarity and in the second sentence, as an alert to the possibility of toxic compounds being formed when substances like chlorine dioxide were mixed with seawater, a footnote was added to the list of treatment agents to indicate: “attention should be paid to the possible formation of toxic compounds when adding chemical disinfectants to seawater”.
70. Paragraph 57: Several changes were made for clarity and inclusiveness referring to “limitations” rather than “disadvantages” of indicator microorganisms and to “naturally occurring pathogenic microorganisms” rather than “bacteria”, so as to be also inclusive of viruses.

71. Paragraph 58: “control” was replaced with “monitoring” for accuracy.
72. Table 1: Discrepancies between this table and the output of the JEMRA meeting were identified and it was agreed to align the information within Table 1 with the JEMRA report<sup>11</sup> and to ensure that both the risk ranking and resistance to chlorine columns of the table were referenced in the text or otherwise removed.
73. While making substantial progress on the Annex, CCFH54 agreed further deliberations were needed within an EWG to further develop Section 8 and complete the work.

### ***Annex III Milk and Milk Products***

74. CCFH54 agreed with most of the revisions to the Annex in CRD04 and in addition to further editorial corrections, and amendments for clarity and consistency, CCFH54 made the following comments and decisions.

#### Primary production and transport from the farm

75. Paragraph 10: One Member highlighted that udder washing as indicated in this paragraph was not recommended in the *Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004)* and this was a potential inconsistency with an existing Codex text. The EWG/PWG chair explained that this was inserted at the request of several Members and noted that it specifically referred to situations when udder washing might be recommended (e.g. dirty udder), rather than saying it was always recommended and therefore was of the view that it did not contradict CXC 57-2004. CCFH54 agreed to retain this paragraph.

#### Dairy Manufacturing Plant

76. Paragraph 23: The language was simplified to refer to “competent authorities” rather than “relevant competent authorities, in most cases the municipality”, as competent authority was clearly defined and did not need further qualification. For consistency throughout the document, it was agreed to refer to competent authorities without further qualification.
77. Paragraph 23 bis: The word “must” was replaced with “should” for consistency with other Codex texts.

#### Technologies for recovery and treatment of water

78. Paragraph 29: In response to a comment that the examples included in parentheses did not provide any clarity in terms of uncertain microbiological quality, they were revised to read “for example in the case of no microbiological testing, when testing indicates poor quality, or when the RO system is unvalidated”.
79. Paragraph 30: This was deleted as it was considered unnecessary.
80. Paragraph 32: One Member expressed concern that this paragraph indicated that pathogenic microorganisms were known to be present in reuse water, but disinfection treatment only needed to be undertaken when required, and it was proposed to remove “when required”. Others noted that there was a lot of effort ongoing in industry to minimise the formation of biofilms which can harbour pathogens; that biofilm formation happened very slowly; and that it could be more appropriate to indicate that operations “may” contain microorganisms rather than they were known to contain microorganism. CCFH54 agreed to replace “known” with “may” to improve clarity of the paragraph.

#### Water fit-for-purpose assessment and water safety management

81. Noting that CCFH54 agreed that paragraphs 32 to 63 (CRD04) were transferred from this annex to a new annex addressing cross-cutting issues, an Observer proposed that one deleted point related to having a back-up fit-for-purpose water supply in case the reuse water system failed was a critically important point and should be maintained in this annex. While the EWG/PWG Chair noted that this was not unique to this annex there was no objection to retaining it in the annex and the following was inserted in the section in the Dairy Manufacturing Plant section immediately after paragraph 26.

*A back-up fit-for-purpose water supply such as an external potable water source that can be used in case a reuse water treatment system is not effective or functioning properly should be available.*

#### Examples of fit-for-purpose water applications in dairy plants

82. Paragraph 36: In response to a question as to whether microbiocidal treatments included heat, it was clarified that it was a broad term that referred to a treatment that kills microorganisms and therefore could include a heat treatment and should not be confused with an antimicrobial treatment. CCFH54, noting the agreement on the term in English, agreed that the other language versions should be reviewed carefully to ensure

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<sup>11</sup> FAO & WHO. 2023. *Safety and quality of water used in the production and processing of fish and fishery products – Meeting report*. Microbiological Risk Assessment Series, No. 41. Rome. <https://doi.org/10.4060/cc4356en> - see Table 1

consistency of terminology.

83. Figure 1: Responding to a comment on the meaning of the two question marks (??) which appeared in this figure the EWG/PWG chair explained that question marks referred to the fact that the number of generations of recirculation of water that may occur was unknown, and that this was further explained in the footnote. To improve clarity, it was agreed to replace the question marks with “xx” and to also include reference to “xx” in the footnote.
84. Figure 2: As pure water was not defined in these guidelines, it was agreed to remove the term from this figure and simply refer to “water going to tanks”, since the term was only used to clarify that none of the other substances from the previous step e.g. acid, were going on to the next stage.
85. Paragraph 44: Responding to a request for a clarification on the meaning of human pathogens, it was explained that this referred to agents which were pathogenic to humans and not pathogens of human origin and consequently “human pathogens” was replaced with “agents pathogenic to humans” for clarity.
86. Paragraph 46: “Identification” was replaced with “assessment” as a more accurate term to indicate the consideration of pH, turbidity etc.
87. CCFH54 agreed that there were no outstanding issues remaining in this Annex.

#### **Annex IV**

88. CCFH54 agreed with the proposal of the PWG regarding a new annex that would capture both new technologies and information removed from Annex III related to water fit-for-purpose assessment and water safety management as these were relevant to all commodity-focussed annexes as well as the general guidelines. CCFH54 did consider whether it may be more appropriate to divide this content between two different annexes, noting both options could work, but finally agreed to proceed with one cross-cutting annex.

#### **Conclusion**

89. CCFH54 agreed to:
  - i. Forward the draft Annex III on Milk and Milk Products (Appendix IV) to CAC47 for adoption at step 5/8 and subsequent inclusion in CXG 100-2023;
  - ii. Return the draft Annex II on Fish and Fishery Products to step 2/3 for further elaboration in particular of Sections 2 and 8, noting the general agreement on all other sections in Annex II, followed by circulation for comments at Step 3; and
  - iii. Establish an EWG chaired by the EU and co-chaired by Morocco, Honduras, Mauritania, India and IDF and working in English only (comments can also be provided in French and Spanish), with the following terms of reference:
    - a. Revise Annex II on Fish and Fishery products, focusing on Section 8 and Section 2, incorporating the figures from CRD33 and revising the text in line with comments received during CCFH54, noting that comments on other sections may also be considered;
    - b. Further develop Annex IV related to water fit-for-purpose assessment, safety management, and technologies for recovery and treatment of water for reuse, taking into account written comments and discussions at CCFH54 and the agreement to move paragraphs 32 to 63 (CRD04) of Annex III to Annex IV ;
    - c. Consider and propose, if needed, revisions to the General Section and other Annexes of CXC 100-2023 by introducing a cross-reference to Annex IV;
    - d. Consider and propose, if needed, possible examples on the use of technologies most relevant for Annexes to CXG 100-2023; and
    - e. Prepare an EWG report for submission to the Codex Secretariat at least 3 months in advance of CCFH55.
90. A PWG chaired by the EU and co-chaired by Honduras, India, Mauritania, Morocco, and IDF, working in English, French and Spanish, may be held in conjunction with CCFH55 to consider all comments received and prepare a revised proposal for consideration by the plenary.
91. CCFH54 further agreed to request CCEXEC86 and CAC47 to extend the timeline for completion of this work until CCFH55, noting the substantial progress made on this document and the identification of the need for an additional annex to complete these guidelines.



92. CCFH54 also noted the intention of Honduras to convene a workshop to test and validate some of the decision tools developed in the course of this work on the *Guidelines for the safe use and reuse of water in food production and processing* (CXG 100-2023) and the related annexes and would welcome the support of JEMRA in this regard.

**PROPOSED DRAFT REVISION ON THE GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF PATHOGENIC *VIBRIO* SPECIES IN SEAFOOD (CXG 73-2010) AT STEP 4 (Agenda Item 7)<sup>12</sup>**

93. Japan, as EWG and Virtual Working Group (VWG) Chair, speaking also on behalf of Chile as co-Chair, introduced the item. It was noted that CCFH53 had decided to initiate the revision, subsequently approved by CAC46, of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010) and established an EWG. After CCFH53, the EWG conducted one round of consultation, followed by a VWG meeting on February 26, 2024.
94. The discussions within the VWG mainly focussed on: i) defining seafood, treated/partially treated, and clean water; ii) addressing water issues; and iii) establishing facility temperature requirements. The outcomes of the VWG discussions were documented in CRD02. Prior to discussion at CCFH54, further revisions were made to CRD02 in response to the discussions on alignment of texts with CXC 1-1969 (Agenda Item 9) and additional comments from Members and Observers (e.g., CRD 32). These revisions aimed to align the document structurally with CXC 1-1969, considering that the technical content of CXC 1-1969 had been considered from the start of the revision process. Revisions to the technical content included:
- Removal of “seaweed” from the definition of “seafood”;
  - Revision of the definition of “partially treated”
  - Inclusion of the definition of “Water fit for purpose” from CXG100-2023 to the “Definition” section, and changing “clean water” in paragraphs 34, 35 and 76 (as per CRD02) to “Water fit for purpose”, which appears in paragraphs 38, 39 and 87 of CRD36; and
  - maintaining option 1 (i.e. 10°C/ to limit growth of pathogenic *Vibrio* spp.) in paragraph 63 of CRD02.
95. The EWG/VWG Chair clarified that all these revisions had been incorporated in CRD36.

**Discussion**

96. CCFH54 considered the revised text contained in CRD36 section by section.
97. CCFH54 agreed to: i) use the wording “naturally occurring” instead of “autochthonous” in paragraphs<sup>13</sup> 7 and 13 to be aligned with the term used under Agenda Item 6; ii) change the word “can” to “should” in paragraph 11; and iii) remove the word “seaweed” from paragraph 12.
98. CCFH54 agreed with most of the revisions in CRD36 and in addition, to editorial corrections and amendments for clarity and consistency, CCFH54 made the following comments and decisions.

**Issues related to water**

99. CCFH54 conducted an extensive discussion on this matter.
100. Regarding the definition of “clean water” and “water fit for purpose”, Members expressed divergent views:
- the definition of clean water was redundant as it was covered by the definition of “water fit for purpose,” and there was no clear distinction between the two terms;
  - the definition of clean water should be retained as it was different from the definition of water fit for purpose and both definitions had served their respective purposes effectively;
  - a definition of clean seawater should be introduced; and
  - the current definition of clean water already covered clean seawater.

<sup>12</sup> CX/FH 24/54/8; CX/FH 24/54/8 Add.1 (Argentina, Australia, Canada, Colombia, Ecuador, European Union, Iraq, Japan, Kenya, New Zealand, Norway, Philippines, United Arab Emirates, United Kingdom, Uruguay, Venezuela (Bolivarian Republic of), Zambia and ICUMSA); CRD02 (Report of the VWG meeting on the proposed draft revision on CXG 73-2010); CRD11 (Argentina, Singapore and Thailand); CRD18 (Ghana); CRD19 (Morocco); CRD20 (African Union); CRD22 (East African Community); CRD23 (India); CRD25 (South Africa); CRD28 (Uganda); CRD29 (Burundi); CRD32 (USA); CRD35 (United Republic of Tanzania); CRD36 (Further revised revision on CXG 73-2010); CRD37 (Russian Federation)

<sup>13</sup> The paragraph numbers thereafter reflect the paragraph numbers in CRD36

101. In response, the EWG/VWG Chair clarified that the definitions of “clean water” and “water fit for purpose” were adopted from published Codex texts, noting that the definition of “water fit for purpose” introduced the concept of a risk-based approach which was not captured in the definition for clean water. Clean water was consistently referenced throughout the document, whereas “water fit for purpose” was deliberately employed in specific sections to prevent repetitive mentions of potable water. It was underscored that clean water and water fit for purpose served distinct roles and were utilized in different contexts within the document.
102. Views on the types of water suitable for storage and handling of seafood aboard fishing vessels intended for raw or partially treated consumption were expressed as follows:
- referring to water fit for purpose was too vague and did not give clear risk management guidance, and in certain contexts it was necessary to recommend use of a specific water type such as potable water, clean water, or clean seawater;
  - priority should be given to potable water, with clean water serving as an alternative if potable water was not feasible or readily available;
  - clean water was a readily understood term compared to water fit for purpose; and
  - referring to water fit for purpose was more appropriate as it highlighted that irrespective of the water source available, efforts must be made to that water used in a specific context did not impact the safety of the food.
103. One Member highlighted that the purpose of developing the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023), which had been previously agreed by CCFH and adopted by the Commission, was to introduce a risk-based approach to the safe use of water, taking into consideration differences in water availability and accessibility. It was further noted that Annex II on Fish and Fishery Products, currently under development, would be the appropriate document in which to address guidance on the use of different water types (e.g. clean water, potable water etc) and alignment with the water fit for purpose concept to avoid inconsistencies across food hygiene texts.
104. Some Members supported the proposal that with the adoption CXG 100-2023, water-related provisions in all texts should be aligned with those in the Guidelines to ensure a consistent approach.
105. Others were of the view that it was not sufficient to cross-reference CXG 100-2023 or simply refer to water fit for purpose, and expressed concerns that systematic replacement of all references to water type with water fit for purpose did not provide sufficient risk management advice.
106. One Member explained that while the definitions of “clean water” and “water fit for purpose” may look the same, the second one required the identification, evaluation, and understanding of potential microbial hazards and other relevant factors.
107. The FAO representative explained that JEMRA had made efforts to define suitable water across various contexts and introduced the concept of “fit for purpose.” Water fit for purpose accurately described the specific requirements for intended uses such as handling and storage, noting that the quality of water required for these different steps may well be different.
108. Suggestions to retain the original term “clean water” or use the wording “water fit for purpose (in this case, at least clean water)” as a compromise solution were also considered, but no consensus was reached.
109. The Codex Secretariat recalled the longevity of discussions on water terminology in CCFH, that CXG 100-2023 had been developed in response to past challenging discussions and noting that work on Annex II of CXG 100-2023 on Fish and Fishery Products was ongoing, encouraged Members to actively engage in those discussions to also consider and address the issues on water terminology which were arising in the revision of this document.
110. In view of the difficulty in reaching consensus on this matter, CCFH54 agreed with the Chairperson’s proposal to place square brackets around all water-related wording and focus the discussion on other aspects of the document.

### ***Guidelines – Main body***

#### **Introduction- Footnote 1:**

111. *V. harveyii* was removed as this was primarily a fish pathogen rather than a human pathogen.

#### **Section 1.2 *Vibrio parahaemolyticus* – paragraph 9**

112. For clarify, CCFH54 agreed to replace this paragraph with the following:

*Virulent strains are seldom detected in the environment or foods. In contrast to strains from clinical cases that will always possess these virulence factors, the probability of detection of environmental or food strains, including seafoods, which possess virulence markers will be very low as most do not contain known virulence markers and their distribution within seafood and across growing areas is not homogeneous. In addition, current selective media cannot distinguish colonies of virulent strains from those of avirulent strains. Given this limitation, failure to detect virulent strains in the environment or in foods does not mean there is no risk to consumers.*

Section 1.3 *Vibrio cholerae* - paragraph 14

113. For clarity, CCFH54 agreed to replace this paragraph with the following:

*Epidemic cholera can be spread by factors such as: infected travellers and the food trade. These factors, but also climate change, may increase the probability of an epidemic in the newly established environments. Detection frequencies of cholerae strains of *V. cholerae* from legal food trade are very low and have seldom been implicated in cholera outbreaks.*

Section 1.4 *Vibrio vulnificus* - paragraph 18

114. CCFH54 agreed to delete the wording "other bivalve molluscs" from the last sentence of this paragraph to avoid duplication.

Section 1.4 *Vibrio vulnificus* - paragraph 20

115. A Member noted that while the last sentence was scientifically accurate, there were doubts about the feasibility of sustaining oyster survival under saline conditions exceeding 30 ppt, and questioned whether this level of technical detail was necessary for these Guidelines.
116. CCFH54 agreed to remove the last sentence from this paragraph.

Section 3 Scope – paragraph 25

117. In response to a proposal to incorporate additional *Vibrio* spp, including both pathogenic and opportunistic strains, the EWG/VWG Chair clarified that this issue had been extensively discussed and it had been decided to include only the three pathogenic *Vibrio* species.
118. CCFH54 agreed to maintain this paragraph unchanged.

Section 4 Use – paragraph 26

119. CCFH54 agreed to remove the words "particularly Annex II on Fishery Products" from this paragraph.

Section 6 Definitions – paragraph 26

Refrigeration

CCFH54 agreed to incorporate the term "and maintaining" into the definition.

Partially treated

CCFH54 agreed to include steam and blanching as examples.

Section 9.2.4 Temperature – paragraph 63

120. CCFH54 agreed to revise the last sentence as "The facility should be capable of controlling product temperature during processing of raw seafood at a temperature of 10°C or lower" since there were multiple control measures beyond ambient temperature control.
121. In response to a proposal to add type E after *Clostridium botulinum*, CCFH54 noted that Type A also had been detected in shellfish. Consequently, CCFH54 agreed not to specify the type of *Clostridium botulinum*.

Section 9.3.1 General – paragraph 69

122. CCFH54 agreed to revise this paragraph as follows:

*Areas where refrigeration is necessary should be equipped with a calibrated thermometer.*

Section 10.1 Awareness and responsibilities – paragraph 71

123. CCFH54 agreed to remove the words "institutional establishment," "special," and "various fishing techniques" from this paragraph to enhance clarity and replace the term "industry" with "FBOs".

Section 13.2.2.1 Washing and processing – paragraph 80

124. Noting the discussion on whether potable running water or clean water should be used and considering that the second sentence was provided as an example, CCFH agreed to delete it.

Section 14.4 Consumer education – bullet point 8 of paragraph 109

125. One Member suggested deleting this bullet point due to the challenges associated with implementing the requirement to use separate utensils and equipment for raw and cooked seafood.
126. CCFH54 noted that this section pertained to consumer education and agreed to insert the wording "or clean between" to offer additional options.

Section 14.4.1 Special attention to susceptible subpopulations – bullet point 3 of paragraph 109

127. CCFH54 agreed to remove this bullet point as it was not directly relevant to foodborne illness, noting a paragraph had been included in the introduction section to highlight the risk associated with transmission of pathogenic vibrio through open wounds.

Section 20.3 Types of analytical methods – paragraph 120

128. CCFH54 agreed to include the phrase "in some circumstances" in this paragraph.

***Guidelines - Annex on the control measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in bivalve molluscs***Section 8.1 Environmental hygiene control – paragraph 16

129. CCFH54 agreed to remove the words "having jurisdiction" from this paragraph as all competent authorities possess jurisdiction.

Section 8.3 Handling, storage and transport - paragraph 18

130. CCFH54 agreed to delete the phrase "where stricter parameters are applied to the former" due to the removal of post-harvest processing.

**Conclusion**

131. CCFH54 agreed to forward the proposed draft revision on the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010) to CAC47 for adoption at Step 5, noting that all references to water remained in square brackets and that this document had been aligned with CXC 1-1969 (Appendix V).
132. CCFH54 also agreed to revisit this text as soon as Annex II on Fish and Fishery Products of the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023) was completed.

**PROPOSED DRAFT GUIDELINES FOR FOOD HYGIENE CONTROL MEASURES IN TRADITIONAL MARKETS FOR FOOD (Agenda Item 8)<sup>14</sup>**

133. Kenya, as chair of the EWG, speaking also on behalf of Bolivia and Nigeria as co-chairs, recalled that the new work on this topic recommended by CCFH53 had been approved by CAC46. In introducing the work undertaken since CCFH53, Kenya highlighted that the draft guidelines had been informed by the regional guidelines/codes of practice related to street-vended foods; that there had been broad Member and Observer engagement in their development; and that they had undergone two rounds of review in the EWG. Kenya noted that that some of the key decisions of the EWG were to retain the title as originally proposed and to develop a unique structure rather than align with CXC 1-1969 so as to adequately address some of the characteristics of traditional markets for foods.
134. With reference to the request of CAC47 to carefully consider the relationship between these new guidelines and the regional guidelines/codes of practice, feedback in response to CL 2024/11/FH indicated that there was general agreement that these guidelines should be complimentary to the existing texts. Kenya noted that a revised version taking into consideration written comments received had been published as CRD06; that in their view there was agreement on most aspects of the guidelines, noting that two key issues for discussion were the extent to which the guidelines should address live animals in markets and how water should be characterized in the text. Kenya proposed that CRD06 be used as the basis for discussion.

<sup>14</sup> CX/FH 24/54/9; CX/FH 24/54/9 Add 1 (Australia, Canada, Colombia, Ecuador, European Union, Iraq, Japan, Malaysia, New Zealand, Peru, Thailand, Togo, Uganda, United Arab Emirates, Uruguay, and Centre for Climate Change and Environmental Studies, ICUMSA, World Food Programme); CRD06 (EWG); CRD12 (Argentina, Malaysia, Republic of Korea, Singapore, Rwanda, GAIN); CRD18 (Ghana), CRD19 (Morocco); CRD20 (African Union); CRD21 (Nigeria); CRD22 (East African Community); CRD23 (India); CRD25 (South Africa); CRD27 (Senegal); CRD28 (Uganda); CRD29 (Burundi); CRD30 (Philippines); CRD31 (Guyana); CRD35 (United Republic of Tanzania)

## Discussion

135. A general discussion indicated the importance of developing these guidelines with Members and Observers sharing a range of views as follows:
- It was important to advance these guidelines to avoid having a vacuum in Codex texts when it came to traditional markets for food.
  - Once adopted such guidance could be revised as new information became available.
  - Specific food safety challenges existed in traditional markets for foods and the guidelines, such as the ones under development, provided an important framework to begin addressing these.
  - The proposed draft guidelines were complementary to the existing regional texts and aligned with the overall objective of the general principles for food hygiene.
  - There were organizations willing to support implementation of these guidelines once adopted including the related capacity development.
  - The guidelines had huge potential to improve global food safety outcomes, and this was in line with the Codex strategic goal to deliver impact through the recognition and use of Codex standards.
  - It's estimated that over 70% of consumers in the African and Asian regions source food for household consumption from these markets, while these same regions experience very high rates of foodborne disease, hence it was critical that such markets were addressed in Codex texts.
  - The guidelines would help market actors to identify and practice better food handling and market management, with the goal of significantly reducing consumer exposure to food safety risks within traditional markets.
  - There was a need for continued investment in improving food safety in traditional markets for food, and this involved upgrading market infrastructure, improving the supply chain, and providing education and training to vendors and consumers.
  - Traditional markets for food existed around the world and played an important role when it came to access to food from both domestic and cross-border supply chains.
136. The WHO Representative explained that WHO was in the process of developing a guideline on traditional markets for food that would focus on the mitigation of public health risks arising from the human-animal interface in food markets including live animals. The Representative noted that the development process was science-based, included systematic reviews and public consultation and was expected to span two years and once available, the Codex guideline could be reviewed and updated as appropriate.
137. Noting overwhelming support to advance the guidelines, CCFH54 agreed to use CRD06 as the basis for its discussions and considered the text paragraph by paragraph. In addition to editorial corrections, and amendments for clarity and consistency, CCFH54 made the following comments and decisions.

### Title

138. There were suggestions to revise the title to refer to traditional food markets to align with other international texts. The Representative from WHO clarified that the current text was in line with WHO terminology. It was further noted that traditional food markets lacked clarity and could be understood to be the type of food marketed. The title was retained as originally proposed.

### Introduction

139. The wording "in the framework of a one health approach" was added to the end of the introduction for the purpose of acknowledging that efforts to improve food safety should be understood within the broader perspective of a one health approach, which emphasizes the integration of human, animal, and environmental health.

### Section 1 - Objectives and Section 2 - Scope and Use

140. One Member while agreeing that the guidance should not apply to markets selling live animals, noted that nevertheless traditional markets may also sell live animals, which may represent an important risk for food contamination and proposed to include a recommendation in the guidance to avoid such contamination e.g. the separation of vending areas. The EWG chair considered that this aspect was addressed in section 4.3 and no further changes were made.

### Section 3 - Definitions

141. Food Grade: "and serving" was added to the end of the definition to reflect the complete food chain.

142. Food Vendor: following a proposal to remove this definition and just use the term “food business operator” (FBO) throughout the text, the need to distinguish those who only sold food (food vendors) compared to those that may also have a role prior to sale of food (FBO), such as processing/preparation was reiterated as requirements in relation to training and education needs etc would vary. Food vendor was retained in the text.
143. Traditional markets for food: examples of types of traditional markets were added as follows to the end of the definition to improve clarity on the scope of the guidelines as follows: “Examples include but are not limited to street food markets, local markets, public markets, community markets, municipal markets, open-air markets, wet markets and farmers markets.”
144. Market Authority: CCFH54 revised the definition as follows for improved clarity and completeness. “The entity or person responsible for the administration of the traditional market which may include market committees and associations of food business operators”.

#### Section 4 - General requirements

145. Paragraph 4.1.2: “and/or locality” was added to the end of the sentence to indicate that risk factors could be specific to a particular locality as well as type of operation.
146. Paragraph 4.1.7: to better reflect the role of competent authorities the sentence was revised to replace “food safety controls” with “and enforce regulatory measures”
147. Paragraph 4.1.10: to increase flexibility “where applicable” was added at the beginning of the sentence.
148. A new paragraph 4.4.5 was added to illustrate the role of a One Health approach in minimizing the potential risks from wild animals and meat of wildlife in the market setting and in regional trade.

#### Section 5 - Food business operators

149. Paragraph 5.2.1: “clothing” was added to the sentence after “clean” to reflect the importance of the behaviour of wearing clean clothing as part of food safety practices.
150. Paragraph 5.2.6: the recommendation was strengthened to indicate that smoking and chewing gum should not be allowed due to related food safety concerns.
151. Paragraph 5.3.3: noting a proposal to define community health workers, to ensure there was clarity on the type of skills such workers would need to provide training, CCFH54 considered that since the text indicated to include these “as appropriate” there was sufficient flexibility on whether they were involved or not according to the local context and hence a definition was not needed.
152. Paragraph 5.4.1: “should” was replaced with “may” to provide more flexibility.
153. Paragraph 5.5.2: “as appropriate to support food safety” was added at the end to ensure that record keeping did not become overburdensome, especially for small FBOs.

#### Section 6 - Location, design, layout and structures

154. Paragraph 6.3.1: noting that some markets may be very small and have limited structure, some Members considered it was important to bring more flexibility to this paragraph and recognize that not all structures needed to be approved by competent authorities but simply reviewed. Others indicated the importance of maintaining approval. In this context both review and approval were included. In addition to competent authorities, the text was also revised to indicate that market authorities or FBO organizations could also undertake these tasks as necessary.
155. Paragraph 6.3.6: to avoid being prescriptive on market structures, reference to being roofed was removed and replaced with “appropriate features/facilities” to minimise effects of extreme weather.
156. Paragraph 6.3.11: an extensive discussion on type of water that should be referred to in this paragraph concluded that reference be made to potable water only, with a cross-reference to CXG 100-2023 where such water was defined, noting that this definition was broad and did not preclude disinfection of the water. Reference to “running” was also removed, as potable water may be provided in different ways. Changes were also made in other parts of the text for consistency with these decisions.

#### 6.5 Sanitation

157. The title was changed to include water as well as sanitation and therefore better reflect the content of the section. It was noted that there might be some duplication in this section with earlier text but given the focus of this section, it was considered important to reiterate guidance related to water.
158. Paragraph 6.5.2.4: Bins was replaced with “receptacles and/or containers” to be more inclusive and the same change was made through the document as needed for consistency.

159. Paragraph 6.5.3: “sufficient” was added to indicate that toilets and sanitary facilities should be adequate considering market size.

#### Section 7 - Food preparation

160. Title: it was proposed that “control of” should be added in front of the words in this title as that was what the section addressed as opposed to preparing food. However, it was noted that the overall title of the guidelines was about “control” and changes to this title would then have to be considered for all other subtitles. It was therefore agreed to retain as written.
161. Paragraph 7.1.7: For consistency with 5.5.2, “as appropriate to support food safety” was added at the end of the sentence.
162. Paragraph 7.2.1: “and disinfected when necessary” was included in addition to keeping equipment clean, with “when necessary” added in recognition that not all equipment may need to be disinfected, for example, if it was going to be heated before or during use.
163. Paragraph 7.3.1: “as required” was added at the end to improve flexibility.
164. Paragraph 7.3.2: “When feasible” was replaced by “when appropriate” as disinfection of fruit and vegetables should be based on the need to implement such a risk management measure, not whether it was possible or not.
165. A new paragraph was inserted after paragraph 7.3.7 on the management of fats and oils used for frying, noting that these not only presented food quality but also food safety concerns.

*Oil and grease used frying should be replaced on a regular basis whenever there is an apparent change in physical/chemical characteristics, such as dark colour, intense foaming, smoke formation, or sensory changes, such as aroma and taste.*

#### 7.4 Serving Food

166. In the chapeau, “observe” was replaced with “comply with” to enhance accuracy.
167. All remaining sections were agreed as presented in CRD06. A proposal to expand the responsibilities in section 8 on consumers to competent and market authorities was considered but it was agreed that the intent of this section was to identify the role consumers could play and hence it was retained as written.
168. CCFH54 noted that there were no outstanding issues on the document.

#### **Conclusion**

169. CCFH54 agreed to forward the proposed draft guidelines for food hygiene control measures in traditional markets for food to CAC47 for adoption at Step 5/8 (Appendix VI).
170. Following adoption of this text by CAC47, and recalling the recent revision of CXC 1-1969, CCFH54 requested the relevant FAO/WHO Coordinating Committees to review their respective texts on street vended foods to ensure consistency with CXC 1-1969 and the guidelines for food hygiene control measures in traditional markets for foods and consider the necessary follow-up action (e.g., revision).

#### **ALIGNMENT OF CODEX TEXTS DEVELOPED BY CCFH WITH THE REVISED *GENERAL PRINCIPLES OF FOOD HYGIENE* (CXC 1-1969) (Agenda Item 9)<sup>15</sup>**

171. The United Kingdom presented the item and recalled that CCFH53 had tasked them with preparing a document for CCFH54 to initiate work and propose options for aligning Codex food hygiene texts with the revised *General Principles of Food Hygiene* (CXC 1-1969). In response to this request, the United Kingdom drafted a document (CX/FH 24/54/10), which outlined three alignment options: option 1 for simple alignment, option 2 for full structural alignment, and option 3 for full structural and technical alignment. The document also included a worked example to illustrate the alignment requirements and considerations for prioritization and feasibility of the work. CL 2024/12-FH was distributed to collect comments, which were then analyzed by the United Kingdom. The United Kingdom made the following recommendations:

- Prioritizing the work, dividing it, and integrating it into the future work plan;

<sup>15</sup> CX/FH 24/54/10; CX/FH 24/54/10 Add.1 (Argentina, Australia, Canada, Colombia, Ecuador, European Union, Iraq, Japan, Kenya, Malaysia, New Zealand, Peru, Russian Federation, Saudi Arabia, United Arab Emirates, Uruguay, USA and ICUMSA); CRD13 (Argentina, Malaysia, Singapore and Thailand); CRD18 (Ghana); CRD19 (Morocco); CRD20 (African Union); CRD21 (Nigeria); CRD22 (East African Community); CRD23 (India); CRD24 (Institute of Food Technologists); CRD25 (South Africa); CRD28 (Uganda); CRD29 (Burundi); CRD31 (Guyana); CRD35 (United Republic of Tanzania); CRD37 (Russian Federation)

- Establishing a standing working group to consider how to prioritize the alignment of existing texts, divide the work, and collaborate with the Chairperson of the EWG on updating the future work plan;
- Adopting a hybrid approach to alignment: aligning texts undergoing technical revisions or part of the forward work plan (Part A) within existing or upcoming EWGs according to Option 3 and aligning remaining texts not included in part A of the forward work plan through a dedicated Alignment Working Group according to Option 2; and
- Considering the age of the text as a possible mechanism for prioritizing alignment. For instance, texts like the *Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015) modified in 2018, and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (53-2003) modified in 2017, could be given priority.

### Discussion

172. Members expressed their appreciation to the United Kingdom for preparing this comprehensive document and generally agreed with the recommendations put forward by the United Kingdom.
173. Members expressed a range of views as follows:
- i. The hybrid approach was an appropriate way forward;
  - ii. Option 3 should be applied to all Codex texts developed by CCFH as it offered the most comprehensive solution to current misalignments and inconsistencies with the revised CXC 1-1969;
  - iii. The application of full structural and technical alignment with CXC 1- 1969 for all texts undergoing development or revisions should be included in the terms of reference of the respective EWGs;
  - iv. EWGs taking on new work proposals should have the flexibility to choose either option 2 or option 3, rather than being limited to option 3; and
  - v. It was important to avoid duplication of work and a relationship between the proposed EWG on alignment and new work/forward work plan working group should be established, to better inform the forward work plan.
174. In response to a question regarding the formal procedures for agreement on changes to texts following structural alignment, with CXC 1-1969, the Codex Secretariat clarified that any alignment work would need to be reviewed and agreed by CCFH before submission for adoption by CAC.
175. Regarding the alignment of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010) with CXC 1-1969, CCFH54 agreed that this matter should be considered under Agenda Item 7, taking into consideration the work that had already been undertaken in revising the guidelines.

### Conclusion

176. CCFH54 agreed to:
- i. prioritize the work on alignment and integrate it into its work plan; and
  - ii. adopt a hybrid approach to alignment as follows:
    - a. texts undergoing technical revision or are included in Part 1 of the Forward Workplan be structurally aligned with CXC 1-1969 by the relevant EWGs and that the EWGs also align the technical content as necessary with CXC 1-1969. This task should also be reflected in the Terms of Reference for the relevant EWGs; and
    - b. texts in Part 2 of the Forward Workplan that require alignment (See Appendix VII), are structurally aligned with CXC 1-1969 by an alignment EWG.
177. CCFH54 further agreed to establish an EWG on alignment, chaired by China and co-chaired by the United Kingdom and the European Union, working in English. The EWG should:
- i. initiate the structural alignment work starting with the most recently modified texts listed in Appendix VII and establish a timeframe for completing alignment with the *General Principles of Food Hygiene* (CXC 1-1969). The alignment work should:
    - a. include a review of the texts for suitability for full structural alignment with CXC 1-1969;
    - b. structurally align the texts with the Main Headings of CXC 1-1969;



- c. provide simple cross-references to CXC 1-1969 where there is no existing text in the document being aligned;
  - d. include cross-reference to sections 16-19 (HACCP) which were not present in earlier versions of CXC 1-1969;
- ii. identify any aspects that prevent or create particular challenges for structural alignment, for example, a unique structure, age of text, outdated text etc. and where feasible provide recommendations on how these might be addressed, for consideration by CCFH55;
  - iii. liaise with the working group on the new work/forward workplan; and
  - iv. submit a report with the proposed aligned texts and any challenges encountered and possible recommendations on next steps. This report should be submitted to the Codex Secretariat three months prior to CCFH55.

**REVISION OF THE GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO CONTROL OF VIRUSES IN FOOD (CXG 79-2112) (Agenda Item 10)<sup>16</sup>**

178. This item was considered under Agenda Item 13.

**DISCUSSION PAPER ON THE REVISION OF GUIDELINES FOR THE CONTROL OF CAMPYLOBACTER AND SALMONELLA IN CHICKEN MEAT (CXG 78-2011) (Agenda Item 11)<sup>17</sup>**

179. This item was considered under Agenda Item 13.

**DISCUSSION PAPER ON THE REVISION OF GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF LISTERIA MONOCYTOGENES IN FOODS (CXG 61-2007) (Agenda Item 12)<sup>18</sup>**

180. This item was considered under Agenda Item 13.

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)<sup>19</sup>**

181. The USA, as the Chair of the PWG, presented the recommendations of the PWG (CRD05), highlighting some of the factors that had been considered in reviewing the forward work plan including the availability of scientific advice and the time until CCFH55, as well as the information available in each of the discussion papers and project documents (Agenda Items 10, 11 and 12). Based on the discussions during the PWG, it was noted that two of the project documents, one concerning the revision of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* (CXG 79-2012), and the other regarding the revision of *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011), had been revised and published as CRD34.
182. The PWG noted that the three proposals had been reviewed and were determined as having the same importance in terms of public health and trade impact and the PWG supported work on all three items.
183. CCFH54 considered the recommendations of the PWG, noted that with the progress made at CCFH54 there was sufficient space on the agenda to take forward all three new work proposals and made the following comments and decisions.

**New work**

*Revision of the Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (CXG 79-2012)*

<sup>16</sup> CX/FH 24/54/11; CRD14 (Argentina, European Union, Singapore, Thailand), CRD18 (Ghana), CRD19 (Morocco); CRD20 (African Union), CRD21 (Nigeria), CRD 22(East African Community); CRD25 (South Africa); CRD28 (Uganda); CRD29 (Burundi); CRD35 (United Republic of Tanzania)

<sup>17</sup> CX/FH 24/54/12; CRD 15 (Argentina, European Union, Thailand); CRD18 (Ghana), CRD19 (Morocco); CRD20 (African Union), CRD21 (Nigeria), CRD22(East African Community); CRD25 (South Africa); CRD28 (Uganda); CRD29 (Burundi); CRD35 (United Republic of Tanzania); CRD37 (Russian Federation)

<sup>18</sup> CX/FH 24/54/13; CRD16 (Argentina, European Union, Singapore, Thailand); CRD18 (Ghana), CRD19 (Morocco); CRD20 (African Union), CRD21 (Nigeria), CRD22(East African Community); CRD25 (South Africa); CRD28 (Uganda); CRD29 (Burundi); CRD35 (United Republic of Tanzania); CRD37 (Russian Federation)

<sup>19</sup> CX/FH 24/54/14; CRD17 (Thailand); CRD20 (African Union); CRD22 (East African Community); CRD24 (Institute of Food Technologists); CRD25 (South Africa); CRD28 (Uganda); CRD29 (Burundi); CRD35 (United Republic of Tanzania)

184. Canada, also on behalf of the Netherlands, introduced the revised project document (CRD34) and noted that the main aspects to be covered by the new work included: expansion of the scope to address HEV and emerging food vehicles such as frozen berries or prepared foods; revisions of interventions along the food chain; addition of information on virus detection in food; any new considerations following the review of the various risk assessment models and also proposed to organize the annexes to cover the various commodities based on the latest JEMRA scientific advice (i.e., shellfish, prepared and ready-to-eat foods, fresh and frozen produce, pork and wild game meat). Canada highlighted the revisions to the project document in response to comments received during the PWG and further noted that four of the requests for scientific advice had already been addressed by JEMRA and that the response to the fifth request was still pending from JEMRA. There were no additional scientific advice requests at this time.
185. CCFH54 supported the new work and agreed:
- i. to forward the revised project document to CAC47 for approval as new work (Appendix VIII);
  - ii. to establish an EWG, chaired by Canada and co-chaired by the Netherlands, working in English (comments in French would also be accepted), subject to approval of Commission, to:
    - a. prepare the proposed draft revisions for circulation for comments at step 3 and consideration at CCFH55; and
    - b. undertake a full alignment of the text with CXC1-1969, as necessary.
186. The report of the EWG should be submitted to the Codex Secretariat at least three months before CCFH55 for circulation for comments at Step 3.
- Revision of *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011)
187. The USA introduced the discussion paper, also on behalf of Brazil, Honduras and New Zealand and highlighted the importance of this work considering the level of foodborne disease associated with *Salmonella* and *Campylobacter*, the importance of chicken meat and the continued growth of the industry. The USA noted that the proposed new work would address pre-harvest and post-harvest interventions, practical interventions, methods of microbiological monitoring and pathogen characterization. Noting some concerns that had been expressed by inclusion of molecular methods, the USA indicated that while these would be considered it was also important that the document was forward looking and considered recent developments. Finally, the USA highlighted that the scientific advice from JEMRA to support this work was already available. There were no further requests for scientific advice at this time.
188. CCFH54 supported the new work and agreed:
- i. to forward the revised project document to CAC47 for approval as new work (Appendix IX); and
  - ii. to establish an EWG, chaired by the USA and co-chaired by Australia, Brazil, Denmark, Honduras, and India, working in English (comments in Spanish would also be accepted), subject to approval of Commission, to:
    - a. prepare the proposed draft revisions for circulation for comments at step 3 and consideration at CCFH55; and
    - b. undertake a full alignment of the text with CXC1-1969, as necessary.
189. The report of the EWG should be submitted to the Codex Secretariat at least three months before CCFH55 for circulation for comments at Step 3.
190. One Member proposed that comments in French should also be accepted. However, the USA clarified that, it did not have the capacity or expertise among the Chair and co-Chairs, to ensure accurate interpretation of comments in French and the Chairperson reminded CCFH54 that when the document was circulated at Step 3, comments could be provided in English, French and Spanish.
- Revision of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods* (CXG 61-2007)
191. Canada, also on behalf of France and the USA, introduced the revised project document (CRD34) and noted that the new work would consider control measures throughout the production-to-consumption chain, microbiological monitoring methods and consumer practices. Canada noted that JEMRA had already undertaken expert meetings on the topic and that there was sufficient scientific advice available to begin this work. There were no further requests for scientific advice at this time.
192. CCFH54 supported the new work and agreed:
- i. to forward the revised project document to CAC47 for approval as new work (Appendix X);

- ii. to establish an EWG, chaired by the USA and co-chaired by Canada, China and France, working in English (comments in French would also be accepted), and, subject to approval of Commission, to:
  - a. prepare the proposed draft revisions for circulation for comments at step 3 and consideration at CCFH55; and
  - b. undertake a full alignment of the text with CXC1-1969, as necessary.
193. The report of the EWG should be submitted to the Codex Secretariat at least three months before CCFH55 for circulation for comments at Step 3.
194. CCFH54 noted that the three EWGs may undertake informal virtual meetings of the EWG to facilitate their discussions and that PWGs for these new work items would not be possible at CCFH55.

#### Food allergens

195. CCFH54 noted that the suggestion from CCFL47 to ensure consistency between the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) and their new provisions on food allergens in the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) in the future and suggested that a Member may wish to prepare a discussion paper ahead of CCFH55, based on the outcomes of CCFL48.

#### **Forward Workplan**

196. CCFH54 agreed to:
  - i. endorse the report of the PWG and revised forward work plan (Appendix XI);
  - ii. establish a PWG on CCFH Work Priorities, chaired by the USA, to be held in conjunction with CCFH55, working in English, French and Spanish;
  - iii. request the Codex Secretariat to issue a Circular Letter requesting proposals for new work with a deadline of 1<sup>st</sup> September 2025 as per normal practice; and
  - iv. encourage Members to submit any new discussions papers/new work proposals (e.g. on food allergens) in response to the Circular Letter.

#### **DATE AND PLACE OF THE NEXT SESSION (Agenda Item 14)**

197. CCFH54 was informed that CCFH55 would be held towards the end of 2025 in the USA with the final arrangements subject to confirmation by the host Government in consultation with the Codex Secretariat.

## APPENDIX I

**LIST OF PARTICIPANTS  
LISTE DES PARTICIPANTS  
LISTA DE PARTICIPANTES**

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## APPENDIX II

## ANNEX II ON FRESH LEAFY VEGETABLES

(at Step 5/8)

## INTRODUCTION

1. Fresh leafy vegetables are grown, processed, and consumed throughout the world. They are grown on open fields or in fully- or partially-protected facilities of varying sizes; distributed and marketed locally and globally, providing year-round availability to consumers; and sold as fresh whole, fresh pre-cut or other ready-to-eat (RTE) products such as pre-packaged salads.
2. Outbreaks of illness caused by a broad range of microbial pathogens, including Shiga toxin-producing *Escherichia coli* (STEC), have been linked to the consumption of fresh leafy vegetables. Epidemiological evidence, outbreak investigations, research, and risk assessments have identified several possible contamination sources of fresh leafy vegetables with STEC, including water, domestic and wild animals, workers, and improperly treated manure-based soil amendments<sup>i</sup>. Fresh leafy vegetables are packed in diverse ways, including field packed for direct transport to market; field cored and prepared for later processing; and as pre-cut fresh leafy vegetable mixtures and blends with other vegetables.
3. Control measures such as antimicrobial treatments to minimize cross-contamination may be applied prior to packaging and/or shipment to market, although internalization of STEC in leaves may reduce the effectiveness of such treatments. As fresh leafy vegetables move through the supply chain, there is also the potential for the introduction and growth of pathogens, including STEC. The increasing worldwide use of pre-packaged fresh-cut leafy vegetables to expand the supply chain might increase the potential for the presence of contaminated product in the marketplace through cross-contamination with STEC, and STEC replication during processing, distribution and storage if fresh-cut leafy vegetables are improperly handled. There is no processing treatment applied to fresh leafy vegetables that would eliminate or inactivate STEC, although contamination can be reduced by measures and treatments such as washing in water that may contain biocides. Examples of field level control measures provided in this document are illustrative only and their use and approval by competent authorities may vary by country.
4. It is recognized that some of the provisions in this Annex may be difficult to implement in areas where primary production is conducted in small holdings, whether in countries with developed or developing economies, and in areas where traditional farming is practiced. The Annex is, therefore, a flexible one, to allow for diverse systems of control and prevention of contamination for different cultural practices and growing conditions. Figure 1 provides a flow diagram illustrating a generalized process flow for fresh leafy vegetables. This flow diagram is for illustrative purposes only. Steps may not occur in all operations (as shown with dotted lines) and may not occur in the order presented in the flow diagram.

## 1. OBJECTIVE

5. The objective of this Annex is to provide guidance to prevent or reduce the risk of foodborne illness from STEC associated with fresh leafy vegetables intended to be consumed raw, during primary production, harvesting, packing, processing, storage, distribution, marketing, and for consumer awareness.

## 2. SCOPE, USE AND DEFINITIONS

## 2.1 Scope

6. This Annex covers specific guidance for the control of STEC related to fresh leafy vegetables that are intended to be consumed raw. The Annex is applicable to fresh leafy vegetables grown in open fields or in fully or partially-protected facilities (hydroponic systems, greenhouses / controlled environments, tunnels, etc.).

## 2.2 Use

7. This Annex should be used in conjunction with the *General Principles of Food Hygiene* (CXC 1-1969),<sup>1</sup> the *Guidelines for the Safe Use and Reuse of Water in Food Production*, Annex I Fresh Produce (CXG 100-2023)<sup>2</sup> and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).<sup>3</sup>

## 2.3 Definitions

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<sup>i</sup> "Soil amendments" are fertilizers soil improvers, conditioners, or other material added to a soil to improve nutrients or the soil's physical properties, such as water retention, permeability, water infiltration, and drainage.

8. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)<sup>1</sup> and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),<sup>3</sup> including Annex I for Ready-to-Eat Fresh, Pre-cut Fruits and Vegetables and Scope of Annex III for Fresh Leafy Vegetables.
  - **Fresh leafy vegetables** – Vegetables of a leafy nature where the leaf is intended for consumption raw, including, but not limited to, all varieties of lettuce, spinach, cabbage, chicory, endive, kale, radicchio, and fresh herbs such as coriander/cilantro, basil, curry leaf, colocasia leaves and parsley, among other local products for foliar consumption.

### 3. PRIMARY PRODUCTION

9. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)<sup>1</sup> and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).<sup>3</sup> As noted in CXC 1-1969,<sup>1</sup> some of the principles of HACCP can be applied at primary production and may be incorporated into good agricultural practices for the production of fresh leafy vegetables to minimize contamination with STEC.
10. In each primary production area, it is necessary to consider the agricultural practices and procedures that could minimize the potential for contamination of fresh leafy vegetables with STEC, taking into account the conditions specific to the primary production area, type of products, and types of methods used in growing, including irrigation source and use of organic fertilization and harvesting.

#### 3.1 Location of the production site

11. Potential sources of STEC contamination should be identified prior to commencement of primary production activities and periodically evaluated for changes. Where possible, growers should evaluate present and previous uses of both indoor and outdoor fresh leafy vegetable primary production sites and the nearby and adjacent land (e.g. animal production, sewage treatment site) in order to identify potential sources of STEC. The assessment of potential sources of contamination is particularly important because subsequent interventions would not be sufficient to fully remove STEC contamination that occurs during primary production, and in some cases, conditions may enable the growth of STEC, thereby increasing the risk of illness for consumers.

##### 3.1.1 Neighbouring animal farms

12. Animal production facilities located in proximity to sites where fresh leafy vegetables are grown and access to the growing site by wildlife can pose a significant likelihood of contamination of production fields or water sources with STEC. Concentrated animal feeding operations, dairy farms, cattle grazing lands, and other similar operations present a significant risk of contamination of fresh leafy vegetables in the field. Although guidelines exist for the distance between fields and nearby animal operations, the safe distance depends on factors that can increase or decrease the risk of contamination, such as topography of the land and opportunity for water runoff through or from such operations. Growers should evaluate the potential for such contamination and take measures to mitigate the risk of STEC contamination associated with runoff and flooding (e.g. terracing, digging a shallow ditch to prevent runoff from entering the field).

##### 3.1.2 Environmental conditions

13. If the environment presents a likelihood of contamination of the primary production site with STEC, measures should be implemented to minimize the potential for contamination of fresh leafy vegetables at the site. When the likelihood of contamination cannot be managed or minimized, the production site should not be used for fresh leafy vegetable production.
14. The effects of some environmental events cannot be controlled and may need to be evaluated. For example, heavy rains or flood events may increase the exposure of fresh leafy vegetables to STEC. When heavy rains occur, growers should evaluate the need to postpone harvesting fresh leafy vegetables for consumption. Fresh leafy vegetables that contact flood waters should not be consumed unless approved by the competent authority. In doing so, the competent authority should require a risk assessment to identify necessary measures to ensure safety of the fresh leafy vegetables. This does not include flooding of furrows for irrigation purposes, where the source of water is known and of appropriate quality and is not the result of a weather event.

##### 3.1.3 Animal activity

15. Some wild and domestic animals present in the primary production environment are known to be potential carriers of STEC. Wild animals represent a particularly difficult risk to manage because their presence is

intermittent. The following are particularly important to minimize the potential for animal activity to contaminate fresh leafy vegetables with STEC:

- Appropriate methods should be used in order to exclude animals from the primary production and handling areas to the extent practicable. Possible methods include the use of physical barriers (e.g. fences) and active deterrents (e.g. noise makers, scarecrows, images of owls, foil strips).
- Primary production and handling areas should be properly designed and maintained to reduce the likelihood of attracting animals that can contaminate fresh leafy vegetables with STEC. Possible methods include minimizing standing water in fields, restricting animal access to water sources from use in production (e.g. irrigation and washing), and maintaining production sites and handling areas free of waste and clutter.
- Fresh leafy vegetable primary production areas should be regularly checked for evidence of the presence of wildlife or domestic animal activity (e.g. presence of animal faeces, bird nests, hairs/fur, large areas of animal tracks, burrowing, decomposing remains, crop damage from grazing), particularly near the time of harvesting. Where such evidence exists, growers should evaluate the risks to determine whether the fresh leafy vegetables in the affected area of the production site should be harvested for consumption with further processing that eliminate STEC (e.g. cooking).

### 3.2 Hygienic primary production of fresh leafy vegetables

#### 3.2.1 Water for primary production

16. Several parameters may influence the likelihood of contamination of fresh leafy vegetables with STEC from water: the source of water used for irrigation and the application of fertilizers and pesticides, the type of irrigation (e.g. drip, furrow, sprinkler, overhead), whether the edible portions of fresh leafy vegetables have direct contact with irrigation or other water, the timing of final irrigation in relation to harvesting and, most importantly, the occurrence of STEC in the water used for irrigation or application of pesticides or fertilizers. Growers should identify and evaluate the sources of water used on the farm for the likelihood of contamination with STEC and identify measures to prevent or minimize STEC contamination (e.g. from livestock, wildlife, sewage treatment, human habitation, manure, and composting operations, or other intermittent or temporary environmental contamination, such as heavy rain or flooding). (Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003)<sup>3</sup> and the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023),<sup>2</sup> including Annex 1 “Fresh Produce”.
17. Depending on the water source and guidelines of the competent authority, growers should assess the microbiological quality of water and its suitability for the intended use by testing the water for indicator microorganisms and, where necessary, STEC. The frequency of testing will depend on the water source (i.e. lower for adequately maintained deep wells, higher for surface waters), the risks of environmental contamination, including intermittent or temporary contamination (e.g. heavy rain, flooding), or the implementation of a new water treatment process by growers.
18. If the intended water source is found to contain unacceptable levels of indicator microorganisms or is contaminated with STEC, corrective actions should be taken to ensure that the water is suitable for its intended use. Possible corrective actions to prevent or minimize contamination of water for primary production may include the installation of fencing to prevent large animal contact, the proper maintenance of wells, water filtering, chemical water treatment, the prevention of the stirring of the sediment when drawing water, the construction of settling or holding ponds or water treatment facilities. The effectiveness of corrective actions should be verified by immediate water testing and then periodically thereafter where appropriate. Where possible, growers should have a contingency plan in place that identifies an alternative source of water fit for purpose. Refer to the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023),<sup>2</sup> including Annex 1 “Fresh Produce”.
19. It is especially critical in hydroponic operations to maintain the microbiological quality of water used as the growth medium for fresh leafy vegetables to reduce the likelihood of contamination and survival of STEC; the nutrient solution used may enhance the survival or growth of STEC. (Refer of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* [CXC 53-2003]).<sup>3</sup>

#### 3.2.2 Manure, biosolids and other natural fertilizers

20. The use of manure, biosolids and other natural fertilizers in the production of fresh leafy vegetables should be managed to limit the potential for contamination with STEC. STEC can persist in manure, biosolids and other natural fertilizers for weeks or even months, if treatment of these materials is inadequate. Composting can be effective in controlling STEC in manure, depending on factors that include time,



temperature, indigenous microorganisms, moisture, composition of the compost, pile size, and turning of the pile. Another manure treatment method involves anaerobic digestion. Treatment methods should be validated to inactivate STEC. Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003)<sup>3</sup> for practices to minimize contamination of fresh leafy vegetables with microbial pathogens such as STEC in manure, biosolids and other natural fertilizers.

### 3.2.3 Personnel health, hygiene, and sanitary facilities

21. Hygiene and health requirements should be followed to ensure that personnel who come into direct contact with fresh leafy vegetables prior to, during or after harvesting, will not contaminate them with STEC (e.g. have not had prior contact with animals). Adequate access to, and use of, hygienic and sanitary facilities, including means to effectively clean and dry hands, are critical to minimize the potential for workers to contaminate fresh leafy vegetables. People known or suspected to be suffering from gastrointestinal illness should not be allowed to enter any area where handling fresh leafy vegetables occurs, including the harvest area. Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003)<sup>3</sup> for practices to minimize microbial pathogens such as STEC.

### 3.2.4 Harvesting

22. The field should be evaluated for animal intrusion, the presence of faecal deposits, or other sources of STEC contamination prior to harvest to determine if the field or portions thereof should not be harvested. Growers should avoid moving harvesting equipment across fields where manure or compost has been applied. Harvesting equipment should be designed and constructed to ensure that, when necessary, it can be cleaned, disinfected, and maintained to avoid the contamination of fresh leafy vegetables (e.g. if the equipment runs over an area with animal intrusion and faecal deposits). Field containers and any containers stored outside to be re-used should be cleaned and, as appropriate, disinfected before being used to transport fresh leafy vegetables.

### 3.2.5 Field packing

23. When packing fresh leafy vegetables in the field, care should be taken to avoid contaminating containers or bins by exposure to manure or other contamination sources, noting that containers are often open-topped and stacked. When fresh leafy vegetables are trimmed or cored in the field, knives and cutting edges should be cleaned and disinfected frequently to minimize the potential for cross-contamination with STEC.

### 3.2.6 Storage and transport from the field to the packing or processing facility

24. Fresh leafy vegetables should be stored and transported under conditions that will minimize the potential for STEC contamination and/or growth and noting that containers are often open-topped and stacked. Fresh leafy vegetables should not be transported in vehicles previously used to carry potentially contaminated materials (e.g. heavily soiled root vegetables, live animals, animal manure, compost, or biosolids). When vehicle receptacles or containers have been used for the transport of products other than fresh leafy vegetables, effective cleaning and disinfection should be carried out between loads to avoid cross-contamination.

## 4. PACKING OPERATIONS

25. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)<sup>1</sup> and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).<sup>3</sup>

### 4.1 Time and temperature control

26. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).<sup>1</sup> Time and temperature control during packing and storage is essential to prevent growth of any STEC that may be present, since an increase in numbers of STEC will increase the risk of illness.

### 4.2 Cooling fresh leafy vegetables

27. The cooling of fresh leafy vegetables should take place as rapidly as possible to minimize growth of any STEC that may be present, and in a manner that does not contribute to contamination of product with STEC. For example, fresh leafy vegetables can be cooled immediately after harvest by using ice (e.g. for parsley), forced-air cooling, vacuum cooling (e.g. for iceberg lettuce), hydrocooling or spray-vacuum (hydro-vac) cooling. When cold damage is not a concern, fresh leafy vegetables should be cooled to appropriate refrigeration temperatures<sup>ii</sup> to prevent the growth of STEC. For fresh leafy vegetables

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<sup>ii</sup> *E. coli* O157:H7 and other STEC are unlikely to grow on fresh leafy vegetables at temperatures lower than 7 °C, based on available scientific evidence.

susceptible to quality damage at refrigeration temperatures, the growth of STEC should be minimized by cooling to temperatures as low as possible while avoiding quality damage.

28. If water, including ice, used for cooling comes into direct contact with fresh leafy vegetables, it should be fit for purpose to minimize the likelihood of cross-contamination. When biocides are used, the concentration and other appropriate parameters (e.g. pH and temperature) in this water should be controlled, monitored, and recorded to ensure that biocides are sufficient to prevent microbial growth in the processing water, and to reduce the potential for cross-contamination.

#### **4.3 Washing fresh leafy vegetables.**

29. The washing of fresh leafy vegetables should follow good hygienic practices (GHPs) to prevent or minimize the potential for the introduction or spread of STEC in wash water. All water used for cooling and washing fresh leafy vegetables should be fit for purpose. If necessary, biocides should be added to wash water as per GHPs, with their levels monitored, controlled and recorded regularly during production to ensure the maintenance of effective concentrations. The characteristics of post-harvest water that may impact the efficacy of the biocidal treatments (e.g. the pH, turbidity and water hardness) should be controlled, monitored and recorded.

### **5. PROCESSING OPERATIONS**

30. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)<sup>1</sup> and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),<sup>3</sup> including Annex III on Fresh Leafy Vegetables and Annex I on Ready-to-Eat, Fresh, Pre-Cut Fruits and Vegetables.

31. It is recommended that unprocessed fresh leafy vegetable handling areas be physically separated from processing areas to minimize contamination with STEC. Processing, with some exceptions (e.g. cooking) cannot fully eliminate STEC contamination that may have occurred during primary production or packing of fresh leafy vegetables. Processors should ensure that growers, harvesters, packers, and distributors have implemented measures to minimize the contamination during primary production and packing of the fresh leafy vegetables and also during subsequent handling in accordance with the provisions in the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).<sup>3</sup>

#### **5.1 Time and temperature control**

32. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).<sup>1</sup> Time and temperature control during pre-processing storage, processing and post-processing storage is essential to prevent growth of any STEC that may be present, since an increase in numbers of the STEC population will increase the risk of consumer illnesses.

#### **5.2 Trimming, coring, cutting, and shredding of fresh leafy vegetables.**

33. Equipment, knives and other cutting tools, and any other contact surfaces, should be cleaned and disinfected frequently to minimize the potential for harbourage or transfer of STEC.
34. The design of equipment, knives and other cutting tools, and any other contact surfaces should allow for effective cleaning and disinfection to minimize the potential for harbourage or transfer of STEC to fresh leafy vegetables.

#### **5.3 Washing and removal of water/drying cut fresh leafy vegetables.**

35. Washing and removal of water/drying are important steps in the control of STEC in fresh-cut leafy vegetables. Refer to Section 4.3 above and Annex I on Ready-to-Eat, Fresh, Pre-Cut Fruits and Vegetables of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).<sup>3</sup>

#### **5.4 Cold storage**

36. It is recommended that fresh leafy vegetables be maintained at appropriate refrigeration temperatures (see footnote 2) after cooling to minimize growth of any STEC that may be present. For fresh leafy vegetables susceptible to quality damage at refrigeration temperatures, the growth of STEC should be minimized by cooling to temperatures as low as possible while avoiding quality damage. The temperature of the cold storage should be controlled, monitored, and recorded.

### **6. MICROBIOLOGICAL TESTING**

37. Microbiological testing of fresh leafy vegetables and of water for primary production for STEC is currently of limited use due to difficulty in detecting STEC because of low and sporadic prevalence and when present, low numbers of the organism in fresh leafy vegetables and in water. This may lead to STEC not being detected even when present. Testing of fresh leafy vegetables for indicator microorganisms, supplemented, where appropriate, by testing for STEC strains considered to be a country's highest priority

(e.g. those strains with virulence factors capable of causing severe illness or considered to cause significant illness in that country), can be a useful tool to evaluate and verify the effectiveness of the control measures, and to provide information about an environment, a process or even a specific product lot when sampling plans and testing methodology are properly designed and performed. Measures to be undertaken in case of positive results for STEC (or when indicator microorganisms reach a pre-defined threshold) need to be established and defined. Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997)<sup>4</sup> and the *Principles and Guidelines for the conduct of microbiological risk management (MRM)* (CXG 63-2007).<sup>5</sup>

## 7. DOCUMENTATION AND RECORDS

38. It is recommended that primary production, harvesting, processing, storage, and distribution records be retained according to the requirements of the competent authority or long enough to facilitate STEC illness investigation and recalls if needed. This period may significantly exceed the shelf life of fresh leafy vegetables. Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003)<sup>3</sup> for the types of records that should be maintained by growers, harvesters and packers that may be important when investigating foodborne illness outbreaks due to STEC.
39. Microbiological test results should be retained for an appropriate period to allow for trend analysis. Increases, often small, in the population of indicator microorganisms over time may suggest that there is an emerging issue (or issues) in the production process which may require remediation.

## 8. ESTABLISHMENT: MAINTENANCE AND SANITATION

40. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)<sup>1</sup> and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).<sup>3</sup>

## 9. ESTABLISHMENT: PERSONAL HYGIENE

41. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).<sup>1</sup>

## 8. TRANSPORTATION

42. Refer to the *General Principles of Food Hygiene* (CXC 1-1969),<sup>1</sup> the *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CXC 47-2001)<sup>6</sup> and the *Code of Practice for the Packaging and Transport of Fresh Fruits and Vegetables* (CXC 44-1995).<sup>7</sup>

## 9. PRODUCT INFORMATION AND CONSUMER AWARENESS

### 9.1 Lot identification

43. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).<sup>1</sup>

### 9.2 Product information

44. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).<sup>1</sup>

### 9.3 Labelling

45. Refer to the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985)<sup>8</sup> and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).<sup>3</sup>

### 9.4 Consumer awareness

46. Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).<sup>3</sup>

## 10. TRAINING

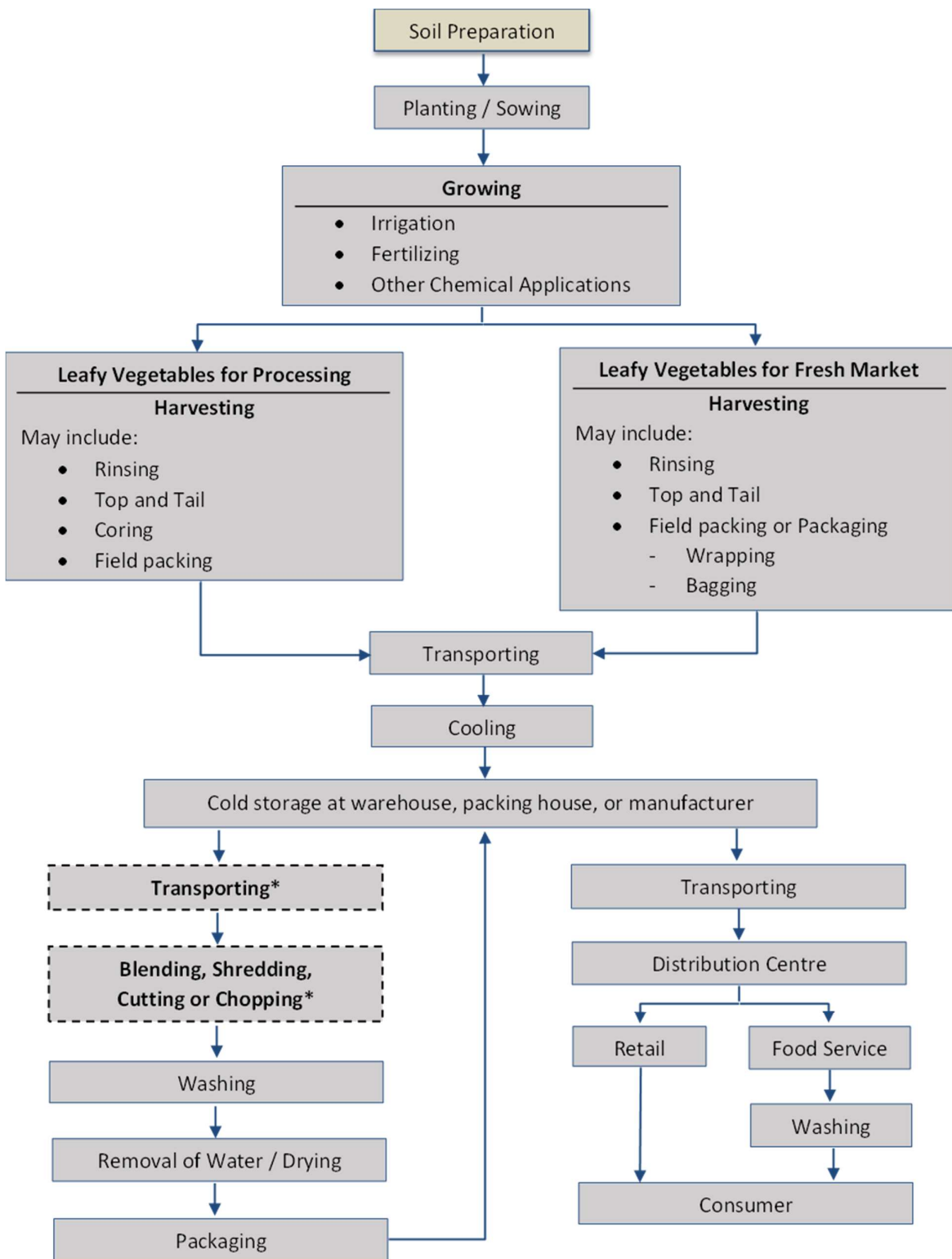
47. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)<sup>1</sup> and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).<sup>3</sup>

## 11. RETAIL AND FOODSERVICE

48. Fresh leafy vegetables (intact and pre-cut) should be held at an appropriate temperature to minimize growth of STEC. Cross-contamination from or to other food items should be prevented. FBOs serving fresh leafy vegetables for consumption without cooking to consumers should take appropriate measures to:
- prevent cross-contamination;
  - maintain appropriate holding and storage temperature;
  - thoroughly wash fresh leafy vegetables in accordance with Section 4.3 prior to use, when appropriate; and
  - ensure proper cleaning of tools and surfaces that may come in contact with these products.

49. When cold damage is not a concern, fresh leafy vegetables should be cooled to appropriate refrigeration temperatures (see footnote 2) to prevent the growth of STEC. For fresh leafy vegetables susceptible to quality damage at refrigeration temperatures, the growth of STEC should be minimized by cooling to temperatures as low as possible while avoiding quality damage.

**Figure1: Process flow for fresh leafy vegetables<sup>iii</sup>**



\* Boxes with broken lines indicate steps that may not be included, depending in part on the commodity.

<sup>iii</sup> The diagram illustrates a generalized process flow for fresh leafy vegetables for illustrative purposes only. Steps may not occur in all operations and may not occur in the order presented in the flow diagram.

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NOTES

<sup>1</sup> FAO and WHO. 1969. *General Principles of Food Hygiene*. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.

<sup>2</sup> FAO and WHO. 2023. *Guidelines for the Safe Use and Reuse of Water in Food Production*. Codex Alimentarius Guideline, No. CXG 100-2023. Codex Alimentarius Commission. Rome.

<sup>3</sup> FAO and WHO. 2003. *Code of Hygienic Practice for Fresh Fruits and Vegetables*. Codex Alimentarius Code of Practice, No. CXC 53-2003. Codex Alimentarius Commission. Rome

<sup>4</sup> FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*. Codex Alimentarius Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome

<sup>5</sup> FAO and WHO. 2007. *Principles and Guidelines for the conduct of microbiological risk management (MRM)*. Codex Alimentarius Guideline, No. CXG 63-2007. Codex Alimentarius Commission. Rome.

<sup>6</sup> FAO and WHO. 2001. *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food*. Codex Alimentarius Code of Practice, No. CXC 47-2001. Codex Alimentarius Commission. Rome.

<sup>7</sup> FAO and WHO. 1995. *Code of Practice for the Packaging and Transport of Fresh Fruits and Vegetables*. Codex Alimentarius Code of Practice, No. CXC 44-1995. Codex Alimentarius Commission. Rome

<sup>8</sup> FAO and WHO. 1985. *General Standard for the Labelling of Pre-packaged Foods*. Codex Alimentarius Standard, No. CXS 1-1985. Codex Alimentarius Commission. Rome

## APPENDIX III

## ANNEX IV ON SPROUTS

(At Step 5/8)

**1. INTRODUCTION**

1. Sprouts are commonly consumed raw and sometimes without a processing step that would eliminate microbial pathogens, prior to consumption. Consequently, it is necessary to ensure safe production of sprouts by preventing or minimizing contamination of incoming seeds, in the production environment and in the finished products. While no single step will reliably eliminate all pathogenic microorganisms that may survive on sprouts, using a series of preventive and risk-reduction steps (i.e. a multi-hurdle approach) can greatly reduce the food safety risks that may be associated with sprouts.

2. Sprouts have different food safety concerns from other fresh fruits and vegetables because the conditions for seeds to sprout (e.g. time, temperature, water activity, pH, and available nutrients) also support the growth of foodborne bacterial pathogens if present.

3. Contaminated seeds have historically been identified as the likely source of most sprout-related outbreaks, particularly those attributed to Shiga toxin-producing *Escherichia coli* (STEC) contamination and continues to be the most common source of sprout contamination.<sup>i</sup> Bacterial pathogens that may be present at low levels on seeds can multiply to very high levels during the sprouting process. Sprout contamination could also be caused by poor hygienic practices and contamination in production environments.<sup>ii</sup>

4. Figure 1 provides a flow diagram illustrating a generalized process flow to produce sprouts. The flow diagram is for illustrative purposes only. All steps may not occur in all operations or may not occur in the order presented in the flow diagram. Sprouts are grown in production environments that vary based in size and resources of the operation, seed type, available equipment, etc.

5. During seed production, conditioning, storage, and distribution for sprouting, the application of good agricultural practices (GAPs) and good hygienic practices (GHPs) should aim to prevent the contamination of seeds by microbial pathogens such as STEC. During sprout production, any step for the microbiological decontamination of seeds is aimed at reducing potential contaminants, while GHPs are aimed at preventing the introduction of microbial pathogens and minimizing their potential growth. The degree of control in these two areas has a significant impact on the safety of sprouts.

**2. OBJECTIVE**

6. The objective of this Annex is to provide guidance to reduce the risk of foodborne illness from STEC associated with sprouts intended to be consumed raw, during production, harvesting, packing, processing, storage, distribution, and marketing as well as addressing consumer awareness.

**3. SCOPE, USE, AND DEFINITIONS****3.1 Scope**

7. This Annex covers specific guidance for the control of STEC related to sprouts that are intended to be consumed raw.

8. Home-sprouting, and shoots, cress, and microgreens<sup>iii</sup> where the seed is not kept in the final product are outside the scope of this document.

**3.2 Use**

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<sup>i</sup> FAO/WHO. 2022. Microbiological Risk Assessment Series 43: *Prevention and control of microbiological hazards in fresh fruits and vegetables – sprouts*.

<sup>ii</sup> See note i above.

<sup>iii</sup> Shoots are grown hydroponically, and true leaves are developed. The shoots and the leaves are cut during harvest and the final product does not include the seed and roots. Cress is grown with substrate and true leaves are developed; as with shoots grown hydroponically, the cut shoots and leaves do not include the seed and roots. For microgreens, plants reach a later stage of growth than sprouts, typically associated with the emergence of “true” leaves. They can be grown in soil or substrate and are harvested above the soil or substrate line; they include both shoots and cress (FAO/WHO, 2022).

9. This Annex should be used in conjunction with the *General Principles of Food Hygiene* (CXC 1-1969),<sup>1</sup> the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),<sup>2</sup> including Annex II for Sprout Production and the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023),<sup>3</sup> including Annex 1 “Fresh Produce”.

### 3.3 Definitions

**Sprouts** – Sprouted seeds or beans harvested when the cotyledons (or seed leaves) are still un- or underdeveloped and true leaves have not begun to emerge. They can be grown in water, soil or substrate and can be harvested with or without the root (cut sprouts).<sup>iv</sup>

**Seeds for sprouting** – Seeds or beans used to produce sprouts for human consumption.<sup>v</sup>

## 4. PRIMARY PRODUCTION OF SEEDS FOR SPROUT PRODUCTION

### 4.1. Control measures for seed production and handling

10. Interventions aimed at reducing the risk from seed-borne contamination should focus on controlling contamination of seeds from animal and human activities and ensuring proper use and application of manure, biosolids, other natural fertilizers, and agricultural water.

#### 4.1.1. Animal and human activities

11. Grazing of domestic animals should not occur in fields while crops are actively being grown for use in sprouted seed/bean production. History of the growing area regarding previous uses for grazing domestic animals should also be considered, as STEC have been shown to survive for several weeks in bovine faeces.

12. In addition, nearby fields with livestock, particularly those located uphill or upstream, can increase the likelihood of STEC contamination. Livestock should be located as far as feasibly possible from fields growing seeds for sprout production, because the risk of seed contamination decreases as the distance to livestock increases.

13. During the growing season, the areas used for growing seeds for sprouting should be assessed for evidence of potential contamination of seeds from domesticated or wild animals (e.g. observation of animals or animal activity, animal excreta, crop destruction).

14. When evidence of potential contamination is found (e.g. the plant or seed is visibly contaminated with animal excreta), growers should evaluate whether the seed should not be harvested due to the potential for contamination with pathogens such as STEC. Growers should then take measures to label (or otherwise indicate) contaminated seed and/or the contaminated area (e.g. mark the affected area) so that such seed will not subsequently be harvested in the event weather conditions, or other occurrences, make the evidence of potential contamination no longer visible.

15. Wild animals should be excluded from the production area to the extent possible. Possible methods include the use of physical barriers (e.g. fences) and active deterrents (e.g. noise makers, scarecrows, images of owls, foil strips).

16. The presence of nearby animal production facilities (e.g. animal feed operations, poultry farms, dairy farms) or other related factors such as slope of land, lack of runoff controls, and manure spreading that could lead to contamination of the seed or irrigation water with untreated manure, should be assessed and appropriate actions taken to prevent contamination of growing areas and seed with STEC.

#### 4.1.2 Water for seed production

17. Water for irrigation and other applications should be fit for purpose and used in a manner to avoid the introduction of pathogens onto seeds.

18. Growers should evaluate the sources of water used on the farm for the likelihood of contamination with STEC (e.g. from livestock, wildlife, sewage treatment, human habitation). The following actions may prevent contamination of water supplies with STEC:

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<sup>iv</sup> FAO/WHO. 2022. Microbiological Risk Assessment Series 43: *Prevention and control of microbiological hazards in fresh fruits and vegetables – sprouts*.

<sup>v</sup> References to “seeds” in this document include other things that are sprouted to produce sprouts for human consumption, such as beans.



- installation of fencing around surface water supplies to prevent large animal contact;
- proper maintenance of wells;
- water filtration system or chemical water treatment;
- prevention of stirring of the sediment when drawing water; and
- construction of settling or holding ponds or water treatment facilities.

19. The effectiveness of these actions should be verified by periodic risk-based water testing. Where necessary, growers should test the water they use for appropriate indicator microorganisms and, where identified as necessary, STEC, according to the risk associated with the production. The frequency of testing will depend on the water source (e.g. lower for adequately maintained deep wells, higher for surface waters), the risks of environmental contamination, including intermittent or temporary contamination (e.g. heavy rain, flooding), or the implementation of a new water treatment process by growers. Analysis of indicator microorganism test results over time may help growers notice emerging issues.

20. Where possible, growers should be able to identify or have a contingency plan in place that identifies an alternative source of fit-for-purpose water if the primary water source is found to have unacceptable levels of indicator microorganisms or is contaminated with STEC. Refer to the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023),<sup>3</sup> including Annex 1 “Fresh Produce”.

#### **4.1.3 Manure, biosolids and other natural fertilizers**

21. Growers who use biological soil amendments of animal origin (e.g. manure) on fields producing seeds for sprouting should only use them in such a way that they do not contaminate the seeds for sprouting. Manure, biosolids, and other natural fertilizers are potential sources of bacterial pathogens. Only properly composted manure/biosolids treated to reduce or eliminate STEC should be used during seed production to reduce the risk of seed contamination.

22. Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003)<sup>2</sup> for practices to minimize microbial pathogens such as STEC in manure, biosolids and other natural fertilizers.

23. If untreated or partially-treated natural fertilizers are used, the time period before harvesting of seed should be maximized, as bacterial pathogens die off over time.

#### **4.1.4 Personnel health, hygiene, and sanitary facilities**

24. Worker hygiene and health requirements should be followed to ensure that personnel who have direct contact with seeds for sprouting prior to, during or after harvesting will not contaminate them with STEC.

25. Adequate access to, and use of, hygienic and sanitary facilities, including the means to effectively clean and dry hands, are critical to minimize the potential for workers to contaminate seeds for sprouting.

26. People known or suspected to be suffering from diarrheal illness should not be allowed to enter any area handling seeds destined for sprouting, including the growing and harvest area.

27. Refer to the *General Principles of Food Hygiene* (CXC 1-1969)<sup>1</sup> and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003)<sup>2</sup> for more recommendations that may apply.

#### **4.1.5 Equipment associated with growing and harvesting of seeds for sprouting**

28. Equipment should be designed for ease of cleaning and maintained to minimize soil intake and seed damage and prevent introduction of pathogens such as STEC onto seeds for sprouting.

29. Growers should avoid moving harvesting equipment across fields where improperly composted manure/biosolids have been applied.

30. To avoid contamination of seeds destined for sprouting, harvesting equipment should be cleaned and disinfected prior to harvesting. In addition, in the event of circumstances that may result in contamination, e.g. equipment runs over an area with animal intrusion and faecal deposits, harvesting should cease, and equipment should be cleaned and disinfected prior to using the equipment for harvesting again.

#### **4.1.6 Handling, storage, and transport of seeds for sprouting**

31. Good hygiene practices (GHPs) should be implemented to avoid possible contamination of seeds during storage and transportation. When possible, temperature and humidity should be controlled.
32. Equipment used to transport the seeds should be clean and, where necessary, disinfected prior to use.
33. Packaging of seeds is recommended to minimize the potential for contamination. Growers should pack and hold seeds under sanitary conditions and pest controls should be implemented in storage facilities.
34. Seeds for sprouting should be held and stored in solid bags (e.g. new or recycled bags) or completely closed/covered containers, in a clean, dry area dedicated only to seed storage. Open weave bags or containers with holes or uncovered openings should not be used to store seeds.
35. Containers stored outdoors should be cleaned and, as appropriate, disinfected before being used to transport seeds for sprouting. Such containers should be positioned off the ground.
36. Each container should be marked to identify the source and lot and if the seed has been treated. This should be clearly indicated on the label.
37. Containers should not be stored on the floor or placed against walls to reduce the possibility of contamination with STEC by rodents or other pests and to facilitate regular monitoring for pest problems.

### **5. SPROUT PRODUCTION**

38. HACCP principles should be applied to sprout production, with all the steps well documented and potential critical control points (e.g. decontamination of the seeds) identified and controlled. If a problem is identified (e.g. STEC contamination of sprouts), corrective actions should be taken and a critical review of all the steps should be performed to determine whether changes are needed.
39. Water used throughout sprouts production should be fit for purpose.

#### **5.1 Sourcing and receiving of seeds for sprouting**

40. Seeds should be obtained from supplier (producers or distributors) who follow GAPs and GHPs during production, storage, and distribution of the seeds for sprouting. When possible, microbiological testing/certificates of analysis or a letter of guarantee should be obtained from the supplier.
41. When seeds arrive at a sprout operation, they should be inspected for physical damage and signs of contamination (e.g. rodent/bird droppings, dirt, and other visible contamination).

#### **5.2 Storage of seeds for sprouting**

42. Seeds should be stored and handled in conditions (e.g. temperature and relative humidity) that will prevent growth of microorganisms, such as STEC.
43. Seeds should also be stored and handled in a manner that will avoid damage and keep them protected from pests and other sources of STEC contamination.
44. Keeping seeds and sprouts from different batches separated can facilitate the identification of contaminated batches and help trace seeds back to the supplier.

#### **5.3 Initial rinse**

45. Seeds should be rinsed thoroughly to remove dirt or debris before any treatment is applied.
46. Seeds should be rinsed and agitated in large volumes of fit-for-purpose water. Repeat the process with fit-for-purpose water until the dirt or debris are removed and rinse water remains clear.
47. The rinsing process should be designed to maximize surface contact of seeds with water (e.g. use large buckets of water and sieves).

#### 5.4 Treatment and pre-germination soak of seeds for sprouting

48. Treatment of seeds to reduce the presence of pathogens such as STEC may be determined to be a critical control point. However, seed treatment can be challenging due to the low water activity of the seeds, and the need to preserve the viability of the seeds, including their ability to germinate. Treating seeds used for sprouting reduces the level of potential contamination but does not reliably eliminate pathogens, such as STEC, therefore treating seeds does not replace the importance of measures to prevent contamination of seeds and sprouts. Known seed treatment methods include those that work by chemical methods (liquid or gas), physical methods, or a combination of these. The use of certain seed treatments may be subject to approval by competent authorities.

49. The following chemicals, when used at appropriate concentrations, may be able to achieve at least a 3-log reduction of pathogens: calcium hydroxide, calcium hypochlorite, sodium hypochlorite, caprylic acid, gaseous acetic acid, hydrogen peroxide, lactic acid, monocaprylin, oxalic acid, and phytic acid. When authorized by competent authorities, the use of treatments, including the duration of treatment and the concentration of the chemical used, should be accurately measured and recorded.

50. Physical treatments have been reported to achieve a 5-log or greater reduction in pathogens, including *E. coli* O157:H7, on seeds. Physical treatments, such as heat (dry heat or hot water), high pressure, and irradiation are reported to have better penetration characteristics for reaching bacteria on microscopically rough surfaces as well as the interior of the seed as compared to chemical treatments. Combinations of several physical and/or chemical treatments have been reported to be the most effective for removing pathogens from seeds for sprouting. Combination treatments applied sequentially or simultaneously may be more effective than using a single treatment alone.

51. Where feasible, sprout growers should treat the seeds used for sprouting with a method validated to reduce microorganisms of public health significance such as STEC.

52. All steps involved in treatment for seeds should be carried out in an area separated from the germination and packaging areas.

#### 5.5. Rinse after seed treatment

53. Seeds may need to be rinsed after a seed treatment (e.g. seeds treated with chemicals) to remove chemical residues. Time duration of the rinse step should be adequate to limit potential microbial growth.

#### 5.6. Germination and growth of sprouts

54. Sprouts are grown hydroponically or in soil. Practices employed for germination, growth, harvest, and post-harvest washing vary, depending on the operation and the type of sprout grown. Growing units include rotating drums, bins, beds, trays, and buckets.

55. Seeds for soil-grown sprouts are generally rinsed and soaked to allow for initial germination before sowing in soil in plastic trays. Water is sprayed over the trays daily. Sprouts such as alfalfa, broccoli, clover, and radish are grown hydroponically, at ambient or higher temperature, in rotating drums with frequent water sprays. Because of the relative high temperature, if present at the growing stage, microbial pathogens such as STEC can multiply, significantly increasing the risk for consumers.

#### 5.7 Harvesting

56. Sprouts are harvested manually by removing them from growing units. Sprouts may be washed to remove hulls and/or to help lower the temperature of the sprouts and then spin-dried. Soil-grown sprouts are harvested by cutting them from the trays, prior to washing and packaging, or the sprout trays are sent to retailers and cut at the point-of-sale. Good hygiene practices should be applied to prevent these operations from being a source of contamination (e.g. if some of the sprouts are contaminated with STEC from the environment or from handlers).

#### 5.8 Cold sprout storage

57. Sprouts should be maintained at appropriate refrigerated temperatures<sup>vi</sup> after cooling to minimize growth of any STEC that may be present. The temperature of cold storage should be controlled, monitored, and recorded.

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<sup>vi</sup> *E. coli* O157:H7 and other STEC are unlikely to grow on fresh leafy vegetables at temperatures lower than 7 °C, based on available scientific evidence.

## 5.9 Personal and environmental hygiene at sprout production

58. Proper storage, handling and disposal of waste, sanitation of equipment and tools, and effective pest control will minimize the risk of sprout contamination with pathogens such as STEC.

59. Facilities should be designed (e.g. differentiation between areas, hygienic zones, flow of operations and personnel) to prevent potential cross-contamination from raw materials to the finished sprouts.

## 5.10 Documentation and records

60. Documentation of key information for incoming seeds (e.g. supplier details, date of receipt, quantity, production batch/lot code etc.) should be maintained.

61. It is recommended that production, harvesting, packing, storage, and distribution records should be retained long enough to facilitate investigation of product recalls and any notified STEC illnesses, if needed. This period may significantly exceed the shelf life of sprouts.

62. It may be appropriate to retain microbiological test results for a longer period since this data should be used for trend analyses. Increases, often small, in the population of indicator microorganisms over time may suggest that there is an emerging issue (or issues) in the production process which may require remediation.

63. Refer to section 5.7 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003)<sup>2</sup> for the types of records that should be maintained by growers, harvesters and packers that may be important when investigating foodborne illness outbreaks due to STEC.

## 6. MICROBIOLOGICAL CRITERIA AND OTHER SPECIFICATIONS FOR LABORATORY TESTING

64. Where appropriate and when possible, spent sprout irrigation water (SSIW) (or in-process sprouts), and possibly seeds, should be tested for the presence of pathogens such as STEC; in particular, strains demonstrated to be a country's highest priority due to their public health burden (e.g. those strains with virulence factors capable of causing severe illness or considered to cause significant illness in that country). The samples collected for testing should be representative of the production batch. Testing SSIW or in-process sprouts collected during sprouting increases the likelihood of detecting the pathogens that may be present in seed. It also enables early detection of contamination in the production batch before products enter the marketplace. Testing SSIW is preferred over testing sprouts because water may pick up bacteria as it passes through the production batch, making it easier to collect a representative sample.

65. Testing for indicator microorganisms, can be a useful tool to evaluate and verify the effectiveness of the control measures, and to provide information about an environment, a process or even a specific product lot when sampling plans and testing methodology are properly designed and performed. Measures to be undertaken in case of positive results for STEC (or when indicator microorganisms reach a pre-defined threshold) need to be established and defined. Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997)<sup>4</sup> and *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007).<sup>5</sup>

### 6.1 Testing of seed lots before entering production

66. Some seed producers or seed suppliers may opt to test their seed for pathogens to help identify contaminated lots before distribution. However, the likelihood of detecting the presence of pathogens such as STEC in seeds is low, due to the heterogeneous distribution and low numbers of STEC contaminating the seeds. This may lead to STEC not being detected when present.

67. Testing of seed lots for indicator microorganisms may be used as an indicator of potential STEC contamination. If initial testing indicates the possible presence of STEC, additional testing for STEC is recommended.

### 6.2 Testing of sprouts and/or spent sprout irrigation water (SSIW).

68. Microbial testing of SSIW (or in-process sprouts) is an important part of a multi-hurdle approach to ensure contaminated sprouts do not enter the marketplace. Testing SSIW (or in-process sprouts) for STEC from each production batch of sprouts is a much more reliable indicator than testing seed to determine whether the sprouts and potentially the seeds used to produce the batch, are contaminated with STEC. The highly perishable nature of sprouts generally makes routine microbiological testing of finished sprouts impractical.

69. Samples of SSIW can be collected as early as 48 hours after the start of sprouting, although the optimal time for sample collection may vary depending on the type of sprouts and sprouting practices. If the seeds are pre-soaked (e.g. soaked in water for a short time and then transferred to growing units for sprouting), include the pre-soak time. Early results will allow sprout growers to take corrective actions sooner, thus ensuring that sprouts grown from that (those) lot(s) of seeds do not enter commerce, and to report positive test findings to the seed grower, distributor, supplier, or other relevant entity.

70. If testing SSIW is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), each production batch of sprouts could be tested at the in-process stage (i.e. while sprouts are still growing).

## **7. DISTRIBUTION AND POINT-OF-SALE**

71. STEC growth and contamination can occur during transport, distribution and at point-of-sale due to improper handling and poor personal hygiene, and contamination through comingling with other raw food commodities and animals/animal products, and exposure to unsanitary surfaces and/or water. Control measures should be applied during distribution and at point-of-sale to prevent contamination with STEC.

### **7.1 Transportation**

72. Sprouts should be transported in clean, enclosed, and refrigerated transport vehicles and the temperature in the refrigerated compartment of such transport vehicles, should be monitored.

## **8. PRODUCT INFORMATION AND CONSUMER AWARENESS**

73. Producers should provide relevant information to the consumer to assure the safety of sprouts during storage, handling, and preparation of the product. This information may include but is not limited to: 1) recommended temperature of storage; 2) the date by which the sprouts should be consumed or discarded (e.g. use-by date); 3) washing instructions, which should be included on the label if the product is intended to be washed before consumption.

74. Consumers should store sprouts at temperatures that will minimize the growth of pathogens such as STEC and adhere to any instructions provided on labelling (e.g. a use-by date or cooking instructions).

## **9. TRAINING**

75. All personnel involved in the production and handling of seeds for sprouting or sprouts across the supply chain should receive training on the principles of food hygiene and food safety, in particular the high-risk nature of sprouts and the illness associated with them, as well as personal health and hygiene requirements.

76. Seed producers, handlers, distributors, and processors should be aware of GAPs, GHPs and their role and responsibility in protecting seeds intended for sprouting from STEC contamination.

77. Control measures designed to reduce microbiological hazards in sprouts can be highly technical and difficult to implement. Specific training related to seed sourcing and storage, seed treatment, cleaning and disinfecting, sampling and microbiological testing, and record-keeping should be done to ensure successful implementation.

## **10. RETAIL AND FOODSERVICE**

78. Sprouts for retail sale should be held at an appropriate refrigeration temperature<sup>vii</sup> to minimize growth of STEC. Temperatures should be monitored and recorded.

79. Food business operators serving sprouts for consumption without cooking to consumers should take appropriate measures to:

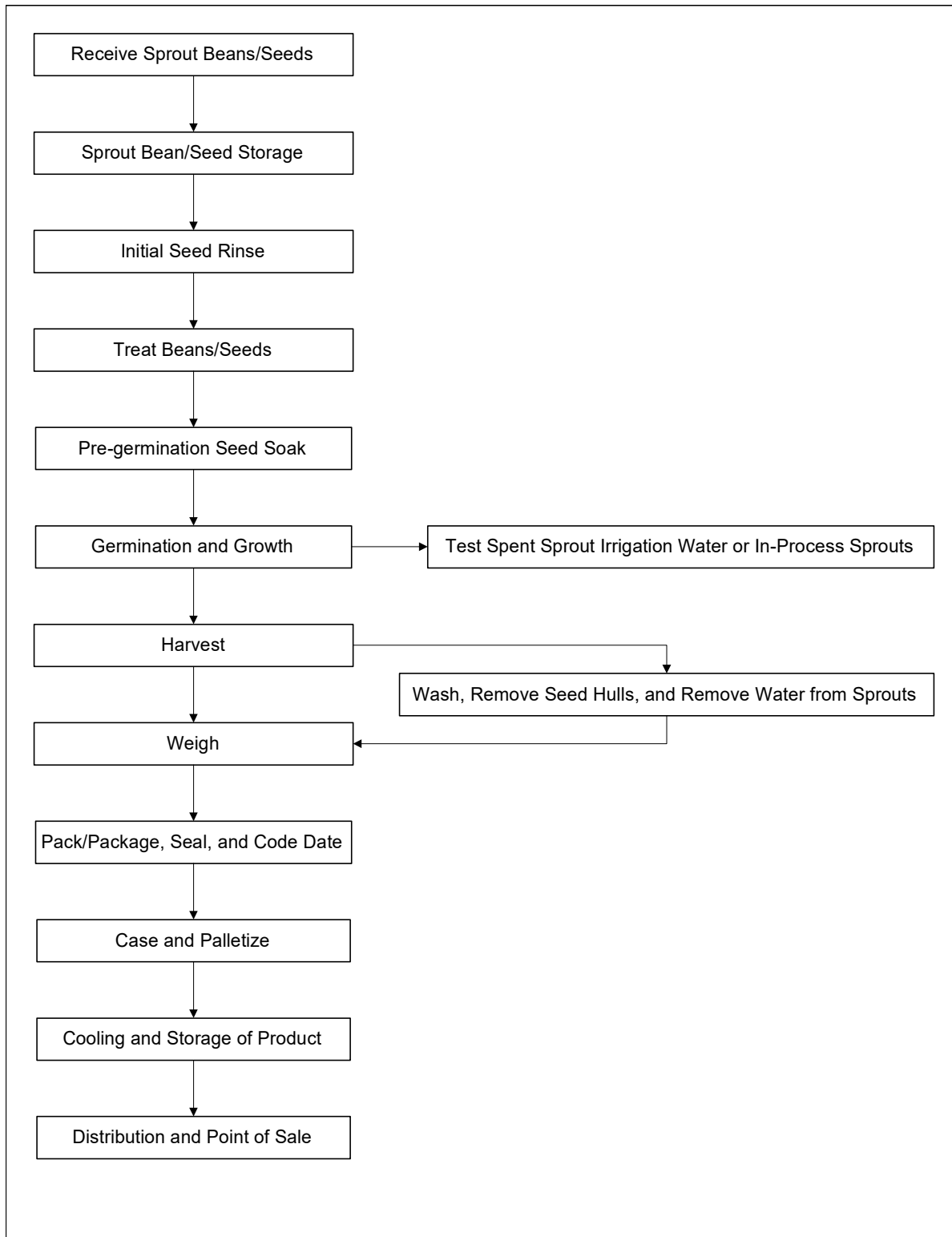
- prevent cross-contamination;
- discard any sprouts that are past the date on their label for which they can be consumed;
- maintain sprouts at an appropriate storage temperature to minimize growth of STEC that may be present; and
- ensure proper cleaning of tools and surfaces that may come in contact with these products.

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<sup>vii</sup> See note vi above.

80. For in-restaurant sprouting, control measures recommended for sprout operations to minimize the potential for STEC should be considered, including seed sourcing programmes, seed treatment (if appropriate), prevention of cross-contamination, sampling, and testing of SSIW (samples to be tested by laboratories), as well as cleaning and disinfecting food contact surfaces.

**Figure1: Sprouts Flow Diagram<sup>viii</sup>**



<sup>viii</sup> The diagram illustrates a generalised process flow to produce sprouts for illustrative purposes only. Steps may not occur in all operations and may not occur in the order presented in the flow diagram and the germination time may be different.

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## NOTES

<sup>1</sup> FAO and WHO. 1969. *General Principles of Food Hygiene*. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.

<sup>2</sup> FAO and WHO. 2003. *Code of Hygienic Practice for Fresh Fruits and Vegetables*. Codex Alimentarius Code of Practice, No. CXC 53-2003. Codex Alimentarius Commission. Rome.

<sup>3</sup> FAO and WHO. 2023. *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing*. Codex Alimentarius Guideline, No. CXG 100-2023. Codex Alimentarius Commission. Rome.

<sup>4</sup> FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*. Codex Alimentarius Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.

<sup>5</sup> FAO and WHO. 2007. *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)*. Codex Alimentarius Guideline, No. CXG 63-2007. Codex Alimentarius Commission. Rome.



## ANNEX III ON MILK AND MILK PRODUCTS

(at Step 5/8)

### 1. INTRODUCTION

1. Milk and milk products are an important and often essential source of food in many parts of the world and are a significantly traded food. Water is used for a wide range of activities in dairy operations, and the sector consumes a substantial volume of water for production processes, cleaning and disinfection. Other activities such as chilling and steam production may also have a high demand for water. At primary production, the availability of water fit for drinking for the animals may have a direct impact on animal health, as well as the amount, quality and safety of the milk being produced.

2. Milk naturally consists of 80 to 85 percent of water which may become available for use during certain processes (e.g. concentration and drying of milk products). Reuse of such water, being reclaimed water provides an additional source of water within dairy manufacturing plants. The reuse of reclaimed water from milk and other milk products, and of recycled water in dairy manufacturing plants provides opportunities to significantly reduce the need for water from external sources. It can be an important tool for food business operators (FBOs) to address water scarcity and reduce the stress of water availability in certain parts of the world and/or under certain environmental circumstances.

3. If water used in the production of milk and milk products is not fit for its intended purpose, it may be a source of microbiological hazards such as *Listeria monocytogenes*, *Campylobacter* spp., *Bacillus cereus*, *Staphylococcus aureus*, *Salmonella* spp. and Shiga toxin-producing *Escherichia coli*. and protozoa from cross-contamination. The use of non-fit-for-purpose water in dairy operations may also contribute to the distribution and multiplication of such pathogens.

4. Guidelines on the fit-for-purpose use and reuse of water are essential to ensure the manufacturing of milk and milk products that are safe for consumption.

### 2. PURPOSE AND SCOPE

5. This annex provides recommendations for the microbiologically safe use and reuse of water from the dairy farm to the dairy manufacturing/processing plant. It is intended for FBOs and competent authorities, as appropriate, to provide for practical and applicable use and reuse of water in the dairy sector by applying the principle of fit for purpose using a risk-based approach. This annex also provides examples of fit-for-purpose use and reuse of water. The scope of the annex strongly focuses on the reuse of water since this provides a significant opportunity to limit the need for external water sources.

### 3. USE

6. This annex should be used in conjunction with the general section of these guidelines and the following Codex Alimentarius guidance:

- *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004);<sup>1</sup>
- *General Principles of Food Hygiene* (CXC 1-1969);<sup>2</sup>
- *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007);<sup>3</sup>
- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999);<sup>4</sup>
- *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008);<sup>5</sup>
- *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997);<sup>6</sup>
- *Guidelines on the Application of General Principles of Food Hygiene to the Control of Foodborne Parasites* (CXG 88-2016);<sup>7</sup> and

- *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* (CXG 79-2012).<sup>8</sup>

#### 4. DEFINITIONS

**Condensate:** water recovered by condensing water vapour, for instance water vapour recovered from the drying of dairy materials/products.

**Dairy effluents:** water from cleaning and disinfection, or other operations involving water, during the manufacture of milk products, including both for-food-contact applications and non-food-contact applications, and which contains identifiable substances.

**Permeate:** the fluid derived from milk or other milk products obtained after removing milk constituents by membrane filtration, microfiltration (MF) ultrafiltration (UF), nanofiltration (NF), reverse osmosis (RO) and/or reverse osmosis and polishing (ROP).

**Retentate:** the product obtained by concentrating milk constituents using membrane filtration (UF/MF/RO/reverse osmosis and polishing water (ROP)/NF) technology for milk or milk products.

**Stagnant water:** water that occurs as the result of setting, pooling or otherwise accumulating, allowing for the accumulation of organic matter and growth of unwanted microorganisms including yeasts and moulds. Usually found on floors and other areas that do not allow water to drain to floor drains.

#### 5. PRIMARY PRODUCTION AND TRANSPORT FROM THE FARM

7. An adequate supply of water fit for purpose should be available for use in the various operations, including further processing on dairy farms.

8. Water used as drinking water for animals should be fit for purpose and free from feed or faecal material to the extent of possible. Drinking troughs (or other vessels) should be regularly inspected and cleaned when dirty.

9. Water intended for drinking by animals should be analysed periodically to determine microbiological quality (e.g. based on coliforms, or turbidity/colour limits that can be done at low cost, such as with a Secchi disk modified for relatively shallow water troughs). The frequency of testing should depend on the risk associated with the water source, results from previous testing, applied treatment and intended use of the milk. The risk associated with the water source generally increases from municipality water, deep well water, hygienically collected rainwater, groundwater to surface water.

10. When washing of the udder is recommended (e.g. when dirty), fit-for-purpose water should be used. In the production of milk for raw milk products, potable water should be used. Attention should be given to proper washing and drying.

11. Stagnant water near drinking troughs or in milking and storage facilities should be avoided.

12. Water fit for purpose should be available in areas designated for milking of dairy animals and milk storage, as well for use when rinsing, cleaning and disinfecting milking equipment, storage containers, vessels and tanks. It should be available at the dairy manufacturing plants, and elsewhere as required for the cleaning of transport facility equipment and tanks. Rinsing equipment, storage containers, vessels and tanks with water fit for purpose, should also be carried out after the use of chemical compounds and biocides for disinfection, when necessary.

13. New water sources used for rinsing, cleaning and disinfecting the product contact surfaces of milking equipment, tanks, vessels and facilities for milk transport from dairy farms, should be checked visually for clarity and odour as well as tested for microbiological quality where appropriate before first use, and then regularly thereafter in a similar way as in dairy manufacturing plants. Records of analyses should be maintained and should be readily available to competent authorities when requested.

14. When economically feasible at dairy farms or during transport, reusable water sourcing and reconditioning (as necessary) could add value for the milk production operations seeking to reduce overall consumption of externally sourced water, by collecting, recovering and reconditioning water used for rinsing and cleaning, e.g. the animal housing facility, milk storage area, floors, walls and ceilings, and for rinsing, cleaning and disinfecting milking equipment, on-farm milk storage containers, vessels and tanks. When reusing and reconditioning water, the guidance provided below for dairy manufacturing plants should be followed.

15. As simple examples of reuse, raw milk is heat treated and concentrated using membrane filtration at the dairy farm, the water from the concentration process may be used as drinking water for animals, cleaning the milking and animal housing facility, as well as milking equipment, provided it is fit for purpose. Properly treated

sewage water or other water collected from the farm (e.g. from rinsing, cleaning and sanitizing, or from possible production of whey or wash of cheeses at the farm) could be used, for example, to irrigate grazing pastures or to clean the milking and animal housing facility.

## 6. DAIRY MANUFACTURING PLANT

16. Within a dairy manufacturing plant, water may be used as an ingredient, for rinsing, cleaning and disinfecting production equipment, for heating and cooling of raw milk, ingredients and finished milk products, as boiler feed water for the production of hot water and steam, and for facility (floors, walls, piping, etc.) cleaning, among other purposes. The availability and volume of fit-for-purpose water required for dairy manufacturing plants, may be limited by geography, climate and competing demands. Also, the dairy industry is continuing to evolve, utilizing facilities with large processing capacities and subsequently, larger water requirements. This large, concentrated demand for water in a small geographic location can stress the availability of water for necessary purposes, such as drinking, irrigation, etc. Water reuse is an important strategy for reducing water consumption from external sources.

### 6.1 GENERAL RECOMMENDATIONS

17. Differentiation should be made between water that is used in food or on surfaces that come into contact with food (e.g. ingredient water, water used to rinse, clean, or disinfect food-contact surfaces of processing equipment and transport vehicles), and water that will not come into contact with food, either directly or indirectly (e.g. boiler feed for technical steam, water needed to extinguish fires, or to wash the exterior of vehicles, for cooling towers, to water lawns, to clean exterior surfaces or to flush toilets).

18. Measures should be taken to avoid or remove stagnant water, condensation, or steam from dairy manufacturing plants by the design, operation and maintenance of the plant as quickly and frequently as possible. Ventilation should be adequate to reduce/eliminate steam and condensation accumulation.

19. Measures should be taken to capture in a sanitary manner, treat and reclaim water from various sources as quickly as possible after its first use or when it originates from milk, whey, or other milk products within a dairy manufacturing plant.

20. As a general recommendation, but subject to adaptation based on testing and evaluation, the following water could be considered as fit for purpose:

- potable water and reclaimed water from milk meeting potable water requirements can be used for any purpose in dairy manufacturing, including:
  - as a food ingredient; examples are:
    - low fat dairy spreads;
    - rehydration of dairy powders and other dry ingredients;
    - addition to concentrated dairy products before drying or filtration; and
    - direct steam injection for pasteurization in cheesemaking or fermented milks.
  - to flush dairy materials out of the pipeline at the end of a production run and before the first rinse of the cleaning process; and
  - for any direct or indirect contact with milk products, including for the first rinsing, cleaning, disinfection and final rinsing of food-contact surfaces of processing equipment.
- recycled water from the final rinsing of food-contact surfaces of processing equipment, tanks, vessels, utensils and milking equipment, or from other sources subject to reconditioning:
  - for the first or intermediate rinse during the cleaning and disinfecting of food-contact surfaces of processing equipment, tanks, vessels and utensils (with the possible addition of an acceptable level of biocides);
  - for cleaning non-food-contact surfaces (for example walls, floors); and
  - for food-contact applications or for the final rinse, if the reuse water is subjected to a microbiocidal (e.g. thermal, UV treatment, filtration, chlorination, ozonation), sufficient to reduce microbiological risk to an acceptable level.

- other water may be used for boiler feed purposes, as cooling water/ice or for washing of other surfaces, if not in direct or indirect contact with food.

21. The dairy plant should have sufficient water supply providing enough water of potable water quality and the water handling systems within the plant should maintain water quality to the point of use. Sampling of water for microbiological testing is relevant upon any suspicion of contamination of the supply water on the premises. It is the responsibility of the FBO to manage any microbiological contamination of the water supply on its premises including informing competent authorities should the food be potentially affected.

22. Any external supply of non-potable water to the dairy plant e.g. for the production of steam, firefighting and cooling, is acceptable provided that the water handling system is dedicated for these purposes and is clearly marked.

23. If the FBO has identified contamination in the water supply, it should conduct an investigation, and assess whether such contamination was a sporadic occurrence or represents a persistent problem that may require more extensive corrective actions. When a source of contamination is not evident, the FBO should contact competent authorities, to determine whether there is a general contamination of the water supply or whether the contamination originates at the plant and implement appropriate corrective actions to mitigate the cause of the contamination.

24. Disinfection to reduce microbiological hazards in any water source should never compromise the safety of any milk or milk products.

## 6.2 WATER INTENDED FOR REUSE

25. At dairy manufacturing plants, the technology to safely reuse water and dairy effluents to meet fit-for-purpose applications does exist, making this a viable option for dairy manufacturing plants to reduce their externally sourced water consumption (see Annex IV).<sup>i</sup> Attention should be given to address any health risks associated with using reuse water in food production.

26. The application for which water may be reused is dependent upon its source and how it is collected, stored and treated. Evaluating these elements will establish if the water is fit for the intended purpose. Water that potentially can be sourced for reuse include:

- reclaimed water from milk, dairy ingredients or was part of a milk product (e.g. in milk powder or cheese manufacturing);
- water that has come into a dairy operation in the form of potable water and is recirculated until it is no longer suitable as potable water;
- water that is being recirculated for heating or cooling purposes;
- water that has been used for cleaning processing equipment;
- water that has been used to clean facility floors, walls, ceilings, the outside of piping and processing equipment, etc.; and
- water that is part of a dairy operation's effluent.

27. Based on the fit-for-purpose assessment, such reuse water can be used for different purposes, subject to appropriate treatment when applicable:

- as an ingredient;
- any direct or indirect contact with milk products and the product contact surfaces of dairy processing or milking equipment;
- the cleaning, disinfection and rinsing of product contact surfaces of processing equipment, tanks, vessels, pipelines, valves, utensils and equipment; water fit for purpose for rinsing before cleaning and disinfection (first rinsing) might not be fit for purpose for rinsing after cleaning and disinfection;
- cleaning non-product contact surfaces (e.g. walls, floors, etc.);
- boiler water feed; and

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<sup>i</sup> Under development

- heating or cooling of raw materials, ingredients and finished product.

28. Further, there might be laws and regulations addressing water reuse established by competent authorities that need to be followed.

29. A back-up fit-for-purpose water supply such as an external potable water source that can be used in case a reuse water treatment system is not effective or functioning properly should be available.

30. External technical expertise might be needed for the design of safe water reuse systems in dairy operations.

## **7 TECHNOLOGIES FOR RECOVERY AND TREATMENT OF WATER**

### **7.1 General recommendations**

31. Membrane filtration, and other technologies of hygienic design, may be applied to reclaimed, recycled or recirculated water (other than potable water) in order to make the water fit for purpose. Refer to Annex IV.<sup>ii</sup>

### **7.2 Specific recommendations for reverse osmosis in the use and reuse of water in dairy production**

32. Reverse osmosis water recovered from permeates, for example whey or water mixtures resulting from equipment and pipeline flushes, typically has very low microbial counts. When the performance efficiency of RO has been subjected to a hazard analysis and validated, and is verified to be consistent, RO water may be used for the following purposes based on a risk assessment or within approximately 24 hours after generation, without additional microbiocidal treatment<sup>iii</sup> for example:

- ingredient in milk products, e.g. reconstitution of dry ingredients and dairy powders, scalding of cheese curds and grains;
- production of ice and steam, including steam for direct injection;
- washing of cheese curd to remove the casein/whey protein and to directly cool cheeses;
- cleaning, disinfection and rinsing in between cleaning steps;
- final cleaning, disinfection and rinsing of product contact surfaces for all processing lines used for heat-treated products;
- cleaning of membrane filtration systems or washing of reusable packaging boxes and product moulds;
- diafiltration, i.e. process applied in combination with another membrane filtration method, where water is added to the membrane filtration retentate to flush out constituents to reduce product viscosity and to make the purification of lactose and minerals more efficient; and
- preparation and dilution of brine used for brining cheese. The microbiological control of reuse water for diluting brine can be done as part of the normal verification process for the microbial quality of the brine.

33. In dairy production, RO water of which the microbiological quality is uncertain (for example in case of no microbiological testing, when testing indicates poor quality or when the RO system is unvalidated) and that will not be used within approximately 24 hours or based on a fit-for-purpose assessment, should be subjected to an effective microbiocidal treatment.

### **7.3 Specific recommendations for the recovery of reclaimed water from milk by condensation of vapours evaporated during concentration of milk and milk products**

34. Due to the presence of organic material (different sources of milk products and technologies result in different qualities of organic material in this reclaimed water) which may support the growth of microorganisms, treatment of such condensate (e.g. by UV treatment, thermal treatment, microbiocidal treatment, biological filters, MF, UF, NF or RO filtration) may be required before this condensate water is reused for some applications, such as a food ingredient or for food-contact application. Untreated condensate water may be directly used for non-food-contact applications.

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<sup>ii</sup> Under development.

<sup>iii</sup> Recommendation from MRA40.

35. Reuse water from dairy processing operations may contain microorganisms that can form biofilms on stainless steel surfaces, as well as pathogenic bacteria. It is therefore important that reuse water has an appropriate disinfection treatment when required, that achieves the guideline values for the verification of microbial quality appropriate to the intended use. Chemical disinfection of water will inevitably generate disinfection residues. The optimal choice of disinfectant will vary between different dairy manufacturing sites, depending upon their individual milk product range and method of recovering water for reuse, which will affect the organic loading.

## 8 WATER FIT-FOR-PURPOSE ASSESSMENT

36. Refer to Section 7 of the General Section and Annex IV<sup>iv</sup> of these guidelines.

## 9 WATER SAFETY MANAGEMENT

37. Refer to Section 8 of the General Section and Annex IV<sup>v</sup> of these guidelines.

## 10 EXAMPLES OF FIT-FOR-PURPOSE WATER APPLICATIONS IN DAIRY PLANTS<sup>vi</sup>

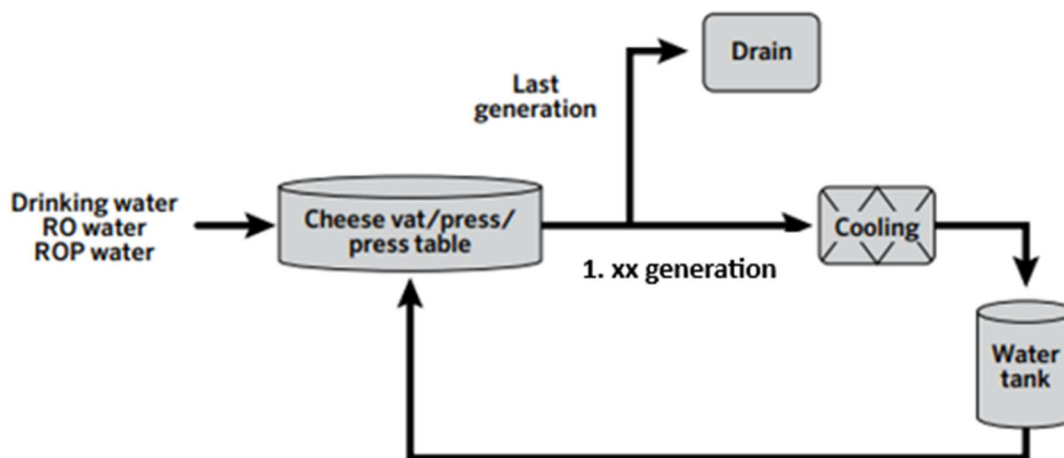
38. The examples below are for illustrative use only. Any reuse scenario should be based on a proper hazard analysis before implementation.

### 10.1 Example of reuse of potable water by recirculation or recycling

39. After introducing potable water in a closed system, the water is recycled for a specific number of times. The number of acceptable cycles is based on the assessment of maximum levels of predefined parameters (e.g. microbiological criteria). The recycled water is then disposed of from the system or is treated with a microbiocidal treatment (e.g. heat, UV or chemical disinfectants) when the number of acceptable cycles has been reached.

40. As an example, during cheese production, reclaimed water is used for the following cooling step and then recycled in a closed system as illustrated in Figure 1. It is derived from a detailed example that can be found in case study 2 of Annex 4 of MRA40.<sup>9</sup>

**Figure 1: Scheme shows the recirculation of water used for cooling cheeses.**



<sup>a</sup> In this scenario, multiple runs of recirculation may apply. Recirculating externally sourced water for a new reuse, will produce a second generation of water and recirculation of the second generation would create the third generation, etc. When the number of recirculations has reached its maximum, xx, (based on microbial testing) then the water is to be discarded as waste (last generation).xx generation

41. In case of recycling, the same principle should be applied, but before the water is reused, a reconditioning/treatment step should be applied as necessary.

<sup>iv</sup> Under development

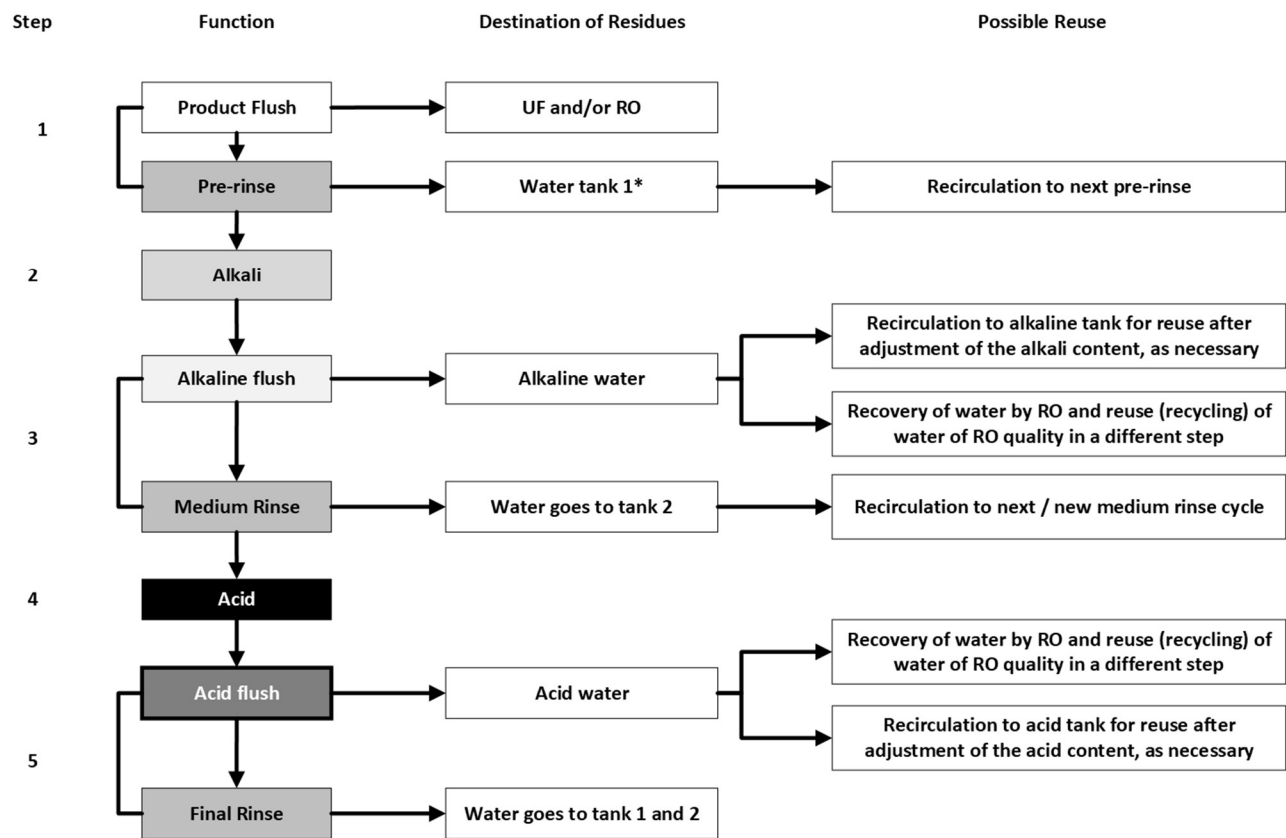
<sup>v</sup> Under development

<sup>vi</sup> Figures in this section were copied from MRA40.

### 10.2 Example of recovery and reuse of water from CIP systems

42. CIP systems are used in dairy manufacturing plants to remove product residues from food-contact surfaces and to remove or reduce biofilm formation. A CIP system consists of a number of consecutive rinsing, cleaning and disinfection steps using fit-for-purpose water at minimum designated temperatures, flow rates, pressures and concentration of chemicals in which the fit-for-purpose water needs to comply with different microbiological, physical and/or chemical parameters. On certain occasions, water used within a step can be recycled for the same step or an earlier step, e.g. potable water needed for the final rinsing step can be recycled for earlier rinsing. This is illustrated in Figure 2, which is derived from a detailed example of the use of a CIP system that can be found in case study 3 of Annex 4 of MRA40.<sup>9</sup>

**Figure 2: Sketch for reuse of water streams in a 5-step CIP system, including recovery of RO water from CIP fluids.** Illustrates the flow of water streams and the associated options for recirculation or recycling the water from CIP fluids at different steps using UF, RO, ROP.



\* When flushing of non-pasteurized product, the water should be pasteurized before reuse. Alternatively it is led to the drain.

Source: Adapted from Heggum, C. 2020. Dairy Sector Guide - Recommendations of the Danish Agriculture and Food Council on implementation of food safety management systems in Danish dairy plants.

### 10.3 Example of recovery and reuse of water from food production/processing (reclaimed water)

43. Water present in milk or milk products can be recovered during processing (reclaimed water) and reused. Reclaimed water can be obtained from different processes which will determine its microbiological safety and its need for reconditioning. Examples are condensate from evaporation processes, casein wash water, milk whey and other permeates with additional treatments and milk product rinse water.

44. This condensate from evaporation processes contains organic materials and chemical compounds such as milk solids and lactic acid, but it is generally very pure. Therefore, it can be used directly or treated in a RO or ROP systems for reuse if it meets fit-for-purpose water criteria as a food ingredient or for cleaning and disinfection of food-contact material.

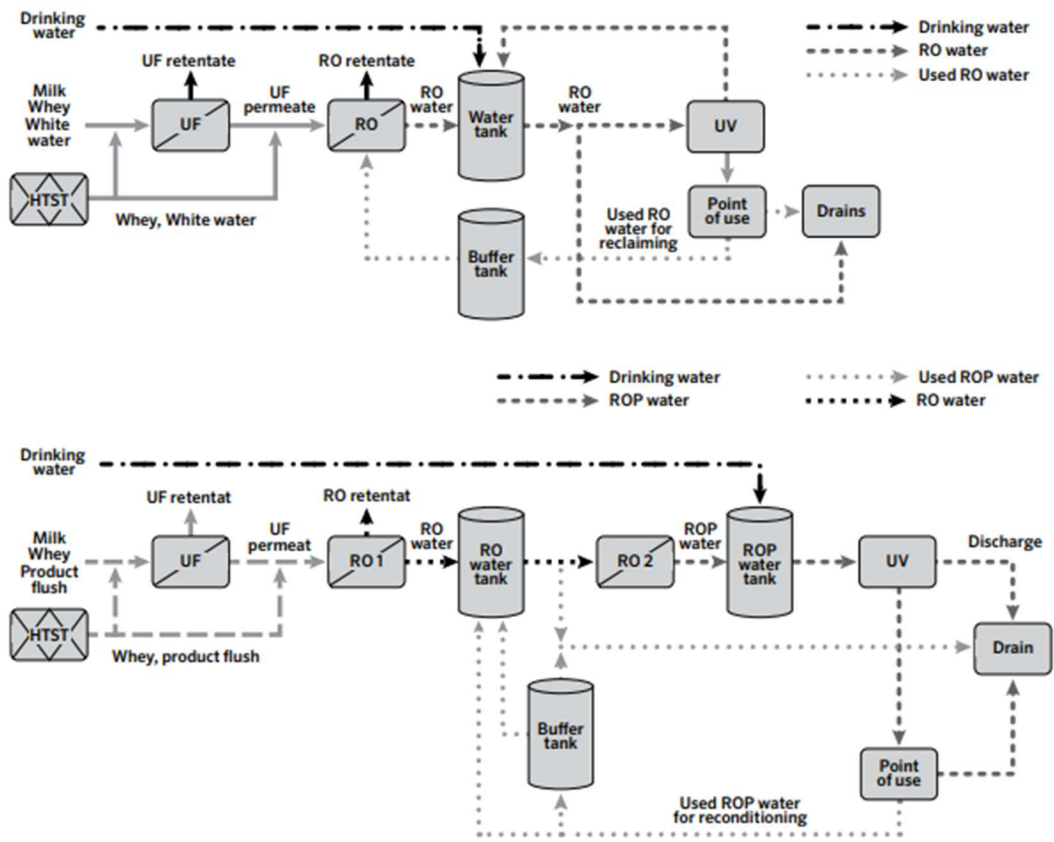
45. Casein wash water, whey permeate, lactose permeate, milk permeate and some other types of permeates are a good source of reuse water but may support microbiological growth due to the presence of small amounts of milk solids such as milk proteins or lactose. Reusing water conditions should therefore be carefully assessed, monitored and verified. Treatment/purification steps such as NF, RO and UF should be considered.

46. Milk product rinse water could be water recovered from the initial rinsing of pipes or tanks for milk and consists of a mixture of water and milk, milk-based food materials and deposits. Depending on the place of rinsing (e.g. equipment before or after pasteurization of the milk) and the presence/absence of biofilms, microbiological contamination might vary. Treatment of recovered and stored rinse water to inhibit microbiological growth may need to be considered.

47. There should be sufficient documentation to identify the source and treatment (if any) of the reuse water (initial lot production) and subsequent use (which subsequent lots were exposed to this reuse water) in case a food safety investigation is needed.

48. Figure 3 provides an example of the recycling of water from whey using RO or ROP. It was derived from a detailed example that can be found in case study 4 of Annex 4, of MRA40.<sup>9</sup>

**Figure 3: Examples of two scenarios involving recycling of reusable water sources through RO/ROP and UV treatment(s).** Top: describes the recovery of reclaimed water from milk, whey and product flushes using RO followed by UV treatment. Bottom: shows how the RO water is further purified by another RO process (a polisher), followed by UV treatment.



Source: Reproduced with permission from Heggum, C. 2020. Dairy Sector Guide - Recommendations of the Danish Agriculture & Food Council on implementation of food safety management systems in Danish dairy plants.

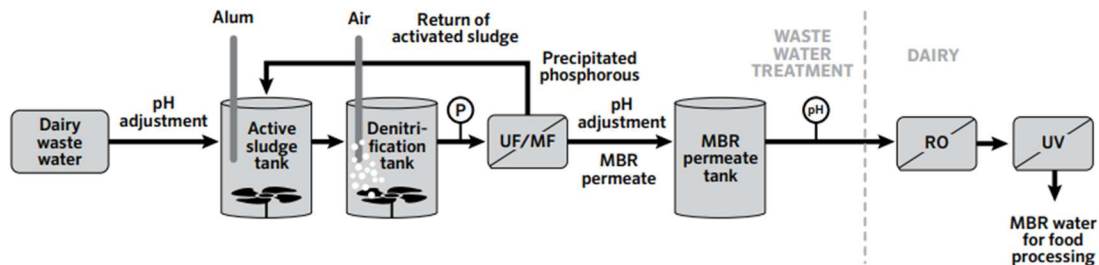
### 10.4 Example of recovery and reuse of dairy effluents

49. Effluents from dairy manufacturing plants such as dairy processing wastewater or sewage (wastewater from showers, bathrooms, toilets, wash stations etc.) that contain agents pathogenic to human, may be captured, treated and reused for certain applications when subjected to appropriate treatment and fit-for-purpose assessment and management measures are in place. These effluents may not only contain milk constituents supporting microbiological growth, but other hazardous substances.



50. Such wastewater should be collected and handled in a manner that prevents cross-contamination of the reuse water, and meets local, regional or national government requirements. Figure 4 provides an example of the recovery of water from dairy effluents using a membrane bioreactor and RO. It was derived from a detailed example that is provided in case study 5 of Annex 4 to MRA40.<sup>9</sup>

**Figure 4: Example of the recovery of water from dairy effluents using MBR and RO.**



Source: Reproduced with permission from Heggum, C. 2020. Dairy Sector Guide - Recommendations of the Danish Agriculture & Food Council on implementation of food safety management systems in Danish dairy plants.

### 10.5 Example of water recovery and reuse from non-food manufacturing operations

51. Water originating from external sources such as private wells may vary in chemical, microbiological and physical content, and may contain unidentified components. If the manufacturing facility has its own wells, the water may or may not be potable. This will need to be determined through a collection of data that includes microbiological sampling and testing as well as organoleptic evaluation (odour and appearance). Assessment of the pH, turbidity, nitrate level and hardness of such water may be helpful. This will need to be determined through an appropriate evaluation. If the well water has come in contact with surface water, it will most likely have microbial contamination but can still be used if properly treated or for any qualifying fit-for-purpose use. A fit-for-purpose assessment and management measures are needed to identify likely hazards and controls to minimize or eliminate them. Treatment of the water, if needed, should be captured in the HACCP plan.

52. Case study 1 in Annex 4 to MRA40<sup>9</sup> illustrates the use of water from local wells at or near the dairy manufacturing plant.

## NOTES

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<sup>1</sup> FAO and WHO. 2004. *Code of Hygienic Practice for Milk and Milk Products*. Codex Alimentarius Code of Practice, No. CXC 57-2004. Codex Alimentarius Commission. Rome.

<sup>2</sup> FAO and WHO. 1969. *General Principles of Food Hygiene*. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.

<sup>3</sup> FAO and WHO. 2007. *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)*. Codex Alimentarius Guideline, No. CXG 63-2007. Codex Alimentarius Commission. Rome.

<sup>4</sup> FAO and WHO. 2008. *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*. Codex Alimentarius Guideline, No. CXG 30-1999. Codex Alimentarius Commission. Rome.

<sup>5</sup> FAO and WHO. 2008. *Guidelines for the Validation of Food Safety Control Measures*. Codex Alimentarius Guideline, No. CXG 69-2008. Codex Alimentarius Commission. Rome.

<sup>6</sup> FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*. Codex Alimentarius Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.

<sup>7</sup> FAO and WHO. 2016. *Guidelines on the Application of General Principles of Food Hygiene to the Control of Foodborne Parasites*. Codex Alimentarius Guideline, No. CXG 88-2016. Codex Alimentarius Commission. Rome.

<sup>8</sup> FAO and WHO. 2012. *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food*. Codex Alimentarius Guideline, No. CXG 79-2012. Codex Alimentarius Commission. Rome.

<sup>9</sup> FAO and WHO. 2023. Safety and quality of water use and reuse in the production and processing of dairy products – Meeting report. *Microbiological Risk Assessment Series*, No. 40. Rome, FAO.

<https://doi.org/10.4060/cc4081en>

## APPENDIX V

**REVISION OF GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE  
TO THE CONTROL OF PATHOGENIC *VIBRIO* SPECIES IN SEAFOOD (CXG 73-2010)**

(at Step 5)

**1. INTRODUCTION**

1. There has been an increase in reported outbreaks in some areas and cases of foodborne disease attributed to pathogenic *Vibrio* species. As a result, there have been several instances where the presence of pathogenic *Vibrio* spp. in seafood has led to a disruption in international trade. This has been particularly evident with *Vibrio parahaemolyticus* where a series of pandemic outbreaks occurred due to the consumption of seafood, and its emergence has been observed in regions of the world where it was previously unreported. A number of *Vibrio* species are increasingly being recognized as potential human pathogens. The food safety concerns associated with these microorganisms have led to the need for specific guidance on potential risk management strategies for their control. These risk management strategies need to be developed and implemented based on the specific harvest area site characteristics such as water and ambient temperatures, salinity and water sources flowing into a harvest area. It was previously thought that the ingestion of a large number of viable cells was needed for pathogenic *Vibrio* spp. to survive the acidic environment of the stomach and establish an infection in the gastrointestinal tract. With the emergence of highly pathogenic strains, there is now recognition that the dose-response may be much lower depending on the individual strains and virulence profiles.

**1.1 General Characteristics of Pathogenic *Vibrio* spp. associated with foodborne illness**

2. Most species of genus *Vibrio* that are pathogenic to humans can cause food-borne illness. The majority of food-borne illness is caused by *V. parahaemolyticus*, choleraogenic *V. cholerae* (O1, O139), or *V. vulnificus*<sup>1</sup>. *V. parahaemolyticus* and *V. cholerae* are mainly isolated from gastroenteritis cases that are attributable to the consumption of contaminated food (both species) or from the intake of contaminated water (*V. cholerae*). In contrast, *V. vulnificus* is primarily reported from extraintestinal infections (e.g. septicaemia, infected wounds, etc.) and primary septicaemia due to *V. vulnificus* infection is often associated with consumption of seafood.

3. Non-foodborne route of infection of *V. vulnificus* is outside the scope of these guidelines, but special attention to the susceptible subpopulations handling shellfish will be needed to prevent *V. vulnificus* infections associated with injuries from knives or shells. In tropical and temperate regions, these species of *Vibrio* occur naturally in marine, coastal and estuarine (brackish) environments and are most abundant in estuaries. Pathogenic *Vibrio* spp., in particular *V. cholerae*, can also be recovered from freshwater reaches of estuaries, where it can be introduced by faecal contamination. *V. cholerae*, unlike most other *Vibrio* species, can survive in freshwater environments.

4. It is now possible to differentiate *V. cholerae* and *V. parahaemolyticus* between virulent and avirulent strains based on their ability to produce major virulence factors. The pathogenic mechanisms of *V. vulnificus* have not been clearly explained, and its virulence appears to be multi-factorial and is not well understood, and therefore it is recommended to implement measures to mitigate the risk assuming that all strains need to be handled as pathogenic.

5. The following are important characteristics common to all *Vibrio* spp. *Vibrio* spp. are sensitive to low pH but can grow at higher pHs, and thus infections caused by *Vibrio* spp. are frequently associated with low-acid foods. It was previously thought that the ingestion of a large number of cells was needed for pathogenic *Vibrio* spp. to transition through the stomach and establish an infection. However, new and highly pathogenic strains of *Vibrio* spp. have emerged with a significantly lower infectious dose than previous strains. These new strains also exhibited different growth characteristics compared to the *V. parahaemolyticus* strains used in the previous risk assessments<sup>2</sup>.

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<sup>1</sup> Other *Vibrio* species that have been reported to cause food-borne illness include but not be limited to *V. alginolyticus*, non-choleraogenic *V. cholerae* (non O1/non O139 strains possessing the ctx gene for cholera toxin), *V. fluvialis*, *V. furnissii*, *V. hollisae* (re-classified as *Grimontia hollisae*), *V. metocus*, *V. metschnikovii*, *V. mimicus*, *V. paracholerae*, *V. ponticus* and *V. tarraie*.

<sup>2</sup> FAO and WHO, 2020, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 35) (Section 3.2).

6. There are, however, characteristics specific to each of the three major pathogenic species of *Vibrio* responsible for the majority of human infections, and therefore of country's public health concern, that require attention as described below.

### 1.2 *Vibrio parahaemolyticus*

7. *V. parahaemolyticus* is considered to be part of the naturally occurring microbiota in the estuarine and coastal environments in tropical to temperate zones. Seawater temperature has been reported as one of the principal environmental factors increasing the abundance of *V. parahaemolyticus* in many areas of the world. Increased levels of *V. parahaemolyticus* are correlated with warming seawater temperatures in spring and summer for temperate regions, and are observed in macro-tidal harbours and creeks with high fluctuation temperatures for tropical regions. While *V. parahaemolyticus* is typically undetectable in seawater at 10°C or lower, it can be cultured from sediments throughout the year at temperatures as low as 1°C. In temperate zones, the life cycle consists of a phase of survival in winter in sediments and a phase of release with the zooplankton when the temperature of the water increases up to 14 - 19 °C. *V. parahaemolyticus* is characterized by its rapid growth in the water under favourable conditions<sup>3</sup>.

8. The vast majority of strains isolated from patients with diarrhoea produce a thermostable direct hemolysin (TDH). Additionally, strains that produce a TDH-related hemolysin (TRH) encoded by the *trh* gene should also be regarded as pathogenic. Although detection of *tdh*- *trh*- strains among clinical strains has been the source of debate on the pathogenic roles of *tdh* and *trh* genes, and the mode of pathogenicity is not fully understood, these genes are still the most well defined markers of virulence.

9. Virulent strains are seldom detected in the environment or foods. In contrast to strains from clinical cases that will always possess these virulence factors, the probability of detection of environmental or food strains, including seafoods, which possess virulence markers will be very low as most do not contain known virulence markers and their distribution within seafood and across growing areas is not homogeneous. In addition, current selective media cannot distinguish colonies of virulent strains from those of avirulent strains. Given this limitation, failure to detect virulent strains in the environment or in foods does not mean there is no risk to consumers.

10. In general, the outbreaks are small in scale, involving fewer than 10 cases, but can occur frequently, especially in the months with high water temperature.

11. In relation to seafood-borne *V. parahaemolyticus* illnesses, harvest and post-harvest are the most critical stage since it is from this point onwards that measures to control *V. parahaemolyticus* should be implemented. Additionally, the pre-harvest control for aquaculture is also important for managing the risks. It is also important to consider control measures at post-harvest, during processing, wet storage, and associated transport and packaging operations, and during retail. Setting appropriate time-temperature requirements of these control measures is important, especially time-temperature controls on post-harvest refrigeration<sup>4</sup>.

12. Foods associated with illnesses due to consumption of *V. parahaemolyticus* include for example finfish (such as mackerel, tuna), crustaceans (such as prawns, crabmeat), bivalve molluscs (such as oysters, scallops), cephalopods (such as squid), and echinoderms (such as sea urchin). These products include raw, partially treated and treated seafood products that have been cross-contaminated, for example through utensils, water and ice, hands, uncooked contaminated seafood, etc.

### 1.3 *Vibrio cholerae*

13. *V. cholerae* is naturally occurring to fresh and brackish water environments in tropical, subtropical and temperate areas worldwide. Over 200 O serogroups have been identified for *V. cholerae*. Strains belonging to O1 and O139 serotypes generally possess the *ctx* gene, which encodes the cholera toxin (CT) and are responsible for epidemic cholera. Epidemic cholera is confined mainly to developing countries with warm climates. Contamination of food production environments (including aquaculture ponds) by human faeces can indirectly introduce cholerae *V.cholerae* into foods. The concentration of free-living cholerae *V. cholerae* in the natural aquatic environment is low, but *V. cholerae* is known to attach and multiply on zooplankton such as copepods.

14. Epidemic cholera can be spread by factors such as: infected travelers and the food trade. These factors,

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<sup>3</sup> FAO and WHO, 2020, Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 3.1).

<sup>4</sup> FAO and WHO, 2016, Selection and application of methods for the detection and enumeration of human-pathogenic halophilic *Vibrio* spp. in seafood (Microbiological Risk Assessment series, No. 22) (Section 2.2).

but also climate change, may increase the probability of an epidemic in the newly established environments. Detection frequencies of cholera strains of *V. cholerae* from legal food trade are very low and have seldom been implicated in cholera outbreaks.

15. Some strains belonging to the O serogroups other than O1 and O139 (referred as non-O1/non-O139) can cause food-borne diarrhoea that is milder than cholera. Recent years have seen an increase in infections associated with these particular strains.

16. Outbreaks of food-borne cholera have been noted in some parts of the world in the past 30 years; seafood, including bivalve molluscs, crustaceans, and finfish, as well as contact with surface water and seafood handling are most often linked to food-borne cholera cases in many countries. A strong association has been observed between continuous changes in environmental and climate-related factors, particularly water temperature and salinity, and cholera infections. However, there are several complex and multifaceted epidemiological factors that are often associated with these factors.

#### **1.4 *Vibrio vulnificus***

17. *V. vulnificus* can occasionally cause mild gastroenteritis in healthy individuals, but it can cause primary septicaemia in individuals with chronic pre-existing conditions, especially liver disease or alcoholism, diabetes, haemochromatosis and HIV/AIDS, following consumption of raw or partially treated bivalve molluscs and other seafood. This is a serious disease with one of the highest fatality rates of any known foodborne bacterial pathogen. The dose response for humans is still unclear and more data are necessary. Incubation period ranges from 7 hours to several days, with the average being 24 hours. Some virulence factors have been identified, however definitive virulence determinants have not yet been established, therefore, it is not clear whether all strains are capable of causing disease. The ability to acquire iron is considered essential for virulence expression of *V. vulnificus*.

18. Most of the foodborne illnesses associated with *V. vulnificus* are sporadic cases although some outbreaks have been reported. *V. vulnificus* has been isolated from oysters and other seafood worldwide.

19. Seawater temperature has been reported as one of the principal environmental factors increasing the abundance of *V. vulnificus* in many areas of the world. *V. vulnificus* can grow in oysters in the temperature range of 13-30°C.

20. According to the available data, the coastal environmental salinity plays an important role in *V. vulnificus* incidence and population levels. Evidence shows that salinity is negatively correlated with *V. vulnificus* concentrations. Salinity levels lower than 1 ppt (parts per thousand) or higher than 30 ppt will not allow *V. vulnificus* growth.

## **2. OBJECTIVES**

21. These Guidelines provide guidance on control of pathogenic *Vibrio* spp. in seafood, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The primary purpose of these Guidelines is to highlight the key control measures that can be used to minimize the likelihood of illness arising from the presence of pathogenic *Vibrio* spp. in seafood. These Guidelines provide information that will be of interest to the food business operators (FBOs), consumers, competent authorities and other interested parties.

## **3. SCOPE**

22. These Guidelines cover seafood that is marketed and may be consumed in a live, raw, chilled/frozen, partially treated, or in a treated state. It is applicable across the whole food chain from primary production to final consumption. Bivalve molluscs are covered more thoroughly in the Annex, which is supplemental to these Guidelines.

23. As major causative agents of foodborne bacterial illnesses associated with seafood, the target microbiological hazards of these Guidelines are three pathogenic *Vibrio* spp. (*V. parahaemolyticus*, *V. vulnificus* and *V. cholerae*). The control measures described in these Guidelines may be applicable to other pathogenic *Vibrio* spp.

## **4. USE**

24. These Guidelines are supplemental to, and should be used in conjunction with, the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG100-2023). The application of these Guidelines by countries may require modifications and amendments, taking into account

regional differences such as the prevalence of pathogenic *Vibrio* spp., air and water temperatures and salinity.

#### 4.1 Roles of competent authorities, food business operators, and consumers

25. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

### 5. GENERAL PRINCIPLES

26. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

#### 5.1 Management commitment to food safety

27. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

### 6. DEFINITIONS

28. For the purpose of these Guidelines, the following definitions apply:

Definitions of the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

Refrigeration: The lowering and maintaining of product temperature to limit microbial activity.

Seafood: Fish, shellfish and other aquatic invertebrates from marine and fresh water sources and their products which are intended for human consumption.

Partially treated: Any treatment intended to reduce or limit, but not eliminate, *Vibrio* spp. in seafood (e.g., steam, blanching).

Treated: Any treatment intended to eliminate *Vibrio* spp. in seafood.

[Clean water: Water that does not meet the criteria for potable water but does not compromise the safety of the food in the context of its use.

Water fit for purpose: Water that is determined to be safe for an intended purpose through the identification, evaluation, and understanding of potential microbiological hazards and other relevant factors (e.g. history of use, the intended use of the food, etc.), including the application of control measures such as treatment options and their efficacy to ensure effective elimination or mitigation of such hazards.]

## PART 1 GOOD HYGIENE PRACTICES

### 7. INTRODUCTION AND CONTROL OF FOOD HAZARDS

29. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

### 8. PRIMARY PRODUCTION

#### 8.1 Environmental control

30. Refer to Section 8.1 of the *General Principles of Food Hygiene* (CXC 1-1969). In addition:

31. Generally, pre-harvest controls are more applicable to farmed bivalve molluscs and fish than to other seafood (e.g. open-sea harvested fish). Where relevant to other seafood, pre-harvest controls should be considered for areas where the likelihood of introduction of pathogenic *Vibrio* spp. is significant and can be controlled.

32. Temperature and salinity should be considered for controlling pathogenic *Vibrio* spp. in seafood. Where applicable, specific water temperature or salinity levels that can be used as control measures should be identified based on epidemiological and exposure studies as well as monitoring of pre-harvest pathogenic *Vibrio* levels.

33. For monitoring bivalve molluscs, at harvest, refer to the Annex of these Guidelines.

34. For seafood grown in coastal localities, especially in cholera-endemic areas, care should be taken to avoid harvest of seafood contaminated with faecal cholerae *V. cholerae*. This includes contamination caused by significant environmental impacts such as flooding and discharges from sewage spills.

#### 8.2 Hygienic production

35. Refer to Section 8.2 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 8.3 Handling, storage and transport

36. Refer to Section 8.3 of the *General Principles of Food Hygiene* (CXC 1-1969).
37. For the storage and handling of seafood aboard fishing vessels, [water fit for purpose (in this case, at least clean water)] should be used for seafood intended to be eaten raw or partially treated, and for preparing ice. The use of sea water taken from near a drainage outlet or river contaminated with sewage should be avoided. Seafood should be held at temperatures that minimize and/or prevent the growth of pathogenic *Vibrio* spp. after harvest, for example, in an ice-water slurry, ice or refrigeration on fishing vessels and at harvest sites. The delay between harvest and refrigeration should be as short as possible.
38. For on board cooked (boiled, blanched) seafood products, ice and/or refrigeration should be used to facilitate the rapid cooling. Ice made from [water fit for purpose (in this case, at least clean water)] should be used to minimize cross-contamination.
39. For the storage of live seafood products, [clean water] should be used to minimize contamination from the water.
40. When the product is required to be washed, whether onboard the boat or at port, [clean water] should be used.
41. During transportation from harvest to the on-shore market and/or processing establishments, to minimize and/or prevent the growth of pathogenic *Vibrio* spp. in seafood, the time elapsed between harvest and refrigeration or freezing is critical and should be minimized. Ice can be used to keep seafood chilled during transportation and sale. Live fish and shellfish should be transported at the lowest temperature tolerable for the species. Covered containers should be used for transport to prevent contamination.

### 8.4 Cleaning, maintenance and personnel hygiene

42. Refer to Section 8.4 of the *General Principles of Food Hygiene* (CXC 1-1969) and the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023).
43. Refer to Section 12.1 of the *General Principles of Food Hygiene* (CXC 1-1969). A carrier who is excreting *V. cholerae* should not handle seafood, water, or ice for the storage of seafood, which may result in the contamination of the seafood with cholerae *V. cholerae*.

## 9. ESTABLISHMENT: DESIGN OF FACILITIES AND EQUIPMENT

44. Equipment and facilities should be designed, constructed and laid out to minimize the potential for cross-contamination and recontamination of seafood with pathogenic *Vibrio* spp.

### 9.1 Location and structure

45. Refer to Section 9.1 of the *General Principles of Food Hygiene* (CXC 1-1969).

#### 9.1.1 Location of establishments

46. Refer to Section 9.1.1 of the *General Principles of Food Hygiene* (CXC 1-1969).

#### 9.1.2 Design and layout of food establishment

47. Refer to Section 9.1.2 of the *General Principles of Food Hygiene* (CXC 1-1969).
48. Premises and rooms should be designed to keep raw material areas separated from finished seafood product areas. This can be accomplished in a number of ways, including linear product flow (raw materials to finished products) or physical partitions.
49. The washing room for food handling equipment used for finished product manufacturing should be physically segregated from the finished product processing area.

#### 9.1.3 Internal structures and fittings

50. Refer to Section 9.1.3 of the *General Principles of Food Hygiene* (CXC 1-1969).

#### 9.1.4 Temporary/mobile premises and vending machines

52. Refer to Section 9.1.4 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 9.2 Facilities

53. Refer to Section 9.2 of the *General Principles of Food Hygiene* (CXC 1-1969).
54. Adequate facilities should be provided for the handling and washing of products.
55. Suitable and adequate facilities should be provided for storage and/or production of ice.

#### **9.2.1 Drainage and waste disposal facilities**

56. Refer to Section 9.2.1 of the *General Principles of Food Hygiene* (CXC 1-1969).
57. All drainage and waste lines should be capable of coping with peak demands.
58. Accumulation of solid, semi-solid or liquid wastes should be minimized to prevent contamination, because pathogenic *Vibrio* spp. may grow rapidly in these wastes under certain conditions.
59. Separate and adequate facilities should be provided to prevent contamination by offal and waste material.

#### **9.2.2 Cleaning facilities**

60. Refer to Section 9.2.2 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

#### **9.2.3 Personnel hygiene facilities and toilets**

61. Refer to Section 9.2.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.5.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

#### **9.2.4 Temperature**

62. Refer to Section 9.2.4 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 4.1 of *Code of Practice for Fish and Fishery Products* (CXC 52-2003).
63. The *Code of Practice for Fish and Fishery Products* indicates maintaining the product at temperature as close to 0°C as possible. For pathogenic *Vibrio* spp., a temperature of 10°C or lower is adequate to limit growth. However, pathogenic bacteria species such as *Listeria monocytogenes*, *Clostridium botulinum* and histamine formers may also be hazards in addition to *Vibrio* spp. Temperature control, as close to 0°C as possible, should be implemented. In the case of bivalve molluscs, a different temperature control specified in the Annex would be required. The facility should be capable of controlling product temperature during processing of raw seafood at a temperature of 10°C or lower.

#### **9.2.5 Air quality and ventilation**

64. Refer to Section 9.2.5 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.2 of *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

#### **9.2.6 Lighting**

65. Refer to Section 9.2.6 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.3 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

#### **9.2.7 Storage**

66. Refer to Section 9.2.7 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

### **9.3 Equipment**

#### **9.3.1 General**

67. Refer to Section 9.3.1 of the *General Principles of Food Hygiene* (CXC 1-1969).

#### **9.3.2 Food control and monitoring equipment**

68. Refer to Section 9.3.2 of the *General Principles of Food Hygiene* (CXC 1-1969).
69. Areas where refrigeration is necessary should be equipped with a calibrated thermometer.

## **10. TRAINING AND COMPETENCE**

### **10.1 Awareness and responsibilities**



70. Refer to Section 10.1 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.8 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) in addition to the following.

71. FBOs (fishermen, primary producers, manufacturers, distributors, retailers and food service) and trade associations play an important role in providing specific instructions and/or training to employees for the control of pathogenic *Vibrio* spp. Consideration should be given to possible differences in prevalence of pathogenic *Vibrio* spp. in the harvesting areas.

## 10.2 Training programmes

72. Refer to Section 10.2 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.8 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) in addition to the following.

73. Personnel involved in the primary production, harvesting, processing and handling of seafood should have appropriate training for the tasks they are performing. This may include:

- The nature of pathogenic *Vibrio* spp., namely *V. parahaemolyticus*, *V. cholerae* and *V. vulnificus*, their harbourage sites, and their resistance to various environmental conditions to be able to conduct a suitable hazard analysis for their products;
- Prevention and control measures for reducing the risk of pathogenic *Vibrio* spp. associated with seafood during harvesting, processing, distribution, marketing, use and storage, for preventing cross-contamination and minimizing the growth of pathogenic *Vibrio* spp.; and
- The means for verifying effectiveness of control programs, including sampling and analytical techniques.

## 10.3 Instruction and supervision

74. Refer to Section 10.3 of the *General Principles of Food Hygiene* (CXC 1-1969).

## 10.4 Refresher training

75. Refer to Section 10.4 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.8 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

## 11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

76. Refer to Section 11 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.4 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

## 12. PERSONAL HYGIENE

77. Refer to Section 12 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.5 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

## 13. CONTROL OF OPERATION

### 13.1 Description of products and process

78. Refer to Section 13.1 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 13.2 Key aspects of Good Hygiene Practices (GHPs)

#### 13.2.1 Time and temperature control

79. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003). Time and temperature are the most important factors affecting the rate of growth of pathogenic *Vibrio* spp. in seafood. During each processing step, the temperature of the product should be controlled and monitored via calibrated thermometers.

#### 13.2.2 Specific process steps

##### 13.2.2.1 Washing and processing

80. [Water fit-for-purpose (in this case, at least clean water)] at low temperature should be used for washing and processing whole seafood.

##### 13.2.2.2 Cooking

81. Time and temperature should be determined for each cooking operation to ensure the inactivation and

elimination of pathogenic *Vibrio* spp.

82. [Water used for cooling fish and fishery products after cooking or blanching should be fit for purpose (in this case, at least clean water).]

### 13.2.2.3 Food processing practices

83. Food processing practices should be used to minimize the growth or reduce the level of the pathogenic *Vibrio* spp. in seafood. Food business operators can apply appropriate interventions depending on their actual situation. Examples of these interventions are:

- Minimizing the growth
  - acidification to pH below 4.8;
  - adding permitted food preservatives which have efficacy in preventing the growth of *Vibrio* spp.
- Reducing the level
  - salting to a sodium chloride concentration of more than 10% to control *V. parahaemolyticus*;
  - adding permitted food preservatives which have efficacy in reducing the level of *Vibrio* spp.
  - seafood to ionising energy, e.g., gamma rays, machine-generated electrons or X-rays.
  - hydrostatic compression in the range of 14,500 to 145,000 pound per square inch (100 to 1,000 megapascal (MPa));
  - depuration under optimal conditions, e.g., at a temperature of 12.5°C and stocking density of two oysters/L of artificial seawater for 5 days, and/or water activity less than 0.94 and high salinity (30 ppt); and
  - cryogenic individual quick freezing (IQF) involving the use of cryogenic or blast freezing technology to rapidly lower the product temperature below freezing.

84. Any practice, or combination of practices selected to reduce/inactivate pathogenic *Vibrio* spp. in seafood or control/minimize the growth of pathogenic *Vibrio* spp. should be adequately validated to ensure that the process is effective. Such validation should be performed according to the *Guidelines for the Validation of the Food Safety Control Measures* (CXG 69-2008).

85. For example, when freezing is used to reduce the level or prevent the growth of pathogenic *Vibrio* spp. in seafood, consideration should be given to the sensitivity of pathogens to freezing. *V. parahaemolyticus* and *V. vulnificus* are especially sensitive to colder temperatures. To reduce *V. parahaemolyticus* and/or *V. vulnificus* to nondetectable levels, the IQF process should be followed by a period of frozen storage, which may vary depending on organism. When freezing, the following should be considered: freezing temperature, length of the time, initial microbial load, and the rate of temperature decrease<sup>5,6</sup>.

86. The food processing practices should be closely monitored and verified to ensure that pathogenic *Vibrio* spp. are controlled and/or reduced as intended.

### 13.2.2.4 Storage

87. Seafood intended for raw consumption should be stored in shallow layers and surrounded by sufficient quantities of finely crushed ice or with a mixture of ice and [water fit for purpose (in this case, at least clean water)]. Live fish and shellfish should be stored at the lowest temperature tolerable for the species (Refer to Section 9 of the *Code of Practice for Fish and Fisher Products* (CXC 52-2003)).

88. Over-stacking and/or over-filling of containers should be avoided to allow cold air to circulate adequately.

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<sup>5</sup> FAO and WHO, 2020, Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (See section 3.5)

<sup>6</sup> FAO and WHO, 2020, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 35) (Section 3.4).

### 13.2.3 Microbiological<sup>7</sup>, physical, chemical and allergen specifications

89. Refer to Section 13.2.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXG 21-1997).

### 13.2.4 Microbiological contamination

90. Refer to Section 13.2.4 of the *General Principles of Food Hygiene* (CXC 1-1969) and Sections 3.2.2 and 3.3.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

### 13.2.5 Physical contamination

91. Refer to Section 13.2.5 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

### 13.2.6 Chemical contamination

92. Refer to Section 13.2.6 the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.3.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

### 13.2.7 Allergen Management

93. Refer to Section 13.2.7 the *General Principles of Food Hygiene* (CXC 1-1969), the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020) and the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

### 13.2.8 Incoming material

94. Refer to Section 13.2.8 of the –*General Principles of Food Hygiene* (CXC 1-1969) and Section 9.5.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

### 13.2.9 Packaging

95. Refer to Section 13.2.9 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 9.5.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

## [13.3 Water

96. Refer to Section 13.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and the *Guidelines for the safe use and reuse of water in food production and processing* (CXG 100-2023).

### 13.3.1 In contact with food

97. Refer to Section 13.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023) except cases specified within this Code where clean water could be used.

98. Coastal seawaters used at landing docks and at markets have been shown to be occasionally contaminated with high level of pathogenic *V. parahaemolyticus*. Therefore, only clean/potable waters should be used in the post-harvest stage.

### 13.3.2. As an ingredient

99. Refer to Section 13.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023).

### 13.3.3. Ice and steam

100. Refer to Section 13.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023).]

## 13.4 Documentation and records

101. Refer to Section 13.4 of the *General Principles of Food Hygiene* (CXC 1-1969) in addition to the following.

102. Records should show information regarding the control measures being monitored, for example time and

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<sup>7</sup> FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*. Codex Alimentarius Guideline, No CXC 21-1997. Codex Alimentarius Commission, Rome.

temperature, at key process steps for mitigation of pathogenic *Vibrio* spp.

### 13.5 Recall procedures – removal from the market of unsafe food

103. Refer to Section 13.5 of the *General Principles of Food Hygiene* (CXC 1-1969).

## 14. PRODUCT INFORMATION AND CONSUMER AWARENESS

### 14.1 Lot identification and traceability

104. Refer to Section 14.1 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 14.2 Product information

105. Refer to Section 14.2 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 14.3 Product labelling

106. Refer to the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

107. In addition, countries should give consideration to labelling of unpackaged live or raw seafood, so that consumers are adequately informed with respect to the safety and true nature (alive or not alive) of these products. In particular, seafood that is at a high risk of being contaminated with pathogenic *Vibrio* spp., should be labelled to alert at-risk consumers to avoid raw consumption or cook these products, in line with the legislation in the countries where these products are retailed or sold. Any treatment (e.g., heat treatment) and storage condition, that is to be applied to the product should be mentioned in the labelling if consumers would be misled by its omission.

### 14.4 Consumer education

108. Since each country has specific food habits, communication and education programs pertaining to pathogenic *Vibrio* spp. are most effective when established by individual governments.

109. Programs should be directed at consumers:

- To educate them on household practices and behaviours, as indicated in Five Keys to Safer Food (WHO), to keep the numbers of pathogenic *Vibrio* spp. that may be present in foods as low as possible and to minimize the potential of cross-contamination from seafood, from food handlers, or from utensils (e.g., cutting board), to other foods by:
  - keeping seafood cold to minimize and/or prevent the growth of pathogenic *Vibrio* spp.;
  - keeping refrigerator temperatures as low as practical;
  - using thermometers inside home refrigerators, ice chests or other storage containers;
  - preparing, cooking and/or consuming seafood immediately after removing them from the refrigerator;
  - promptly refrigerating leftover seafood in shallow containers for rapid and even cooling;
  - washing and disinfecting hands, utensils and equipment whenever raw seafood is handled and;
  - using separate utensils and equipment or clean between raw and cooked seafood.
- To help them make informed choices about the purchase, storage, shelf-life labelling and appropriate consumption of certain raw seafood that have been identified in relevant risk assessment and other studies, taking into consideration the specific regional conditions and consumption habits.

#### 14.4.1 Special attention to susceptible subpopulations

110. Liver disease is a prominent risk factor for human infection with pathogenic *Vibrio* spp., especially *V. vulnificus*. Additional risk factors include diabetes, haemochromatosis and HIV/AIDS<sup>8</sup>. Subpopulations with increased susceptibility should follow the advice below:

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<sup>8</sup> FAO and WHO, 2005, Risk assessment of *Vibrio vulnificus* in raw oysters (Microbiological Risk Assessment Series, No.8).

- Avoid the consumption of raw or partially treated seafood.
- Cook seafood thoroughly before consumption.

## 15. TRANSPORTATION

111. Refer to Section 15 of the *General Principles of Food Hygiene* (CXC 1-1969) and Sections 3.6 and 21 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

112. Transportation is an integral step in the food chain and should be carried out using suitable means, and temperature during this period should be as low as possible and should be controlled, monitored and recorded where appropriate.

## PART II HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

### 16. INTRODUCTION TO HACCP

113. Refer to Section 16 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 17. PRINCIPLES OF THE HACCP SYSTEM

114. Refer to Section 17 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 18. GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

115. Refer to Section 18 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 19. APPLICATION

116. Refer to Section 19 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 20. SELECTION AND APPLICATION OF METHODS FOR DETECTION AND ENUMERATION OF PATHOGENIC *VIBRIO* SPP.

#### 20.1.1 Purpose of analytical testing

117. The purpose of analytical testing for bacterial foodborne pathogens, including pathogenic *Vibrio* spp., can be divided into the following categories:

- harvest area monitoring (to assist with establishing harvest area *Vibrio* spp. management plans, where *Vibrio* abundance can be linked to specific harvest area water temperatures, salinity or other parameters, as determined by the assessment of the area)
- post-harvest process verification including end-product monitoring (as part of a quality assurance program)
- public health investigation following an incident.

118. Sampling plans and design must consider the purpose for which it will be used.

#### 20.2 Choice of analytical method

119. The choice of analytical method should reflect:

- the type of sample to be tested;
- the purpose for which the data collected will be used (as per paragraph 117);
- the desired level of sensitivity and test frequency;
- whether a presence/absence or quantitative test is more appropriate;
- whether detections of sub-populations (e.g., virulence markers) is necessary; and
- whether typing (e.g., serotype) of pathogenic strains is required.

#### 20.3 Types of analytical methods

120. Additional guidance on selecting analytical methods is available in FAO and WHO, 2016, Selection and application of methods for the detection and enumeration of human pathogenic halophilic *Vibrio* spp. In seafood (Microbiological Risk Assessment series No. 22) and 2021, Advances in science and risk assessment tools for

*Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Section 3.5) (MRA series No.35)

121. Research on virulence factors and virulence related genes of *V. parahaemolyticus*, *V. vulnificus*, and *V. cholerae* is ongoing, in some circumstances these genes can be used as PCR targets to assess the pathogenicity of the bacterial strains.

## ANNEX ON THE CONTROL MEASURES FOR *VIBRIO PARAHAEMOLYTICUS* AND *VIBRIO VULNIFICUS* IN BIVALVE MOLLUSCS<sup>9</sup>

### 1. INTRODUCTION

1. Bivalve molluscs are a well-documented vehicle for transmission of illnesses caused by *Vibrio* spp., especially *Vibrio parahaemolyticus* and *Vibrio vulnificus*. Bivalve molluscs are unique in that they are harvested, handled and consumed differently from most other seafood products and therefore present unique risks and control options. They are inherently riskier than other seafood because of their filter feeding activity that concentrates pathogens present in the water. They are often consumed live and raw or after insufficient cooking. According to FAO/WHO risk assessments for both of these pathogens in many countries, bivalve molluscs are often kept alive out of water for days after harvest at ambient temperatures which allows the growth of *V. parahaemolyticus* and *V. vulnificus*.

### 2. OBJECTIVES

2. The purpose of this Annex is to provide guidance on control measures that minimize the risk arising from the presence of pathogenic *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs. It deals with the means to minimize and/or prevent the introduction/contamination and/or the growth of these pathogens, and adequate partial treatment<sup>18</sup> of bivalve molluscs before consumption. Control measures required for these pathogens are similar but not the same to the extent that they have different characteristics for growth and survival. The control measures outlined in this Annex reflects these differences, where they exist. This Annex further provides information that may be of interest to competent authorities, FBOs, consumers, and other interested parties.

### 3. SCOPE

3. This Annex covers bivalve molluscs that are intended for consumption in a live, raw, or partially treated state. Bivalve molluscs (e.g., clams, mussels and oysters) consumed after treated are not covered in this Annex, noting that the control measures presented in the main documents are sufficient to control the safety of these products. The target microbiological hazards of this Annex are only pathogenic *V. parahaemolyticus* and *V. vulnificus*.

4. This Annex highlights the key control measures that influence the introduction/contamination of and minimize levels of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs and thus the risk of foodborne diseases caused by these pathogens.

5. This Annex provides guidance applicable throughout the food chain, from primary production through to final consumption of bivalve molluscs and particular guidance on post-harvest processing. Controls measures presented in Part I apply to live and raw bivalve molluscs (including those that receive post-harvest processing), while those in Part II apply to bivalve molluscs consumed after partial treatment<sup>19</sup>.

### 4. USE

6. This Annex is supplemental to and should be used in conjunction with, the *General Principles of Food Hygiene* (CXC 1-1969), the *Code of Practice for Fish and Fishery Products* (CXC 52-2003), Hygiene section of the *Standard for Live and Raw Bivalve Molluscs* (CXS 292-2008) and the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*. This Annex may require modifications and amendments in use, taking into account such factors as regional differences in the prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* and the epidemiological data, including the susceptibility of the population.

### 5. GENERAL PRINCIPLES

7. Refer to the Section 5 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*

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<sup>9</sup> Phylum Mollusca: Class Bivalvia

<sup>18</sup> Including cooking.

<sup>19</sup> Risk assessment of *V. parahaemolyticus* in *Anadara granosa* (bloody clams)

## 6. DEFINITIONS

8. For the purpose of this Annex, the following definitions apply:

Definitions contained in the *General Principles of Food Hygiene* (CXC 1-1969), the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*; and live and raw bivalve molluscs production definitions defined in the *Standard for Live and Raw Bivalve Molluscs* (CXS 292-2008).



## A: BIVALVE MOLLUSCS CONSUMED LIVE AND RAW

### PART I GOOD HYGIENE PRACTICES

#### 7. INTRODUCTION AND CONTROL OF FOOD HAZARDS

9. Refer to the Section 7 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*

#### 8. PRIMARY PRODUCTION

##### 8.1 Environmental control

10. Refer to Section 8.1 of the *General Principles of Food Hygiene (CXC 1-1969)*, Section 7 of the *Code of Practice for Fish and Fishery Products (CXC 52-2003)* and Section 8.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

11. The control measures described in this section generally apply to pre-harvest environmental conditions and practices during and immediately following harvest. Effective control measures for *V. parahaemolyticus* and *V. vulnificus* will typically require an evaluation in terms of the risk associated with environmental factors in the harvesting area and harvesting practices based on epidemiology and environmental conditions (i.e., air and water temperature and salinity). An important element in estimating risk is that *V. parahaemolyticus* grows faster and at colder temperatures than *V. vulnificus*. Predictive tools using these environmental monitoring parameters and growth rates as inputs have been elaborated based on the FAO/WHO risk assessments and, when validated, may be used to estimate corresponding *V. parahaemolyticus* and *V. vulnificus* levels and risk. The predictive ability can be improved by incorporating local data and considering additional factors such as hydrodynamic effects (occurrence of tidal waves, rainfall) and sunlight. In addition to seawater temperature and salinity, some additional abiotic and biotic factors have been identified modulating the presence and abundance of *V. vulnificus* and *V. parahaemolyticus* in coastal water around the world. However, the effects of these variables are not conclusive and, in some cases, have been reported in a particular study affecting a specific area. The presence of chlorophyll, turbidity, and the bacteriophages are known to be related to *Vibrio* abundance<sup>20</sup>.

12. In cases where predictive models are used to estimate the concentration and risks of pathogenic *Vibrio* spp. in seawater and/or bivalve molluscs based on air and water temperatures and/or salinity, their accuracy would be enhanced by incorporating local data on levels of total and pathogenic *V. parahaemolyticus* and *V. vulnificus* and growth in local bivalve species. Factors such as hydrodynamic effects (e.g., currents, tides, hurricanes and rainfall) and sunlight influence the levels of *Vibrio* spp. The dose response model used in the predictive tool may need modifications based on epidemiology, as regional differences exist in the prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* including attack rate relative to exposure to *V. parahaemolyticus* strains occurred in those areas concerned<sup>21</sup>.

13. Monitoring of bivalve molluscs for the levels of total *V. vulnificus* and total and pathogenic *V. parahaemolyticus* should be conducted periodically overtime to determine the regional and seasonal variation. Prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* and the epidemiological data, including the susceptibility of the population, should be considered<sup>22</sup>. This information and some factors articulated in paragraph 15 are useful for model inputs and evaluation of model outputs as well as for the application of appropriate controls.

14. The impact of ballast discharge in or around harvesting areas should be controlled due to potential for contamination by a range of hazards, including the presence of *Vibrio* spp., especially in areas that are in close proximity to international shipping lanes.

15. Factors to be considered in determining the need for controls in a given harvest area include:

- The number of sporadic illnesses and outbreaks of *V. parahaemolyticus* and *V. vulnificus* associated with bivalve molluscs harvested from a distinct hydrographic area, and whether these illnesses are indicative of an annual reoccurrence or an unusual increase of *Vibrio* spp. illnesses is reported;

<sup>20</sup> FAO and WHO, 2020, the Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 3.5).

<sup>21</sup> FAO and WHO, 2020, the Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 4.5.1.2).

<sup>22</sup> As an example, pandemic *V. parahaemolyticus* may require more stringent controls than other strains of pathogenic *V. parahaemolyticus* because epidemiological evidence indicates higher attack rates.

- Water temperatures representative of harvesting conditions. Water temperatures below 15°C for *V. parahaemolyticus* and below 20°C for *V. vulnificus* have generally not been historically associated with illnesses;
- Time period to first refrigeration and post-harvest air temperatures above the minimum growth temperatures for *V. parahaemolyticus* (10°C) and *V. vulnificus* (13°C), which may increase risk regardless of harvest water temperature;
- Harvest practices that allow radiant solar heating to raise temperatures of bivalve molluscs to temperatures above ambient air temperatures prior to harvest (i.e., intertidal harvest) and exposure time;
- Salinity ranges and optima are different for *V. parahaemolyticus* and *V. vulnificus*. Environmental and epidemiological data indicate that there are low *V. parahaemolyticus* and *V. vulnificus* levels and few cases of illnesses associated with bivalve molluscs when salinity exceeds 35 ppt (g/l) and 30 ppt (g/l), respectively. The effects of salinity and temperature on abundance of *Vibrio* differ depending on the range of fluctuations in water temperature and salinity throughout the year<sup>24</sup>.

16. The competent authority should inform food business operators of the control measures contained in Sections 3.2 (Hygienic production), 3.3 (Handling, storage and transportation) and 5.1 (Description of products and process) and 5.2 (Key aspects of GHPs) of this Annex when at least:

- Levels of *V. parahaemolyticus* and/or *V. vulnificus*, or environmental parameters exceed testing/monitoring criteria that are based on risk assessment, if applicable.
- Environmental conditions on harvesting areas could represent a risk for *V. parahaemolyticus* and/or *V. vulnificus*, for example seawater average temperature.
- An unusual increase of *Vibrio* spp. illnesses is reported.

17. The activities described in this section should be implemented by producers in cooperation with the competent authority.

## 8.2 Hygienic production

18. Pre-harvest and harvest measures should be applied as necessary based upon the factors identified in Section 3.1 above, such as:

- Restrict harvest or otherwise prevent use of product for raw consumption (e.g., avoid harvesting from a specified lease/harvest area or divert product for further processing).
- Where possible, cultivate bivalve molluscs below the thermocline where the growth of pathogenic *Vibrio* spp. should not occur.
- Restrict the time from harvest to refrigeration.
- Relay bivalve molluscs to areas where risk is sufficiently reduced (e.g., relay bivalve molluscs with *V. vulnificus* to high salinity offshore waters).

## 8.3 Handling, storage and transport

19. Bivalve molluscs destined to be consumed live or untreated raw should be handled separately from those harvested in other areas destined for treatment (including partial treatment) to avoid cross-contamination.

20. During handling, storage and transport of harvested bivalve molluscs, the following control measures should be applied as necessary, based upon the factors identified in Section 3.1. It is important that any control for *V. parahaemolyticus* and/or *V. vulnificus* is not less than that required for the control of any other pathogenic organisms that may be present in bivalve molluscs.

- Limit time from harvest or first exposure to ambient air temperature to initial refrigeration based on modelling and sampling.

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<sup>24</sup> FAO and WHO, 2020, the Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 3.6).

- Minimize time and temperature conditions that would allow the growth of *V. parahaemolyticus* and *V. vulnificus* during wet storage of bivalve molluscs.
- Bivalve molluscs are to be transported at the lowest temperature that minimizes growth of *V. parahaemolyticus* and *V. vulnificus*. The time between refrigeration and reaching a temperature that does not support growth of *V. parahaemolyticus* and *V. vulnificus* should be minimized, and the time between harvest and raw consumption should be limited appropriately or the product should undergo additional treatment to reduce pathogenic *Vibrio* levels. Special attention should be paid to maintaining the characteristics of bivalve molluscs to be consumed live following Section 7.3 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).
- It may be useful to periodically survey levels of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs at various points in the distribution chain to verify effectiveness of recommended control measures.
- Anyone involved in the harvest, handling, storage or transport of bivalve molluscs should be educated in the relationship between temperature control and growth of *V. parahaemolyticus* and *V. vulnificus* and trained in proper handling, storage and transport.

#### **8.4 Cleaning, maintenance and personnel hygiene**

21. Refer to the Section 8.4 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*

#### **9. ESTABLISHMENT: DESIGN OF FACILITIES AND EQUIPMENT**

22. Refer to Section 9 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section IV of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

#### **10. TRAINING AND COMPETENCE**

23. Refer to Section 10 of the *General Principles of Food Hygiene*, (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products*, (CXC 52-2003) and Section 10 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

#### **11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL**

24. Refer to Section 11 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section VI of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

#### **12. PERSONAL HYGIENE**

25. Refer to Section 12 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 12 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

#### **13. CONTROL OF OPERATION**

##### **13.1 Description of products and process**

26. Refer to Section 13.1 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003), the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and Section 5.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

27. The control measures described in this section generally apply to post-harvest handling and processing. Control of *V. parahaemolyticus* and *V. vulnificus* typically requires the stringent application of GHPs and other supportive programs. These prerequisite programs, together with HACCP, can provide a sound framework for the control of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

28. Any control measures or practices selected as a partial treatment for *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs (e.g., freezing, high pressure and mild heating), should be adequately validated to ensure that the control measure is effective. Such validated control measures/practices should be implemented under the

HACCP system. *V. parahaemolyticus* is generally more resistant than *V. vulnificus* to any given treatment. Therefore, a process that is effective for *V. vulnificus* may not be as effective for *V. parahaemolyticus*.

### **13.2 Key aspects of GHPs**

#### **13.2.1 Time and temperature control**

29. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003). Time and temperature control to reduce the temperature to the point that *V. parahaemolyticus* and *V. vulnificus* do not grow should be used and maintained during processing operation and subsequently until consumption.

#### **13.2.2 Specific process steps**

30. Bivalve molluscs destined to be consumed live or untreated raw should be handled separately from those destined for treatment (including partial treatment).

#### **13.2.3 Microbiological<sup>10</sup>, physical, chemical and allergen specifications**

31. Refer to Section 13.2.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXG 21-1997).

#### **13.2.4 Microbiological contamination**

32. Control measures should be in place to avoid cross contamination between bivalve molluscs destined to be consumed live or untreated raw and those that have been subject to treatment (including partial treatment).

## **14. PRODUCT INFORMATION AND CONSUMER AWARENESS**

33. Refer to Section 14 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section IX of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

34. In addition, programs for consumer information should be directed at consumers with increased susceptibility to contracting vibriosis (see paragraph 100 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*) to help consumers make informed choices about purchase, storage, shelf-life labelling and appropriate food preparation, handling and consumption of live and raw bivalve molluscs, taking into consideration the specific regional conditions and consumption habits.

### **14.1 Lot identification and traceability**

35. Refer to section 14.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

### **14.2 Product information**

36. Refer to section 14.2 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

### **14.3 Product labelling**

37. Refer to Section 9.3 (Product labelling) of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* and Section 1-7 and 2-7 of the *Standard for Live and Raw Bivalve Molluscs* (CXS 292-2008).

### **14.4 Consumer education**

38. Refer to Section 9.4 (Consumer education) of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

39. Programmes for consumer education should inform consumers of safe consumption practice and handling and preparation of bivalve molluscs aimed at avoiding food safety risks associated with *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

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<sup>10</sup> FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*. Codex Alimentarius Guideline, No CXC 21-1997. Codex Alimentarius Commission, Rome.

**15. TRANSPORTATION**

40. Refer to Section 15 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and the Section VIII of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

## **B. BIVALVE MOLLUSCS CONSUMED IN PARTIALLY TREATED STATE<sup>25</sup>**

### **PART I GOOD HYGIENE PRACTICES**

#### **7. INTRODUCTION AND CONTROL OF FOOD HAZARDS**

9. Refer to the Section 7 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*

#### **8. PRIMARY PRODUCTION**

##### **8.1 Environmental control**

41. Refer to Section 8.1 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 3.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

42. The controls described in Section III (Primary production) of Part I should be implemented. The combination of measures of the treatment and those described in Section III of this part should achieve at least an equivalent level of protection to the level of protection provided for raw or live bivalve molluscs in Section III of Part I.

43. If data on log reduction achieved by partial treatment is available, predictive tools in Part I could be applicable.

##### **8.2 Hygienic production**

44. Refer to Section 8.2 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 3.2 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

- The control measures described in Section III (Primary production) of Part I should be implemented to achieve at least an equivalent level of protection for bivalve molluscs to be consumed live or raw even though these bivalve molluscs are to be consumed after partial treatment.

##### **8.3 Handling, storage and transport**

45. Refer to Section 8.3 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 3.3 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

46. Control measures described in Section III (Primary production) of Part I should be implemented to achieve at least an equivalent level of protection for bivalve molluscs to be consumed live or raw even though these bivalve molluscs are to be consumed after partial treatment.

#### **9. ESTABLISHMENT: DESIGN OF FACILITIES AND EQUIPMENT**

47. Refer to Section 9 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and the Section IV of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

#### **10. TRAINING AND COMPETENCE**

48. Refer to Section 10 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section X of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

#### **11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL**

49. Refer to Section 11 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section VI of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

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<sup>25</sup> Part II applies only to products which are partially treated, excluding post-harvest processing. For products in thoroughly treated state, refer to relevant parts of the Good Hygienic Practices as specified in the *General Principles of Food Hygiene* (CXC 1-1969), *Code of Practice for fish and fishery products* (CXC 52-2003) and other applicable Codex documents as those are generally suitable to control *V. parahaemolyticus* and *V. vulnificus* in fully cooked bivalve molluscs.

## 12. PERSONAL HYGIENE

50. Refer to Section 12 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section VII of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

## 13. CONTROL OF OPERATION

### 13.1 Description of products and process

51. Refer to Section 13.1 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003), the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and Section 5.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*. Competent authorities should ensure that the food business operator is able to verify the delivery of any partial treatment and additional control measures necessary to ensure the safety of the product.

52. The controls described in this section generally apply to post-harvest handling and processing. Control of *V. parahaemolyticus* and *V. vulnificus* will typically require the stringent application of GHPs and other supportive programs. These prerequisite programs, together with HACCP, can provide a sound framework for the control of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

53. *V. parahaemolyticus* is generally more resistant than *V. vulnificus* to any given treatment. Therefore, a process that is effective for *V. vulnificus* may not be as effective for *V. parahaemolyticus*. Any control measure or practice selected as a partial treatment for *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs should be adequately validated to ensure that the control measures are effective and such validated control measures/practices should be implemented under the HACCP system.

### 13.2 Key aspects of GHPs

#### 13.2.1 Time and temperature control

54. Refer to Section 13.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003). The partial heat treatment of bivalve molluscs should ensure that the internal temperature of the bivalve molluscs reaches the temperature to secure a reduction of *V. parahaemolyticus* and *V. vulnificus*. Achievement of the validated time and temperature treatment should be guaranteed. After partial heat treatment, growth of *V. parahaemolyticus* and *V. vulnificus* should be controlled.

#### 13.2.2 Specific process steps

55. The partial treatment of bivalve molluscs should be validated to ensure the intended reduction of *V. parahaemolyticus* and *V. vulnificus*. The parameters (e.g., target pH, salt concentration, water activity) should be controlled, monitored and verified.

#### 13.2.4 Microbiological contamination

56. Control measures should be in place to avoid cross contamination between bivalve molluscs before partial treatment and after partial treatment.

## 14. PRODUCT INFORMATION AND CONSUMER AWARENESS

57. Refer to Section 14 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 14 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*, in addition to the following.

### 14.3 Product labelling

58. Refer to the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) and Section 2-7 Labelling in the *Standard for Live and Raw Bivalve Molluscs* (CXS 292-2008). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

59. In addition, where appropriate, labelling for bivalve molluscs should include advice on specific safe handling practices (e.g., time, temperature) and consumption.

**14.4 Consumer education**

60. Refer to Section 9.4 (Consumer education) of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

61. Programs for consumer education should inform consumers of safe consumption practice and handling and preparation of bivalve molluscs aimed at avoiding food safety risk associated with *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

**15. TRANSPORTATION**

62. Refer to Section 14 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 9.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.



**PART II HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION****16. INTRODUCTION TO HACCP**

63. Refer to Section 16 of the *General Principles of Food Hygiene* (CXC 1-1969).

**17. PRINCIPLES OF THE HACCP SYSTEM**

64. Refer to Section 17 of the *General Principles of Food Hygiene* (CXC 1-1969).

**18. GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM**

65. Refer to Section 18 of the *General Principles of Food Hygiene* (CXC 1-1969).

**19. APPLICATION**

66. Refer to Section 19 of the *General Principles of Food Hygiene* (CXC 1-1969).

**20. SELECTION AND APPLICATION OF METHODS FOR DETECTION AND ENUMERATION OF PATHOGENIC *VIBRIO* SPP.**

67. Refer to Section 9.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010).

## GUIDELINES FOR FOOD HYGIENE CONTROL MEASURES IN TRADITIONAL MARKETS FOR FOOD

(at Step 5/8)

### INTRODUCTION

Traditional markets for food are dedicated spaces for food wholesalers, retailers and consumers to sell and purchase food for direct consumption, preparation and other uses. These markets have many names around the globe that include, but are not limited to, street food markets, local markets, public markets, community markets, municipal markets, open-air markets, wet markets and farmers' markets. These markets could either be open air or enclosed and vary widely in size and the number of people who trade in them. They could also have formal or informal management structures with varying levels of infrastructure. Handling, preparation, artisanal processing and packaging also take place in these markets.

Traditional markets for food are important food sources that supply affordable and readily-accessible food to households, both raw and ready-to-eat foods. They also provide employment opportunities in the various nodes of the food value chain.

Despite the benefits derived from traditional markets for food, hygienic handling practices in these markets are often inadequate. These guidelines will provide competent authorities, food business operators (FBOs) and consumers with the necessary knowledge to strengthen food hygienic capacities in these markets to assure food safety in the framework of a One Health approach.

### SECTION 1 – OBJECTIVES

The guideline is intended to provide guidance in developing and implementing policies and regulations to ensure that traditional markets for food are designed and managed effectively to promote food safety.

The guidelines provide FBOs, consumers, market authorities and other stakeholders with advice on food hygiene – including food handling, personnel health, training and education, environment and hygiene relevant to ensuring food safety.

### SECTION 2 – SCOPE AND USE

#### 2.1 Scope

These guidelines provide guidance on food safety regulation and hygienic handling activities to all stakeholders relevant to traditional markets for food where raw, prepared and/or ready-to-eat foods are sold.

#### 2.2 Use

These guidelines are intended for use by competent authorities and other stakeholders in the development and/or implementation of food safety control measures in traditional markets for food where:

2.2.1 Competent authorities have an overall responsibility to decide how this guideline is applied, in coordination with the market authorities, where they exist.

2.2.2 FBOs should apply the hygienic practices set out in this document to provide food that is safe and suitable for consumption.

2.2.3 Consumers should follow relevant instructions and apply appropriate hygiene measures.

2.2.4 This guideline should be used in conjunction with relevant Codex texts, including but not limited to the *General Principles of Food Hygiene* (CXC 1-1969).<sup>1</sup>

### SECTION 3 - DEFINITIONS

For the purposes of these guidelines, the terms used herein should have the following definitions:

**Competent authority:** The government authority or official body authorized by the government that is responsible for the setting of regulatory food safety requirements and/or for the organization of official controls including enforcement (CXC 1-1969).<sup>1</sup>

**Consumer:** Persons and families purchasing and receiving food in order to meet their personal needs (*General Standard for the Labelling of Pre-packaged Foods* [CXS 1-1985]).<sup>2</sup>

**Crockery/Cutlery:** All tools used for food serving and consumption, whether non-disposable or disposable and they may include cups (glasses), dishes, plates, sauce-trays, mugs, spoons, forks, ladles, chopsticks, etc. (*Regional Code of Hygienic Practice for Street-Vended Foods in Asia* [CXC 76R-2017]).<sup>3</sup>

**Equipment:** The whole or part of any apparatus, vessels, containers, utensils, machines, instruments, or appliances for use in preparing, storing, handling, cleaning, selling, or supplying/delivering food.

**Food:** Any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum, and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs (CXS 1-1985).<sup>2</sup>

**Food business operator (FBO):** The entity responsible for operating a business at any step in the food chain (CXC 1-1969).<sup>1</sup>

**Food handler:** Any person who directly handles packaged or unpacked food, food equipment, utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements (CXC 1-1969).<sup>1</sup>

**Food hygiene:** All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain (CXC 1-1969).<sup>1</sup>

**Food grade:** Refers to materials and products that are safe for use in food handling, processing, storage, packaging, and serving.

**Food safety:** Assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eaten according to its intended use (CXC 1-1969).<sup>1</sup>

**Food vendors:** Refers to those who sell food in a traditional market for food.

**Hazard:** A biological, chemical or physical agent in food with the potential to cause an adverse health effect (CXC 1-1969).<sup>1</sup>

**Perishable food:** Food that is subject to rapid decay, spoilage and/or growth of microorganisms with or without the production of toxins or metabolites when not kept under the required storage conditions including but not limited to milk and milk products, eggs, meat, poultry and fish (CXC 76R-2017).<sup>3</sup>

**Potable water:** Water fit for human consumption (*Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* [CXG 100-2023]).<sup>4</sup>

**Traditional markets for food:** Spaces open to the public with physical infrastructures including premises or individual stalls for the food trade, generally from local FBOs, such as fruits, vegetables, food of animal origin, seeds/grains, ready-to-eat foods, street foods, preparation, and other uses. Examples include, but are not limited to, street food markets, local markets, public markets, community markets, municipal markets, open-air markets, wet markets and farmers’ markets.

**Market authority:** The entity or person responsible for the administration of the traditional market which may include market committees and associations of FBOs.

## SECTION 4 – GENERAL REQUIREMENTS

### 4.1 Policies and regulations

4.1.1 Appropriate policies and regulations should be formulated and implemented with the aim of guiding operations to ensure food safety during food purchase, preparation, processing, storage, packaging, and consumption. Such requirements should be elaborated either separately or incorporated into existing food regulations with an outcome-based approach.

4.1.2 The general hygienic requirements and practices to be followed by the FBOs should be translated by the competent authorities which can be applied considering the conditions and risk factors specific to each operation and/or locality.

4.1.3 The risk of the operation should be evaluated in terms of market size, especially the size of the population of the city or town where it is placed, infrastructure, type of food sold and kind of activities.

4.1.4 Competent authorities should regulate and promote food safety controls and the use of the guidelines established in this document in addition to the *General Principles of Food Hygiene* (CXC 1-1969).<sup>1</sup>

4.1.5 Competent authorities should put in place and implement surveillance systems to detect and support foodborne illness outbreak investigations and management.

4.1.6 Competent and /or market authorities should approve the types of food that can be marketed, the location and characteristics of the points of sale, and incorporate details regarding the sanitary conditions that should be met.

4.1.7 Competent authorities should implement and enforce regulatory measures including, but not limited to, the issuance of permits and licences, and where applicable, apply sanctions.

4.1.8 Roles and responsibilities of competent authorities, and market authorities, FBOs and consumers should be clearly defined and documented, including their legal obligations.

4.1.9 Market authorities in coordination with the FBOs should be responsible for-day-to-day operations of the traditional market for food.

4.1.10 Where applicable, market authorities should be empowered to assist the competent authorities with licensing and registration through a mutually agreed mechanism to oversee and-promote food safety by FBOs.

#### **4.2 Market infrastructure**

4.2.1 The traditional markets for foods should be designed and built to provide the basic infrastructure that promotes good hygienic practices for food handling and business operations as provided for by competent and/or market authorities to ensure food safety.

4.2.2 The infrastructure should be suitable (e.g. smooth, easy to clean, free of cracks, not accumulating dirt etc.) for maintenance and sanitation activities.

4.2.3 When planning market infrastructure, high-risk areas, such as where live animals, raw meat, poultry and fish are handled, should be physically separated from incompatible activities to-prevent cross-contamination of foods.

#### **4.3 Conditions for licensing/registration**

4.3.1 FBOs should meet the minimum requirements as set by competent authorities.

4.3.2 It is essential that food handlers are competent in food hygiene practices before the FBO is issued with an operating licence/registration.

4.3.3 The frequency and the type of training should be agreed upon by stakeholders considering the market requirements, kind of food products offered, FBO practices, and other aspects as appropriate.

#### **4.4 Pest, animal and zoonotic foodborne agents control**

4.4.1 The market authorities and FBOs in traditional markets for food should provide effective mechanisms for the control of animals and pests (rats, mice, pigeons, insects, etc.).

4.4.2 Any food found to have become contaminated/infested by animals and/or pests should be hygienically disposed of in a manner to prevent contamination/infestation of other foods.

4.4.3 Pest and animal control with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food and people.

4.4.4 Zoonotic foodborne agents should be managed with appropriate preventive measures, which may include washing hands after touching animals; cleaning and disinfection; and other steps necessary to prevent infection.

4.4.5 In line with the One Health approach, handlers of wild animals and meat of wildlife should be made aware of the hazards associated with regional trade thereof, especially in order to prevent known and emerging zoonoses.

### **SECTION 5 – FOOD BUSINESS OPERATORS**

#### **5.1 Health status of food handlers**

5.1.1 Food handlers in traditional markets should be healthy. Where necessary, they should have regular health checks, medical examinations, and immunizations and medical certificates to support their health status.

5.1.2 No food handlers shall be allowed to perform their duties if showing any symptoms of jaundice, diarrhoea, vomiting, fever, sore throat with fever, discharge from ear, eye, and nose, visibly infected skin lesions such as boils and cuts. In such cases, they shall cease from handling food in any capacity and seek medical treatment.

5.1.3 Any food handler who has been identified as or is known to be a carrier of foodborne disease organism(s), shall not be involved in any food handling activity until certified fit by a medical practitioner.

## **5.2 Personal hygiene and behaviour**

Food handlers, during the conduct of their business, should observe the following:

5.2.1 Wear clean clothing and appropriate personal protective equipment (PPE).

5.2.2 Wash hands with soap and water, rinse, and dry them in a manner that does not re-contaminate the hands. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.

5.2.3 Keep fingernails short and clean at all times and avoid wearing jewellery or ornaments during food preparation.

5.2.4 Keep the hair, including facial hair clean, tidy, and covered during food handling.

5.2.5 Cover cuts and wounds with suitable waterproof plasters.

5.2.6 Smoking or chewing gum should not be allowed while preparing or serving food.

5.2.7 Refrain from any unhygienic practices such as spitting and picking nose, ears, or touching any body part while handling food.

5.2.8 Avoid sneezing or coughing over or onto the food.

5.2.9 Use food stalls exclusively for their intended purpose.

## **5.3 Training and competence**

5.3.1 Food handlers should undergo adequate training in food hygiene and demonstrate competence-in safe food handling.

5.3.2 Training on food hygiene should be provided by the competent authorities or other institutions recognized by the competent authorities. Food vendors should also be trained on their responsibility to offer safe and suitable food products to consumers.

5.3.3 Relevant authorities, including extension and community health workers as appropriate, should engage market authorities and other stakeholders to assist in food handler training, especially those that are required before licensing, to facilitate the adoption of food handler training by FBOs.

5.3.4 Simple posters illustrating the “dos” and “don’ts” of food handling during vending should be widely and prominently displayed in relevant places for the benefit of both food handlers and consumers.

5.3.5 The training material should incorporate pictorials. The key information should be reinforced in short and crisp messages and where possible translated into the local languages. The training material may be waterproof so that food vendors can refer to it/ keep it/hang it on their food vending cart/stall

5.3.6 Training programmes should take into consideration the knowledge and skills levels of the food handlers being trained.

## **5.4 FBO associations**

5.4.1 The formation of FBO associations or cooperatives may be encouraged to provide support and a liaison point with the relevant authorities to facilitate the implementation of hygiene measures.

5.4.2 FBO associations should encourage continuous capacity building and self-regulation for improved adherence to food safety requirements.

## **5.5 FBOs responsibilities**

FBOs are responsible for the hygiene and protection of the food they handle and for all aspects related to its safety including:

5.5.1 developing, implementing, and verifying processes that provide food that is safe and suitable for its intended use;

5.5.2 providing an efficient record-keeping system, as appropriate to support food safety;

5.5.3 ensuring personnel are competent as appropriate to their job activities;

5.5.4 ensuring there is a simple one-step forward, one-step back traceability system in the food chain where applicable;

5.5.5 implementing a complaint management system for consumers;

5.5.6 building a positive food safety culture by demonstrating their commitment to providing safe and suitable food and encouraging appropriate food safety practices;

5.5.7 ensuring that consumers have clear and easy-to-understand information on use and to enable them to identify the presence of food hazards including allergens, protect their food from contamination, and prevent the growth/survival of foodborne pathogens during storage, handling, and preparation of food hygienically;

5.5.8 taking appropriate measures to keep market stalls free from animals, pests and insects to prevent contamination of food. However, animals such as guide dogs may be allowed but precautions should be taken to avoid food contamination; and

5.5.9 immediately take all practicable measures to get rid of the identified pest or harbourage sites and to prevent re-infestation.

## **SECTION 6 – LOCATION, DESIGN, LAYOUT, AND STRUCTURES**

### **6.1 Location**

6.1.1 Competent authorities have overall responsibility for setting standards to ensure the adequacy of the location, infrastructure and utilities. Market authorities and FBOs should therefore comply with the set standards. Where market improvements are required, they should be done in consultation with food safety experts, which may include relocation advice for FBOs.

6.1.2 The traditional markets for food should be located away from:

6.1.2.1 environmentally polluted areas and industrial activities that are reasonably likely to contaminate food;

6.1.2.2 areas prone to flooding;

6.1.2.3 areas prone to infestations of pests; and

6.1.2.4 areas where waste, either solid or liquid, cannot be removed effectively.

### **6.2 Design and layout**

6.2.1 The design and layout of the traditional market for food should:

6.2.1.1 be reviewed and approved beforehand by the competent authority and/or market authority, FBO associations, where necessary;

6.2.1.2 provide adequate space for food vendor stalls, carts, display cases, food preparation, handling, storing, serving, and selling areas;

6.2.1.3 allow for the flow of materials and goods, in and out of the markets, in a manner which will prevent food contamination;

6.2.1.4 have graded and compacted pathways such that they allow adequate drainage of expected levels of rainfall;

6.2.1.5 have stalls with access to an inlet and outlet of a drainage system or other suitable means of hygienic disposal of wastewater;

6.2.1.6 allow for market segmentation/demarcation to separate areas for sale of high-risk foods from areas allocated to low-risk foods;

6.2.1.7 allow for the proper placement of client and vendor facilities, such as toilets, handwashing basins, and eating facilities in a manner that prevents food contamination;

6.2.1.8 provide suitable, sufficient, and properly placed areas for solid waste collection and storage, crockery/cutlery and appliance cleaning, washing, and disinfecting;

6.2.1.9 be adequately ventilated to remove hazardous gases and offensive odours such as cooking fuel fumes and provide a continuous and sufficient supply of fresh air;

6.2.1.10 provide adequate power supply to operate appliances, processing and cooling equipment, and other implements used in the preparation, handling, storage, serving, and selling of food;

6.2.1.11 have provision for an ample supply of potable water, under adequate pressure and of suitable temperature, with adequate facilities for its storage, distribution, and protection against contamination;

6.2.1.12 be designed in such a way that it allows for adequate lighting;

6.2.1.13 provide space in and around the food stalls which should be free of unnecessarily stored goods or items to permit easy access for cleaning; and

6.2.1.14 provide adequate space for loading/offloading.

### 6.3 Structures

6.3.1 Structures in traditional markets for food should be reviewed and approved by the competent authority and/or the market authority, FBO association when necessary and should be made of impervious materials that can be cleaned, disinfected, and maintained in a good state of repair.

6.3.2 Food preparation areas should be made of smooth, non-absorbent materials, and be inert to the food, detergents, and disinfectants under normal operating conditions.

6.3.3. Surfaces that come into direct contact with food should be made from food-grade materials, be in sound condition, durable, and easy to clean, disinfect, and maintain.

6.3.4 All cooking areas, washing equipment, working tables, shelves, and cupboards on or in which food is placed should be at an appropriate height above the ground.

6.3.5 There should be adequate light to ensure reasonable illumination in every part of a food stall to facilitate all activities in the traditional market for food.

6.3.6 Structures in traditional markets for food should have appropriate facilities to minimize the effects of extreme weather conditions on food and the build-up of dirt and condensate from the atmosphere and to protect from flying animals overhead.

6.3.7 Where appropriate, suitable facilities should be available for temperature, humidity and moisture controls to maintain food safety and food product integrity.

6.3.8 Effective protection against pest access and harbourage should be provided for.

6.3.9 Floor drains for purposes of removing surface water to facilitate cleaning and disinfection should be provided.

6.3.10 Where applicable, provide for smoke hoods and flues above cooking areas to enable the removal of cooking gases, smoke, and fumes into the open air.

6.3.11 Provide for centralized or individualized appliances, crockery/cutlery, and other implements' washing facilities, equipped with potable water (see CXG 100-2023)<sup>4</sup> and where necessary hot potable water, with appropriate drains to an approved sewer or drain system, to ensure thorough cleaning.

6.3.12 Traditional markets for food should comply with any other requirements by the competent authority.

### 6.4 Food storage equipment

6.4.1 Equipment used for storage of food should be appropriately designed using food-grade materials that are easy to clean and disinfect.

6.4.2 Refrigerator and freezer temperatures should be monitored. Where ice is used for cooling raw food, i.e. fishery products, it should be made from potable water in order not to be a source of contamination for the food in direct contact. It should be added in adequate quantity and replenished to keep the products chilled and covered.

6.4.3 Monitoring devices and any other equipment that could impact food safety should not be used for purposes other than their intended use.

6.4.4 Monitoring devices such as thermometers, refrigeration unit controls, weighing scales and recording thermometers should be calibrated.

6.4.5 Frequency of calibration, responsible person, monitoring and verification procedures, appropriate corrective actions, and record-keeping should be specified.

### 6.5 Water and sanitation

6.5.1 **Water supply** – Traditional markets for food should ensure a sufficient supply of potable water.

6.5.2 **Liquid waste disposal** – Traditional markets for food should have an efficient wastewater disposal system compliant with national regulations, which should be maintained in a good state of repair and working condition. The system should be large enough to carry peak loads and be provided with traps to prevent solid waste material from being discharged into the drain/sewer.

6.5.3 **Solid waste disposal** –Traditional markets for food should ensure:

6.5.3.1 solid waste material is handled in such a manner as to avoid contamination of food and/or potable water;

6.5.3.2 solid waste is removed from the working area of the stalls as often as necessary and at least once daily;

6.5.3.3 provision of waste receptacles and/or containers at strategic places within the markets;

6.5.3.4 all solid waste is segregated and properly disposed into suitable containers, including recycling bins or waste receptacles and/or containers which are secured with tight-fitting lids;

6.5.3.5 the waste receptacles and/or containers are emptied and cleaned as often as necessary to ensure a hygienic environment;

6.5.3.6 in areas without garbage collection service, solid waste is disposed of in a sanitary manner, as recommended or approved by the competent authority;

6.5.3.7 waste equipment and waste storage areas are cleaned and disinfected as and/or when required by the competent authority;

6.5.3.8 only appropriate disinfecting agents are used; and

6.5.3.9 routine inspection of solid waste disposal areas for the presence or harbourage of pests, taking any practical measures to eliminate and further prevent any infestation by either market and/or competent authorities or FBO associations.

#### **6.5.4 Toilets and sanitary facilities**

6.5.4.1 Every traditional market for food should have sufficient and easily accessible toilets and other sanitary facilities which should be kept clean and operational.

### **SECTION 7 – FOOD PREPARATION**

#### **7.1 Requirements**

Every FBO involved in food preparation should ensure the following:

7.1.1 supply of all raw materials and ingredients including ice be from appropriate known and reliable sources;

7.1.2 freshness and wholesomeness of ingredients;

7.1.3 containers for raw materials and other ingredients should be dedicated for food and should not be used for other purposes;

7.1.4 transportation of raw materials and other ingredients be done in a manner to prevent contamination;

7.1.5 cold chain transportation of foods should be implemented where necessary; and

7.1.6 only permitted food additives are to be used and the amount added should be as per the relevant national, regional or international specifications such as the *General Standard for Food Additives* (CXS 192-1995).<sup>5</sup>

7.1.7 Maintain traceability/product tracing and record-keeping systems, as appropriate to support food safety.

#### **7.2 Equipment maintenance, cleaning and sanitation/disinfection**

7.2.1 All equipment used in food preparation should be kept clean and disinfected when necessary, before and after use. Only food-safe cleaning agents should be used.

7.2.2 The equipment, including containers for storing potable water, should be food grade, resistant to corrosion, and capable of withstanding repeated cleaning and disinfection.

7.2.3-FBOs should ensure that all defective, damaged, cracked, rusted, chipped and unsuitable equipment and crockery/cutlery are removed from use and discarded. All food handling equipment should be maintained in a good state of repair and working condition.

7.2.4 Every cutting surface used in the preparation of food should be free from cracks and crevices and should be easy to clean and disinfect.

7.2.5 All non-disposable utensils should be regularly cleaned by thoroughly washing them in potable water using soap or other suitable detergents.

7.2.6 Disposable utensils should be used only once and properly disposed of.

#### **7.3 Cooking and handling**

7.3.1 Food handlers should thoroughly wash fresh fruits and vegetables with potable water to remove surface contamination, as required.



7.3.2 When appropriate, and approved by competent authority, food handlers should also disinfect fresh fruits and vegetables which will be consumed raw.

7.3.3 To prevent cross-contamination, food vendors should not store or wash raw food including raw meat, fish and poultry with other foods that will be consumed raw or in a semi-cooked state. There should be at least an area for handling, storing, cleaning, and preparing raw food, separate from the cooked food handling, display and serving areas.

7.3.4 Utensils used for cooked and uncooked food should be handled separately to prevent cross-contamination.

7.3.5 Thawed meat, fish, and poultry products should be checked frequently to make sure the thawing process is complete before further processing, or the processing time should be increased to take into account the initial temperature of the products. Frozen foods should be thawed once using appropriate methods (e.g. under refrigeration, cold potable water) and used immediately for food preparation. Thawed foods should not be frozen again.

7.3.6 Food that requires refrigeration should be maintained in those conditions during handling and storage until its use.

7.3.7 The time and temperature of cooking should be sufficient to destroy or reduce to safe levels any pathogens that may be present in the food.

7.3.8 Oil and grease used for frying should be replaced on a regular basis whenever there is an apparent change in physical/chemical characteristics, such as dark colour, intense foaming, smoke formation, or sensory changes, such as aroma and taste.

7.3.9 Potable water should be used for drinking, and preparation of hot or cold drinks and beverages.

7.3.10 Ice should be made from potable water, handled and stored to prevent contamination.

7.3.11 Containers used to transport or store ice should meet the requirements for potable water containers.

7.3.12 Food should be reheated until piping hot but not more than once and only the portion of the food to be served should be reheated.

7.3.13 Utensils used for tasting food should be washed immediately after each use or if disposable, discarded after use.

#### **7.4 Serving food**

Every food handler should comply with the following:

7.4.1 Cooked or ready-to-eat foods should not be touched with bare hands. If gloves are worn, appropriate measures should be applied to ensure the gloves do not become a source of contamination.

7.4.2 Clean tongs, forks and spoons should be used when handling, serving or selling food.

7.4.3 All utensils used should be clean and dry and not handled by touching the food contact surfaces.

7.4.4 Plates filled with food should not be stacked one on top of the other during display, storing, or serving.

7.4.5 Food-grade packaging materials should be used when packaging and serving ready-to-eat food.

7.4.6 Printed material such as newspapers, magazines etc.-shall not be used as a primary packaging for food wrapping or serving food.

7.4.7 Polythene bags and wrappers should not be used to serve warm or heat food.

7.4.8 Food handlers shall not blow into plastic bags, wrappers, or packages used for food.

7.4.9 All beverages offered for sale should be dispensed only in their individual, original, sealable containers or from taps fitted to bulk containers and made of food-grade material. Bulk containers should be covered with tight-fitting lids.

7.4.10 Cut fruit or other foods ordinarily consumed in the state in which they are sold should be set out in an enclosed display case, cabinet, or similar type of protective device and should be displayed in a manner to protect the food from contamination and at appropriate temperatures.

7.4.11 Food handlers should avoid handling money. If this is unavoidable, the food handler should wash their hands and/or change gloves before handling food.

7.4.12 Ready-to-eat foods intended for continuous serving should be protected from environmental contamination.

7.4.13 Where-appropriate, food intended for continuous serving should be kept at the following recommended holding temperatures to minimize or prevent the growth of pathogens and spoilage microorganisms:

- a) above 60 °C for food served hot;
- b) below 5 °C for food served cold; and
- c) -18 °C or below for food served frozen.

7.4.14 A food warmer should be used to maintain continuous holding temperatures and should not be used for re-heating purposes.

### **7.5 Unsold food**

7.5.1 Unsold cooked/prepared food should be properly packaged and chilled/frozen and stored under conditions that do not contaminate or cause deterioration.

7.5.2 All unsold cooked food and prepared beverages that cannot be properly preserved should be safely disposed of at the end of the day.

7.5.3 Cooked chilled/frozen unsold foods should be reheated until piping hot before serving or consumption.

### **7.6 Transportation of raw/fresh/prepared/cooked foods**

7.6.1 Food requiring transportation to the point of sale/stall should be placed in a well-protected, covered and clean container to avoid contamination.

7.6.2 Any means used in transporting food should be clean and in good hygienic condition, appropriately equipped to accommodate any special requirements of the food being transported and provide protection from environmental contamination.

7.6.3 Vehicles used to transport prepared/cooked food should be exclusively used for that purpose.

7.6.4 Perishable food should be transported under temperature control to minimize or prevent the growth of harmful microorganisms or cause deterioration.

7.6.5 Prepared/cooked food should not be transported together with raw food, ingredients, and any other materials which may contaminate the food.

7.6.6 All equipment in contact with food used for transportation should be of food-grade material.

### **7.7 Food storage**

7.7.1 Food should be adequately protected from pests, environmental contaminants and stored at recommended temperatures.

7.7.2 Readily perishable food should be placed or stacked so that it is not likely to be contaminated by contact with pet food, toxic materials, or any other materials which may cause contamination.

7.7.3 The bulk of readily perishable foods should be stored in clean containers at recommended temperature.

7.7.4 All dry and non-dry ingredients should be stored and maintained in their original labelled commercial container where possible. Any other container used for storing dry ingredients should be properly labelled and designed to prevent moisture absorption.

7.7.5 All non-perishable food should be stored in a clean, protected, and closed container/cupboard to prevent cross-contamination by pests.

7.7.6 Perishable raw food and non-dry ingredients including wet milled legumes, cereals and pulses, ginger and garlic pastes should be stored in separate clean containers, preferably placed in a clean ice box, a refrigerator or a freezer to prevent spoilage and/or pathogen growth.

7.7.7 Low moisture foods such as cereals and dry legumes should be stored in air-tight packages and elevated from the floor using pallets.

7.7.8 Refrigerators and freezers should not be overloaded, and their food temperatures should be maintained as low as necessary in the interest of food safety and suitability.

7.7.9 All enclosed spaces, cupboards, shelves, and racks used for the storage of food should be made in such a way that they are easily accessible for routine cleaning and inspection. All bulky food should be stored in an orderly fashion to facilitate ventilation, inspection, and the detection of pests.

7.7.10 In stock rotation, the principles of 'first in, first out' and 'first expiry, first out' should be applied considering labelling and storage date information to avoid food wastage.

7.7.11 Date marking on all food containers should be checked before the food is used. Expired food shall not be sold or used for the preparation of food.

## **SECTION 8 – CONSUMERS**

### **8.1 General requirements**

All consumers in the traditional markets for food should adhere to general hygienic practices which include but are not limited to:

- 8.1.1 prevention of contamination of food;
- 8.1.2 washing or disinfecting hands before touching food;
- 8.1.3 avoidance of unnecessary contact with ready-to-eat food;
- 8.1.4 avoidance of spitting, sneezing, coughing, littering, smoking, or use of tobacco in areas where there is unprotected food or surfaces likely to contact food;
- 8.1.5 proper disposal of leftovers in waste receptacles and/or containers;
- 8.1.6 report to the market authorities any unhygienic behaviour of any food handler if noted; and
- 8.1.7 report and seek medical attention whenever foodborne illness-related symptoms such as diarrhoea, vomiting and stomach pain is experienced.

### **8.2 Consumer awareness**

All consumers should:

- 8.2.1 obtain sufficient information from relevant sources on guidance and instructions for food handling, preparation, storage, and waste disposal;
- 8.2.2 be aware of the importance of reading and understanding information on product label;
- 8.2.3 be aware of the need for proper hand washing before handling food;
- 8.2.4 understand the intended use of the food e.g. whether it is ready-to-eat or whether it is intended for further processing;
- 8.2.5 be informed of their responsibility of not contaminating food vending areas; and
- 8.2.6 be informed of the presence of allergens in food.
- 8.2.7 Competent authority should provide adequate communication and guidance to consumers in order to raise consumer awareness.

### **8.3 Waste disposal**

All consumers should:

- 8.3.1 dispose waste appropriately into the designated waste disposal systems and facilities; and
- 8.3.2 comply with any other relevant authority requirements related to liquid and solid waste disposal.

## **SECTION 9 – MONITORING AND EVALUATION**

### **9.1 Monitoring and evaluation programmes**

9.1.1 Competent and/or market authority and FBOs should use monitoring and evaluation systems to assess the food hygiene and safety practices in traditional markets for food and request and/or take corrective actions when needed.

9.1.2 Competent authorities must implement a water safety management plan in accordance with current regulatory requirements.

9.1.3 Market assessments should be regularly employed to identify areas for improvement and determine priorities and pathways to improve food hygiene control measures in traditional markets for food. Market authorities can support regular monitoring activities.

### **9.2 Stakeholder committee**

Each market, whether in permanent or temporary premises, should be encouraged to form a stakeholder committee consisting of FBOs, competent authorities, consumers associations, and market authorities, where

they exist, to advise on regular market cleaning, repairs, and access to critical services like potable water and waste management.

### 9.3 Incentive programmes

Incentive-based programmes can be used to facilitate and improve FBOs and consumer food safety practices.

## NOTES

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<sup>1</sup> FAO and WHO. 1969. *General Principles of Food Hygiene*. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.

<sup>2</sup> FAO and WHO. 1985. *General Standard for the Labelling of Pre-packaged Foods*. Codex Alimentarius Standard, No. CXS 1-1985. Codex Alimentarius Commission. Rome.

<sup>3</sup> FAO and WHO. 2017. *Regional Code of Hygienic Practice for Street-Vended Foods in Asia*. Codex Alimentarius Code of Practice No. CXC 76R-2017. Codex Alimentarius Commission. Rome.

<sup>4</sup> FAO and WHO. 2023. *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing*. Codex Alimentarius Guideline, No. CXG 100-2023. Codex Alimentarius Commission. Rome.

<sup>5</sup> FAO and WHO. 1995. *General Standard for Food Additives*. Codex Alimentarius Standard, No. CXS 192-1995 Codex Alimentarius Commission. Rome.

**TEXTS TO BE CONSIDERED FOR STRUCTURAL ALIGNMENT WITH CXC 1- 1969**

CXC 75-2015	Code of Hygienic Practice for Low-Moisture Foods	2018
CXC 53-2003	Code of Hygienic Practice for Fresh Fruits and Vegetables	2017
CXG 87-2016	Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat	2016
CXG 88-2016	Guidelines on the Application of General Principles of Food Hygiene to the Control of Foodborne Parasites	2016
CXG 86-2015	Guidelines for the Control of <i>Trichinella</i> Spp. in Meat of Suidae	2015
CXG 85-2014	Guidelines for the Control of <i>Taenia saginata</i> in Meat of Domestic Cattle	2014
CXC 33-1985	Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters	2011
CXC 57-2004	Code of Hygienic Practice for Milk and Milk Products	2009
CXC 66-2008	Code of Hygienic Practice for Powdered Formulae for Infants and Young Children	2009
CXC 15-1976	Code of Hygienic Practice for Eggs and Egg Products	2007
CXC 19-1979	Code of Practice for Radiation Processing of Food	2003
CXC 47-2001	Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food	2001
CXC 48-2001	Code of Hygienic Practice for Bottled/Packaged Drinking Waters (Other than Natural Mineral Waters)	2001
CXC 46-1999	Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life	1999
CXC 23-1979	Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods	1993
CXC 39-1993	Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering	1993
CXC 40-1993	Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods	1993
CXC 30-1983	Code of Hygienic Practice for the Processing of Frog Legs	1983

## APPENDIX VIII

## PROJECT DOCUMENT

**REVISION OF THE GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD (CXG 79-2012)****1. Purpose and scope of the standard**

The purpose and scope of the work is to revise and update the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* (CXG 79-2012). CXG 79-2012 currently covers human enteric viruses, more specifically hepatitis A virus (HAV) and norovirus (NoV) and is applicable to all foods, with a focus on ready-to-eat food. It also contains two annexes for the control of HAV and NoV in specific commodities, one for bivalve molluscs (Annex I) and the other for fresh produce (Annex II). The revision will provide updated advice to competent authorities and food business operators on a framework for the control of human foodborne viruses in food. The revision will be mainly based on the latest scientific advice from FAO/WHO. It will also include alignment of CXG 79-2012 with the revision of the *General Principles of Food Hygiene* (CXC 1-1969).

**2. Relevance and timeliness**

Since the publication of CXG 79 in 2012, new scientific information for the control of viruses in food has been made available. Risk assessment models have been developed, including a quantitative risk model on NoV in bivalve molluscan shellfish. FAO/WHO published *Technical guidance for the development of the growing area aspects of Bivalve Mollusc Sanitation Programmes*<sup>1</sup>. There have been technical advancements in viral detection in specific commodities and in assessing potential infectivity of viruses, as well as new scientific findings on the use of indicators to monitor seawater quality of molluscs growing areas.

The Codex Committee on Food Hygiene (CCFH) requested the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) to provide scientific advice on five areas:

1. An up-to-date review of the foodborne viruses and relevant food commodities of highest public health concern.
2. A review of the scientific evidence on prevention and intervention measures and the efficacy of interventions in the food continuum.
3. A review of the analytical methods for relevant enteric viruses in food commodities.
4. A review of scientific evidence on the potential utility of viral indicators or other indicators of contamination.
5. A review of the various risk assessment models with a view towards constructing more applicable models for wide use among member countries, including a simplified risk calculator.

The JEMRA meeting of viruses in foods, *Part 1: Food attribution, analytical methods and indicators* was held on September 18-22, 2023. A public call for data and experts was issued to support this work<sup>2</sup>. A summary of the conclusions of the meeting was published thereafter<sup>3</sup>. The full report will be published as part of the FAO/WHO Microbiological Risk Assessment (MRA) Series at a later date. A second JEMRA meeting of viruses in foods took place in February 2024 to review the prevention and intervention measures, as well as the various risk assessment models.

The available information as well as the new scientific advice to be provided by FAO/WHO in 2024 highlights the need for and the timeliness of the revision of CXG 79-2012. While the fundamental principles in CXG 79-2012 are likely to remain the same, additional guidance based on new scientific information will help competent authorities and food business operators in the control of human enteric viruses in food to protect the health of consumers and ensure fair practices in food trade.

**3. Main aspects to be covered**

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<sup>1</sup> FAO and WHO. 2021. Technical guidance for the development of the growing area aspects of Bivalve Mollusc Sanitation Programmes. Second edition. Food Safety and Quality Series No.5A. Rome. <https://doi.org/10.4060/cb5072en>

<sup>2</sup> FAO and WHO. Call for experts and data on microbiological risk assessment of viruses in foods. <https://www.fao.org/3/cc4295en/cc4295en.pdf>.

<sup>3</sup> FAO and WHO. [Joint FAO/WHO Expert Meeting on microbiological risk assessment of viruses in foods. Part 1: Food attribution, analytical methods, and indicators, Summary and conclusions, 2023](#)

The new work is intended to revise CXG 79-2012 to take into account the latest scientific information and will consider various aspects relevant to the control of viruses in foods, including:

- Expansion of the scope to address viruses other than HAV and NoV such as Hepatitis E viruses (HEV) and emerging vehicles of foodborne illnesses such as frozen berries or prepared foods;
- Revision of interventions in the food chain focusing on process-specific control systems, surface disinfection as well as hand disinfection and food handler hygiene according to available evidence;
- Possible inclusion of additional information on testing of foods for foodborne viruses taking into account technical advancements in viral detection in specific food commodities and in assessing potential infectivity of viruses; and
- Consideration of new scientific findings to control HAV, NoV in shellfish (bivalve molluscs), fresh and frozen produce made available since the publication of CXG 79-2012 including indicators to monitor seawater quality of molluscs growing areas and risk assessment models.

The expansion of the scope may result in reorganisation of the annexes by commodities based on the latest JEMRA executive summary, i.e. shellfish, fresh and frozen produce, prepared and RTE foods, pork and wild game meat. The revision will also ensure full alignment with the *General Principles of Food Hygiene* (CXC 1-1969) (revised in 2022).

#### 4. An assessment against the *Criteria for establishment of work priorities*

##### General criterion

- **Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries**

The proposed new work will support competent authorities and food business operators in implementing control measures to prevent or minimize the presence of human enteric viruses in food to reduce the risk of foodborne illness caused by viruses. The new work will consider the inclusion of measures to minimize the presence of zoonotic viruses i.e., HEV, a route of transmission not currently covered by CXG 79-2012.

##### Criteria applicable to general subjects

- **Diversification of national legislations and apparent resultant or potential impediments to international trade**

The revised CXG 79-2012 is expected to assist countries in adopting hygiene practices to reduce the risks of foodborne illness from viruses and to support international fair food trade practices.

- **Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)**

FAO/WHO has already initiated work on human enteric viruses in food, including the work of the WHO Foodborne Disease Burden Epidemiology Reference Group (FERG), which has included foodborne illnesses caused by viruses in its work plan.

- **Consideration of the global magnitude of the problem or issue**

Foodborne viral infections are very common in many parts of the world. Viruses differ in size, structure and biological characteristics from bacteria which can result in different management strategies compared to bacterial pathogens. A revision of CXG 79-2012, especially on newly identified foodborne viruses is key in supporting the reduction of the public health burden of foodborne viral infections.

#### 5. Relevance to the Codex strategic objectives

The proposed new work directly relates to the following goals from the *Codex Strategic Plan 2020–2025*.

Goal 1: *Address current, emerging and critical issues in a timely manner*

The review and update of CXG 79-2012 are in response to new scientific information that can improve the control of viruses in food and in response to new information to be provided by FAO/WHO in 2024.

Goal 2: Develop standards based on science and Codex risk-analysis principles

Relevant reports from JEMRA meetings will inform the revision of CXG 79-2012. CXG 79-2012 will continue to provide risk analysis principles, implemented through food hygiene systems at multiple levels, to help reduce the risk of foodborne illness from viruses. During this review process, developments in recently available scientific information will be considered with input from member countries.

Goal 3: Increase impact through the recognition and use of Codex standards

The practical use of science-based Codex standards and related texts in food trade contributes to a high level of food safety. The revision of CXG 79-2012 should promote a better understanding and application of its principles internationally.

Goal 4: Facilitate the participation of all Codex Members throughout the standards setting process

The revision of CXG 79-2012 and participation will be open to all member countries interested in order to obtain constructive and relevant contributions.

Goal 5: Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals

The consensus-driven review and update of CXG 79-2012 will be performed effectively and with transparency for timely adoption. Initial discussions are likely to take place through an electronic working group (EWG) to establish a framework in performing the update. Wide participation will be encouraged as free web-based technologies will be used. Translation of the latest versions of the texts into the official languages of the Commission will be performed ahead of the annual Committee meetings.

**6. Information on the relation between the proposal and other existing Codex documents as well as other ongoing work**

The review of CXG 79-2012 will continue to complement existing Codex texts. These include the *General Principles of Food Hygiene* (CXC 1-1969), the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003). The scope extension, to include additional virus-commodity combinations, could complement other Codex documents such as the *Code of Hygienic Practice for Meat* (CXC 58-2005). The ongoing work to align the Codex texts developed by CCFH with the revised *General Principles of Food Hygiene* (CXC 1-1969) will also be relevant for this review process. In addition, the *Guidelines for the Safe Use and Reuse of Water in Food Protection and Processing* (General Section and Annex I on Fresh Produce adopted at CAC46) as well as Annex II on Fishery Products (at Step 2/3), will also be considered for this review process.

**7. Identification of any requirement for and availability of expert scientific advice**

A first meeting of the *JEMRA of viruses in foods. Part 1: Food attribution, analytical methods and indicators* was held on September 18-22, 2023. A second JEMRA meeting of viruses in foods is planned for February 2024 to review the prevention and intervention measures, as well as the various risk assessment models. The summary reports and full reports of these two meetings will be necessary for the review and update of CXG 79-2012.

The report of the work on the alignment of CCFH documents with the revised *General Principles of Food Hygiene* (CXC 1-1969) will be taken into account for the review of CXG 79-2012.

**8. Identification of any need for technical input to the standard from external bodies so that this can be planned for**

Additional technical input from external bodies is not anticipated at this time.

**9. Proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years**

Provided acceptance of the work at CCFH54 in 2024, and subject to the Codex Alimentarius Commission (CAC) approval at its 47<sup>th</sup> Session in November 2024, the following timeline is proposed:

- Consideration at Step 4 by CCFH55
- Re-consideration at Step 4 by CCFH56
- Recommendation for adoption at Step 5/8 by CCFH57



- Adoption by CAC the subsequent meeting.

The proposed timeline is provisional since the final publication date of the JEMRA report and the scheduling of CCFH55 is not known.

## APPENDIX IX

## PROJECT DOCUMENT

**NEW WORK PROPOSAL FOR THE REVISION OF *GUIDELINES FOR THE CONTROL OF CAMPYLOBACTER AND SALMONELLA IN CHICKEN MEAT (CXG 78-2011)*****1. Purpose and Scope of the Standard**

The purpose of the work is to revise and update the *Guidelines on the Application of General Principles of Food Hygiene to the control of pathogenic Salmonella and Campylobacter in chicken meat (CXG 78-2011)*. The revision will provide risk management options based on the latest scientific advice from FAO/WHO and will incorporate relevant aspects of the latest revision of the *General Principles of Food Hygiene (CXG 1-1969)*.

The intended scope of the guidelines will not be changed from the original guidelines.

**2. Relevance and Timeliness**

At the request of CCFH, FAO/WHO through JEMRA brought together two expert panels to provide scientific advice on *Campylobacter* and *Salmonella* in chicken meat (on September 12-16, 2022 and February 6-10, 2023 respectively) and noted several critical developments in the last decade. These include:

***Campylobacter***

- Biosecurity and production management approaches that employ multiple good production practices, such as hygiene practices and sanitation, that can enhance control of *Campylobacter* in meat chickens.
- Incorporating risk mitigation measures for *Campylobacter* contamination at primary production sites, including partial depopulation, litter management, down period length, proximity to other livestock, and slaughter age.
- Feed and water additives such as short chain fatty acids, peroxyacetic acid (PAA), and caprylic acid.
- Review of processing interventions to include processing effects and pre-harvest interventions designed to reduce the pathogen load on incoming flocks.
- Review interventions such as carcass chilling or freezing to reduce *Campylobacter* loads in broiler chickens.

***Salmonella***

- Guidelines should be updated to include controlled access to breeding flocks, recognizing the heightened risk factors of access and the downstream impacts of flocks contaminated with *Salmonella*. Clarification of the use of cleaning compounds and disinfectants as Good Hygienic Practices (GHP), are recommended. Economic incentives can promote adoption of GHP and should be part of an updated Codex document.
- Updated guidelines for the control of *Salmonella* in raw poultry include discussions about using quantitative data to evaluate process controls during the farm to fork journey, and there is an additional need to hone testing paradigms to look more closely for pathogens of public health concern to ensure public safety. More work is needed to improve available technology and scientific applications before these techniques can be implemented. A review of interventions and their role in preventing contamination is needed, which will include a response to recent reports of salmonellosis from consumption of poultry liver and *Salmonella* infection that leads to osteomyelitis.
- More research is still needed to produce commercially available vaccines that do not negatively impact lifespan of chickens or the time-to-entry for broiler slaughter and processing.

**3. Main aspects to be covered**

The new work is intended to update the *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* based on the latest scientific information, and to incorporate relevant aspects of the *General Principles and Food Hygiene (CXG 1-1969)* (revised in 2022). The guidelines will provide guidance on selection of the most appropriate risk management options and risk management tools.

The new work will consider factors relevant to the control of *Campylobacter* and *Salmonella*, including:

- The need for pre-harvest interventions to reduce pathogen load prior to harvesting, to address the risk of horizontal and vertical transmission, and recent reports of disease associated with organ meat which can be addressed by implementing controls during flock rearing.

- practical interventions that can be used to reduce foodborne illness risks associated with the consumption of poultry meat, include preharvest intervention e.g., feed treatment, and post-harvest treatments, e.g. antimicrobial or organic acid drip interventions
- microbiological monitoring methods, particularly molecular-based process control and monitoring approaches
- recently available scientific data, in particular information on new pathogenic strains and their geographical spread and clinical incidence
- methods for the detection and characterization of pathogens by serotype and eventually by virulence-associated loci

#### **4. An assessment against the *Criteria for the Establishment of Work Priorities***

##### **General Criterion**

##### **Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries**

The proposed new work will support competent authorities and food business operators to implement practical interventions that can be used to reduce risk of campylobacteriosis and salmonellosis.

##### **Criteria applicable to general subjects**

##### **(a) Diversification of national legislations and apparent resultant or potential impediments to international trade.**

The revised CXG 78-2011 can aid countries in adopting practices to mitigate the risk of pathogenic *Salmonella* and *Campylobacter* in chicken meat, promoting international fair trade practices.

##### **(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).**

Codex has already undertaken risk management work on *Campylobacter* and *Salmonella* in meat chickens.

##### **(e) Consideration of the global magnitude of the problem or issue.**

There is some evidence for increasing rates of illness associated with *Campylobacter* and *Salmonella* strains. Codex guidance is an essential contribution to reducing the global public health burden of campylobacteriosis and salmonellosis.

#### **5. Relevance to the Codex strategic objectives**

The proposed work is directly related to the purposes of the Codex Alimentarius Commission. Namely, goals one of the Codex Strategic Plan 2020-2025, to “Address current, emerging and critical issues in a timely manner” In particular, this work is relevant to Strategic Objective 1.2 “Prioritize needs and emerging issues” where the outcome is a “Timely Codex response to emerging issues and the needs of members”. This work will address the gap in guidance in particular in light of new information provided by JEMRA.

#### **6. Information on the relation between the proposal and other existing Codex documents as well as other ongoing work**

The revision of specific guidance on pathogenic *Campylobacter* and *Salmonella in chicken meat* will complement existing CCFH texts. This includes the *General Principles of Food Hygiene* (CXG 1-1969).

#### **7. Identification of any requirement for and availability of expert scientific advice**

CCFH made a request for expert scientific advice and two JEMRA meetings were created and reports are in final stages of completion. But during revision, CCFH may need additional scientific advice to validate proposed intervention language.

#### **8. Identification of any need for technical input to the standard from external bodies so that this can be planned for**

Not required at this time.

#### **9. Proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for**

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**developing a standard should not normally exceed five years.**

Subject to the Codex Alimentarius Commission approval at its 47th Session in 2024, it is hoped that the new work can be expedited (i.e. within two sessions of CCFH).

## PROJECT DOCUMENT

**NEW WORK PROPOSAL FOR THE REVISION OF THE *GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF LISTERIA MONOCYTOGENES IN FOODS* (CXG 61-2007)****1. Purpose and scope of the standard**

The purpose and scope of the work is to revise and update the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods* (CXG 61-2007) to provide advice to competent authorities and food business operators (FBOs) on a framework for the control of *L. monocytogenes* in ready-to-eat foods. Furthermore, as everyone has a role to play in reducing the risk of foodborne listeriosis, CXG 61-2007 will also provide information to consumers to this end. This revision will be mainly based on the latest scientific advice from JEMRA and will incorporate relevant aspects of the revision of *General Principles of Food Hygiene* (CXC 1-1969).

The original intent of CXG 61-2007 will not change.

**2. Relevance and timeliness**

In 2020, a virtual meeting of the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) reviewed recent data on *L. monocytogenes* to assess the need to modify, update, or develop new risk assessment models and tools for this pathogen. A public call for data and experts was issued in 2019 to support this work<sup>11</sup>.

A full report of the meeting entitled “*Listeria monocytogenes* in ready-to-eat (RTE) foods: attribution, characterization and monitoring” was published in 2022 (Microbiological Risk Assessment (MRA) Series No. 38; MRA38)<sup>12</sup>, principally recommending expanding future risk assessments on *L. monocytogenes* in RTE food to diverse commodity sub-groups, incorporating a primary-production-to-consumption perspective, and reviewing groupings of susceptible populations. Several critical gaps in the current JEMRA risk assessment model were identified and the expert group collectively agreed that updating the model would be valuable for informing risk analysis strategies, including in low- and middle-income countries.

At the 52nd session of the Codex Committee on Food Hygiene (CCFH52) in 2022, the Committee supported the proposal that JEMRA undertake full primary-production-to-consumption risk assessments of *L. monocytogenes* in foods. In response, a second call for data and experts was issued on 29 April 2022<sup>13</sup> to inform two meetings, one each in 2022 and 2023. Summaries and conclusions of the meetings were published thereafter, which included recommendations and considerations to inform a possible revision of CXG 61-2007. A full report of the meetings on microbiological risk assessment of *L. monocytogenes* in foods is still pending publication.

New scientific information provided by JEMRA justifies the need and timeliness of the revision of CXG 61-2007.

While the fundamental principles in the original CXG 61-2007 are likely to largely remain the same, an update to CXG 61-2007 will continue to provide current advice to competent authorities on a framework for the control of

*L. monocytogenes* in RTE foods, with a view towards protecting the health of consumers and ensuring fair practices in food trade.

**3. Main aspects to be covered**

The new work is intended to update CXG 61-2007 based on the latest scientific information. CXG 61-2007 will provide advice to competent authorities and FBOs on a framework for the control of *L. monocytogenes* in RTE foods. It will also provide information that will be of interest to the food industry, consumers, and other relevant parties. To reduce the risk of foodborne listeriosis, everyone has a role to play.

The new work should consider various factors relevant to the control of *L. monocytogenes*, including:

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<sup>11</sup> FAO and WHO. 2019. Call for experts and data on microbiological risk assessment of *Listeria monocytogenes* in ready-to-eat (RTE) food: attribution, characterization and monitoring. <https://www.fao.org/3/ca7352en/ca7352en.pdf>

<sup>12</sup> FAO and WHO. 2022. *Listeria monocytogenes* in ready-to-eat (RTE) foods: attribution, characterization and monitoring – Meeting report. Microbiological Risk Assessment Series No. 38. Rome. <https://doi.org/10.4060/cc2400en> or <https://www.who.int/publications/i/item/9789240034969>

<sup>13</sup> FAO and WHO. 2022. Call for experts and data on microbiological risk assessment of *Listeria monocytogenes* in foods. <https://www.fao.org/3/cb9930en/cb9930en.pdf> or <https://www.who.int/news-room/articles-detail/call-for-experts-and-data-on-microbiological-risk-assessment-of-listeria-monocytogenes-in-foods>

- Activities at primary production, including the need for food business operators (including primary producers) to apply effective control measures as appropriate to their operations
- New and pertinent information to be considered throughout the primary-production-to-consumption continuum regarding resource management, time-temperature control, environmental hygiene practices, and climate change
- Microbiological monitoring methods, including molecular or genomic-based approaches, as complements to conventional cultural methods
- Consumer practices and the relevance of factors impacting listeriosis risk among different regions of the world including underlying health conditions, socio-economic factors, as well as behavioural and cultural factors
- Other recently available scientific information, including new risk assessment models and listeriosis outbreaks

#### 4. An assessment against the *Criteria for establishment of work priorities*

##### General criterion

- **Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries**

The proposed new work will broadly support competent authorities and food business operators in implementing control measures against *L. monocytogenes*, which is a worldwide microorganism of public health significance in RTE foods.

##### Criteria applicable to general subjects

- **Diversification of national legislations and apparent resultant or potential impediments to international trade**

The large scope of food covered under CXG 61-2007 suggests a global impact to food trade. The updated CXG 61-2007 is anticipated to assist countries in the adoption of practices to reduce the risk of listeriosis and support international fair trade practices.

- **Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)**

JEMRA has already initiated work on *L. monocytogenes* in food. The Terrestrial Manual of the World Organization for Animal Health (WOAH) includes a chapter ([Chapter 3.10.5](#)) dedicated to the detection and identification methods for *L. monocytogenes* (last revisions in May 2021).

- **Consideration of the global magnitude of the problem or issue**

Listeriosis cases have been reported widely around the world, hence making this a global concern. There are multiple venues throughout the primary-production-to-consumption continuum by which a wide range of food can be contaminated by *L. monocytogenes*. CXG 61-2007 is key in supporting the reduction of the public health burden of listeriosis.

#### 5. Relevance to the Codex strategic objectives

The proposed work directly relates to the following goals from the *Codex Strategic Plan 2020–2025*.

##### Goal 1: Address current, emerging and critical issues in a timely manner

The review and update of CXG 61-2007 is in response to recommendations by JEMRA, as indicated in MRA38 and in response to recent information that impacts the control of *L. monocytogenes* in RTE foods. This work will address the gap in guidance, in particular related to primary production.

##### Goal 2: Develop standards based on science and Codex risk-analysis principles

Following scientific recommendations from JEMRA, the review and update of CXG 61-2007 has been flagged to provide current advice for the control of *L. monocytogenes* in RTE foods throughout the entire food chain. CXG 61-2007 will continue providing important principles to consider in reducing the risk of listeriosis which can be implemented through food safety control systems. During this review process, developments in recently available scientific information will be considered with input from member countries.

##### Goal 3: Increase impact through the recognition and use of Codex standards

The practical use of science-based Codex standards and related texts in food trade contributes to a high level of food safety. The update and review of CXG 61-2007 should promote better understanding and application of their principles internationally.

Goal 4: Facilitate the participation of all Codex Members throughout the standards setting process

The review and update of CXG 61-2007 should generate interest and participation and will be open to all Members in order to obtain constructive and relevant contributions.

Goal 5: Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals

The consensus-driven review and update of CXG 61-2007 will be performed effectively and with transparency for timely adoption. Initial discussions are likely to take place through an electronic working group (EWG) to establish a framework and approach in undertaking the update. Wide participation will be encouraged as free web-based technologies will be used. Translation of the latest versions of the texts, to the official languages of the Committee, will be performed ahead of the annual Committee meetings.

**6. Information on the relation between the proposal and other existing Codex documents as well as other ongoing work**

The review of CXG 61-2007 will complement existing CCFH texts. As such, the updated CXG 61-2007 will consider, for example, the 2022 revision to *General Principles of Food Hygiene* (CXC 1-1969) and the 2013 revision to the Guidelines - *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997) to refer to the latest information and provide special attention related to *L. monocytogenes* in RTE food, as needed.

**7. Identification of any requirement for and availability of expert scientific advice**

Given that JEMRA have already provided recommendations for the update of CXG 61-2007, these will be used as the basis for the work. To maintain consistency among all existing CCFH texts that reference the *General Principles of Food Hygiene* (CXC 1-1969), CCFH will likely engage with the Members that are leading the review and update of these documents and also take into consideration the ongoing work on the alignment of CCFH developed texts with the *General Principles of Food Hygiene* (CXC 1-1969).

**8. Identification of any need for technical input to the standard from external bodies so that this can be planned for**

Additional scientific expert advice is not anticipated.

**9. Proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years**

Provided the new is agreed upon by CCFH54 in 2024 and approved by CAC47 in 2024, conceivably it could be considered at Step 4 by CCFH55 depending on the timing of this meeting, followed by Step 5 at CCFH56 and Step 5/8 at CCFH57. The timeline, i.e., within 3 sessions of CCFH, is envisioned since scientific advice from JEMRA is close to completion.

APPENDIX XI

CCFH FORWARD WORKPLAN

Part 1									
Title of Work	Last Revision	Information to Update <sup>1</sup>	Impact to Public Health <sup>2</sup>	Trade Impact <sup>3</sup>	Project document / discussion paper <sup>4</sup>	FAO/WHO assistance needed? <sup>5</sup>	Alignment required with the revised CXC 1-1969	Comments	Total
<i>Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat (CXG 78-2011)</i>		Yes ( <i>Salmonella</i> ) Yes ( <i>Campylobacter</i> )	20	10	Yes	Yes. CCFH has requested JEMRA to collate the relevant scientific information on <i>Salmonella</i> and <i>Campylobacter</i> in chicken meat in preparation for an update	Yes	FAO noted at the New work working group at CCFH53 that during the JEMRA meeting on <i>Salmonella</i> in chicken, the experts recommended two CXC documents to be updated: CXC/RCP 39-1993, Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (which is currently listed in the Forward Workplan) and CXC/RCP 8-1976, Code of Practice for the Processing and Handling of Quick Frozen Foods (which is not in the Forward Workplan). As both of these were referenced in CXG78-2011 – See <a href="#">MRA 45</a> , page 62	30
<i>Code of Practice on Food Allergen Management for Food Business Operators (CXC 80- 2020)</i>	2019	Yes (FAO/WHO Expert consultations) /No (CCFL input)	20	10	Yes		Yes	CCFL met in May 2023 and addressed the input from the FAO/WHO Expert Consultation on Allergens, including priority allergens, thresholds and allergen advisory labelling. The work in CCFL is ongoing so the CCFH should anticipate the need for revisions to this document in the	30

<sup>1</sup> Information to Update (Currency of information): Yes/No - Is there new information/data that would justify the need to review the existing code(s) or establish a new one? Are there new technologies that would justify the need to review existing codes or establish a new one? Is there duplication or inconsistency with existing codes that should be addressed? If there is an existing code in place and a determination is made that the code is sufficient, no new work should proceed.

<sup>2</sup> (High= 20/ Medium = 14/ Low = 8)

<sup>3</sup> 10/5/4/2/0: Global Trade Impact, High Consumption: 10; Regional Trade Impact, High Consumption: 5; Global Trade Impact, Low Consumption: 4; Regional Trade Impact, Low Consumption: 2; No trade impact: 0

<sup>4</sup> Yes/No

<sup>5</sup> Yes/No



								near future. FAO Side Event on Allergens planned during CCFH54.	
<i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (CXG 79-2012)</i>	2012	Yes	20	10	Yes	Yes. Discussion Paper identifies 5 elements where JEMRA input is needed	Yes	Structure based on old GPFH sections will need revision to align with revised GPFH	30
Code of Hygienic Practice for the Storage of Cereals	N/A	Yes	8	5	Yes <sup>6</sup>		N/A		13
<i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods (CXG 61-2007)</i>	2009	Yes	20	10	Yes	Yes	Yes	JEMRA report <i>Listeria monocytogenes</i> in ready-to- eat (RTE) food: attribution, characterization and monitoring; FAO/WHO to conduct a full farm to table risk assessment for <i>Listeria monocytogenes</i> in foods. Text should be aligned to revised sections of GPFH and new wording for headings	30

<sup>6</sup> Discussion paper on development of Code of Hygienic Practice for the storage of cereals (prepared by India) FH/44 CRD 9, included in the Forward Workplan by the 44th session of the CCFH, 12-16 November 2012

Part 2									
Texts below are ordered most recent to oldest. There is no new information for an update, however, revisions may be needed for alignment with CXC 1 and other documents.									
Title of Work	Last Revision	Information to Update <sup>7</sup>	Impact to Public Health <sup>8</sup>	Trade Impact <sup>9</sup>	Project document / discussion paper <sup>10</sup>	FAO/WHO assistance needed? <sup>11</sup>	Alignment required with the revised CXC 1- 1969	Comments	Total
<i>Code of Hygienic Practice for Low-Moisture Foods (CXC 75- 2015)</i>	2018	No					Yes	Sections should be re- aligned with revised GPFH sections.	
<i>Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003)</i>	2017	No					Yes	GPFH definitions - types of water should reference updated text of GPFH/ expert information	
<i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Foodborne Parasites (CXG 88- 2016)</i>	2016	No					Yes	Section 3.1 - should update reference to align with revised GPFH to 'section 2.1'.	
<i>Guidelines for the control of non-typhoidal Salmonella in Beef and Pork (CXG 87-2016)</i>	2016	No					Yes	Editorial: 8h) Should move superscript 17 to end of second sentence and reference direct to Section 7.3 of revised GPFH. Similar for superscript 22 – repeat as above.	
<i>Guidelines for the Control of Trichinella spp. in Meat of Suidae (CXG 86-2015)</i>	2015	No					Yes		
<i>Guidelines for the Control of Taenia saginata in Meat of Domestic Cattle (CXG 85-2014)</i>	2014	No					Yes		
<i>Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG 30-1999)</i>	2014	No					No	Hazard definition should be updated. Hazard identification should reference GPFH as a starting point.	

<sup>7</sup> Information to Update (Currency of information): Yes/No - Is there new information/data that would justify the need to review the existing code(s) or establish a new one? Are there new technologies that would justify the need to review existing codes or establish a new one? Is there duplication or inconsistency with existing codes that should be addressed? If there is an existing code in place and a determination is made that the code is sufficient, no new work should proceed.

<sup>8</sup> (High= 20/ Medium = 14/ Low = 8)

<sup>9</sup> 10/5/4/2/0: Global Trade Impact, High Consumption: 10; Regional Trade Impact, High Consumption: 5; Global Trade Impact, Low Consumption: 4; Regional Trade Impact, Low Consumption: 2; No trade impact: 0

<sup>10</sup> Yes/No

<sup>11</sup> Yes/No

<i>Principles and Guidelines for the Establishment and Application of Microbiological Criteria related to Foods (CXG 21-1997)</i>	2013	No					No	Editorial updates: 4.1 (para 11) should be updated with reference to GPFH. Suggest "The choice of the approach should be aligned with GPFH (CXC 1-1969), the risk management objectives and decisions relating to food safety and suitability." 4.12 should be updated to refer to Section 7.4 of revised GPFH document.
<i>Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CXC 33-1985)</i>	2011	No					Yes	GPFH reference should be dated (CAC/RCP 1-1969). HACCP should be referenced to revised GPFH. Sections references to GPFH should be updated to align with revised GPFH sections.
<i>Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 66- 2008)</i>	2009	No					Yes	Section formatting should be updated to align with revised GPFH sections. Review of HACCP should occur to align with revised GPFH GHP and HACCP use. Remove reference to HACCP annex.
<i>Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004)</i>	2009	No					Yes	Format follows GPFH sections therefore will need re-alignment with revised GPFH.  HACCP reference should be changed from 'Annex' to 'Chapter Two'.  Use of HACCP should be re- evaluated in line with revised GPFH approach. Consider use of GHP and HACCP as appropriate to cover hygienic practice, rather than HACCP alone.  Allergens need re-evaluating in relation to milk itself as an allergen, rather than allergens from other sources. Water should be re-evaluated to align with revised GPFH and water advice.
<i>Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CXG 63-2007)</i>	2008	No					No	Annex II. The Introduction should reference GPFH as the foundation for integration of MRM metrics within a food safety control system. Other wording within this annex should be re-considered for revision given the revised GHP/HACCP approach within the revised GPFH  Editorial:  Definitions - should reference GPFH and cover both GHP and HACCP. This would also include relevant definitions (hazard, control measure, CCP, CL etc.). 6.1.2 – should reference GPFH as source guidance for specific documents and guidelines.
<i>Code of Hygienic Practice for Eggs and Egg Products (CXC 15-1976)</i>	2007	No					Yes	Context of use of hazard analysis, HACCP / HACCP system should be reviewed and updated in line with revised GPFH. Contents and referenced sections of GPFH should be updated throughout the document aligning as appropriate to revised sections of GPFH. Allergen information should be specifically referenced.
<i>Code of Hygienic Practice for</i>	2005	No					Yes	Should be updated for sections referenced to GPFH to align with revised GPFH sections.

<i>Meat (CXC 58-2005)<sup>12</sup></i>								
<i>General Standard for Irradiated Food (CXS 106-1983)</i>	2003	No						Remove reference to Rev 3 and wording on HACCP as HACCP covered within GPFH text
<i>Code of Practice for Radiation Processing of Food (CXC 19- 1979)</i>	2003	No					Yes	Introduction – last paragraph should be updated to reflect HACCP application as in revised GPFH. Sections should be updated to align with revised GPFH.
<i>Code of Hygienic Practice for Bottled/Packaged Drinking Waters (other than natural mineral waters) (CXC 48-2001)</i>	2001	No					Yes	GPFH reference should be updated to be consistent with requirements (remove Rev 3).  Sections should be re- aligned to referenced sections within revised GPFH.  Definitions reference should be updated to revised GPFH Definitions (not section 2.3).  HACCP reference should be to the revised GPFH, not an Annex. Should consider water usage and reference to updated water section within GPFH and expert reports.
<i>Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CXC 47-2001)</i>	2001	No					Yes	GPFH references should be consistent with current requirements, e.g. CAC/RCP 1- 1969.  Sections should be aligned with the revised GPFH sections. HACCP and hazard identification as mentioned in
								Section 5 should be checked to see whether the wording here adds any further specific application above the HACCP approach in Chapter 2 of the revised GPFH.  5.5 Water should reference updated information in line with revised GPFH. Appendix on Hurdles – should be revised with consideration of HACCP text within Chapter 2 revised GPFH
<i>Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf-life (CXC 46-1999)</i>	1999	No					Yes	Sections will need re- alignment with the revised GPFH. Section 5.1 should be revised in accordance with chapter 2 HACCP in the revised GPFH

<sup>12</sup> Code developed by the Codex Committee on Meat Hygiene

<p><i>Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CXC 39-1993)</i></p>	<p>1993</p>	<p>No</p>						<p>GPFH references should be updated (first reference to GPFH has no dated number; second reference in 5.2.1 is obsolete referring to 1985 GPFH). Explanatory preface C should be revised and aligned with HACCP application within the revised GPFH. Remove out-of-date references. Use of hazard and CCP notes throughout the document should be revised and aligned as necessary with GHP/HACCP application in the revised GPFH. Sections should be updated to align with revised GPFH sections and be complementary to the GPFH. Definitions (contamination, disinfection, food handler, food hygiene) should be updated to align with the revised GPFH definitions and other definitions should be included, e.g. to replace 'potentially hazardous food'. HACCP definitions should be referenced to GPFH if not included. Section 4.3.12 Water Supply should be updated and aligned with revised GPFH. Allergen management should get specific mention for mass catering and be referenced to the revised GPFH.</p>	
<p><i>Code of Hygienic Practice for Low-acid and Acidified Low-acid Canned Foods (CXC 23-1979)</i></p>	<p>1993</p>	<p>No</p>					<p>Yes</p>	<p>Definitions - cleaning, disinfection, and potable water should be updated to align with revised GPFH. Sections should be updated to align as appropriate with revised GPFH. GHP and HACCP application should be considered and updated to align with use in revised GPFH, including Appendix IV (should have wider application than salvaged cans).</p>	
<p><i>Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods (CXC 40-1993)</i></p>	<p>1993</p>	<p>No</p>					<p>Yes</p>	<p>GPFH references should be updated to align with revised GPFH. Section and sub section references should be updated to align with revised GPFH. Sections and contents should be updated to align with and be complementary to revised GPFH. HACCP and its application should be referenced to revised GPFH. Definitions (cleaning, disinfection), should be updated to align with revised GPFH. Water should be aligned with revised GPFH.</p>	
<p><i>Guideline Procedures for the Visual Inspection of Lots of Canned Foods for Unacceptable Defects (CXG 17-1993)<sup>13</sup></i></p>	<p>1993</p>	<p>No</p>					<p>Yes</p>		

<sup>13</sup> Documents developed by the Codex Committee on Processed Fruits and Vegetables

<p><i>Code of Hygienic Practice for Canned Fruit and Vegetable Products (CXC 2-1969)</i></p>	<p>1969</p>	<p>No</p>					<p>Yes</p>	<p>Needs revision and should reference GPFH as supporting text in a Scope and Use section. Sections should be aligned with the revised GPFH, including definitions. References to water use and supply should refer also to updated information provided by FAO/WHO on water. Note use of hazard (hygienic and health) and this should be revised in line with current definition of hazard.</p>	
<p><i>Code of Hygienic Practice for the Processing of Frog Legs (CXC 30-1983)</i></p>	<p>1983</p>	<p>No</p>					<p>Yes</p>	<p>GPFH should be referenced earlier as supporting text for whole document.                  Definitions should be updated (contamination, disinfection) to align with revised GPFH.                  Sections should be updated to align with revised GPFH, including 5.2.1 which currently has reference to GPFH. GHP and HACCP should be applied across the whole document as appropriate and in accordance with the revised GPFH</p>	